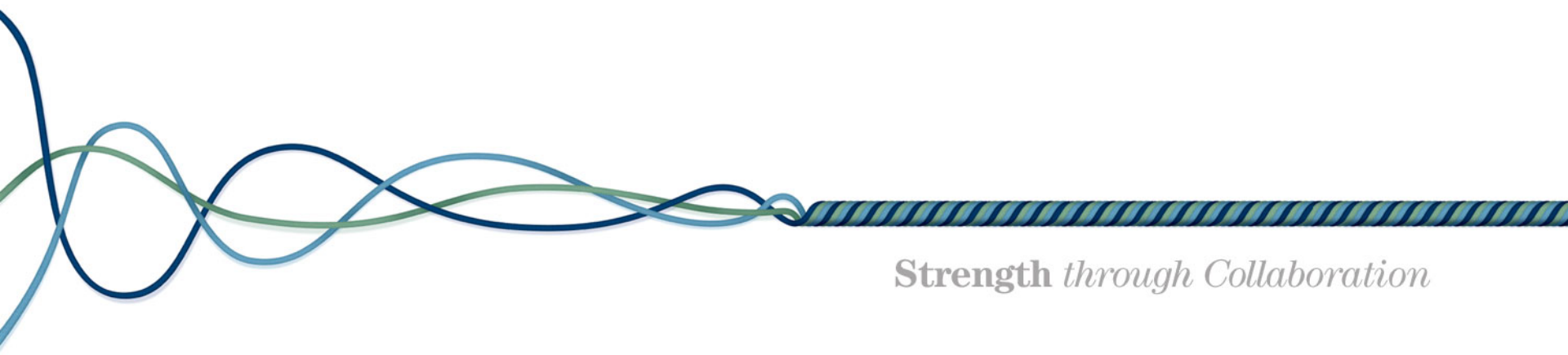
CDISC Public Webinar – Standards Updates and Additions

20 March 2014



Agenda

- ADaM IG
  - Susan Kenny
- Diabetes UG
  - Rhonda Facile, CDISC
  - Rachael Zirkle, Eli Lilly
- Multiple Sclerosis
  - Bess Leroy, C-Path
  - Jon Neville, C-Path
- Cardiovascular UG
  - Amy Palmer, CDISC
  - Steve Kopko, CDISC

Question & Answer

- ‘Presenter’: Question

OR

- ‘Presentation’: Question

Examples:

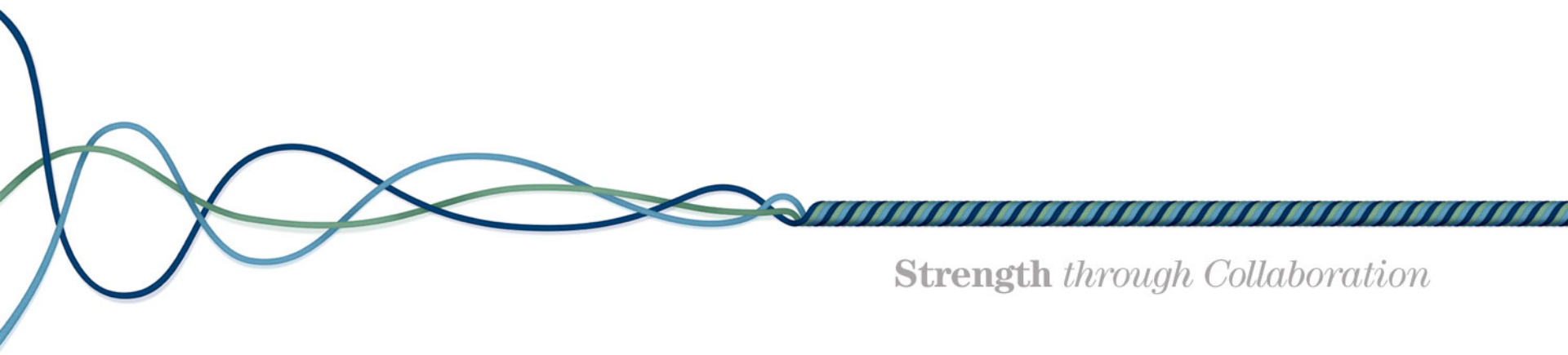
Rhonda Facile: What does UG stand for?

Or

Diabetes: What are diabetes?

ADaM Implementation Guide: Summary of Updates

Presented by Susan J. Kenny



Current ADaM Documents

- ADaM Model Document 2.1
- ADaMIG 1.0
- Examples
- ADAE
- ADTTE
- Compliance checks
- Updated Pilot 1 data

ADaM Documents In Progress

- ODS document
- ADaM metadata submission guideline
- Document to cover multivariate analyses
- Compliance checks to cover ADAE and ADTTE
- ISS/ISE Integration

Updating of Implementation Guide

- Current IG Version Update
  - Based on comments from public
  - Based on team member experiences
  - Done so far
    - Removed/updated
    - Clarifications
    - Additions
    - Changes
- Will wait for next IG version for more major issues
  - Update CRITy section
  - Grouping Variable for PARAM
  - Real time plotting variable
  - Multiple treatments
  - Function of multiple rows
  - And more ☺

Removed/Updated

- Announcing retirement of PARAMTYP
  - Too much confusion between PARAMTYP and DTYPE
  - No value added
- Error in variable type for ANRLO, ANRHI, AyLO, AyHI
  - Harmonized with STNRLO/STNRHI which are numerics
  - Added ANRLOC/ANRHIC/etc to capture character values

Clarifications

- Parameter invariant
  - Added text to definition
- ADaM datasets vs analysis datasets
  - Added picture showing what goes where
- What goes from ADSL into other datasets
  - Added language that not all ADSL variables should be copied to other ADaM
- Index variables do not have to go from “a” to “z”
  - Having SITEGR2 without SITEGR1 is valid
- Length does not have to match from SDTM to ADaM
  - Length can be shortened to optimize file space

Clarifications (cont)

- When paired variables have to be one-to-one
  - Only when both are populated and only within PARAM value
- Conditions for requirement (COND variables)
  - Added language to capture what the condition for requirement is
- Added clarification regarding use of SRC variables to point to ADaM datasets
  - Described when SRC--- are used vs --SEQ
- Cleaned up examples

Additions

- w as an index value
  - PHwSDT (Phase w Start Date)
- Added AGEGRy, ACTARM, TSEQPGy (Planned Pooled Treatment Sequence y), DOSExxP (Planned Treatment Dose for Period xx) for ADSL
- Added new timing variables for phase, subperiod
  - PHwSDT, PxxSwSDT (Period xx Subperiod w Start Date)
- Added new subject-level trial experience variables
  - EOSSTT (End of Study Status)
  - EOSDT (End of Study Date)
  - DCTREAS (Reason for Discontinuation from Study)
  - Similar for “treatment”
  - Lots more variables (e.g. TRCMP (Compliance withTreatment (%)), TRTDURY (Total Treatment Duration (Yrs)), etc)
- Added ASEQ (Analysis Sequence Number) to tie an ADaM dataset record to a predecessor ADaM dataset record (SRCSEQ is for SDTM)
  - Added example to illustrate this

Additions (Con't)

- Added analysis period dose variables (DOSExxP/DOSExxA/DOSExxU)
- Additional record-level timing variables added
  - ASPER (Subperiod within Period)
  - ASPRSDT (Subperiod Start Date)
- Added MCRITy and corresponding flags (MCRITyML)
  - A text string identifying a pre-specified criterion within a parameter, where the criterion can have multiple responses (as opposed to CRITy which has binary responses).
- Added text regarding which variables to copy onto a new record

Additions (Con't)

- Added table of naming fragments
  - GRy/FL/ML/DT/TM/DTM/DTF/TMF/DY
    - Any variable that ends with one of these fragments must follow the fragment conventions
  - CHG/BL/FU/OT/RU/SC/TA/TI/WA
    - Any variable that contains one of these fragments should follow the meaning of the variable but it is not mandated

Changes

- y can go from 1 to 99
- Allowed variability in more labels
  - descriptive text is allowed at the end of the labels of variables whose names contain indexes “y” or “zz”
  - variable labels containing a word or phrase in brackets, e.g. {Time}, should be replaced by the producer with appropriate text that contains the bracketed word or phrase somewhere in the text, e.g. the label for a *TM variable is indicated as {Time} in this document, indicating any producer-defined label is permitted as long as the word Time is incorporated in it.

Changes

- Modified treatment variables required for BDS
  - TRTP or TRTA is no longer required
  - Treatment variable(s) must either be from ADSL OR be TRTP / TRTA
  - If TRTP or TRTA are used, the value must align with the value in one of the ADSL treatment variables
  - At least 1 treatment variable is required

Schedule for Release

- Will be released for public comments within a few weeks
  - ADaM IG needs final quick review from SRC
- Comment period will be 6 weeks
- Please watch for CDISC announcement and provide comments!

