



2022

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INTERCHANGE

13-14 JUNE | VIRTUAL EVENT

## SDTM Mapping for the T1Dexi Trial Using the T1D TAUG

John Owen, CDISC

# Meet the Speaker

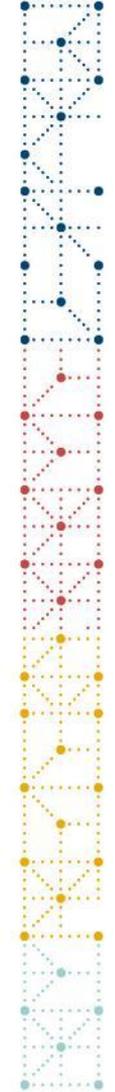
John Owen

**Title:** Head, PMO

**Organization:** CDISC



John Owen has worked with CDISC for over 7-years. After supporting the project management of various Therapeutic Area User Guides, John now also works in identifying and growing CDISC's development activities to advance standards across a wide range of therapeutic areas and heads up the CDISC Project Management Office. John graduated from The University of Wales, Collage of Cardiff with a Bachelors Degree in Biology. Working within the pharmaceutical industry in clinical data management, clinical programming, and standards development roles.



# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

# Type 1 Diabetes TAUGs



## Therapeutic Area Data Standards for Type 1 Diabetes - Pediatrics and Devices Modules

Version 2.0 (Provisional)

Prepared by the  
CDISC Type 1 Diabetes Standards Development Team

### Notes to Readers

- This is the provisional Version 2.0 of the Therapeutic Area Data Standards for Type 1 Diabetes - Pediatrics and Devices Modules.
- This document is based on CDASHIG v2.1, CDASH Model v1.1, SDTM v1.7, the SDTM Implementation Guides (SDTMIG v3.3, SDTMIG-MD v1.1, and SDTMIG PGx 1.0), ADaM v2.1, and ADaMIG v1.2.

### Revision History

Date	Version	Summary of Changes
2021-05-20	2.0 Provisional	<ul style="list-style-type: none"><li>• Addition of Analysis Modules</li><li>• Minor corrections to v1.0</li></ul>
2020-09-22	1.0 Provisional	

See [Appendix D](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.



## Therapeutic Area Data Standards for Type 1 Diabetes - Exercise and Nutrition Modules

Version v1.0 (Provisional)

Prepared by the  
CDISC Type 1 Diabetes Standards Development Team

### Notes to Readers

- This is the Provisional Version 1.0 of the Therapeutic Area Data Standards for Type 1 Diabetes - Exercise and Nutrition Modules.
- This document is based on CDASHIG v2.1, CDASH Model v1.1, SDTM v1.7, SDTM Implementation Guides (SDTMIG v3.3 and SDTMIG-MD v1.1), and Define-XML v2.1.

### Revision History

Date	Version
2021-06-10	1.0 Provisional

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## Therapeutic Area Data Standards for Type 1 Diabetes - Screening, Staging, and Monitoring for Preclinical Type 1 Diabetes Modules

Version v1.0 (Provisional)

Prepared by the  
CDISC Type 1 Diabetes Standards Development Team

### Notes to Readers

- This is the provisional Version 1.0 of the Therapeutic Area Data Standards Modules for Type 1 Diabetes - Screening, Staging and Monitoring for Preclinical Type 1 Diabetes.
- This document is based on CDASHIG v2.1, CDASH Model v1.1, SDTM v1.7 and the SDTM Implementation Guides (SDTMIG v3.3 and SDTMIG-MD v1.1), ADaMIG v1.1.

### Revision History

Date	Version
2021-12-16	1.0 Provisional

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# T1Dexi Study



An at-home exercise study for people with Type 1 diabetes

## Help us learn how exercise can affect blood sugar

The Type 1 Diabetes EXercise Initiative is a 4-week at-home data collection study. Data contributed by study participants will help researchers to learn more about the effect of exercise on blood sugar.

### You may be eligible to participate if you:

- Had had type 1 diabetes for at least 2 years
- Are 18 to 70 years old
- Regularly use or willing to use a Dexcom G6 continuous glucose monitor (CGM)
- Use an Android or iOS smartphone and have access to a computer with internet
- Live in the U.S. during the study



## What does the study involve?

- Being active for at least 2 and half hours a week including study exercise
- Using a study app to track your food and exercise
- Wearing a CGM and physical activity recorder
- Sharing diabetes device data

<https://www.jaeb.org/t1dexi/>



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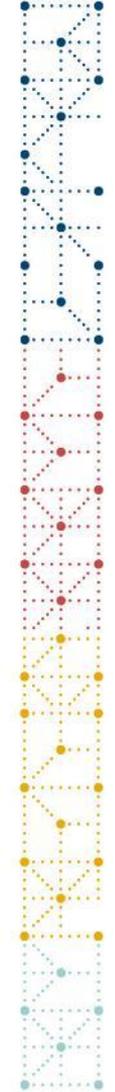


Domains Used	
Abbreviation	Name
CM	Concomitant/Prior Medications
DM	Demographics
DX	Device Exposure
FA	Findings About
FADX	Findings About Device Exposure
FAML	Findings About Meal Data
FAPR	Findings About Procedures
FACM	Findings About Concomitant Medications
LB	Laboratory Test Results
ML	Meal Data
NV	Nervous System Findings
PR	Procedures
RP	Reproductive System Findings
QS	Questionnaires
SC	Subject Characteristics
VS	Vital Signs

