

Public Review Webinar: Type 1 Diabetes Therapeutic Area User Guide: Exercise and Nutrition

John Owen, Head of Partnerships and Development, CDISC
Rebecca Baker, Standards Developer, CDISC
Kathleen Mellars, Consultant Standards Developer, CDISC
Richard Marshall, Consultant Standards Developer, CDISC



Tuesday, 22 SEP 2020
11:00AM – 12:00PM EDT



Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources



Housekeeping

Housekeeping

- You will remain on **mute** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
 - To access – make sure that you create a login for the CDISC website if you haven't already
 - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!

Submitting Questions

- To send a question, use the “QUESTIONS” function on your GoToWebinar app. (See red arrow)
- You can submit questions at any time during the presentation, we’ll answer them during the Q&A.
- If you have a question for a specific presenter, please indicate the presenter’s name at the beginning of the question
 - Examples:
 - John: ‘Question’
 - Alana: ‘Question’

A screenshot of the GoToWebinar app's 'Questions' interface. It features a dark blue header with the word 'Questions' and a downward arrow. Below the header is a large white text area for entering a question. At the bottom of the interface is a grey bar containing a 'Send' button with a paper plane icon.



Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.



Our Presenters

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Type 1 Diabetes (T1D) –Exercise and Nutrition Modules Public Review Webinar

Presented by

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22nd September 2020



Type 1 Diabetes (T1D) –Exercise and Nutrition Modules Public Review Webinar

John Owen, Head of Partnerships and Development, CDISC

22nd September 2020





Agenda

Project update (Pediatrics, Devices, Exercise and Prevention)

Overview of Exercise & Nutrition

Q&A

Type 1 Diabetes

Pediatrics and Devices

- Diabetes History
- On-study DKA
- Devices in Diabetes
- CGM
- Insulin Management
- Pediatric Growth & Growth Percentiles
- Pubertal Status in Diabetes
- QRS

Exercise and Nutrition

Prevention — Screening, Staging and Monitoring Pre-Clinical T1D

- Islet Autoantibodies
- Polygenic Risk Score
- Staging Module
- Viral Infections/Microbiome
- QRS

Pediatrics &
Devices

Diabetes Hx

Devices in T1D

Puberty in T1D

Exercise &
Nutrition

Screening,
Staging and
Monitoring
Pre-Clinical
T1D

Screen

Stage

Monitor

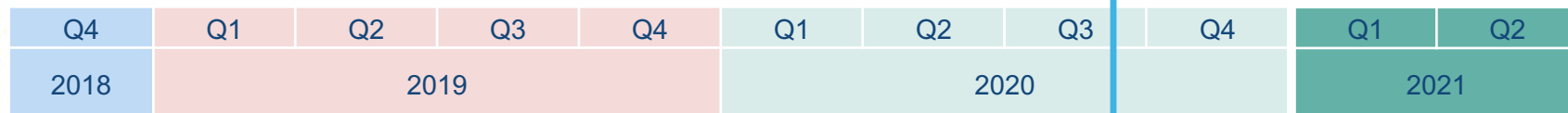
Standards Development Process and timelines

