Notes to Readers

- This is version 1.0 of the Therapeutic Area Data Standards User Guide for Diabetes. It makes use of domains and assumptions which are not final as of its publication, and is therefore a provisional, rather than final, release.
- This document is intended to be used in conjunction with the SDTM v1.4 and SDTMIG v3.2, and with the CDASH Standard v1.1.
- The TAUG-Diabetes v1.0 includes a user guide, a set of proposed SDTM variables, a set of draft SDTMIG assumptions, four draft SDTMIG domains, five sets of CDASH metadata tables with example CRFs, and six workbooks of somewhat simplified, prototype SHARE metadata displays.

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014-08-01</td>
<td>1.0</td>
<td>Provisional Release</td>
</tr>
<tr>
<td>2014-04-03</td>
<td>1.0 Draft</td>
<td>Draft for Public Review</td>
</tr>
</tbody>
</table>

See Appendix F for Representations and Warranties, Limitations of Liability, and Disclaimers.
CONTENTS

1 INTRODUCTION ................................................................................................................................................. 5
  1.1 PURPOSE ...................................................................................................................................................... 5
  1.2 ORGANIZATION OF THIS DOCUMENT .................................................................................................... 6
  1.3 CONCEPT MAPS ........................................................................................................................................... 6
  1.4 CONTROLLED TERMINOLOGY .................................................................................................................... 7
  1.5 RELATIONSHIPS TO OTHER STANDARDS ............................................................................................... 7
  1.6 KNOWN ISSUES ........................................................................................................................................... 8

2 SUBJECT AND DISEASE CHARACTERISTICS ..................................................................................................... 10
  2.1 DIABETES HISTORY ................................................................. 10
     2.1.1 Examples for Diabetes History ........................................................................................................... 11
  2.2 DIABETES COMPLICATION HISTORY .......................................................... 13
     2.2.1 Examples for Diabetes Complication History ................................................................................... 13
  2.3 TREATMENT-NAÏVETÉ .......................................................................................................................... 14
     2.3.1 Examples for Treatment-Naïveté ....................................................................................................... 15

3 DISEASE ASSESSMENTS ....................................................................................................................................... 17
  3.1 LABORATORY TESTS ................................................................. 17
     3.1.1 Glucose Homeostasis and Diabetes Related Markers .......................................................................... 17
     3.1.2 Lipid Panel ........................................................................................................................................... 20
     3.1.3 Kidney Function .................................................................................................................................. 21
     3.1.4 Liver Function ..................................................................................................................................... 22
     3.1.5 Miscellaneous ................................................................................................................................... 23
  3.2 GLUCOSE MEASUREMENTS .......................................................................................................................... 23
     3.2.1 Self-Monitoring of Blood Glucose ..................................................................................................... 24
        3.2.1.1 Examples for Self-Monitoring of Blood Glucose ........................................................................ 25
     3.2.2 Tolerance Tests .................................................................................................................................. 29
        3.2.2.1 Meal Data in a Meal Tolerance Test .............................................................................................. 30
        3.2.2.2 Examples for Tolerance Tests .................................................................................................... 31
  3.3 HYPOGLYCEMIC EVENTS ............................................................................................................................ 34
     3.3.1 Classification of Hypoglycemia in Diabetes ......................................................................................... 35
     3.3.2 Examples for Hypoglycemic Events .................................................................................................... 38
        3.3.2.1 Event and Symptom Data ............................................................................................................. 39
        3.3.2.2 Blood Glucose Concentration Data ............................................................................................ 40
        3.3.2.3 Last Meal and Last Diabetic Study Treatment .......................................................................... 41
        3.3.2.4 Precipitating Factors, Third Party Assistance, Adverse Event .................................................... 42
        3.3.2.5 Treatment for the Hypoglycemic Event ....................................................................................... 43
  3.4 CARDIOVASCULAR EVENTS/OUTCOMES ............................................................................................... 44

4 ROUTINE DATA ..................................................................................................................................................... 45
  4.1 CONCOMITANT MEDICATIONS ..................................................................................................................... 45
  4.2 VITAL SIGNS ................................................................................................................................................ 46
     4.2.1 Waist & Hip Circumference, Waist/Hip Ratio ...................................................................................... 46

APPENDICES ......................................................................................................................................................... 48
  APPENDIX A: PROJECT PROPOSAL ...................................................................................................................... 48
  APPENDIX B: CDASH DIABETES TEAM ............................................................................................................... 48
  APPENDIX C: GLOSSARY AND ABBREVIATIONS ............................................................................................. 49
  APPENDIX D: METADATA ..................................................................................................................................... 50
  Appendix D1: CDASH Metadata ........................................................................................................................ 50
  Appendix D2: Prototype SHARE Metadata ....................................................................................................... 50
  APPENDIX E: REFERENCES .................................................................................................................................. 52
1 Introduction

This Therapeutic Area Data Standards User Guide for Diabetes (TAUG-Diabetes) is a provisional standard, which means that it has been published for initial use, but is dependent upon completion of other standards and thus may involve risk of upcoming change. This TAUG-Diabetes was developed under the Coalition for Accelerating Standards and Therapies (CFAST) initiative.

CFAST, a joint initiative of CDISC and the Critical Path Institute (C-Path), was launched to accelerate clinical research and medical product development by facilitating the establishment and maintenance of data standards, tools, and methods for conducting research in therapeutic areas important to public health. CFAST partners include TransCelerate BioPharma Inc. (TCB), the U.S. Food and Drug Administration (FDA), and the National Cancer Institute Enterprise Services (NCI-EVS), with participation and input from many other organizations. See http://www.cdisc.org/cfast-0 for a list of CFAST participating organizations.

CDISC has developed industry-wide data standards enabling the harmonization of clinical data and streamlining research processes from protocol (study plan) through analysis and reporting, including the use of electronic health records to facilitate study recruitment, study conduct and the collection of high quality research data. CDISC standards, implementations and innovations can improve the time/cost/quality ratio of medical research, to speed the development of safer and more effective medical products and enable a learning healthcare system.

The goal of the CFAST initiative is to identify a core set of clinical concepts and endpoints for targeted therapeutic areas and translate them into CDISC standards to improve semantic understanding, support data sharing and facilitate global regulatory submission.

1.1 Purpose

The focus of this Version 1.0 (v1.0) of the TAUG-Diabetes is on Phase III-IV clinical trials of drugs to treat diabetes in an adult outpatient population. Guidelines for handling data specific to pediatric or inpatient studies are not addressed in this version. See Appendix A for the project proposal that was approved by the CFAST Steering Committee.

This TAUG-Diabetes v1.0 describes the most common data needed for diabetes studies, so that those handling the data (e.g. data managers, statisticians, programmers) can understand the data and can apply standards appropriately. Descriptions addressed in this TAUG-Diabetes v1.0 include the clinical situations from which the data arise, and the
reasons these data are relevant for diabetes. The overall goal is to provide the metadata needed to assist in the move toward closer semantic interoperability between health care and clinical trials.

The TAUG-Diabetes v1.0 also strives to define research concepts unambiguously, so that consistent terminology can be used in diabetes studies to enable aggregation and comparison of data across studies and drug programs.

Further, this standard includes metadata for the research concepts, including the properties of the data items that are part of the concepts, controlled terminology for those data items, and the ways in which the concepts relate to each other. These metadata, useful in their current form to create define files, are described further in Appendix D2. They will be further developed and included in the CDISC SHARE metadata repository (http://www.cdisc.org/cdisc-share).

And finally, the TAUG-Diabetes v1.0 describes how to use CDISC standards to represent the data:

- For Clinical Data Acquisition Standards Harmonization (CDASH), the guidance includes examples of CDASH-conformant annotated case report forms (CRFs) and CDASH metadata tables for data collection. Conformance rules are specified in the CDASH UG v1.1. The examples provided are consistent with the CDASH Best Practice Recommendations described in CDASH v1.1.
- For the Study Data Tabulation Model (SDTM) and the SDTM Implementation Guide for Human Clinical Trials (SDTMIG), these instructions include guidance on the domains and other datasets in which data should be represented, how variables should be used, and data examples.
- For the Analysis Data Model (ADaM), work is currently underway on ADaM guidance that will be included in future iterations of this document. The exact form of the guidance has yet to be determined.

These CDISC standards are freely available at http://www.cdisc.org/standards-and-implementations. It is recommended that implementers consult the Study Data Tabulation Model (SDTM) and the CDASH standard prior to implementing these diabetes clinical data standards.

It is important to note that this document does not contain guidance from any regulatory authority and should not be construed as substituting for or replacing any documents published by such an authority. **The inclusion of concepts in this user guide should not be construed as a requirement to collect data on these concepts in any particular study in diabetes.** The examples included are intended to show how data of particular kinds can be represented using CDISC standards. They are not intended as commentary on whether such data should be collected or not. In some areas, there is no consensus on an approach in assessing a specific aspect of diabetes (e.g. data collection on severity of hypoglycemia). In those areas, this user guide emphasizes that examples given are for illustrative purposes only and should not be over-interpreted.

## 1.2 Organization of this Document

This document is divided into the following sections:

- **Section 1, Introduction**, provides an overall introduction to the purpose and goals of the Diabetes project.
- **Section 2, Subject and Disease Characteristics**, describes data that are usually collected once at the beginning of a study.
- **Section 3, Disease Assessments**, covers data that are used to evaluate disease severity, control, or progression. These are usually collected repeatedly during a study, and may be used as efficacy endpoints.
- **Section 4, Routine Data**, covers background data that are collected in most studies. Only aspects of these data that arise in diabetes studies and that are not covered by existing standards are discussed.
- **Appendices** provide additional background material and describe other supplemental material relevant to diabetes.
A list of domains used in the examples in this document, and the sections in which they appear, is given below:

<table>
<thead>
<tr>
<th>Domains from SDTMIG</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions</td>
<td></td>
</tr>
<tr>
<td>AG</td>
<td>3.2.2.2</td>
</tr>
<tr>
<td>CM</td>
<td>3.2.1, 3.3.2.5</td>
</tr>
<tr>
<td>EX</td>
<td>3.3.2.3</td>
</tr>
<tr>
<td>ML</td>
<td>3.3.2.3</td>
</tr>
<tr>
<td>Devices domains are used for ancillary devices only.</td>
<td></td>
</tr>
<tr>
<td>Events</td>
<td></td>
</tr>
<tr>
<td>CE</td>
<td>3.3.2.1</td>
</tr>
<tr>
<td>MH</td>
<td>2.1.1, 2.2.1</td>
</tr>
<tr>
<td>Findings</td>
<td></td>
</tr>
<tr>
<td>LB</td>
<td>3.2.1.1, 3.2.2.2, 3.3.2.2</td>
</tr>
<tr>
<td>FA</td>
<td>3.3.2.4</td>
</tr>
<tr>
<td>Trial Design</td>
<td></td>
</tr>
<tr>
<td>TS</td>
<td>3.3.2.2</td>
</tr>
<tr>
<td>Domains from SDTMIG-MD</td>
<td></td>
</tr>
<tr>
<td>DI</td>
<td>3.2.1.1</td>
</tr>
</tbody>
</table>

* Domain is not final.

1.3 Concept Maps

This document uses concept maps to explain clinical processes and research concepts. Concept maps, also sometimes called mind maps, are diagrams which include “bubbles” representing concepts/ideas/things and labeled arrows that represent the relationships between the concepts/ideas/things. They are generally easier to draw and more accessible than more formal modeling diagrams, such as Universal Modeling Language diagrams.

The diagrams in this document use the following coding for classification of concepts. This classification is based on classes in the Biomedical Research Integrated Domain Group (BRIDG) model. These color-symbol pairs have been used to highlight kinds of things that occur commonly in clinical data and therefore give rise to common patterns of data. Some concepts are not coded; they have a thinner, black outline, and accompanying symbol. These may include the subject of an observation, as well as characteristics, or attributes, of the coded concepts.

1.4 Controlled Terminology

CDISC Controlled Terminology is a set of standard value lists that are used throughout the clinical research process, from data collection through analysis and submission. Terminology applicable to CDASH data collection fields is
either in production or under development by the CDISC Terminology Team at the time of publication of this document. It is possible to allow the conversion of legacy data that was not based on CDASH, but is submitted using SDTM as its basis. Production terminology is published by the National Cancer Institute’s Enterprise Vocabulary Services (NCI EVS) and is available at: 

CDISC Controlled Terminology is updated quarterly. Because this document is a static publication, it refers readers to the NCI EVS page for CDISC terminology (at the link given above). For the same reason, this document cannot claim to use controlled terminology in either the lists of laboratory tests or in the examples provided; users should not refer to these as the ultimate authority on what terms to use.

Heretofore, domain specification tables have listed any codelists that are associated with a particular variable. In the future, it is envisioned that the CDISC SHARE metadata repository (which is not static) will provide not only the codelist associated with a particular variable, but also a list of values from the codelist applicable to a particular concept. For more on SHARE metadata, see Appendix D2.

1.5 Relationships to Other Standards

This section describes the relationship of this document to other standards, whether CDISC or external.

This document does not replace the foundational CDISC standards or their implementation guides. The user should read those standards and implementation guides before applying the advice in this user guide.

Representations of the research concepts used in this document, in an expanded format consistent with the CDISC SHARE metadata repository, will be developed separately. An example set of somewhat simplified concept metadata displays as they may be represented in SHARE is included as part of the TAUG-Diabetes v1.0. The metadata displays are listed in Appendix D2.

Representations of CDASH-compliant example CRFs and associated metadata for some concepts used in this document are included as a part of the TAUG-Diabetes v1.0. For more information on CDASH, see http://www.cdisc.org/cdash. For a brief overview of CDASH metadata as it appears in this therapeutic area user guide, see Appendix D1.

This document uses domains and assumptions which are not final at the time of publication and therefore are subject to change or deletion without formal notice. Please check the most recent version of SDTM and SDTMIG (http://www.cdisc.org/sdtm) to ascertain their current status.

• The Meals (ML) domain is still a work in progress (i.e. a “draft” domain), which has not appeared prior to this TAUG-Diabetes.
• The Procedure Agents (AG) domain is a draft domain that originally appeared as part of the Therapeutic Area Data Standards User Guide for Asthma (TAUG-Asthma).
• The Disease Milestones proposal is a set of proposed additions to the SDTM and SDTMIG which has not appeared prior to this TAUG-Diabetes.
  o MIDS, RELMIDS, and MIDSDTC are proposed new SDTM variables.
  o “Disease Milestones and Disease Milestone Timing Variables” is a draft set of general assumptions for all domains proposed for inclusion in Section 4 of the SDTMIG.
  o The Subject Disease Milestones (SM) domain is a draft domain.
  o The Trial Disease Milestones (TM) domain is a draft trial design dataset specification.

In some cases where a definitive SDTM modeling approach does not exist, a suggested approach is offered but may be subject to change over time. See Section 1.6 below for a list of known issues.

1.6 Known Issues

• Date of Diagnosis: The SDTMIG does not provide advice on how to represent date of diagnosis of an event. Various solutions have been proposed, but this document treats the date of diagnosis of a medical
history event as the value of a supplemental qualifier with QNAM=MHDXDTC. Some users have simply mapped a collected “date of diagnosis” to MHSTDTC. Although date of diagnosis can reasonably be treated as the start of an event, this mapping alone does not provide the information that this particular start date is specifically the date of diagnosis.

- **Data triggered by an event of special interest:** Most advice in the SDTMIG assumes that assessments are scheduled at a visit or time point, so provides little guidance for assessments that are triggered by the occurrence of something unplanned. For diabetic subjects, hypoglycemic events trigger the collection of a variety of assessments, as described in Section 3.3.1, and representing the timing of these assessments and their relationship to the triggering event in SDTM datasets is challenging. In this document, the triggering hypoglycemic event has been handled as a disease milestone. Disease milestones are a new construct proposed for the SDTM and described in the draft SDTMIG Section 4.1.2.11.

- **Symptoms of an Event:** Symptoms of an event are themselves events, so questions about the occurrence of a symptom of a particular event can be handled with records in the Clinical Events (CE) domain with PRESP and OCCUR populated, or as records in the Findings About Events or Interventions (FA) domain with OBJ=<name of event> and TEST=<name of symptom> with a result of Yes or No indicating occurrence of the symptom with the hypoglycemic event. Examples in the SDTMIG would support either approach, and do not provide definitive guidance for choosing between the two approaches, particularly when only a yes/no response to occurrence of the symptom is collected. In this document, the first approach has been used.

- **Collection of Single Doses for Interventions Otherwise Recorded Using Constant Dosing Records:** In some studies, interventions may be adequately described using constant dosing records for most purposes, but details of particular doses may also be needed. Examples include cases where details of the last dose before a particular activity or event are needed. This arises in studies which include population pharmacokinetics data, where a PK sample is drawn at a convenient time rather than at a fixed time after dosing, and the time of the last dose prior to the sample is collected. This also arises in this TAUG-Diabetes where the timings of the most recent meals and doses of diabetes medications prior to a hypoglycemic event can be critical. The SDTMIG does not provide advice on how to record such data. The approach taken in this document is to record data about single doses in addition to constant-dosing-record data, but to flag the “extra” single-dose records by populating --CAT or --SCAT with the value “HIGHLIGHTED DOSE” to help avoid having these records result in “double counting” of these doses when deriving cumulative dose or in other summaries.

- **Choice of Domain for Substance Administration:** The growing number of interventions domains in the SDTMIG has created uncertainty about the choice of domain for meals. In this document, the domain for data about meals is chosen depending on the role of the meal. Meals given as part of a meal tolerance test are treated as procedure agents and reported in the AG domain. Food and drink used to treat hypoglycemic events are recorded in the concomitant medications domain. Meals taken in the normal course of events, but reported in relation to a hypoglycemic event, are recorded in the ML domain. Guidance on where to put interventions data is being developed by the SDS team.
2 Subject and Disease Characteristics

2.1 Diabetes History

Diabetes studies usually collect data on the diagnosis of diabetes, including the date of diagnosis (which may be defined as the subject-reported date, the date based on medical records, or another definition), and the type of diabetes (e.g. Type 1 diabetes mellitus (T1DM), Type 2 diabetes mellitus (T2DM)) if patients with more than one type of diabetes are included in the study.

Some aspects of a subject’s diabetes history, such as date of diagnosis, may be collected at the start of a study and summarized as part of the subject’s baseline characteristics.

Concept Map 1: Diagnosis of Diabetes

The diagram above shows the process of deciding on a diagnosis is an observation with a date. For studies which enroll subjects with multiple types of diabetes, the diagnosis, including type of diabetes, will be collected.
2.1.1 Examples for Diabetes History

Example CRF 1: Diabetes History

<table>
<thead>
<tr>
<th>Diabetes</th>
<th>(pre-specified)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Diagnosis of Diabetes</td>
<td>--- --- (DD-MM-YYYY)</td>
</tr>
<tr>
<td>Type of Diabetes</td>
<td>MHTERM</td>
</tr>
<tr>
<td>Medical History Category</td>
<td>DIABETES (pre-specified)</td>
</tr>
</tbody>
</table>

MHRESP= Y  MHOCCUR= Y

MHSTDTC  MHSTDAT

QVAL in SUPPMH where QNAM = "MHDXDTCP" and QLABEL = "Date of diagnosis"

Example 1
Subjects enrolled in this study can have either T1DM or T2DM.

The example shows two different subjects, one with T1DM and the other with T2DM.
One of the methods of determining the start date of event is by the initial diagnosis of the event. The date of diagnosis of diabetes is mapped to MHSTDTC.
The date of diagnosis is also mapped to SUPPMH and the value of QLABEL shows that this date is the “Date of Diagnosis”.

**mh.xpt**

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>MHSEQ</th>
<th>MHTERM</th>
<th>MHCAT</th>
<th>MHRESP</th>
<th>MHOCCUR</th>
<th>MHDTC</th>
<th>MHSTDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>1</td>
<td>TYPE 1 DIABETES</td>
<td>DIABETES</td>
<td>Y</td>
<td>Y</td>
<td>2010-09-26</td>
<td>2010-03-25</td>
</tr>
<tr>
<td>2</td>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-002</td>
<td>1</td>
<td>TYPE 2 DIABETES</td>
<td>DIABETES</td>
<td>Y</td>
<td>Y</td>
<td>2010-10-26</td>
<td>2010-04-25</td>
</tr>
</tbody>
</table>

**suppmh.xpt**

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDID</th>
<th>RDOMAIN</th>
<th>USUBJID</th>
<th>IDVAR</th>
<th>IDVARVAL</th>
<th>QNAM</th>
<th>QLABEL</th>
<th>QVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>MHSEQ</td>
<td>1</td>
<td>MHDXDTCP</td>
<td>Date of Diagnosis</td>
<td>2010-01-25</td>
</tr>
<tr>
<td>2</td>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-002</td>
<td>MHSEQ</td>
<td>1</td>
<td>MHDXDTCP</td>
<td>Date of Diagnosis</td>
<td>2010-04-25</td>
</tr>
</tbody>
</table>

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
Provisional
September 1, 2014
2.2 Diabetes Complication History

During clinical evaluation, the most common medical complications of diabetes are assessed using a predefined list. Examples of such diabetic complications include:

- Retinopathy
- Distal Neuropathy
- Autonomic Neuropathy
- Nephropathy
- Peripheral artery disease (PAD)
- Atherosclerotic disease
- Diabetic ketoacidosis (DKA)
- Hyperglycemic hyperosmolar syndrome (HHS)
- Cerebrovascular Disease

Data collected for complication history may include the following:

- Whether a subject has had any of the complications, followed by specific questions about the occurrence of each pre-specified complications, with a Y/N response
- Complication history details recorded as verbatim terms on the medical history form
- Additional details such as dates of procedures as a result of the complications

Concept Map 2: Diabetic Retinopathy

This concept map depicts an observation related to diabetic retinopathy only, although a clinical trial may collect information on several complications. The observation on the left asks whether the subject had diabetic retinopathy. A “Yes” answer may trigger the observation on the right, collection of additional information about the retinopathy.
2.2.1 Examples for Diabetes Complication History

Example CRF 2: Diabetes Complications

<table>
<thead>
<tr>
<th>MHTERM</th>
<th>MHPRESP= Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM, Neutropathy</td>
<td></td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td></td>
</tr>
<tr>
<td>Atherosclerotic Heart Disease</td>
<td></td>
</tr>
<tr>
<td>Diabetic Ketoacidosis</td>
<td></td>
</tr>
<tr>
<td>Hyperglycemic Hyperosmolar Syndrome</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>MHSEQ</th>
<th>MHTERM</th>
<th>MHSCAT</th>
<th>MHCAT</th>
<th>MHPRESP</th>
<th>MHOCUR</th>
<th>MHSTDTC</th>
<th>MHSTDAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>1</td>
<td>DIABETIC RETINOPATHY</td>
<td>COMPLICATION</td>
<td>DIABETES</td>
<td>Y</td>
<td>N</td>
<td>2010-03-01</td>
<td></td>
</tr>
<tr>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>2</td>
<td>NEPHROPATHY</td>
<td>COMPLICATION</td>
<td>DIABETES</td>
<td>Y</td>
<td>N</td>
<td>2010-03-01</td>
<td></td>
</tr>
<tr>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>3</td>
<td>NEUROPATHY</td>
<td></td>
<td>DIABETES</td>
<td>Y</td>
<td>Y</td>
<td>2010-03-01</td>
<td>2007-01-01</td>
</tr>
<tr>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>4</td>
<td>Atherosclerotic Heart Disease</td>
<td>COMPLICATION</td>
<td>DIABETES</td>
<td>Y</td>
<td>N</td>
<td>2010-03-01</td>
<td></td>
</tr>
<tr>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>5</td>
<td>PERIPHERAL VASCULAR DISEASE</td>
<td>COMPLICATION</td>
<td>DIABETES</td>
<td>Y</td>
<td>N</td>
<td>2010-03-01</td>
<td></td>
</tr>
<tr>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>6</td>
<td>DIABETIC KETOACIDOSIS</td>
<td>COMPLICATION</td>
<td>DIABETES</td>
<td>Y</td>
<td>N</td>
<td>2010-03-01</td>
<td></td>
</tr>
<tr>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>7</td>
<td>HYPERGLYCEMIC HYPEROSMOLAR SYNDROME</td>
<td>COMPLICATION</td>
<td>DIABETES</td>
<td>Y</td>
<td>N</td>
<td>2010-03-01</td>
<td></td>
</tr>
</tbody>
</table>

Example 1

In this example, the complications of diabetes are pre-specified on the CRF.

Rows 1-7: Show pre-specified diabetic complications for one subject. MHOCUR is Y for the conditions that the subject had prior to starting the study.

Row 3: This shows that the subject had Neuropathy 3 years prior to starting the study and the condition is still ongoing at the time of starting the study.
The date of diagnosis is also mapped to SUPPMH and the value of QLABEL shows that this date is the “Date of Diagnosis”.

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>RDOMAIN</th>
<th>USUBJID</th>
<th>IDVAR</th>
<th>IDVARVAL</th>
<th>QNAM</th>
<th>QLABEL</th>
<th>QVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>XYZ</td>
<td>MH</td>
<td>XYZ-001-001</td>
<td>MHSEQ</td>
<td>3</td>
<td>MHDXDT</td>
<td>Date of Diagnosis</td>
<td>2007-01-01</td>
</tr>
</tbody>
</table>

### 2.3 Treatment-Naïveté

The term “treatment-naïve” is used to describe a subject who has not previously received medication (or a particular type of medication) for a particular disease. The protocol should include the definition of “treatment-naïve” used for the study, and the definition should specify which treatments or kinds of treatments are considered in deciding whether a subject is treatment-naïve, and may also include a time frame to be considered in this determination (e.g. the subject’s lifetime, the past 10 years). Treatment-naïveté may be defined differently for different studies and analyses. Some studies admit only treatment-naïve or only treatment-experienced subjects. However, if a study admits both, it may be important to record whether a subject is treatment-naïve.

For diabetes studies, the definition of treatment-naïveté may specify either all anti-hyperglycemic medications, only oral medications, only injectable medications, or only insulin. The protocol may define treatment-naïve subjects as those who have never received any of the specified drugs, or who have not received the specified drugs within a certain period before entering the study. Information regarding prior use of anti-hyperglycemic medications is important as these affect the treatment response during the study. For example, subjects who are treatment-naïve to insulin may have a different response to initial therapy than those who are receiving additional therapy. Depending on the study design, it may be important to capture whether a subject is insulin-naïve, because starting insulin therapy for the first time is different from adding therapy to a subject already on insulin.

Treatment-naïve data may be used for a variety of purposes in a study including: inclusion/exclusion criteria; clinical assessment of subject response to study drug therapy, a stratification factor in randomization, or a baseline characteristic in analyses. The definition of treatment-naïve used in each study must be defined in the protocol. Typical treatment-naïve definitions to consider may include:

- Total treatment-naïveté to all anti-hyperglycemic medications, oral and injectable
- Treatment-naïve within a certain time period and/or drug or drug class
- Treatment-naïve to injectable drug vs. oral drug
The details of medications and time periods depend on the study’s definition of “treatment-naïve”. Depending on the protocol, this may be used in screening for subjects who are or are not treatment-naïve according to protocol requirements, or may be used for distinguishing between treatment-naïve and non-treatment-naïve subjects within a single study.

### 2.3.1 Examples for Treatment-Naïveté

#### Example 1
In this study, both treatment-naïve and previously-treated subjects are enrolled, and it is important to make a distinction between the two for sub-group analyses. In this study, a subject is considered treatment-naïve if they have not received treatment with any anti-hyperglycemic drugs during the 10 years prior to screening. The example lists the anti-hyperglycemic medications taken by a subject in the 10 years prior to screening. The total daily dose of the medication was collected. This example shows two subjects: one is not naïve to anti-hyperglycemic medications, the other is naïve to anti-hyperglycemic medications.

- **Row 1:** Shows an example of a subject that took anti-hyperglycemic medications prior to study entry. This subject is not treatment-naïve according to the protocol definition. CMDTC is the date the subject responded to the pre-specified question on the eCRF.
- **Rows 2-4:** Show the details of the anti-hyperglycemic medications taken by the subject in the 10 years prior to study entry.
- **Row 5:** Shows an example of a subject that did not take any anti-hyperglycemic medications prior to study entry. This subject is treatment-naïve according to the protocol definition. CMDTC is the date the subject responded to the pre-specified question on the eCRF.
Example 2

In this study, both treatment-naïve and previously-treated subjects are enrolled, and a subject is considered treatment-naïve if they have received no treatment with insulin during the 6 months prior to screening. This example shows data for two subjects: one is insulin-naïve according to the protocol definition, and the other took insulin during the 6 months prior to study entry.

Row 1: Shows an example of a subject who took insulin prior to study entry. This subject is not treatment-naïve according to the protocol definition. Since this is a record about whether the subject received any of a group of medications, both CMTRT and CMCAT are populated with the name of group of medications.

Rows 2-3: Show the details of the insulin medications that the subject took in the 6 months prior to study entry.

Row 4: Shows an example of a subject that did not take any insulin prior to study entry. This subject is treatment-naïve according to the protocol definition.
3 Disease Assessments

3.1 Laboratory Tests

The audience for this laboratory section is not targeted for medical professionals, but is meant to find a balance between general and detailed.

3.1.1 Glucose Homeostasis and Diabetes Related Markers

Diabetes is generally diagnosed by blood tests; pre-diabetes and early T2DM may have few or no markers. Blood glucose concentrations are affected by many factors, but particularly by meals, so random blood glucose may not be a reliable basis for diagnosis, unless markedly elevated (e.g. >200 mg/dL or 11.1 mmol/L) and accompanied by typical symptoms of hyperglycemia. Fasting blood glucose and measurements obtained during an oral glucose tolerance test (see Section 3.2.2) are more reliable, but they measure glucose concentrations only in the short term and require fasting or glucose loading. Standardized glycosylated hemoglobin A1c assays reliably estimate average glucose concentrations over a longer term, have less variability during stress and illness, and are sometimes more specific for identifying individuals with diabetes or at increased risk for diabetes.

The test names in the following tables should not be relied upon for current controlled terminology. Refer to the NCI EVS page (http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc) for current CDISC terminology.

<table>
<thead>
<tr>
<th>Common Test Abbreviation</th>
<th>Test Name</th>
<th>Description</th>
<th>Specimen(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1c HbA1c</td>
<td>Glycosylated Hemoglobin, Glycated Hemoglobin, Hemoglobin A1c, Glycosylated Hemoglobin A1c</td>
<td>Glycosylated hemoglobin is formed in a non-enzymatic glycation pathway by hemoglobin's exposure to plasma glucose. As the average amount of plasma glucose increases, the fraction of glycosylated hemoglobin increases in a predictable way. This serves as a marker for average blood glucose concentrations over the previous two to three months prior to the measurement.</td>
<td>Blood</td>
</tr>
<tr>
<td>Glucose</td>
<td></td>
<td>Glucose is a carbohydrate and is the most important simple sugar in human metabolism. The body naturally tightly regulates the glucose concentrations as a part of metabolic homeostasis. Glucose is transported from the intestines or liver to body cells via the bloodstream and is made available for cell absorption via the hormone insulin. Glucose concentrations are usually lowest in the morning before the first meal of the day or an extended time (e.g. 8 hours) since the last meal. This is called &quot;fasting glucose&quot;. A consistently high glucose concentration is referred to as hyperglycemia. Low glucose concentrations are referred to as hypoglycemia. Diabetes mellitus is characterized by consistent hyperglycemia from any of several causes. T1DM is characterized by a state of insulin deficiency, while T2DM is characterized by insulin resistance. It is the most prominent disease related to failure of blood glucose regulation.</td>
<td>Serum, Plasma, Blood, Urine</td>
</tr>
<tr>
<td>Insulin</td>
<td></td>
<td>Insulin is a peptide hormone produced by beta-cells of the pancreas that is central to regulating carbohydrate and fat metabolism. Insulin promotes the use of glucose as an energy source, stimulating cells in the liver and skeletal muscles to take in glucose from the bloodstream and either burn the glucose as energy, or to store it as glycogen. The presence of insulin inhibits the use of fat as an energy source by inhibiting the release of stored fats. Simply put, as glucose concentrations normally rise after a meal, insulin increases in the bloodstream and promotes use and storage of glucose. During fasting, insulin concentrations decrease commensurate with the</td>
<td>Serum, Plasma</td>
</tr>
</tbody>
</table>
glucose concentrations, and the body increases its release of stored glucose (glycogenolysis) and fat (lipolysis) that can be used as energy. In diabetes, there is either an absolute or relative insulin deficiency, resulting in abnormal glucose homeostasis.

Subjects with T1DM have a total lack of insulin, brought about by an autoimmune process that destroys beta cells, and as a result depend on exogenous insulin to live. In contrast, individuals with T2DM have a relative insulin deficiency and insulin ‘resistance’, wherein the insulin is not as effective in enhancing glucose transport into the liver and muscle cells. As a result, glucose concentrations increase in the blood. During the early years of T2DM, insulin concentrations in the blood may actually increase, only to decrease later in the disease. Over time, oral anti-hyperglycemic agents tend to lose efficacy, and many patients with T2DMs require insulin injections.

Proinsulin
Proinsulin is the precursor to insulin and C-peptide. It is made in the beta-cells of the islets of Langerhans, specialized regions of the pancreas.

Determining proinsulin in blood may help to identify the risk for T1DM or T2DM and to decide which treatment is best.

C-peptide
C-peptide is a peptide that connects the A-chain and B-chain of insulin in the proinsulin molecule. When insulin is secreted from the pancreatic beta cells, equal amounts of C-peptide are released into the blood stream.

Measuring the concentration of C-peptide reflects the amount of insulin being produced by beta cells. C-peptide concentrations are more stable than those of insulin, which tends to be highly variable. Measuring the concentration of C-peptide is sometimes useful to assess beta cell function.

Glucagon
Glucagon, a peptide hormone secreted by alpha-cells in the pancreas, raises blood glucose and increases the release of fats from storage. Thus, its effects are opposite to those of insulin. In face of decreasing glucose concentrations, the pancreas releases more glucagon in an effort to increase the blood glucose. Glucagon causes the liver to convert stored glycogen into glucose (glycogenolysis) and release the glucose into the bloodstream. Glucagon and insulin are part of a feedback system that is designed to keep blood glucose levels within a rather narrow range.

GIP
Glucose-Dependent Insulinotropic Peptide, Gastric Inhibitory Peptide
GIP is a secretin hormone, meaning that it is produced by particular intestinal cells. Along with GLP, GIP is an incretin hormone, which means that it enhances the release of insulin in response to a meal. Subjects with T2DM are relatively unresponsive to GIP and their GIP concentrations after a meal are lower than normal.

GLP-1
Glucagon-Like Peptide-1
Glucagon-like peptide 1 (GLP-1) is an incretin hormone produced in the intestinal L cells and released into the bloodstream in response to a meal. GLP-1 has a variety of actions, including enhancing insulin release from pancreatic beta cells, inhibiting glucagon secretion, and slowing gastric emptying. All these actions tend to control increasing glucose concentrations. Drugs that mimic the actions of GLP-1 are available and are useful in the treatment of T2DM.

1,5-AG
1,5-Anhydroglucitol
1,5-Anhydroglucitol is a naturally occurring monosaccharide found in nearly all foods. It may be useful in identifying glycemic variability in people with diabetes who have normal or near normal hemoglobin A1c values. As an example, 1,5-anhydroglucitol values decrease during times of hyperglycemia (above 180 mg/dL), and return to normal levels after about 2 weeks in the absence of hyperglycemia.
<table>
<thead>
<tr>
<th>Common Test Abbreviation</th>
<th>Test Name</th>
<th>Description</th>
<th>Specimen(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOMA</td>
<td>HOMA</td>
<td>HOMA is an indirect method to estimate insulin resistance (HOMA-IR), insulin sensitivity (HOMA-S), and beta-cell function (HOMA-B) by examining the relationships between measured insulin and glucose concentrations. They provide relatively crude measures of beta cell function and insulin resistance/sensitivity. The original model was calibrated to give normal beta-cell function a value of 100% and normal insulin resistance a value of 1. Higher insulin resistance is characterized by higher steady state insulin concentrations, relative to glucose concentration. Other tests, such as the “glucose clamp” and the frequently sampled iv glucose tolerance test provide better estimates of beta cell function and insulin resistance but are more burdensome for patients and take longer to perform. These latter tests are not suitable for performance in large clinical trials because of time, expense and patient burden.</td>
<td>Derived from Serum or Plasma measurements</td>
</tr>
<tr>
<td>HOMA-B</td>
<td>HOMA-B</td>
<td>HOMA model to calculate the β-cell function (%B) from fasting glucose and fasting insulin.</td>
<td>Derived from Serum or Plasma measurements</td>
</tr>
<tr>
<td>HOMA-IR</td>
<td>HOMA-IR</td>
<td>HOMA model to calculate the insulin resistance (IR) from fasting glucose and fasting insulin. HOMA-IR (100/S%) is the reciprocal of HOMA-S (%S).</td>
<td>Derived from Serum or Plasma measurements</td>
</tr>
<tr>
<td>HOMA-S</td>
<td>HOMA-S</td>
<td>HOMA method to calculate the insulin sensitivity from fasting glucose and fasting insulin. HOMA-S (%S) is the reciprocal of HOMA-IR (100/S%).</td>
<td>Derived from Serum or Plasma measurements</td>
</tr>
<tr>
<td>IA2 ICA</td>
<td>IA2 ICA</td>
<td>Antibodies to various components of the beta cell can be measured and can be useful in assessing immune etiologies of T1DM. Measuring antibody concentrations, however, has no direct role in the clinical management of patients with T1DM.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>Anti-Insulin Antibodies</td>
<td>Anti-Insulin Antibodies</td>
<td>The anti-insulin antibody test may be performed in subjects having or being at risk for T1DM. It also may be done if the subject appears to have an allergic response to insulin, or if insulin no longer seems to control the blood glucose.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>Ketones</td>
<td>Ketones</td>
<td>Ketones are chemicals produced when the body breaks down stored fat, such as during prolonged fasting. With extremely low or absent insulin concentrations, such as during ketoacidosis in T1DM, the ketones can accumulate to dangerous concentrations and lead to high amounts of acid formation in the blood. Diabetic ketoacidosis can be fatal if left untreated. Ketone concentrations can be measured in both the blood and urine.</td>
<td>Serum, Plasma, Urine</td>
</tr>
<tr>
<td>GAD</td>
<td>GAD</td>
<td>GAD is an enzyme that contributes to the synthesis of gamma-aminobutyric acid. Measurement of GAD antibodies does not confirm the presence of T1DM, but together with other autoantibodies, can help to assess risk for development of T1DM and, as a single test, makes the diagnosis of T1DM more likely. Isolated GAD, however, can occur in persons who have a clinical course that appears like that of type 2 diabetes.</td>
<td>Plasma, Serum</td>
</tr>
</tbody>
</table>
3.1.2 Lipid Panel

As diabetes is associated with a high risk of cardiovascular disease (CVD), laboratory tests may look at levels of blood lipids such as triglycerides and cholesterol. The management of diabetic dyslipidemia, a well-recognized and modifiable risk factor, is a key element in the multifactorial approach to preventing CVD in individuals with T2DM. Although age-adjusted rates of CVD death have fallen in recent years, CVD risk remains elevated in patients with diabetes. Lifestyle changes and treatment to lower LDL-cholesterol as well as control of other major CVD risk factors such as hypertension are key elements of prevention.