Study Reference Domains	
Abbreviation	Name
SUPPDM	Supplemental Demographics

Study Reference Domains	
Abbreviation	Name
DI	Device Identifiers

Relationship Domains	
Abbreviation	Name
RELREC	Related Records

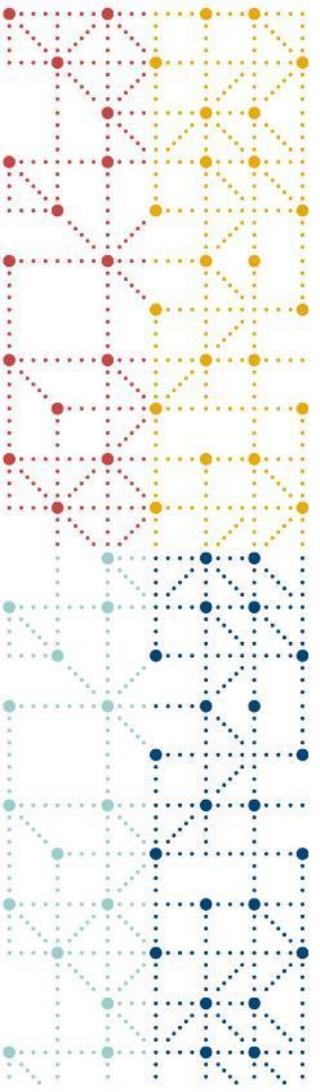


**This presentation will focus on**

**Continuous Glucose  
Monitoring Data**

**Exercise Data**

**Meal Data**



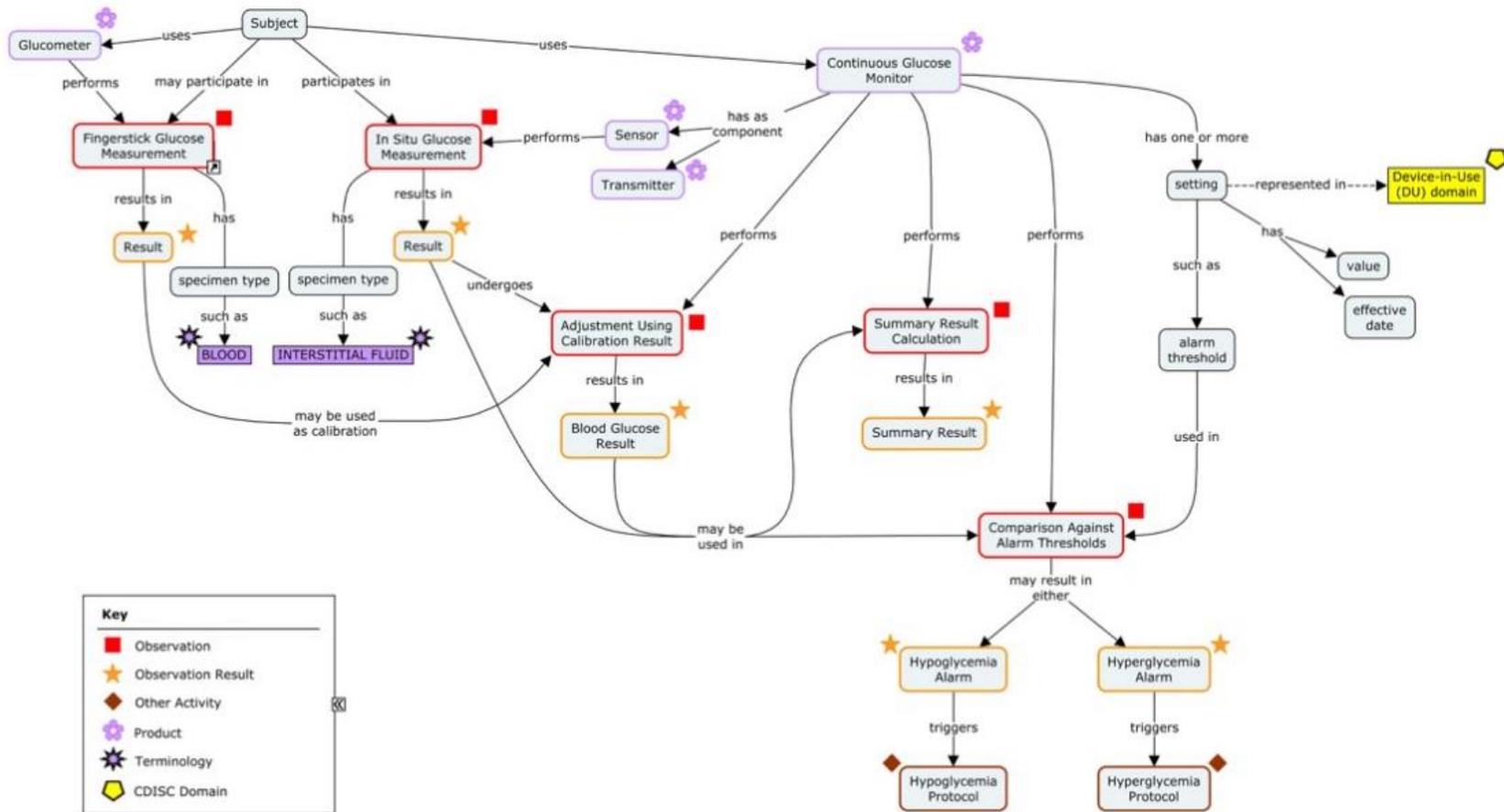
# Continuous Glucose Monitoring Data

# Continuous Glucose Monitoring



- Minimally invasive device
- Continuously measure and record real time glucose levels
- Measures glucose values in interstitial fluid

# Concept Map. CGM



*di.xpt*

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	T005	DI	CGM-001	1	DEVTYPE	Device Type	Implantable glucose monitoring system