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Standards Update

T1D Pediatrics and Devices

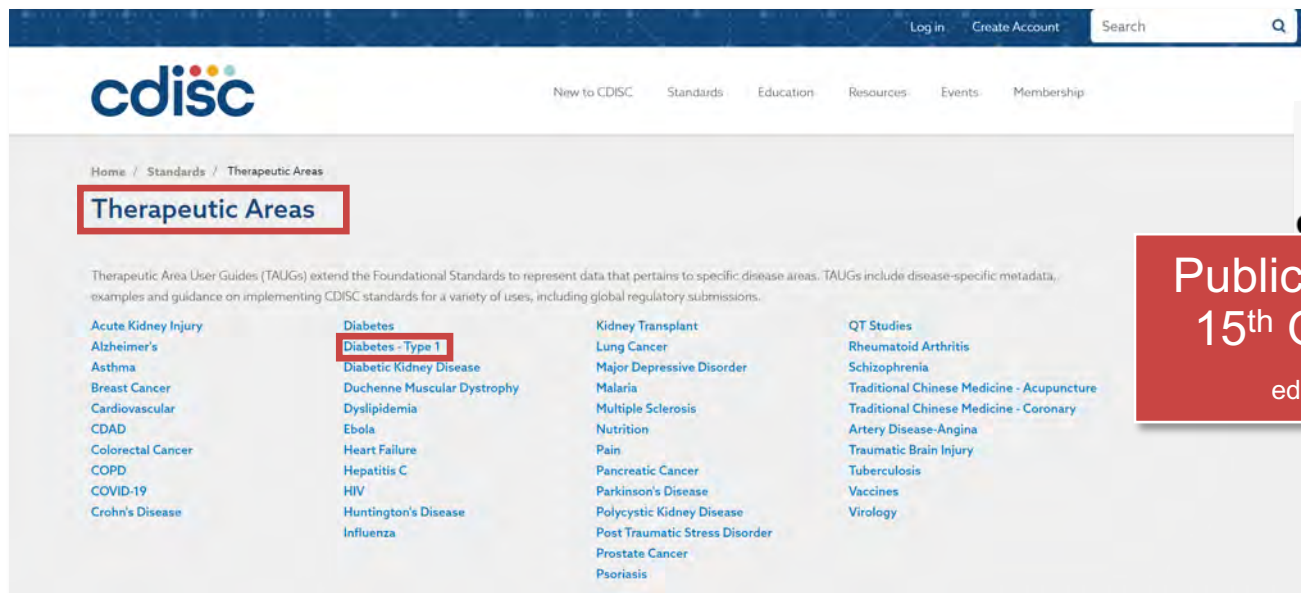
T1D Exercise and Nutrition

T1D Prevention –Screening, Staging, and Monitoring of Pre-Clinical T1D

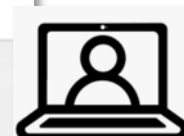


T1D Pediatrics and Devices

- Publication week of 21st September 2020

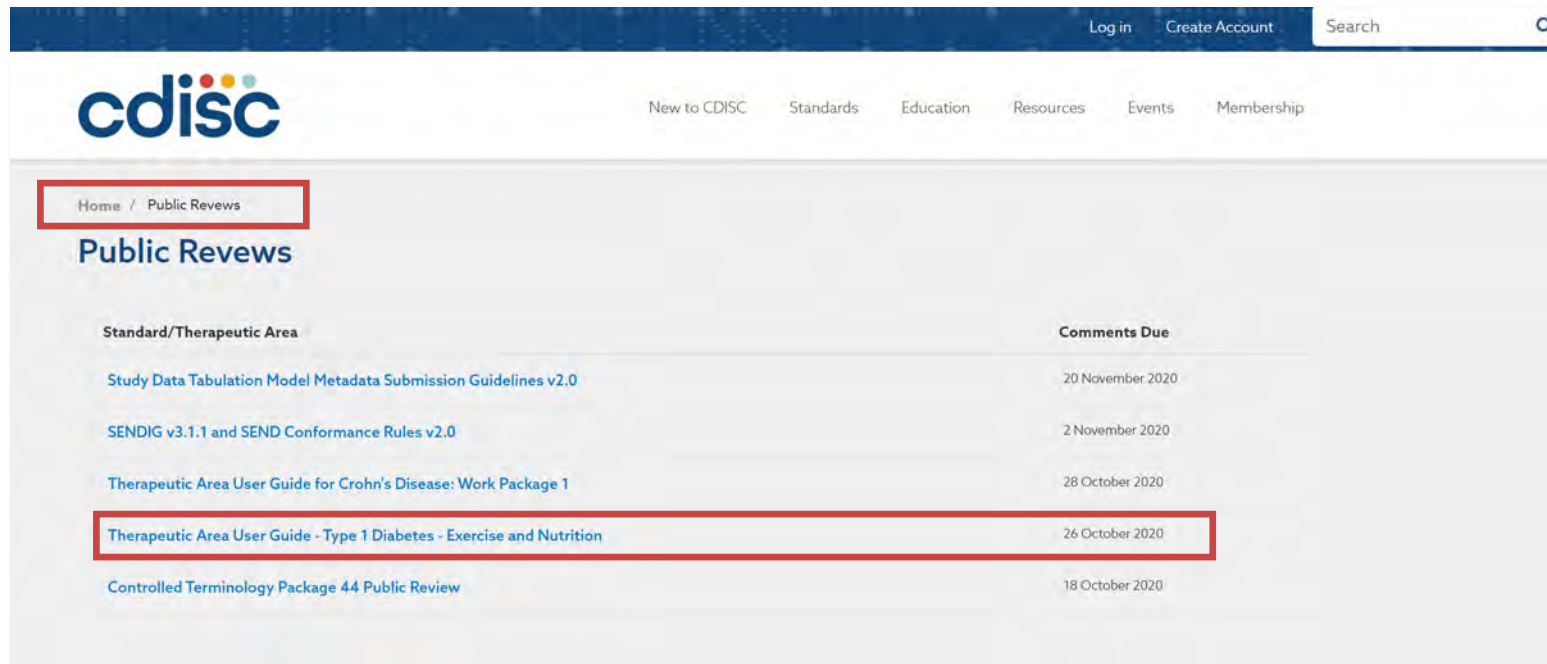


The screenshot shows the CDISC website's 'Therapeutic Areas' page. The page title 'Therapeutic Areas' is highlighted with a red box. Below the title, there is a paragraph explaining that Therapeutic Area User Guides (TAUGs) extend Foundational Standards to specific disease areas. A grid of links lists various therapeutic areas, with 'Diabetes - Type 1' highlighted by a red box. Other links include Acute Kidney Injury, Alzheimer's, Asthma, Breast Cancer, Cardiovascular, CDAD, Colorectal Cancer, COPD, COVID-19, Crohn's Disease, Diabetes, Diabetic Kidney Disease, Duchenne Muscular Dystrophy, Dyslipidemia, Ebola, Heart Failure, Hepatitis C, HIV, Huntington's Disease, Influenza, Kidney Transplant, Lung Cancer, Major Depressive Disorder, Malaria, Multiple Sclerosis, Nutrition, Pain, Pancreatic Cancer, Parkinson's Disease, Polycystic Kidney Disease, Post Traumatic Stress Disorder, Prostate Cancer, Psoriasis, QT Studies, Rheumatoid Arthritis, Schizophrenia, Traditional Chinese Medicine - Acupuncture, Traditional Chinese Medicine - Coronary, Artery Disease-Angina, Traumatic Brain Injury, Tuberculosis, Vaccines, and Virology.



Publication Webinar
15th October 2020
education/webinars

T1D Exercise and Nutrition



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Public Reviews

Standard/Therapeutic Area	Comments Due
Study Data Tabulation Model Metadata Submission Guidelines v2.0	20 November 2020
SENDIG v3.1.1 and SEND Conformance Rules v2.0	2 November 2020
Therapeutic Area User Guide for Crohn's Disease: Work Package 1	28 October 2020
Therapeutic Area User Guide - Type 1 Diabetes - Exercise and Nutrition	26 October 2020
Controlled Terminology Package 44 Public Review	18 October 2020



Exercise & Nutrition

Fitness &
Strength

Nutrition

Exercise Types &
Activity Devices

QRS



Fitness and Strength Status

Rebecca Baker

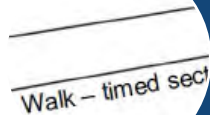
Overview



Handgrip Strength Test



VO₂ Max - Direct

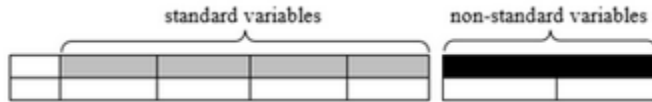


Estimated VO₂ Max

Known Issues

- **Non-standard Variables (NSVs)**

- SDTM-based examples containing data requiring use of variable outside of the standard set of variables.



- **Use of the --CAT (Category) and --SCAT (Subcategory) Variables**

- The --CAT variable is described as “used to define a category of topic-variable values”
- The --SCAT variable is described as “used to define a further categorization of --CAT values”
- Guidance in SDTMIG describes categorization at different levels of specificity

Handgrip Strength Test – CRF part 1

Repeating form designed to collect all injuries/disabilities

Title: Handgrip Strength Test

Medical History Hand or Arm Disabilities Section

CRF Completion Instructions

Complete this form for each hand and each arm injury or disability, including any that may affect the handgrip test. Repeat until all hand and arm injuries are collected.

Record whether the subject has any disability or injury that may affect the handgrip test.

If No, skip the rest of this section.

If Yes, complete this form for each hand and each arm injury or disability, then repeat until all hand and arm injuries are collected.

Answer questions for each injury/disability location, one at a time.

If yes, please enter the injury/disability in the Medical History CRF. Complete an entry for each hand and each arm injury or disability, including any that may affect performance of the handgrip test; then repeat until all hand and arm injuries are collected.

Answer questions for each injury/disability location, one at a time.

If both hand and arm have injuries, complete separate data collection entry for each. For example, if the right hand and arm are broken, complete an entry for right broken arm and a form for right broken hand.

Medical History Category	MHCAT	Hidden/pre-populated	HANDGRIP STRENGTH ASSESSMENT
Does the participant have an injury or disability in either hand/arm?			
MHOCCUR	MHOCCUR where MHTERM = "INJURY OR DISABILITY IN HAND OR ARM"		<input type="radio"/> Yes <input type="radio"/> No
			<From NY codelist>
Injury	MHPRESP	Hidden/pre-populated	Y
Injury/Disability	INJDIS_MHTERM	MHTERM	Hidden/pre-populated
What is the injury/disability?			
MHTERM			
Indicate whether the hand or arm has the injury/disability.			
MHCLOC	MHCLOC = "ARM" or "HAND" AND MHLAT = "RIGHT" or "LEFT"		<input type="radio"/> Right Hand <input type="radio"/> Right Arm <input type="radio"/> Left Hand <input type="radio"/> Left Arm

Handgrip Strength Test – CRF part 2

<p>Was the handgrip test performed?</p> <p>MKPERF If MKPERF="N", MKSTAT is "NOT DONE" where MKTESTCD = "GRIPSTR". If MKPERF = "Y", MKSTAT is null.</p>	<p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><From NY codelist></p>
<p>Which hand is dominant?</p> <p>SCORRES SCORRES where SCTESTCD = "DOMHAND"</p>	<p><input type="radio"/> Right Hand</p> <p><input type="radio"/> Left Hand</p> <p><input type="radio"/> Ambidextrous</p>
<p>Was the handgrip test performed for the right hand?</p> <p>GRIPSTR_RIGHT_MKPERF If "No" then MKSTAT = "NOT DONE" where MKTESTCD = "GRIPSTR" and MKLOC = "HAND" AND MKLAT = "RIGHT" If "Yes", then NOT SUBMITTED</p>	<p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><From NY codelist></p>
<p>Was the handgrip test performed for the left hand?</p> <p>GRIPSTR_LEFT_MKPERF If "NO" then MKSTAT = "NOT DONE" where MKTESTCD = "GRIPSTR" and MKLOC = "HAND" and MKLAT = "LEFT" IF "YES", then NOT SUBMITTED</p>	<p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><From NY codelist></p>
<p>Handgrip Strength Test Location MKLOC Hidden/pre-populated</p>	<p>HAND</p>
<p>What was the result of Right Handgrip Strength Test #1?</p> <p>GRIPSTR_RIGHT_MKORRES1 MKORRES where MKTESTCD = "GRIPSTR" and MKLOC = "HAND" and MKLAT = "RIGHT" and MKREPNUM = "1"</p>	<p><input type="text"/></p>
<p>What was the result of Left Handgrip Strength Test #1?</p> <p>GRIPSTR_LEFT_MKORRES1 MKORRES where MKTESTCD = "GRIPSTR"</p>	<p><input type="text"/></p>
<p>What was the result of Right Handgrip Strength Test #2?</p> <p>GRIPSTR_RIGHT_MKORRES2 MKORRES where MKTESTCD = "GRIPSTR"</p>	<p>What was the device type used for the handgrip strength test?</p> <p>DEVTYPE_CDIVAL If not "Other" then DIVAL where DIPARMCD = "DEVTYPE"</p> <p><input type="radio"/> Grip Dynamometer</p> <p><input type="radio"/> Other</p>
<p>What was the result of Left Handgrip Strength Test #2?</p> <p>GRIPSTR_LEFT_MKORRES2 MKORRES where MKTESTCD = "GRIPSTR"</p>	<p>If Other, what was the device type used for the handgrip strength test?</p> <p>CDEVTYPEOTH_CDIVAL DIVAL where DIPARMCD = "DEVTYPE"</p> <p><input type="text"/></p>
<p>What was the result of Right Handgrip Strength Test #3?</p> <p>GRIPSTR_RIGHT_MKORRES3 MKORRES where MKTESTCD = "GRIPSTR"</p>	<p>Who was the manufacturer of the device?</p> <p>MANUF_DIVAL DIVAL where DIPARMCD = "MANUF"</p> <p><input type="text"/></p>
<p>What was the result of Left Handgrip Strength Test #3?</p> <p>GRIPSTR_LEFT_MKORRES3 MKORRES where MKTESTCD = "GRIPSTR"</p>	<p>What is the model number of the device?</p> <p>MODEL_DIVAL DIVAL where DIPARMCD="MODEL"</p> <p><input type="text"/></p>
<p>Handgrip Strength Unit</p> <p>GRIPSTR_MKORRESU MKORRESU = "Other" then NULL</p>	<p><input type="radio"/> kg</p> <p><input type="radio"/> Other</p> <p><From UNIT codelist></p>

Does the participant have an injury or disability in either hand or arm? Y/N

What is the injury or disability?