<table>
<thead>
<tr>
<th>Common Test Abbreviation</th>
<th>Test Name</th>
<th>Description</th>
<th>Specimen(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amylase</td>
<td>Amylase</td>
<td>Amylase is an enzyme that digests starches into sugars and is secreted by the salivary glands and the pancreas. Serum amylase is produced by the pancreas and low levels have been found to be associated with decreased basal insulin levels, reduced insulin secretion, and insulin resistance.</td>
<td>Serum</td>
</tr>
<tr>
<td>TG</td>
<td>Triglycerides</td>
<td>Triglycerides are lipids (fat molecules) present in food and carried by lipoproteins in the blood plasma. When triglycerides enter the body through food, they may ultimately be transferred to and stored in the fat cells if not used for energy immediately. Later, hormones release fatty acids for energy between meals. Elevated triglyceride-rich lipoprotein levels in the blood are a risk factor for atherosclerosis, and may contribute to the increased risk of heart attack, stroke, and peripheral artery disease, as well as be associated with other diseases including poorly controlled diabetes mellitus. Lowering triglyceride levels with drugs is much less effective in reducing the risk of heart disease than lowering LDL-cholesterol.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>Cholesterol</td>
<td>Cholesterol is a lipid (fat molecule) ingested in foods and synthesized in the body. One of the primary sites of cholesterol synthesis is the liver. Due to its hydrophobic nature, cholesterol cannot travel in the blood on its own, but needs to be transported within lipoproteins. The individual lipoproteins that carry cholesterol and contribute to its total blood level are low-density (LDL), high-density (HDL), and very-low-density (VLDL) lipoproteins. A high total cholesterol level may indicate a problem with cholesterol, but it is more important to measure the content in the individual lipoproteins.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>LDL-C</td>
<td>Low-Density Lipoprotein Cholesterol</td>
<td>LDL-C enables the transport of fats such as cholesterol in the bloodstream. LDL-C together with other substances can form plaque, a thick, hard deposit that can narrow the arteries and make them less flexible. As a result, the amount of blood and oxygen available to the heart is decreased. This condition is known as atherosclerosis, and can lead to heart disease and heart attacks. Therefore LDL-C is often referred to as &quot;bad cholesterol&quot;. The concentration of LDL-C is often calculated using the Friedewald equation.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>HDL-C</td>
<td>High-Density Lipoprotein Cholesterol</td>
<td>HDL-C enables the transport of cholesterol back to the liver for excretion or re-utilization. Having higher levels of HDL-C is associated with a lower risk of cardiovascular diseases, while low HDL-C levels lead to increased risk for heart disease. Therefore HDL-C is sometimes called &quot;good cholesterol&quot;.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>VLDL-C</td>
<td>Very Low-Density Lipoprotein Cholesterol</td>
<td>VLDL-C is made up mostly of triglycerides and enables the transport of fats such as cholesterol in the bloodstream. In the bloodstream, VLDL-C is converted to intermediate density lipoprotein cholesterol and to LDL-C.</td>
<td>Serum, Plasma</td>
</tr>
</tbody>
</table>
### 3.1.3 Kidney Function

Following a diagnosis of diabetes, laboratory urine testing can be used to follow the progression of the disease and predict treatment response. Individuals with diabetes are at increased risk of kidney disease. Routine blood pressure, creatinine, and eGFR testing are recommended to detect the onset and monitor progression of complications affecting the kidney.

<table>
<thead>
<tr>
<th>Common Test Abbreviation</th>
<th>Test Name</th>
<th>Description</th>
<th>Specimen(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine</td>
<td>Creatinine</td>
<td>Creatinine is a breakdown product of creatine phosphate when muscles expend energy, and is usually produced at a fairly constant rate by the body. Creatinine is normally filtered from the blood by the kidneys and excreted in the urine. Creatinine levels in blood and urine may be used to calculate the creatinine clearance, which reflects the glomerular filtration rate. Creatinine and creatinine clearance are inversely related: a decrease in creatinine clearance results in increase in serum creatinine. One of the complications of diabetes is kidney damage, which can result in kidney failure. When kidneys start to fail, creatinine builds up in the blood. Measuring the levels of creatinine in the bloodstream and in the urine can be helpful for tracking the progression of diabetic nephropathy.</td>
<td>Urine, Serum, Plasma</td>
</tr>
<tr>
<td>CCr</td>
<td>Creatinine Clearance</td>
<td>Creatinine clearance rate is defined as the volume of blood that is cleared of creatinine per unit time and is a useful measure for approximating the glomerular filtration rate. Creatinine clearance is important in assessing the excretory function of the kidneys. A creatinine clearance test is done by measuring both a serum creatinine concentration along with a urine creatinine in a urine sample collected over a specific time period.</td>
<td>Derived from Urine and Serum or Plasma measurements</td>
</tr>
<tr>
<td>CrCl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>eGFR</td>
<td>Estimated Glomerular Filtration Rate</td>
<td>Instead of requiring the laborious creatinine clearance test, which involves collecting urine over time, a variety of formulas have been developed that rely on a single measurement of serum creatinine, taking into account variables such as the subject’s age, gender, race, and weight. An estimated glomerular filtration rate (eGFR) can be derived from the following formulae 1) Modification of Diet in Renal Disease (MDRD) formula 2) CKD-EPI formula 3) Mayo Quadratic formula 4) Schwartz formula, used for children 5) Cockcroft-Gault formula</td>
<td>Derived from Serum or Plasma measurements</td>
</tr>
<tr>
<td>ACR</td>
<td>Albumin/Creatinine Ratio</td>
<td>ACR reflects urinary albumin excretion and is a useful measure of renal function used in diabetic renal disease. This ratio helps to make the measurement of albumin in the urine more accurate and less prone to random fluctuations.</td>
<td>Urine</td>
</tr>
<tr>
<td>BUN</td>
<td>Blood Urea Nitrogen</td>
<td>Pronounced “B-U-N”, not “bun”. BUN is the amount of nitrogen in the blood that comes from urea. The liver produces urea as a waste product of the digestion of protein and passes it out of the body in the urine. The BUN test helps to see how well the kidneys are working. If the kidneys are not able to remove urea from the blood normally, the BUN level rises. Heart failure, dehydration, or a diet high in protein can also increase the BUN level, whereas liver disease or damage can lower the BUN level.</td>
<td>Blood, Plasma</td>
</tr>
<tr>
<td>Uric Acid</td>
<td></td>
<td>High uric acid concentrations occur when the body produces too much uric acid, or the kidney does not eliminate uric acid quickly enough. Numerous factors contribute to high uric acid concentrations, including but not limited to, obesity, hypothyroidism, use of diuretics and renal insufficiency.</td>
<td>Urine, serum</td>
</tr>
</tbody>
</table>
### 3.1.4 Liver Function

Most often, fatty liver (also known as liver steatosis) occurs in persons with obesity or T2DM. The body’s sensitivity to insulin can be reduced with increasing body weight, age, or be related to a family history of T2DM. People with increased fat around the abdomen (central obesity) are more likely to have insulin resistance than people with fat elsewhere. With decreased sensitivity to insulin, the body must make more insulin to regulate blood sugar. High blood insulin levels are associated with increased blood triglycerides and fatty liver.

<table>
<thead>
<tr>
<th>Common Test Abbreviation</th>
<th>Test Name</th>
<th>Description</th>
<th>Specimen(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST</td>
<td>Aspartate Transaminase</td>
<td>AST is found in the liver, heart, skeletal muscle, kidneys, brain, and red blood cells, and is commonly measured clinically as a marker for liver health. Blood levels of AST are normally low. When body tissue or an organ such as the heart or liver is diseased or damaged, additional AST is released into the bloodstream. The amount of AST in the blood is directly related to the extent of the tissue damage.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>ASAT</td>
<td>Aspartate</td>
<td>ál</td>
<td></td>
</tr>
<tr>
<td>SGOT</td>
<td>Aminotransferase</td>
<td>ál</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serum Glutamic-Oxaloacetic Transaminase</td>
<td>ál</td>
<td></td>
</tr>
<tr>
<td>ALT</td>
<td>Alanine Transaminase</td>
<td>ALT is found in plasma and in various body tissues but is most commonly associated with the liver. It is measured clinically as a part of a diagnostic evaluation of hepatocellular injury. Significantly elevated levels of ALT often suggest the existence of other medical problems that affect the liver.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>ALAT</td>
<td>Alanine Aminotransferase</td>
<td>ál</td>
<td></td>
</tr>
<tr>
<td>SPGT</td>
<td>Serum Glutamic-Pyruvic Transaminase</td>
<td>ál</td>
<td></td>
</tr>
<tr>
<td>ALP</td>
<td>Alkaline phosphatase</td>
<td>ALP is present in all tissues of the body, but is concentrated in the liver, bile duct, kidney, bone, and placenta. Elevated levels of ALP can be an indication of bone or liver disease.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>BILI</td>
<td>Bilirubin</td>
<td>Bilirubin is the yellow product of normal heme catabolism. Heme is found in hemoglobin, a principal component of red blood cells. Bilirubin is excreted in the bile and urine, and elevated levels may indicate certain diseases. It is responsible for the yellow color of urine, the brown color of feces, and the yellow of the skin and whites of the eyes as associated with jaundice. Serum bilirubin has been consistently shown to be inversely correlated with severe liver disease and cardiovascular diseases as well as related diseases and risk factors such as arterial hypertension, diabetes mellitus, MetS, and obesity.</td>
<td>Serum, Plasma, Urine</td>
</tr>
<tr>
<td>Direct Bilirubin</td>
<td>Also called conjugated bilirubin, is formed in the liver when indirect (or unconjugated) bilirubin reacts with glucuronic acid. Indirect bilirubin concentration will be higher during the early phase of liver damage, but as the damage progresses, direct bilirubin concentrations will rise.</td>
<td>Serum, Plasma, Urine</td>
<td></td>
</tr>
<tr>
<td>Gamma-GT</td>
<td>Gamma-Glutamyltransferase</td>
<td>Elevated GGT concentrations indicated the presence of abnormalities in the liver or bile duct system. The most common reason for elevate GGT concentrations is overconsumption of alcohol.</td>
<td>Serum, Plasma</td>
</tr>
</tbody>
</table>
3.1.5 Miscellaneous

There are further laboratory tests not functioning as diabetes markers, and not produced by the above mentioned organs. The concentrations of these variables are often useful in assessing risk factors for diabetes.

<table>
<thead>
<tr>
<th>Common Test Abbreviation</th>
<th>Test Name</th>
<th>Description</th>
<th>Specimen(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRP</td>
<td>C-Reactive Protein</td>
<td>CRP is a protein found in the blood and is used mainly as a marker of inflammation. CRP is synthesized by the liver. High levels of CRP are caused by infections, burns, trauma, inflammation, active inflammatory arthritis, and certain cancers. Apart from liver failure, there are few known factors that interfere with CRP production. Recent research suggests that subjects with elevated basal levels of CRP are at an increased risk of diabetes mellitus, hypertension, and cardiovascular disease. Test to detect elevated basal levels must be highly sensitive.</td>
<td>Serum, Plasma, Blood</td>
</tr>
<tr>
<td>hsCRP</td>
<td>Highly Sensitive CRP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipase</td>
<td>Lipase</td>
<td>Lipase is an enzyme that catalyzes the hydrolysis of fats (lipids). Lipases perform essential roles in the digestion, transport, and processing of dietary lipids like triglycerides and fats. Lipase may be elevated with inflammation of the pancreas (pancreatitis). Lipase activity may be low in diabetes.</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>NT-ProBNP</td>
<td>N-Terminal of the Pro-Brain Natriuretic Protein</td>
<td>NT-ProBNP, 76 amino acid long N-terminal of the pro-brain natriuretic protein, is a marker used to assess the severity of congestive heart failure</td>
<td>Serum, Plasma</td>
</tr>
</tbody>
</table>

3.2 Glucose Measurements

Glucose is measured in many contexts in diabetes clinical trials. Self-monitoring blood glucose (SMBG) is a routine part of self-care for subjects with diabetes, and diabetes clinical trials may include such glucose values. SMBG involves collecting a very small sample of blood using a finger stick, and then measuring the glucose concentration (either as whole blood or plasma) in a small, handheld glucose meter. Many blood glucose meters use test strips calibrated to plasma values. Therefore, all measurements performed with capillary blood are automatically calibrated to plasma equivalent glucose values, which are shown on the display. The collected specimen and the reported specimen could be different. Throughout the document the terminology of BG and SMBG will be used and is interchangeable with PG and SMPG respectively.

Routine clinical laboratory procedures are used for other glucose measurements in a trial, such as fasting plasma glucose (FPG), post-prandial plasma glucose (PPG) and/or those that are part of oral glucose tolerance tests (OGTT) or meal tolerance tests (MTT). For routine clinical laboratory tests, blood is collected by means of a venous blood draw, and the glucose is analyzed in a laboratory. In clinical trials that involve glucose clamps (e.g. PK/PD clinical trials), location (right or left arm) is important data to include. Neither glucose clamps nor continuous glucose monitoring (CGM) is in scope for this version of the user’s guide.

The two concept maps below show processes that may produce a glucose measurement, depending on whether the sample is drawn by the subject, or collected in a lab. See Section 3.3 for further discussion of the additional assessments that may be required if a blood glucose measurement indicates hypoglycemia.
Glucose measurements typically performed by subjects with diabetes are indicated. The glucose meter device requires a whole blood sample, but the glucose reading may be read as either a whole blood equivalent or a plasma equivalent.

3.2.1 Self-Monitoring of Blood Glucose

Self-monitoring of blood glucose (SMBG) is an important component of modern therapy for diabetes. SMBG has been recommended for people with diabetes in order to achieve a target level of glycemic control and to prevent hypoglycemia. According to the American Diabetes Association (ADA), target ranges are not
universal, but rather depend on several criteria: duration of diabetes, age/life expectancy, co-morbid conditions, known cardiovascular disease or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations. For most non-pregnant adults with diabetes, the ADA suggests these targets:

- A1C: 7%
  A1C may also be reported as average blood glucose: 154 mg/dl
- Before a meal (preprandial) plasma glucose: 70–130 mg/dl
- 1-2 hours after beginning of the meal (postprandial) plasma glucose: < 180mg/dl

The goal of SMBG is to collect detailed information about blood glucose concentrations at multiple time points to reach target values and to reduce variability. It is used to help individuals adjust their dietary intake, physical activity, and glucose-lowering agents to improve glycemic control on a day-to-day basis.

In SMBG, a subject performs a number of glucose tests each day or each week. The test most commonly involves pricking a finger with a lancet device to obtain a small blood sample, applying a drop of blood onto a reagent strip, and determining the glucose concentration via an automated reading. Test results are then recorded in a logbook or stored in the glucose meter’s electronic memory. People with diabetes can be taught to use their SMBG results to correct any deviations out of a desired target range by changing their carbohydrate intake, exercising, or using more or fewer oral or injectable agents.

Glucose meters may give a glucose reading as either “whole blood equivalent” or “plasma equivalent”, although the specimen is whole blood. The plasma equivalent is calculated using an equation built into the glucose meter. Plasma readings are approximately 10-12% higher than whole blood readings.

In clinical trials, the frequency with which subjects with diabetes monitor their blood glucose concentration depends upon the clinical trial protocol requirements. SMBG readings may be performed for the purpose of monitoring subject safety and may be checked as frequently as needed to ensure subject safety. Subjects may record SMBG measurements in a subject diary for review by clinical study site personnel. In addition, a protocol may require SMBG profiles at pre-specified time points on a certain number of days within a time period. The number of time points (e.g. four, seven, nine) and number of days (e.g. 3 nonconsecutive days within a 14 day period) will depend on the protocol. The protocol defines the time before and after meals (e.g. 2 hours post beginning or end of meal) and other time points at which the subject is instructed to monitor the blood glucose concentrations. The following is an example of a nine-point glucose profile:

1. Pre-morning meal (fasting)
2. Post-morning meal
3. Pre-midday meal
4. Post-midday meal
5. Pre-evening meal
6. Post-evening meal
7. Bedtime
8. Overnight
9. Next day pre-morning meal (fasting)

The example concept map below shows a nine-point self-monitoring of blood glucose, which consists of blood specimen collection and glucose testing at each specified time point (e.g. before or <n> hours after meal). The meal times (e.g. MID-DAY MEAL) are considered as reference time points. Note that SMBG measurements at time points “bedtime” and “overnight” are not relative to any meal.
A profile usually includes at least one early morning time point (fasting). The time point may be as soon as the subject wakes up or just before morning meal. The clinical study protocol determines the following:

1. Number of time points (e.g. up to nine)
2. Number of hours \(<n>\) post-meal
3. Number of hours \(<m>\) after bedtime
### 3.2.1.1 Examples for Self-Monitoring of Blood Glucose

**Example CRF 3: Self-Monitored Blood Glucose**

<table>
<thead>
<tr>
<th>SMBG Collection</th>
<th>No</th>
<th>Yes (if yes complete)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of Measurement</th>
<th>LBDTC</th>
<th>LBDD</th>
<th>LBMO</th>
<th>LBYR</th>
</tr>
</thead>
</table>

**Pre-Morning Meal Measurement** --::: (24 hour clock) Glucose Result mg/dL Not Done LBSTAT

**Post-Morning Meal Measurement** --::: (24 hour clock) Glucose Result mmol/L LBORRSLBORRESU

**Pre-Midday Meal Measurement** --::: (24 hour clock) Glucose Result mg/dL Not Done LBSTAT

**Post-Midday Meal Measurement** --::: (24 hour clock) Glucose Result mmol/L LBORRSLBORRESU

**Pre-Evening Meal Measurement** --::: (24 hour clock) Glucose Result mg/dL Not Done LBSTAT

**Post-Evening Meal Measurement** --::: (24 hour clock) Glucose Result mmol/L LBORRSLBORRESU

**Bedtime Measurement** --::: (24 hour clock) Glucose Result mg/dL Not Done LBSTAT

**Next Day Date of Measurement** --::: (DD-MM-YYYY)

<table>
<thead>
<tr>
<th>Overnight Measurement</th>
<th>LBDTC</th>
<th>LBDD</th>
<th>LBMO</th>
<th>LBYR</th>
</tr>
</thead>
</table>

**Next Day Pre-Morning Meal Measurement** --::: (24 hour clock) Glucose Result mmol/L LBORRSLBORRESU

**Specimen Type** LBSPEC Specimen Type

**Device** SPDEVID Device Identifier

CRF annotated to show mapping. SDTM variables in **Red**. If CDASH variable differs from SDTM the CDASH variable is in **Blue**.
Example 1
This example shows a 9-point SMBG profile.

The subject used a glucose meter that reported the results in plasma equivalents. SPDEVID links to the Device Identification (DI) domain, which holds the records indicating that measurements were taken using a glucose meter. This means glucose results can clearly be identified in LB domain as being reported as concentrations in plasma, not in blood (although actual specimen is blood). Three different upper limits of the normal were used: one for fasting, one for pre-midday or pre-evening meal, and one for post-meal.

Rows 1, 8:  
LBFAST=Y showing that the SMBG measurements (LBTPTNUM=1 and 8) were performed when the subject was fasting according to the protocol definition.

Rows 2-8:  
LBORRES show glucose measurements taken at specified time points. Post-Midday Meal time point was not done.

Row 9:  
LBDTC, LBFAST and LBTPT show that in a 9-point SMBG profile the 9th measurement is taken fasting (pre-morning meal) according to the protocol definition.

The data below shows device identifier information for glucose meters referenced in the 9-point SMBG profile above.
3.2.2 Tolerance Tests

Oral Glucose Tolerance Testing (OGTT) and Meal Tolerance Testing (MTT) may be performed on a subject with diabetes to measure the effects of the study treatment on the levels of glucose in the subject’s blood after administration of a glucose drink or a standard meal. Measurement of glucose is standard and measurement of insulin and C-peptide are optional and would be defined in the protocol. Additional tests such as pro-insulin, glucagon, incretins (e.g. GLP-1, GIP) and other parameters can be taken based on the study design and mechanism of action of the study medication. See Section 3.1 for more information and descriptions of these measurements.

Both OGTT and MTT are performed after a specified fasting period. In OGTT, the subject is administered a glucose drink. In MTT, the subject is administered some form of a solid, liquid, or mixed meal. Energy drinks and/or energy bars of known nutritional content are often used. A baseline tolerance test would be completed (e.g. all blood samples obtained) before investigational drug is given. When a tolerance test is performed after a period of investigational treatment, the investigational drug may be given before the test is started.

Data collected from the glucose or meal administration can include:

- Confirmation of fasting (i.e. that the subject has not eaten in a specified period)
- Confirmation that the scheduled glucose or meal administration occurred, and if not, the reason
- Start and end dates and times of glucose or meal administration
- Substance administered (e.g. glucose or meal)
- Dose administered (amount of glucose or volume of drink or amount of food administered/consumed). For an MTT, see Section 3.2.2.1 below
- Time investigational drug given

Blood samples are drawn prior to the glucose/meal administration and at specified intervals after the glucose/meal administration. The sample times will vary depending on the study design. A typical duration of sample collection for an OGTT is 2 hours, but testing may extend over 24 hours with three or more meals provided during that time. The number of samples and their timing may also vary depending on the goal of the test. For example, the measurement of β-cell function may require a longer observation period (e.g. 3-5 hours) with more frequent blood sample collections.

The number of blood samples and the timing should be specified in the study design.

Data collected about the blood samples can include:

- Confirmation the blood sample draw occurred, and if it was not, the reason why
- The time at which the sample was taken, including
  - Date and time
  - Descriptors of the planned time point, including
    - Time point name
    - Time point number
    - The name of the reference time point (e.g. “meal” or “glucose dose”)
    - Planned elapsed time between the time point and the reference time point
3.2.2.1 Meal Data in a Meal Tolerance Test

The meal administered as part of an MTT will typically be standardized for a study. Nutrient composition of the meal consumed (e.g. total calories, protein, carbohydrates, fat, etc.) will typically be defined at the protocol level and may be provided in the SDTM Trial Summary dataset (see Example 2), although CDISC controlled terminology for Trial Summary Parameters does not currently include a parameter for this information.

Data on substance administrations, which include meals, are represented in SDTM interventions domains. The appropriate domain is determined less by the type of substance than by the reason for the substance administration and the role the substance plays in the study. For example, an opiate administration would be represented in the Exposure (EX) domain if the opiate were a study treatment, in the Concomitant Medications (CM) domain if the opiate was not a study treatment but was administered as a medication, or in the Substance Use (SU) domain if the opiate was used as an illicit recreational drug. Diabetic subjects take meals as nutrition, of course, but may also use food as a treatment for hypoglycemia, and, as discussed in this section, may be given meals as part of a testing procedure to determine their glycemic response to a standard meal. This context determines the SDTM domain in which the meal is represented. In the context of a meal tolerance test, the meal is represented in the Procedure Agents (AG) domain.

Typical data points to collect, in addition to those for any tolerance test, may include:

- Type of meal (e.g. liquid, solid, or mixed)
- Portion of meal actually consumed by subject (e.g. <25%, ≥25 to <50%, ≥50 to <75%, ≥75% to <100%, 100%)
- If the meal was to take place at a time point relative to investigational drug, descriptors of that time point, including
  - Time point name
  - Time point number
  - The name of the reference time point (e.g. “study drug dose”)
  - Planned elapsed time between the time point and the reference time point
3.2.2.2 Examples for Tolerance Tests

Example CRF 4: Meal Tolerance Test

<table>
<thead>
<tr>
<th>Field Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the Meal Tolerance Testing Performed?</td>
<td>No</td>
</tr>
<tr>
<td>Planned Timepoint of the Meal</td>
<td>AGPTPT</td>
</tr>
<tr>
<td>Was the Meal for Meal Tolerance Testing Administered?</td>
<td>No</td>
</tr>
<tr>
<td>Meal Date</td>
<td>AGSTDTC</td>
</tr>
<tr>
<td>Meal Start Time</td>
<td>LBRFTDTC</td>
</tr>
<tr>
<td>Meal End Time</td>
<td>AGSTTIM</td>
</tr>
<tr>
<td>What Portion of the Meal was Consumed?</td>
<td>AGDOSTXT</td>
</tr>
<tr>
<td>Meal Tolerance</td>
<td>LBSCAT</td>
</tr>
<tr>
<td>Planned Timepoint</td>
<td>LBSTAT</td>
</tr>
<tr>
<td>Was the sample collected?</td>
<td>No</td>
</tr>
<tr>
<td>For what reason was the blood sampling not done?</td>
<td>LBREASND</td>
</tr>
<tr>
<td>What was the blood sampling time?</td>
<td>LBTIM</td>
</tr>
<tr>
<td>Glucose Result</td>
<td>LBORRES</td>
</tr>
<tr>
<td>Insulin Result</td>
<td>LBORRES</td>
</tr>
<tr>
<td>C-Peptide Result</td>
<td>LBORRES</td>
</tr>
<tr>
<td>Laboratory Reference Ranges (provided with laboratory results)</td>
<td>LBORNLO when LBTEST= Glucose</td>
</tr>
<tr>
<td>Specimen Type</td>
<td>LBSPEC</td>
</tr>
</tbody>
</table>

CRF annotated to show mapping. SDTM variables in **Red**. If CDASH variable differs from SDTM the CDASH variable is in **Blue**.
Example 1
This example shows the administration of oral glucose. Since glucose is administered as part of a test procedure, the data are represented in the Procedure Agents (AG) domain.

Rows 1-4: Show examples of oral Glucose administration for two subjects at each of two different visits. The date and time of the start and end of the glucose administration was collected.

<table>
<thead>
<tr>
<th>Row</th>
<th>VISIT</th>
<th>AGDTC</th>
<th>AGSTDTC</th>
<th>AGENDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>VISIT 1</td>
<td>2008-05-01</td>
<td>2008-05-01T08:50</td>
<td>2008-05-01T08:53</td>
</tr>
<tr>
<td>2</td>
<td>VISIT 5</td>
<td>2008-08-01</td>
<td>2008-08-01T07:30</td>
<td>2008-08-01T07:33</td>
</tr>
<tr>
<td>3</td>
<td>VISIT 1</td>
<td>2008-06-07</td>
<td>2008-06-07T08:30</td>
<td>2008-06-07T08:35</td>
</tr>
<tr>
<td>4</td>
<td>VISIT 5</td>
<td>2008-09-01</td>
<td>2008-09-01T08:00</td>
<td>2008-09-01T08:05</td>
</tr>
</tbody>
</table>

Example 2
In this example, a standard meal was administered to the subject. The protocol prescribed that the meal be administered at a certain time relative to study drug administration. The planned timing of the meal is thus described using time point variables which include study drug administration as the reference time and a planned elapsed time. The planned elapsed time is the time between the start of the meal and the study drug administration. Since the meal is administered as part of a challenge test, it is treated as a procedure agent, and the data are in the AG domain. Lab samples are drawn at planned time points relative to the time of meal administration (not study drug administration). The meal is a standard meal whose nutrient content is prescribed in the protocol, so the nutrient content is described in the Trial Summary dataset.

The meal “dose” is collected using categorical responses for the portion of the standard meal consumed. These categories appear on the CRF using text such as “90-100%” meaning “between 90% and 100% of one standard meal.” Representing this using the SDTM dosing variables presents some challenge. The AGDOSTXT variable can be used to represent ranges, and one solution would be to place “90-100” in AGDOSTXT and “%” in AGDOSU. However, in this context, the % symbol alone seemed ambiguous, since the base of the percent is not given. In laboratory tests expressed as percentages, the base of the percent is part of the definition of the laboratory test. However, there is no test code definition to rely on in an interventions domain, and since AGDOSTXT can hold any needed text, the amount of meal administered has been represented using text in AGDOSTXT that includes the % symbol and the base of the percent (the meal).

Row 1: A meal was administered 2 hours prior to study drug administration.
Row 2: A meal was administered 30 minutes after study drug administration. This visit happens approximately 26 weeks after the initiation of study treatment.
The TS dataset shows the representation of the nutrient content of the standardized meal as a parameter in Trial Summary dataset.

The RELREC example shows that the meal data in AG and laboratory data in LB can be linked by the variables shown in IDVAR.

The TS dataset shows the representation of the nutrient content of the standardized meal as a parameter in Trial Summary dataset.
Example 3
This is an example of a study where the end time of the meal was collected. If the meal was not administered, the reason for not administering the meal was collected. This example shows data for two subjects where a standard meal is administered. The date and time of meal administration, the percentage of meal consumed, and the end time of meal administration were collected.

Row 1: Subject “XYZ-001-001” was given a standard meal 2 hours prior to study drug administration at baseline.
Row 2: Subject “XYZ-001-001” was given a standard meal 30 minutes after study drug administration after 26 weeks.
Row 3: Subject “XYZ-001-002” was given a standard meal 2 hours prior to study drug administration at baseline.
Row 4: The meal was not administered at 26 weeks.

If the reason the meal is not administered is collected, this information can be represented in SUPPAG as below.

### 3.3 Hypoglycemic Events
Hypoglycemia is a clinical event that involves an abnormally diminished blood glucose concentration. It can produce a variety of symptoms and effects, but the principal problems arise from an inadequate supply of glucose to the brain, resulting in impairment of function. Sometimes subjects do not experience any signs or symptoms of hypoglycemia, a condition known as “hypoglycemia unawareness”.

The occurrence of hypoglycemia is usually identified by measuring a person’s blood or plasma glucose concentration and assessing the symptoms typical of hypoglycemia, which include, but are not limited to: palpitations, tremor, hunger, sweating, dizziness, behavioral changes, difficulty thinking, and/or frank confusion. Treatment for a hypoglycemic event usually involves the immediate administration of food, drink, glucose tablets, a glucagon injection or intravenous glucose. It may also require emergency care or hospitalization, possibly including intensive care. In some cases, hypoglycemia may lead to serious sequelae, such as loss of consciousness, seizures, or injury.
The identification of an episode of hypoglycemia will trigger additional assessments. The probable cause of the hypoglycemic event may be sought. In a clinical trial of diabetes medications, study agents will always be evaluated as a possible cause, but other causes (precipitating factors), such as concomitant medications, disruptions in diabetes medication or meal schedules, concomitant illness, and recent exercise, may also be considered. There may also be an assessment of the subject’s awareness of their hypoglycemia, since unawareness can lead to a delay in treatment and increases the likelihood of serious consequences.

### 3.3.1 Classification of Hypoglycemia in Diabetes

The American Diabetes Association assembled a Workgroup on Hypoglycemia in 2004, and again in 2012 in conjunction with the Endocrine Society, to address how hypoglycemia in diabetes should be defined and reported. The following table articulates those definitions and what corresponding data could be captured to address those criteria. In a subject with hypoglycemia unawareness, these definitions may be difficult to apply.

<table>
<thead>
<tr>
<th>Working Group Definition</th>
<th>Corresponding Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Severe hypoglycemia</strong> is an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions. Plasma glucose concentrations may not be available during an event, but neurological recovery following the return of plasma glucose to normal is considered sufficient evidence that the event was induced by a low plasma glucose concentration.</td>
<td>Requirement of assistance to administer treatment</td>
</tr>
<tr>
<td><strong>Documented symptomatic hypoglycemia</strong> is an event during which typical symptoms of hypoglycemia are accompanied by a measured plasma glucose concentration ≤ 70 mg/dL (≤ 3.9 mmol/L).</td>
<td>Occurrence of symptoms Glucose result</td>
</tr>
<tr>
<td><strong>Asymptomatic hypoglycemia</strong> is an event not accompanied by typical symptoms of hypoglycemia but with a measured plasma glucose concentration ≤ 70 mg/dL (≤ 3.9 mmol/L).</td>
<td>Glucose result Hypoglycemia unawareness</td>
</tr>
<tr>
<td><strong>Probable symptomatic hypoglycemia</strong> is an event during which symptoms typical of hypoglycemia are not accompanied by a plasma glucose determination but that was presumably caused by a plasma glucose concentration ≤ 70 mg/dL (≤ 3.9 mmol/L).</td>
<td>Occurrence of symptoms Absence of glucose result</td>
</tr>
<tr>
<td><strong>Pseudohypoglycemia</strong> (also called relative hypoglycemia) is an event during which the person with diabetes reports any of the typical symptoms of hypoglycemia with a measured plasma glucose concentration &gt;70 mg/dL (&gt;3.9 mmol/L) but approaching that level.</td>
<td>Occurrence of symptoms Glucose result</td>
</tr>
</tbody>
</table>

* Working Group Definitions taken from *Diabetes Care*, 2013;36(5):1384-95. Corresponding data created by the CFAST Diabetes team.

Depending on the protocol, the investigator in a clinical trial may decide whether an episode of hypoglycemia constitutes an adverse event. If the hypoglycemia is determined to be an adverse event, the usual assessments of an adverse event will be made, including assessments of severity, outcome, and seriousness.

A hypoglycemic event will be deemed serious if it meets the usual criteria (results in death, or disability, is life threatening, requires or prolongs hospitalization), but additional criteria may be applied, such as hypoglycemic event neurological (cognitive) impairment during (and thought to be caused by) the hypoglycemic event, requirement of assistance, coma, or injury to self or others (e.g. an accident).
A hypoglycemic event triggers several assessments that help characterize and classify the event. Other collection points regarding diagnostic factors, treatment, and who administered treatment may also be included to describe the event. Classification of hypoglycemic events will usually be part of analysis, rather than data collection.

Data collected about a hypoglycemic event may include some or all of the following:
- The occurrence of each of several symptoms typical of hypoglycemia
- Blood glucose measurement(s) at the time of the event
- The subject’s awareness of the event (e.g. presence of signs/symptoms)
• Judgments about the relevance of possible precipitating factors
• Details about the last anti-hyperglycemic medication administration and/or the last meal before the event
• The occurrence of each of several possible sequelae of hypoglycemia
• Each/any of several treatments that may be given for hypoglycemia
• The occurrence of a healthcare encounter, and if so what kind(s) (e.g. ER visit, hospitalization, ICU stay) and details of the timing/duration
• Whether the subject required assistance to obtain treatment for the event (as this can be used in classifying the event)
• Classification of the event according to criteria such as the Working Group definitions given above
• The investigator’s determination of whether this event constitutes an adverse event
• Whether the event was “nocturnal”. The definition of nocturnal hypoglycemia may vary from trial to trial and should be stated in the protocol. An event may be considered nocturnal if it takes place between bedtime and waking during the subject's longest period of sleep, or specific times (e.g. 10 PM to 6 AM) may be used to define nocturnal.
### 3.3.2 Examples for Hypoglycemic Events

#### Example CRF 5: Hypoglycemia

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Hypoglycemic Events Experienced?</td>
<td>No (if yes complete for each event)</td>
</tr>
<tr>
<td>Sponsor Defined ID</td>
<td>CESPID</td>
</tr>
<tr>
<td>Date/Time of Event</td>
<td>CESTDTC</td>
</tr>
<tr>
<td>When Did the Hypoglycemic Event Occur?</td>
<td>Between Bedtime and Waking Between Waking and Bedtime QVAL when QNM= WHENOCC and QLABEL=&quot;When Did the Hypoglycemic Event Occur?&quot;</td>
</tr>
<tr>
<td>In the Opinion of the Investigator Was This an Adverse Event?</td>
<td>No (WASAEN)</td>
</tr>
<tr>
<td>Was a Glucose Measurement Obtained at the Time of the Event?</td>
<td>No (If yes enter result and unit below)</td>
</tr>
<tr>
<td>Last Study Medication Taken</td>
<td>EXACT= HIGHLIGHTED DOSE</td>
</tr>
<tr>
<td>Last Concomitant Diabetic Medication Taken</td>
<td>CMCAT= ANTI-HYPERGLYCEMIC MED, CMCAT= HIGHLIGHTED DOSE</td>
</tr>
<tr>
<td>Date/Time of Last Meal</td>
<td>MLSTDTC</td>
</tr>
<tr>
<td>Were Signs/Symptoms Present?</td>
<td>No (If yes complete following)</td>
</tr>
<tr>
<td>CEAT= HYPO SYMPTOMS</td>
<td>CETERM= SWEATING</td>
</tr>
<tr>
<td></td>
<td>Tremors/Trembling</td>
</tr>
<tr>
<td></td>
<td>Dizziness</td>
</tr>
<tr>
<td></td>
<td>Cognitive Impairment</td>
</tr>
<tr>
<td></td>
<td>Loss of Consciousness</td>
</tr>
<tr>
<td></td>
<td>Convulsions/Seizure</td>
</tr>
<tr>
<td></td>
<td>Coma</td>
</tr>
<tr>
<td></td>
<td>Other (Specify)</td>
</tr>
<tr>
<td>Were Any Precipitating Factors Reported?</td>
<td>No (If yes complete following)</td>
</tr>
<tr>
<td>FATE= Alcohol Consumption as a Precip Factor</td>
<td>Alcohol Consumption</td>
</tr>
<tr>
<td>FATE= Concurrent Illness as a Precip Factor</td>
<td>Concurrent Illness</td>
</tr>
<tr>
<td>FATE= Dosing Deviation as a Precip Factor</td>
<td>Deviation from Dosing Instructions</td>
</tr>
<tr>
<td>FATE= Meal Variance as a Precip Factor</td>
<td>Missed, Delayed or Smaller Meal</td>
</tr>
<tr>
<td>FATE= Physical Activity as a Precip Factor</td>
<td>Physical Activity</td>
</tr>
<tr>
<td></td>
<td>Other (Specify)</td>
</tr>
<tr>
<td>CMCAT= HYPO TREATMENT</td>
<td>No (If yes complete following)</td>
</tr>
<tr>
<td></td>
<td>CMTRT= DRINK</td>
</tr>
<tr>
<td></td>
<td>Drink</td>
</tr>
<tr>
<td></td>
<td>Food</td>
</tr>
<tr>
<td></td>
<td>CMTRT= GLUCOSE TABLETS</td>
</tr>
<tr>
<td></td>
<td>Glucose Tablets</td>
</tr>
<tr>
<td></td>
<td>CMTRT= GLUCAGON INJECTION</td>
</tr>
<tr>
<td></td>
<td>Glucagon Injection</td>
</tr>
<tr>
<td></td>
<td>CMTRT= INTRAVENOUS GLUCOSE</td>
</tr>
<tr>
<td></td>
<td>Intravenous Glucose</td>
</tr>
<tr>
<td>If Treatment Given Indicate Assistance Needed?</td>
<td>None - Subject Treated Self</td>
</tr>
<tr>
<td></td>
<td>Subject was Treated, but Required Assistance</td>
</tr>
<tr>
<td></td>
<td>Subject was Not Treated, and Required Assistance</td>
</tr>
</tbody>
</table>

**Legend:** CDASH variables in **blue** and SDTM variables in **red**.
The occurrence of a hypoglycemic event in a study subject triggers collection of data about things that happened before the event that may have contributed to its occurrence, characteristics of the event (e.g. blood glucose value and symptoms), and actions taken to treat the event, as well as assessments of the event’s causality and significance.