*do.xpt*

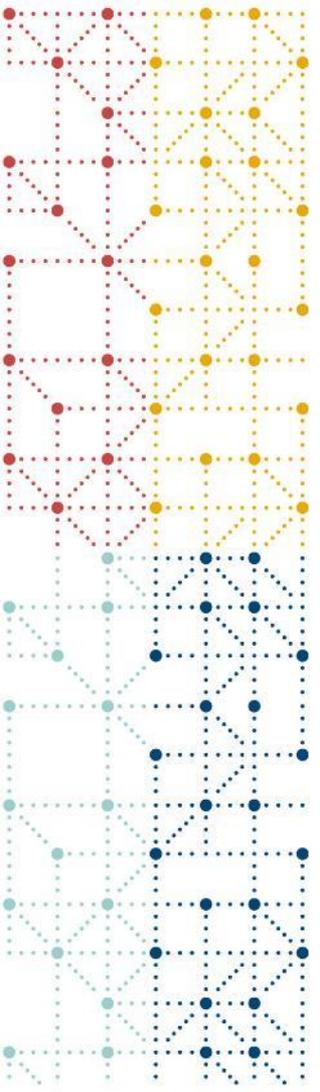
Row	STUDYID	DOMAIN	SPDEVID	DOSEQ	DOTESTCD	DOTEST	DOTSTDTL	DOORRES	DOORRESU
1	T005	DO	CGM-001	1	GLUCTGLV	Glucose Target Level	LOW	80	mg/dL
2	T005	DO	CGM-001	2	GLUCTGLV	Glucose Target Level	HIGH	130	mg/dL
3	T005	DO	CGM-001	3	GLUCALTH	Glucose Alert Threshold	CRITICAL LOW	<50	mg/dL
4	T005	DO	CGM-001	4	GLUCALTH	Glucose Alert Threshold	LOW	<69	mg/dL
5	T005	DO	CGM-001	5	GLUCALTH	Glucose Alert Threshold	HIGH	>180	mg/dL
6	T005	DO	CGM-001	6	GLUCALTH	Glucose Alert Threshold	CRITICAL HIGH	>250	mg/dL

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBMETHOD	LBANMETH	VISITNUM	LBDBC	LBDBY
1	TD011	LB	001-001	CGM-001	1	GLUCPE	Plasma Equivalent Glucose	118	mg/dL	118	118	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM		2016-09-08 T10:09:33	7
2	TD011	LB	001-001	CGM-001	2	GLUCPE	Plasma Equivalent Glucose	117	mg/dL	117	117	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM		2016-09-08 T10:14:36	7
3	TD011	LB	001-001	CGM-001	3	GLUCPE	Plasma Equivalent Glucose	110	mg/dL	110	110	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM		2016-09-08 T10:19:36	7
4	TD011	LB	001-001	CGM-001	4	GLUCPE	Plasma Equivalent Glucose	90	mg/dL	90	90	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM		2016-09-08 T10:24:52	7
5	TD011	LB	001-001	CGM-001	4033	GLUCPE	Plasma Equivalent Glucose	107	mg/dL	107	107	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM		2017-09-06 T10:09:33	369
6	TD011	LB	001-001	CGM-001	4034	GLUCPE	Plasma Equivalent Glucose	106	mg/dL	106	106	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM		2017-09-06 T10:14:20	369
7	TD011	LB	001-001	CGM-001	4035	GLUCPE	Plasma Equivalent Glucose	100	mg/dL	100	100	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM		2017-09-06 T10:19:03	369

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBMETHOD	LBANMETH	VISITNUM	VISIT	VISITDY	LBDBC	LBENDTC	LBDBY	LBENDY	LBLCBSRT
1	T005	LB	001	CGM-001	1	GLUCPE	Plasma Equivalent Glucose	113.7	mg/dL	113.7	113.7	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	MEAN
2	T005	LB	001	CGM-001	2	GLUCPED	Plasma Equivalent Glucose Distribution	15		15	15		INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	STANDARD DEVIATION
3	T005	LB	001	CGM-001	3	GLUCPED	Plasma Equivalent Glucose Distribution	13.7		13.7	13.7		INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	COEFFICIENT VARIATION
4	T005	LB	001	CGM-001	4	GLUCPED	Plasma Equivalent Glucose Distribution	0	%	0	0	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	PROPORTIO LOW
5	T005	LB	001	CGM-001	5	GLUCPED	Plasma Equivalent Glucose Distribution	0	%	0	0	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	PROPORTIO HIGH
6	T005	LB	001	CGM-001	6	GLUCPED	Plasma Equivalent Glucose Distribution	100	%	100	100	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	PROPORTIO WITHIN TARG RANGE
7	T005	LB	001	CGM-001	7	GLUCPED	Plasma Equivalent Glucose Distribution	0	min	0	0	min	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	TIME IN CRITH LOW RANG
8	T005	LB	001	CGM-001	8	GMI	Glucose Management Indicator	6.04	%	6.04	6.04	%	INTERSTITIAL FLUID	CALCULATION	GMI % FORMULA	2	WEEK 2	15	2016-09-15T08:00	2016-09-29T08:00	1	15	
9	T005	LB	001	CGM-001	9	GLUCPE	Plasma Equivalent Glucose	110.7	mg/dL	110.7	110.7	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	10	WEEK 52	365	2017-09-13T08:02	2017-09-14T07:57	364	365	MEAN
10	T005	LB	001	CGM-001	10	GLUCPED	Plasma Equivalent Glucose Distribution	15		15	15		INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	10	WEEK 52	365	2017-09-13T08:02	2017-09-14T07:57	364	365	STANDARD DEVIATION
11	T005	LB	001	CGM-001	11	GLUCPED	Plasma Equivalent Glucose Distribution	13.7		13.7	13.7		INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	10	WEEK 52	365	2017-09-13T08:02	2017-09-14T07:57	364	365	COEFFICIENT VARIATION
12	T005	LB	001	CGM-001	12	GLUCPED	Plasma Equivalent Glucose Distribution	0	%	0	0	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	10	WEEK 52	365	2017-09-13T08:02	2017-09-14T07:57	364	365	PROPORTIO LOW
13	T005	LB	001	CGM-001	13	GLUCPED	Plasma Equivalent Glucose Distribution	0	%	0	0	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	10	WEEK 52	365	2017-09-13T08:02	2017-09-14T07:57	364	365	PROPORTIO HIGH
14	T005	LB	001	CGM-001	14	GLUCPED	Plasma Equivalent Glucose Distribution	100	%	100	100	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	10	WEEK 52	365	2017-09-13T08:02	2017-09-14T07:57	364	365	PROPORTIO WITHIN TARG RANGE
15	T005	LB	001	CGM-001	15	GLUCPED	Plasma Equivalent Glucose Distribution	0	min	0	0	min	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	10	WEEK 52	365	2017-09-13T08:02	2017-09-14T07:57	364	365	TIME IN CRITH LOW RANG
16	T005	LB	001	CGM-001	16	GMI	Glucose Management Indicator	5.93	%	5.93	5.93	%	INTERSTITIAL FLUID	CALCULATION	GMI % FORMULA	10	WEEK 52	365	2017-08-31T08:02	2017-09-14T07:57	351	365	