Therapeutic Area User Guide – Diabetes V1.0
Public Review Webinar
March 20, 2014

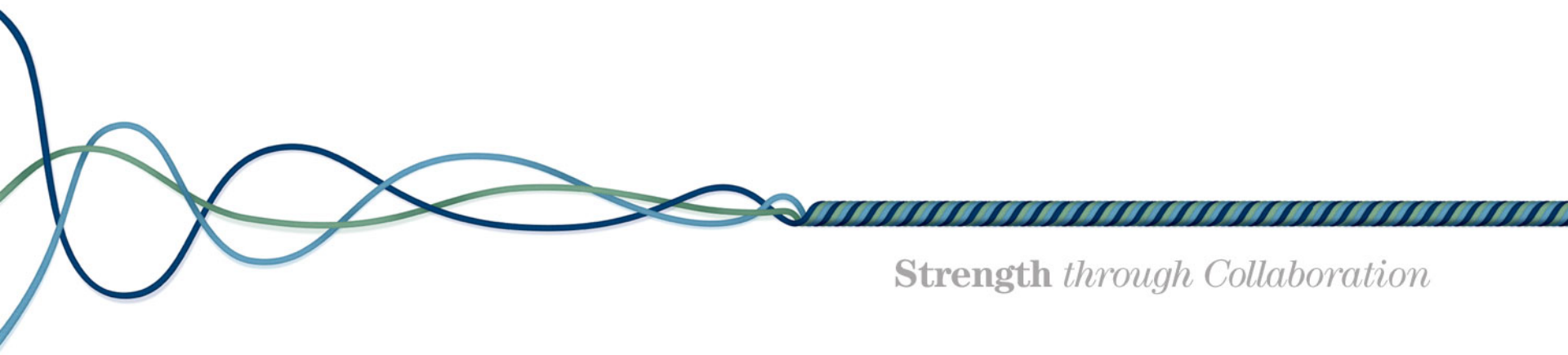
CDISC®

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research

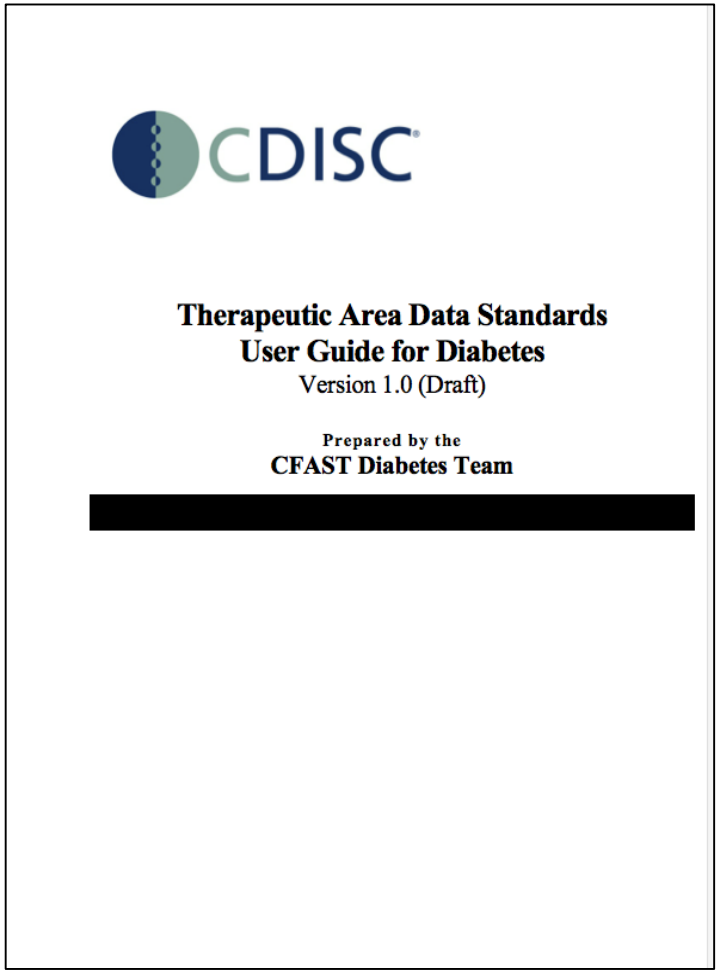
Therapeutic Area User Guide – Diabetes V1.0 Public Review Webinar March 20, 2014

Rachael Zirkle, Lilly, CFAST Diabetes Project Manager
Rhonda Facile, CDISC, CFAST Program Manager



Diabetes TA

- CFAST Program
- Development Principles
- Diabetes Background
- Project Scope
- Key Diabetes Concepts
- Public Review
  - Areas to focus
  - How to submit comments
- Q & A



- The Coalition for Accelerating Standards and Therapies (CFAST)
- CFAST sponsors the development of standards for key therapy areas
- A joint initiative of CDISC and the Critical Path Institute (C-Path)
- 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 Vocabulary Service (NCI-EVS), with participation and input from many other organizations
- See http://www.cdisc.org/therapeutic for more information

Program Overview – February 2014

Approved Therapeutic Area Standards Projects

Therapeutic Area	Coordinating Organization(s) / Project Manager	Proposal Approval Date	Stage 0 Scoping & Input	Stage 1 Concept Modeling	Stage 2 Standards Development	Stage 3a Internal Review	Stage 3b Public Review	Stage 3c Publication	Notes
Cardiovascular Endpoints v1	CDISC/DCRI Amy Palmer	Jun 13	Jul	Sep	Nov	Feb	Mar	*Q214*	
Multiple Sclerosis v1	CPATH Bess Leroy	Mar 13	May	*Oct*	Dec	Jan	Apr	*Q214*	
Diabetes v1	TCB Rachael Zirkle	Apr 13	May	Aug	Dec	Mar	May	*Q214*	
QT Studies v1	TCB John Owen	Aug 13	Oct	Feb	Mar	May		*Q314*	
Traumatic Brain Injury v1	CDISC Rhonda Facile	Oct 13	June					*2014*	
Hepatitis C v1	TCB John Owen	Nov 13	Feb	Apr				*Q414*	
Schizophrenia v1	CDISC/DCRI Amy Palmer	Nov 13	Apr	June				*Q414/Q115*	
Breast Cancer v1	TCB Sarah Davis	Nov 13	Apr	Jul				*2015*	
Influenza	C-PATH Jon/Bess/Laura	Feb 14	Mar					*Q414*	
Lipid Lowering Drugs	TCB John Glover	Dec 13							
COPD v1	TCB John Glover	Nov 13							

Key: | Stage completed | Stage ongoing | All Months reflect when stage is or is projected to be completed.

Development Principles

- Scope
  - core, clinically meaningful concepts
  - manage content to meet defined timelines (10-12 months)
- Re-use existing standards (SDTM, CDASH, ADaM)
  - include examples only for situations not covered by existing implementation guide(s)
- Propose new variables for existing domains or new domains
  - only where needed
- Propose new controlled terminology
  - only where needed

What is Different from Previous CDISC TA Standards?

- Disease background & context
- Concept maps
  - To diagram the relationships between concepts and among attributes of a concept
- Regulatory and medical references
  - To help ensure regulatory compliance and medical appropriateness
- SHARE model based metadata development
  - Not just SDTM; but also CDASH and ADaM in later iterations
- Focused indication and population under study
  - Studies of drugs for diabetes in adult subjects

Concept Maps

- Illustrates relationships among concepts and attributes
- Facilitates understanding (semantic interoperability) among functions involved in standards development

Self-Monitoring Glucose – example

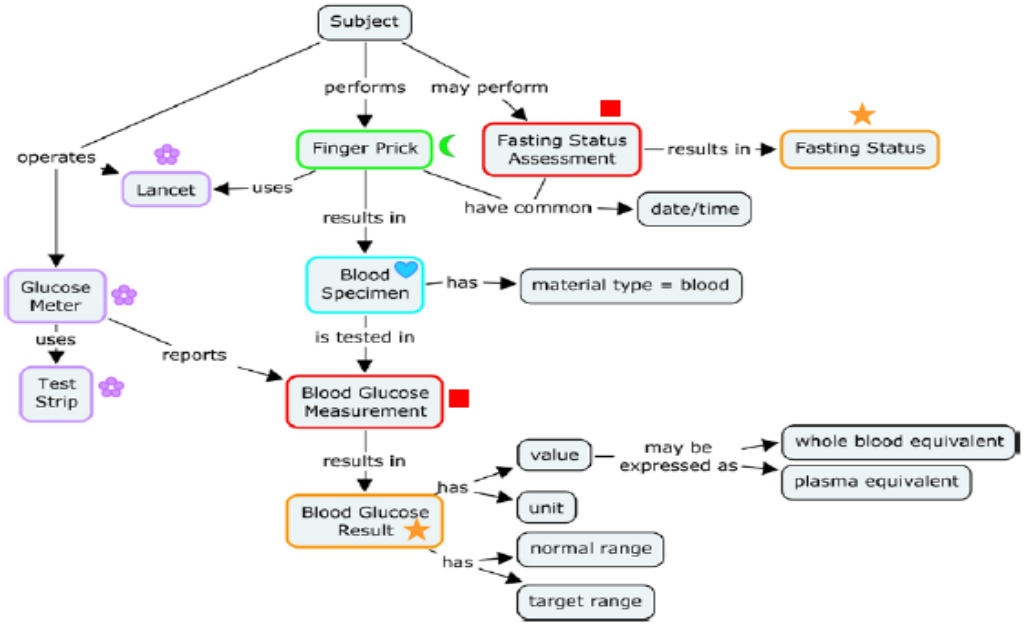


Diagram 2: Self-Monitoring Blood Glucose
Glucose measurements typically performed by subjects with diabetes are indicated. The glucose meter device requires a whole blood sample, but the glucose reading may be read as either a whole blood equivalent or a plasma equivalent.

Regulatory and Medical References

- Regulatory and key medical literature is being reviewed and referenced during the early stages of CFAST projects.
- Bibliography and footnotes included

Appendix G: References

1. Matthews DR, Hosker JP, Rudenski AS, Naylor BA, Treacher DF, Turner RC. Homeostasis model assessment: insulin resistance and beta-cell function from fasting plasma glucose and insulin concentrations in man. *Diabetologia*. 1985;28(7):412-9. doi: 10.1007/BF00280883.
2. American Diabetes Association. Checking Your Blood Glucose. *American Diabetes Association*. Available at: http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/checking-your-blood-glucose.html.
3. Joslin Diabetes Center. Plasma Glucose Meters and Whole Blood Glucose Meters. *Joslin Diabetes Center*. Available at: http://www.joslin.org/info/plasma_glucose_meters_and_whole_blood_meters.html. Accessed October 20, 2013.
4. Seaquist ER, Anderson J, Childs B, et al. Hypoglycemia and diabetes: a report of a workgroup of the american diabetes association and the endocrine society. *Diabetes Care*. 2013;36(5):1384-95. doi: 10.2337/dc12-2480.
5. FDA. *Guidance for Industry: Diabetes Mellitus — Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes*: U.S. Food and Drug Administration; PDF 2008.
6. American Diabetes Association. Insulin Basics. *American Diabetes Association*. Available at: http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/insulin/insulin-basics.html. Accessed August 15, 2013.
7. Langenberg C, Sharp SJ, Schulze MB, et al. Long-term risk of incident type 2 diabetes and measures of overall and regional obesity: the EPIC-InterAct case-cohort study. *PLoS Med*. 2012;9(6):e1001230. doi: 10.1371/journal.pmed.1001230.
8. World Health Organization. *Waist Circumference and Waist-Hip Ratio: Report of a WHO Expert Consultation, Geneva, 8-11*. Geneva, Swizerland: WHO Document Production Services; 2008.
9. NAASO, NHLBI. *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*: National Heart, Lung, and Blood Institute; Epub 2000.

SHARE Model-Based Metadata Package

- Future plans to develop all CDISC SHARE metadata:
  - **BRIDG**
  - **SDTM**
  - **CDASH**
  - ADaM
  - **Controlled Terminology**
  - Data types
  - **Definitions**
  - Trial Summary Parameters/Protocol

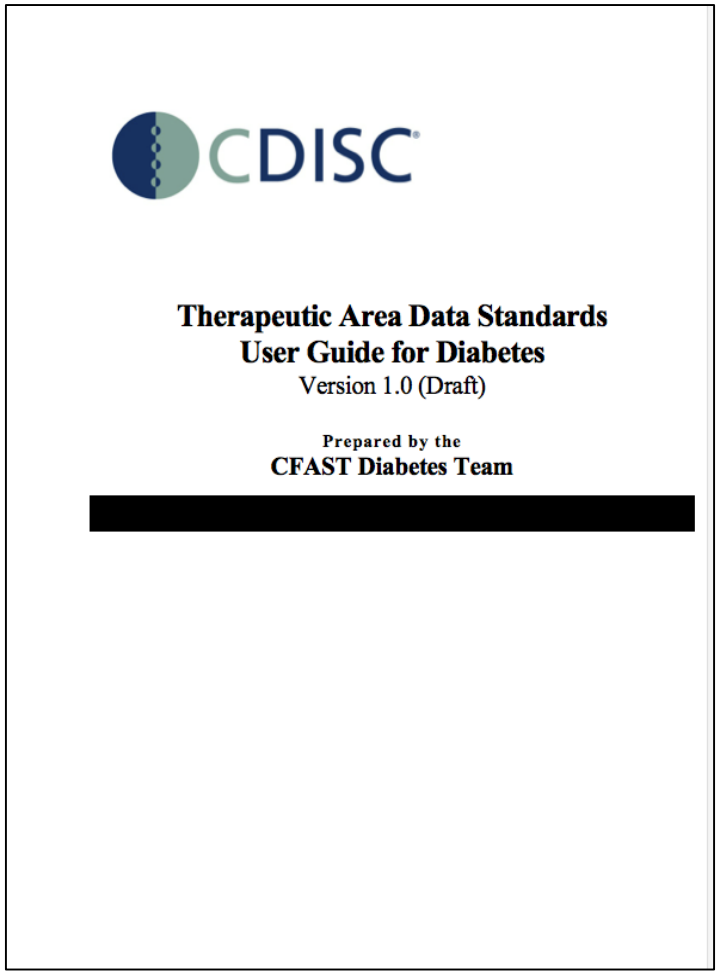
Current CDISC SHARE Content:
SDTM 1.2 (IG 3.1.2), CDASH 1.1, BRIDG 3.2 and ISO21090, CDISC Terminologies

CDISC SHARE

- Will be a global electronic repository for developing, integrating and accessing CDISC metadata standards in electronic format.
- SHARE is envisioned to help users find, understand and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently, and to improve integration and traceability of clinical data from protocol through analysis.