The hypoglycemic event is handled as a “disease milestone” and as a new construct in SDTM described in the supplementary materials. At the study level, the events and activities to be treated as disease milestones are defined in a new dataset, Trial Milestones. At the individual subject level, the timing of disease milestones for that subject are summarized in a new dataset, Subject Milestones. In general observation class domains, records of assessments triggered by the disease milestone (in this case, a hypoglycemic event), are linked to the event by means of new timing variables: MIDS, Disease Milestone Name, RELMIDS, Temporal Relation to Disease Milestone, MIDSDTC, and Disease Milestone Date/Time. See the discussion about the known issue assessments triggered by events of special interest in Section 1.6.

The start date of each unique hypoglycemic event is only collected one time on the CRF. However, the hypoglycemic event start date (MIDSDTC), which is collected once, may be programmatically appended to more than one SDTM Domain. There should not be an issue with consistency in the start date, since the date is entered once and the MIDSDTC will always be reflective of that associated start date.

### 3.3.2.1 Event and Symptom Data

Data about the hypoglycemic event itself is mapped to the Clinical Events domain. If the sponsor determines the event is also an adverse event, then adverse event data collection is triggered, including serious adverse event data if the event is determined to be serious. Each event a subject experiences must have a unique identifier so that information related to that event can be correctly identified. If the sponsor wishes to link hypoglycemic CE records with AE records, this can be done using a RELREC dataset.

Data about symptoms related to the hypoglycemic event have been mapped to the Clinical Events domain. (It is acknowledged that the SDTMIG also contains examples which map symptom data to the FA domain. The SDS team is working to provide guidance on this point.) The sponsor may choose simply to assess if the subject experienced any symptoms, or may collect more detail about symptoms.

**Example 1**

In this example, the only data collected about symptoms of hypoglycemic events is whether certain pre-specified symptoms or other symptoms occurred.

**Row 1:** Shows the subject’s first hypoglycemic event. Because this is a disease milestone, MIDS is populated with HYPO 1, but the variables RELMIDS and MIDSDTC are not populated. The timing of the hypoglycemic event is provided in CESTDTC Whether the event was nocturnal (i.e., its timing relative to the subject’s sleeping/waking cycle) is represented as a supplemental qualifier.

**Rows 2-8:** Show the responses to occurrence questions about particular symptoms of hypoglycemia in conjunction with HYPO 1. The subject experienced cognitive impairment and loss of consciousness.

**Row 9:** Records the date of the subject’s second hypoglycemic event, and identifies this as the disease milestone named HYPO 2. Data on symptoms has been omitted to save space.
### 3.3.2.2 Blood Glucose Concentration Data

**Example 1**

This example shows glucose concentrations collected at the time of a hypoglycemic event. These glucose results are recorded in the LB domain.

**Rows 1-2:** Show the subject’s blood glucose concentrations at the time of the subject’s first and second hypoglycemic events. In both cases, the test was performed with a glucose meter on blood, so SPDEVID is included in the dataset and populated. RELMIDS and MIDS are populated to indicate that these tests were performed “AT TIME OF” “HYPO 1” and “DURING” “HYPO 2.” The time of a low glucose result will often be used as the time of a hypoglycemic event, as in Row 1. However, sometimes, as in Row 2, the start time of the hypoglycemic event will be considered to be earlier than the time of the glucose test.
3.3.2.3 Last Meal and Last Diabetic Study Treatment

**Example 1**

This example shows data about the last meal before a hypoglycemic event. Information on the last meal prior to a hypoglycemic event is held in the ML domain.

**Row 1:** Shows the last meal start date is recorded in MLSTDTC. Its relationship to the hypoglycemic event is recorded through the use of MIDS="HYPO 1” and RELMIDS="LAST MEAL PRIOR TO.” The inclusion of MIDSDTC allows easy comparison of the time of the last meal with the time of the hypoglycemic event.

**Row 2:** Shows the last meal prior to HYPO 2.

**Example 2**

This example shows data about the last study treatment before a hypoglycemic event. Last study medication before the event is recorded in the EX domain. The EXCAT value “HIGHLIGHTED DOSE” has been used to indicate that a record is for an individual dose which is being reported in addition to the regular reporting of exposure. This proposed use of a special value of EXCAT to indicate that the individual dose is reported for a special purpose but is also included in a constant dosing interval is only a proposal. How to report individual doses whose timing is collected for a specific purpose, such as their relationship to a sample drawn for population PK assessment, is a long-standing issue. It can be difficult to “break up” exposure dosing otherwise reported as a constant dosing interval to report the interval before the individual dose, the individual dose, and the interval after the individual dose.

**Row 1:** Shows that DRUG A was given twice a day over a constant dosing interval from 2013-08-10 to 2013-11-05.

**Row 2:** Records the individual dose of study medication (DRUG A) that was the “LAST DOSE PRIOR TO” the disease milestone “HYPO 1.”

**Row 3:** Shows the last dose of DRUG A prior to HYPO 2.
### 3.3.2.4 Precipitating Factors, Third Party Assistance, Adverse Event

**Example 1**

This example shows findings about hypoglycemic events, including whether certain factors were judged to be precipitating factors for the hypoglycemic event, whether the subject needed assistance from a third party, and whether the event was determined to be an adverse event. In this example the subject has had two hypoglycemic events.

**Rows 1-5:** Show that the results of questions about possible causes of hypoglycemic event “HYPO 1”. A missed, delayed, or smaller meal was judged to be a possible cause, but alcohol consumption, concurrent illness, deviation from dosing instructions, and physical activity were not.

**Row 6:** Shows the response to the question about need for assistance for “HYPO 1.”

**Row 7:** Shows that this hypoglycemic event (“HYPO 1”) was considered reportable as an adverse event.

**Rows 8-14:** Show similar data for “HYPO 2”.

---

### CDISC Therapeutic Area Data Standards User Guide for Diabetes (Version 1.0)

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>FASEQ</th>
<th>FACAT</th>
<th>FATESTCD</th>
<th>FATEST</th>
<th>FAOBJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>1</td>
<td>PRECIPITATING FACTORS</td>
<td>ALCPF</td>
<td>Alcohol Consumption as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>2</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>2</td>
<td>PRECIPITATING FACTORS</td>
<td>ILLPF</td>
<td>Concurrent Illness as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>3</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>3</td>
<td>PRECIPITATING FACTORS</td>
<td>DSDVPF</td>
<td>Dosing Deviation as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>4</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>4</td>
<td>PRECIPITATING FACTORS</td>
<td>MEALPF</td>
<td>Meal Variance as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>5</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>5</td>
<td>PRECIPITATING FACTORS</td>
<td>PAPF</td>
<td>Physical Activity as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>6</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>6</td>
<td>TREATMENT ADMINISTRATION</td>
<td>TXASSIST</td>
<td>Treatment Assistance</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>7</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>7</td>
<td></td>
<td>WASAEN</td>
<td>Was This an Adverse Event?</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>8</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>8</td>
<td>PRECIPITATING FACTORS</td>
<td>ALCPF</td>
<td>Alcohol Consumption as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>9</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>9</td>
<td>PRECIPITATING FACTORS</td>
<td>ILLPF</td>
<td>Concurrent Illness as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>10</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>10</td>
<td>PRECIPITATING FACTORS</td>
<td>DSDVPF</td>
<td>Dosing Deviation as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>11</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>11</td>
<td>PRECIPITATING FACTORS</td>
<td>MEALPF</td>
<td>Meal Variance as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>12</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>12</td>
<td>PRECIPITATING FACTORS</td>
<td>PAPF</td>
<td>Physical Activity as a Precip Factor</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>13</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>13</td>
<td>TREATMENT ADMINISTRATION</td>
<td>TXASSIST</td>
<td>Treatment Assistance</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
<tr>
<td>14</td>
<td>XYZ</td>
<td>FA</td>
<td>XYZ-001-001</td>
<td>14</td>
<td></td>
<td>WASAEN</td>
<td>Was This an Adverse Event?</td>
<td>HYPOGLYCEMIC EVENT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Row</th>
<th>FAORRES</th>
<th>RELMIDS</th>
<th>MIDS</th>
<th>MIDSCTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (cont)</td>
<td>N</td>
<td>AFTER</td>
<td>HYPO1</td>
<td>2013-09-01T11:00</td>
</tr>
<tr>
<td>2 (cont)</td>
<td>N</td>
<td>AFTER</td>
<td>HYPO1</td>
<td>2013-09-01T11:00</td>
</tr>
<tr>
<td>3 (cont)</td>
<td>N</td>
<td>AFTER</td>
<td>HYPO1</td>
<td>2013-09-01T11:00</td>
</tr>
<tr>
<td>4 (cont)</td>
<td>Y</td>
<td>AFTER</td>
<td>HYPO1</td>
<td>2013-09-01T11:00</td>
</tr>
<tr>
<td>5 (cont)</td>
<td>N</td>
<td>AFTER</td>
<td>HYPO1</td>
<td>2013-09-01T11:00</td>
</tr>
<tr>
<td>6 (cont)</td>
<td>SUBJECT WAS NOT CAPABLE OF TREATING SELF AND REQUIRED ASSISTANCE</td>
<td>DURING</td>
<td>HYPO1</td>
<td>2013-09-01T11:00</td>
</tr>
<tr>
<td>7 (cont)</td>
<td>Y</td>
<td>AFTER</td>
<td>HYPO1</td>
<td>2013-09-01T11:00</td>
</tr>
<tr>
<td>8 (cont)</td>
<td>N</td>
<td>AFTER</td>
<td>HYPO2</td>
<td>2013-09-24T08:48</td>
</tr>
<tr>
<td>9 (cont)</td>
<td>Y</td>
<td>AFTER</td>
<td>HYPO2</td>
<td>2013-09-24T08:48</td>
</tr>
<tr>
<td>10 (cont)</td>
<td>N</td>
<td>AFTER</td>
<td>HYPO2</td>
<td>2013-09-24T08:48</td>
</tr>
<tr>
<td>11 (cont)</td>
<td>Y</td>
<td>AFTER</td>
<td>HYPO2</td>
<td>2013-09-24T08:48</td>
</tr>
<tr>
<td>12 (cont)</td>
<td>N</td>
<td>AFTER</td>
<td>HYPO2</td>
<td>2013-09-24T08:48</td>
</tr>
<tr>
<td>13 (cont)</td>
<td>NONE – SUBJECT TREATED SELF</td>
<td>DURING</td>
<td>HYPO2</td>
<td>2013-09-24T08:48</td>
</tr>
<tr>
<td>14 (cont)</td>
<td>N</td>
<td>AFTER</td>
<td>HYPO2</td>
<td>2013-09-24T08:48</td>
</tr>
</tbody>
</table>
3.3.2.5 Treatment for the Hypoglycemic Event

Example 1
This example shows data about treatments given for a hypoglycemic event. In this study, data about concomitant medications is collected using the categories “ANTI-HYPERGLYCEMIC MED” and “TREATMENT ADMINISTRATION.” CMCAT is not populated for other concomitant medications.

When a hypoglycemic event occurs, the last dose of each anti-hyperglycemic concomitant medication is collected. For the subject in this example, DRUG Z is the only anti-hyperglycemic concomitant medication. As with study treatments, there may be an overlap between a constant dosing interval record for a concomitant medication and records for single doses of the medication recorded as the last dose before a hypoglycemic event. The records with the “extra” data about single doses are flagged with CMSCAT="HIGHLIGHTED DOSE.”

When a hypoglycemic event occurs, data is also collected about whether certain pre-specified substances were given to treat the hypoglycemic event. Since these are substances, including food and drink, which are given as treatments, they are in CM. For these records, CMCAT = “HYPO TREATMENT.”

Row 1: Shows the constant dosing record for DRUG Z, an anti-hyperglycemic concomitant medication. This drug was started in 2010 and was ongoing as of 2013-09-01.

Row 2: Records the highlighted individual dose of DRUG Z that was the “LAST DOSE PRIOR TO” “HYPO 1”

Rows 3-4: Show information collected about the occurrence of Drink and Food as Hypoglycemia treatments. Since “DRINK” and “FOOD” are groups of substances, rather than single substances, they appear in both CMSCAT and CMTRT. The questions are about the period of time “IMMEDIATELY AFTER” “HYPO 1”, and the date/time of HYPO 1 is given in MIDSDT. The subject did not receive drink or food in this period.

Rows 5-7: Show information collected about specific treatments within the Medication subcategory of the Hypoglycemic Treatments category. The questions are about the period of time “IMMEDIATELY AFTER” “HYPO 1”, and the date/time of HYPO 1 is given in MIDSDT. The subject received glucose tablets, but did not receive either glucagon injection or intravenous glucose.

Rows 8-13: Parallel the data in Rows 2-7, but record data collected in response to the subject’s second hypoglycemic event. The subject was given only food in the period “IMMEDIATELY AFTER” “HYPO 2”.
### 3.4 Cardiovascular Events/Outcomes

In recent years, the assessment of cardiovascular (CV) safety has become an important focus in the development of new anti-diabetic therapies for T2DM. According to the FDA Guidance for Industry, in order to establish the safety of a new anti-diabetic therapy to treat T2DM, sponsors should demonstrate that the therapy will not result in an unacceptable increase in cardiovascular risk. To ensure that a new therapy does not increase cardiovascular risk to an unacceptable extent, the development program for a new Type 2 anti-diabetic therapy should include the following:

- Establish an independent CV endpoints committee for prospective adjudication for all Phase 2 and 3 trials
- Events of interest should include CV death, MI, and stroke
- Can include hospitalization for acute coronary syndrome, urgent revascularization procedures, and possibly other endpoints
- Study population should include those at higher risk for a CV event (e.g. longer duration of diabetes, elderly, renal impairment)
- Studies are designed and conducted such that a meta-analysis can be performed
- Protocol describing statistical methods for the proposed meta-analysis should be submitted

Cardiovascular endpoint concepts (including those related to diabetes trials) are being developed as part of the Therapeutic Area Data Standards User Guide for Cardiovascular Disease (TAUG-CVD).

---

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>CMSEQ</th>
<th>CMTRT</th>
<th>CMCAT</th>
<th>CMSCAT</th>
<th>CMPRESP</th>
<th>CMOCCUR</th>
<th>CMDOSE</th>
<th>CMDOSU</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>XYZ</td>
<td>CM</td>
<td>XYZ-001-001</td>
<td>13</td>
<td>INTRAVENOUS GLUCOSE</td>
<td>HYPO TREATMENT</td>
<td>MEDICATION</td>
<td>Y</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Row</th>
<th>CMDOSFRQ</th>
<th>CMSTDTC</th>
<th>CMENDTC</th>
<th>CMENRTPT</th>
<th>CMENTPT</th>
<th>RELMIDS</th>
<th>MIDS</th>
<th>MIDSDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (cont)</td>
<td>TID</td>
<td>2010</td>
<td>ONGOING</td>
<td>2013-09-01</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 (cont)</td>
<td></td>
<td>2013-09-01T07:00</td>
<td>2013-09-01T07:00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 (cont)</td>
<td></td>
<td>2013-09-24T07:00</td>
<td>2013-09-24T07:00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 (cont)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4 Routine Data

4.1 Concomitant Medications

Medications given for diabetes are often categorized by their route of administration as oral or injectable. All people with T1DM require insulin injections to regulate glycemic control. People with T2DM utilize diet and oral and/or injectable medications (or various combinations thereof, including insulin) to regulate glycemic control.

**Insulin**

Insulin is a naturally occurring hormone secreted by β-cells in the pancreas, and is prescribed to persons with T1DM because their β-cells have been destroyed, so they are not able to produce it themselves. Insulin is also given to people with T2DM whose bodies do not properly utilize the insulin that their β-cells produce. It is injected into the fat under the skin (subcutaneously) and eventually reaches the subject’s bloodstream. The recommended method of administration is subcutaneous (as compared to intramuscular or intravenous), given the increased risk of hypoglycemia with intramuscular or intravenous injections of insulin. Buccal administration of insulin is approved in some countries and inhaled administration of insulin is under investigation.

**Types of Insulin**

Types of insulin are described according to how quickly they work, when they peak, and how long they last.

- Rapid-acting insulin begins to work about 15 minutes after injection, peaks in about 1 hour, and continues to work for 2 to 4 hours.
- Regular or short-acting insulin usually reaches the bloodstream within 30 minutes after injection, peaks 2 to 3 hours after injection, and is effective for approximately 3 to 6 hours.
- Intermediate-acting insulin generally reaches the bloodstream about 2 to 4 hours after injection, peaks 4 to 12 hours later, and is effective for about 12 to 18 hours.
- Long-acting insulin reaches the bloodstream several hours after injection and tends to lower glucose concentrations fairly evenly over a 24-hour period.
- Premixed insulin is a mixture of different types of insulin. It can be helpful for people who have trouble with the complexity of drawing insulin in different dosages from two different bottles. It is also useful for those who have poor eyesight or dexterity, and is convenient for people whose diabetes has been stabilized on this combination.

**Insulin Strength**

All insulins come dissolved or suspended in liquids. The standard and most commonly used strength in the United States is U-100, which means it has 100 units of insulin per milliliter of fluid. U-200 and U-500 insulins are available for subjects who are more insulin resistant.

**Insulin Data Collection**

When insulin is taken as part of background therapy (e.g. a concomitant medication rather than a study medication), individual doses are not usually recorded, since insulin may be injected in varying doses multiple times per day. Instead, total daily doses or average daily doses may be collected.

Other injectable drugs used to treat T2DM include:

- GLP-1 receptor agonist
- Amylin analog

Oral medications used to treat T2DM include:

- Sulfonylureas
- Glinides
- Biguanides
- Thiazolidinediones
- Alpha-glucosidase inhibitors
- DPP-4 inhibitors
- SGLT-2 inhibitors
CDASH and SDTM standards cover all the data generally collected for anti-hyperglycemic agents, which may include:

- Medication/therapy name
- Start date
- Stop date or an indication that treatment is ongoing as of the time of collection
- Dose or total daily dose
- Unit
- Route
- Frequency
- Reason for dose adjustment

Data for anti-hyperglycemic agents may be collected for what was taken both prior to randomization and after randomization. More-detailed information may be collected for anti-hyperglycemic agents taken after randomization. For example, “reason for dose adjustment” may be collected only for agents taken after randomization. Reasons for dose adjustment may be selected from a list which includes, for example, hypoglycemia, hyperglycemia or protocol titration requirements.

Other medications that affect glucose concentrations (e.g. steroids), or other medications of interest in overall diabetes treatment (e.g. beta blockers), may be handled with CDASH and SDTM standards, so this document includes no special guidance on their collection.

4.2 Vital Signs

Vital signs that are key data in diabetes trials include the following:

- **Height**: Important in calculating the body mass index (BMI)
- **Weight**: Weight gain is associated with insulin resistance and MetS, and weight loss is associated with a hypocaloric diet. In addition, some antidiabetes medications are associated with weight gain, weight loss, or weight neutrality
- **BMI**: Reflects weight in relation to height and is the measurement used to define the cutoff for obesity. (Definitions of obesity may vary e.g. varies in different ethnic populations)
- **Heart rate and blood pressure (systolic and diastolic)**: Important because of their effect on heart complications (e.g. congestive heart failure, heart attack, stroke)
- **Waist and hip circumference and waist/hip ratio**: Are used to assess the degree of abdominal (central) obesity, which is associated with MetS

4.2.1 Waist & Hip Circumference, Waist/Hip Ratio

Waist circumference, hip circumference, and waist/hip ratio are of interest in diabetes because they provide information about body fat distribution. Waist circumference can be used to diagnose abdominal obesity, and all three factors can be helpful in identifying individuals at increased risk of T2DM. For example, information about waist circumference can be useful in distinguishing high- and low-risk individuals at different levels of BMI, which is important for targeting those at highest absolute risk for individually focused lifestyle interventions to prevent T2DM. 7

Methods for obtaining waist and hip circumference vary, and it is recommended that the study protocol define the specific method to be used. For example, according to the World Health Organization 8, waist circumference should be measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest, using a stretch-resistant tape that provides a constant 100g tension. However, according to the National Institute of Health, waist measurement should be taken at the highest point of the iliac crest 9.

According to the World Health Organization, hip circumference should be measured around the widest portion of the buttocks, with the tape parallel to the floor 8.
The diagram below displays the key factors to be defined when performing a waist measurement. At minimum, this can be defined at the protocol level, but consistency should also be considered across compound programs or diabetes sub-populations.

Concept Map 8: Waist Measurement
Appendices

Appendix A: Project Proposal

CFAST is proposing development of v1.0 of the CDISC Diabetes therapeutic area data standard. This standard will build on the existing SDTM and related CDASH standards to facilitate the collection and use of data relevant to diabetes clinical trials.

The workgroup proposes developing a CDISC therapeutic area user guide, including concept maps, metadata, examples, and controlled terminology. The standardization effort is expected to focus on the following areas of specific interest to diabetes: labs, glucose profiles, hypoglycemia, antihyperglycemic agents, cardiovascular events/outcomes, diabetes history, diabetes complication history, tolerance tests, and vital signs.

For more information on diabetes, see: http://www.who.int/mediacentre/factsheets/fs312/en/

Appendix B: CFAST Diabetes Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution/Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rachael Zirkle, Team Leader</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Maria Alba</td>
<td>Johnson &amp; Johnson</td>
</tr>
<tr>
<td>Caryl J. Antalis</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Melissa Cook</td>
<td>Accenture</td>
</tr>
<tr>
<td>Dan Crawford</td>
<td>Accenture</td>
</tr>
<tr>
<td>Debbie Cummings</td>
<td>Takeda</td>
</tr>
<tr>
<td>Rene Dahlheimer</td>
<td>CDISC</td>
</tr>
<tr>
<td>Rhonda Facile</td>
<td>CDISC</td>
</tr>
<tr>
<td>Stephen Faulkner</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Scott Getzin</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Lorna Griffin</td>
<td>Merck</td>
</tr>
<tr>
<td>Jody Hawes</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Brooke Hinkson</td>
<td>Sanofi</td>
</tr>
<tr>
<td>Jennie G. Jacobson</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Gloria Jones</td>
<td>Johnson &amp; Johnson</td>
</tr>
<tr>
<td>Dawn Kaminski</td>
<td>Accenture</td>
</tr>
<tr>
<td>Lakshmi Mallela</td>
<td>Johnson &amp; Johnson</td>
</tr>
<tr>
<td>Jim Malone</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Sarah McLaughlin</td>
<td>Biogen Idec</td>
</tr>
<tr>
<td>Elizabeth Mendel</td>
<td>Novartis</td>
</tr>
<tr>
<td>Erin Muhlbradt</td>
<td>NCI EVS</td>
</tr>
<tr>
<td>Birgitte Ronn</td>
<td>Novo Nordisk</td>
</tr>
<tr>
<td>Benjamin Shim</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Lorraine Spencer</td>
<td>Takeda</td>
</tr>
<tr>
<td>Petra Struecker</td>
<td>Roche</td>
</tr>
<tr>
<td>Madavi Vemuri</td>
<td>Johnson &amp; Johnson</td>
</tr>
<tr>
<td>Gary Walker</td>
<td>Quintiles</td>
</tr>
<tr>
<td>Michael Ward</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Darcy Wold</td>
<td>CDISC consultant</td>
</tr>
<tr>
<td>Diane Wold</td>
<td>GSK</td>
</tr>
<tr>
<td>Fred Wood</td>
<td>Accenture</td>
</tr>
<tr>
<td>Bernice Yost</td>
<td>CDISC</td>
</tr>
<tr>
<td>Shuyu Zhang</td>
<td>Eli Lilly and Company</td>
</tr>
</tbody>
</table>
Appendix C: Glossary and Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index; kg/m². An individual’s BMI may be used when judging their obesity.</td>
</tr>
<tr>
<td>BRIDG</td>
<td>Biomedical Research Integrated Domain Group</td>
</tr>
<tr>
<td>CDASH</td>
<td>Clinical Data Acquisition Standards Harmonization. This standard describes basic data collection fields.</td>
</tr>
<tr>
<td>CDISC</td>
<td>Clinical Data Interchange Standards Consortium, a Collaborative Group Member</td>
</tr>
<tr>
<td>CFAST</td>
<td>Coalition for Accelerating Standards and Therapies</td>
</tr>
</tbody>
</table>
| Collected    | Within this document “collected” refers to information that is recorded and/or transmitted to the sponsor. This includes data entered by the site on CRFs/eCRFs as well as vendor data such as core lab data. This term is a synonym for “captured”.
| Controlled Terminology | A finite set of values that represent the only allowed values for a data item. These values may be codes, text, or numeric. A codelist is one type of controlled terminology. |
| CRF          | Case Report Form (sometimes Case Record Form). A printed, optical, or electronic document designed to record all required information to be reported to the sponsor for each trial subject. |
| CGM          | Continuous glucose monitoring |
| Domain       | A collection of observations with a topic-specific commonality about a subject. |
| eCRF         | Electronic Case Report Form |
| Glucose Clamp | A laboratory procedure to assess insulin resistance and/or insulin secretion. In a hyperinsulinemic-euglycemic clamp, the concentration of insulin in the subject’s blood is kept constant (clamped) and the rate of glucose infusion is used to assess insulin resistance. In a hyperglycemic clamp the concentration of insulin in the subject’s blood is clamped and the rate of glucose infusion is used to assess insulin secretion. |
| MedDRA       | Medical Dictionary for Regulatory Activities. A global standard medical terminology designed to supersede other terminologies (such as COSTART and ICD9) used in the medical product development process. |
| MetS         | Metabolic syndrome. A group of symptoms associated with a risk of T2DM, including high fasting blood glucose, A1c, hypertension, lipid dysregulation (high triglycerides, low HDL), and increased waist circumference (abdominal obesity). |
| MTT; OGTT    | Meal tolerance testing; oral glucose tolerance testing. Tolerance tests are a method of assessing a subject’s response to glycemic intake. |
| SDTM         | Study Data Tabulation Model |
| SDTMIG       | SDTM Implementation Guide (for Human Clinical Trials) |
| SHARE        | CDISC SHARE (Shared Health and Research Electronic Library) is envisioned to be a global, accessible electronic library, which through advanced technology enables standardized data element definitions and richer metadata that can be used in software applications and research studies to improve biomedical research and its links with healthcare. SHARE metadata is envisioned to help find, understand and use clinical metadata efficiently. |
| T1DM         | Type 1 Diabetes Mellitus |
| T2DM         | Type 2 Diabetes Mellitus |
Appendix D: Metadata

Appendix D1: CDASH Metadata

CDASH metadata is a deliverable for this first version of the TAUG-Diabetes. CDASH metadata for a concept provides the following:

- Question text
- Prompt
- CDASH variable name
- CDASH core (HR, R/C, O)
- SDTM variable name
- SDTM core
- Form completion instructions
- Mapping instructions
- Implementation instructions

Each table of CDASH metadata corresponds to an example CRF, which has been annotated to show how the data collected on the CRF may be mapped to SDTM. CDASH metadata tables included in the TAUG-Diabetes v1.0 are:

- Diabetes history (see Section 2.1)
- Diabetes complications (see Section 2.2)
- Self-monitoring blood glucose (see Section 3.2.1)
- Meal tolerance tests (see Section 3.2.2)
- Hypoglycemic events (see Section 3.3)

Appendix D2: Prototype SHARE Metadata

SHARE metadata will be a new CDISC deliverable once the SHARE metadata repository, currently in development, is released for full production use. In this first version of the Diabetes User Guide, examples of prototype metadata are represented in spreadsheets as supplemental information since the SHARE metadata repository is still in development. These metadata are a sample subset of the metadata to be ultimately provided by SHARE. In their current form, they provide metadata needed to construct define files, including value-level metadata. This is a first step toward producing more robust and complete metadata study specifications via SHARE. A study specification initiated at the time of protocol writing will enable automation of processes such as eCRF development, database specification, and analysis dataset creation.

SHARE metadata for a concept provides the following:

- Representation of the properties of the concept in terms of BRIDG class, class attribute, the complex datatype of the class attribute, and a component of the complex datatype
- A list of relevant controlled terminology values, e.g. units relevant for representing the test result value, for properties which use controlled terminology
- Representation of the properties of the concept in SDTM. This includes the SDTM variable(s) in which a concept property is represented, the domain, and, where relevant, TEST and TESTCD values
- Other concepts which may or must be associated with the concept

Each workbook includes two introductory sheets that describe the contents of the workbook and the layout of the individual spreadsheets. One spreadsheet, labeled “Template” includes all the BRIDG-based concept properties used in the rest of the workbook. The remaining spreadsheets hold metadata for one concept or type of concept.

The metadata provided in the spreadsheets associated with this UG do not represent the full range of metadata that will be available in the SHARE metadata repository. Metadata is not provided for all concepts described in the UG. SHARE metadata for laboratory data is being developed by the Controlled Terminology Lab sub-team.
<table>
<thead>
<tr>
<th>Metadata Display Workbook</th>
<th>Worksheet</th>
<th>Concept Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CM and Treatment-Naïve</td>
<td>OCCUR CM Group</td>
<td>Query about occurrence of any of &lt;group of pre-specified concomitant medication administrations&gt; in an evaluation interval</td>
</tr>
<tr>
<td>CM and Treatment-Naïve</td>
<td>PRESP CM Group</td>
<td>Collection of details of administrations of &lt;pre-specified group of concomitant medication&gt; during an evaluation interval</td>
</tr>
<tr>
<td>CM and Treatment-Naïve</td>
<td>LOG CM</td>
<td>Collection concomitant medication details</td>
</tr>
<tr>
<td>CM and Treatment-Naïve</td>
<td>TRT NAIVE_OCCUR</td>
<td>Query about occurrence of any administration of Anti-hyperglycemic medications (oral and injectable) in an evaluation interval</td>
</tr>
<tr>
<td>CM and Treatment-Naïve</td>
<td>TRT NAIVE PRESP</td>
<td>Collection of details of administrations of Anti-hyperglycemic (oral and injectable) during an evaluation interval</td>
</tr>
<tr>
<td>HbA1c and Glucose</td>
<td>HbA1c per Total Hemoglobin</td>
<td>Hemoglobin A1c as a proportion of total hemoglobin</td>
</tr>
<tr>
<td>HbA1c and Glucose</td>
<td>Glucose Blood</td>
<td>Concentration of glucose in blood</td>
</tr>
<tr>
<td>HbA1c and Glucose</td>
<td>Glucose Plasma Serum</td>
<td>Concentration of glucose in plasma or serum</td>
</tr>
<tr>
<td>HbA1c and Glucose</td>
<td>Glucose Urine</td>
<td>Concentration of glucose in urine</td>
</tr>
<tr>
<td>HbA1c and Glucose</td>
<td>SQ Glucose Urine</td>
<td>Semi-quantitative concentration of glucose in urine</td>
</tr>
<tr>
<td>HbA1c and Glucose</td>
<td>Glucose CSF</td>
<td>From CT for Glucose/GLUC</td>
</tr>
<tr>
<td>Hypoglycemia Symptom Assessment</td>
<td>HYPO OCCUR</td>
<td>Query about the occurrence of hypoglycemia</td>
</tr>
<tr>
<td>Hypoglycemia Symptom Assessment</td>
<td>PRESP HYPO</td>
<td>Collection of data about an event of hypoglycemia</td>
</tr>
<tr>
<td>Hypoglycemia Symptom Assessment</td>
<td>HYPO NOCTURNAL</td>
<td>When in the diurnal sleep cycle an event occurred, between bedtime and waking or between waking and bedtime.</td>
</tr>
<tr>
<td>Hypoglycemia Symptom Assessment</td>
<td>HYPO 3RD ASSIST</td>
<td>The part third party assistance played in treating the subject's event</td>
</tr>
<tr>
<td>Hypoglycemia Symptom Assessment</td>
<td>HYPO PRECIP MEAL</td>
<td>Whether a missed or delayed meal was a possible precipitating factor for the subject's hypoglycemic event</td>
</tr>
<tr>
<td>Hypoglycemia Symptom Assessment</td>
<td>HYPO PRECIP PA</td>
<td>Whether physical activity was a possible precipitating factor for the subject's hypoglycemic event</td>
</tr>
<tr>
<td>Hypoglycemia Symptom Assessment</td>
<td>HYPO PRECIP ALC</td>
<td>Whether alcohol was a possible precipitating factor for the subject's hypoglycemic event</td>
</tr>
<tr>
<td>Hypoglycemia Symptom Assessment</td>
<td>HYPO PRECIP ILL</td>
<td>Whether illness was a possible precipitating factor for the subject's hypoglycemic event</td>
</tr>
<tr>
<td>Most Recent Meal</td>
<td>PRESP ML TRT</td>
<td>Collection of details of administrations of last meal before a hypoglycemic event</td>
</tr>
<tr>
<td>Most Recent Treatment</td>
<td>PRESP CM TRT</td>
<td>Collection of details of administrations of last diabetic treatments before a hypoglycemic event</td>
</tr>
<tr>
<td>Hypoglycemia Treatment</td>
<td>OCCUR CM TRT</td>
<td>Query whether individual hypoglycemic treatments were taken for a hypoglycemic event</td>
</tr>
<tr>
<td>Hypoglycemia Treatment</td>
<td>OCCUR Group</td>
<td>Query about occurrence of any of hypoglycemic treatments for the hypoglycemic event</td>
</tr>
</tbody>
</table>
Appendix E: References


Appendix E1: Further Reading

Appendix F: Representations and Warranties, Limitations of Liability, and Disclaimers

CDISC Patent Disclaimers
It is possible that implementation of and compliance with this standard may require use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any claim or of any patent rights in connection therewith. CDISC, including the CDISC Board of Directors, shall not be responsible for identifying patent claims for which a license may be required in order to implement this standard or for conducting inquiries into the legal validity or scope of those patents or patent claims that are brought to its attention.

Representations and Warranties
“CDISC grants open public use of this User Guide (or Final Standards) under CDISC’s copyright.”

Each Participant in the development of this standard shall be deemed to represent, warrant, and covenant, at the time of a Contribution by such Participant (or by its Representative), that to the best of its knowledge and ability: (a) it holds or has the right to grant all relevant licenses to any of its Contributions in all jurisdictions or territories in which it holds relevant intellectual property rights; (b) there are no limits to the Participant’s ability to make the grants, acknowledgments, and agreements herein; and (c) the Contribution does not subject any Contribution, Draft Standard, Final Standard, or implementations thereof, in whole or in part, to licensing obligations with additional restrictions or requirements inconsistent with those set forth in this Policy, or that would require any such Contribution, Final Standard, or implementation, in whole or in part, to be either: (i) disclosed or distributed in source code form; (ii) licensed for the purpose of making derivative works (other than as set forth in Section 4.2 of the CDISC Intellectual Property Policy (“the Policy”)); or (iii) distributed at no charge, except as set forth in Sections 3, 5.1, and 4.2 of the Policy. If a Participant has knowledge that a Contribution made by any Participant or any other party may subject any Contribution, Draft Standard, Final Standard, or implementation, in whole or in part, to one or more of the licensing obligations listed in Section 9.3, such Participant shall give prompt notice of the same to the CDISC President who shall promptly notify all Participants.

No Other Warranties/Disclaimers. ALL PARTICIPANTS ACKNOWLEDGE THAT, EXCEPT AS PROVIDED UNDER SECTION 9.3 OF THE CDISC INTELLECTUAL PROPERTY POLICY, ALL DRAFT STANDARDS AND FINAL STANDARDS, AND ALL CONTRIBUTIONS TO FINAL STANDARDS AND DRAFT STANDARDS, ARE PROVIDED “AS IS” WITH NO WARRANTIES WHATSOEVER, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, AND THE PARTICIPANTS, REPRESENTATIVES, THE CDISC PRESIDENT, THE CDISC BOARD OF DIRECTORS, AND CDISC EXPRESSLY DISCLAIM ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, FITNESS FOR ANY PARTICULAR OR INTENDED PURPOSE, OR ANY OTHER WARRANTY OTHERWISE ARISING OUT OF ANY PROPOSAL, FINAL STANDARDS OR DRAFT STANDARDS, OR CONTRIBUTION.

Limitation of Liability
IN NO EVENT WILL CDISC OR ANY OF ITS CONSTITUENT PARTS (INCLUDING, BUT NOT LIMITED TO, THE CDISC BOARD OF DIRECTORS, THE CDISC PRESIDENT, CDISC STAFF, AND CDISC MEMBERS) BE LIABLE TO ANY OTHER PERSON OR ENTITY FOR ANY LOSS OF PROFITS, LOSS OF USE, DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, WHETHER UNDER CONTRACT, TORT, WARRANTY, OR OTHERWISE, ARISING IN ANY WAY OUT OF THIS POLICY OR ANY RELATED AGREEMENT, WHETHER OR NOT SUCH PARTY HAD ADVANCE NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

Note: The CDISC Intellectual Property Policy can be found at http://www.cdisc.org/about/bylaws_pdfs/CDISCIPPolicy-FINAL.pdf.
Supplementary Material
SHARE
Prototype
SHARE Metadata Displays

The Excel workbooks contain somewhat simplified versions of SHARE metadata. The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based, along with a component of the complex datatype for the class attribute
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The **Key to Layout** worksheet explains the metadata and how it is organized. Also included are explanations of the formats of contents of the table.

The **Template** worksheet shows the set of BRIDG-based components from which the metadata for individual concepts were drawn. The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains metadata for five concepts. The first three are for concomitant medications. The last two deal with treatment naive.