MHPRESP
MHOCCUR

MHTERM

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHGRPID	MHLNKID	MHTERM	MHCAT	MHPRESP	MHOCCUR	MHLOC	MHLAT	MHDTC	MHSTDTC	MHENDTC
1	ABC123	MH	1001	1	1	1	INJURY OR DISABILITY IN HAND OR ARM	HANDGRIP STRENGTH ASSESSMENT	Y	Y			2018-07-01	2018-06-25	
2	ABC123	MH	1001	2	1	1	BROKEN WRIST	HANDGRIP STRENGTH ASSESSMENT			HAND	RIGHT	2018-07-01	2018-06-25	
3	ABC123	MH	1002	1	1		INJURY OR DISABILITY IN HAND OR ARM	HANDGRIP STRENGTH ASSESSMENT	Y	N			2018-07-18		
4	ABC123	MH	1003	1	1		INJURY OR DISABILITY IN HAND OR ARM	HANDGRIP STRENGTH ASSESSMENT	Y	Y			2018-07-25	2018-07-15	
5	ABC123	MH	1003	2	1		SWELLING	HANDGRIP STRENGTH ASSESSMENT			ARM	RIGHT	2018-07-25	2018-07-15	
6	ABC123	MH	1003	3	1		SWELLING	HANDGRIP STRENGTH ASSESSMENT			ARM	LEFT	2018-07-25	2018-07-15	
7	ABC123	MH	1003	4	1		SWELLING	HANDGRIP STRENGTH ASSESSMENT			HAND	RIGHT	2018-07-25	2018-07-15	

Indicate whether the hand or arm has injury or disability?

MHLOC
MHLAT

HANDGRIP STENGTH ASSESMENT

MHCAT

Was the handgrip test performed? Y/N

sc.xpt

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCLNKID	SCTESTCD	SCTEST	SCCAT	SCORRES	SCSTRESC	SCDTC
1	ABC123	SC	1001	1	2	DOMHAND	Dominant Hand	HANDGRIP STRENGTH ASSESSMENT	LEFT	LEFT	2018-07-01
2	ABC123	SC	1002	1		DOMHAND	Dominant Hand	HANDGRIP STRENGTH ASSESSMENT	RIGHT	RIGHT	2018-07-18
3	ABC123	SC	1003	1		DOMHAND	Dominant Hand	HANDGRIP STRENGTH ASSESSMENT	AMBIDEXTROUS	AMBIDEXTROUS	2018-07-25

Which hand is dominant? Right hand/Left hand/Ambidextrious

SCORRES where SCTESTCD = DOMHAND

mk.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MKSEQ	MKSPID	MKLNKID	MKTESTCD	MKTEST	MKCAT	MKORRES	MKORRESU	MKSTRESC	MKSTRESN	MKSTRESU	MKLOC	MKLAT	MKREPNUM	MKDTC
1	ABC123	MK	1001	ABC400	1	1	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	40.2	kg	40.2	40.2	kg	HAND	LEFT	1	2018-07-01
2	ABC123	MK	1001	ABC400	2	2	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.4	kg	16.4	16.4	kg	HAND	RIGHT	1	2018-07-01
3	ABC123	MK	1001	ABC400	3	3	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.2	kg	47.2	47.2	kg	HAND	LEFT	2	2018-07-01
4	ABC123	MK	1001	ABC400	4	4	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	14.2	kg	14.2	14.2	kg	HAND	RIGHT	2	2018-07-01
5	ABC123	MK	1001	ABC400	5	5	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.1	kg	47.1	47.1	kg	HAND	LEFT	3	2018-07-01
6	ABC123	MK	1001	ABC400	6	6	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.2	kg	16.2	16.2	kg	HAND	RIGHT	3	2018-07-01

Was the handgrip test performed for the right hand? Y/N

Was the handgrip test performed for the left hand? Y/N

What was the result of the right handgrip test #1?

What was the result of the left handgrip test #1?

MKORRES
MKLOC MKLAT
MKREPNUM

What was the device type used for the handgrip strength test?

DIVAL where DIPARMCD = "DEVTYPE"

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC123	DI	ABC400	1	DEVTYPE	Device Type	GRIP DYNAMOMETER
2	ABC123	DI	ABC400	2	MANUF	Manufacturer	Grips Inc.
3	ABC123	DI	ABC400	2	MODEL	Model	GRIPIT123

Who was the manufacturer of the device?

DIVAL where DIPARMCD = "MANUF"

What is the model number of the device?

DIVAL where DIPARMCD = "MODEL"

mk.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MKSEQ	MKSPID	MKLNKID	MKTESTCD	MKTEST	MKCAT	MKORRES	MKORRESU	MKSTRESC	MKSTRESN	MKSTRESU	MKLOC	MKLAT	MKREPNUM	MKDTC
1	ABC123	MK	1001	ABC400	1	1	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	40.2	kg	40.2	40.2	kg	HAND	LEFT	1	2018-07-01
2	ABC123	MK	1001	ABC400	2	2	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.4	kg	16.4	16.4	kg	HAND	RIGHT	1	2018-07-01
3	ABC123	MK	1001	ABC400	3	3	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.2	kg	47.2	47.2	kg	HAND	LEFT	2	2018-07-01
4	ABC123	MK	1001	ABC400	4	4	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	14.2	kg	14.2	14.2	kg	HAND	RIGHT	2	2018-07-01
5	ABC123	MK	1001	ABC400	5	5	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.1	kg	47.1	47.1	kg	HAND	LEFT	3	2018-07-01
6	ABC123	MK	1001	ABC400	6	6	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.2	kg	16.2	16.2	kg	HAND	RIGHT	3	2018-07-01

SPDEVID

SPDEVID = the Sponsor Device Identifier

VO2 Max - Direct

Title. VO2 Max Direct

Indicate whether any data was collected for the VO2 max test.	VO2 Max Test Name PRTRT <i>Hidden/pre-populated</i>	GRADED EXERCISE TEST
Record date of measurements using this format (DD-MON-YY).	Was the direct VO2 max test performed? REPERF If REPERF = "N", RESTAT is "NOT DONE" and RETESTCD = "VO2". If REPERF = "Y", Not Submitted.	<input type="radio"/> Yes <input type="radio"/> No <From NY codelist>
Record time of measurement (as complete as possible).	What was the date of the VO2 max test? REDAT REDTC PRSTDTC	<input type="text"/>
	What was the time of the VO2 max test? RETIM REDTC PRSTDTC	<input type="text"/>
Record the kind of the test.	Test Name for VO2 RETEST <i>Hidden/pre-populated</i>	Oxygen Consumption
	Test Type for VO2 RECOLSRT NSRE.RECOLSRT <i>Hidden/pre-populated</i>	Maximal
Record the device used for the VO2 max exercise test.	What kind of VO2 max test was performed? RETSTCND NSRE.RETSTCND	<input type="radio"/> Submaximal <input type="radio"/> To Exhaustion
Record the device used for the oxygen consumption measurement/gas exchange.	If applicable, what was device used for the exercise test? EXER_SPDEVID PR.SPDEVID DI.SPDEVID and DI.DIVAL where DIPARMCD = "DEVTYPE"	<input type="radio"/> Treadmill <input type="radio"/> Cycle ergometer <input type="radio"/> Rowing machine
Record test result.	What was device used for the oxygen consumption measurement? VO2EXC_SPDEVID RE.SPDEVID DI.SPDEVID and DI.DIVAL where DIPARMCD = "DEVTYPE"	<input type="radio"/> Ergospirometer <input type="radio"/> Douglas bag <input type="radio"/> Tissot tank
	What was the result of the VO2 max test? VO2MAX_REORRES REORRES where RETESTCD = "VO2"	<input type="text"/>
	Unit VO2MAX_REORRESU REORRESU where RETESTCD = "VO2" <i>Hidden/pre-populated</i>	mL/kg/min

What kind of VO2 Max test was performed? Submaximal/To Exhaustion

RETSTCND

What was the result of the VO2 Max Test?