Bold = included in Diabetes UG

Diabetes TAUG



Diabetes Background

- Prevalence (worldwide)*
  - Estimated **366 million** people had diabetes in 2011
  - By 2030, this number will rise to **552 million**
  - **183 million** people (50%) with diabetes are **undiagnosed**
- Mortality*
  - IDF – **4.6 million** people (ages 20-79) died from diabetes in 2011, 8.2% of this age group
- Main types of diabetes
  - Type I - Auto-immune, requires insulin
  - Type II - Insulin resistance, which may be combined with reduced insulin secretion

- Source - International Diabetes Federation (IDF) http://www.idf.org

SDTMIG-style examples

Example 2

In this example the sponsor asked about three specific symptoms. These three symptoms only examples; the sponsor will decide which symptoms are of interest in a particular study. In the case shown in this example, the subject experienced a hypoglycemic event with two of the three symptoms queried.

Row 1: Shows the subject's first hypoglycemic event. Since the CRF probed for hypoglycemia, CEPRESP=Y. The pre-specified term from the CRF appears in CETERM, while the MedDRA Preferred Term appears in CEDECOD. The timing of this event is described by CESTDTC and by treating the first hypoglycemic event as a time point for data collection, represented by CETPT = HYPO 1.

Rows 2: Shows that the subject experienced tremors/trembling in conjunction with hypoglycemic event. The pre-specified term from the CRF is shown in CETERM, while the MedDRA preferred term is shown in CEDECOD. It is generally good practice to choose CRF text which corresponds to a MedDRA term, but in this case the sponsor felt that the combined term "TREMORS/TREMBLING" would be clearer than either "TREMORS" or "TREMBLING" alone. However, since both "Tremor" and "Trembling" are MedDRA Lower Level Terms under the Preferred Term "Tremor" the coding of the term used on the CRF is unambiguous.

Rows 3-4: Show that the subject experienced sweating, but did not experience dizziness in conjunction with hypoglycemic event. The terms shown in CETERM are both MedDRA Lower Level Terms, while those shown in CEDECOD are the associated MedDRA Preferred Terms. The sponsor chose to use the Lower Level Term "SWEATING" in preference to the Preferred Term "Hyperhidrosis."

ce.xpt

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CEDECOD	CECAT	CEPRESP	CEOCCUR	CESTDTC	CETPT
1	XYZ	CE	XYZ-001-001	1	HYPOGLYCEMIA	Hypoglycaemia	HYPO EVENTS	Y	Y	2013-09-01T11:00	HYPO 1
2	XYZ	CE	XYZ-001-001	4	TREMORS/TREMBLING	Tremor	HYPO SYMPTOMS	Y	Y		HYPO 1
3	XYZ	CE	XYZ-001-001	5	SWEATING	Hyperhidrosis	HYPO SYMPTOMS	Y	Y		HYPO 1
4	XYZ	CE	XYZ-001-001	6	DIZZINESS	Dizziness	HYPO SYMPTOMS	Y	N		HYPO 1

CDISC SHARE Metadata

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable	
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.code	*from drug dictionary*	Pre-specified class	in CMCAT	Block for pre-specified properties of kind of medication on which question or data collection is focused
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.displayName.value	*from drug dictionary*			
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.originalText.value	*free text*			
MEDCRIT.Defined.Drug.code.CD.code	*from drug dictionary*	Pre-specifieddrug	CMTRT	
MEDCRIT.Defined.Drug.code.CD.displayName.value	*from drug dictionary*			
MEDCRIT.Defined.Drug.code.CD.originalText.value	*free text*			
MEDCRIT.Defined.Drug.formCode.CD.code	*from codelist C66726*	Pre-specified dose form	in CMCAT	
MEDCRIT.Defined.Drug.formCode.CD.displayName.value	*from codelist C66726*			
MEDCRIT.Defined.Drug.formCode.CD.originalText.value	*free text*			
MEDCRIT.Defined.Drug.description.ST.value	*free text*	Pre-specified description	in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code	*from codelist C66729*	Pre-specified route of administration	in CMCAT	Block for pre-specified properties of kind of medication administration on which question or data collection is focused
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	*from codelist C66729*			
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code	*from codelist C74456*	Pre-specified target site	in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value	*from codelist C74456*			
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.originalText.value	*free text*			
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code	*from codelist C74456*	Pre-specified site of administration	in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value	*from codelist C74456*			
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value	*free text*			
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229		in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value	RIGHT, LEFT			
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.code	*sponsor codelist*	Pre-specified indication	in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.displayName.value	*sponsor codelist*			
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.originalText.value	*free text*			
CMQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601			Block for pre-

Shows BRIDG basis and detailed values

CDASH Annotated CRF example

CETERM = Hypoglycemic Event
CECAT = HYPO EVENTS

Any Hypoglycemic Events Experienced?	No Yes (If yes complete for each event) CEYN
Sponsor Defined ID CESPID	001
Date/Time of Event CESTDTC	-- --- ---- (DD-MMM-YYYY) - -:- - (24 hour clock) CESTDAT CESTTIM
When Did the Hypoglycemic Event Occur?	Between Bedtime and Waking Between Waking and Bedtime FAORRES when OBJ= Hypoglycemic Event and FATEST= "When Did the Hypoglycemic Event Occur?"
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? LBSTAT	No Yes (If yes enter result and unit below) LBPERF
	- - - - Glucose Result LBORRES mg/dL mmol/L LBORRESU
Last Study Medication Taken	----------Name/Reference EXTRT
EXSTDTC	-- --- ---- (DD-MMM-YYYY) - -:- - (24 hour clock) EXSTDAT EXSTTIM
	- - - dose EXDOSE - - - units EXDOSU EXDSTXT
Last Concomitant Diabetic Medication Taken	----------Name/Reference CMTRT
CMSTDTC	-- --- ---- (DD-MMM-YYYY) - -:- - (24 hour clock) CMSTDAT CMSTTIM
	- - - dose CMDOSE - - - units CMDOSU CMDSTXT
Date/Time of Last Meal MLSTDTC	-- --- ---- (DD-MMM-YYYY) - -:- - (24 hour clock) MLSTDAT MLSTTIM

CDASH Metadata Table

Question Text	Prompt	CDASH Variable Name	CDASH Core	SDTM Variable Name	SDTM Core	Case Report Form completion instructions	Mapping Instructions	Implementation Instructions
Any Hypoglycemic Events Experienced?	Any Hypoglycemic Events Experienced?	CEYN	O	N/A	N/A	Indicate whether or not any hypoglycemic events occurred	This variable does not map to SDTM	Primary intent/purpose of field is to help with data cleaning and monitoring
Sponsor Defined ID		CESPID	HR	CESPID	Perm			Can be pre-populated Row or Sequence Number to Identify Event (SPID)
Date/Time of Event		CESTDAT CESTTIM	HR	CESTDTC	Exp	Record start date using DD-MMM-YYYY format. Record time using a 24 hour clock.	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.	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.
Hypoglycemic Term		NA	O	CETERM	Req			Not typically entered by an investigative site. May appear as a label or header on the case report form.
When Did the Hypoglycemic Event Occur?		FAORRES	HR	FAORRES	Exp	Record the time period during which the hypoglycemic event occurred	FAORRES when OBJ= Hypoglycemic Event, and FATEST= "When Did the Hypoglycemic Event Occur?"	Recommend response choices: "Between Bedtime and Waking" and "Between Waking and Bedtime".

Key Diabetes Concepts (1)