## Meal Data

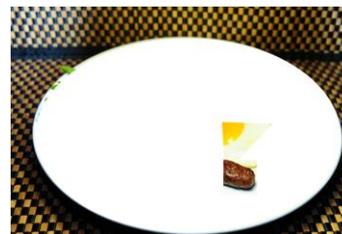
# Meal Data



Photograph  
pre-eating



Eat Meal

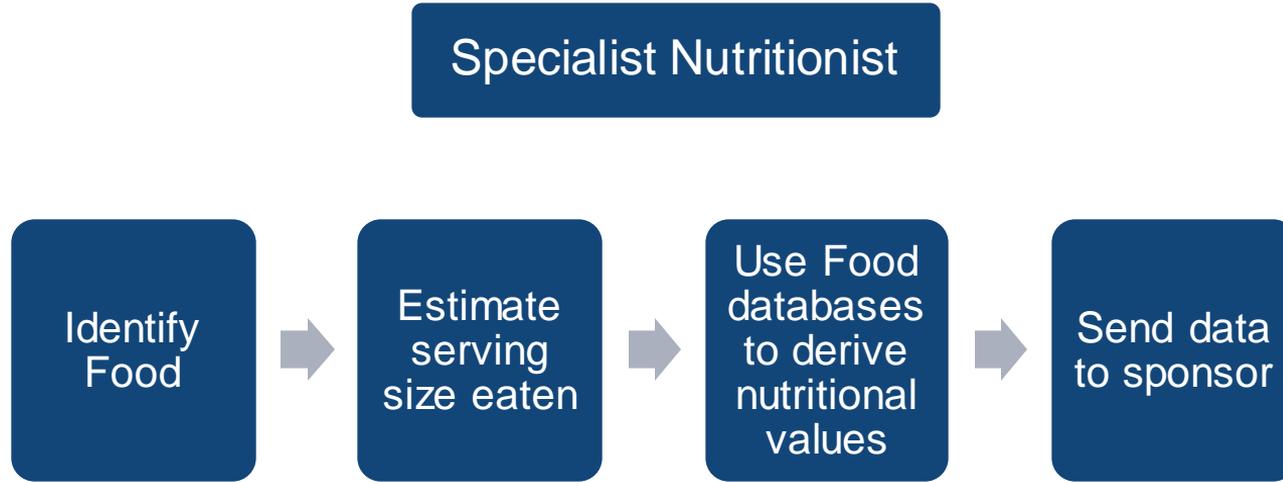


Photograph  
post-eating

Specialist  
Nutritionist

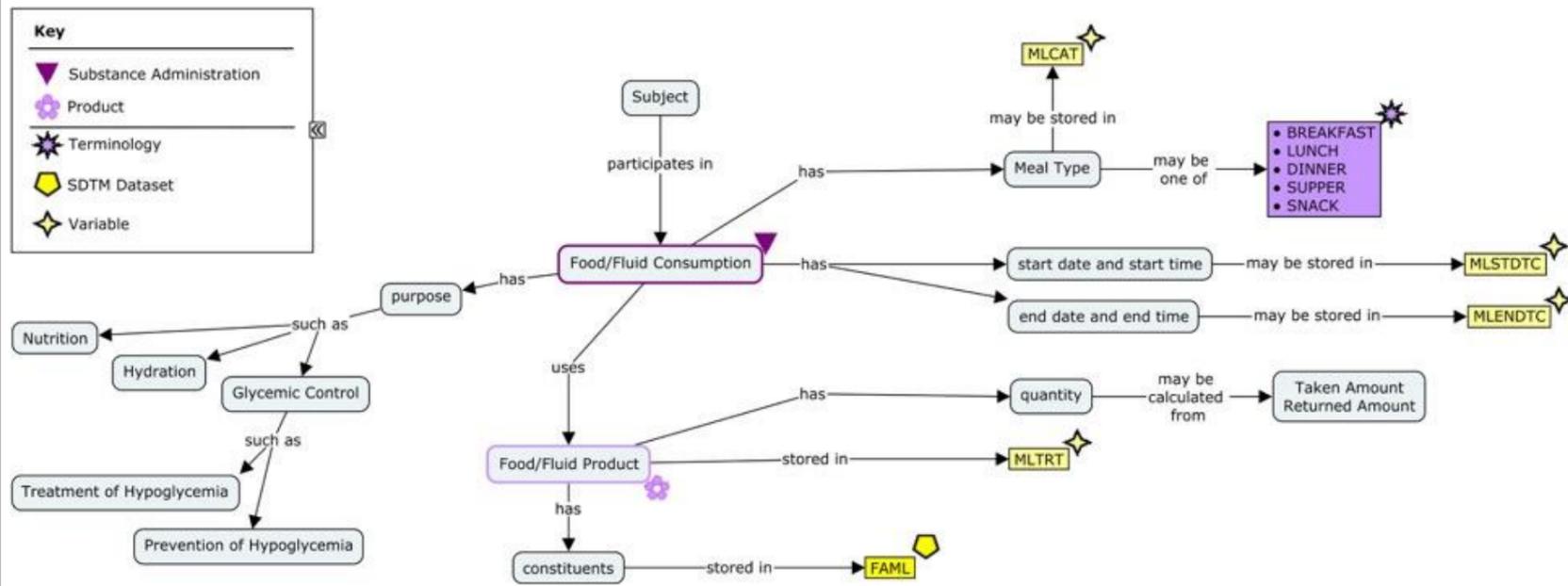


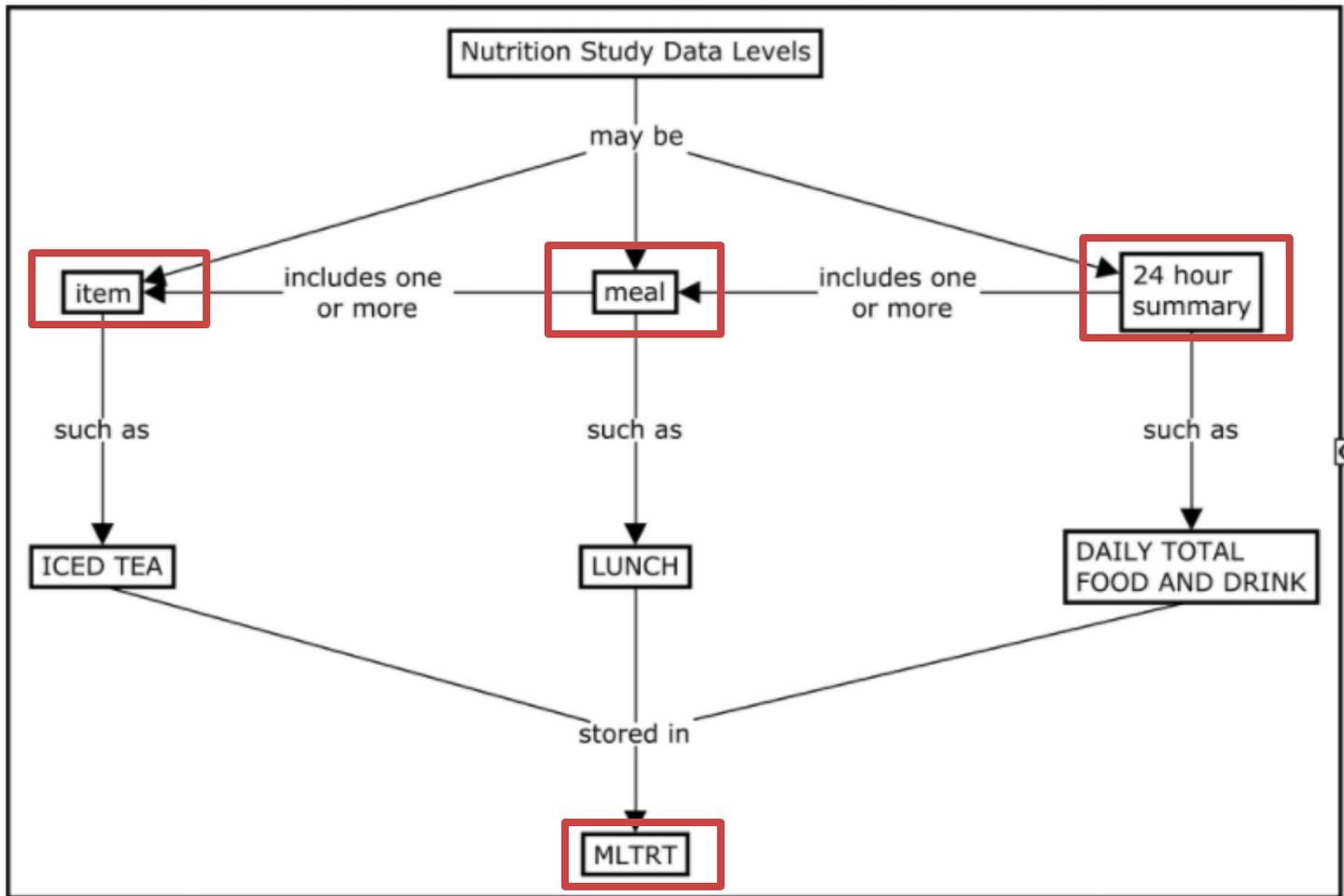
# Meal Data



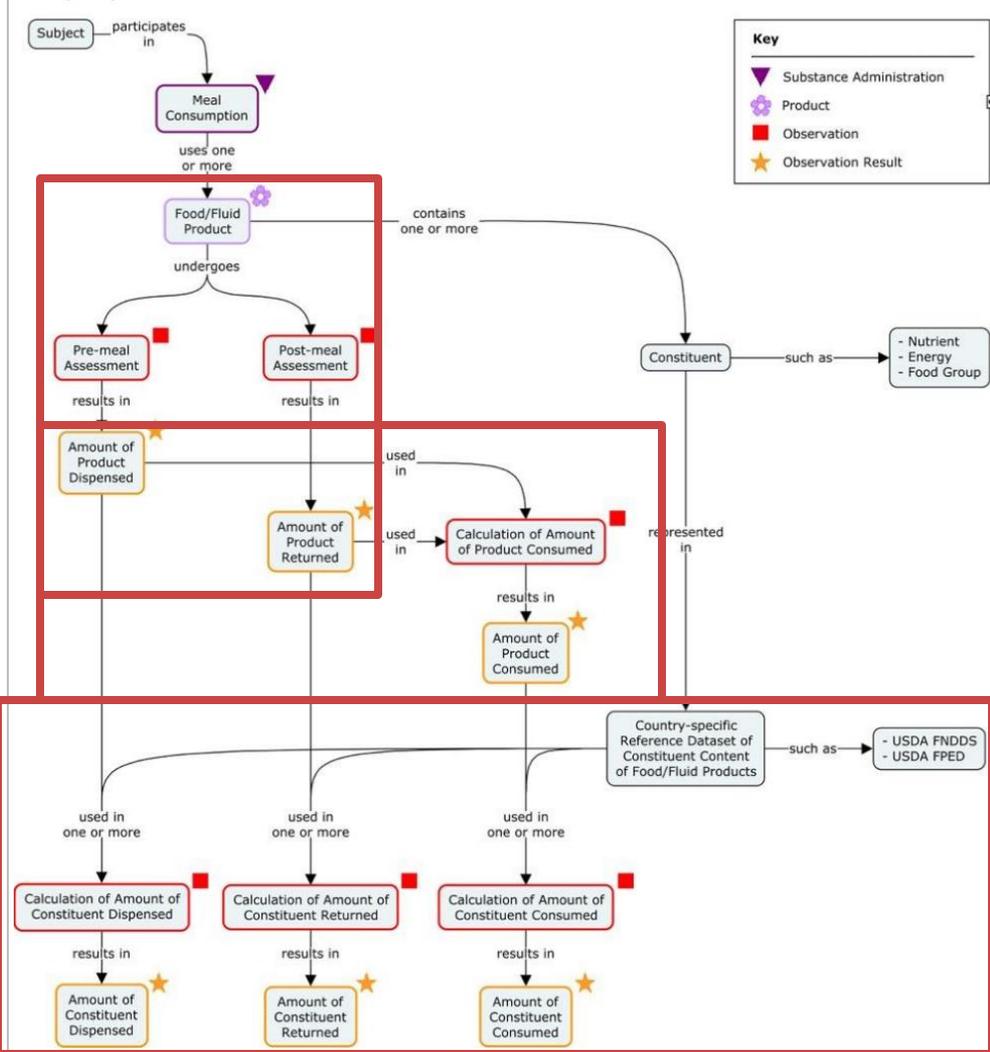
# Meal Data

## Concept Map. Meal Description and Nutrient Content