REORRES where RETESTCD = VO2

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RELNKID	RETSTCD	RETEST	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	VISITNUM	VISIT	REDTC
1	ABC123	RE	1003	Ergospirometer	1	3	VO2	Oxygen Consumption	38	mL/kg/min	38	38	mL/kg/min	1	SCREENING	2019-07-01

RECOLSRT	RETSTCND
MAXIMAL	EXERCISE TO EXHAUSTION CONDITION

RE NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
RECOLSRT	Collected Summary Result Type	text	Non-standard Record Qualifier	CRF	
RETSTCND	Test Condition	text	Non-standard Record Qualifier	CRF	

Title: VO2 Max Direct

Indicate whether any data was collected for the VO2 max test.

Record date of measurements using this format (DD-MON-YYYY).

Record time of measurement (as complete as possible).

VO2 Max Test Name	PRTRT <small>Hidden/pre-populated</small>	GRADED EXERCISE TEST
Was the direct VO2 max test performed?	<input type="radio"/> Yes <input type="radio"/> No <small><From NY codelist></small>	
REPERF	<small>If REPERF = "N", RESTAT is "NOT DONE" and RETESTCD = "VO2". If REPERF = "Y", Not Submitted.</small>	
What was the date of the VO2 max test?	<input type="text"/>	
REDAT	REDTC	PRSTDTC
What was the time of the VO2 max test?	<input type="text"/>	
RETIM	REDTC	PRSTDTC
Test Name for VO2	RETEST <small>Hidden/pre-populated</small>	Oxygen Consumption
Test Type for VO2	RECOLSRT	NSRECOLSRT <small>Hidden/pre-populated</small>
		Maximal

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	PRSEQ	PRLNKID	PRTRT	VISITNUM	VISIT	PRSTDTC	PRENDTC
1	ABC123	PR	1003	Treadmill	1	3	GRADED EXERCISE TEST	1	SCREENING	2019-07-01	2019-07-01



Estimated VO2 Max

Title: Estimated VO2 Max CRF		
Indicate whether any data was collected for the VO2 max test.	Was the estimated VO2 max test performed? REPERF If REPERF="N", RESTAT is "NOT DONE" and RETESTCD="VO2MAXE". If REPERF="Y", Not Submitted.	<input type="radio"/> Yes <input type="radio"/> No <From NY codelist>
Record date of test using this format (DD-MON-YYYY).	What was the date of VO2 max test? REDAT REDTC PRSTDTC	<input type="text"/>
Record time of test (as complete as possible).	What was the time of VO2 max test? RETIM REDTC PRSTDTC	<input type="text"/>
Record the kind of the test.	Test Name for VO2 RETEST <i>Hidden/pre-populated</i> What kind of VO2 max test was performed? RETSCND NSRE.RETSCND	<input type="radio"/> Submaximal <input type="radio"/> To Exhaustion
Record the name of VO2 max test performed.	What is the name of the exercise test for the estimated VO2 max? PRTRT PRTRT if not "Other"	<input type="radio"/> Graded exercise test <input type="radio"/> Rockport One Mile Walk Test <input type="radio"/> Step Test <input type="radio"/> Other
Record the name of VO2 max test performed.	If the exercise test for estimated VO2 max is Other, what was the name of the test? PRTRTOH PRTRT	<input type="text"/>
Record the device used for the VO2 max test.	If applicable, what was the device used for the estimated VO2 max test? SPDEVID PR.SPDEVID DL.SPDEVID and DL.DIVAL where DIPARMCD = "DEVTYPE" If SPDEVID = "None" then NULL	<input type="radio"/> Treadmill <input type="radio"/> Cycle ergometer <input type="radio"/> Rowing machine <input type="radio"/> None
Record the test result.	What was the result of the estimated VO2 max test? VO2MAXE_REORRES REORRES where RETESTCD="VO2MAXE"	<input type="text"/>
	Unit VO2MAXE_REORRESU REORRESU where RETESTCD="VO2MAXE" <i>Hidden/pre-populated</i>	mL/kg/min

Estimated VO2 Max Modeling

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	PRSEQ	PRLNKID	PRTRT	VISITNUM	VISIT	PRSTDTC
1	ABC123	PR	1001	Treadmill	1	1	GRADED EXERCISE TEST	1	SCREENING	2019-07-01T08:00
2	ABC123	PR	1002	Cycle Ergometer	1	1	GRADED EXERCISE TEST	1	SCREENING	2019-07-01T09:15
3	ABC123	PR	1003	Treadmill	1	1	COOPER TEST	1	SCREENING	2019-07-01T11:10
4	ABC123	PR	1004		1	1	STEP TEST	1	SCREENING	2019-07-02T12:30
5	ABC123	PR	1005		1	1	ROCKPORT ONE MILE WALK TEST	1	SCREENING	2019-07-02T14:15

What is the name of the exercise test for the estimated VO2 max?

PRTRT

re.xpt

Row	STUDYID	DOMAIN	USUBJID	RESEQ	RELNKID	RETESTCD	RETEST	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	REDTC
1	ABC123	RE	1001	1	1	VO2MAXE	Maximal Oxygen Consumption, Estimated	45	mL/kg/min	45	45	mL/kg/min	2019-07-01T08:00
2	ABC123	RE	1002	1	1	VO2MAXE	Maximal Oxygen Consumption, Estimated	48	mL/kg/min	48	48	mL/kg/min	2019-07-01T09:15
3	ABC123	RE	1003	1	1	VO2MAXE	Maximal Oxygen Consumption, Estimated	48	mL/kg/min	48	48	mL/kg/min	2019-07-01T11:10
4	ABC123	RE	1004	1	1	VO2MAXE	Maximal Oxygen Consumption, Estimated	25	mL/kg/min	25	25	mL/kg/min	2019-07-01T13:00
5	ABC123	RE	1005	1	1	VO2MAXE	Maximal Oxygen Consumption, Estimated	31	mL/kg/min	31	31	mL/kg/min	2019-07-01T15:15

RETSTCND
EXERCISE TO EXHAUSTION CONDITION
EXERCISE TO SUBMAXIMAL CONDITION
EXERCISE TO SUBMAXIMAL CONDITION
EXERCISE TO SUBMAXIMAL CONDITION
EXERCISE TO SUBMAXIMAL CONDITION

RE NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
RETSTCND	Test Condition	text	Non-standard Record Qualifier		CRF

What kind of VO2 Max test was performed? Submaximal/To Exhaustion

What was the result of the VO2 Max Test?