Disease Assessments

- 9-Point Self-Monitoring Blood Glucose Profile

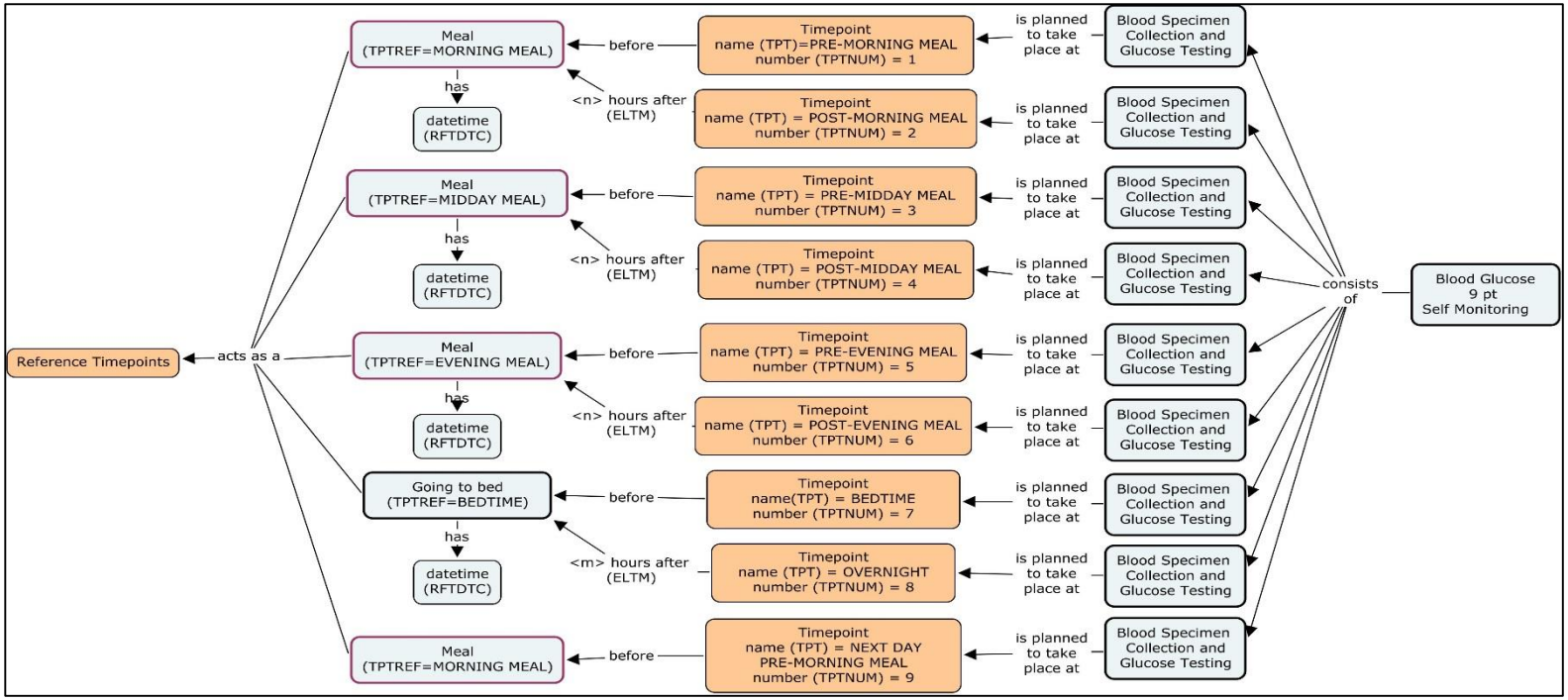
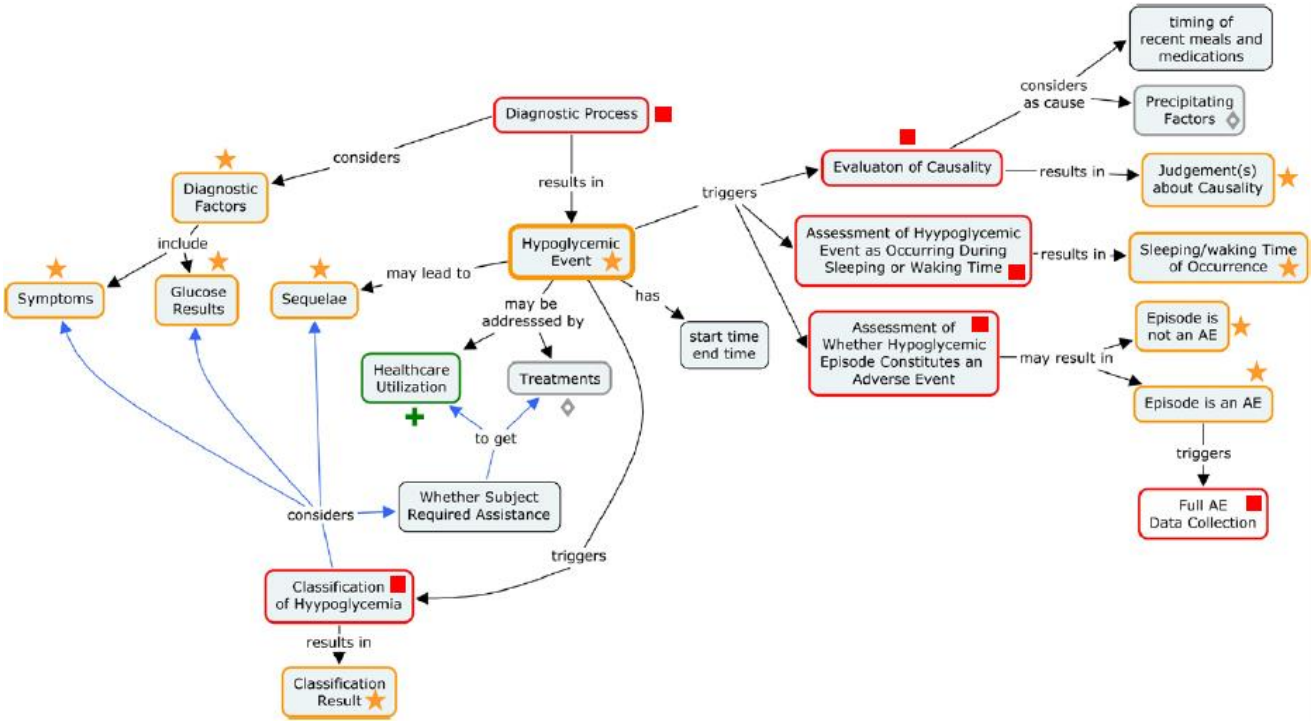


Diagram 6: 9-Point Self-Monitoring Blood Glucose Profile

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 breakfast. The clinical study protocol determines the following: (1) Number of time points (e.g., up to 9); (2) Number of hours <*n*> post-meal; (3) Number of hours <*m*> after bedtime.

Key Diabetes Concepts (2)

- Hypoglycemia



Hypoglycemic Event
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.

Diabetes – Public Review – New Draft Domains

- Two new SDTM Draft Domains for review
- Procedure Agents (AG) – also reviewed in Asthma

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.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	AG	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
AGSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req

- Meal Data (ML) – new in Diabetes UG

ML - Meal Data

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

ml.xpt, Meals — Interventions, Version 3.x.x,. One record per recorded meal per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	ML	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
MLSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MLGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm

Diabetes – Public Review – Disease Milestone Proposal

- Disease Milestone Proposal
  - draft modification to SDTM
  - Illustrated with examples for Hypoglycemia Events

Subject Disease Milestones (SM)

Code – Description/Overview for Name Domain Model

[No Controlled Terminology definition at this time.]

This domain is designed to record the timing, for a particular subject, of disease milestones, observations or activities which have been defined in the Trial Disease Milestones (TM) dataset.

Code – Specification for Name Domain Model

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

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study	Req
DOMAIN	Domain	Char	SM	Identifier	Two-character abbreviation for the domain	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies	Req
SMSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a	Req

Trial Disease Milestones (TM)

Code – Description/Overview for Name Domain Model

[No Controlled Terminology definition at this time.]

This domain is used to declare as "disease milestones" observations or activities which are expected to occur in the course of the disease under study and whose timing is of interest for the study.

Code – Specification for Name Domain Model

tm.xpt – Trial Disease Milesteons, Type, version 3.x.x. One record per disease milestone type.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study	Req
DOMAIN	Domain	Char	TM	Identifier	Two-character abbreviation for the domain	Req
MIDS	Disease Milestone Short	Char		Timing	Name of the disease milestone (for those that can occur only once) or of the	Req

Diabetes – Public Review

- 30-day public review upcoming
- Download the document using Adobe Reader (http://get.adobe.com/reader/)
- Submit comments using the CDISC public commenting tool located on the CDISC website located here: http://cdiscportal.digitalinfuzion.com/CT/Review%20Documents/Forms/AllItems.aspx

Future Diabetes Training

- Future diabetes implementation training will include:
  - Implementation examples
  - Exercises
  - Tests to check knowledge level
  - And additional detail
- Training will be delivered online soon after publication of the standard
  - so you can train at your convenience

CFAST Diabetes Team

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Diabetes – Public Review Webinar

Multiple Sclerosis Therapeutic Area User Guide – v1.0

Bess LeRoy
Jon Neville
CDISC Webinar, 20 March 2014

Acknowledgements

- Developed under the Multiple Sclerosis Outcomes Assessment Consortium (MSOAC) funded by the National MS Society

- Inputs were based on common data elements from the National Institute for Neurological Disorder and Stroke (NINDS)

AGENDA

- *Concepts covered in this TA Guide*
- *Use cases and examples*
  - *Domains*
  - *Variables*
  - *Controlled Terminology*
- *Public review– feedback request*
- *Q & A*

Orientation to the MS User Guide

- Section 1- Introduction
- Section 2 - Diagnosis and Disease Characteristics
- Section 3 - Disease Assessments
  - Visual Acuity/Contrast Sensitivity
  - Retinal Nerve Fiber Layer Thickness
  - Visual Evoked Potential
  - Functional Tests and Questionnaires
- Section 4 - Additional Assumptions for Domains

Diagnosis and disease characteristics

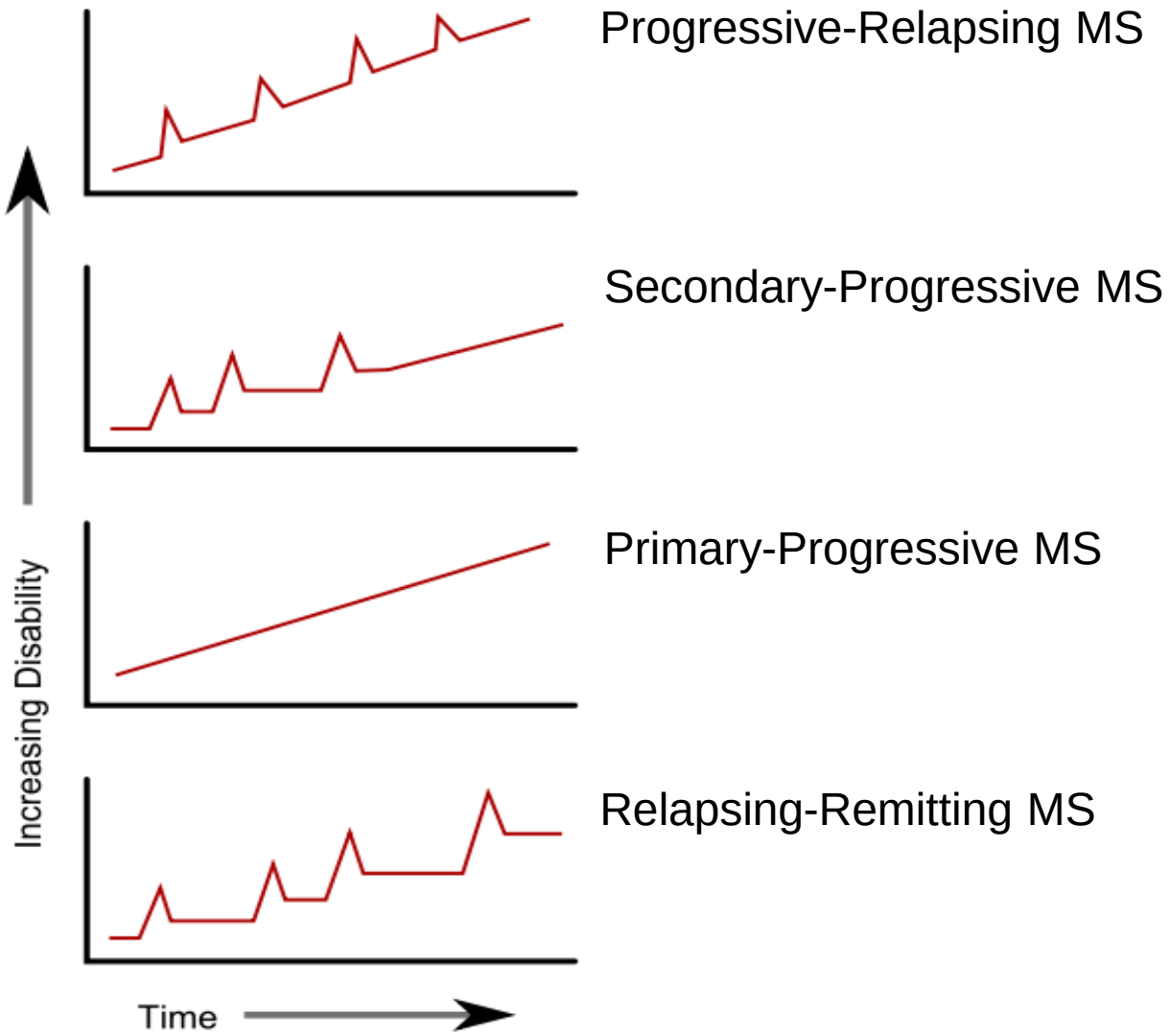
- MS is a neurodegenerative *autoimmune disease*; the immune system attacks components of the central nervous system (CNS) including the brain, spinal cord, and optic nerves. Associated symptoms and sequelae result from lesions (scarring) on these CNS components