- **OCCUR CM Group**, a query about a particular type of administration of concomitant medication during an evaluation interval.
- **PRESP CM Group**, recording of details of a particular type of administration of a concomitant medication during an evaluation interval.
- **LOG CM**, collection of concomitant medications that are not pre-specified. This is standard concomitant medication collection with an implicit evaluation interval of "during the study."
- **TRT NAV OCCUR**, a query about whether a subject has taken any anti-hyperglycemics in the last ten years.
- **TRT NAV PRESP**, records details about any anti-hyperglycemics taken in the last ten years.
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MECRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.code</td>
<td>ATC-A10</td>
<td>Pre-specified class</td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>MECRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>ALIMENTARY TRACT AND METABOLISM; DRUGS USED IN DIABETES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The main body of the sheet contains the data items (variables) that make up the concept, described in terms of the BRIDG class and attributes on which they are based, along with a component of the complex datatype for the class attribute, controlled terminology (if applicable) and where the data item is represented in SDTM.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MECRIT.Defined.Drug.formCode.CD.code</td>
<td>from codeList C66726</td>
<td></td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>MECRIT.Defined.Drug.formCode.CD.displayName.value</td>
<td>from codeList C66726</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MECRIT.Defined.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.value</td>
<td>-P10Y</td>
<td>Pre-specified focal duration</td>
<td>CMEVLINT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.unit.code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negotiationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negotiationReason.DSET&lt;SC&gt;.item.code</td>
<td>sponsor codeList</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.code</td>
<td>from codeList C66742</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.displayName.value</td>
<td>sponsor codeList</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possible associated concepts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At the bottom of the sheet are other research concepts to which the research concept may or must be connected.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concept: Query about occurrence of any administration of anti-hyperglycemic medications (oral and injectable) in an evaluation interval</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Domain: CM |

| Anti-hyperglycemic medications |
| PRES=Y |

| Key to Layout |

| The main body of the sheet contains the data items (variables) that make up the concept, described in terms of the BRIDG class and attributes on which they are based, along with a component of the complex datatype for the class attribute, controlled terminology (if applicable) and where the data item is represented in SDTM. |
|  |
| The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer). |
| The third column describes an "attribute" of the test. There may be several BRIDG-based data items for a single attribute. |
| The fourth column shows the where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed. |

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.code</td>
<td>from drug dictionary</td>
<td>Pre-specified class</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>from drug dictionary</td>
<td>Pre-specified drug</td>
<td>CMTRT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td>Pre-specified dose form</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td>Pre-specified description</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.description.ST.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>from codelist C66729</td>
<td>Pre-specified route of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>from codelist C66729</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td>Pre-specified target site</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td>Pre-specified site of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
<td>C25228, C25229</td>
<td>Pre-specified indication</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.code</td>
<td>sponsor codelist</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.value</td>
<td>SDTM uses ISO8601 duration format</td>
<td>Focal time period</td>
<td>CMEVLINT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.unit.code</td>
<td></td>
<td></td>
<td>CMEVLINTX</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.dateRange.IVL&lt;INT&gt;.low.value</td>
<td>datetime</td>
<td>Question date time</td>
<td>CMDTC</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Question study day</td>
<td>CMDY</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negotiationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negotiationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negotiationReason.DSET&lt;SC&gt;.item.code.code</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negotiationReason.DSET&lt;SC&gt;.item.code.displayName.value</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negotiationReason.DSET&lt;SC&gt;.item.code.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R.PerformedObservation.result.value.CD.code</td>
<td>C49488, C49487</td>
<td>Result value</td>
<td>CMOCCUR (if occurrence question)</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.codeModifiedText.ST.value</td>
<td>YES, NO</td>
<td>Medication administered</td>
<td>CMMODIFY</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.code</td>
<td>from drug dictionary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.displayName.value</td>
<td>from drug dictionary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
Prototype
Page 3 of 15
9/10/2014
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>from codelist C66729</td>
<td>Route of administration of administered medicine</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>from codelist C66729</td>
<td>Route of administration of administered medicine</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value</td>
<td>free text</td>
<td>Route of administration of administered medicine</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value</td>
<td>free text</td>
<td>Amount of product administered</td>
<td>CMDOSE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.value</td>
<td>decimal</td>
<td>Amount of product administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>Amount of product administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td>Amount of product administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.originalText.value</td>
<td>free text</td>
<td>Amount of product administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value</td>
<td>free text</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value</td>
<td>decimal</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.originalText.value</td>
<td>free text</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.originalText.value</td>
<td>free text</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.originalText.value</td>
<td>free text</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code</td>
<td>C25301, C29844, C29846</td>
<td>Period for total amount administered</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value</td>
<td>DAY, WEEK, MONTH</td>
<td>Period for total amount administered</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.originalText.value</td>
<td>from codelist C66726</td>
<td>Period for total amount administered</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value</td>
<td>free text</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value</td>
<td>decimal</td>
<td>Reason for dose change</td>
<td>CMADI</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.displayName.value</td>
<td>from codelist C77456</td>
<td>Reason for dose change</td>
<td>CMADI</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.originalText.value</td>
<td>from codelist C77456</td>
<td>Reason for dose change</td>
<td>CMADI</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value</td>
<td>free text</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
<td>C25228, C25229</td>
<td>Site of medication administration</td>
<td>CMLAT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
<td>RIGHT, LEFT</td>
<td>Site of medication administration</td>
<td>CMLAT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL-TS.low.value</td>
<td>datetime</td>
<td>Start datetime of medication administration</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL-TS.low.originalText.value</td>
<td>free text</td>
<td>Start datetime of medication administration</td>
<td>CMSTDTC</td>
</tr>
</tbody>
</table>

| Block for collected properties of medication administered | | | |

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved

Protocly

CDISC Prototype SHARE Metadata: CM and Treatment Naive

Page 4 of 15

9/10/2014
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td>Negative Infinity</td>
<td>Uncertain start datetime of medication administration</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.value</td>
<td></td>
<td>datetime</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.lowClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.lowClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.high.nullFlavor.code</td>
<td>PINF</td>
<td>Positive Infinity</td>
<td>Uncertain end datetime of medication administration</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.nullFlavor.code</td>
<td>PINF</td>
<td>Positive Infinity</td>
<td>Uncertain end datetime of medication administration</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.low.value</td>
<td></td>
<td>datetime</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.value</td>
<td></td>
<td>datetime</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Start study date of med admin</td>
<td>CMSTDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>End study day of med admin</td>
<td>CMENDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.code</td>
<td>sponsor codelist?</td>
<td>Indication for medication administration</td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>sponsor codelist?</td>
<td>Indication for medication administration</td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Block for collected properties of medication administered
<table>
<thead>
<tr>
<th>Concept: Query about occurrence of any of &lt;group of pre-specified concomitant medication administrations&gt; in an evaluation interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BRIDG-based concept variable</strong></td>
</tr>
<tr>
<td>MEDCRIT. Defined.Drug.classCode.DSET&lt;CD&gt;.item.code</td>
</tr>
<tr>
<td>MEDCRIT. Defined.Drug.classCode.DSET&lt;CD&gt;.item.displayName.value</td>
</tr>
<tr>
<td>MEDCRIT. Defined.Drug.classCode.DSET&lt;CD&gt;.item.originalText.value</td>
</tr>
<tr>
<td>MEDCRIT. Defined.Drug.formCode.CD.code</td>
</tr>
<tr>
<td>MEDCRIT. Defined.Drug.formCode.CD.displayName.value</td>
</tr>
<tr>
<td>MEDCRIT. Defined.Drug.formCode.CD.originalText.value</td>
</tr>
<tr>
<td>MEDCRIT. Defined.Drug.description.ST.value</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.originalText.value</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.code</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.displayName.value</td>
</tr>
<tr>
<td>ADMINCRIT. DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.focalDuration.PQ.value</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.focalDuration.PQ.unit.code</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.focalDuration.PQ.unit.displayName.value</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.focalDateRange.IVL&lt;TS&gt;.originalText.value</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.focalDateRange.IVL&lt;TS&gt;.low.value</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.negationIndicator.BL.value</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.negationReason.DSET&lt;SC&gt;.item.code</td>
</tr>
<tr>
<td>CMQ_ O. DefinedObservation.negationReason.DSET&lt;SC&gt;.item.displayName.value</td>
</tr>
<tr>
<td>CMQ_ R. DefinedObservationResult.value.CD.code</td>
</tr>
<tr>
<td>CMQ_ R. DefinedObservationResult.value.CD.displayName.value</td>
</tr>
</tbody>
</table>
### Possible associated concepts

<table>
<thead>
<tr>
<th>Collection of details of pre-specified group of CM administrations</th>
<th>Triggered by Yes response to this concept</th>
<th>PRESP CM Group</th>
</tr>
</thead>
</table>
### Concept:
Collection of details of administrations of a **pre-specified group of concomitant medication** during an evaluation interval

### Domain: CM

**TRT:** pre-specified group of concomitant medications

**PRESP= Y**

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.code</td>
<td>from drug dictionary</td>
<td>Pre-specified class</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>from drug dictionary</td>
<td>Pre-specified class</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td>Pre-specified class</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td>Pre-specified dose form</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td>Pre-specified dose form</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td>Pre-specified dose form</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>from codelist C66729</td>
<td>Pre-specified route of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>from codelist C66729</td>
<td>Pre-specified route of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td>Pre-specified target site</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td>Pre-specified target site</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.originalText.value</td>
<td>free text</td>
<td>Pre-specified target site</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td>Pre-specified site of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td>Pre-specified site of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value</td>
<td>free text</td>
<td>Pre-specified site of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.code</td>
<td>sponsor codelist</td>
<td>Pre-specified indication</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>sponsor codelist</td>
<td>Pre-specified indication</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td>Pre-specified indication</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.value</td>
<td>SDTM uses ISO8601 duration format</td>
<td>Focal time period</td>
<td>CMEVLINT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.unit.code</td>
<td></td>
<td></td>
<td>CMEVLINT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value</td>
<td></td>
<td></td>
<td>CMEVLINT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDateRange.IVL&lt;TS&gt;.originalText.value</td>
<td>free text</td>
<td></td>
<td>CMEVLINT</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.codeModifiedText.ST.value</td>
<td>free text</td>
<td>Medication administered</td>
<td>CMMODIFY</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.code</td>
<td>from drug dictionary</td>
<td>Doseform of administered medication</td>
<td>CMDDECOD</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.displayName.value</td>
<td>from drug dictionary</td>
<td>Doseform of administered medication</td>
<td>CMDDECOD</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.originalText.value</td>
<td>free text</td>
<td>Doseform of administered medication</td>
<td>CMDDECOD</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>from codelist C66729</td>
<td>Route of administration of administered medication</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>from codelist C66729</td>
<td>Route of administration of administered medication</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value</td>
<td>free text</td>
<td>Route of administration of administered medication</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value</td>
<td>free text</td>
<td>Amount of product</td>
<td>CMDOSE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.value</td>
<td>decimal</td>
<td>Amount of product</td>
<td>CMDOSE</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>Value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------</td>
<td>-----------</td>
<td>---------------</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td>administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value</td>
<td>free text</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value</td>
<td>decimal</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td>administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.originalText.value</td>
<td>free text</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT (if period is a day)</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.value</td>
<td>decimal</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT (if period is a day)</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td>administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code</td>
<td>C25301, C29844, C29846</td>
<td>Period for total amount administered</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value</td>
<td>free text</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value</td>
<td>decimal</td>
<td>Reason for dose change</td>
<td>CMADJ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value</td>
<td>free text</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
<td>C25228, C25229</td>
<td>Site of medication administration</td>
<td>CMLAT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
<td>RIGHT, LEFT</td>
<td>Site of medication administration</td>
<td>CMLAT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Start datetime of medication</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.originalText.value</td>
<td>free text</td>
<td>Start datetime of medication</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTPT &amp; CMSTTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.nullFlavor.displayName.value</td>
<td>Negative Infinity</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTPT &amp; CMSTTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.value</td>
<td>free text</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTPT &amp; CMSTTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.lowClosed.value</td>
<td>TRUE, FALSE</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTPT &amp; CMSTTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.high.value</td>
<td>datetime</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTPT &amp; CMSTTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.highClosed.value</td>
<td>TRUE, FALSE</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTPT &amp; CMSTTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.value</td>
<td>datetime</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTPT &amp; CMSTTPT</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>Value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.originalText.value</td>
<td>free text</td>
<td>End datetime of medication administration</td>
<td>CMENDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain end datetime of medication administration</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.low.nullFlavor.displayName.value</td>
<td>Negative Infinity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.low.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.lowClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.nullFlavor.code</td>
<td>PINF</td>
<td>Start study date of medication administration</td>
<td>CMENDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.nullFlavor.displayName.value</td>
<td>Positive Infinity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td></td>
<td>CMSTDDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.high.value</td>
<td>integer</td>
<td>End study day of medication administration</td>
<td>CMENDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.code</td>
<td>sponsor codelist?</td>
<td></td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>sponsor codelist?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Possible associated concepts

Query whether any of <pre-specified group of concomitant medication administrations> occurred during an evaluation interval

May trigger this concept OCCUR CM Group
**Concept:** Collection concomitant medication details

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCOLL.Performed.Drug.codeModifiedText.ST.value</td>
<td>free text</td>
<td>Medication administered</td>
<td>CMMODIFY</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.code</td>
<td>from drug dictionary</td>
<td></td>
<td>CMDECOD</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.displayName.value</td>
<td>from drug dictionary</td>
<td></td>
<td>CMTRT</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td>CMTRT</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td></td>
<td>CMROUTE</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td>Amount of product administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>from codelist C66729</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>free text</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value</td>
<td>free text</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT (if period is a day)</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.value</td>
<td>decimal</td>
<td></td>
<td>CMDOSTOT (if period is a day)</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value</td>
<td>decimal</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value</td>
<td>free text</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDoseTotal.PQ.originalText.value</td>
<td>free text</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDoseTotal.PQ.value</td>
<td>decimal</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDoseTotal.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code</td>
<td>C25301, C29844, C29846</td>
<td>Period for total amount administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value</td>
<td>DAY, WEEK, MONTH</td>
<td></td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value</td>
<td>from codelist C71113</td>
<td></td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value</td>
<td>decimal</td>
<td>Reason for change dose change</td>
<td>CMADJ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td></td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td></td>
<td>CMLOC</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>Value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------</td>
<td>--------------------</td>
<td>---------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value</td>
<td>free text</td>
<td>Site of medication administration</td>
<td>CMLAT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
<td>C25228, C25229</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
<td>RIGHT, LEFT</td>
<td>Start datetime of medication</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>End datetime of medication</td>
<td>CMENDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain start datetime of medication</td>
<td>CMENRF or CMSTRTP &amp; CMSTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain end datetime of medication</td>
<td>CMENRF or CMENRTPT &amp; CMENTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.code</td>
<td>sponsor codelist? MedDRA?</td>
<td>Indication for medication administration</td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>sponsor codelist? MedDRA?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Start study date of med admin</td>
<td>CMSTDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.high.value</td>
<td>integer</td>
<td>End study day of med admin</td>
<td>CMENDY</td>
</tr>
</tbody>
</table>
Concept: Query about occurrence of any administration of anti-hyperglycemic medications (oral and injectable) in an evaluation interval

### BRIDG-based concept variable

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.code</td>
<td>ATC-A10</td>
<td>Pre-specified class</td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>ALIMENTARY TRACT AND METABOLISM; DRUGS USED IN DIABETES</td>
<td>Pre-specified class</td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>ANTI-HYPERGLYCEMIC</td>
<td>Pre-specified class</td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td>Pre-specified dose form</td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td>Pre-specified dose form</td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td>Pre-specified dose form</td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.description.ST.value</td>
<td>free text</td>
<td>Pre-specified description</td>
<td>CMTRT, CMCAT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.value</td>
<td>-P10Y</td>
<td>Focal time period</td>
<td>CMEVLINT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.unit.code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Question datetime</td>
<td>CMDTC</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Question study day</td>
<td>CMDY</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code</td>
<td>sponsor codelist</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.code</td>
<td>C49488, C49487</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.displayName.value</td>
<td>Y, N</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
</tbody>
</table>

### Possible associated concepts

Collection of details of pre-specified group of CM administrations

Triggered by Yes response to this concept

TRT NAIVE PRES"
CDISC Prototype SHARE Metadata: CM and Treatment Naive

Concept: Collection of details of administrations of anti-hyperglycemic (oral and injectable) during an evaluation interval

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.code</td>
<td>ATC-A10</td>
<td>Pre-specified class</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>ALIMENTARY TRACT AND METABOLISM; DRUGS USED IN DIABETES</td>
<td>Pre-specified dose form</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>ANTI-HYPERGLYCEMIC</td>
<td>Pre-specified description</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.description.ST.value</td>
<td>free text</td>
<td>Pre-specified description</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.value</td>
<td>-P10Y</td>
<td>Focal time period</td>
<td>CMEVLINT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Start datetime of medication administration</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRNF or CMSTTPT &amp; CMENDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.OriginalDateTime.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.Closed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.high.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.value</td>
<td>datetime</td>
<td>End datetime of medication administration</td>
<td>CMENDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.nullFlavor.code</td>
<td>NINF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.OriginalDateTime.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.Closed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.low.value</td>
<td>datetime</td>
<td>Uncertain end datetime of medication administration</td>
<td>CMENRNF or CMENRTPT &amp; CMENDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.low.OriginalDateTime.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.low.Closed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.value</td>
<td>PINF</td>
<td>Positive Infinity</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.OriginalDateTime.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.Closed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved

Prototype

Page 14 of 15

9/10/2014
### BRIDG-based concept variable

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Start study date of med admin</td>
<td>CMSTDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.high.value</td>
<td>integer</td>
<td>End study day of med admin</td>
<td>CMENDY</td>
</tr>
</tbody>
</table>

### Possible associated concepts

Query whether any of <pre-specified group of concomitant medication administrations> occurred during an evaluation interval

<table>
<thead>
<tr>
<th>May trigger this concept</th>
<th>TRT NAÏVE OCCUR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SHARE Metadata Displays
The Excel workbooks contain somewhat simplified versions of SHARE metadata.
The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based, along with a component of the complex datatype for the class attribute
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The Key to Layout worksheet explains the metadata and how it is organized.
Also included are explanations of the formats of contents of the table.

The Template worksheet shows the set of BRIDG-based components from which the metadata for individual concepts were drawn.
The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains metadata describing six laboratory tests with quantitative or semi-quantitative results.

- **HbA1c per Total Hemoglobin**, hemoglobin A1c as a proportion of total hemoglobin
- **Glucose Blood**, concentration of glucose in blood
- **Glucose Plasma_Serum**, concentration of glucose in plasma or serum
- **Glucose Urine**, concentration of glucose in urine
- **SQ Glucose Urine**, semi-quantitative concentration of glucose in urine
- **Glucose CSF**, concentration of glucose in cerebrospinal fluid
| Concept: Semi-quantitative concentration of glucose |

**Domain:** LB  
**TEST:** Glucose  
**TESTCD:** Glucose

---

**Possible associated concepts**

- Collection of the specimen on which the test was performed  
  - Specimen collection  
  - LBDTC, LBDY
- Laboratory which performed the test  
  - Laboratory  
  - LBNAM

---

**BRIDG-based concept variable**

<table>
<thead>
<tr>
<th>Concept</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLUCURS Q_O. DefinedObservation.methodCode.CD.code</td>
<td>C50322,</td>
<td>Test Strip</td>
<td>METHOD</td>
</tr>
<tr>
<td>GLUCURS Q_O. DefinedObservation.methodCode.CD.displayName.value</td>
<td>Test Strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_O. DefinedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Date of Test</td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_O. DefinedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Study Day of Test</td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_O. DefinedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE</td>
<td>Negation Indicator</td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_O. DefinedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Negation Reason</td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_R. PerformedClinicalResult.value.CD.originalText.value</td>
<td>from sponsor code system</td>
<td>Coded Result Value</td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_R. PerformedClinicalResult.value.CD.code</td>
<td>from sponsor code system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_R. PerformedClinicalResult.value.CD.displayName.value</td>
<td>from sponsor code system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_R. PerformedClinicalResult.baselineIndicator.BL.value</td>
<td>TRUE, FALSE</td>
<td>Baseline Indicator</td>
<td></td>
</tr>
<tr>
<td>GLUCURS Q_R. PerformedClinicalResult.comment.ST.value</td>
<td>free text</td>
<td>Comment</td>
<td></td>
</tr>
</tbody>
</table>

**At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.**

**The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.**

**The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datet ime or free text or integer).**

**The third column describes an “attribute” of the test. There may be several BRIDG-based data items for a single attribute.**

**The fourth column shows the where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed.**

**At the bottom of the sheet are other research concepts to which the research concept may or must be connected.**

**Shaded cells represent paired values.**

**Blue text (not shown) indicates terminology that has not yet been approved.**
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
<th>Domain: LB</th>
<th>TEST: TESTCD:</th>
</tr>
</thead>
<tbody>
<tr>
<td>LabTest. DefinedObservation. methodCode.CD.code</td>
<td>c-codes from METHOD CT</td>
<td></td>
<td>METHOD</td>
<td>Block for pre-specified properties of the test</td>
<td></td>
</tr>
<tr>
<td>LabTest. DefinedObservation. methodCode.CD. displayName.value</td>
<td>submission values from METHOD CT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabTest. PerformedObservation. dateRange.IVL&lt;TS&gt;. low.value</td>
<td>datetime</td>
<td>Date of Test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabTest. PerformedObservation. studyDayRange.IVL&lt;INT&gt;. low.value</td>
<td>integer</td>
<td>Study Day of Test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabTest. PerformedObservation. negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Negation Indicator</td>
<td>LBSTAT</td>
<td>Block for collected properties of the test</td>
<td></td>
</tr>
<tr>
<td>LabTest. PerformedObservation. negationReason.DSET&lt;SC&gt;. item.value</td>
<td>free text</td>
<td>Negation Reason</td>
<td>LBREASND</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. value.CD. originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. value.CD. code</td>
<td>from sponsor code system</td>
<td>Coded Result Value</td>
<td>LBORRES,</td>
<td>Block for collected properties of the result</td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. value.CD. displayName.value</td>
<td>from sponsor code system</td>
<td></td>
<td>LBSTRESN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. value.PQ. originalText.value</td>
<td>free text</td>
<td>Numeric Result Value</td>
<td>LBORRESU,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. value.PQ. code</td>
<td>decimal</td>
<td></td>
<td>LBSTRESU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. value.PQ. unit.code</td>
<td>codes from UNIT CT</td>
<td>Result Unit</td>
<td>LBORRESU,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. value.PQ. unit.displayName.value</td>
<td>submission values from UNIT CT</td>
<td></td>
<td>LBSTRESU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. baselineIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM Y, null)</td>
<td>Baseline Indicator</td>
<td>LBBLFL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. comment.ST.value</td>
<td>free text</td>
<td>Comment</td>
<td>COVAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabResult. PerformedClinicalResult. normalRangeComparisonCode.CD.code</td>
<td>C78727, C78800, C78801</td>
<td>Normal Range</td>
<td>LBNRIND</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comparison</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabNR. ReferenceResult. value.IVL&lt;PQ&gt;. low.value</td>
<td>decimal</td>
<td>Normal Range Lower Limit</td>
<td>LBORNRL,</td>
<td></td>
<td>Block for normal range</td>
</tr>
<tr>
<td>LabNR. ReferenceResult. value.IVL&lt;PQ&gt;. low.unit.code</td>
<td>codes from UNIT CT</td>
<td>Normal Range Lower Limit</td>
<td>LBORRESU,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabNR. ReferenceResult. value.IVL&lt;PQ&gt;. low.displayName.value</td>
<td>submission values from UNIT CT</td>
<td>Normal Range Lower Limit Unit</td>
<td>LBSTNRLO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabNR. ReferenceResult. value.IVL&lt;PQ&gt;. high.value</td>
<td>decimal</td>
<td>Normal Range Upper Limit</td>
<td>LBRORRH,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabNR. ReferenceResult. value.IVL&lt;PQ&gt;. high.unit.code</td>
<td>codes from UNIT CT</td>
<td>Normal Range Upper Limit Unit</td>
<td>LBSTNRH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabNR. ReferenceResult. value.IVL&lt;PQ&gt;. high.displayName.value</td>
<td>submission values from UNIT CT</td>
<td>Normal Range Upper Limit Unit</td>
<td>LBORRESU,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LabNR. ReferenceResult. value.IVL&lt;PQ&gt;. high.unitName.value</td>
<td>submission values from UNIT CT</td>
<td>Normal Range Upper Limit Unit</td>
<td>LBSTRESU</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
Prototype
Page 3 of 14
9/10/2014
Concept: Hemoglobin A1c as a proportion of total hemoglobin

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBA1CHBBL_O.DefinedObservation.methodCode.CD.code</td>
<td>C54125, C111096, C65109, C16434, C50322, C16536, C16714, C16553</td>
<td>Pre-specified method</td>
<td>METHOD</td>
</tr>
<tr>
<td>HBA1CHBBL_O.DefinedObservation.methodCode.CD.displayName.value</td>
<td>Calculation; Colorimetry; Photometry; HPLC; Test Strip; Electrophoresis; Immunoassay; ELISA; Cyanmethemoglobin; Conductometric; Boronate Affinity Chromatography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBA1CHBBL_O.PerformedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Date of Test</td>
<td></td>
</tr>
<tr>
<td>HBA1CHBBL_O.PerformedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Study Day of Test</td>
<td></td>
</tr>
<tr>
<td>HBA1CHBBL_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Negation Indicator</td>
<td>LBSTAT</td>
</tr>
<tr>
<td>HBA1CHBBL_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Negation Reason</td>
<td>LBREASND</td>
</tr>
<tr>
<td>HBA1CHBBL_R.PerformedClinicalResult.value.PQ.originalText.value</td>
<td>free text</td>
<td>Numeric Result Value</td>
<td>LBORRES, LBSTRESC, LBSTRESN</td>
</tr>
<tr>
<td>HBA1CHBBL_R.PerformedClinicalResult.value.PQ.value</td>
<td>decimal</td>
<td>Result Unit</td>
<td>LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>HBA1CHBBL_R.PerformedClinicalResult.value.PQ.unit.code</td>
<td>C25613; C105484</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBA1CHBBL_R.PerformedClinicalResult.value.PQ.unit.displayName.value</td>
<td>percent; fraction of 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBA1CHBBL_R.PerformedClinicalResult.baselineIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM Y, null)</td>
<td>Baseline Indicator</td>
<td>LBBLFL</td>
</tr>
<tr>
<td>HBA1CHBBL_R.PerformedClinicalResult.comment.ST.value</td>
<td>free text</td>
<td>Comment</td>
<td>COVAL</td>
</tr>
<tr>
<td>HBA1CHBBL_R.PerformedClinicalResult.normalRangeComparisonCode.CD.code</td>
<td>C78727, C78800, C78801</td>
<td>Normal Range Comparison</td>
<td>LBNRIND</td>
</tr>
<tr>
<td>HBA1CHBBL_R.PerformedClinicalResult.normalRangeComparisonCode.CD.displayName.value</td>
<td>NORMAL, HIGH, LOW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBA1CHBBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.value</td>
<td>decimal</td>
<td>Normal Range Lower Limit</td>
<td>LBORNRLO, LBSTNRLO</td>
</tr>
<tr>
<td>HBA1CHBBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.code</td>
<td>C25613; C105484</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBA1CHBBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.displayName.value</td>
<td>percent; fraction of 1</td>
<td>Normal Range Lower Limit Unit</td>
<td>uses LBORRES, LBSTRESU</td>
</tr>
<tr>
<td>HBA1CHBBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.value</td>
<td>decimal</td>
<td>Normal Range Upper Limit</td>
<td>LBORNRHI, LBSTNRHI</td>
</tr>
<tr>
<td>HBA1CHBBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.code</td>
<td>C25613; C105484</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBA1CHBBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.displayName.value</td>
<td>percent; fraction of 1</td>
<td>Normal Range Upper Limit Unit</td>
<td>uses LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>Possible associated concepts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------</td>
<td>----------------</td>
<td></td>
</tr>
<tr>
<td>Blood</td>
<td>Specimen</td>
<td>Source of LBSPEC=BLOOD, LBSPCCND</td>
<td></td>
</tr>
<tr>
<td>Collection of the specimen on which the test was performed</td>
<td>Specimen collection</td>
<td>Source of LBDTC, LBDY</td>
<td></td>
</tr>
<tr>
<td>Erythrocytes</td>
<td>Specimen</td>
<td>LBSPEC=ERYTHROCYTES, LBSPCCND</td>
<td></td>
</tr>
<tr>
<td>Collection of the specimen on which the test was performed</td>
<td>Specimen collection</td>
<td>Source of LBDTC, LBDY</td>
<td></td>
</tr>
<tr>
<td>Laboratory which performed the test</td>
<td>Laboratory</td>
<td>LBNAM</td>
<td></td>
</tr>
</tbody>
</table>
Concept: Concentration of glucose in blood

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLUCBL_O.DefinedObservation.methodCode.CD.code</td>
<td>C19340, C17156</td>
<td>Pre-specified method</td>
<td>METHOD</td>
</tr>
<tr>
<td>GLUCBL_O.DefinedObservation.methodCode.CD.displayName.value</td>
<td>Reflectance Spectroscopy; Mass Spectrometry; Enzymatic Spectrophotometry; Electrochemical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCBL_O.PerformedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Date of Test</td>
<td></td>
</tr>
<tr>
<td>GLUCBL_O.PerformedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Study Day of Test</td>
<td></td>
</tr>
<tr>
<td>GLUCBL_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Negation Indicator</td>
<td>LBSTAT</td>
</tr>
<tr>
<td>GLUCBL_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Negation Reason</td>
<td>LBREASND</td>
</tr>
<tr>
<td>GLUCBL_R.PerformedClinicalResult.value.PQ.value</td>
<td>decimal</td>
<td>Numeric Result Value</td>
<td>LBORRES, LBSTRESC, LBSTRESN</td>
</tr>
<tr>
<td>GLUCBL_R.PerformedClinicalResult.value.PQ.unit.code</td>
<td>mmol/L; g/L; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td>Result Unit</td>
<td>LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>GLUCBL_R.PerformedClinicalResult.baselineIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM Y, null)</td>
<td>Baseline Indicator</td>
<td>LBBLFL</td>
</tr>
<tr>
<td>GLUCBL_R.PerformedClinicalResult.comment.ST.value</td>
<td>free text</td>
<td>Comment</td>
<td>COVAL</td>
</tr>
<tr>
<td>GLUCBL_R.PerformedClinicalResult.normalRangeComparisonCode.CD.code</td>
<td>NORMAL, HIGH, LOW</td>
<td>Normal Range Comparison</td>
<td>LBNRIND</td>
</tr>
<tr>
<td>GLUCBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.value</td>
<td>decimal</td>
<td>Normal Range Lower Limit</td>
<td>LBORNRLO, LBSTNRLO</td>
</tr>
<tr>
<td>GLUCBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.code</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td>Normal Range Lower Limit Unit</td>
<td>uses LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>GLUCBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.displayName.value</td>
<td>null</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.value</td>
<td>decimal</td>
<td>Normal Range Upper Limit</td>
<td>LBORNRHI, LBSTNRHI</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------</td>
<td>-----------</td>
<td>---------------</td>
</tr>
<tr>
<td>GLUCBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Normal Range Upper Limit Unit</td>
<td>uses LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>GLUCBL_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Possible associated concepts**

<table>
<thead>
<tr>
<th>Blood</th>
<th>Specimen</th>
<th>Source of LBSPEC=BLOOD, LBSPCCND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection of the specimen on which the test was performed</td>
<td>Specimen collection</td>
<td>Source of LBDTC, LBDY</td>
</tr>
<tr>
<td>Laboratory which performed the test</td>
<td>Laboratory</td>
<td>LBNAM</td>
</tr>
<tr>
<td>BRIDGE-based concept variable</td>
<td>value(s)</td>
<td>Attribute</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------</td>
<td>-----------</td>
</tr>
<tr>
<td>GLUCPS_O.DefinedObservation.methodCode.CD.code</td>
<td>C19340, C17156</td>
<td>Pre-specified method</td>
</tr>
<tr>
<td>GLUCPS_O.DefinedObservation.methodCode.CD.displayName.value</td>
<td>Reflectance Spectroscopy; Mass Spectrometry; Enzymatic Spectrophotometry; Electrochemical</td>
<td></td>
</tr>
<tr>
<td>GLUCPS_O.PerformedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Date of Test</td>
</tr>
<tr>
<td>GLUCPS_O.PerformedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Study Day of Test</td>
</tr>
<tr>
<td>GLUCPS_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Negation Indicator</td>
</tr>
<tr>
<td>GLUCPS_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Negation Reason</td>
</tr>
<tr>
<td>GLUCPS_R.PerformedClinicalResult.value.PQ.originalText.value</td>
<td>free text</td>
<td>Numeric Result Value</td>
</tr>
<tr>
<td>GLUCPS_R.PerformedClinicalResult.value.PQ.value</td>
<td>decimal</td>
<td></td>
</tr>
<tr>
<td>GLUCPS_R.PerformedClinicalResult.value.PQ.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Result Unit</td>
</tr>
<tr>
<td>GLUCPS_R.PerformedClinicalResult.value.PQ.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
</tr>
<tr>
<td>GLUCPS_R.PerformedClinicalResult.baselineIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM Y, null)</td>
<td>Baseline Indicator</td>
</tr>
<tr>
<td>GLUCPS_R.PerformedClinicalResult.comment.ST.value</td>
<td>free text</td>
<td>Comment</td>
</tr>
<tr>
<td>GLUCPS_R.PerformedClinicalResult.normalRangeComparisonCode.CD.code</td>
<td>C78727, C78800, C78801</td>
<td>Normal Range Comparison</td>
</tr>
<tr>
<td>GLUCPS_R.PerformedClinicalResult.normalRangeComparisonCode.CD.displayName.value</td>
<td>NORMAL, HIGH, LOW</td>
<td></td>
</tr>
<tr>
<td>GLUCPS_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.value</td>
<td>decimal</td>
<td>Normal Range Lower Limit</td>
</tr>
<tr>
<td>GLUCPS_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Normal Range Lower Limit Unit</td>
</tr>
<tr>
<td>GLUCPS_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
</tr>
<tr>
<td>GLUCPS_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.value</td>
<td>decimal</td>
<td>Normal Range Upper Limit</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>value(s)</td>
<td>Attribute</td>
</tr>
<tr>
<td>------------------------------------------------------------------</td>
<td>----------------------------------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>GLUCPS_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Normal Range Upper Limit Unit</td>
</tr>
<tr>
<td>GLUCPS_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
</tr>
</tbody>
</table>

### Possible associated concepts

<table>
<thead>
<tr>
<th>Brain-related concept variable</th>
<th>value(s)</th>
<th>Source of Specimen collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma</td>
<td>Specimen</td>
<td>Source of LBSPEC=PLASMA, LBSPCCND</td>
</tr>
<tr>
<td>Collection of the specimen on which the test was performed</td>
<td>Specimen collection</td>
<td>Source of LBDTC, LBDY</td>
</tr>
<tr>
<td>Serum</td>
<td>Specimen</td>
<td>Source of LBSPEC=SERUM, LBSPCCND</td>
</tr>
<tr>
<td>Collection of the specimen on which the test was performed</td>
<td>Specimen collection</td>
<td>Source of LBDTC, LBDY</td>
</tr>
<tr>
<td>Laboratory which performed the test</td>
<td>Laboratory</td>
<td>LBNAM</td>
</tr>
</tbody>
</table>
Concept: Concentration of glucose in urine

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLUCUR_O.DefinedObservation.methodCode.CD.code</td>
<td>C19340, C17156</td>
<td>Pre-specified method</td>
<td>METHOD</td>
</tr>
<tr>
<td>GLUCUR_O.DefinedObservation.methodCode.CD.displayName.value</td>
<td>Reflectance Spectroscopy; Mass Spectrometry; Enzymatic Spectrophotometry; Electrochemical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCUR_O.PerformedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>Date of Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCUR_O.PerformedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>Study Day of Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCUR_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Negation Indicator</td>
<td>LBSTAT</td>
</tr>
<tr>
<td>GLUCUR_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Negation Reason</td>
<td>LBREASND</td>
</tr>
<tr>
<td>GLUCUR_R.PerformedClinicalResult.value.PQ.originalText.value</td>
<td>free text</td>
<td>Numeric Result Value</td>
<td>LBORRES, LBSTRESFC, LBSTRESFN</td>
</tr>
<tr>
<td>GLUCUR_R.PerformedClinicalResult.value.PQ.value</td>
<td>decimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCUR_R.PerformedClinicalResult.value.PQ.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Result Unit</td>
<td>LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>GLUCUR_R.PerformedClinicalResult.value.PQ.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCUR_R.PerformedClinicalResult.baselineIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM Y, null)</td>
<td>Baseline Indicator</td>
<td>LBBLFL</td>
</tr>
<tr>
<td>GLUCUR_R.PerformedClinicalResult.comment.ST.value</td>
<td>free text</td>
<td>Comment</td>
<td>COVAL</td>
</tr>
<tr>
<td>GLUCUR_R.PerformedClinicalResult.normalRangeComparisonCode.CD.code</td>
<td>C78727, C78800, C78801</td>
<td>Normal Range Comparison</td>
<td>LBNRIND</td>
</tr>
<tr>
<td>GLUCUR_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.value</td>
<td>decimal</td>
<td>Normal Range Lower Limit</td>
<td>LBORNRLLO, LBSTNRLO</td>
</tr>
<tr>
<td>GLUCUR_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Normal Range Lower Limit Unit</td>
<td>uses LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>GLUCUR_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCUR_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.value</td>
<td>decimal</td>
<td>Normal Range Upper Limit</td>
<td>LBORNRLHI, LBSTNRHI</td>
</tr>
</tbody>
</table>
### BRIDG-based concept variable

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLUCUR_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Normal Range Upper Limit Unit</td>
<td>uses LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>GLUCUR_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Possible associated concepts

<table>
<thead>
<tr>
<th>Concept</th>
<th>Source of</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine</td>
<td>Specimen</td>
<td>LBSPEC=URINE, LBSPCCND</td>
</tr>
<tr>
<td>Collection of the specimen on which the test was performed</td>
<td>Specimen collection</td>
<td>LBDTC, LBDY</td>
</tr>
<tr>
<td>Laboratory which performed the test</td>
<td>Laboratory</td>
<td>LBNAM</td>
</tr>
</tbody>
</table>
Concept: Semi-quantitative concentration of glucose in urine

<table>
<thead>
<tr>
<th>Concept</th>
<th>Domain</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose Urine</td>
<td>LB</td>
<td>Test Strip</td>
<td>Pre-specified method</td>
<td>METHOD</td>
</tr>
<tr>
<td>Glucose Urine</td>
<td>LB</td>
<td>Date of Test</td>
<td>Date Time</td>
<td>DATE</td>
</tr>
<tr>
<td>Glucose Urine</td>
<td>LB</td>
<td>Study Day of Test</td>
<td>Integer</td>
<td>INT</td>
</tr>
<tr>
<td>Glucose Urine</td>
<td>LB</td>
<td>Negation Indicator</td>
<td>TRUE, FALSE</td>
<td>LBSTAT</td>
</tr>
<tr>
<td>Glucose Urine</td>
<td>LB</td>
<td>Negation Reason</td>
<td>Free Text</td>
<td>LBREASND</td>
</tr>
<tr>
<td>Glucose Urine</td>
<td>LB</td>
<td>Coded Result Value</td>
<td>From Sponsor Code System</td>
<td>LBORRES</td>
</tr>
<tr>
<td>Glucose Urine</td>
<td>LB</td>
<td>Baseline Indicator</td>
<td>TRUE, FALSE</td>
<td>LBBLFL</td>
</tr>
<tr>
<td>Glucose Urine</td>
<td>LB</td>
<td>Comment</td>
<td>Free Text</td>
<td>COVAL</td>
</tr>
</tbody>
</table>

Possible associated concepts

<table>
<thead>
<tr>
<th>Concept</th>
<th>Domain</th>
<th>Value(s)</th>
<th>Source of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine</td>
<td>Specimen</td>
<td>LBSPEC=URINE, LBSPCCND</td>
<td></td>
</tr>
<tr>
<td>Collection of the specimen on which the test was performed</td>
<td>Specimen collection</td>
<td>LBDTC, LBDY</td>
<td></td>
</tr>
<tr>
<td>Laboratory which performed the test</td>
<td>Laboratory</td>
<td>LBNAM</td>
<td></td>
</tr>
</tbody>
</table>
### Concept: Concentration of glucose in cerebral spinal fluid

#### BRIDG-based concept variable

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLUCCSF_O.DefinedObservation.methodCode.CD.code</td>
<td>C19340, C17156</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCCSF_O.DefinedObservation.methodCode.CD.displayName.value</td>
<td>Reflectance Spectroscopy; Mass Spectrometry; Enzymatic Spectrophotometry; Electrochemical</td>
<td>Pre-specified method</td>
<td>METHOD</td>
</tr>
<tr>
<td>GLUCCSF_O.PerformedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Date of Test</td>
<td></td>
</tr>
<tr>
<td>GLUCCSF_O.PerformedObservation.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Study Day of Test</td>
<td></td>
</tr>
<tr>
<td>GLUCCSF_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Negation Indicator</td>
<td>LBSTAT</td>
</tr>
<tr>
<td>GLUCCSF_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Negation Reason</td>
<td>LBREASND</td>
</tr>
<tr>
<td>GLUCCSF_R.PerformedClinicalResult.value.PQ.originalText.value</td>
<td>free text</td>
<td>Numeric Result Value</td>
<td></td>
</tr>
<tr>
<td>GLUCCSF_R.PerformedClinicalResult.value.PQ.value</td>
<td>decimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCCSF_R.PerformedClinicalResult.value.PQ.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Result Unit</td>
<td>LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>GLUCCSF_R.PerformedClinicalResult.value.PQ.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCCSF_R.PerformedClinicalResult.baselineIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM Y, null)</td>
<td>Baseline Indicator</td>
<td>LBBBFL</td>
</tr>
<tr>
<td>GLUCCSF_R.PerformedClinicalResult.comment.ST.value</td>
<td>free text</td>
<td>Comment</td>
<td>COVAL</td>
</tr>
<tr>
<td>GLUCCSF_R.PerformedClinicalResult.normalRangeComparisonCode.CD.code</td>
<td>C78727, C78800, C78801</td>
<td>Normal Range Comparison</td>
<td>LBNRIND</td>
</tr>
<tr>
<td>GLUCCSF_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.value</td>
<td>decimal</td>
<td>Normal Range Lower Limit</td>
<td>LBORNRL, LBSTNRLO</td>
</tr>
<tr>
<td>GLUCCSF_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Normal Range Lower Limit Unit</td>
<td></td>
</tr>
<tr>
<td>GLUCCSF_NR.ReferenceResult.value.IVL&lt;PQ&gt;.low.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCCSF_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.value</td>
<td>decimal</td>
<td>Normal Range Upper Limit</td>
<td>LBORNRI, LBSTNRRI</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------</td>
<td>-----------</td>
<td>---------------</td>
</tr>
<tr>
<td>GLUCCSF_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.code</td>
<td>C64387; C42576; C67327; C67326; C67306; C48508; C67434</td>
<td>Normal Range Upper Limit Unit</td>
<td>uses LBORRESU, LBSTRESU</td>
</tr>
<tr>
<td>GLUCCSF_NR.ReferenceResult.value.IVL&lt;PQ&gt;.high.unit.displayName.value</td>
<td>mmol/L; g/L; Null; ng/L; ng/dL; ug/L; umol/L; pmol/L</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Possible associated concepts

<table>
<thead>
<tr>
<th>Cerebrospinal Fluid</th>
<th>Specimen</th>
<th>Source of LBSPEC=CEREBROSPINAL FLUID, LBSPCCND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection of the specimen on which the test was performed</td>
<td>Specimen collection</td>
<td>Source of LBDTC, LBDY</td>
</tr>
<tr>
<td>Laboratory which performed the test</td>
<td>Laboratory</td>
<td>LBNAM</td>
</tr>
</tbody>
</table>
SHARE Metadata Displays
The Excel workbooks contain somewhat simplified versions of SHARE metadata. The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based, along with a component of the complex datatype for the class attribute
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The Key to Layout worksheet explains the metadata and how it is organized. Also included are explanations of the formats of contents of the table.