### Concept Map: Constituent Content



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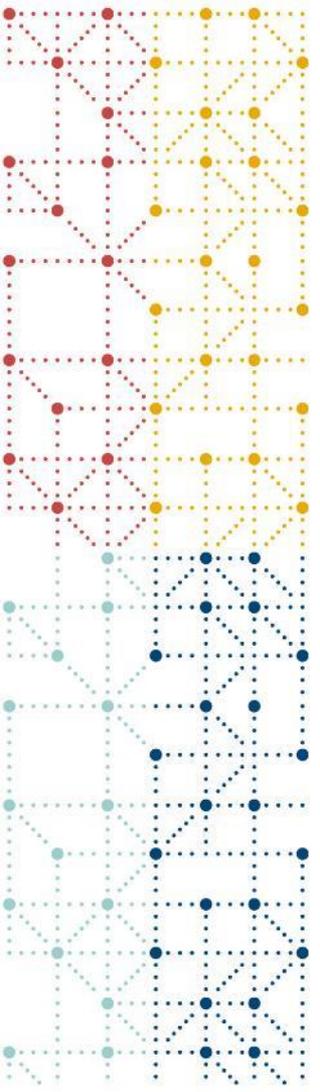
Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLLNKID	MLTRT	MLDECOD	MLCAT	MLDOSE	MLDOSU	MLSTDTC	MLENDTC	MLSTDY	MLENDY	MLSVGNUM	MLREAS	MLDECDCD
1	NUT123	ML	0001	1	A	GRANOLA BAR	Cereal or Granola bar, NFS	BREAKFAST	30	g	2019-01-15T08:00	2019-01-15T08:05	1	1	1	NUTRITION	53712100
2	NUT123	ML	0001	2	B	ORANGE JUICE	Orange juice, 100%, NFS	SNACK	347	g	2019-01-15T10:00	2019-01-15T10:02	1	1	1.4	GLYCEMIC CONTROL	61210000

**ML NSV Metadata**

Variable	Label	Type	Role	Codelist	Origin
MLSVGNUM	Number of Servings	float	Non-standard Record Qualifier		eDT
MLREAS	Reason for the Intervention	text	Non-standard Record Qualifier		eDT
MLDECDCD	Decode Code	text	Non-standard Variable Qualifier of --DECOD	FNDDS	eDT