- Typical symptoms include problems with motor function, vision, coordination, and sensory disturbances

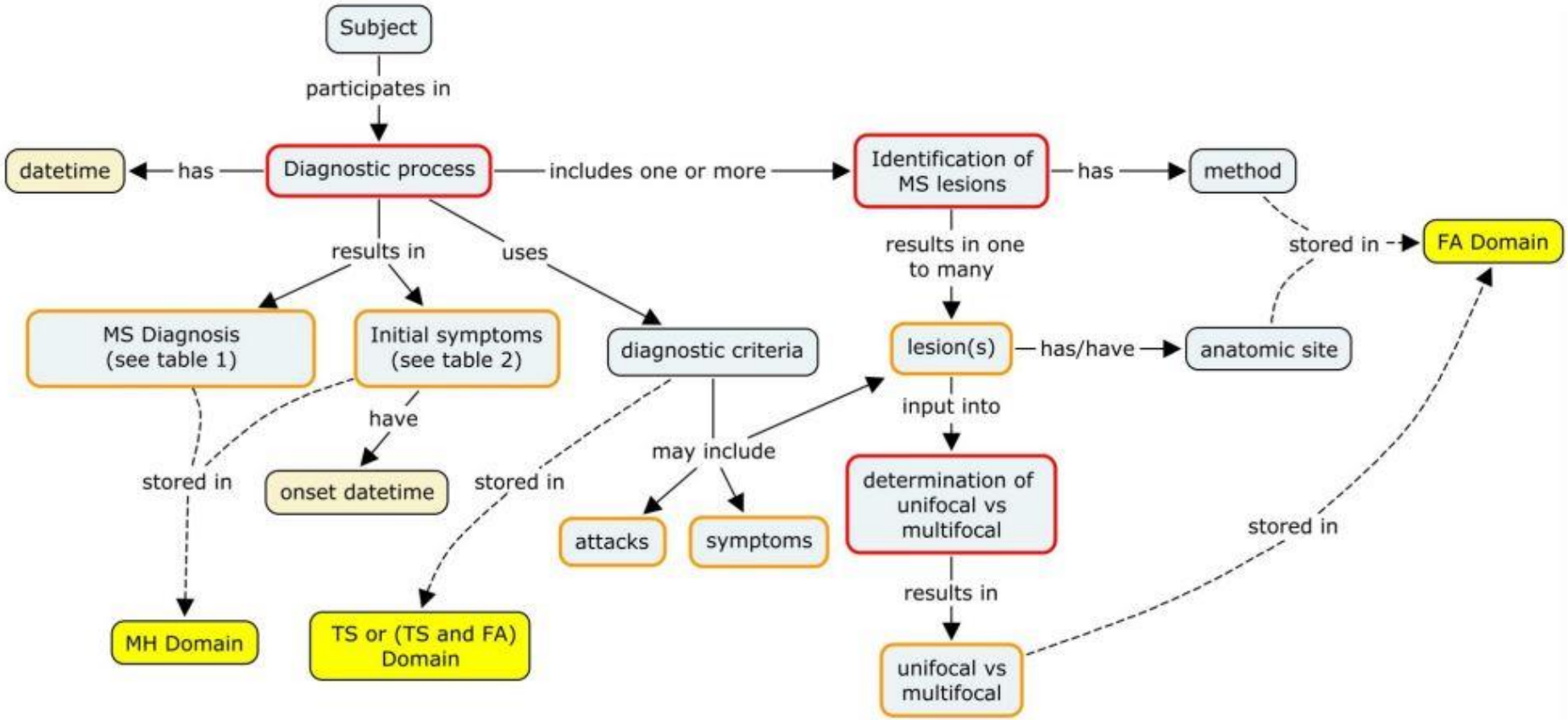
- Diagnosis is typically made via a combination of clinical exam and imaging, and is based on a set of diagnostic criteria (e.g., the McDonald 2010 criteria).
  - Depending on variation across subjects, these criteria are represented at the trial- or subject-level

- Disease course can be highly variable and may change (worsen) over time. There are four distinct disease courses that describe the majority of cases

Disease course



Diagnosis and disease characteristics



McDonald 2010 Criteria

*RRMS**:

☐ ≥ 2 attacks; objective clinical evidence of ≥ 2 lesions or objective clinical evidence of 1 lesion with reasonable historical evidence of a prior attack

☐ ≥ 2 attacks; objective clinical evidence of 1 lesion

Dissemination in space, demonstrated by

- ≥ 1 T2 lesion in at least 2 of 4 MS-typical regions of the CNS (periventricular, juxtacortical, infratentorial, or spinal cord); or

☐ 1 attack; objective clinical evidence of ≥ 2 lesions

Dissemination in time, demonstrated by:

- Simultaneous presence of asymptomatic gadolinium-enhancing and nonenhancing lesions at any time; or
- A new T2 and/or gadolinium-enhancing lesion(s) on follow-up MRI, irrespective of its timing with reference to a baseline scan; or

☐ 1 attack; objective clinical evidence of 1 lesion (clinically isolated syndrome)

Dissemination in space and time, demonstrated by:

For DIS:

- ≥ 1 T2 lesion in at least 2 of 4 MS-typical regions of the CNS (periventricular, juxtacortical, infratentorial, or spinal cord); and

For DIT:

- Simultaneous presence of asymptomatic gadolinium-enhancing and nonenhancing lesions at any time; or
- A new T2 and/or gadolinium-enhancing lesion(s) on follow-up MRI, irrespective of its timing with reference to a baseline scan; or

Data examples for diagnostic criteria: trial level

Rows 1-2: Show medical history records for two different subjects both diagnosed with RRMS.

mh.xpt

Row	STUDYID	DOMAIN	USUB	MHTERM	MHDECOD	MHCAT		MHSTDTC
1	ABC123	MH	MS01	RRMS	Relapsing Remitting Multiple Sclerosis	PRIMARY DIAGNOSIS		2011-04-03
2	ABC123	MH	MS01	RRMS	Relapsing Remitting Multiple Sclerosis	PRIMARY DIAGNOSIS		2011-11-16

Representing Diagnostic Cr

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSPARMCD	TSPARM	TSVAL
1	ABC123	TS	1	DXCRIT	Diagnostic Criteria	MCDONALD 2010

McDonald 2010 Criteria

RRMS:*

☐ ≥ 2 attacks; objective clinical evidence of ≥ 2 lesions or objective clinical evidence of 1 lesion with reasonable historical evidence of a prior attack

☐ ≥ 2 attacks; objective clinical evidence of 1 lesion

Dissemination in space, demonstrated by

- ≥ 1 T2 lesion in at least 2 of 4 MS-typical regions of the CNS (periventricular, juxtacortical, infratentorial, or spinal cord); or

☐ 1 attack; objective clinical evidence of ≥ 2 lesions

Dissemination in time, demonstrated by:

- Simultaneous presence of asymptomatic gadolinium-enhancing and nonenhancing lesions at any time; or
- A new T2 and/or gadolinium-enhancing lesion(s) on follow-up MRI, irrespective of its timing with reference to a baseline scan; or

☐ 1 attack; objective clinical evidence of 1 lesion (clinically isolated syndrome)

Dissemination in space and time, demonstrated by:

For DIS:

- ≥ 1 T2 lesion in at least 2 of 4 MS-typical regions of the CNS (periventricular, juxtacortical, infratentorial, or spinal cord); and

For DIT:

- Simultaneous presence of asymptomatic gadolinium-enhancing and nonenhancing lesions at any time; or
- A new T2 and/or gadolinium-enhancing lesion(s) on follow-up MRI, irrespective of its timing with reference to a baseline scan; or

Data examples for diagnostic criteria: subject level

Rows 1-2: Show how to represent subject-level diagnostic criteria information. In this example, each subject met the McDonald 2010 criteria through a different presentation and evidence of RRMS. The specific diagnostic sub-criterion met is represented in FAORRES/FASTRESC. . The McDonald 2010 criteria were used to obtain this diagnosis as indicated in the FARESRNM/FARESRVR values. FALNKID and FAOBJ tie this record to the subject's diagnosis of RRMS in the mh.xpt example above.

famh.xpt

Row	STUDYID	DOMAIN	USUBJID
1	ABC123	FAMH	MS01-102
2	ABC123	FAMH	MS01-103

FATESTCD	FATEST	FAOBJ
DXCRITMT	Diagnostic Criteria Met	Relapsing Remitting Multiple Sclerosis
DXCRITMT	Diagnostic Criteria Met	Relapsing Remitting Multiple Sclerosis