The Template worksheet shows the set of BRIDG-based components from which the metadata for individual concepts were drawn. The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains metadata for eight concepts:

- HYPO OCCUR, a query about the occurrence of a hypoglycemic event in an evaluation interval
- PRESP HYPO, collection of details about a hypoglycemic event
- HYPO NOCTURNAL, when in the diurnal sleep cycle an event occurred, between bedtime and waking or between waking and bedtime
- HYPO 3RD ASSIST, the part third party assistance played in treating the subject's event
- HYPO PRECIP MEAL, whether a missed or delayed meal was a possible precipitating factor for the subject's hypoglycemic event
- HYPO PRECIP PA, whether physical activity was a possible precipitating factor for the subject's hypoglycemic event
- HYPO PRECIP ALC, whether alcohol was a possible precipitating factor for the subject's hypoglycemic event
- HYPO PRECIP ILL, whether illness was a possible precipitating factor for the subject's hypoglycemic event
Concept: Whether illness was a possible precipitating factor for the subject's hypoglycemic event

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.code</td>
<td>10020993</td>
<td>clinical term</td>
<td>FAOBJ</td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.displayName.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.originalText.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ILLCAUS_O.PerformedObservation.nameCode.CD.code</td>
<td>to be determined</td>
<td></td>
<td>FATESTCD, FATEST</td>
</tr>
<tr>
<td>ILLCAUS_O.PerformedObservation.nameCode.CD.displayName.value</td>
<td>ILLCAUS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ILLCAUS_O.PerformedObservation.description.ST.value</td>
<td>Concurrent illness a possible cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ILLCAUS_R.PerformedObservationResult.valueNullFlavorReason.ST</td>
<td>free text</td>
<td></td>
<td>FAREASND</td>
</tr>
<tr>
<td>ILLCAUS_R.PerformedObservationResult.CD.code</td>
<td>C49488, C49487</td>
<td>result</td>
<td>FAORRES</td>
</tr>
</tbody>
</table>

This workbook contains metadata for seven concepts. Y, N result FASTESC

Possible associated concepts

At the bottom of the sheet are other research concepts to which the research concept may or must be connected.

The main body of the sheet contains the data items (variables) that make up the concept, described in terms of the BRIDG class and attributes on which they are based, along with a component of the complex datatype for the class. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.

The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).

The third column describes an "attribute" of the test. There may be several BRIDG-based data items for a single attribute.

The fourth column shows the where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed.

The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.

Blue text indicates terminology that has not yet been approved.

Shaded cells represent paired values.

DOMAIN: FA

TEST: Concurrent illness a possible cause
TESTCD: ILLCAUS
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>value(s)</th>
<th>Attribute</th>
<th>SDTM variable(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CECRIT. DefinedMedicalConditionResult.value.CD.code</td>
<td>10020993</td>
<td>Pre-specified term</td>
<td>CETERM</td>
</tr>
<tr>
<td>CECRIT. DefinedMedicalConditionResult.value.CD.displayName.value</td>
<td>Hypoglycemia</td>
<td>Block for pre-specified event</td>
<td></td>
</tr>
<tr>
<td>CECRIT. DefinedMedicalConditionResult.value.CD.originalText.value</td>
<td>&lt;pre-specified&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEQUERY_ O. DefinedObservation.focalDuration.PQ.value</td>
<td>&lt;decimal (in SDTM, ISO8601 duration)&gt;</td>
<td>Focal time period</td>
<td>CEEVLINT</td>
</tr>
<tr>
<td>CEQUERY_ O. DefinedObservation.focalDuration.PQ.unit.code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEQUERY_ O. DefinedObservation.focalDuration.PQ.unit.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEQUERY_ O. DefinedObservation.focalDateRange.IVL&lt;EXPR&lt;TS&gt;&gt;low.expression.ED.value</td>
<td>&lt;text describing start of focal time period&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEQUERY_ O. DefinedObservation.focalDateRange.IVL&lt;EXPR&lt;TS&gt;&gt;high.expression.ED.value</td>
<td>&lt;text describing end of focal time period&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEQUERY_ O. performedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>&lt;datetime&gt;</td>
<td>Date of question</td>
<td>CEDTC</td>
</tr>
<tr>
<td>CEQUERY_ O. negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM: NOT DONE, null)</td>
<td>Negation Indicator</td>
<td>CESTAT</td>
</tr>
<tr>
<td>CEQUERY_ O. performedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>&lt;free text&gt;</td>
<td>Negation Reason</td>
<td>CEREASND</td>
</tr>
<tr>
<td>This workbook contains metadata for seven concepts.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEQUERY_ R. performedObservationResult.value.CD.displayName.value</td>
<td>Y, N</td>
<td>Result Value</td>
<td>CEOCCUR</td>
</tr>
<tr>
<td>CECOLL_ O. DefinedObservation.focalDuration.PQ.value</td>
<td>&lt;decimal (in SDTM, ISO8601 duration)&gt;</td>
<td>focal time period</td>
<td>CEEVLINT</td>
</tr>
<tr>
<td>CECOLL_ O. DefinedObservation.focalDuration.PQ.unit.code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CECOLL_ O. DefinedObservation.focalDuration.PQ.unit.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CECOLL_ O. DefinedObservation.focalDateRange.IVL&lt;EXPR&lt;TS&gt;&gt;low.expression.ED.value</td>
<td>&lt;text describing start of focal time period&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CECOLL_ O. DefinedObservation.focalDateRange.IVL&lt;EXPR&lt;TS&gt;&gt;high.expression.ED.value</td>
<td>&lt;text describing end of focal time period&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CECOLL_ O. performedObservation.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>&lt;datetime&gt;</td>
<td>Date Range</td>
<td>CEDTC</td>
</tr>
<tr>
<td>CECOLL_ R. performedMedicalConditionResult.occurrenceDateRange.IVL&lt;TS&gt;.low.value</td>
<td>&lt;datetime&gt;</td>
<td>Occurrence date range</td>
<td>CESTDTC</td>
</tr>
<tr>
<td>CECOLL_ R. performedMedicalConditionResult.occurrenceDateRange.IVL&lt;TS&gt;.high.value</td>
<td>&lt;datetime&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CECOLL_ R. performedMedicalConditionResult.value.CD.code</td>
<td>&lt;from MedDRA&gt;</td>
<td>pre-specified result</td>
<td>CETERM</td>
</tr>
<tr>
<td>CECOLL_ R. performedMedicalConditionResult.value.CD.displayName.value</td>
<td>&lt;pre-specified&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CECOLL_ R. performedMedicalConditionResult.value.CD.originalText.value</td>
<td>&lt;pre-specified&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEFA_ O. DefinedObservation.nameCode.CD.code</td>
<td>&lt;sponsor-defined&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEFA_ O. DefinedObservation.nameCode.CD.displayName.value</td>
<td>&lt;sponsor-defined&gt;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concept:</th>
<th>TERM: or TEST:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRESP= or TESTCD:</td>
<td></td>
</tr>
</tbody>
</table>

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>value(s)</th>
<th>Attribute</th>
<th>SDTM variable(s)</th>
<th>Template</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEFA_O_.DefinedObservation_.description._ST_.value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;PrespecifiedClinicalEvent&gt;DefinedMedicalConditionResult.value.CD.code</td>
<td>to be determined</td>
<td>Clinical Term</td>
<td></td>
<td>Block for observation about event</td>
</tr>
<tr>
<td>&lt;PrespecifiedClinicalEvent&gt;DefinedMedicalConditionResult.value.CD.displayName.value</td>
<td>&lt;pre-specified&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;PrespecifiedClinicalEvent&gt;DefinedMedicalConditionResult.value.CD.originalText.value</td>
<td>&lt;pre-specified&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEFA_O_.PerformedObservation_.dateRange.IVL&lt;TS&gt;_.low.value</td>
<td>datetime</td>
<td>Date Collected</td>
<td></td>
<td>FADTC</td>
</tr>
<tr>
<td>CEFA_O_.PerformedObservation_.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Negation Indicator</td>
<td>FASTAT</td>
<td></td>
</tr>
<tr>
<td>CEFA_O_.PerformedObservation_.negationReason.DSET&lt;SC&gt;</td>
<td>free text</td>
<td>Negation Reason</td>
<td></td>
<td>FAREASND</td>
</tr>
<tr>
<td>CEFA_R_.PerformedObservationResult.value.ANY</td>
<td>free text</td>
<td>Result</td>
<td></td>
<td>Block for result of observation about event</td>
</tr>
<tr>
<td>CEFA_R_.PerformedObservationResult.valueCodeModifiedText</td>
<td>C66742</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Concept: Query about the occurrence of hypoglycemia

### BRIDG-based concept variable

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.code</td>
<td>10020993</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.displayName.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.originalText.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OCCUR_O.DefinedObservation.focalDuration.PQ.value</td>
<td>\textit{decimal} (in SDTM, ISO8601 duration)</td>
<td>focal time period</td>
<td>CEEVLINT</td>
</tr>
<tr>
<td>OCCUR_O.DefinedObservation.focalDuration.PQ.unit.code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OCCUR_O.DefinedObservation.focalDuration.PQ.unit.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OCCUR_O.DefinedObservation.focalDateRange.IVL&lt;EXPR&lt;TS&gt;&gt;.low.expression.ED.value</td>
<td>\textit{text describing start of focal time period}</td>
<td>focal time period</td>
<td>CEEVLTXT</td>
</tr>
<tr>
<td>OCCUR_O.DefinedObservation.focalDateRange.IVL&lt;EXPR&lt;TS&gt;&gt;.high.expression.ED.value</td>
<td>\textit{text describing end of focal time period}</td>
<td>focal time period</td>
<td>CEEVLTXT</td>
</tr>
<tr>
<td>OCCUR_O.PerformedObservation.negationIndicator.BL.value</td>
<td>\textit{TRUE, FALSE (SDTM NOT DONE, null)}</td>
<td>Negation Indicator</td>
<td>CESTAT</td>
</tr>
<tr>
<td>OCCUR_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>\textit{free text}</td>
<td>Negation Reason</td>
<td>CEREASND</td>
</tr>
<tr>
<td>This workbook contains metadata for seven concepts.</td>
<td>\textit{free text}</td>
<td>valueNullFlavorReason</td>
<td>CEREASND</td>
</tr>
<tr>
<td>OCCUR_R.PerformedObservationResult.value.CD.code</td>
<td>\textit{C49488, C49487}</td>
<td>result value</td>
<td>CEOCCUR</td>
</tr>
<tr>
<td>OCCUR_R.PerformedObservationResult.value.CD.displayName.value</td>
<td>\textit{Y, N}</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Possible associated concepts**

- Observation triggered by "Yes" response to this concept
  - Collection of hypoglycemia event
Concept: Collection of data about an event of hypoglycemia

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.code</td>
<td>10020993</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.displayName.value</td>
<td>Hypoglycemia</td>
<td>pre-specified term</td>
<td>CETERM</td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.originalText.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCOLL_R.PerformedMedicalConditionResult.occurrenceHYPODateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Occurrence date range</td>
<td>CESTDTC</td>
</tr>
</tbody>
</table>

Possible associated concepts

Observation that may trigger this concept
Occurrence query about hypoglycemia event
Concept: When in the diurnal sleep cycle an event occurred, between bedtime and waking or between waking and bedtime.

**BRIDG-based concept variable** | **Value(s)** | **Attribute** | **SDTM variable**
---|---|---|---
HYPOCRIT. DefinedMedicalConditionResult.value.CD.code | 10020993 |  |  
HYPOCRIT. DefinedMedicalConditionResult.value.CD.displayName.value | Hypoglycemia | Clinical term | CETERM 
HYPOCRIT. DefinedMedicalConditionResult.value.CD.originalText.value | Hypoglycemia |  |  
WHENOCC_ O. DefinedObservation. nameCode.CD.code | to be determined | Test | QNAM, QLABEL 
WHENOCC_ O. DefinedObservation. nameCode.CD.displayName.value | WHENOCC |  |  
WHENOCC_ O. DefinedObservation. description.ST.value | When did the hypoglycemic event occur? |  |  
WHENOCC_ R. PerformedObservationResult.CD.code | to be determined | Result | QVAL 
WHENOCC_ R. PerformedObservationResult.CD.displayName.value | BETWEEN BEDTIME AND WAKING, BETWEEN WAKING AND BEDTIME |  |  

**QNAM:** When did the hypoglycemic event occur?  
**QLABEL:** WHENOCC
Concept: The part third party assistance played in treating the subject's event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOCRIT. DefinedMedicalConditionResult.value.CD.code</td>
<td>10020993</td>
<td>Clinical term</td>
<td>FAOBJ</td>
</tr>
<tr>
<td>HYPOCRIT. DefinedMedicalConditionResult.value.CD.displayName.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT. DefinedMedicalConditionResult.value.CD.originalText.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASSIST_O. DefinedObservation. nameCode.CD.code</td>
<td>to be determined</td>
<td>Test</td>
<td>FATESTCD/FATEST</td>
</tr>
<tr>
<td>ASSIST_O. DefinedObservation. nameCode.CD.displayName.value</td>
<td>TXASSIST</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASSIST_O. DefinedObservation. description.ST.value</td>
<td>Need for Assistance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASSIST_O. PerformedObservation. negationIndicator.BL.value</td>
<td>code list C66789</td>
<td>Negation indicator</td>
<td>FASTAT</td>
</tr>
<tr>
<td>ASSIST_O. PerformedObservation. negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Negation reason</td>
<td>FAREASND</td>
</tr>
<tr>
<td>ASSIST_R. PerformedObservationResult.valueNullFlavorReason.ST</td>
<td>free text</td>
<td>Reason not done</td>
<td>FAREASND</td>
</tr>
<tr>
<td>ASSIST_R. PerformedObservationResult.CD.code</td>
<td>to be determined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASSIST_R. PerformedObservationResult.CD.displayName.value</td>
<td>NONE - SUBJECT TREATED SELF, SUBJECT WAS CAPABLE OF TREATING SELF, BUT RECEIVED ASSISTANCE, SUBJECT WAS NOT CAPABLE OF TREATING SELF, AND REQUIRED ASSISTANCE</td>
<td>Result</td>
<td>FAORRES, FASTRESP</td>
</tr>
</tbody>
</table>
Concept: Whether a missed or delayed meal was a possible precipitating factor for the subject's hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOCRIT.PriceMedicalConditionResult.value.CD.code</td>
<td>10020993</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT.PriceMedicalConditionResult.value.CD.displayName.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT.PriceMedicalConditionResult.value.CD.originalText.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEALCAUS.O.PriceDefinedObservation.nameCode.CD.code</td>
<td>to be determined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEALCAUS.O.PriceDefinedObservation.nameCode.CD.displayName.value</td>
<td>MEALCAUS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEALCAUS.O.PriceDefinedObservation.description.ST.value</td>
<td>Missed or delayed meal a possible cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEALCAUS.O.PricePerformedObservation.negationIndicator.BL.value</td>
<td>code list C66789</td>
<td>negation indicator</td>
<td>FASTAT</td>
</tr>
<tr>
<td>MEALCAUS.O.PricePerformedObservation.negationReason.DSET&lt;SC&gt;</td>
<td>free text</td>
<td>negation reason</td>
<td>FAREASND</td>
</tr>
<tr>
<td>MEALCAUS_R.PricePerformedObservationResult.valueNullFlavorReason.ST</td>
<td>free text</td>
<td>reason not done</td>
<td>FAREASND</td>
</tr>
<tr>
<td>MEALCAUS_R.PricePerformedObservationResult.CD.code</td>
<td>C49488, C49487</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This workbook contains metadata for seven concepts.

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
Prototype

HYPO PRECIP MEAL

DOMIAN: FA
TEST: Missed or delayed meal a possible cause
TESTCD: MEALCAUS
Concept: Whether physical activity was a possible precipitating factor for the subject's hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.code</td>
<td>10020993</td>
<td>clinical term</td>
<td>FAOBJ</td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.displayName.value</td>
<td>Hypoglycemia</td>
<td>test</td>
<td>FATESTCD, FATEST</td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.originalText.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACAUS_O.DefinedObservation.nameCode.CD.code</td>
<td>to be determined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACAUS_O.DefinedObservation.nameCode.CD.displayName.value</td>
<td>PACAUS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACAUS_O.DefinedObservation.description.ST.value</td>
<td>Physical activity a possible cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACAUS_O.PerformedObservation.negationIndicator.BL.value</td>
<td>code list C66789</td>
<td></td>
<td>FASTAT</td>
</tr>
<tr>
<td>PACAUS_O.PerformedObservation.negationReason.DSET&lt;SC&gt;</td>
<td>free text</td>
<td></td>
<td>FAREASND</td>
</tr>
<tr>
<td>PACAUS_R.PerformedObservationResult.valueNullFlavorReason.ST</td>
<td>free text</td>
<td></td>
<td>FAREASND</td>
</tr>
<tr>
<td>PACAUS_R.PerformedObservationResult.CD.code</td>
<td>C49488, C49487</td>
<td></td>
<td>FASTRES</td>
</tr>
</tbody>
</table>

This workbook contains metadata for seven concepts.
Concept: Whether alcohol was a possible precipitating factor for the subject's hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.code</td>
<td>10020993</td>
<td>clinical term</td>
<td>FAOBJ</td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.displayName.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT.DefinedMedicalConditionResult.value.CD.originalText.value</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALCCAUS_O.DefinedObservation.nameCode.CD.code</td>
<td>to be determined</td>
<td>test</td>
<td>FATESTCD, FATEST</td>
</tr>
<tr>
<td>ALCCAUS_O.DefinedObservation.nameCode.CD.displayName.value</td>
<td>ALCCAUS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALCCAUS_O.DefinedObservation.description.ST.value</td>
<td>Alcohol a possible cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALCCAUS_O.PerformedObservation.negationIndicator.BL.value</td>
<td>code list C66789</td>
<td>negation indicator</td>
<td>FASTAT</td>
</tr>
<tr>
<td>ALCCAUS_O.PerformedObservation.negationReason.DSET&lt;SC&gt;</td>
<td>free text</td>
<td>negation reason</td>
<td>FAREASND</td>
</tr>
<tr>
<td>ALCCAUS_R.PerformedObservationResult.valueNullFlavorReason.ST</td>
<td>free text</td>
<td>reason not done</td>
<td>FAREASND</td>
</tr>
<tr>
<td>ALCCAUS_R.PerformedObservationResult.CD.code</td>
<td>C49488, C49487</td>
<td>result</td>
<td>FAORRES</td>
</tr>
<tr>
<td>This workbook contains metadata for seven concepts.</td>
<td>Y, N</td>
<td>result</td>
<td>FASTRESC</td>
</tr>
</tbody>
</table>
Concept: Whether illness was a possible precipitating factor for the subject's hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOCRIT_DEFINEDMEDICALCONDITIONRESULT_value_CD_code</td>
<td>10020993</td>
<td>clinical term</td>
<td>FAOBJ</td>
</tr>
<tr>
<td>HYPOCRIT_DEFINEDMEDICALCONDITIONRESULT_value_CD_displayName</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPOCRIT_DEFINEDMEDICALCONDITIONRESULT_value_CD_originalText</td>
<td>Hypoglycemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ILLCAUS_O_DEFINEDOBSERVATION_nameCode_CD_code</td>
<td>to be determined</td>
<td>test</td>
<td>FATESTCD, FATEST</td>
</tr>
<tr>
<td>ILLCAUS_O_DEFINEDOBSERVATION_nameCode_CD_displayName</td>
<td>ILLCAUS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ILLCAUS_O_DEFINEDOBSERVATION_description_ST</td>
<td>Concurrent illness a possible cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ILLCAUS_O_PERFORMEDOBSERVATION_negationIndicator_BL_value</td>
<td>code list C66789</td>
<td>negation indicator</td>
<td>FASTAT</td>
</tr>
<tr>
<td>ILLCAUS_O_PERFORMEDOBSERVATION_negationReason_DSET&lt;SC&gt;</td>
<td>free text</td>
<td>negation reason</td>
<td>FAREASND</td>
</tr>
<tr>
<td>ILLCAUS_R_PERFORMEDOBSERVATIONRESULT_valueNullFlavorReason_ST</td>
<td>free text</td>
<td>reason not done</td>
<td>FAREASND</td>
</tr>
<tr>
<td>ILLCAUS_R_PERFORMEDOBSERVATIONRESULT_CD_code</td>
<td>C49488, C49487</td>
<td>result</td>
<td>FAORRES</td>
</tr>
<tr>
<td>This workbook contains metadata for seven concepts.</td>
<td>Y, N</td>
<td>result</td>
<td>FASTRESP</td>
</tr>
</tbody>
</table>
SHARE Metadata Displays
The Excel workbooks contain somewhat simplified versions of SHARE metadata.
The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based, along with a component of the complex datatype for the class attribute
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The Template worksheet shows the set of BRIDG-based components from which the metadata for individual concepts were drawn. It includes explanations for some of the terminology. The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains metadata for one concept:

- **Most Recent Meal**, collecting the single meal that occurred most recently before the hypoglycemic event
<table>
<thead>
<tr>
<th>BRIDGi-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEALCOLL.Performed.Product.codeModifiedText.ST.value</td>
<td>free text</td>
<td>Meal consumed</td>
<td>MLMODIFY</td>
<td>Block for properties of meal</td>
</tr>
<tr>
<td>MEALCOLL.Performed.Product.code.CD.code</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEALCOLL.Performed.Product.code.CD.displayName.value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEALCOLL.Performed.Product.code.CD.originalText.value</td>
<td>free text</td>
<td>Doseform of meal consumed</td>
<td>MLDECOD</td>
<td></td>
</tr>
<tr>
<td>MEALCOLL.Performed.Product.formCode.CD.code</td>
<td>C42953</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEALCOLL.Performed.Product.formCode.CD.displayName.value</td>
<td>LIQUID, SOLID, MIXED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>C38288</td>
<td>Route of administration of meal</td>
<td>MLROUTE</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.displayName.value</td>
<td>ORAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.originalText.value</td>
<td>free text</td>
<td>Amount of meal consumed</td>
<td>MLDOSE</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.uncertainRange.low.value</td>
<td>decimal</td>
<td>Range of meal consumed</td>
<td>MLDOSTXT</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.uncertainRange.high.value</td>
<td>decimal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>Total amount of meal consumed in period</td>
<td>MLDOSU</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDoseTotal.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code</td>
<td>C25301, C29844, C29846</td>
<td>Period for total amount consumed</td>
<td>MLDOSTOT (if period is a day)</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value</td>
<td>DAY, WEEK, MONTH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code</td>
<td>from codelist C71113</td>
<td>Frequency of meal administration</td>
<td>MLDOSSFRQ</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value</td>
<td>from codelist C71113</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value</td>
<td>decimal</td>
<td>Reason for dose change</td>
<td>MLADJ</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Start datetime of meal</td>
<td>MLSTDTC</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange. low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain start datetime of meal</td>
<td>MLENRF or MLSTRTP &amp; MLSTTPT</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange. low.nullFlavor.displayName.value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange. low.value</td>
<td>datetime</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange. high.value</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange. highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.value</td>
<td>datetime</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain end datetime</td>
<td>MLENRF or MLNRTPT &amp;</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. low.nullFlavor.displayName.value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. low.value</td>
<td>datetime</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute of meal</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.nullFlavor.code</td>
<td>PINF</td>
<td>Positive Infinity</td>
<td>MLENRTPT &amp; MLENTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.nullFlavor.displayName.value</td>
<td>Positive Infinity</td>
<td>Positive Infinity</td>
<td>MLENRTPT &amp; MLENTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.value</td>
<td>datetime</td>
<td>datetime</td>
<td>MLENDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td>free text</td>
<td>MLINDC</td>
</tr>
</tbody>
</table>

**Template**

**Start study day of meal (MLSTDY)**

**End study day of meal (MLENDY)**

**Indication for meal (MLINDC)**
Concept: Collection of details of administrations of last meal before hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>LSTMLCOLL.Performed.Product.codeModifiedText.ST.value</td>
<td>free text</td>
<td>Meal consumed</td>
<td>MLMODIFY</td>
</tr>
<tr>
<td>LSTMLCOLL.Performed.Product.code.CD.code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTMLCOLL.Performed.Product.code.CD.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTMLCOLL.Performed.Product.code.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTMLCOLL.Performed.Product.formCode.CD.code</td>
<td>C42953</td>
<td>Doseform of meal consumed</td>
<td>MLDOCSFRM</td>
</tr>
<tr>
<td>LSTMLCOLL.Performed.Product.formCode.CD.displayName.value</td>
<td>LIQUID, SOLID, MIXED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTMLCOLL.Performed.Product.formCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>C38288</td>
<td>Route of administration of meal</td>
<td>MLROUTE</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>ORAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value</td>
<td>free text</td>
<td>Amount of meal consumed</td>
<td>MLDOSE</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.productDose.PQ.value</td>
<td>decimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.productDose.PQ.uncertainRange.low.value</td>
<td>decimal</td>
<td>Range of meal consumed</td>
<td>MLDOCTXT</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code</td>
<td>C64576</td>
<td>Frequency of meal administration</td>
<td>MLDOCSFRQ</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value</td>
<td>ONCE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Start datetime of meal</td>
<td>MLSTDTC</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain start datetime of meal</td>
<td>MLENRF or MLSTRPTPT &amp; MLSTPTT</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange. low.nullFlavor.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.lowClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.high.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.value</td>
<td>datetime</td>
<td>End datetime of meal</td>
<td>MLENDTC</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. low.nullFlavor.code</td>
<td>NINF</td>
<td>Uncertain end datetime of meal</td>
<td>MLENRF or MLNRPTPT &amp; MLNTPTT</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. low.nullFlavor.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. low.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. lowClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange. low.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>Value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------------------</td>
<td>--------------</td>
<td>-----------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.nullFlavor.code</td>
<td>PINF</td>
<td>uncertain end datetime of meal</td>
<td>MLENRF or MLENRTPT &amp; MLENTPT</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.nullFlavor.displayName.value</td>
<td>Positive Infinity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.high.value</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Start study day of meal</td>
<td>MLSTDY</td>
</tr>
<tr>
<td>LSTADMCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;.high.value</td>
<td>integer</td>
<td>End study day of meal</td>
<td>MLENDY</td>
</tr>
</tbody>
</table>
Introduction

**SHARE Metadata Displays**

The Excel workbooks contain somewhat simplified versions of SHARE metadata. The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, described in terms of the BRIDG class and attributes on which they are based, along with a component of the complex datatype for the class attribute
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The **Template** worksheet shows the set of BRIDG-based components from which the metadata for individual concepts were drawn. It includes explanations of some of the terminology.

This workbook contains metadata for one concept.

- **Most Recent Treatment**, the most recent treatment with a medication in a pre-specified group of medications (anti-hyperglycemics) prior to a specified event (a hypoglycemic event).
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;::item.code</td>
<td>from drug dictionary</td>
<td>Pre-specified class</td>
<td>CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;::item.displayName.value</td>
<td>from drug dictionary</td>
<td>Pre-specified drug</td>
<td>CMTRT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;::item.originalText.value</td>
<td>free text</td>
<td>Pre-specified dose form</td>
<td>CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.code.CD.code</td>
<td>from drug dictionary</td>
<td>Medication administered</td>
<td>CMMODIFY</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.code.CD.displayName.value</td>
<td>from drug dictionary</td>
<td>Medication administered</td>
<td>CMMODIFY</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.code.CD.originalText.value</td>
<td>free text</td>
<td>Medication administered</td>
<td>CMMODIFY</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td>Block for collected properties of medication administration</td>
<td></td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td>Block for collected properties of medication administration</td>
<td></td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td>Block for collected properties of medication administration</td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.codeModifiedText.ST.value</td>
<td>free text</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>from codelist C66729</td>
<td>Route of administration of administered medication</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>from codelist C66729</td>
<td>Route of administration of administered medication</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value</td>
<td>free text</td>
<td>Amount of product administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.code</td>
<td>free text</td>
<td>Amount of product administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.displayName.value</td>
<td>free text</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value</td>
<td>free text</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.code</td>
<td>decimal</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.displayName.value</td>
<td>from codelist C71620</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.originalText.value</td>
<td>free text</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.code</td>
<td>decimal</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.displayName.value</td>
<td>from codelist C71620</td>
<td>Total amount of product administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.originalText.value</td>
<td>free text</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.code</td>
<td>decimal</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.displayName.value</td>
<td>from codelist C71620</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSTOT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code</td>
<td>C25301, C29844, C29846</td>
<td>Period for total amount administered</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value</td>
<td>DAY, WEEK, MONTH</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value</td>
<td>free text</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>Value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------</td>
<td>-----------</td>
<td>---------------</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value</td>
<td>decimal</td>
<td>Reason for change dose change</td>
<td>CMADI</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CDdisplayName.value</td>
<td>free text</td>
<td></td>
<td>CMLAT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
<td>C25228, C25229</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
<td>RIGHT, LEFT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. low.value</td>
<td>datetime</td>
<td>Start datetime of medication</td>
<td>CMSTDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. low.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. high.value</td>
<td>datetime</td>
<td>End datetime of medication administration</td>
<td>CMENDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. high.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;. item.code</td>
<td>sponsor codelist? MedDRA?</td>
<td>Indication for medication administration</td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;. item.displayName.value</td>
<td>sponsor codelist? MedDRA?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;. item.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Possible associated concepts

Uncertain start datetime of medication administration CMENRF or CMSTTPT & CMENTPT
Uncertain end datetime of medication administration CMENSRTPT & CMENSTPT
Block for collected properties of medication administered
Concept: Collection of details of administrations of the last dose of an anti-hyperglycemic drug before a hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.code</td>
<td>from drug dictionary</td>
<td>Pre-specified class</td>
<td>CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>from drug dictionary</td>
<td>Medication administered</td>
<td>CMMODIFY</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>Anti-hyperglycemic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.codeModifiedText.ST.value</td>
<td>free text</td>
<td>Doseform of administered medication</td>
<td>CMDOSFRM</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.code</td>
<td>from drug dictionary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.displayName.value</td>
<td>from drug dictionary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>free text</td>
<td>Route of administration of administered medication</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.value</td>
<td>decimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value</td>
<td>decimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code</td>
<td>from codelist C71113</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value</td>
<td>from codelist C71113</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value</td>
<td>free text</td>
<td>Reason for change dose change</td>
<td>CMADJ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
<td>C25228, C25229</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
<td>RIGHT, LEFT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>Start datetime of medication</td>
<td>CMSTDTIC</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.low.displayName.value</td>
<td>Negative Infinity</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTPT &amp; CMSTTPT</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>Value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------------------</td>
<td>------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. low.uncertainRange.lowClosed</td>
<td>TRUE, FALSE</td>
<td>DateTime</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. low.uncertainRange.high.value</td>
<td>datetimpe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. low.uncertainRange.highClosed</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. high.value</td>
<td>datetime</td>
<td>End datetime of medication administration</td>
<td>CMENDTC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. high.uncertainRange.low.nullFlavor.code</td>
<td>NINF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. high.uncertainRange.low.nullFlavor.displayName.value</td>
<td>Negative Infinity</td>
<td>Uncertain end datetime of medication administration</td>
<td>CMENRF or CMENRTPT &amp; CMENRTPT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. high.uncertainRange.low.value</td>
<td>datetimpe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. high.uncertainRange.high.nullFlavor.code</td>
<td>PINF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;. high.uncertainRange.high.nullFlavor.displayName.value</td>
<td>Positive Infinity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;. item.code</td>
<td>sponsor codelist? MedDRA?</td>
<td></td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;. item.displayName.value</td>
<td>sponsor codelist? MedDRA?</td>
<td></td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;. item.originalText.value</td>
<td>free text</td>
<td></td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;. low.value</td>
<td>integer</td>
<td></td>
<td>CMSTDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL&lt;INT&gt;. high.value</td>
<td>integer</td>
<td></td>
<td>CMENDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;. item.code</td>
<td>sponsored codelist? MedDRA?</td>
<td></td>
<td>CMINDC</td>
</tr>
</tbody>
</table>
SHARE Metadata Displays

The Excel workbooks contain somewhat simplified versions of SHARE metadata. The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, described in terms of the BRIDG class and attributes on which they are based, along with a component of the complex datatype for the class attribute
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The Key to Layout worksheet explains the metadata and how it is organized.

The Template worksheet shows the set of BRIDG-based components from which the metadata for individual concepts were drawn. It includes explanations of some of the terminology.

This workbook contains metadata for six concepts.

- **OCCUR HYPO TRT GRP**, a query about whether any of a group of treatments were given for a hypoglycemic event
- **OCCUR FOOD TRT**, a query about whether food was taken for a hypoglycemic event
- **OCCUR DRINK TRT**, a query about whether drink was taken for a hypoglycemic event
- **OCCUR GLUC TAB TRT**, a query about whether glucose, in the form of tablets, was taken for a hypoglycemic event
- **OCCUR IV GLUC TRT**, a query about whether glucose was given intravenously for a hypoglycemic event
- **OCCUR GLUCAGON TRT**, a query about whether glucagon was given by injection for a hypoglycemic event
Concept: Query whether food was taken for a hypoglycemic event

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

Domain: CM
TRT: FOOD
PRESP=Y
CMCAT = HYPOGLYCEMIA TREATMENTS

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOODCRIT. Defined Drug code.CD.code</td>
<td>TBD</td>
<td>Pre-specified drug</td>
<td>CMTRT, CMSCAT</td>
</tr>
<tr>
<td>FOODCRIT. Defined Drug code.CD.displayName.value</td>
<td>FOOD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FOODCRIT. Defined Drug code.CD.originalText.value</td>
<td>FOOD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.code</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.displayName.value</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.code</td>
<td>C49488, C49487</td>
<td>The third column describes an “attribute” of the test. There may be several BRIDG-based data items for a single attribute.</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.displayName.value</td>
<td>Y, N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This workbook contains metadata for six concepts.