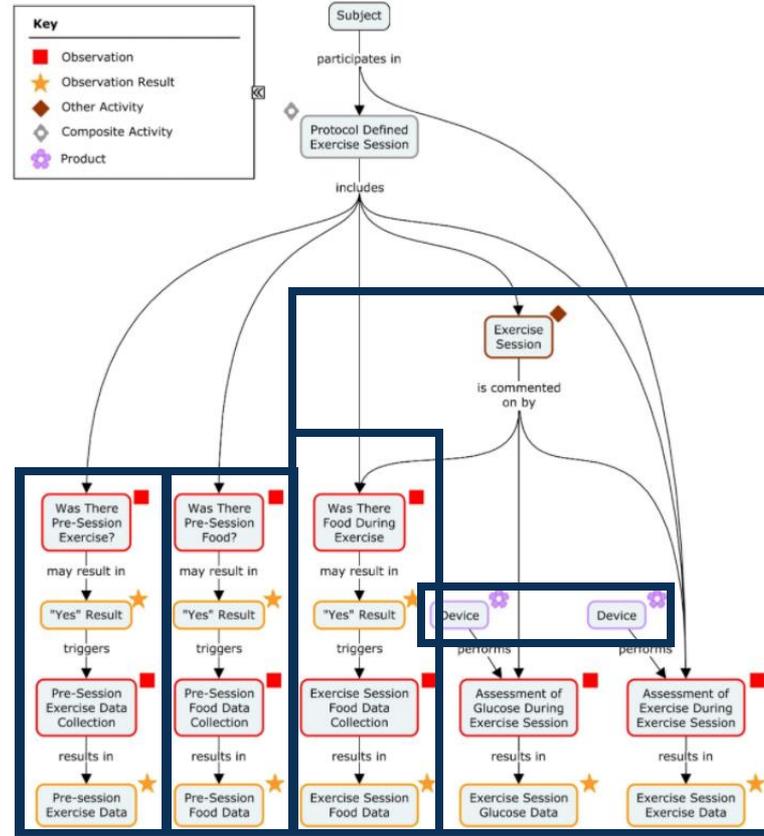
famL.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	FAANMETH	FADTC	FADY
1	NUT123	FA	0001	1	A	PREPAMT	Prepared Amount	Cereal or Granola bar, NFS	TOTAL	1	SERVING	30	30	g	FNDDS 2015-2016	2019-01-15	1
2	NUT123	FA	0001	2	A	REAMAMT	Remaining Amount	Cereal or Granola bar, NFS	TOTAL	0	SERVING	0	0	g	FNDDS 2015-2016	2019-01-15	1
3	NUT123	FA	0001	3	A	DPROT	Dietary Protein	Cereal or Granola bar, NFS	MACRONUTRIENTS	2.94	g	2.94	2.94	g	FNDDS 2015-2016	2019-01-15	1
4	NUT123	FA	0001	4	A	DFATT	Dietary Fat, Total	Cereal or Granola bar, NFS	MACRONUTRIENTS	5.28	g	5.28	5.28	g	FNDDS 2015-2016	2019-01-15	1
5	NUT123	FA	0001	5	A	DCARB	Dietary Total Carbohydrate	Cereal or Granola bar, NFS	MACRONUTRIENTS	20.01	g	20.01	20.01	g	FNDDS 2015-2016	2019-01-15	1
6	NUT123	FA	0001	6	A	DMG	Dietary Magnesium	Cereal or Granola bar, NFS	MICRONUTRIENTS	30	mg	30	30	mg	FNDDS 2015-2016	2019-01-15	1
7	NUT123	FA	0001	7	B	PREPAMT	Prepared Amount	Orange juice, 100%, NFS	TOTAL	2.2	SERVING	545	545	g	FNDDS 2015-2016	2019-01-15	1
8	NUT123	FA	0001	8	B	REAMAMT	Remaining Amount	Orange juice, 100%, NFS	TOTAL	0.8	SERVING	198	198	g	FNDDS 2015-2016	2019-01-15	1
9	NUT123	FA	0001	9	B	DPROT	Dietary Protein	Orange juice, 100%, NFS	MACRONUTRIENTS	2.77	g	2.77	2.77	g	FNDDS 2015-2016	2019-01-15	1
10	NUT123	FA	0001	10	B	DFATT	Dietary Fat, Total	Orange juice, 100%, NFS	MACRONUTRIENTS	0	g	0	0	g	FNDDS 2015-2016	2019-01-15	1
11	NUT123	FA	0001	11	B	DCARB	Dietary Total Carbohydrate	Orange juice, 100%, NFS	MACRONUTRIENTS	36.10	g	36.10	36.10	g	FNDDS 2015-2016	2019-01-15	1
12	NUT123	FA	0001	12	B	DMG	Dietary Magnesium	Orange juice, 100%, NFS	MICRONUTRIENTS	40	mg	40	40	mg	FNDDS 2015-2016	2019-01-15	1



# Activity Data

Concept Map. Protocol Defined Exercise Session





pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRREFID	PRSPID	PRLNKID	PRTRT	PRCAT	PRPRES	PROCCUR	PRDTC	PRSTDTC	PRENDTC	PRDUR	PREVLINT	PRSETTNG
1	EX008	PR	5001	1	NON-CLINIC SESSION 1		NC1	AEROBIC EXERCISE	PROTOCOL DEFINED EXERCISE	Y	Y	2016-08-10	2016-08-10T09:30	2016-08-10T10:25			NOT IN CLINIC
2	EX008	PR	5001	2	CLINIC SESSION 1	1	C1P-1	EXERCISE	PROTOCOL DEFINED EXERCISE	Y	Y	2016-08-23T:08:00			PT20M	-PT24H	
3	EX008	PR	5001	3	CLINIC SESSION 1	2	C1P-2	EXERCISE	PROTOCOL DEFINED EXERCISE	Y	Y	2016-08-23T:08:00			PT40M	-PT24H	
4	EX008	PR	5001	4	CLINIC SESSION 1		C1	AEROBIC EXERCISE	PROTOCOL DEFINED EXERCISE	Y	Y	2016-08-23	2016-08-23T08:00	2016-08-23T09:10			CLINIC
5	EX008	PR	5001	5	NON-CLINIC SESSION 2		NC2	AEROBIC EXERCISE	PROTOCOL DEFINED EXERCISE	Y	Y	2016-10-01	2016-10-01T09:45	2016-10-01T10:45			NOT IN CLINIC
6	EX008	PR	5001	6	CLINIC SESSION 2	1	C2P	EXERCISE	PROTOCOL DEFINED EXERCISE	Y	Y	2016-10-23T08:00			PT60M	-PT24H	
7	EX008	PR	5001	7	CLINIC SESSION 2		C2	AEROBIC EXERCISE	PROTOCOL DEFINED EXERCISE	Y	Y	2016-10-23	2016-10-23T08:00	2016-10-23T08:57			CLINIC
8	EX008	PR	5001	8	NON-CLINIC SESSION 3		NC3	AEROBIC EXERCISE	PROTOCOL DEFINED EXERCISE	Y	Y	2016-12-01	2016-12-01T09:30	2016-12-01T10:40			NOT IN CLINIC
9	EX008	PR	5001	9	CLINIC SESSION 3		C3	AEROBIC EXERCISE	PROTOCOL DEFINED EXERCISE	Y	N	2016-12-23					CLINIC

PR NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
PRSETTNG	Environmental Setting	text	Non-standard Record Qualifier	(SETTING)	CRF



fapr.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FAREFID	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	FAMETHOD	VISITNUM	FADTC	FAEVLINT
1	EX008	FA	5001	1	CLINIC SESSION 1P	C1P-1	EXCINTSY	Exercise Intensity	EXERCISE	PROTOCOL DEFINED EXERCISE	MODERATE		MODERATE			TALK TEST		2016-08-23T08:00	-PT24H
2	EX008	FA	5001	1	CLINIC SESSION 1P	C1P-2	EXCINTSY	Exercise Intensity	EXERCISE	PROTOCOL DEFINED EXERCISE	VIGOROUS		VIGOROUS			TALK TEST		2016-08-23T08:00	-PT24H
3	EX008	FA	5001	3	CLINIC SESSION 2P	C2P	EXCINTSY	Exercise Intensity	EXERCISE	PROTOCOL DEFINED EXERCISE	VIGOROUS		VIGOROUS			TALK TEST		2016-10-23T08:00	-PT24H