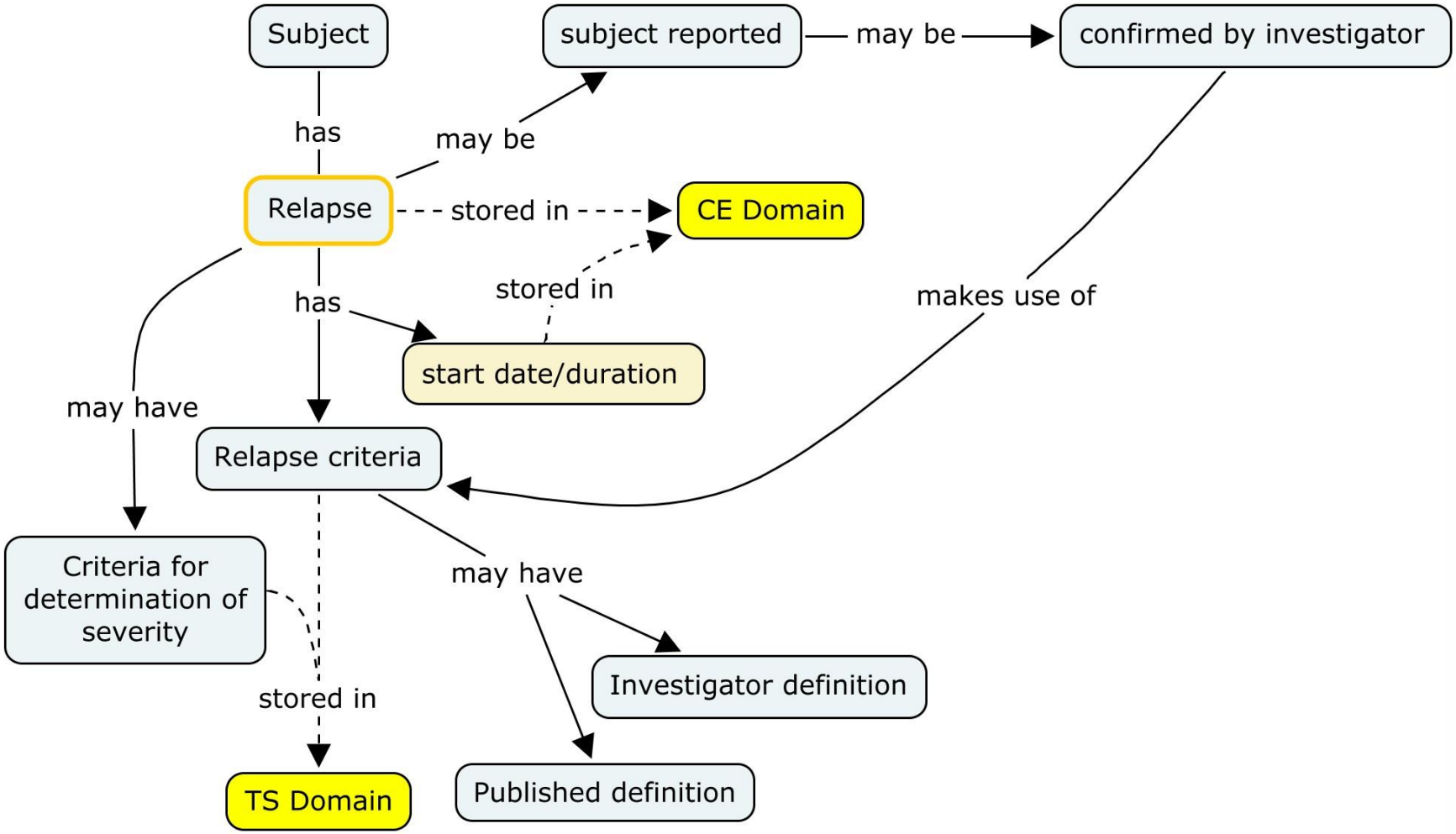
famh.xpt

Row		FASTRESC	FARESRNM	FARESRVR
1 (cont)	Greater ti evidence clinical e evidence	Greater than or equal to 2 attacks; objective clinical evidence of greater than or equal to 2 lesions or objective clinical evidence of 1 lesion with reasonable historical evidence of a prior attack	MCDONALD	2010
2 (cont)	Greater ti evidence by greate typical re	Greater than or equal to 2 attacks; objective clinical evidence of 1 lesion. Dissemination in space, demonstrated by greater than or equal to 1 T2 lesion in at least 2 of 4 MS-typical regions of the CNS	MCDONALD	2010

Relapse

- Relapses are symptomatic flare-ups associated with progression of the disease and are monitored as outcomes in MS trials
- Determination of whether relapse has occurred is made via a series of criteria that may be vary across protocols
  - Criteria may be investigator-defined
  - Criteria may have a published definition
- Depending on variation across subjects, these criteria are represented at the trial- or subject-level

Relapse



Data examples for relapse

Row 1: Shows that the subject was diagnosed with RRMS in 1999.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD		MHSCAT	MHSTDTC
1	ABC123	MH	MS01-104	1	RRMS	Relapsing Remitting Multiple Sclerosis	OSIS	ONSET COURSE	1999-03

Row 1: Shows that subject had a relapse event in 2012 of moderate severity as defined by FREEDOMS study protocol (2 point increase on the Expanded Disability Status Scale, data not shown).

Row 2: Shows that subject had another relapse event in 2013 of mild severity as defined by FREEDOMS study protocol (0.5 point increase on the Expanded Disability Status Scale, data not shown).

ce.xpt

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CESEV	TC	CEENDTC
1	ABC123	CE	MS01-104	1	Multiple Sclerosis Relapse	MODERATE	13	2012-05-29
2	ABC123	CE	MS01-104	2	Multiple Sclerosis Relapse	MILD	01	2013-08-04

Row 1: Shows how to represent data about relapse criteria at the trial level.

Row 2: Shows how to represent data about severity criteria at the trial level.

ts.xpt

Row	STUD	TSPARMCD	TSPARM	TSVAL	TSVAL1	TSVAL2
1	ABC	RLPSCRIT	Relapse Criteria	Appearance of a new neurologic abnormality or the worsening of a pre-existing neurologic abnormality that was previously stable or improving, at least 30 days after onset of a preceding clinical	demyelinating event, present for at least 24 hours, and occurring in the absence of fever or infection. Confirmation was made by an independent rater and had to be	accompanied by an increase of at least half a step (0.5) on the EDSS, 1 point on 2 different function systems (FSs) of the EDSS, or 2 points on 1 FS (excluding the bowel/bladder or cerebral FS)
2	ABC	SEVCRIT	Severity Criteria	Mild severity is defined as a 0.5 point EDSS increase. Moderate severity is defined as a 1 to 2 point EDSS increase. Severe severity is defined as a greater than a 2 point EDSS increase.		

Visual acuity and contrast sensitivity

- Due to optic nerve involvement, visual tests are often used as outcomes assessments in MS, including:
  - High-contrast visual acuity charts (ETDRS)
  - Low-contrast visual acuity charts (Sloan Letter)
  - Contrast sensitivity (Pelli-Robson Test)
- These tests are represented in the new OE domain in SDTM, which makes use of the new EXPUNIT variable

Data examples for visual acuity and contrast sensitivity

Rows 1-3: Show the number of letters correctly identified at 3.2 meters during visual acuity testing using a high-contrast Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart. Each eye is tested separately and then both eyes are together.

Rows 4-6: Show the number of letters correctly identified at 2 meters during visual acuity testing using a Low-Contrast Sloan Letter Chart with a contrast level of 2.5%. Each eye is tested separately and then both eyes are tested together.

Rows 7-9: Show the number of letters correctly identified at 2 meters during visual acuity testing using a Low-Contrast Sloan Letter Chart with a contrast level of 1.25%. ately and then both eyes are

Rows 10-12: Show th sensitivity log score. Each

oe.xpt

Row	STUDYID	DOMAIN	U	EXPUNIT		OEGRPID	OETESTCD		OETSTDTL	OECAT	
1	MS123	OE	M	OD		1	NUMLCOR	Num	Chart Distance 3.2 m	HIGH CONTRAST VISUAL ACUITY	
2	MS123	OE	M	OS		1	NUMLCOR	Num	Chart Distance 3.2 m	HIGH CONTRAST VISUAL ACUITY	
3	MS123	OE	M	OU		1	NUMLCOR	Num	Chart Distance 3.2 m	HIGH CONTRAST VISUAL ACUITY	
4	MS123	OE	M	OD		2	NUMLCOR	Num	Chart Distance 2 m	LOW CONTRAST VISUAL ACUITY	
5	MS123	OE	M	OD		2	NUMLCOR	Num	Chart Distance 2 m	LOW CONTRAST VISUAL ACUITY	
6	MS123	OE	M	OS		2	NUMLCOR	Num	Chart Distance 2 m	LOW CONTRAST VISUAL ACUITY	
7	MS123	OE	M	OS		3	NUMLCOR	Num	Chart Distance 2 m	LOW CONTRAST VISUAL ACUITY	
8	MS123	OE	M	OU		3	NUMLCOR	Num	Chart Distance 2 m	LOW CONTRAST VISUAL ACUITY	
9	MS123	OE	M	OU		3	NUMLCOR	Num	Chart Distance 2 m	LOW CONTRAST VISUAL ACUITY	
10	MS123	OE	M	OD		4	LOGSCORE			CONTRAST VISUAL ACUITY	
11	MS123	OE								CONTRAST SENSITIVITY	
12	MS123	OE								CONTRAST SENSITIVITY	

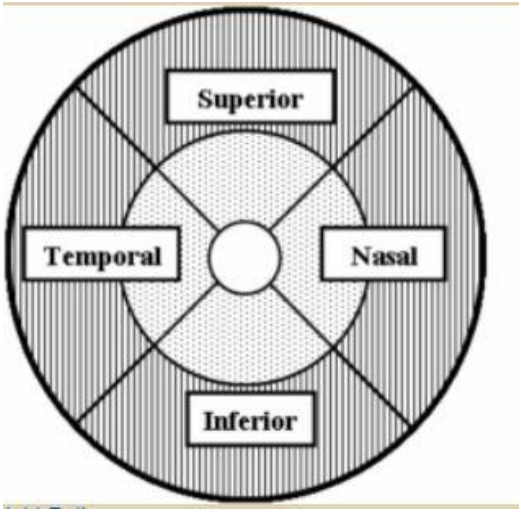
oe.xpt

Row	OESTRESC	OELOC	OELAT	OEMETHOD
1 (cont)	60	EYE	RIGHT	ETDRS EYE CHART
2 (cont)	62	EYE	LEFT	ETDRS EYE CHART
3 (cont)	64	EYE	BILATERAL	ETDRS EYE CHART
4 (cont)	54	EYE	RIGHT	SLOAN LETTER EYE CHART 2.5%
5 (cont)	52	EYE	LEFT	SLOAN LETTER EYE CHART 2.5%
6 (cont)	56	EYE	BILATERAL	SLOAN LETTER EYE CHART 2.5%
7 (cont)	45	EYE	RIGHT	SLOAN LETTER EYE CHART 1.25%
8 (cont)	41	EYE	LEFT	SLOAN LETTER EYE CHART 1.25%
9 (cont)	45	EYE	BILATERAL	SLOAN LETTER EYE CHART 1.25%
10 (cont)	1.49	EYE	RIGHT	PELLI-ROBSON EYE CHART
11 (cont)	1.52	EYE	LEFT	PELLI-ROBSON EYE CHART
12 (cont)	1.65	EYE	BILATERAL	PELLI-ROBSON EYE CHART

Optical coherence tomography (OCT)

- In patients with MS, OCT is used to show thinning of the innermost layer of the retina called the retinal nerve fiber layer (RNFL), which reflects degeneration of neurons and axons in the retina

- Average RNFL thickness is measured in each of the four quadrants (superior, nasal, inferior, and temporal) of both the left and right eyes. Additionally, an average thickness over all four quadrants is calculated



Source: Gupta PK, Asrani S, Freedman SF, El-Dairi M, Bhatti MT. Differentiating glaucomatous from non-glaucomatous optic nerve cupping by optical coherence tomography. Open Neurol J. 2011;5:1–7.