Possible associated concepts

Triggered by Yes response to this concept

The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.

The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).

The fourth column shows the where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed.

At the bottom of the sheet are other research concepts to which the research concept may or must be connected.
### Concept:

#### BRIDG-based concept variable

<table>
<thead>
<tr>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.code</td>
<td>Pre-specified class</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>Pre-specified class</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.classCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>Pre-specified class</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.code.CD.code</td>
<td>Pre-specified drug</td>
<td>CMTRT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.code.CD.displayName.value</td>
<td>Pre-specified drug</td>
<td>CMTRT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.code.CD.originalText.value</td>
<td>Pre-specified drug</td>
<td>CMTRT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.code</td>
<td>Pre-specified dose form</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.displayName.value</td>
<td>Pre-specified dose form</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.formCode.CD.originalText.value</td>
<td>Pre-specified dose form</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>MEDCRIT.Defined.Drug.description.ST.value</td>
<td>Pre-specified description</td>
<td>in CMCAT</td>
</tr>
</tbody>
</table>

This workbook contains metadata for six concepts.

<table>
<thead>
<tr>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>Pre-specified route of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code</td>
<td>Pre-specified target site</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value</td>
<td>Pre-specified target site</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.originalText.value</td>
<td>Pre-specified target site</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>Pre-specified site of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
<td>Pre-specified site of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value</td>
<td>Pre-specified site of administration</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
<td>C25228, C25229</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
<td>RIGHT, LEFT</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.code</td>
<td>Pre-specified indication</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>Pre-specified indication</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>Pre-specified indication</td>
<td>in CMCAT</td>
</tr>
<tr>
<td>CMQ_O.DefinedObservation.focalDuration.PQ.value</td>
<td>Focal time period</td>
<td>CMEVLINT</td>
</tr>
</tbody>
</table>

SDTM uses ISO8601 duration format

Block for pre-specified properties of kind of medication on which question or data collection is focused

Block for pre-specified properties of kind of medication administration on which question or data collection is focused

Block for pre-specified properties of kind of substance administration on which question or data collection is focused

Block for pre-specified properties of kind of substance on which question or data collection is focused

Block for pre-specified properties of kind of indication on which question or data collection is focused
<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMQ_O.DefinedObservation.focalDateRange.IVL.&lt;TS&gt;.originalText.value</td>
<td>free text</td>
<td>question</td>
<td>CMEVLTXT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.dateRange.IVL.&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Question datetime</td>
<td>CMEVLTXD</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.studyDayRange.IVL.&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Question study day</td>
<td>CMDTY</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.code</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.displayName.value</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.code</td>
<td>YES, NO</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.codeModifiedText.ST.value</td>
<td>free text</td>
<td>Medication administered</td>
<td>CMMODIFY</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.code</td>
<td>from drug dictionary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.code.CD.displayName.value</td>
<td>from drug dictionary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.Code.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.code</td>
<td>from codelist C66726</td>
<td>Doseform of administered medication</td>
<td>CMDOSE</td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.displayName.value</td>
<td>from codelist C66726</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDCOLL.Performed.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>from codelist C66729</td>
<td>Route of administration of administered medication</td>
<td>CMROUTE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>from codelist C66729</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value</td>
<td>free text</td>
<td>Amount of product administered</td>
<td>CMDOSE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.value</td>
<td>decimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value</td>
<td>free text</td>
<td>Amount of active ingredient administered</td>
<td>CMDOSE</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value</td>
<td>decimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.originalText.value</td>
<td>free text</td>
<td>CMDOSTOT (if period is a day)</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.value</td>
<td>decimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>Value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------</td>
<td>-----------</td>
<td>---------------</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.value</td>
<td>decimal</td>
<td>Total amount of product administered in period</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.value</td>
<td>free text</td>
<td>Total amount of active ingredient administered in period</td>
<td>CMDOSU</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.code</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.displayName.value</td>
<td>from codelist C71620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code</td>
<td>C25301, C29844, C2984</td>
<td>Period for total amount administered</td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value</td>
<td>DAY, WEEK, MONTH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code</td>
<td>from codelist C71113</td>
<td>Frequency of medication administration</td>
<td>CMDOSFRQ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value</td>
<td>from codelist C71113</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value</td>
<td>decimal</td>
<td>Reason for change dose change</td>
<td>CMADJ</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code</td>
<td>from codelist C74456</td>
<td>Site of medication administration</td>
<td>CMLOC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value</td>
<td>from codelist C74456</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code</td>
<td>C25228, C25229</td>
<td></td>
<td>CMLAT</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value</td>
<td>RIGHT, LEFT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.value</td>
<td>datetime</td>
<td>Start datetime of medication administration</td>
<td>CMSTDT</td>
</tr>
<tr>
<td>BRIDG-based concept variable</td>
<td>Value(s)</td>
<td>Attribute</td>
<td>SDTM variable</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------------------</td>
<td>-------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.</td>
<td>Negative Infinity</td>
<td>Uncertain start datetime of medication administration</td>
<td>CMENRF or CMSTRTP &amp; CMSTTP</td>
</tr>
<tr>
<td>low.nullFlavor.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.</td>
<td>datetime</td>
<td>End datetime of medication administration</td>
<td>CMENDTC</td>
</tr>
<tr>
<td>low.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.low.uncertainRange.</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>lowClosed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.</td>
<td>TRUE, FALSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>highClosed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.</td>
<td>NINF</td>
<td>Uncertain end datetime of medication administration</td>
<td>CMENRF or CMERNRTP &amp; CMENTPT</td>
</tr>
<tr>
<td>high.nullFlavor.code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.</td>
<td>Negative Infinity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high.nullFlavor.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high.nullClosed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.</td>
<td>PINF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high.nullFlavor.code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.</td>
<td>Positive Infinity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high.nullFlavor.displayName.value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;TS&gt;.high.uncertainRange.</td>
<td>datetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high.nullClosed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;INT&gt;.low.value</td>
<td>integer</td>
<td>Start study date of medication administration</td>
<td>CMSTDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL&lt;INT&gt;.high.value</td>
<td>integer</td>
<td>End study date of medication administration</td>
<td>CMENDY</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.code</td>
<td>TBD</td>
<td>Indication for medication administration</td>
<td>CMINDC</td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.displayName.value</td>
<td>TBD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET&lt;CD&gt;.item.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CDISC Prototype SHARE Metadata: Hypoglycemia Treatment

Concept: Query about occurrence of any of a group of treatments for the hypoglycemic event

Domain: CM
TRT: HYPOGLYCEMIA TREATMENTS
CMCAT = HYPO TREATMENT
PRESp=Y

### BRIDG-based concept variable

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPOTRTCRIT. Defined.Drug. classCode. DSET&lt;CD&gt;. item.code</td>
<td>TBD</td>
<td>Pre-specified class</td>
<td>in CMTRT and CMCAT</td>
</tr>
<tr>
<td>HYPOTRTCRIT. Defined.Drug. classCode. DSET&lt;CD&gt;. item.displayName. value</td>
<td>from drug dictionary</td>
<td>Pre-specified class</td>
<td>in CMTRT and CMCAT</td>
</tr>
<tr>
<td>HYPOTRTCRIT. Defined.Drug. classCode. DSET&lt;CD&gt;. item. originalText. value</td>
<td>HYPOGLYCEMIA TREATMENTS</td>
<td>Pre-specified class</td>
<td>in CMTRT and CMCAT</td>
</tr>
<tr>
<td>HYPOTRTCRIT. Defined.Drug. formCode. CD. code</td>
<td>from codelist C66726</td>
<td>Pre-specified dose form</td>
<td>in CMTRT and CMCAT</td>
</tr>
<tr>
<td>HYPOTRTCRIT. Defined.Drug. formCode. CD. displayName. value</td>
<td>from codelist C66726</td>
<td>Pre-specified dose form</td>
<td>in CMTRT and CMCAT</td>
</tr>
<tr>
<td>HYPOTRTCRIT. Defined.Drug. formCode. CD. originalText. value</td>
<td>free text</td>
<td>Pre-specified description</td>
<td>in CMTRT and CMCAT</td>
</tr>
<tr>
<td>HYPOTRTCRIT. Defined.Drug. description. ST. value</td>
<td>free text</td>
<td>Pre-specified description</td>
<td>in CMTRT and CMCAT</td>
</tr>
<tr>
<td>CMQ_O. PerformedObservation. negationIndicator. BL. value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O. PerformedObservation. negationReason. DSET&lt;SC&gt;. item. value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>This workbook contains metadata for six concepts.</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O. PerformedObservation. negationReason. DSET&lt;SC&gt;. item. code. displayName. value</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R. PerformedObservationResult. value. CD. code</td>
<td>C49488, C49487</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>CMQ_R. PerformedObservationResult. value. CD. displayName. value</td>
<td>Y, N</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
</tbody>
</table>

### Possible associated concepts

Triggered by Yes response to this concept

Collection of details of administrations of hypoglycemia treatments
Concept: Query whether food was taken for a hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOODCRIT.Defined.Drug.code.CD.code</td>
<td>TBD</td>
<td>Pre-specified drug</td>
<td>CMTRT, CMSCAT</td>
</tr>
<tr>
<td>FOODCRIT.Defined.Drug.code.CD.displayName.value</td>
<td>FOOD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FOODCRIT.Defined.Drug.code.CD.originalText.value</td>
<td>FOOD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.code</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.displayName.value</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.code</td>
<td>C49488, C49487</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.displayName.value</td>
<td>Y, N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This workbook contains metadata for six concepts.

Possible associated concepts

| Triggered by Yes response to this concept | Collection of details of food administration |
Concept: Query whether drink was taken for a hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRINKCRIT.Defined.Drug.code.CD.code</td>
<td>TBD</td>
<td>Pre-specified drug</td>
<td>CMTRT, CMSCAT</td>
</tr>
<tr>
<td>DRINKCRIT.Defined.Drug.code.CD.displayName.value</td>
<td>DRINK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRINKCRIT.Defined.Drug.code.CD.originalText.value</td>
<td>DRINK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.code</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.displayName.value</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.code</td>
<td>C49488, C49487</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.displayName.value</td>
<td>Y, N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This workbook contains metadata for six concepts.

Possible associated concepts

Triggered by Yes response to this concept

Collection of details of drink administration
Concept: Query whether glucose tablets were taken for a hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLTABCRT.Defined.Drug.code.CD.code</td>
<td>TBD</td>
<td>Pre-specified drug</td>
<td>CMTRT, in CMSCAT</td>
</tr>
<tr>
<td>GLTABCRT.Defined.Drug.code.CD.displayName.value</td>
<td>GLUCOSE</td>
<td>Pre-specified dose form</td>
<td>in CMSCAT</td>
</tr>
<tr>
<td>GLTABCRT.Defined.Drug.formCode.CD.code</td>
<td>C42998</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLTABCRT.Defined.Drug.formCode.CD.displayName.value</td>
<td>TABLET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLTABCRT.Defined.Drug.formCode.CD.originalText.value</td>
<td>free text</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>This workbook contains metadata for six concepts,..</td>
<td></td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservationResult.value.CD.code</td>
<td>C49488, C49487</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservationResult.value.CD.displayName.value</td>
<td>Y, N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Possible associated concepts

| Triggered by Yes response to this concept | Collection of details of glucose administration (See PRESP CM TRT spreadsheet) |

Domain: CM
TRT: <pre-specified>
PRESPY
CMCAT = HYPO TREATMENT
CMSCAT = GLUCOSE TABLETS
Concept: Query whether intravenous glucose tablets was given for a hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLCRIT. Defined. Drug. code. CD. code</td>
<td>TBD</td>
<td>Pre-specified drug</td>
<td>CMTRT, in CMSCAT</td>
</tr>
<tr>
<td>GLCRIT. Defined. Drug. code. CD. displayName. value</td>
<td>GLUCOSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLCRIT. Defined. Drug. code. CD. originalText. value</td>
<td>GLUCOSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IVCRIT. DefinedSubstanceAdministration. routeOfAdministrationCode. CD. code</td>
<td>C38276</td>
<td>Pre-specified route of administration</td>
<td>in CMSCAT</td>
</tr>
<tr>
<td>IVCRIT. DefinedSubstanceAdministration. routeOfAdministrationCode. CD. displayName. value</td>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O. PerformedObservation. negationIndicator. BL. value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O. PerformedObservation. negationReason. DSET&lt;SC&gt;. item. value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O. PerformedObservation. negationReason. DSET&lt;SC&gt;. item. code. code</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R. PerformedObservationResult. value. CD. code</td>
<td>C49488, C49487</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>CMQ_R. PerformedObservationResult. value. CD. displayName. value</td>
<td>Y, N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Possible associated concepts

Triggered by Yes response to this concept
Collection of details of intravenous glucose
Concept: Query whether glucagon injection was given for a hypoglycemic event

<table>
<thead>
<tr>
<th>BRIDG-based concept variable</th>
<th>Value(s)</th>
<th>Attribute</th>
<th>SDTM variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLGNCRT.Defined.Drug.code.CD.code</td>
<td>TBD</td>
<td>Pre-specified drug</td>
<td>CMTRT, in CMSCAT</td>
</tr>
<tr>
<td>GLGNCRT.Defined.Drug.code.CD.displayName.value</td>
<td>GLUCAGON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLGNCRT.Defined.Drug.code.CD.originalText.value</td>
<td>GLUCAGON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INJCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code</td>
<td>C42946</td>
<td>Pre-specified route of administration</td>
<td>in CMSCAT</td>
</tr>
<tr>
<td>INJCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value</td>
<td>INJECTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationIndicator.BL.value</td>
<td>TRUE, FALSE (SDTM NOT DONE, null)</td>
<td>Question not asked</td>
<td>CMSTAT</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.value</td>
<td>free text</td>
<td>Reason question not asked</td>
<td>CMREASND</td>
</tr>
<tr>
<td>CMQ_O.PerformedObservation.negationReason.DSET&lt;SC&gt;.item.code.code</td>
<td>sponsor codelist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>This workbook contains metadata for six concepts.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.code</td>
<td>C49488, C49487</td>
<td>Result value</td>
<td>CMOCCUR</td>
</tr>
<tr>
<td>CMQ_R.PerformedObservationResult.value.CD.displayName.value</td>
<td>Y, N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Possible associated concepts
Triggered by Yes response to this concept
Collection of details of glucagon administration
CDASH
<table>
<thead>
<tr>
<th>Question Text</th>
<th>Prompt</th>
<th>CDASH Variable Name</th>
<th>CDASH Core</th>
<th>SDTM Variable Name</th>
<th>SDTM Core</th>
<th>Case Report Form completion instructions</th>
<th>Mapping Instructions</th>
<th>Implementation Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Diagnosis of Diabetes</td>
<td>DD-MMM-YYYY</td>
<td>MHSTDAT</td>
<td>HR</td>
<td>MHSTDTC</td>
<td>Perm</td>
<td>Enter the date of diagnosis of diabetes.</td>
<td>Map directly to SDTM. Also maps to QVAL in SUPPMH with QNAM= MHDXTDC and QLABEL= Date of Diagnosis</td>
<td>Full Date Optional, Year expected.</td>
</tr>
<tr>
<td>Type of Diabetes</td>
<td>codeclist</td>
<td>MHTERM</td>
<td>HR</td>
<td>MHTERM</td>
<td>Req</td>
<td>Select the specific type of diabetes.</td>
<td>Map directly to SDTM</td>
<td>Examples of code list could be &quot;Type 1 Diabetes&quot; and &quot;Type 2 Diabetes&quot;, which types to collect is a judgment to be made by the sponsor.</td>
</tr>
<tr>
<td>Not specified</td>
<td>N/A</td>
<td>MHPRESP</td>
<td>R/C</td>
<td>MHPRESP</td>
<td>Perm</td>
<td>Pre-specified = Y</td>
<td>Map directly to SDTM</td>
<td>When MHTERM is pre-specified, this value is &quot;Y&quot;.</td>
</tr>
<tr>
<td>Not specified</td>
<td>N/A</td>
<td>MHOCCUR</td>
<td>R/C</td>
<td>MHOCCUR</td>
<td>Perm</td>
<td>Map directly to SDTM</td>
<td>When MHTERM is pre-specified, this value is &quot;Y&quot;.</td>
<td></td>
</tr>
<tr>
<td>Not specified</td>
<td>N/A</td>
<td>MHCAT</td>
<td>R/C</td>
<td>MHCAT</td>
<td>Perm</td>
<td>Pre-specified = DIABETES</td>
<td>Map directly to SDTM</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>(pre-specified)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>----------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MHPRESP= Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MHOCCUR= Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Diagnosis of Diabetes</td>
<td>-- --- ---- (DD-MMM-YYYY)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MHSTDTC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MHSTDAT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QVAL in SUPPMH where QNAM = &quot;MHDXDTDC&quot; and QLABEL = &quot;Date of diagnosis&quot;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of Diabetes</td>
<td>MHTERM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1 Diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical History Category</td>
<td>DIABETES (pre-specified)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MHCAT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CRF annotated to show mapping SDTM variables are in **Red**. If CDASH variable differs from SDTM the CDASH variable is in **Blue**.

This CRF is only an example and is not meant to imply any particular layout is preferable over another.
<table>
<thead>
<tr>
<th>Question Text</th>
<th>Prompt</th>
<th>CDASH Variable Name</th>
<th>CDASH Core</th>
<th>SDTM Variable Name</th>
<th>SDTM Core</th>
<th>Case Report Form completion instructions</th>
<th>Mapping Instructions</th>
<th>Implementation Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor Defined ID</td>
<td></td>
<td>MHSPID</td>
<td>HR</td>
<td>MHSPID</td>
<td></td>
<td>Map directly to SDTM</td>
<td>Can be pre-populated Row or Sequence Number to Identify condition (SPID)</td>
<td></td>
</tr>
<tr>
<td>Not specified</td>
<td>N/A</td>
<td>MHPRESP</td>
<td>O</td>
<td>MHPRESP</td>
<td>Perm</td>
<td>Map directly to SDTM</td>
<td></td>
<td>This value field is not entered and it may be hidden from users.</td>
</tr>
<tr>
<td>Did the subject have <em>&lt;specific condition&gt;</em>: Example: Did the subject have a history of Neuropathy?</td>
<td>No/Yes</td>
<td>MHOCCUR</td>
<td>HR</td>
<td>MHOCCUR</td>
<td>Perm</td>
<td>Select “Yes” or “No” to indicate if the subject experienced this condition as a result of complications from Diabetes.</td>
<td>Map directly to SDTM</td>
<td></td>
</tr>
<tr>
<td>What is the verbatim term for the medical history condition/event? Pre-specified terms: Diabetic Retinopathy Neuropathy Nephropathy Peripheral Vascular Disease Atherosclerotic Heart Disease Diabetic Ketoacidosis Hyperglycemic Hyperosmolar Syndrome</td>
<td>Pre-specified</td>
<td>MHTERM</td>
<td>HR</td>
<td>MHTERM</td>
<td>Req</td>
<td>Complications are pre-specified on the CRF. For each complication listed indicate if it has occurred.</td>
<td>Map directly to SDTM</td>
<td>The conditions to collect is a scientific judgment made by the sponsor. Example conditions/terms have been listed to show how chosen conditions/terms would appear in a CRF or in a dataset. Sponsor should consider coding when choosing terms.</td>
</tr>
<tr>
<td>Not specified</td>
<td>N/A</td>
<td>MHCAT</td>
<td>R/C</td>
<td>MHCAT</td>
<td>Perm</td>
<td>Pre-specified = DIABETES</td>
<td>Map directly to SDTM</td>
<td></td>
</tr>
<tr>
<td>Not specified</td>
<td>N/A</td>
<td>MHSCAT</td>
<td>R/C</td>
<td>MHSCAT</td>
<td>Perm</td>
<td>Pre-specified = COMPLICATION</td>
<td>Map directly to SDTM</td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>-------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Date of Diagnosis</td>
<td>DD-MMM-YYYY</td>
<td>MHSTDAT</td>
<td>HR</td>
<td>MHSTDTC</td>
<td>Perm</td>
<td>Enter the start date of the complication.</td>
<td>Map directly to MHSTDTC in SDTM. Also maps to QVAL in SUPPMH where QNAM = &quot;MHDXDTIC&quot; and QLABEL = &quot;Date of diagnosis&quot;.</td>
<td>Full Date Optional, Year expected.</td>
</tr>
</tbody>
</table>
**Example conditions/terms:**
- Diabetic Retinopathy
- Neuropathy
- Nephropathy
- Peripheral Vascular Disease
- Atherosclerotic Heart Disease
- Diabetic Ketoacidosis
- Hyperglycemic Hyperosmolar Syndrome

**Note:**
Which conditions to collect is a scientific judgment made by the sponsor. The questions below would be completed for each condition selected.

<table>
<thead>
<tr>
<th>Did the subject have &lt;specific condition&gt;?</th>
<th>No</th>
<th>Yes (If yes complete for each condition)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Diagnosis</td>
<td>-- -- ---- (DD-MMM-YYYY)</td>
<td></td>
</tr>
<tr>
<td>Medical History Category</td>
<td>DIABETES (pre-specified)</td>
<td></td>
</tr>
<tr>
<td>Medical History Subcategory</td>
<td>COMPLICATION (pre-specified)</td>
<td></td>
</tr>
</tbody>
</table>

CRF annotated to show mapping SDTM variables are in **Red**. If CDASH variable differs from SDTM the CDASH variable is in **Blue**.

**This CRF is only an example and is not meant to imply any particular layout is preferable over another.**
<table>
<thead>
<tr>
<th>Question Text</th>
<th>Prompt</th>
<th>CDASH Variable Name</th>
<th>SDTM Variable Name</th>
<th>Case Report Form completion instructions</th>
<th>Mapping Instructions</th>
<th>Implementation Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was SMBG Performed?</td>
<td>SMBG Performed?</td>
<td>LBPERRF</td>
<td>HR</td>
<td>NA</td>
<td>NA</td>
<td>Pre-printed on the CRF or programmed into the EDC system-the sequence number of the test (1, 2, 3) Maps directly to SDTM</td>
</tr>
<tr>
<td>Test Sequence Number</td>
<td>Sequence Number</td>
<td>LBTPTNUM</td>
<td>O</td>
<td>LBTPTNUM</td>
<td>Perm</td>
<td>Concatenates into LBDTC</td>
</tr>
<tr>
<td>Day of Measurement</td>
<td>Day</td>
<td>LBDD</td>
<td>HR</td>
<td>N/A</td>
<td>N/A</td>
<td>Day of measurement. UNK should not be an option Concatenates into LBDTC</td>
</tr>
<tr>
<td>Month of Measurement</td>
<td>Month</td>
<td>LBMO</td>
<td>HR</td>
<td>N/A</td>
<td>N/A</td>
<td>Month of measurement. UNK should not be an option Concatenates into LBDTC</td>
</tr>
<tr>
<td>Year of Measurement</td>
<td>Year</td>
<td>LBYR</td>
<td>HR</td>
<td>N/A</td>
<td>N/A</td>
<td>Year of measurement. UNK should not be an option Concatenates into LBDTC</td>
</tr>
<tr>
<td>Date of Measurement</td>
<td>Date</td>
<td>LBDAT</td>
<td>HR</td>
<td>LBDTC</td>
<td>Exp</td>
<td>Date of measurement. Should be a programmatic representation of Day, Month, Year and not entered by a user. Concatenates into LBDTC</td>
</tr>
<tr>
<td>Pre-Morning Meal Measurement</td>
<td>Pre-Morning Meal</td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Label of Test per Protocol Maps directly to SDTM</td>
</tr>
<tr>
<td>Post-Morning Meal Measurement</td>
<td>Post-Morning Meal</td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Label of Test per Protocol Maps directly to SDTM</td>
</tr>
<tr>
<td>Pre-Midday Meal Measurement</td>
<td>Pre-Midday Meal</td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Label of Test per Protocol Maps directly to SDTM</td>
</tr>
<tr>
<td>Post-Midday Meal Measurement</td>
<td>Post-Midday Meal</td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Label of Test per Protocol Maps directly to SDTM</td>
</tr>
<tr>
<td>Pre-Evening Meal Measurement</td>
<td>Pre-Evening Meal</td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Label of Test per Protocol Maps directly to SDTM</td>
</tr>
<tr>
<td>Post-Evening Meal Measurement</td>
<td>Post-evening Meal</td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Label of Test per Protocol Maps directly to SDTM Post meal measurements are dependent on the study protocol</td>
</tr>
<tr>
<td>Bedtime Measurement</td>
<td>Bedtime</td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Label of Test per Protocol Maps directly to SDTM</td>
</tr>
<tr>
<td>Overnight Measurement</td>
<td>Overnight</td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Label of Test per Protocol Maps directly to SDTM Record the time taken overnight. This is a protocol specific timepoint and should follow what the protocol states for this measurement</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>--------------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Next Day Pre-Morning Meal Measurement</td>
<td>Next Day Pre-Morning Meal Measurement</td>
<td>LBTPD</td>
<td>O</td>
<td>LBTPD</td>
<td>Perm</td>
<td>Label of Test per Protocol</td>
</tr>
<tr>
<td>Pre-Morning Meal Timepoint</td>
<td>Pre-Morning Meal Timepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Post-Morning Meal Timepoint</td>
<td>Post-Morning Meal Timepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Pre-Midday Meal Timepoint</td>
<td>Pre-Midday Meal Timepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Post-Midday Meal Timepoint</td>
<td>Post-Midday MealTimepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Pre-Evening Meal Timepoint</td>
<td>Pre-Evening Meal Timepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Post-Evening Meal Timepoint</td>
<td>Post-Evening Meal Timepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Bedtime Timepoint</td>
<td>Bedtime Timepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Overnight Timepoint</td>
<td>Overnight Timepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Next Day Pre-Morning Meal Timepoint</td>
<td>Next Day Pre-Morning Meal Timepoint</td>
<td>LBTIM</td>
<td>R/C</td>
<td>LBDTCE</td>
<td>Exp</td>
<td>Time of measurement HH:MM. Should be recorded in HH:MM and 24 hour clock time</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Next Day of Measurement</td>
<td>Day</td>
<td>LBDD</td>
<td>HR</td>
<td>N/A</td>
<td>N/A</td>
<td>Day of measurement. UNK should not be an option</td>
</tr>
<tr>
<td>Next Month of Measurement</td>
<td>Month</td>
<td>LBMO</td>
<td>HR</td>
<td>N/A</td>
<td>N/A</td>
<td>Month of measurement. UNK should not be an option</td>
</tr>
<tr>
<td>Next Year of Measurement</td>
<td>Year</td>
<td>LBYR</td>
<td>HR</td>
<td>N/A</td>
<td>N/A</td>
<td>Year of measurement. UNK should not be an option</td>
</tr>
<tr>
<td>Next Date of Measurement</td>
<td>Date</td>
<td>LBDAT</td>
<td>HR</td>
<td>LBDTC</td>
<td>Exp</td>
<td>Date of measurement. Should be a programmatic representation of Day, Month, Year and not entered by a user.</td>
</tr>
<tr>
<td>Blood glucose value Pre-Morning Meal</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Blood glucose unit Pre-Morning Meal</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Blood glucose value Post-Morning Meal</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Blood glucose unit Post-Morning Meal</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Blood glucose value Pre-Midday Meal</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Blood glucose unit Pre-Midday Meal</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Blood glucose value Post-Midday Meal</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Blood glucose unit Post-Midday Meal</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Blood glucose value Pre-Evening Meal</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Blood glucose unit Pre-Evening Meal</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Blood glucose value Post-Evening Meal</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Blood glucose unit Post-Evening Meal</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Blood glucose value Bedtime</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>---------------------------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Blood glucose unit Bedtime</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRESU</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Blood glucose value Overnight</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Blood glucose unit Overnight</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRESU</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Blood glucose value Next Day Pre-Morning Meal</td>
<td>Value</td>
<td>LBORRES</td>
<td>HR</td>
<td>LBORRES</td>
<td>Req</td>
<td>Value of blood glucose</td>
</tr>
<tr>
<td>Blood glucose unit Next Day Pre-Morning Meal</td>
<td>Unit</td>
<td>LBORRESU</td>
<td>R/C</td>
<td>LBORRESU</td>
<td>Exp</td>
<td>Unit of blood glucose. mg/dL or mmol/L</td>
</tr>
<tr>
<td>Pre-Morning Measurement Not Done</td>
<td>Pre-Morning Measurement Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Post-Morning Measurement Not Done</td>
<td>Post-Morning Measurement Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Pre-Midday Measurement Not Done</td>
<td>Pre-Midday Measurement Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Post-Midday Measurement Not Done</td>
<td>Post-Midday Measurement Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Pre-Evening Measurement Not Done</td>
<td>Pre-Evening Measurement Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Post-Evening Measurement Not Done</td>
<td>Post-Evening Measurement Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Bedtime Measurement Not Done</td>
<td>Bedtime Measurement Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Overnight Measurement Not Done</td>
<td>Overnight Measurement Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Next Day Pre-Morning Meal Measurement Not Done</td>
<td>Next Day Pre-Morning Not Done</td>
<td>LBSTAT</td>
<td>R/C</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Check if the assessment was not done</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Specimen Type</td>
<td>Specimen Type</td>
<td>LBSPEC</td>
<td>O</td>
<td>LBSPEC</td>
<td>Perm</td>
<td>Maps directly to SDTM</td>
</tr>
<tr>
<td>Device</td>
<td>Device</td>
<td>SPDEVID</td>
<td>O</td>
<td>SPDEVID</td>
<td>Exp</td>
<td>Name of the device used</td>
</tr>
<tr>
<td>SMBG Collection</td>
<td>No</td>
<td>Yes (If yes complete)</td>
<td><strong>LBPERF</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>----</td>
<td>-----------------------</td>
<td>------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Date of Measurement</strong></td>
<td><strong>LBDTC</strong></td>
<td><strong>LBDAT</strong></td>
<td><strong>LBDD</strong></td>
<td><strong>LBMO</strong></td>
<td><strong>LBYR</strong></td>
<td></td>
</tr>
<tr>
<td>Pre-Morning Meal Measurement</td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong> when <strong>LBTEST</strong> = Glucose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Morning Meal Measurement</td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Midday Meal Measurement</td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Midday Meal Measurement</td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Evening Meal Measurement</td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Evening Meal Measurement</td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bedtime Measurement</td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Next Day Date of Measurement</strong></td>
<td>--:-- (DD-MMM-YYYY)</td>
<td><strong>LBAT</strong></td>
<td><strong>LBDD</strong></td>
<td><strong>LBMO</strong></td>
<td><strong>LBYR</strong></td>
<td></td>
</tr>
<tr>
<td>Overnight Measurement</td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Next Day Pre-Morning Meal Measurement</strong></td>
<td>--:-- (24 hour clock)</td>
<td>- - - - Glucose Result</td>
<td>Not Done</td>
<td><strong>LBORRES/LBORRESU</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen Type</td>
<td><strong>LBSPEC</strong></td>
<td>Specimen Type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device</td>
<td><strong>SPDEVID</strong></td>
<td>Device Identifier</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CRF annotated to show mapping. SDTM variables in **Red**. If CDASH variable differs from SDTM the CDASH variable is in **Blue**.
<table>
<thead>
<tr>
<th>Question Text</th>
<th>Prompt</th>
<th>CDASH Variable Name</th>
<th>CDASH Core</th>
<th>SDTM Variable Name</th>
<th>SDTM Core</th>
<th>Case Report Form completion instructions</th>
<th>Mapping Instructions</th>
<th>Implementation Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the meal tolerance testing procedure performed?</td>
<td>Meal tolerance testing performed</td>
<td>MTTYN</td>
<td>O</td>
<td>Not Applicable</td>
<td>Perm</td>
<td>Indicate whether or not the meal tolerance testing procedure was performed.</td>
<td>Mapping this field to SDTM is optional. If this field is not mapped to SDTM, annotate the field as &quot;Not Submitted&quot;. If the sponsor chooses to map to SDTM, a response of &quot;Yes&quot; is not submitted. A response of &quot;No&quot; is mapped to AGSTAT and LBSTAT as the value &quot;NOT DONE&quot;. In the LB domain, LBTESTCD will be &quot;LBALL&quot;, LBTEST will be &quot;Lab All&quot; and a value must be assigned to LBCAT to distinguish the meal tolerance testing panel.</td>
<td>The primary intent/purpose of collecting this field is to help with data cleaning and monitoring. The sponsor may map a response of &quot;No&quot; as directed to document testing that was not performed. A response of &quot;Yes&quot; will not be mapped to the SDTM data. Because this field does not map to an SDTM domain, the sponsor may assign a naming prefix according to internal conventions.</td>
</tr>
<tr>
<td>Was the meal for meal tolerance testing administered?</td>
<td>Meal administration done</td>
<td>AGOCCUR</td>
<td>O</td>
<td>AGOCCUR</td>
<td>Perm</td>
<td>Indicate whether or not the meal for meal tolerance testing was administered.</td>
<td>If the sponsor chooses to map to SDTM, a response of &quot;Yes&quot; is not submitted. A response of &quot;No&quot; is mapped to AGSTAT as the value &quot;NOT DONE&quot;.</td>
<td>This is intended to be used as a data management tool to verify that missing results are confirmed missing. See Best Practice Section 3.4, FAQ #6. The question text used might be reflected in the reason not done (AGREASND).</td>
</tr>
<tr>
<td>What was the planned time point (numeric) of the meal?</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>AGTPTNUM</td>
<td>Exp</td>
<td></td>
<td>This is a numeric code and would not typically appear on the (eCRF</td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>----------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Planned time point of the meal</td>
<td><code>&lt;Time point (text) of meal&gt;</code></td>
<td>AGTPT</td>
<td>O</td>
<td>AGTPT</td>
<td>Perm</td>
<td>Record the planned time point of meal. Can be pre-printed.</td>
<td>Maps directly to SDTM.</td>
<td>Text description of planned time point when the meal should be taken. Use when multiple sequential assessments are done. Typically preprinted on the CRF. Expected values - Morning Meal, Mid-day Meal, Evening Meal, Snack, Nutritional Bar, Standardized Meal Sponsors must ensure that subjects with reversed sleep wake cycles (i.e., shift workers) use the terms as others would even though they do not match. In other words, “Morning Meal” will be shift workers' 'breakfast' even though they are waking and breaking their fast late in the day.</td>
</tr>
<tr>
<td>Meal Date</td>
<td>Meal Date</td>
<td>AGSTDA</td>
<td>T</td>
<td>AGSTDTC</td>
<td>Exp</td>
<td>Record the meal date using this format (DD-MM-YYYY).</td>
<td>For the SDTM-based dataset, the SDTM IG variable AGSTDTC is derived by concatenating CDASH Start Date (AGSTDAT) and Time (AESTTIM if time is collected) and converting to the ISO 8601 format. For more detail see the CDASH v1.1 Best Practice section This field does not map directly into SDTM.</td>
<td>CDASH recommends the unambiguous format DD-MM-YYYY where “DD” is the day as a 2-digit numeric value, “MMM” is the month as a 3-character letter abbreviation in English, or similar character abbreviation or representation in the local language, and “YYYY” is the year as a 4-digit numeric value.</td>
</tr>
<tr>
<td>Meal Start Time</td>
<td>Start Time</td>
<td>AGSTTIM</td>
<td>HR</td>
<td>AGSTDTC</td>
<td>Exp</td>
<td>Record the meal start time.</td>
<td>For the SDTM-based dataset, the SDTM IG variable AGSTDTC is derived by concatenating CDASH Start Date (AGSTDAT) and Time (AESTTIM if time is collected) and converting to the ISO 8601 format. The same data is also used to populate the reference date LBRFTDTC. For more detail see the CDASH v1.1 Best Practice section This field does not map directly into SDTM.</td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>--------------</td>
<td>--------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
<td>----------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Meal End Time</td>
<td>End Time</td>
<td>AGENTIM</td>
<td>HR</td>
<td>AGENDTC</td>
<td>Exp</td>
<td>Record the mean end time.</td>
<td>For the SDTM-based dataset, the SDTM IG variable AGENDTC is derived by concatenating the date the meal ended with eth time the meal ended and converting to ISO 8601 format. In most cases the end date will be the same as the start date so CDASH Start Date (AGSTDAT) and End Time (AEENTIM if time is collected) would be concatenated and converting to the ISO 8601 format. For more detail see the CDSH v1.1 Best Practice section This field does not map directly into SDTM.</td>
<td>If the meal could end on a later date than it began, AGENDAT would also be collected on the (e)CRF.</td>
</tr>
<tr>
<td>What portion of the meal was consumed?</td>
<td>Portion of meal consumed</td>
<td>AGDSTXT</td>
<td>HR</td>
<td>AGDOSTXT</td>
<td>Perm</td>
<td>Record the portion of the meal consumed.</td>
<td>This field does not map directly to an SDTM variable. The data collected in this dose text-format field should be separated or mapped to either SDTM IG AGDOSE if numeric or AGDOSTXT if text. If the sponsor wishes to collect separate values for the amount of food and the amount of drink consumed, the data will map to SDTM as two records. The records will share the values for most other variables (AGTPT, AGSTDTC, AGENDTC, etc.). Adjust the values for AGTRT and AGDOSTXT accordingly.</td>
<td>Where this level of dosing information is required by a sponsor, this field may be included. Defining this data collection field as a dose text field allows for flexibility in capturing dose entries as numbers, text or ranges. Recommended values are: &lt;25%, ≥25 to &lt;50%, ≥50 to &lt;75%, ≥75 to &lt;100%, 100%. If the sponsor wishes, it is permissible to collect separate values for the amount of meal (solid agent) and amount of drink (liquid agent) consumed. Modify the question text (or prompt) and the CDASH variable name appropriately.</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>SDTM Variable Name</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>---------------------------------------</td>
<td>--------------------</td>
<td>--------------------</td>
<td>-------------------------------------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meal Tolerance</td>
<td>&lt;Preprinted no response required&gt;</td>
<td>LBSCAT</td>
<td>HR</td>
<td>Perm</td>
<td>N/A</td>
<td>LBSCAT both map directly to SDTM.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>To be included if lab status is collected for the entire panel (e.g., &quot;Meal Tolerance&quot;).</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If required, this should be preprinted on the (e)CRF rather than collected in a field that requires the site to enter text.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The decision to map to LBCAT or LBSCAT is made by the sponsor based upon analysis and reporting requirements.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;Time point (number) of blood sampling &gt;</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Exp</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Numeric code corresponding to a text description of time when the meal should be taken. May be preprinted on the CRF, but not typically displayed on eCRFs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Planned Timepoint</td>
<td><code>&lt;Time point (text) of blood sampling&gt;</code></td>
<td>LBTPT</td>
<td>O</td>
<td>LBTPT</td>
<td>Perm</td>
<td>Record the planned time point labels for the lab test, if not pre-printed on the CRF. (Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td>Text description of planned time point when a sample should be collected. Use when multiple sequential assessments are done. Planned time point would be needed to differentiate multiple sequential assessments. It is recommended that time points be pre-printed on the CRF rather than collected in a field that requires the site to enter text. If the form is laid out as a grid, then words such as “Planned Time Point” can be included as the column header. Possible values include: Fasting/0 minutes, 15 minutes postprandial, 30 minutes postprandial, 60 minutes postprandial, 1 hour postprandial, 90 minutes postprandial, 120 minutes postprandial, 2 hours postprandial etc. *See the BRIDG model for complete path.</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Was the sample collected?</td>
<td>Lab Status</td>
<td>LBPERF</td>
<td>O</td>
<td>LBSTAT</td>
<td>Perm</td>
<td>Indicate whether or not the sample was collected. (Expected for each planned timepoint.)</td>
<td>This field does not map directly to an SDTM variable.</td>
<td>Status of whether or not lab specimen was collected or measurement performed. This may be implemented for an entire panel, or on a specific test basis. This is intended to be used as a data management tool to verify that missing results are confirmed missing. See CDASH v1.1 Best Practice Section 3.4, FAQ #6. For the SDTM-based dataset, the SDTM IG variable LBSTAT is derived from LBPERF when and entire panel or a specific test/sample is not done. The question text used might be reflected in the reason not done (LBREASND). Record for each sample collection timepoint. Values are Yes or No.</td>
</tr>
<tr>
<td>For what reason was the blood sampling not done?</td>
<td>Reason blood sampling not done (can be pre-specified list)</td>
<td>LBREASN D</td>
<td>O</td>
<td>LBREASN D</td>
<td>Perm</td>
<td>Record the reason blood sampling was not done. (If collected, expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td>Can be free text or pre-specified list defined by the sponsor.</td>
</tr>
<tr>
<td>What was the blood sampling time?</td>
<td>Time of blood sampling</td>
<td>LBTIM</td>
<td>O</td>
<td>LBDTC</td>
<td>Perm</td>
<td>Record the time of blood sampling. (Expected for each planned timepoint.)</td>
<td>For the SDTM-based dataset, the SDTM IG variable LBDTC is derived by concatenating CDASH Date (LBDAT) and Time (LBTIM if time is collected) and converting to the ISO 8601 format. For more detail see the CDASH v1.1 Best Practice section. This field does not map directly into SDTM.</td>
<td></td>
</tr>
<tr>
<td>Glucose Result</td>
<td>Blood Glucose result</td>
<td>LBORRE S.GLUC (OSE)</td>
<td>O</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Record test results (Expected for each planned timepoint.)</td>
<td>Result of the measurement or finding as originally received or collected. Key data collected.</td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>-----------------------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
<td>----------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Glucose Unit</td>
<td>Blood Glucose unit</td>
<td>LBORRE SU.GLUC (OSE)</td>
<td>O</td>
<td>LBORRESU</td>
<td>Exp</td>
<td>Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file. (Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td>Original units in which the data were collected. Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color). *See the BRIDG model for complete path. mg/dl, mmol/L</td>
</tr>
<tr>
<td>Glucose Reference Range Indicator (provided with laboratory results)</td>
<td>Low High Normal</td>
<td>LBORNRI ND.GLUC (OSE)</td>
<td>O</td>
<td>LBORNRINGD</td>
<td>Exp</td>
<td>(Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td></td>
</tr>
<tr>
<td>Insulin Result</td>
<td>Insulin result</td>
<td>LBORRE S.INSULIN</td>
<td>O</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Record test results (Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td>Result of the measurement or finding as originally received or collected. Key data collected.</td>
</tr>
<tr>
<td>Insulin Unit</td>
<td>Insulin unit</td>
<td>LBORRE SU.INSULIN</td>
<td>O</td>
<td>LBORRESU</td>
<td>Exp</td>
<td>Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file. (Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td>Original units in which the data were collected. Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color). *See the BRIDG model for complete path. mIU/L</td>
</tr>
<tr>
<td>Insulin Reference Range Indicator (provided with laboratory results)</td>
<td>Low High Normal</td>
<td>LBORNRI ND.INSULIN</td>
<td>O</td>
<td>LBORNRINGD</td>
<td>Exp</td>
<td>(Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td></td>
</tr>
<tr>
<td>C-Peptide Result</td>
<td>C-Peptide result</td>
<td>LBORRE S.CPEPTIDE</td>
<td>O</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Record test results (Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td>Result of the measurement or finding as originally received or collected. Key data collected.</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>-------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>-----------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>What was the C-peptide unit?</td>
<td>C-Peptide unit</td>
<td>LBORRESU.CPEP TIDE</td>
<td>O</td>
<td>LBORRESU</td>
<td>Exp</td>
<td>Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file. (Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td>Original units in which the data were collected. Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color). *See the BRIDG model for complete path. ug/l, ng/ml</td>
</tr>
<tr>
<td>C-Peptide Reference Range Indicator (provided with laboratory results)</td>
<td>Low High Normal</td>
<td>LBORNRIND.CPEP TIDE</td>
<td>O</td>
<td>LBORNRIN D</td>
<td>Exp</td>
<td>(Expected for each planned timepoint.)</td>
<td>Maps directly to SDTM.</td>
<td></td>
</tr>
<tr>
<td>Glucose Laboratory Low Normal Reference Range (provided with laboratory results)</td>
<td>Low Normal</td>
<td>LBORNRL0.GLUC (OSE)</td>
<td>O</td>
<td>LBORNRL0</td>
<td>Exp</td>
<td>Record the lower limit of the reference range of the lab test. Expected to be captured only one time if all specimen processed from the same laboratory.</td>
<td>Maps directly to SDTM.</td>
<td>The lowest continuous numeric value of a given lab result expected in the population of interest. LBORNLO and LBORNRI should be populated only for continuous results; LBSTNRC should be populated only for non-continuous results. These data may be obtained from the lab or the electronic equipment. These data could be derived from a site or lab specific set of normal ranges stored in a look up table. See SDTM IG for details on mapping and selecting the proper variable name. *See the BRIDG model for complete path.</td>
</tr>
</tbody>
</table>