# Retrospective SDTM Mapping Process

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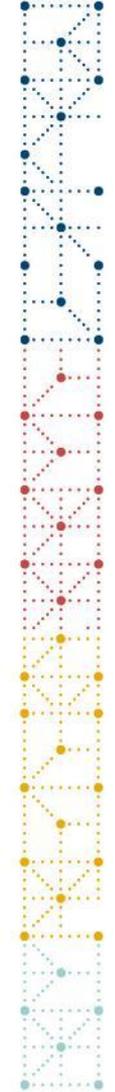


# Mapping Spreadsheet

Variable Name	STUDYID	DOMAIN	USUBJID	SUBJID	SITEID	BRTHDYC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS	ACTARMUD	COUNTRY
<b>Variable Label</b>	Study Identifier	Domain Abbreviation	Unique Subject Identifier	Subject Identifier for the Study	Study Site Identifier	Date/Time of Birth	Age	Age Units	Sex	Race	Ethnicity	Planned Arm Code	Description of Planned Arm	Actual Arm Code	Description of Actual Arm	Reason Arm and/or Actual Arm is Null	Description of Unplanned Actual Arm	Country
<b>Variable Type</b>	Char	Char	Char	Char	Char	Char	Num	Char	Char	Char	Char	Char	Char	Char	Char	Char	Char	Char
<b>Variable Format</b>	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM	DM
<b>Variable Qualifier</b>	Identifier	Identifier	Identifier	Topic	Record Qualifier	Record Qualifier	Record Qualifier	Variable Qualifier	Record Qualifier	Record Qualifier	Record Qualifier	Record Qualifier	Synonym Qualifier	Record Qualifier	Synonym Qualifier	Record Qualifier	Record Qualifier	Record Qualifier
<b>Variable Description</b>	Unique Identifier for a study.	Two-character abbreviation for the domain.	Identifier used to uniquely identify a subject across all studies.	Subject identifier, which must be unique within the study.	Unique identifier for a site within a study.	Date/time of birth of the subject.	Age expressed in years. May be derived from AGEU.	Units associated with AGE.	Sex of the subject.	Race of the subject.	The ethnicity of the subject.		Name of the Arm to which the subject was assigned.	Code of actual Arm.	Description of actual Arm.	A coded reason that Arm variables are null.	A description of actual treatment.	Country.
<b>Variable Data Type</b>	varchar	varchar	varchar	varchar	varchar	datetime	varchar	varchar	varchar	varchar	varchar	varchar	varchar	varchar	varchar	varchar	varchar	varchar
<b>Variable Max Length</b>	6	2	20	20	1	20	20	5	6	38	22	10	10	10	10	10	10	10
<b>Variable Significant Digits</b>	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
<b>Variable Formula</b>			tblT1DexiBaseline.PID	tblPRoster.PID where Protocol="T1DEXI" and PStatus not in 'Dropped'	SiteID - remove from public/third party datasets		Calculate from tblPRoster.BirthDt		tblT1DexiPreScreen.Sex	tblT1DexiBaseline.Race if ne 'More than one race'; tblT1DexiBaseline.RaceDs if Race="More than one race"	tblT1DexiBaseline.ConsiderHispanic		tblT1DexiPRoster.TrtGroup	tblT1DexiPRoster.TrtGroup	tblT1DexiPRoster.TrtGroup	tblT1DexiPRoster.TrtGroup	tblT1DexiPRoster.TrtGroup	tblSiteLocatnID.tblPRoster.tstID

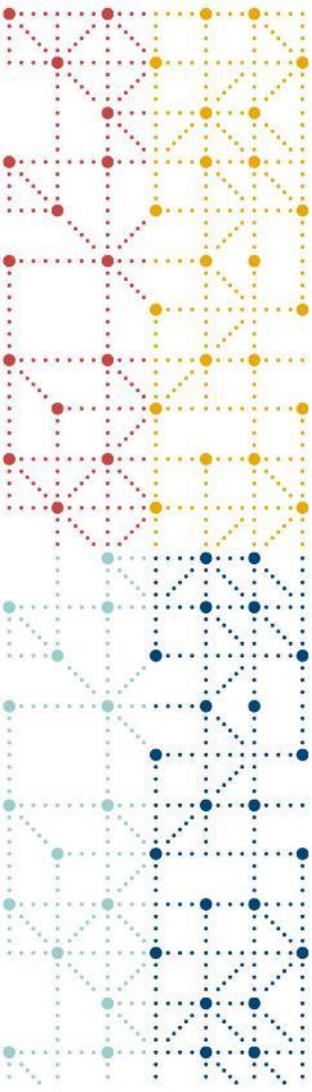
Domains Used	
Abbreviation	Name
CM	Concomitant/Prior Medications
DM	Demographics
DX	Device Exposure
FA	Findings About
FADX	Findings About Device Exposure
FAML	Findings About Meal Data
FAPR	Findings About Procedures
FACM	Findings About Concomitant Medications
LB	Laboratory Test Results
ML	Meal Data
NV	Nervous System Findings
PR	Procedures
RP	Reproductive System Findings
QS	Questionnaires
SC	Subject Characteristics
VS	Vital Signs

Study Reference Domains	
Abbreviation	Name
SUPPDM	Supplemental Demographics
Study Reference Domains	
Abbreviation	Name
DI	Device Identifiers
Relationship Domains	
Abbreviation	Name
RELREC	Related Records



# Observations

- Exercise and treatments were not considered to be exposure therefore there was no EX dataset
- Meal domains (ML and FAML) was used to represent data about nutrition
- Insulin exposure data were represented in Concomitant Medications (CM) domain
  - Which included a variety of insulin pumps and monitors
- The study used a variety of wearable devices to measure activity levels
- Retrospective mapping to SDTM variables was challenging for some pieces of data
- Lack of available terms in CT/ need for requesting many new terms
- Application of trial domains did not fit with nature of T1DEXI study



**Thank You!**

**cdisc**