Data examples for OCT

Rows 1-2: Show the average RNFL thickness of the superior quadrant in the right and left eye.
Rows 3-4: Show the average RNFL thickness of the nasal quadrant in the right and left eye.
Rows 5-6: Show the average RNFL thickness of the inferior quadrant in the right and left eye.
Rows 7-8: Show the average RNFL thickness of the temporal quadrant in the right and left eye.
Rows 9-10: Show the average RNFL thickness over all four quadrants in the right and left eye.
Rows 11-12: Show the signal strength of the OCT images from the right and left eye and link them to the thickness measurements via MOGRPID.

mo.xpt

Row	STUDYID	DOMAIN	USU	EXPUNIT	DEVID	MOSEQ	MOGR	MOTESTCD	MOTEST	MOTSTDTL	RESU	MOSTRESC	MOSTRESN
1	MS123	MO	MS0	OD	345	1	1	AVGTHICK	Average Thickness	Intra-quadrant		90.9	90.9
2	MS123	MO	MS0	OS	345	2	2	AVGTHICK	Average Thickness	Intra-quadrant		91.6	91.6
3	MS123	MO	MS0	OD	345	3	1	AVGTHICK	Average Thickness	Intra-quadrant		92.7	92.7
4	MS123	MO	MS0	OS	345	4	2	AVGTHICK	Average Thickness	Intra-quadrant		91.5	91.5
5	MS123	MO	MS0	OD	345	5	1	AVGTHICK	Average Thickness	Intra-quadrant		90.3	90.3
6	MS123	MO	MS0	OS	345	6	2	AVGTHICK	Average Thickness	Intra-quadrant		93.1	93.1
7	MS123	MO	MS0	OD	345	7	1	AVGTHICK	Average Thickness	Intra-quadrant		92.3	92.3
8	MS123	MO	MS0	OS	345	8	2	AVGTHICK	Average Thickness	Intra-quadrant		93.3	93.3
9	MS123	MO	MS0	OD	345	9	1	AVGTHICK	Average Thickness	Intra-quadrant		91.6	91.6
10	MS123	MO	MS0	OS	345	10	2	AVGTHICK	Average Thickness	Intra-quadrant		92.4	92.4
11	MS123	MO	MS0	OD	345	11	1	AVGTHICK	Av	ll Quadrants		8	8
12	MS123	MO	MS0	OS	345	12	2	AVGTHICK	Av	ll Quadrants		9	9
				OD				SIGSTRTH					
				OS				SIGSTRTH					

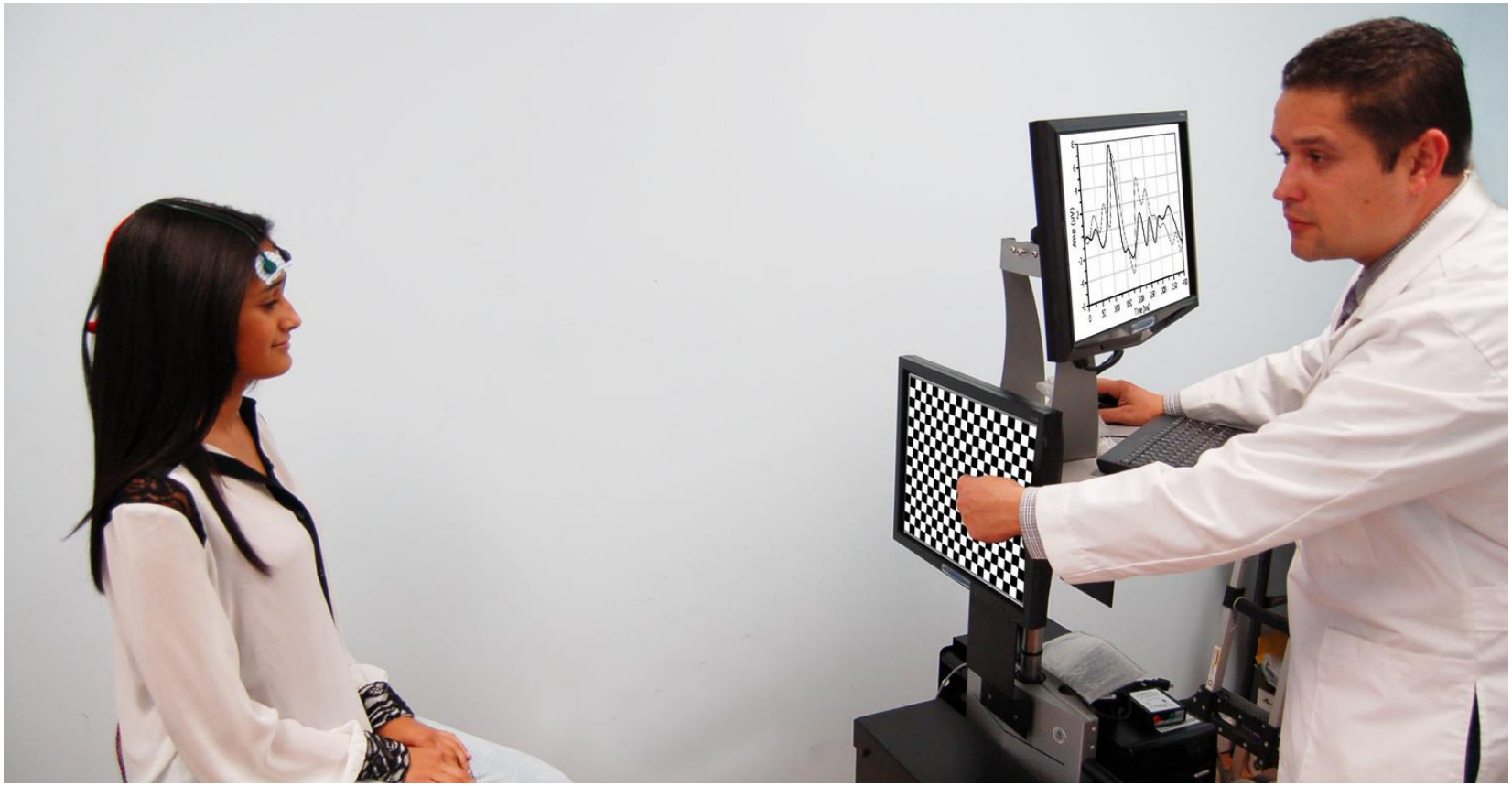
mo.xpt

Row	MOSTRESU		MOLOC		MODIR		
1 (cont)	um	RNFL	RETINAL NERVE FI		SUPERIOR		-08
2 (cont)	um	RNFL	RETINAL NERVE FI		SUPERIOR		-08
3 (cont)	um	RNFL thickness is normal	RETINAL NERVE FIBER LAYER		NASAL		-08
4 (cont)	um	RNFL thickness is normal	RETINAL NERVE FIBER LAYER	LEFT	NASAL	RUS OCT	2011-02-08
5 (cont)	um	RNFL thickness is normal	RETINAL NERVE FIBER LAYER	RIGHT	INFERIOR	RUS OCT	2011-02-08
6 (cont)	um	RNFL thickness is normal	RETINAL NERVE FIBER LAYER	LEFT	INFERIOR	RUS OCT	2011-02-08
7 (cont)	um	RNFL thickness is normal	RETINAL NERVE FIBER LAYER	RIGHT	TEMPORAL	RUS OCT	2011-02-08
8 (cont)	um	RNFL thickness is normal	RETINAL NERVE FIBER LAYER	LEFT	TEMPORAL	RUS OCT	2011-02-08
9 (cont)	um	RNFL thickness is normal	RETINAL NERVE FIBER LAYER	RIGHT		RUS OCT	2011-02-08
10 (cont)	um	RNFL thickness is normal	RETINAL NERVE FIBER LAYER	LEFT		RUS OCT	2011-02-08
11 (cont)				RIGHT		RUS OCT	2011-02-08
12 (cont)				LEFT		RUS OCT	2011-02-08

Visual evoked potential (VEP)

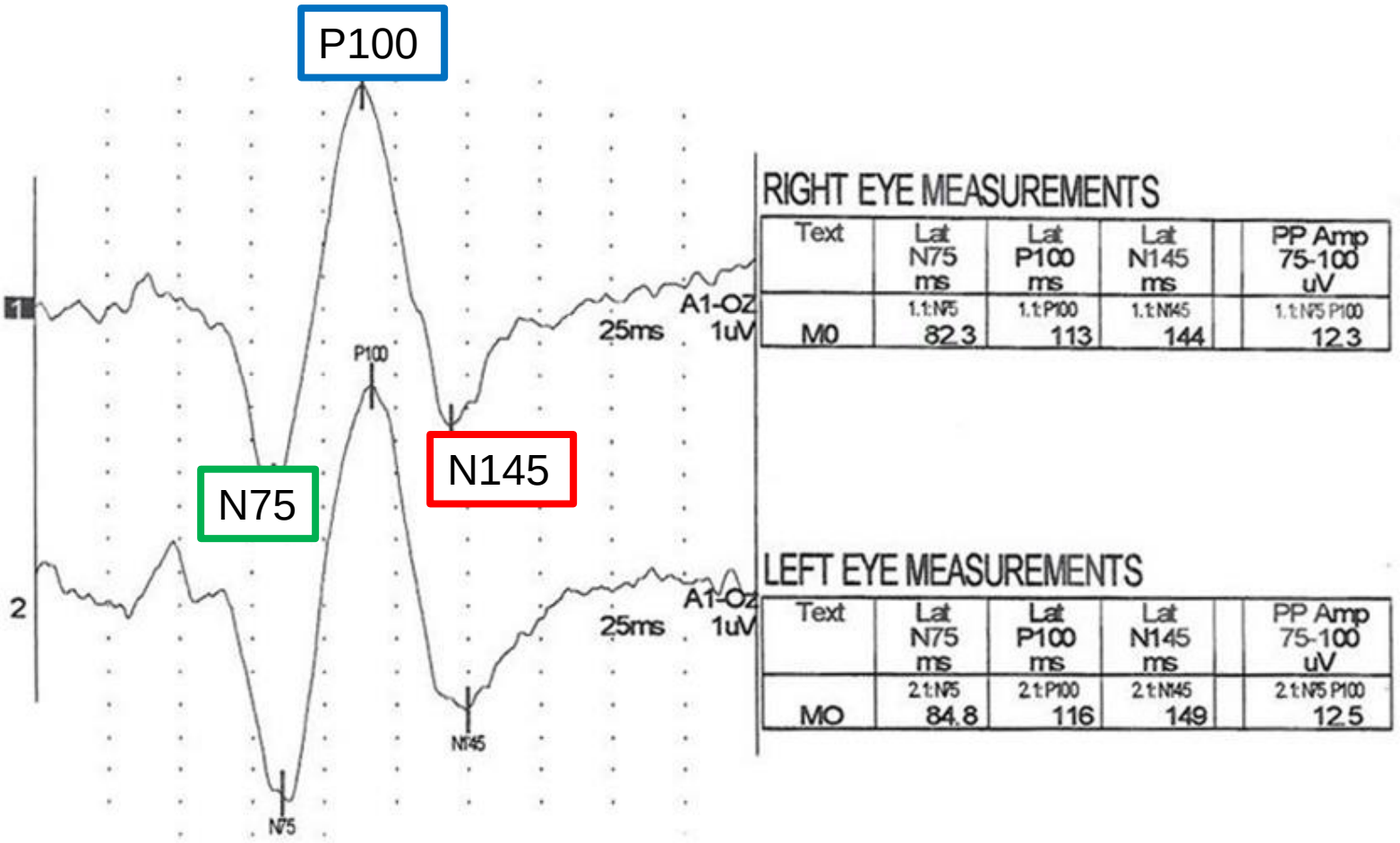
- VEP tests are used to measure the brain's electrical activity and can detect the slowing of electrical conduction along the optic nerve