REORRES where RETESTCD = VO2MAXE



Nutrition

Rebecca Baker

Concept Map – Meal Description & Nutrient Content

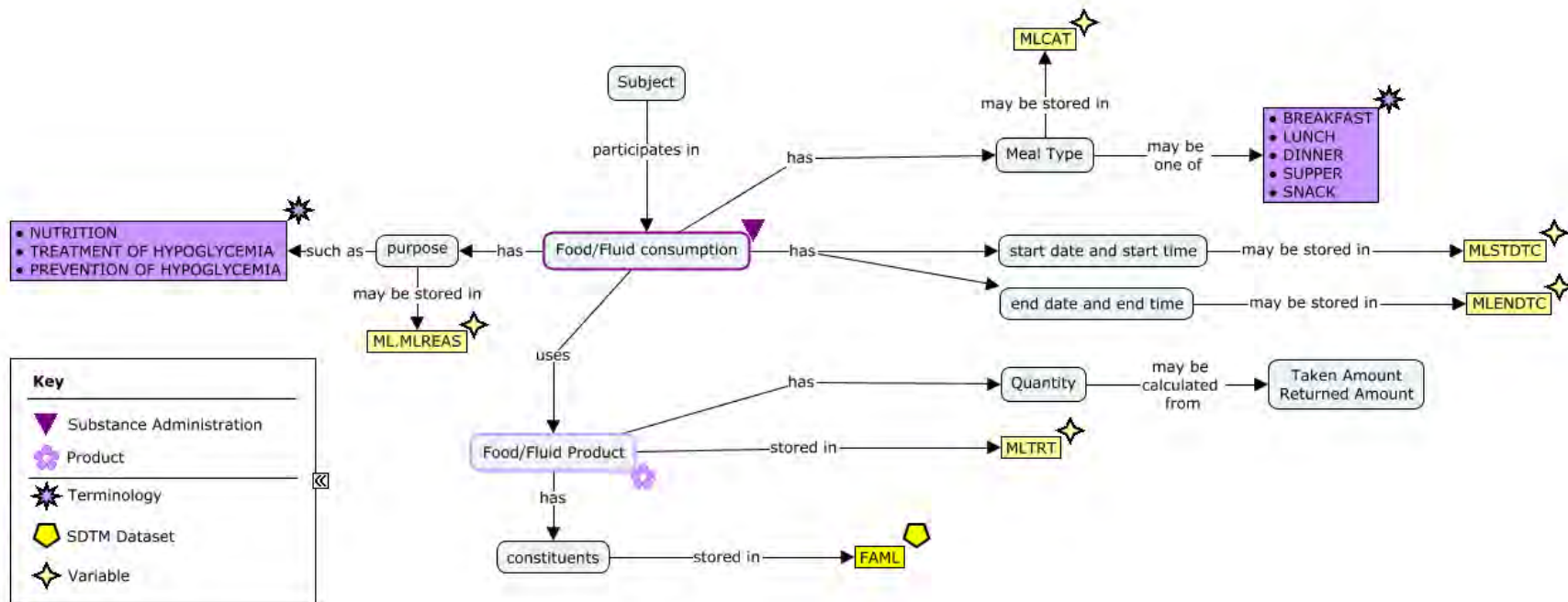
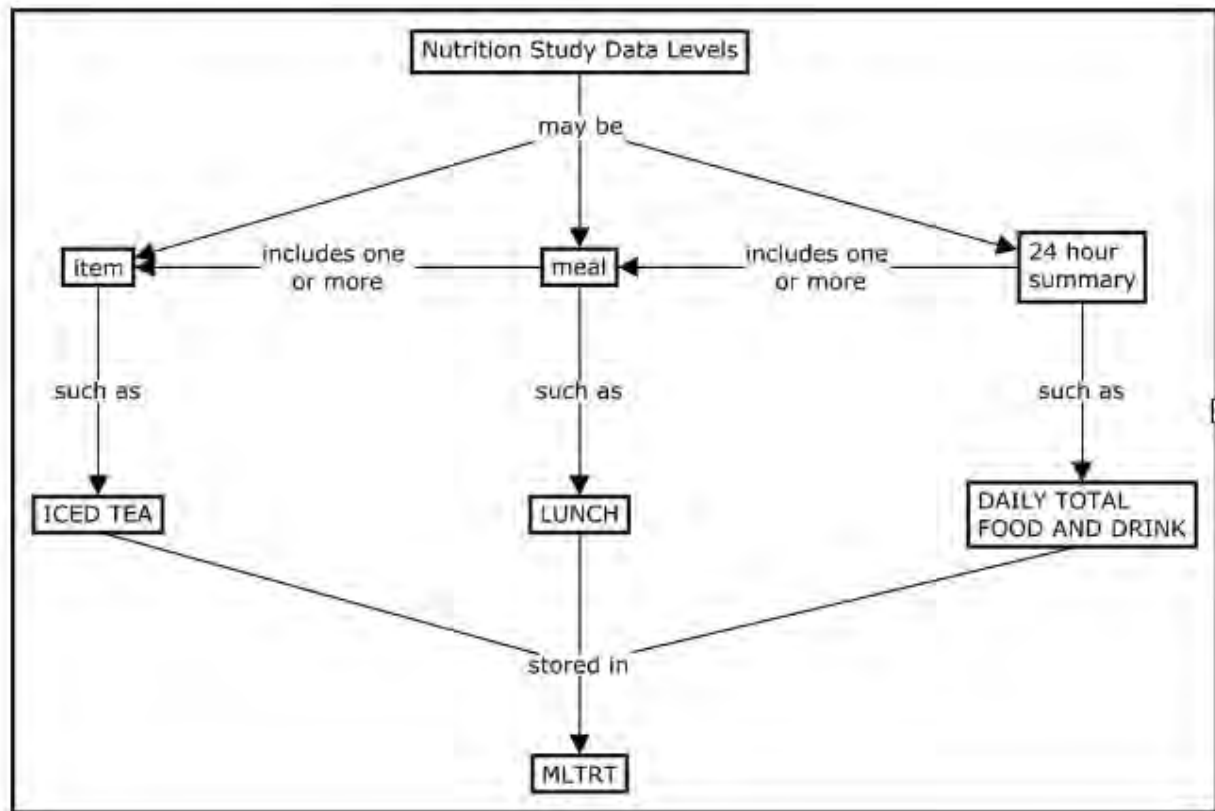


Figure 1. Nutrient Data Levels



Modeling Highlights

Examples

1

Item Level

Shows hypoglycemia in glycemic control



2

Components of the Meal

Item Level



3

Meal

Constituents



4

Daily Total Food and Drink

Constituents



5

Daily Total Food and Drink

Constituents



Lunch – Item Level

mLxpt

Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLGRPID	MLLNKID	MLTRT	MLCAT	MLDOSE	MLDOSU	MLSTDTC	MLENDTC	MLSTDY	MLENDY
1	ABC123	ML	0001	1	3	D	Chili beef soup	LUNCH	332.5	grams	2019-01-15T12:00	2019-01-15T13:00	1	1
2	ABC123	ML	0001	2	3	E	Bread, garlic, toasted	LUNCH	34	grams	2019-01-15T12:00	2019-01-15T13:00	1	1
3	ABC123	ML	0001	3	3	F	Tea, leaf, presweetened with sugar	LUNCH	472	grams	2019-01-15T12:00	2019-01-15T13:00	1	1

MLNUMSVG	MLREAS	MLDECCDCD	MLDCDICT
1.33	NUTRITION	28310210	FNDDS
1	NUTRITION	51121041	FNDDS
2	NUTRITION	92302200	FNDDS

ML NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
MLNUMSVG	Number of Servings	float	Non-standard Record Qualifier		eDT
MLREAS	Reason for the intervention	text	Non-standard Record Qualifier		eDT
MLDECCDCD	Decode Code	integer	Non-standard Record Qualifier	(see value-level metadata)	eDT
MLDCDICT	Dictionary Version	text	Non-standard Record Qualifier		eDT

Difference in the different level of models is the MLTRT & FAOBJ

Value Level Metadata - ML [MLDECCDCD]

Variable	Where	Codelist
MLDECCDCD	MLDCDICT="FNDDS"	Food and Nutrient Database for Dietary Studies (FNDDS)

famLxpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FAGRPID	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FASCAT	FAORRES	FAORRESU	FASTRESC	FASTRESU	FADTC
40	ABC123	FA	0001	40	1	D	DPROT	Dietary Protein	Chili beef soup	CONSUMED	MACRONUTRIENTS	8.28	g	8.28	g	2019-01-15
41	ABC123	FA	0001	41	1	D	DFATT	Dietary Fat, Total	Chili beef soup	CONSUMED	MACRONUTRIENTS	4.12	g	4.12	g	2019-01-15
42	ABC123	FA	0001	42	1	D	DCARBT	Dietary Total Carbohydrate	Chili beef soup	CONSUMED	MACRONUTRIENTS	30.69	g	30.69	g	2019-01-15
43	ABC123	FA	0001	43	1	D	DADDSUG	Dietary Added Sugar	Chili beef soup	CONSUMED	ADDED SUGAR	1.43	tsp eq	1.43	tsp eq	2019-01-15
44	ABC123	FA	0001	44	1	D	DCAL	Dietary Calories	Chili beef soup	CONSUMED	CALORIES	190	kcal	190	kcal	2019-01-15
45	ABC123	FA	0001	45	1	D	DFRUIT	Dietary Fruit	Chili beef soup	CONSUMED	FOOD GROUPS	0	cup eq	0	cup eq	2019-01-15
46	ABC123	FA	0001	46	1	D	DVEG	Dietary Vegetable	Chili beef soup	CONSUMED	FOOD GROUPS	0.2	cup eq	0.2	cup eq	2019-01-15
47	ABC123	FA	0001	47	1	D	DGRAIN	Dietary Grain	Chili beef soup	CONSUMED	FOOD GROUPS	0.17	cup eq	0.17	cup eq	2019-01-15
48	ABC123	FA	0001	48	1	D	DMEAT	Dietary Meat	Chili beef soup	CONSUMED	FOOD GROUPS	0.57	oz eq	0.57	oz eq	2019-01-15
49	ABC123	FA	0001	49	2	E	DPROT	Dietary Protein	Bread, garlic, toasted	CONSUMED	MACRONUTRIENTS	3.12	g	3.12	g	2019-01-15
50	ABC123	FA	0001	50	2	E	DFATT	Dietary Fat, Total	Bread, garlic, toasted	CONSUMED	MACRONUTRIENTS	6.21	g	6.21	g	2019-01-15
51	ABC123	FA	0001	51	2	E	DCARBT	Dietary Total Carbohydrate	Bread, garlic, toasted	CONSUMED	MACRONUTRIENTS	15.59	g	15.59	g	2019-01-15
52	ABC123	FA	0001	52	2	E	DADDSUG	Dietary Added Sugar	Bread, garlic, toasted	CONSUMED	ADDED SUGAR	0.07	tsp eq	0.07	tsp eq	2019-01-15
53	ABC123	FA	0001	53	2	E	DCAL	Dietary Calories	Bread, garlic, toasted	CONSUMED	CALORIES	131	kcal	131	kcal	2019-01-15
54	ABC123	FA	0001	54	2	E	DFRUIT	Dietary Fruit	Bread, garlic, toasted	CONSUMED	FOOD GROUPS	0	cup eq	0	cup eq	2019-01-15
55	ABC123	FA	0001	55	2	E	DVEG	Dietary Vegetable	Bread, garlic, toasted	CONSUMED	FOOD GROUPS	0	cup eq	0	cup eq	2019-01-15
56	ABC123	FA	0001	56	2	E	DGRAIN	Dietary Grain	Bread, garlic, toasted	CONSUMED	FOOD GROUPS	1.16	cup eq	1.16	cup eq	2019-01-15
57	ABC123	FA	0001	57	2	E	DMEAT	Dietary Meat	Bread, garlic, toasted	CONSUMED	FOOD GROUPS	0	oz eq	0	oz eq	2019-01-15

Lunch – Meal Level

mLxpt

Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLLNKID	MLTRT	MLDOSE	MLDOSU	MLSTDTC	MLENDTC	MLSTDY	MLENDY
1	ABC123	ML	0001	1	C	LUNCH	838.5	g	2019-01-15T12:00	2019-01-15T13:00	1	1

MLNUMSVG	MLDECD	MLDCDICT
4.33		FNDDS

ML NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
MLNUMSVG	Number of Servings	float	Non-standard Record Qualifier		eDT
MLDECD	Decode Code	integer	Non-standard Record Qualifier	(see value-level metadata)	eDT
MLDCDICT	Dictionary Version	text	Non-standard Record Qualifier		eDT

Difference in the different level of models is the MLTRT & FAOBJ

Value Level Metadata - ML [MLDECD]

Variable	Where	Codelist
MLDECD	MLDCDICT="FNDDS"	Food and Nutrient Database for Dietary Studies (FNDDS)

famLxpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FAGRPID	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FASCAT	FAORRES	FAORRESU	FASTRES	FASTRESN	FASTRESU	FADTC
23	ABC123	FA	0001	23	1	C	DPROT	Dietary Protein	LUNCH	CONSUMED	MACRONUTRIENTS	11.4	g	11.4	11.4	g	2019-01-15
24	ABC123	FA	0001	24	1	C	DFATT	Dietary Fat, Total	LUNCH	CONSUMED	MACRONUTRIENTS	10.33	g	10.33	10.33	g	2019-01-15
25	ABC123	FA	0001	25	1	C	DCARBT	Dietary Total Carbohydrate	LUNCH	CONSUMED	MACRONUTRIENTS	85.74	g	85.74	85.74	g	2019-01-15
26	ABC123	FA	0001	26	1	C	DADDSUG	Dietary Added Sugar	LUNCH	CONSUMED	ADDED SUGAR	10.56	tsp eq	10.56	10.56	tsp eq	2019-01-15
27	ABC123	FA	0001	27	1	C	DCAL	Dietary Calories	LUNCH	CONSUMED	CALORIES	472.3	kcal	472.3	472.3	kcal	2019-01-15
28	ABC123	FA	0001	28	1	C	DFRUIT	Dietary Fruit	LUNCH	CONSUMED	FOOD GROUPS	0	cup eq	0	0	cup eq	2019-01-15
29	ABC123	FA	0001	29	1	C	DVEG	Dietary Vegetable	LUNCH	CONSUMED	FOOD GROUPS	0.2	cup eq	0.2	0.2	cup eq	2019-01-15
30	ABC123	FA	0001	30	1	C	DGRAIN	Dietary Grain	LUNCH	CONSUMED	FOOD GROUPS	1.33	cup eq	1.33	1.33	cup eq	2019-01-15
31	ABC123	FA	0001	31	1	C	DMEAT	Dietary Meat	LUNCH	CONSUMED	FOOD GROUPS	0.57	oz eq	0.57	0.57	oz eq	2019-01-15

Daily Total Food and Drink – Summary Level

ml.xpt

Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLLNKID	MLTRT	MLDOSTOT	MLDOSU	MLSTDTC	MLENTC	MLSTDY	MLENDY
1	ABC123	ML	0001	1	A	DAILY TOTAL FOOD AND DRINK	1708.75	g	2019-01-15T00:00	2019-01-15T23:59	1	1
2	ABC123	ML	0001	2	B	DAILY TOTAL FOOD AND DRINK	1045.84	g	2019-01-16T00:00	2019-01-16T23:59	2	2

MLNUMSVG	MLREAS	MLDECD	MLDCDICT
11.25	NUTRITION		FNDDS
9.32	NUTRITION		FNDDS

ML NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
MLNUMSVG	Number of Servings	float	Non-standard Record Qualifier		eDT
MLREAS	Reason for the Intervention	text	Non-standard Record Qualifier		eDT
MLDECD	Decode Code	integer	Non-standard Record Qualifier (see value-level metadata)		eDT
MLDCDICT	Dictionary Version	text	Non-standard Record Qualifier		eDT

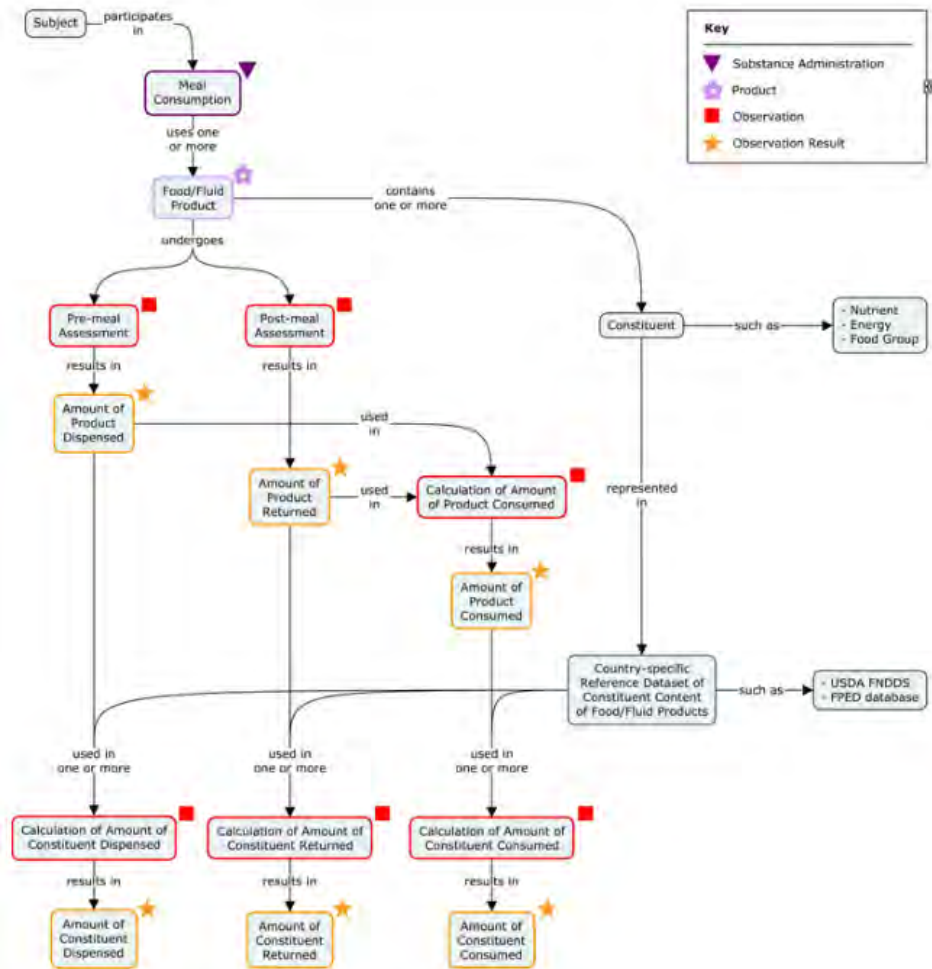
Difference in the different level of models is the MLTRT & FAOBJ