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
 Provisional
August 1, 2014
Page 8 of 11
<table>
<thead>
<tr>
<th>Question Text</th>
<th>Prompt</th>
<th>CDASH Variable Name</th>
<th>SDTM Variable Name</th>
<th>Case Report Form completion instructions</th>
<th>Mapping Instructions</th>
<th>Implementation Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose Laboratory High Normal Reference Range (provided with laboratory results)</td>
<td>High Normal</td>
<td>LBORNRLHIGLUCEO</td>
<td>LBORNRHII</td>
<td>Record the upper limit of the reference range of the lab test. Expected to be captured only one time if all specimen processed from the same laboratory.</td>
<td>Maps directly to SDTM.</td>
<td>The highest continuous numeric value of a given lab result expected in the population of interest. LBORNRLO and LBORNRHII should be populated only for continuous results; LBSTNRCL should be populated only for non-continuous results. These data may be obtained from the lab or the electronic equipment. These data could be derived from a site or lab specific set of normal ranges stored in a look up table. See SDTM IG for details on mapping and selecting the proper variable name. *See the BRIDG model for complete path.</td>
</tr>
<tr>
<td>Insulin Laboratory Low Normal Reference Range (provided with laboratory results)</td>
<td>Low Normal</td>
<td>LBORNRLOINSULIN</td>
<td>LBORNRLO</td>
<td>Record the lower limit of the reference range of the lab test. Expected to be captured only one time if all specimen processed from the same laboratory.</td>
<td>Maps directly to SDTM.</td>
<td>The lowest continuous numeric value of a given lab result expected in the population of interest. LBORNRLO and LBORNRHII should be populated only for continuous results; LBSTNRCL should be populated only for non-continuous results. These data may be obtained from the lab or the electronic equipment. These data could be derived from a site or lab specific set of normal ranges stored in a look up table. See SDTM IG for details on mapping and selecting the proper variable name. *See the BRIDG model for complete path.</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Insulin Laboratory High Normal Reference Range (provided with laboratory results)</td>
<td>High Normal</td>
<td>LBORNRH1.INSULIN</td>
<td>O</td>
<td>LBORNRHI</td>
<td>Exp</td>
<td>Record the upper limit of the reference range of the lab test.</td>
</tr>
<tr>
<td>C-Peptide Laboratory Low Normal Reference Range (provided with laboratory results)</td>
<td>Low Normal</td>
<td>LBORNRO.CPepTIDE</td>
<td>O</td>
<td>LBORNRL0</td>
<td>Exp</td>
<td>Record the lower limit of the reference range of the lab test.</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>SDTM Variable Name</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>---------------------</td>
<td>--------------------</td>
<td>------------------------------------------</td>
<td>-----------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>C-Peptide Laboratory High Normal Reference Range</td>
<td>High Normal</td>
<td>LBORNRL.HCPEPTIDE</td>
<td>O</td>
<td>Exp</td>
<td>Record the upper limit of the reference range of the lab test.</td>
<td>Maps directly to SDTM.</td>
</tr>
<tr>
<td>(provided with laboratory results)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The highest continuous numeric value of a given lab result expected in the population of interest. LBORNRLLO and LBORNRLHI should be populated only for continuous results; LBSTNRC should be populated only for non-continuous results. These data may be obtained from the lab or the electronic equipment. These data could be derived from a site or lab specific set of normal ranges stored in a look up table. See SDTM IG for details on mapping and selecting the proper variable name. *See the BRIDG model for complete path.</td>
</tr>
<tr>
<td>Specimen Type (indicated on laboratory results)</td>
<td>Specimen</td>
<td>LBSPEC</td>
<td>O</td>
<td>Perm</td>
<td>Record the specimen.</td>
<td>Maps directly to SDTM.</td>
</tr>
</tbody>
</table>

**NOTE:**
- LBORNRLLO and LBORNRLHI should be populated only for continuous results.
- LBSTNRC should be populated only for non-continuous results.
- These data may be obtained from the lab or the electronic equipment.
- These data could be derived from a site or lab specific set of normal ranges stored in a look up table.
- See SDTM IG for details on mapping and selecting the proper variable name.
- *See the BRIDG model for complete path.*
<table>
<thead>
<tr>
<th>Question</th>
<th>Option 1</th>
<th>Option 2</th>
<th>CDASH Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the Meal Tolerance Testing Procedure Performed?</td>
<td>No</td>
<td>Yes (If yes complete the following)</td>
<td>MTTYN</td>
</tr>
<tr>
<td>Planned Timepoint of the Meal</td>
<td>&lt;Time point (text) of meal can be preprinted&gt;</td>
<td></td>
<td>AGTPT</td>
</tr>
<tr>
<td>Was the Meal for Meal Tolerance Testing Administered?</td>
<td>No</td>
<td>Yes (If yes complete the following)</td>
<td>AGOCCUR</td>
</tr>
<tr>
<td>Meal Date</td>
<td>AGSTDTC</td>
<td></td>
<td>AGSTDAT</td>
</tr>
<tr>
<td>Mealt Start Time</td>
<td>LBRFTDTC</td>
<td></td>
<td>AGSTTIM</td>
</tr>
<tr>
<td>Meal End Time</td>
<td>AGENDTC</td>
<td></td>
<td>AGENTIM</td>
</tr>
<tr>
<td>What Portion of the Meal was Consumed?</td>
<td>AGDOSTXT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meal Tolerance</td>
<td>&lt;Preprinted no response required&gt;</td>
<td></td>
<td>LBSCAT</td>
</tr>
<tr>
<td>Planned Timepoint</td>
<td>LBPT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the sample collected?</td>
<td>No</td>
<td>Yes</td>
<td>LBPERF</td>
</tr>
<tr>
<td>For what reason was the blood sampling not done? (Specify)</td>
<td>&lt;enter text or select from pre-specified reasons&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What was the blood sampling time?</td>
<td>- - - (24 hour clock)</td>
<td></td>
<td>LBASND</td>
</tr>
<tr>
<td>Glucose Result</td>
<td>LBORRES,GLUC(OSE)</td>
<td></td>
<td>LBORRESU,GLUC(OSE)</td>
</tr>
<tr>
<td>Glucose Reference Range Indicator</td>
<td>LBNRIND,GLUC(OSE)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin Result</td>
<td>LBORRES,INSULIN</td>
<td></td>
<td>LBORRESU,INSULIN</td>
</tr>
<tr>
<td>Insulin Reference Range Indicator</td>
<td>LBNRIND,INSULIN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-Peptide Result</td>
<td>LBORRES,CPEDITE</td>
<td></td>
<td>LBORRESU,CPEDITE</td>
</tr>
<tr>
<td>C-Peptide Reference Range Indicator</td>
<td>LBNRIND,CPEDITE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Reference Ranges (provided with laboratory results)</td>
<td>- - - Glucose NRLO</td>
<td></td>
<td>LBORNRLO,GLUC(OSE)</td>
</tr>
<tr>
<td>Specimen Type (indicated on laboratory results)</td>
<td>- - - Specimen Type</td>
<td></td>
<td>LBSPEC</td>
</tr>
</tbody>
</table>

CRF annotated to show mapping. SDTM variables in Red. If CDASH variable differs from SDTM the CDASH variable is in Blue.

This CRF is only an example and is not meant to imply any particular layout is preferable over another.
<table>
<thead>
<tr>
<th>Question Text</th>
<th>Prompt</th>
<th>CDASH Variable Name</th>
<th>CDASH Core</th>
<th>SDTM Variable Name</th>
<th>SDTM Core</th>
<th>Case Report Form completion instructions</th>
<th>Mapping Instructions</th>
<th>Implementation Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Hypoglycemic Events Experienced?</td>
<td>Any Hypoglycemic Events Experienced?</td>
<td>CEYN</td>
<td>O</td>
<td>N/A</td>
<td>N/A</td>
<td>Indicate whether or not any hypoglycemic events occurred.</td>
<td>This variable does not map to SDTM.</td>
<td>Primary intent/purpose of field is to help with data cleaning and monitoring.</td>
</tr>
<tr>
<td>Sponsor Defined ID</td>
<td></td>
<td>CESPID</td>
<td>HR</td>
<td>CESPID</td>
<td>Perm</td>
<td></td>
<td></td>
<td>Can be pre-populated Row or Sequence Number to Identify Event (SPID).</td>
</tr>
<tr>
<td>Date/Time of Event</td>
<td>Date/Time of Event</td>
<td>CESTDAT</td>
<td>HR</td>
<td>CESTDTC</td>
<td>Exp</td>
<td>Record start date using DD-MMM-YYYY format. Record time using a 24 hour clock.</td>
<td>For SDTM-based dataset, SDTM IG variable ECSTDTC is derived by concatenating CDASH Start Date (CESTDAT) and Time (CESTTIM if time is collected) and converting to ISO 8601 format. For more detail see the CDASH v1.1 Best Practice section This field does not map directly into SDTM.</td>
<td>CDASH recommends the unambiguous format DD-MMM-YYYY where “DD” is a 2-digit numeric value for day, “MMM” is a 3-character letter abbreviation for month, and “YYYY” is a 4-digit numeric value for year.</td>
</tr>
<tr>
<td>Hypoglycemic Term</td>
<td></td>
<td>NA</td>
<td>O</td>
<td>CETERM</td>
<td>Req</td>
<td>CETERM = &quot;Hypoglycemic Event&quot; where CECAT = &quot;HYPO EVENTS&quot;.</td>
<td>Not typically entered by an investigative site. May appear as a label or header on the case report form.</td>
<td></td>
</tr>
<tr>
<td>When Did the Hypoglycemic Event Occur?</td>
<td>When Did the Hypoglycemic Event Occur?</td>
<td>WHENOCC</td>
<td>HR</td>
<td>QVAL</td>
<td>Req</td>
<td>Record the time period during which the hypoglycemic event occurred.</td>
<td>QVAL when QNAM= WHENOCC and QLABEL= &quot;When Did the Hypoglycemic Event Occur?&quot;.</td>
<td>Recommend response choices: &quot;Between Bedtime and Waking&quot; and &quot;Between Waking and Bedtime&quot;.</td>
</tr>
<tr>
<td>In the Opinion of the Investigator Was This an Adverse Event?</td>
<td>Y/N</td>
<td>WASAEYN</td>
<td>R/C</td>
<td>FAORRES</td>
<td>Req</td>
<td>Indicate whether or not the investigator has determined this to be an adverse event.</td>
<td>The response will map to FAORRES where FATESTCD= &quot;WASAEYN&quot;, FATEST= &quot;Was this an adverse event?&quot; and FAOBJ=&quot;HYPOGLYCEMIC EVENT&quot;.</td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
<td>--------</td>
<td>---------------------</td>
<td>------------</td>
<td>-------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Was a Glucose Measurement Obtained at the Time of the Event?</td>
<td>Y/N</td>
<td>LBPERF</td>
<td>HR</td>
<td>LBSTAT</td>
<td>Exp</td>
<td>Indicate whether or not glucose measurement obtained.</td>
<td>&quot;Yes&quot; response is not submitted. &quot;No&quot; is mapped to LBSTAT as the value &quot;NOT DONE&quot;.</td>
<td>Primary intent/purpose of field is to help with data cleaning and monitoring. The sponsor may map a response of &quot;No&quot; as directed to document testing that was not performed. A response of &quot;Yes&quot; will not be mapped to the SDTM data. Because this field does not map to an SDTM domain, the sponsor may assign a naming prefix according to internal conventions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>In LB domain, LBTESTCD will be &quot;GLUC&quot;, LBTEST will be &quot;GLUCOSE&quot; and a value must be assigned to LBCAT to distinguish this from other results.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose Result</td>
<td></td>
<td>LBORRES</td>
<td>R/C</td>
<td>LBORRES</td>
<td>Exp</td>
<td>Enter result value.</td>
<td>&quot;xxx.xx&quot; for result</td>
<td></td>
</tr>
<tr>
<td>Glucose Units</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Enter the unit related to the result value.</td>
<td>Expected values for Glucose Result Units are &quot;mg/dL&quot; or &quot;mmol/L&quot;.</td>
<td></td>
</tr>
<tr>
<td>Last Study Medication Taken</td>
<td>Name/Reference</td>
<td>ECTRTR or EXTRT</td>
<td>O</td>
<td>EXTRT</td>
<td>Req</td>
<td>Map ECTRTR to EXTRT as discussed in the SDTMIG.</td>
<td>Collection of the data related to Last Medication Taken is Optional. Medication label can be pre-populated in question text, and section can be repeated if multiple labels. EXCAT= HIGHLIGHTED DOSE required to differentiate EX records added exclusively for hypoglycemic reference. Though this value will not typically be included as a field for entry, it may be preprinted on the CRF. If collected, the sponsor should use variables from the EC or EX domain as appropriate for the CDISC implementation by sponsor.</td>
<td></td>
</tr>
<tr>
<td>Date/Time</td>
<td></td>
<td></td>
<td></td>
<td>EXSTDTC</td>
<td>Exp</td>
<td>Record using DD-MM-MY YYYY format. Record time using a 24 hour clock.</td>
<td>Optional to include if Last Medication Taken is collected.</td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>-------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
<td>----------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Dose</td>
<td></td>
<td>ECDSTXT or EXDSTXT</td>
<td>O</td>
<td>EXDOSE</td>
<td>Exp</td>
<td></td>
<td></td>
<td>Include if Last Medication Taken is also collected.</td>
</tr>
<tr>
<td>Units</td>
<td></td>
<td>ECDOSU or EXDOSU</td>
<td>O</td>
<td>EXDOSU</td>
<td>Exp</td>
<td></td>
<td></td>
<td>Include if Last Medication Taken Dose is collected. May be printed.</td>
</tr>
<tr>
<td>Last Concomitant Diabetic Medication Taken</td>
<td>Name/Reference</td>
<td>CMTRT</td>
<td>O</td>
<td>CMTRT</td>
<td>Req</td>
<td></td>
<td></td>
<td>Collection of the data related to Last Concomitant Diabetic Medication Taken is Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medication(s) of interest can be pre-populated in question text. Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>implementation would utilized a sponsor ID from CM entry to identify medication name/dose/units</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>and only capture date/time of last dose.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CMCAT= ANTI-HYPERGLYCEMIC MED and CMSCAT = HIGHLIGHTED DOSE required to differentiate CM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>records added exclusively for hypoglycemic reference.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Though this value will not typically be included as a field for entry, it may be</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>preprinted on the CRF.</td>
</tr>
<tr>
<td>Date/Time</td>
<td></td>
<td>CMSTDAT/CMSTTIM</td>
<td>O</td>
<td>CMSTDTC</td>
<td>Exp</td>
<td>Record using DD-MMM-YYYY format. Record</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>time using a 24 hour clock.</td>
<td></td>
<td>Include if Last Concomitant Diabetic Medication Taken is also collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td></td>
<td>CMDSTXT</td>
<td>O</td>
<td>CMDOSE</td>
<td>Exp</td>
<td>Include if Last Concomitant Diabetic</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medication Taken is also collected.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Units</td>
<td></td>
<td>CMDOSU</td>
<td>O</td>
<td>CMDOSU</td>
<td>Exp</td>
<td>Include if Last Concomitant Diabetic</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medication Taken Dose is also collected.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date/Time of Last Meal</td>
<td>Date/Time</td>
<td>MLSTDAT/MLSTTIM</td>
<td>O</td>
<td>MLSTDTC</td>
<td>Exp</td>
<td>Record using DD-MMM-YYYY format. Record</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>time using a 24 hour clock.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>-------------------------------------------</td>
<td>----------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Were Signs/Symptoms Present? (If yes complete following)</td>
<td>Y/N</td>
<td>CEYN</td>
<td>R/C</td>
<td>TBD</td>
<td>TBD</td>
<td>Findings about the Hypoglycemic Event.</td>
<td>If this question is used, then for the following signs/symptoms, it is possible to use checkboxes or only yes responses. If this question is not used, then both yes and no responses must be collected for each item listed. Sponsor to decide if only &quot;Yes&quot; responses retained in SDTM.</td>
<td></td>
</tr>
<tr>
<td>Sweating</td>
<td>CEOCCUR</td>
<td>R/C</td>
<td>CEOCCUR</td>
<td>Perm</td>
<td></td>
<td>If response is Y, the prompt “Sweating” will populate SDTM variable CETERM. CEPRESP will be populated as &quot;Y&quot;. CECAT will be populated as &quot;HYPO SYMPTOMS&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted. Use of a coding dictionary is at the sponsor's discretion.</td>
<td></td>
</tr>
<tr>
<td>Tremors/Trembling</td>
<td>CEOCCUR</td>
<td>R/C</td>
<td>CEOCCUR</td>
<td>Perm</td>
<td></td>
<td>If response is Y, the prompt “Tremors/Trembling” will populate SDTM variable CETERM. CEPRESP will be populated as &quot;Y&quot;. CECAT will be populated as &quot;HYPO SYMPTOMS&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted. Use of a coding dictionary is at the sponsor's discretion.</td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>CEOCCUR</td>
<td>R/C</td>
<td>CEOCCUR</td>
<td>Perm</td>
<td></td>
<td>If response is Y, the prompt “Dizziness” will be used to populate SDTM variable CETERM. CEPRESP will be populated as &quot;Y&quot;. CECAT will be populated as &quot;HYPO SYMPTOMS&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted. Use of a coding dictionary is at the sponsor's discretion.</td>
<td></td>
</tr>
<tr>
<td>Cognitive Impairment</td>
<td>CEOCCUR</td>
<td>R/C</td>
<td>CEOCCUR</td>
<td>Perm</td>
<td></td>
<td>If response is Y, the prompt “Cognitive Impairment” will be used to populate SDTM variable CETERM. CEPRESP will be populated as &quot;Y&quot;. CECAT will be populated as &quot;HYPO SYMPTOMS&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted. Use of a coding dictionary is at the sponsor's discretion.</td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>-------------------</td>
<td>-----------</td>
<td>------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Loss of Consciousness</td>
<td>CEOCCUR R/C</td>
<td>CEOCCUR Perm</td>
<td></td>
<td></td>
<td></td>
<td>If response is Y, the prompt &quot;Loss of Consciousness&quot; will be used to populate SDTM variable CETERM. CEPRESP will be populated as “Y”. CECAT will be populated as &quot;HYPO SYMPTOMS&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted. Use of a coding dictionary is at the sponsor's discretion.</td>
<td></td>
</tr>
<tr>
<td>Convulsions/Seizure</td>
<td>CEOCCUR R/C</td>
<td>CEOCCUR Perm</td>
<td></td>
<td></td>
<td></td>
<td>If response is Y, the prompt &quot;Convulsions/Seizure&quot; will be used to populate SDTM variable CETERM. CEPRESP will be populated as “Y”. CECAT will be populated as &quot;HYPO SYMPTOMS&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted. Use of a coding dictionary is at the sponsor's discretion.</td>
<td></td>
</tr>
<tr>
<td>Coma</td>
<td>CEOCCUR R/C</td>
<td>CEOCCUR Perm</td>
<td></td>
<td></td>
<td></td>
<td>If response is Y, the prompt &quot;Coma&quot; will be used to populate SDTM variable CETERM. CEPRESP will be populated as &quot;Y&quot;. CECAT will be populated as &quot;HYPO SYMPTOMS&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted. Use of a coding dictionary is at the sponsor's discretion.</td>
<td></td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>CEOCCUR R/C</td>
<td>CEOCCUR Perm</td>
<td></td>
<td></td>
<td></td>
<td>If response is Y, the value entered for the Specify field will be used to populate CETERM. CEPRESP will be null. CECAT will be populated as &quot;HYPO SYMPTOMS&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted. Use of a coding dictionary is at the sponsor's discretion.</td>
<td></td>
</tr>
<tr>
<td>Were Any Precipitating Factors Reported?</td>
<td>Y/N</td>
<td>HPFYN HR</td>
<td>N/A N/A</td>
<td></td>
<td></td>
<td>Findings about the Hypoglycemic Event.</td>
<td>If this question is used, then for the following precipitating factors, it is possible to use checkboxes or only yes responses. If this question is not used, then both yes and no responses must be collected for each item listed. Sponsor to decide if only &quot;Yes&quot; responses retained in SDTM.</td>
<td>FAOBJ = HYPOGLYCEMIC EVENT; number consecutively.</td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>-------------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Alcohol Consumption</td>
<td>FAORRES</td>
<td>HR</td>
<td>FAORRES</td>
<td>Exp</td>
<td></td>
<td>The prompt &quot;Alcohol Consumption as a Precip Factor&quot; will be used to populate SDTM variable FATEST. FACAT will be populated as &quot;PRECIPITATING FACTORS&quot;. FAOBJ will be populated as &quot;HYPOGLYCEMIC EVENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
</tr>
<tr>
<td>Concurrent Illness</td>
<td>FAORRES</td>
<td>HR</td>
<td>FAORRES</td>
<td>Exp</td>
<td></td>
<td>The prompt &quot;Concurrent Illness as a Precip Factor&quot; will be used to populate SDTM variable FATEST. FACAT will be populated as &quot;PRECIPITATING FACTORS&quot;. FAOBJ will be populated as &quot;HYPOGLYCEMIC EVENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
</tr>
<tr>
<td>Deviation from Dosing Instructions</td>
<td>FAORRES</td>
<td>HR</td>
<td>FAORRES</td>
<td>Exp</td>
<td></td>
<td>The prompt &quot;Dosing Deviation as a Precip Factor&quot; will be used to populate SDTM variable FATEST. FACAT will be populated as &quot;PRECIPITATING FACTORS&quot;. FAOBJ will be populated as &quot;HYPOGLYCEMIC EVENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
</tr>
<tr>
<td>Missed, Delayed or Smaller Meal</td>
<td>FAORRES</td>
<td>HR</td>
<td>FAORRES</td>
<td>Exp</td>
<td></td>
<td>The prompt &quot;Meal Variance as a Precip Factor&quot; will be used to populate SDTM variable FATEST. FACAT will be populated as &quot;PRECIPITATING FACTORS&quot;. FAOBJ will be populated as &quot;HYPOGLYCEMIC EVENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>---------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Physical Activity</td>
<td>FAORRES</td>
<td>HR</td>
<td>FAORRES</td>
<td>Exp</td>
<td>The prompt &quot;Physical Activity as a Precip Factor&quot; will be used to populate SDTM variable FATEST. FACAT will be populated as &quot;PRECIPIATING FACTORS&quot;. FAOBJ will be populated as &quot;HYPOGLYCEMIC EVENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>FAORRES</td>
<td>HR</td>
<td>FAORRES</td>
<td>Exp</td>
<td>If response is Y, the value in the Specify field will be used to populate SDTM variable FATEST. (Alternately, &quot;Other&quot; concatenated with the data in the Specify field may be used to populate FATEST.) FATESTCD will be &quot;OTHER&quot;. FAOBJ will be populated as &quot;HYPOGLYCEMIC EVENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was Any Treatment Given for the Hypoglycemic Event? (If yes complete following)</td>
<td>Y/N</td>
<td>HTGYN</td>
<td>HR</td>
<td>N/A</td>
<td>N/A</td>
<td>Question used for data cleaning and does not map to SDTM.</td>
<td>On the annotated CRF, note as Not Submitted. If sponsor elects to submit this response recommend using CECONTRT.</td>
<td></td>
</tr>
<tr>
<td>Drink</td>
<td>CMOCCUR</td>
<td>HR</td>
<td>CMOCCUR</td>
<td>Perm</td>
<td>If response is Y, the prompt &quot;Drink&quot; will be used to populate SDTM variable CMTRT. CMPRESP will be Y. CMCAT will be &quot;HYPO TREATMENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food</td>
<td>CMOCCUR</td>
<td>HR</td>
<td>CMOCCUR</td>
<td>Perm</td>
<td>If response is Y, the prompt &quot;Food&quot; will be used to populate SDTM variable CMTRT. CMPRESP will be Y. CMCAT will be &quot;HYPO TREATMENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>CDASH Variable Name</td>
<td>CDASH Core</td>
<td>SDTM Variable Name</td>
<td>SDTM Core</td>
<td>Case Report Form completion instructions</td>
<td>Mapping Instructions</td>
<td>Implementation Instructions</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>-----------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Glucose Tablets</td>
<td>CMOCCUR HR</td>
<td>CMOCCUR Perm</td>
<td>If response is Y, the prompt &quot;Glucose Tablets&quot; will be used to populate SDTM variable CMTRT. CMPRESP will be Y. CMCAT will be &quot;HYPO TREATMENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucagon Injection</td>
<td>CMOCCUR HR</td>
<td>CMOCCUR Perm</td>
<td>If response is Y, the prompt &quot;Glucagon Injection&quot; will be used to populate SDTM variable CMTRT. CMPRESP will be Y. CMCAT will be &quot;HYPO TREATMENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous Glucose</td>
<td>CMOCCUR HR</td>
<td>CMOCCUR Perm</td>
<td>If response is Y, the prompt &quot;Intravenous Glucose&quot; will be used to populate SDTM variable CMTRT. CMPRESP will be Y. CMCAT will be &quot;HYPO TREATMENT&quot;.</td>
<td>Expected responses are Y or N. Yes responses will result in a record in SDTM. Responses of N may be omitted; if they are, the annotated CRF should note that N are Not Submitted.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If Treatment Given Indicate Assistance Needed?</td>
<td>Need for Assistance</td>
<td>FAORRES R/C</td>
<td>Exp</td>
<td>Investigator assessment. FACAT will be populated as &quot;TREATMENT ADMINISTRATION&quot;, FATESTCD= &quot;TXASSIST&quot;, FATEST=&quot;Treatment Assistance&quot;, FAOBJ will be populated as &quot;HYPOGLYCEMIC EVENT&quot; concatenated with consecutive numbers to differentiate between groups of findings when multiple events are reported.</td>
<td>The sponsor may choose to collect responses to this question only if treatment for the hypoglycemic event is given. The expected responses are &quot;None - Subject Treated Self&quot;, &quot;Subject was Capable of Treating Self, but Received Assistance&quot; and &quot;Subject was Not Capable of Treating Self, and Required Assistance&quot;.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Hypoglycemia CRF Example

<table>
<thead>
<tr>
<th>Any Hypoglycemic Events Experienced?</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (If yes complete for each event)</td>
<td>CEYN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sponsor Defined ID</th>
<th>CESPID</th>
<th>001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date/Time of Event</td>
<td>CESTDC</td>
<td>-- --- (DD-MMM-YYYY) - -:- (24 hour clock)</td>
</tr>
</tbody>
</table>
| When Did the Hypoglycemic Event Occur? | QVAL when QNAM= WHENOCC and QLABEL="When Did the Hypoglycemic Event Occur?"
| Between Bedtime and Waking Between Waking and Bedtime | |
| In the Opinion of the Investigator Was This an Adverse Event? | No |
| Yes | WASAEYN |

| Was a Glucose Measurement Obtained at the Time of the Event? | No |
| Yes (If yes enter result and unit below) | LBSTAT |
| - - - - Glucose Result | mg/dL |
| mmol/L |
| Last Study Medication Taken | ---------------Name/Reference | EXTRT |
| Date/Time of Last Meal | MLSTDTC | -- --- (DD-MMM-YYYY) - -:- (24 hour clock) |

| Were Signs/Symptoms Present? | No |
| Yes (If yes complete following) | CEYN |

<table>
<thead>
<tr>
<th>CECAT= HYPO SYMPTOMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CETERM= SWEATING</td>
</tr>
<tr>
<td>Sweating</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CETERM= TREMORS/TREMLING</td>
</tr>
<tr>
<td>Tremors/Trembling</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CETERM= DIZZINESS</td>
</tr>
<tr>
<td>Dizziness</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CETERM= COGNITIVE IMPAIRMENT</td>
</tr>
<tr>
<td>Cognitive Impairment</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CETERM= LOSS OF CONSCIOUSNESS</td>
</tr>
<tr>
<td>Loss of Consciousness</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CETERM= CONVULSIONS/SEIZURE</td>
</tr>
<tr>
<td>Convulsions/Seizure</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CETERM= COMA</td>
</tr>
<tr>
<td>Coma</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Other (Specify)</td>
</tr>
<tr>
<td>Yes (if yes enter below)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FACAT= PRECIPITATING FACTORS, FAOBJ= HYPOGLYCEMIC EVENT and:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CETERM=</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

| Were Any Precipitating Factors Reported? | No |
| Yes (If yes complete following) | HPFYN |

<table>
<thead>
<tr>
<th>FATEST= Alcohol Consumption as a Precip Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Consumption</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>FATEST= Concurrent Illness as a Precip Factor</td>
</tr>
<tr>
<td>Concurrent Illness</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>FATEST= Dosing Deviation as a Precip Factor</td>
</tr>
<tr>
<td>Deviation from Dosing Instructions</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>FATEST= Meal Variance as a Precip Factor</td>
</tr>
<tr>
<td>Missed, Delayed or Smaller Meal</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>FATEST= Physical Activity as a Precip Factor</td>
</tr>
<tr>
<td>Physical Activity</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Other (Specify)</td>
</tr>
<tr>
<td>Yes (if yes enter below)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CMCAT= HYPO TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMTRT= DRINK</td>
</tr>
<tr>
<td>Drink</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CMTRT= FOOD</td>
</tr>
<tr>
<td>Food</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CMTRT= GLUCOSE TABLETS</td>
</tr>
<tr>
<td>Glucose Tablets</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>CMTRT= INTRAVENOUS GLUCOSE</td>
</tr>
<tr>
<td>Intravenous Glucose</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If Treatment Given Indicate Assistance Needed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject was Capable of Treating Self, but Received Assistance</td>
</tr>
<tr>
<td>Subject was Not Capable of Treating Self, and Required Assistance</td>
</tr>
</tbody>
</table>

CRF annotated to show mapping SDTM variables are in Red. If CDASH variable differs from SDTM the CDASH variable is in Blue.

This CRF is only an example and is not meant to imply any particular layout is preferable over another.
SDTM
## 2 Model Fundamentals

### 2.2 The General Observation Classes

#### 2.2.5 Timing Variables for All Classes

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIDS</td>
<td>Disease Milestone Name</td>
<td>Char</td>
<td>The name of a specific instance of a type of Disease Milestone described in the Trial Disease Milestones dataset. This should be unique within a subject.</td>
</tr>
<tr>
<td>RELMIDS</td>
<td>Temporal Relation to Disease Milestone</td>
<td>Char</td>
<td>The relationship of the observation to the Disease Milestone. Examples: IMMEDIATELY BEFORE, AT TIME OF, AFTER.</td>
</tr>
<tr>
<td>MIDSDTC</td>
<td>Disease Milestone Date/Time</td>
<td>Char</td>
<td>The start date/time of the disease milestone named in MIDS, in ISO8601 format.</td>
</tr>
</tbody>
</table>
SDTMIG
4 Assumptions for Domain Models

4.1 General Assumptions for All Domains

4.1.4 Actual and Relative Time Assumptions

4.1.4.11 Disease Milestones and Disease Milestone Timing Variables

A “Disease Milestone” is an event or activity that can be anticipated in the course of a disease, but whose timing is not controlled by the study schedule. The types of Disease Milestones for a study are defined in the study-level Trial Disease Milestones dataset (TM). For a particular study, they may be events or activities that would have occurred before the study, such as diagnosis of the disease under study, or events or activities anticipated to occur during the study that are not scheduled activities. Disease Milestones during the study are often disease-related events that trigger the collection of data outside of scheduled visits.

4.1.4.11.1 Disease Milestone Name (MIDS)

The occurrence of a Disease Milestone will be recorded in the special-purpose Subject Disease Milestones domain (SM) and in the appropriate Event, Intervention, or Findings domains. In the general-observation-class records for the Disease Milestone, the MIDS variable will be populated with the name of the Disease Milestone. The names of disease milestone are composed of a character string that depends on the disease milestone type, and, if the type of disease milestone is one which may occur multiple times, a chronological sequence number for this disease milestone among others of the same time for the subject. The character string used in the same of a disease milestone is usually a short form of the type of disease milestone. For example, if the type of disease milestone were EPISODE OF DISEASE UNDER STUDY, the values of MIDS for instances of this type of event could be EPISODE1, EPISODE2, etc.

In a general observation class record for a finding, event, or intervention which is a disease milestone, MIDS will be populated, but RELMIDS and MIDSDTC will not be populated; the usual timing variables (e.g., --DTC, --STDTC, --ENDTC) provide timing for this observation and will be used to derive the dates and study days in the Subject Disease Milestones domain.