VEP



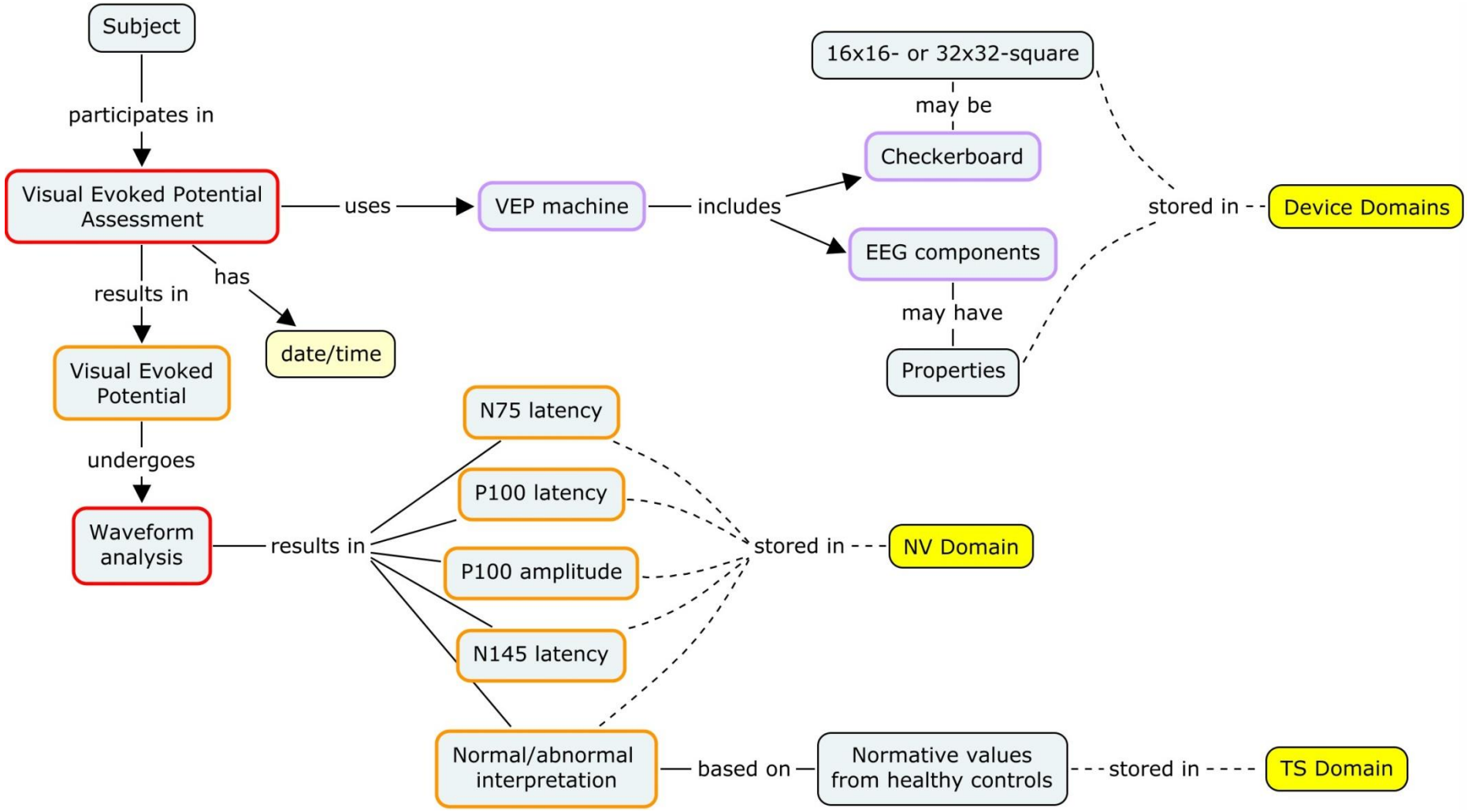
Source: http://www.emimaging.net/

VEP



Source: http://webvision.med.utah.edu/book/electrophysiology/visually-evoked-potentials

VEP


Subject
participates in
Visual Evoked Potential Assessment
uses
VEP machine
includes
Checkerboard
16x16- or 32x32-square
may be
EEG components
may have
Properties
stored in
Device Domains
has
date/time
results in
Visual Evoked Potential
undergoes
Waveform analysis
results in
N75 latency
P100 latency
P100 amplitude
N145 latency
stored in
NV Domain
Normal/abnormal interpretation
based on
Normative values from healthy controls
stored in
TS Domain

VEP data examples

Example 1

The NV domain should be used to represent the VEP latencies, P100 peak to peak amplitude, and their interpretations. SPDEVID allows the results to be connected to both the VEP testing device as well as the checkerboard size.

Rows 1-4: Show
Row 5: Show
Rows 6-9: Show
Row 10: Show

nv.xpt

Row	STUDYID	DOMAIN	U
1	MS123	NV	
2	MS123	NV	
3	MS123	NV	
4	MS123	NV	
5	MS123		
6	MS123		
7	MS123		
8	MS123		
9	MS123		
10	MS123		

NVGRPID	NVTESTCD	NVTEST	NVTSTDTL	NVORRES	NVORRESU
1	VEP	Visual Evoked Potential	N75 Latency	79.8	ms
1	VEP	Visual Evoked Potential	P100 Latency	129	ms
1	VEP	Visual Evoked Potential	N145 Latency	181	ms
1	VEP	Visual Evoked Potential	P100 Amplitude	5.02	uV
1	INTP	Interpretation		ABNORMAL	
2	VEP	Visual Evoked Potential	N75 Latency	83.8	ms
					ms
					ms
					uV
				AL	

NVORNRLO	NVORNRHI	NVNRIND	NVLOC	NVLAT	NVMETHOD
54.68	94	NORMAL	EYE	RIGHT	EEG
76.75	113.71	ABNORMAL	EYE	RIGHT	EEG
114.27	156.03	ABNORMAL	EYE	RIGHT	EEG
5.26	12.64	ABNORMAL	EYE	RIGHT	EEG
			EYE	RIGHT	EEG
54.42	95.1	NORMAL	EYE	LEFT	EEG
76.9	115.78	ABNORMAL	EYE	LEFT	EEG
115.65	157.65	ABNORMAL	EYE	LEFT	EEG
4.78	12.7	ABNORMAL	EYE	LEFT	EEG
			EYE	LEFT	EEG

nv.xpt

Row	NVST									VDTC
1 (cont)	7									3-02-08
2 (cont)	1									3-02-08
3 (cont)	1									3-02-08
4 (cont)	5									3-02-08
5 (cont)	ABNO									3-02-08
6 (cont)	8									3-02-08
7 (cont)	1									3-02-08
8 (cont)	1									3-02-08
9 (cont)	4.37	4.37	uV	4.78	12.7	ABNORMAL	EYE	LEFT	EEG	2013-02-08
10 (cont)	ABNORMAL						EYE	LEFT	EEG	2013-02-08

Functional Tests and Questionnaires

- The majority of the outcomes assessments described as part of MS v1.0 fall in this category
- A new domain, Functional Tests (FT), was developed to accommodate task-based scales that measure subjects' mobility, dexterity, or cognitive ability
- New variable –REPNUM: used to indicate the chronological order of repeated tests. Enables the reuse of FTTESTCD and FTTEST values when tests are repeated.
- These assessments are maintained as standalone supplements on the CDISC website

FT/QS table

Kurtzke Expanded Disabilty Status Scale (EDSS)	Fatigue Severity Scale (FSS)
Kurtzke Functional Systems Scores (KFSS)	Visual Functioning Questionnaire – 25 (VFQ-25 INTERVIEWER ADMINISTERED) Version 2000
Bladder Control Scale (BLCS)	Visual Functioning Questionnaire – 25 (VFQ-25 SELF-ADMINISTERED) Version 2000
Bowel Control Scale (BWCS)	European Quality of Life Five Dimension Three Level Scale (EQ-5D-3L)
Impact of Visual Impairment Scale (IVIS)	European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L)
Modified Fatigue Impact Scale (MFIS)	Timed 25-Foot Walk (T25FW)*
Multiple Sclerosis Quality of Life-54 (MSQOL-54)	Nine-Hole Peg Test (NHPT)*
RAND 36-Item Health Survey 1.0 (RAND-36 V1.0)	Paced Auditory Serial Addition Test (PASAT)*
36-Item Short-Form Health Survey (SF-36)	Symbol Digit Modalities Test (SDMT)*
Disease Steps	Hauser Ambulation Index*
Patient Determined Disease Steps (PDDS)	Timed Up and Go (TUG)*
Functional Assessment of Multiple Sclerosis (FAMS)	6 Minute Walk Test (6MWT)*

*Supplement in development

Conclusion

- The MS User Guide is currently out for public review until April 1st
- Submit comments via the CDISC tracker on the CDISC Portal
- We are organizing a deep dive webinar for next week, please let us know if you are interested!
- For questions please contact Bess LeRoy (bleroy@c-path.org) or Jon Neville (jneville@c-path.org)

Cardiovascular User Guide

Amy Palmer, CDISC
Steve Kopko, CDISC
CDISC Webinar, 20 March 2014

Strength *through Collaboration*

Therapeutic Area Data Standards
User Guide for Cardiovascular Disease

Version 1.0 Draft

Prepared by the

CFAST Cardiovascular Team

[redacted]

Notes to Readers

- This is the draft version 1.0 of the Therapeutic Area Data Standards User Guide for Cardiovascular Disease. It is intended for public review only and is not a final version.
- This document is aligned with the SDTM v1.4 and SDTMIG v3.2, but anticipates upcoming changes in version 1.5/3.3.
- The TAUG v1.0 package includes this user guide, as well as separate documents including 13 released and one draft domains.

Revision History

Date	Version	Summary of Changes
2014-03-20	1.0 Draft	Draft for Public Review

See Appendix G for Representations and Warranties, Limitations of Liability, and Disclaimers

Therapeutic Area User Guide for Cardiovascular Diseasev1.0 (TAUG-CV v1.0)

Organized into 2 sections – Cardiovascular (CV) Endpoints and Acute Coronary Syndrome (ACS)

The CV Endpoints section includes the following:

- Death (attribution of cause of death)
- Myocardial infarction (MI)
- Stroke / transient ischemic attack (TIA)
- Percutaneous coronary intervention (PCI)
- Peripheral vascular intervention (PVI)
- Unstable angina hospitalization
- Heart failure event

These data elements were provided by Duke Clinical Research Institute (DCRI)

Therapeutic Area User Guide for Cardiovascular Diseasev1.0 (TAUG-CV v1.0)

The ACS section will provide use-case examples of:

- ST elevation myocardial infarction (STEMI)
- Myocardial ischemia
- Pacemaker implant

The Therapeutic Area User Guide-Cardiovascular Disease v1.0 will be released for public review in the next few weeks.

More detailed webinar planned for Thursday, April 3rd

Questions