Value Level Metadata - ML [MLDECD]

Variable	Where	Codelist
MLDECD	MLDCDICT="FNDDS"	Food and Nutrient Database for Dietary Studies (FNDDS)

famL.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FAGRPID	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FASCAT	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	FADTC
13	ABC123	FA	0001	13	3	A	DCARBT	Dietary Total Carbohydrate	DAILY TOTAL FOOD AND DRINK	CONSUMED	MACRONUTRIENTS	229.54	g	229.54	229.54	g	2019-01-15
14	ABC123	FA	0001	14	3	A	DMG	Dietary Magnesium	DAILY TOTAL FOOD AND DRINK	CONSUMED	MICRONUTRIENTS	162	mg	162	162	mg	2019-01-15
15	ABC123	FA	0001	15	3	A	DCAL	Dietary Calories	DAILY TOTAL FOOD AND DRINK	CONSUMED	CALORIES	1955	kcal	1955	1955	kcal	2019-01-15
16	ABC123	FA	0001	16	3	A	DVEG	Dietary Vegetable	DAILY TOTAL FOOD AND DRINK	CONSUMED	FOOD GROUPS	0	cup eq	0	0	cup eq	2019-01-15
29	ABC123	FA	0001	29	6	B	DCARBT	Dietary Total Carbohydrate	DAILY TOTAL FOOD AND DRINK	CONSUMED	MACRONUTRIENTS	255.37	g	255.37	255.37	g	2019-01-16
30	ABC123	FA	0001	30	6	B	DMG	Dietary Magnesium	DAILY TOTAL FOOD AND DRINK	CONSUMED	MICRONUTRIENTS	190	mg	190	190	mg	2019-01-16
31	ABC123	FA	0001	31	6	B	DCAL	Dietary Calories	DAILY TOTAL FOOD AND DRINK	CONSUMED	MACRONUTRIENTS	1497	kcal	1497	1497	kcal	2019-01-16
32	ABC123	FA	0001	32	6	B	DVEG	Dietary Vegetable	DAILY TOTAL FOOD AND DRINK	CONSUMED	FOOD GROUPS	0.91	cup eq	0.91	0.91	cup eq	2019-01-16



Modeling Highlights

- Only consumed is represented in ML

mLxpt

Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLLNKID	MLTRT	MLCAT	MLDOSE	MLDOSU	MLSTDTG	MLENDTC	MLSTDY	MLENDY	MLNUMSVG	MLREAS	MLDECD	MLDCDICT
1	NUT123	ML	0001	1	A	Granola bar	BREAKFAST	30	grams	2019-01-15T08:00	2019-01-15T08:05	1	1	1	NUTRITION	53542100	FNDDS
2	NUT123	ML	0001	2	B	Orange juice	SNACK	347	grams	2019-01-15T10:00	2019-01-15T10:02	1	1	1.4	GLYCEMIC CONTROL - HYPOGLYCEMIA	64134000	FNDDS

- Served, returned and all constituents in FAML

famLxpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FAGRPID	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FASCAT	FAORRES	FAORRESU	FASTRES	FASTRESN	FASTRESU	FADTC
1	NUT123	FA	0001	1	1	A	ESTWT	Estimated Weight	Granola bar	SERVED	TOTAL	30	g	30	30	g	2019-01-15
2	NUT123	FA	0001	2	1	A	NUMSV	Number of Servings	Granola bar	SERVED	SERVINGS	1		1			2019-01-15
3	NUT123	FA	0001				PROT	Dietary Protein	Granola bar	SERVED	MACRONUTRIENTS	2.94	g	2.94	2.94	g	2019-01-15
4	NUT123	FA	0001				FATT	Dietary Fat, Total	Granola bar	SERVED	MACRONUTRIENTS	5.28	g	5.28	5.28	g	2019-01-15
5	NUT123	FA	0001	5	1	A	DCARB	Dietary Total Carbohydrate	Granola bar	SERVED	MACRONUTRIENTS	20.01	g	20.01	20.01	g	2019-01-15
6	NUT123	FA	0001	6	1	A	DMG	Dietary Magnesium	Granola bar	SERVED	MICRONUTRIENTS	30	mg	30	30	mg	2019-01-15
7	NUT123	FA	0001	7	1	A	ESTWT	Estimated Weight	Granola bar	RETURNED	TOTAL	0	g	0	0	g	2019-01-15
8	NUT123	FA	0001	8	1	A	NUMSV	Number of Servings	Granola bar	RETURNED	SERVINGS	0	g	0	0	g	2019-01-15
9	NUT123	FA	0001				PROT	Dietary Protein	Granola bar	RETURNED	MACRONUTRIENTS	0	g	0	0	g	2019-01-15
10	NUT123	FA	0001				FATT	Dietary Fat, Total	Granola bar	RETURNED	MACRONUTRIENTS	0	g	0	0	g	2019-01-15
11	NUT123	FA	0001	11	1	A	DCARB	Dietary Total Carbohydrate	Granola bar	RETURNED	MACRONUTRIENTS	0	g	0	0	g	2019-01-15
12	NUT123	FA	0001	12	1	A	DMG	Dietary Magnesium	Granola bar	RETURNED	MICRONUTRIENTS	0	mg	0	0	mg	2019-01-15
13	NUT123	FA	0001	13	1	A	DPROT	Dietary Protein	Granola bar	CONSUMED	MACRONUTRIENTS	2.94	g	2.94	2.94	g	2019-01-15
14	NUT123	FA	0001				FATT	Dietary Fat, Total	Granola bar	CONSUMED	MACRONUTRIENTS	5.28	g	5.28	5.28	g	2019-01-15
15	NUT123	FA	0001				DCARB	Dietary Total Carbohydrate	Granola bar	CONSUMED	MACRONUTRIENTS	20.01	g	20.01	20.01	g	2019-01-15
16	NUT123	FA	0001	16	1	A	DMG	Dietary Magnesium	Granola bar	CONSUMED	MICRONUTRIENTS	30	mg	30	30	mg	2019-01-15



Known Issues

- **Meal Data (ML) Domain Description and Assumption**

- The SDTMIG v3.3 indicates that food and nutrition information is stored in the proper domain depending on the context (e.g., EC/EX, CM, AG, or SU) otherwise use ML domain.
- This module uses ML for all intake of food or fluid extending the description of the domain for the use case.

- **Approach for Modeling Nutrition Data**

- Use case was for modeling meal data for served food, returned food and consumed food in order to show nutrition offered, nutrition waste and nutrition consumed
- Still under discussion and subject to change

- **Use of Non-standard Variables (NSVs) MLDECD CD and MLDCDICT**

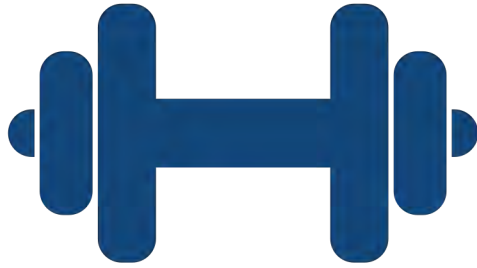
- Changes in NSV format in prior TAUGs



Types of Activity and Activity Devices

Kathleen Mellars

Exercise



- *Exercise* is physical activity that is **planned, structured, repetitive**, and designed to improve or maintain physical fitness, physical performance, or health. Exercise encompasses all intensity levels.