4.1.4.11.2 Timing relative to a Disease Milestone (MIDS, RELMIDS, MIDSDTC)

Observations made in conjunction with the Disease Milestone use the Disease Milestones Timing variables MIDS, RELMIDS and MIDSDTC to describe the timing of the observation.

- MIDS is populated with the name of a Disease Milestone that appears in the SM domain for this subject. MIDS is the “anchor” for describing the timing of the observation relative to the disease milestone. In this sense, its function is similar to –REFTPT for time points.
- RELMIDS is populated with a textual description of the temporal relationship between the observation and the Disease Milestone named in MIDS. Controlled vocabulary has not yet been developed for RELMIDS, but is likely to include terms such as IMMEDIATELY BEFORE, AT START OF, DURING, AT END OF, and SHORTLY AFTER.
- MIDSDTC is populated with the date/time of the Disease Milestone, as recorded in the SM domain. Its function is similar to –RFTDTC for time points.

In some cases, data collected in conjunction with a Disease Milestone will not have included the collection of a separate date for the related observation. This is particularly common for pre-study Disease Milestones, but may occur with on-study Disease Milestones as well. In such cases, MIDSDTC provides a related date/time in records that would not otherwise contain any date. In records that do contain date/time(s) of the observation, MIDSDTC allows easy comparison of the date(s) of the observation to the (start) date of the Disease Milestone. In such cases, it functions much like the reference time point date/time (--RFTDTC) in observations at time points.

When a Disease Milestone is an event or intervention, some data triggered by the Disease Milestone may be modeled as Findings About the Disease Milestone (i.e., FAOBJ is the Disease Milestone). In such cases, RELMIDS...
should be used to describe the temporal relationship between the Disease Milestone and the subject of the question being asked in the finding, rather than as describing when the question was asked.

- When the subject of the question is the Disease Milestone itself, RELMIDS may be populated with a value such as “ENTIRE EVENT” or “ENTIRE TREATMENT.”
- When the subject of the question is a question about the occurrence of some activity or event related to the Disease Milestone, RELMIDS acts like an evaluation interval, describing the period of time over which the question is focused.
  - For questions about a possible cause of an event or about the indication for a treatment, RELMIDS would have a value such as “WEEK PRIOR” or “IMMEDIATELY BEFORE” or even just “BEFORE.”
  - RELMIDS would be “DURING” for questions about things that may have occurred while an Event or Intervention Disease Milestone was in progress.
  - For sequelae of a Disease Milestone, RELMIDS would have a value such as “AT DISCHARGE” or “WEEK AFTER” or simply “AFTER.”

4.1.4.11.3 Use of Disease Milestone Timing variables with other Timing variables.

The Disease Milestone timing variables provide timing relative to an activity or event that has been identified, for the particular study, as a Disease Milestone. Their use does not preclude the use of variables that collect actual date/times or timing relative to the study schedule.

- The use of actual date/times is unaffected. The Disease Milestone Timing variables may provide timing information in cases where actual date/times are unavailable, particularly for pre-study Disease Milestones. When the question text for an observation references a Disease Milestone, but a separate date for the observation is not collected, the Disease Milestone Timing variables should populated but the actual date/s should not be imputed by populating them with the date of the Disease Milestone. Examples of such questions: Disease stage at initial diagnosis of disease under study, Treatment for most recent disease episode.
- Study-day variables should be populated wherever complete actual date/times are populated. This includes negative study days for pre-study observations.
- EPOCH and TAETORD may be populated for on-study observations associated with Disease Milestones. However, pre-study Disease Milestones, by definition, do not have an associated EPOCH or TAETORD.
- Visit variables are expected in many findings domains, but findings triggered by the occurrence of a study milestone may not occur at a scheduled visit.
  - Findings associated with pre-study Disease Milestones are often collected at a screening visit, although the test was not performed at that visit.
  - For findings associated with on-study Disease Milestones but not conducted at a scheduled visit, practices for populating VISITNUM as for an unscheduled visit should be followed.
- The use of time-point variables with Disease Milestone variables may occur in cases where a Disease Milestone triggers treatment, and time points relative to treatment are part of the study schedule. For instance, a migraine trial may call for assessments of symptom severity at prescribed times after treatment of the migraine. If the migraine episodes were treated as Disease Milestones, then the Disease Milestone timing variables might be populated in the exposure and symptom-severity records. If the study planned to treat multiple migraine episodes, the MIDS variable would provide a convenient way to determine the episode with which data were associated.
- An evaluation interval variable (--EVLINT or --EVLTXT) could be used in conjunction with Disease Milestone variables. For instance, patient-reported outcome instruments might be administered at the time of a Disease Milestone, and the questions in the instrument might include an evaluation interval.
- The timing variables for start and end of an event or intervention relative to the study reference period (--STRF and --ENRF) or relative to a reference time point (--STRTPT and --STTPT, --ENRTPT and --ENTPT) could be used in conjunction with Disease Milestone variables. For example, a concomitant medication could be collected in association with a Disease Milestone, so that the Disease Milestone timing variables were populated, but relative timing variables could be used for the start or end of the concomitant medication.
- The timing variables for start and end of a planned assessment interval might be populated for an assessment triggered by a Disease Milestone, if applicable. For example, the occurrence of a particular event might trigger both a treatment and Holter monitoring for 24 hours after the treatment.
5 Models for Special Purpose Domains

Subject Disease Milestones (SM)

SM – Description/Overview for Name Domain Model

[No Controlled Terminology definition at this time.]

This domain is designed to record the timing, for each subject, of Disease Milestones that have been defined in the Trial Disease Milestones (TM) dataset.

SM – Specification for Name Domain Model

sm.xpt – Subject Disease Milestones, Type, version 3.x.x. One record per disease milestone per subject.

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Controlled Terms, Codelist or Format</th>
<th>Role</th>
<th>CDISC Notes</th>
<th>Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Unique identifier for a study</td>
<td>Req</td>
</tr>
<tr>
<td>DOMAIN</td>
<td>Domain</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Two-character abbreviation for the domain</td>
<td>Req</td>
</tr>
<tr>
<td>USUBJID</td>
<td>Unique Subject Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Identifier used to uniquely identify a subject across all studies</td>
<td>Req</td>
</tr>
<tr>
<td>SMSEQ</td>
<td>Sequence Number</td>
<td>Num</td>
<td></td>
<td>Identifier</td>
<td>Sequence Number given to ensure uniqueness of subject records. Should be</td>
<td>Req</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>assigned to be consistent chronological order.</td>
<td></td>
</tr>
<tr>
<td>MIDSTYPE</td>
<td>Disease Milestone Type</td>
<td>Char</td>
<td></td>
<td></td>
<td>The type of Disease Milestone. Example: HYPOGLYCEMIC EVENT</td>
<td>Req</td>
</tr>
<tr>
<td>MIDS</td>
<td>Disease Milestone Name</td>
<td>Char</td>
<td></td>
<td>Timing</td>
<td>Name of the specific Disease Milestone. For types of Disease Milestones</td>
<td>Req</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>that can occur multiple times, the name will end with a sequence number.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Example: HYPO 1.</td>
<td></td>
</tr>
<tr>
<td>SMSTDTC</td>
<td>Start Date/Time of Milestone</td>
<td>Char</td>
<td>ISO 8601</td>
<td>Timing</td>
<td>Start date/time of milestone, if milestone is an intervention or event, or</td>
<td>Exp</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>date of milestone if milestone is a finding.</td>
<td></td>
</tr>
<tr>
<td>SMENDTC</td>
<td>End Date/Time of Milestone</td>
<td>Char</td>
<td>ISO 8601</td>
<td>Timing</td>
<td>End date/time of milestone.</td>
<td>Exp</td>
</tr>
<tr>
<td>SMSTDY</td>
<td>Study Day of Start of Milestone</td>
<td>Num</td>
<td></td>
<td>Timing</td>
<td>Study day of start of disease milestone, relative to the sponsor-defined</td>
<td>Exp</td>
</tr>
<tr>
<td>SMENDY</td>
<td>Study Day of End of Milestone</td>
<td>Num</td>
<td></td>
<td>Timing</td>
<td>Study day of end of disease milestone, relative to the sponsor-defined</td>
<td>Exp</td>
</tr>
</tbody>
</table>
SM – Assumptions for Subject Disease Milestones Domain Model

1. Disease Milestones are observations or activities whose timings are of interest in the study. The types of disease milestones are defined at the study level in the Trial Disease Milestones (TM) dataset. The purpose of the Subject Disease Milestones dataset is to provide a summary timeline of the milestones for a particular subject.

2. The name of the disease milestone is recorded in MIDS.
   a. For Disease Milestones that can occur only once (TMRPT = N) the value of MIDS may be the value in MIDSTYPE or may an abbreviated version.
   b. For disease milestones types that can occur multiple times, MIDS will usually be an abbreviated version of MIDSTYPE and will always end with a sequence number. Sequence numbers should start with one and indicate the chronological order of the instances of this type of disease milestone.

3. The timing variables SMSTDTC and SMENDY hold start and end date/times of data collected for the Disease Milestone(s) for each subject. SMSTDY and SMENDY represent the corresponding Study Day variables.
   a. The start date/time of the disease milestone is the critical date/time, and must be populated. If the disease milestone is an event, then the meaning of “start date” for the event may need to be defined.
   b. The start study day will not be populated if the start date/time includes only a year or only a year and month.
   c. The end date/time for the disease milestone is less important than the start date/time. It will not be populated if the disease milestone is a finding without an end date/time or if it is an event or intervention for which an end date/time was not collected.
   d. The end study day will not be populated if the end date/time includes only a year or only a year and month.

SM – Examples for Subject Disease Milestone Domain Model

Example 1
In this study, the disease milestones of interest are initial diagnosis of diabetes and hypoglycemic events.

Row 1: Shows that this subject’s initial diagnosis of diabetes occurred in October of 2005. Since this is a partial date, SMDY is not populated. No end date/time was recorded for this milestone.

Rows 2-3: Show that this subject had two hypoglycemic events. In this case, only start date/times have been collected. Since these date/times include full dates, SMSTDY has been populated in each case.

Row 4: Shows that this subject’s initial diagnosis of diabetes occurred on May 15, 2010. Since a full date was collected, the study day of this milestone was populated. Since diagnosis was pre-study, the study day of the disease milestone is negative. No hypoglycemic events were recorded for this subject.

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>SMSEQ</th>
<th>MIDSTYPE</th>
<th>MIDS</th>
<th>SMSTDTC</th>
<th>SMENDTC</th>
<th>SMSTDY</th>
<th>SMENDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>XYZ</td>
<td>SM</td>
<td>001</td>
<td>1</td>
<td>DIAGNOSIS</td>
<td>DIAG</td>
<td>2005-10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>XYZ</td>
<td>SM</td>
<td>001</td>
<td>2</td>
<td>HYPOGLYCEMIC EVENT</td>
<td>HYPO 1</td>
<td>2013-09-01T11:00</td>
<td></td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>XYZ</td>
<td>SM</td>
<td>001</td>
<td>3</td>
<td>HYPOGLYCEMIC EVENT</td>
<td>HYPO 2</td>
<td>2013-09-24T08:48</td>
<td></td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>XYZ</td>
<td>SM</td>
<td>002</td>
<td>1</td>
<td>DIAGNOSIS</td>
<td>DIAG</td>
<td>2010-05-15</td>
<td></td>
<td>-1046</td>
<td></td>
</tr>
</tbody>
</table>
6 Domain Models Based on the General Observation Classes

6.1 Interventions

AG – Procedure Agents

AG – Description/Overview for Procedure Agents Domain Model

The Procedure Agents domain is a draft domain at the time of this publication. No CDISC controlled terminology definition exists for the domain yet.

AG – Specification for Procedure Agents Domain Model

ag.xpt, Procedure Agents — Interventions, Version 3.x.x. One record per recorded intervention occurrence per subject, Tabulation.

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Controlled Terms, Codelist or Format</th>
<th>Role</th>
<th>CDISC Notes</th>
<th>Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>Char</td>
<td>Identifier</td>
<td>Unique identifier for a study.</td>
<td>Req</td>
<td></td>
</tr>
<tr>
<td>DOMAIN</td>
<td>Domain Abbreviation</td>
<td>Char</td>
<td>AG</td>
<td>Identifier</td>
<td>Two-character abbreviation for the domain.</td>
<td>Req</td>
</tr>
<tr>
<td>USUBJID</td>
<td>Unique Subject Identifier</td>
<td>Char</td>
<td>Identifier</td>
<td>Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.</td>
<td>Req</td>
<td></td>
</tr>
<tr>
<td>AGSEQ</td>
<td>Sequence Number</td>
<td>Num</td>
<td>Identifier</td>
<td>Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.</td>
<td>Req</td>
<td></td>
</tr>
<tr>
<td>AGGRPID</td>
<td>Group ID</td>
<td>Char</td>
<td>Identifier</td>
<td>Used to tie together a block of related records in a single domain for a subject.</td>
<td>Perm</td>
<td></td>
</tr>
<tr>
<td>AGSPID</td>
<td>Sponsor-Defined Identifier</td>
<td>Char</td>
<td>Identifier</td>
<td>Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the procedure or test page.</td>
<td>Perm</td>
<td></td>
</tr>
<tr>
<td>AGTRT</td>
<td>Reported Agent Name</td>
<td>Char</td>
<td>Topic</td>
<td>Verbatim medication name that is either pre-printed or collected on a CRF.</td>
<td>Req</td>
<td></td>
</tr>
<tr>
<td>AGMODIFY</td>
<td>Modified Reported Name</td>
<td>Char</td>
<td>Synonym Qualifier</td>
<td>If AGTRT is modified to facilitate coding, then AGMODIFY will contain the modified text.</td>
<td>Perm</td>
<td></td>
</tr>
<tr>
<td>AGDECOD</td>
<td>Standardized Agent Name</td>
<td>Char *</td>
<td>Synonym Qualifier</td>
<td>Standardized or dictionary-derived text description of AGTRT or AGMODIFY. Equivalent to the generic medication name in WHO Drug. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes. If an intervention term does not have a decode value in the dictionary then AGDECOD will be left blank.</td>
<td>Perm</td>
<td></td>
</tr>
</tbody>
</table>
### AGCAT
- **Category for Agent**
  - **Char** * Grouping Qualifier
  - Used to define a category of agent. Examples: CHALLENGE AGENT, or PET TRACER.

### AGSCAT
- **Subcategory for Agent**
  - **Char** * Grouping Qualifier
  - Further categorization of agent.

### AGPRESP
- **AG Pre-Specified**
  - **Char** (NY) Variable Qualifier
  - Used to indicate whether (Y/null) information about a specific agent was solicited on the CRF.

### AGOCCUR
- **AG Occurrence**
  - **Char** (NY) Record Qualifier
  - When the use of specific agent is solicited, AGOCCUR is used to indicate whether or not (Y/N) use of the agent occurred. Values are null for agents not specifically solicited.

### AGSTAT
- **Completion Status**
  - **Char** (ND) Record Qualifier
  - Used to indicate that a question about a pre-specified agent was not answered. Should be null or have a value of NOT DONE.

### AGREASND
- **Reason Test Not Performed**
  - **Char** Record Qualifier
  - Describes the reason procedure agent was not collected. Used in conjunction with AGSTAT when value is NOT DONE.

### AGCLAS
- **Agent Class**
  - **Char** * Variable Qualifier
  - Drug class. May be obtained from coding. When coding to a single class, populate with class value. If using a dictionary and coding to multiple classes, then follow assumption 4.1.2.8.3 or omit AGCLAS.

### AGCLASCD
- **Agent Class Code**
  - **Char** * Variable Qualifier
  - Class code corresponding to AGCLAS. Drug class. May be obtained from coding. When coding to a single class, populate with class code. If using a dictionary and coding to multiple classes, then follow assumption 4.1.2.8.3 or omit AGCLASCD.

### AGDOSE
- **Dose per Administration**
  - **Num** Record Qualifier
  - Amount of AGTRT taken.

### AGDOSTXT
- **Dose Description**
  - **Char** Record Qualifier
  - Dosing amounts or a range of dosing information collected in text form. Units may be stored in AGDOSU. Example: 200-400, 15-20.

### AGDOSU
- **Dose Units**
  - **Char** (UNIT) Variable Qualifier
  - Units for AGDOSE and AGDOSTXT. Examples: ng, mg, or mg/kg.

### AGDOSFRM
- **Dose Form**
  - **Char** (FRM) Variable Qualifier
  - Dose form for AGTRT. Examples: TABLET, AREOSOL.

### AGDOSFRQ
- **Dosing Frequency per Interval**
  - **Char** (FREQ) Variable Qualifier
  - Usually expressed as the number of repeated administrations of AGDOSE within a specific time period. Example: ONCE

### AGROUTE
- **Route of Administration**
  - **Char** (ROUTE) Variable Qualifier
  - Route of administration for AGTRT. Examples: ORAL.

### VISITNUM
- **Visit Number**
  - **Num** Timing
  - 1. Clinical encounter number.
  - 2. Numeric version of VISIT, used for sorting.

### VISIT
- **Visit Name**
  - **Char** Timing
  - 2. May be used in addition to VISITNUM and/or VISITDY.

### VISITDY
- **Planned Study Day of Visit**
  - **Num** Timing
  - Planned study day of the visit based upon RFSTDTC in Demographics.

### AGSTDTC
- **Start Date/Time of Agent**
  - **Char** ISO 8601 Timing
  - The date/time when administration of the treatment indicated by AGTRT and the dosing variables began.

### AGENDTC
- **End Date/Time of Agent**
  - **Char** ISO 8601 Timing
  - The date/time when administration of the treatment indicated by AGTRT and the dosing variables ended.

### AGSTDY
- **Study Day of Start of Agent**
  - **Num** Timing
  - Study day of start of agent relative to the sponsor-defined RFSTDTC.
AGENDY | Study Day of End of Agent | Num | Timing | Study day of end of agent relative to the sponsor-defined RFSTDTC. |
| AGDUR | Duration of Agent | Char | ISO 8601 | Timing | Collected duration for an agent episode. Used only if collected on the CRF and not derived from start and end date/times. |
| AGSTRF | Start Relative to Reference Period | Char | (STENRF) | Timing | Describes the start of the agent relative to sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into AGSTRF. |
| AGENRF | End Relative to Reference Period | Char | (STENRF) | Timing | Describes the end of the agent relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into AGENRF. |
| AGSTRTPT | Start Relative to Reference Time Point | Char | (STENRF) | Timing | Identifies the start of the agent as being before or after the reference time point defined by variable AGSTTPT. |
| AGSTTPT | Start Reference Time Point | Char | | Timing | Description or date/time in ISO 8601 character format of the reference point referred to by AGSTRTPT. Examples: "2003-12-15" or "VISIT 1". |
| AGENRPTPT | End Relative to Reference Time Point | Char | (STENRF) | Timing | Identifies the end of the agent as being before or after the reference time point defined by variable AGENRPTPT. |
| AGENTPT | End Reference Time Point | Char | | Timing | Description or date/time in ISO 8601 character format of the reference point referred to by AGENRPTPT. Examples: "2003-12-25" or "VISIT 2". |

* Indicates variable may be subject to controlled terminology. (Parenthesis indicates CDISC/NCI codelist code value)

**AG – Assumptions for Procedure Agents Domain Model**

1. **AG Definition and Structure**
   a. CRF data that captures the agents administered to the subject as part of a procedure or assessment as opposed to drugs, medications and therapies administered with therapeutic intent. An example is a short-acting bronchodilator administered as part of a reversibility assessment. Other examples of substance administrations that could be submitted in this domain include contrast agents and radio labeled substances used in imaging studies. Discussions are ongoing on the handling of radiation (e.g., x-rays or visible light) in SDTM interventions domains.
   b. The structure of the AG domain is one record per agent intervention episode, or pre-specified agent assessment per subject. It is the sponsor's responsibility to define an intervention episode. This definition may vary based on the sponsor's requirements for review and analysis.

2. **Procedure Agent Description and Coding**
   a. AGTRT captures the name of the agent and it is the topic variable. It is a required variable and must have a value. AGTRT should include only the agent name, and should not include dosage, formulation, or other qualifying information. For example, ALBUTEROL 2 PUFF is not a valid value for AGTRT. This example should be expressed as AGTRT = ALBUTEROL, AGDOSE = 2, AGDOSU = PUFF, and AGDOSFRM = AEROSOL
   b. AGMODIFY should be included if the sponsor's procedure permits modification of a verbatim term for coding.
c. AGDECOD is the standardized agent term derived by the sponsor from the coding dictionary. It is possible that the reported term (AGTRT) or the modified term (AGMODIFY) can be coded using a standard dictionary. In this instance the sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.

3. Pre-specified Terms; Presence or Absence of Procedure Agents
   a. AGPRES is used to indicate whether an agent was pre-specified.
   b. AGOCCUR is used to indicate whether a pre-specified agent was used. A value of Y indicates that the agent was used and N indicates that it was not.
   c. If an agent was not pre-specified the value of AGOCCUR should be null. AGPRES and AGOCCUR are permissible fields and may be omitted from the dataset if all agents were collected as free text. Values of AGOCCUR may also be null for pre-specified agents if no Y/N response was collected; in this case, AGSTAT = NOT DONE, and AGREASND could be used to describe the reason the answer was missing.

4. Additional Permissible Interventions Qualifiers
   a. The variables --INDC, --DOSTOT, and --DOSRGM from the Interventions general observation class would not generally be used in the AG domain because AG should only contain agents used as part of a procedure or an assessment.
   b. Other additional Qualifiers from the SDTM Interventions Class may be added to this domain.

AG – Examples for Procedure Agents Domain Model

Example 1
This example shows the administration of a procedure agent administered as part of a reversibility assessment with the associated spirometer results, as well as the spirometry measurements (RE domain) obtained before and after agent administration. Depending on the study design, the route of bronchodilator administration (via meter dose inhaler (MDI) or nebulizer) and dose per actuation (puff) or nebul may also be collected.

Reversibility Assessment
Date of assessment: DD-MMM-YYYY
Was the subject administered a short-acting bronchodilator in the previous 4 hours? Yes No
Pre-Bronchodilator Spirometry (5 Minutes before Albuterol Dosing)
   Time of Assessment: HH:MM
   Forced Expiratory Volume in 1 Second (FEV1) Result: _____ L
Albuterol Administration
   Was the subject administered Albuterol? Yes No
   Time of Assessment: HH:MM
   Number of Puffs administered: _____
Post-Bronchodilator Spirometry (20 Minutes after Albuterol Dosing)
   Time of Assessment: HH:MM
   Forced Expiratory Volume in 1 Second (FEV1) Result: _____ L
Percentage Reversibility: _____ %

Row 1: Shows the administration data of an agent (Albuterol) which was pre-specified on the CRF as part of the reversibility procedure.
Row 1: Shows the record where the question as to whether a short-acting bronchodilator was administered in the 4 hours prior to the reversibility assessment. A short-acting bronchodilator administered prior to the reversibility test, is used with therapeutic intent so is tabulated in the CM domain. Note that AGTRT has been populated with a description of a kind of medication rather than a single medication.

Row 1:

Row 2:

Row 3:

Row 1:

Row 2:

Row 3:

Row 1:

Row 2:

Row 3:

Row 1:
Rows 1-3: Shows the relationship of the test agent to the spirometry measurements obtained before and after its administration and to the prior occurrence of short acting bronchodilator administration.

Example 2
This example captures data about the allergen used by the subject as part of a bronchial allergen challenge (BAC) test. Initially, the subject had a skin prick allergen test to help identify the allergen to be used for the BAC test. The allergens tested were cat dander, house dust mite, and grass. For this subject, grass provided the largest skin test reaction and was the allergen chosen to be used in the BAC test. A predetermined set of ascending doses of the chosen allergen are used in the screening BAC test. The results of the screening BAC are used to choose the allergen dose that will be used in subsequent BAC tests (not shown).

<table>
<thead>
<tr>
<th>Allergen Used?</th>
<th>Inhalation End Time</th>
<th>Allergen Concentration SQ-u/mL</th>
<th>Time of FEV1</th>
<th>FEV1 (L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Cat Dander</td>
<td></td>
<td>Saline=0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ House Dust Mites</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Grass</td>
<td></td>
<td>Dose1 250</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose2 1000</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose3 2000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rows 1-3: Correspond to the first part of the CRF. The skin response results corresponding to these allergen administrations were used to choose grass as the allergen for the BAC.

Rows 4: The first dose given in the BAC was saline.

Rows 5-6: Three successively higher doses of grass allergen were given.
## RE6  Domain Models Based on the General Observation Classes

### 6.1 Interventions

**Meal Data (ML)**

#### ML - Definition/Overview for Meal Data Domain Model

Information regarding the subject's meal consumption, such as fluid intake, amounts, form (solid or liquid state), frequency, etc., typically used for pharmacokinetic analysis.

#### ML – Specification for Meal Data Domain Model

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Controlled Terms, Codelist or Format</th>
<th>Role</th>
<th>CDISC Notes</th>
<th>Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Unique identifier for a study.</td>
<td>Req</td>
</tr>
<tr>
<td>DOMAIN</td>
<td>Domain Abbreviation</td>
<td>Char</td>
<td>ML</td>
<td>Identifier</td>
<td>Two-character abbreviation for the domain.</td>
<td>Req</td>
</tr>
<tr>
<td>USUBJID</td>
<td>Unique Subject Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.</td>
<td>Req</td>
</tr>
<tr>
<td>MLSEQ</td>
<td>Sequence Number</td>
<td>Num</td>
<td></td>
<td>Identifier</td>
<td>Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.</td>
<td>Req</td>
</tr>
<tr>
<td>MLGRPID</td>
<td>Group ID</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Used to tie together a block of related records in a single domain for a subject.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLSPID</td>
<td>Sponsor-Defined Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Sponsor-defined reference number. Examples: a number pre-printed on the CRF as an explicit line identifier or record identifier defined in the sponsor’s operational database. Example: line number on a meal page.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLTRT</td>
<td>Reported Name of Meal</td>
<td>Char</td>
<td></td>
<td>Topic</td>
<td>Verbatim meal name that is either pre-printed or collected on a CRF.</td>
<td>Req</td>
</tr>
<tr>
<td>MLMODIFY</td>
<td>Modified Meal Name</td>
<td>Char</td>
<td></td>
<td>Synonym Qualifier</td>
<td>If MLTRT is modified, then MLMODIFY will contain the modified text.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDECOD</td>
<td>Standardized Meal Name</td>
<td>Char</td>
<td>*</td>
<td>Synonym Qualifier</td>
<td>Standardized or dictionary-derived text description of MLTRT or MLMODIFY if the sponsor chooses to code the meal. The sponsor is expected to provide the dictionary name and version used to map the</td>
<td>Perm</td>
</tr>
</tbody>
</table>

© 2014 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Controlled Terms, Codelist or Format</th>
<th>Role</th>
<th>CDISC Notes</th>
<th>Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLCAT</td>
<td>Category for Meal</td>
<td>Char</td>
<td>*</td>
<td>Grouping Qualifier</td>
<td>Used to define a category of meal.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLSCAT</td>
<td>Subcategory for Meal</td>
<td>Char</td>
<td>*</td>
<td>Grouping Qualifier</td>
<td>A further categorization of meal.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLPRESP</td>
<td>ML Pre-Specified</td>
<td>Char</td>
<td>(NY)</td>
<td>Record Qualifier</td>
<td>Used to indicate whether (Y/null) information about the consumption of a specific meal was solicited on the CRF.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLOCCUR</td>
<td>ML Occurrence</td>
<td>Char</td>
<td>(NY)</td>
<td>Record Qualifier</td>
<td>When the consumption of specific meal is solicited, MLOCCUR is used to indicate whether or not (Y/N) consumption of the meal occurred. Values are null for meals not specifically solicited.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLSTAT</td>
<td>Completion Status</td>
<td>Char</td>
<td>(ND)</td>
<td>Record Qualifier</td>
<td>Used to indicate that a question about a pre-specified meal was not answered. Should be null or have a value of NOT DONE.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLREASND</td>
<td>Reason Meal Not Collected</td>
<td>Char</td>
<td></td>
<td>Record Qualifier</td>
<td>Describes the reason meal was not collected. Used in conjunction with MLSTAT when value is NOT DONE.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLINDC</td>
<td>Indication</td>
<td>Char</td>
<td></td>
<td>Record Qualifier</td>
<td>Denotes why a meal was taken or administered.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDOSE</td>
<td>Meal Consumption</td>
<td>Num</td>
<td></td>
<td>Record Qualifier</td>
<td>Amount of MLRT taken.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDOSTXT</td>
<td>Meal Consumption Text</td>
<td>Char</td>
<td></td>
<td>Record Qualifier</td>
<td>Dosing amounts or a range of dosing information collected in text form. Units may be stored in MLDOSU. Example: 200-400. 15-20.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDOSU</td>
<td>Consumption Units</td>
<td>Char</td>
<td>(UNIT)</td>
<td>Variable Qualifier</td>
<td>Units for MLDOSE, MLDOSTXT, and MLDOSTOT. Examples: ng, mg, or mg/kg.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDOSFRM</td>
<td>Meal Form</td>
<td>Char</td>
<td>(FRM)</td>
<td>Record Qualifier</td>
<td>Dose form for MLRT. Examples: SOLID, LIQUID.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDOSFRQ</td>
<td>Meal Frequency per Interval</td>
<td>Char</td>
<td>(FREQ)</td>
<td>Variable Qualifier</td>
<td>Usually expressed as the number of repeated administrations of MLDOSE within a specific time period.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDOSTOT</td>
<td>Total Daily Consumption</td>
<td>Num</td>
<td></td>
<td>Record Qualifier</td>
<td>Total daily dose of MLRT using the units in MLDOSU. Total dose over a period other than day could be recorded in a separate Supplemental Qualifier variable. MLDOSTOT should be used in addition to MLDOSE, and not in place of it.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDOSRGM</td>
<td>Intended Meal Regimen</td>
<td>Char</td>
<td></td>
<td>Variable Qualifier</td>
<td>Text description of the (intended) schedule or regimen for the Intervention. Examples: TWO WEEKS ON, TWO WEEKS OFF.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLROUTE</td>
<td>Route of Administration</td>
<td>Char</td>
<td>(ROUTE)</td>
<td>Variable Qualifier</td>
<td>Route of administration for MLRT.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLSTDTC</td>
<td>Start Date/Time of Meal</td>
<td>Char</td>
<td>ISO 8601</td>
<td>Timing</td>
<td></td>
<td>Perm</td>
</tr>
<tr>
<td>MLENSTDTC</td>
<td>End Date/Time of Meal</td>
<td>Char</td>
<td>ISO 8601</td>
<td>Timing</td>
<td></td>
<td>Perm</td>
</tr>
<tr>
<td>MLSTDY</td>
<td>Study Day of Start of Meal</td>
<td>Num</td>
<td></td>
<td>Timing</td>
<td>Study day of start of meal relative to the sponsor-defined RFSTDTC.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLENODY</td>
<td>Study Day of End of Meal</td>
<td>Num</td>
<td></td>
<td>Timing</td>
<td>Study day of end of meal relative to the sponsor-defined RFSTDTC.</td>
<td>Perm</td>
</tr>
<tr>
<td>MLDUR</td>
<td>Duration of Meal</td>
<td>Char</td>
<td>ISO 8601</td>
<td>Timing</td>
<td>Collected duration for a meal. Used only if collected on the CRF and not derived from start and end date/times.</td>
<td>Perm</td>
</tr>
<tr>
<td>Variable Name</td>
<td>Variable Label</td>
<td>Type</td>
<td>Controlled Terms, Codelist or Format</td>
<td>Role</td>
<td>CDISC Notes</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>----------------</td>
<td>------</td>
<td>-----------------------------------</td>
<td>------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>MLSTRF</td>
<td>Start Relative to Reference Period</td>
<td>Char</td>
<td>(STENRF)</td>
<td>Timing</td>
<td>Describes the start of the meal relative to sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as &quot;PRIOR&quot;, ONGOING or &quot;CONTINUING&quot; was collected, this information may be translated into MLSTRF.</td>
<td></td>
</tr>
<tr>
<td>MLENRF</td>
<td>End Relative to Reference Period</td>
<td>Char</td>
<td>(STENRF)</td>
<td>Timing</td>
<td>Describes the end of the meal relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as &quot;PRIOR&quot;, ONGOING, or &quot;CONTINUING&quot; was collected, this information may be translated into MLENRF.</td>
<td></td>
</tr>
<tr>
<td>MLSTRTPT</td>
<td>Start Relative to Reference Time Point</td>
<td>Char</td>
<td>(STENRF)</td>
<td>Timing</td>
<td>Identifies the start of the meal as being before or after the reference time point defined by variable MLSTTPT.</td>
<td></td>
</tr>
<tr>
<td>MLSTTPT</td>
<td>Start Reference Time Point</td>
<td>Char</td>
<td></td>
<td>Timing</td>
<td>Description or date/time in ISO 8601 character format of the reference point referred to by MLSTRTPT. Examples: &quot;2003-12-15&quot; or &quot;VISIT 1&quot;.</td>
<td></td>
</tr>
<tr>
<td>MLENRTPT</td>
<td>End Relative to Reference Time Point</td>
<td>Char</td>
<td>(STENRF)</td>
<td>Timing</td>
<td>Identifies the end of the meal as being before or after the reference time point defined by variable MLENRTPT.</td>
<td></td>
</tr>
<tr>
<td>MLENTPT</td>
<td>End Reference Time Point</td>
<td>Char</td>
<td></td>
<td>Timing</td>
<td>Description or date/time in ISO 8601 character format of the reference point referred to by MLENRTPT. Examples: &quot;2003-12-25&quot; or &quot;VISIT 2&quot;.</td>
<td></td>
</tr>
</tbody>
</table>

* Indicates variable may be subject to controlled terminology. (Parenthesis indicates CDISC/NCI codelist code value)

**ML - Assumptions for Meal Data Domain Model**

1. Assumptions for this domain are still a work in progress.

**ML - Examples for Meal Data Domain Model**

*Example 1*

This example shows an existing-variables approach to data about the last meal before a hypoglycemic event. Data about the subject's last meal before the hypoglycemic event is mapped to the ML domain.

**Row 1:** Shows the subject’s last meal before their first and hypoglycemic event. The time of the meal is treated as a data collection time point relative to the hypoglycemic event, which is treated as a reference (MLTPT=LAST DOSE PRIOR and MLTPTREF=HYPOGLYCEMIC EVENT 1). The date/time of the last meal was not collected, but the date/time for the reference time point provides indirect information on timing of the meal.

**Rows 2-3:** Show last meal prior to two subsequent hypoglycemic events

```
ml.xpt

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>MLSEQ</th>
<th>MLTRT</th>
<th>MLTPT</th>
<th>MLTPTREF</th>
<th>MLRFTDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>XYZ</td>
<td>ML</td>
<td>XYZ-001-001</td>
<td>1</td>
<td>EVENING MEAL</td>
<td>LAST DOSE PRIOR</td>
<td>HYPOGLYCEMIC EVENT 1</td>
<td>2013-09-01T11:00</td>
</tr>
</tbody>
</table>
```
SDTMIG Draft Domain: Meal Data (ML)

Data about the subject's last diabetes medication can be collected as study treatment data or concomitant medication, depending on the nature of the study. Since it is important to collect the date and/or time of the last medication before the event, this may require having more than one record for a single dosing period.

**Example 2**
This example shows a disease milestones approach to data about the last meal before a hypoglycemic event. Information on the last meal prior to a hypoglycemic event is held in the ML domain.

**Row 1:** Records an evening meal and its start date and the fact that this was the “LAST MEAL PRIOR TO” the disease milestone “HYPO 1.”

**Row 2:** Shows the last meal prior to HYPO 2.
7 Trial Design Datasets

Trial Disease Milestones (TM)

TM – Description/Overview for Name Domain Model

[No Controlled Terminology definition at this time.]

This domain is used to describe Disease Milestones, which are observations or activities expected to occur in the course of the disease under study, and whose timing is of interest for the study.

TM – Specification for Name Domain Model

tm.xpt – Trial Disease Milestones, Type, version 3.x.x. One record per Disease Milestone type.

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Controlled Terms, Codelist or Format</th>
<th>Role</th>
<th>CDISC Notes</th>
<th>Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Unique identifier for a study</td>
<td>Req</td>
</tr>
<tr>
<td>DOMAIN</td>
<td>Domain</td>
<td>Char</td>
<td>TM</td>
<td>Identifier</td>
<td>Two-character abbreviation for the domain</td>
<td>Req</td>
</tr>
<tr>
<td>MIDSTYPE</td>
<td>Disease Milestone Type</td>
<td>Char</td>
<td></td>
<td>Timing</td>
<td>The type of Disease Milestone. Example: HYPOGLYCEMIC EVENT</td>
<td>Req</td>
</tr>
<tr>
<td>TMDEF</td>
<td>Disease Milestone Definition</td>
<td>Char</td>
<td></td>
<td>Rule</td>
<td>Definition of the Disease Milestone.</td>
<td>Req</td>
</tr>
<tr>
<td>TMRPT</td>
<td>Disease Milestone Repetition Indicator</td>
<td>Char</td>
<td>(NY)</td>
<td>Record Qualifier</td>
<td>Indicates whether this is a Disease Milestone that can occur only once (Y) or a type of Disease Milestone that can occur multiple times (N).</td>
<td>Req</td>
</tr>
</tbody>
</table>

TM – Assumptions for Trial Disease Milestones Domain Model

1. Disease Milestones may be things that would be expected to happen before the study, or may be things that are anticipated to happen during the study. Disease Milestones that happen to particular subjects will be recorded in the Subject Disease Milestone (SM) dataset

2. The data contains a record for each type of Disease Milestone. The Disease Milestone is defined in TMDEF.

TM – Examples for Trial Disease Milestones Domain Model

Example 1
In this diabetes trial, initial diagnosis of diabetes and the hypoglycemic events that occur during the trial have been identified as Disease Milestones of interest.

Row 1: Shows that the initial diagnosis is given the MIDSTYPE of DIAGNOSIS and is defined in TMDEF. It is not repeating (occurs only once).
Rows 2-3: Show that hypoglycemic events are given MIDSTYPE values of HYPOGLYCEMIC EVENT, and a definition in TMDEF. For an actual study, the definition would be expected to include a particular threshold level, rather than the text “[threshold level]” used in this example. A subject may experience multiple hypoglycemic events as indicated by TMRPT=Y.

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>MIDSTYPE</th>
<th>TMDEF</th>
<th>TMRPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>XYZ</td>
<td>TM</td>
<td>DIAGNOSIS</td>
<td>Initial diagnosis of diabetes, the first time a physician told the subject they had diabetes.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>XYZ</td>
<td>TM</td>
<td>HYPOGLYCEMIC EVENT</td>
<td>Hypoglycemic Event, the occurrence of a glucose level below [threshold level].</td>
<td>Y</td>
</tr>
</tbody>
</table>