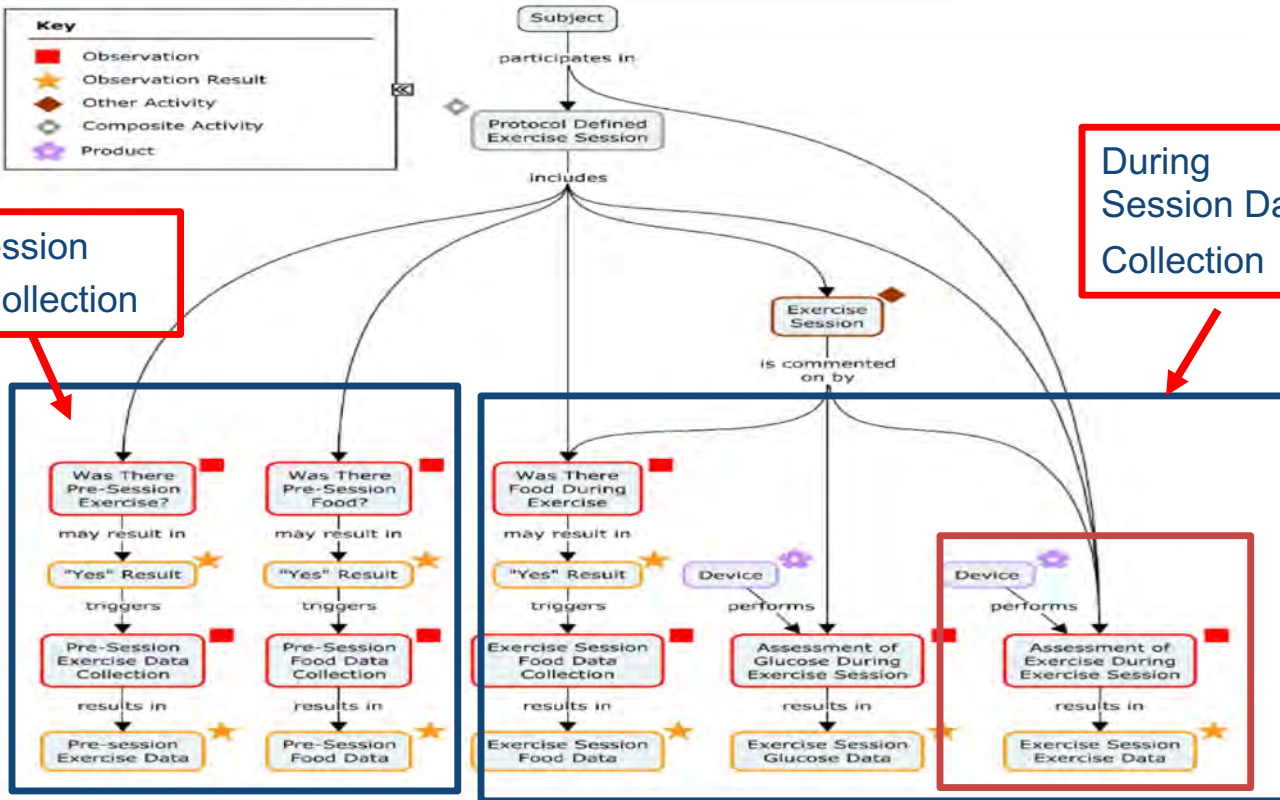
Protocol Defined Exercise Sessions

Concept Map. Protocol Defined Exercise Session

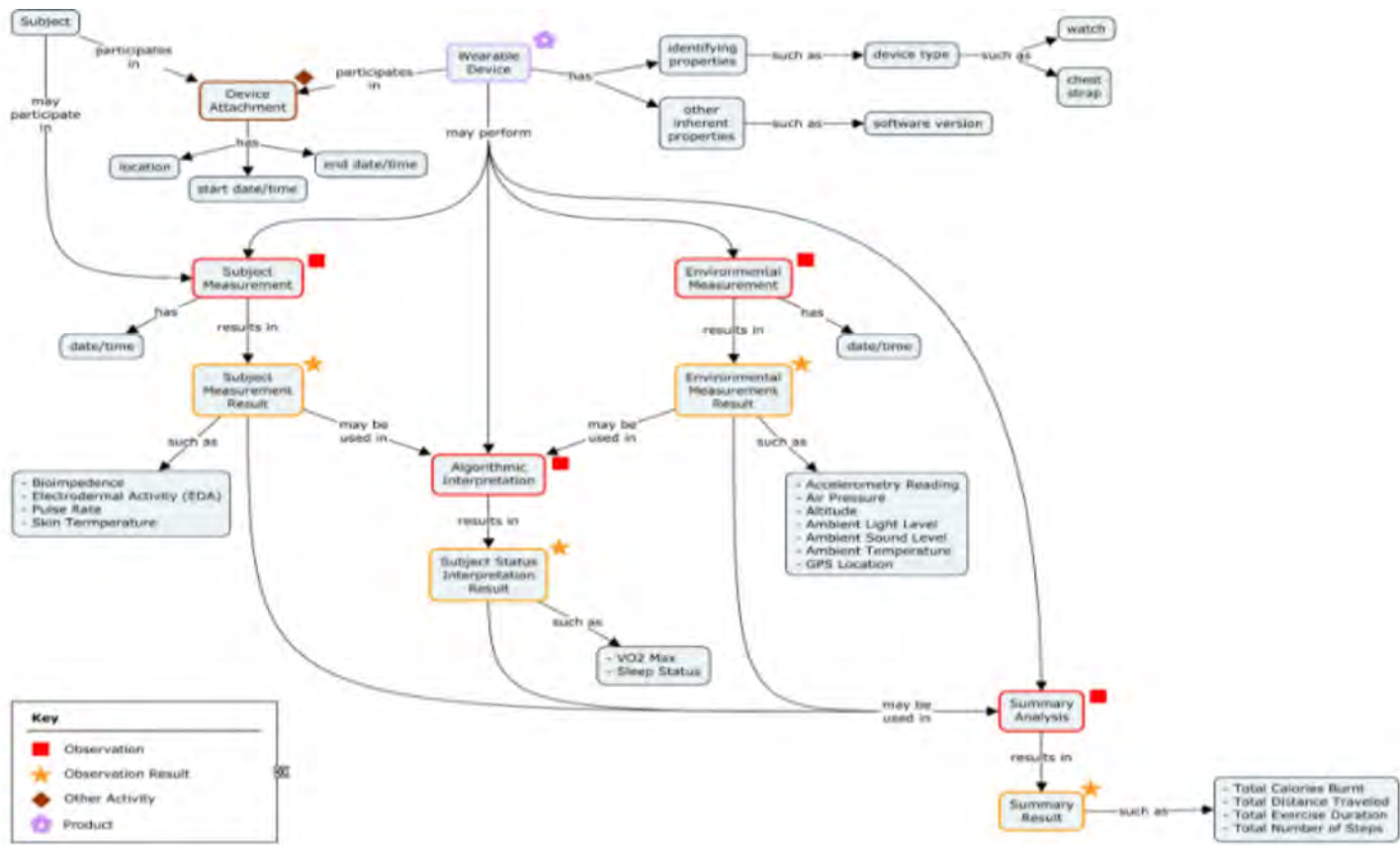


Pre-Session Data Collection

During Session Data Collection



Concept Map: Wearable Devices





1. Synchronization of Dates/Times Reported by Devices

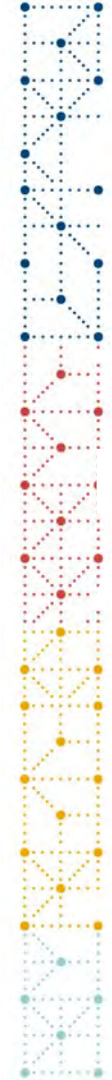
- Devices output dates and times for collected data based on the actual date and times recorded in the device. These dates, times and time zones may be automatically set by the device, or manually entered by the users. These dates and times may not be identical to the times recorded by individuals from other sources. The device date/times may be set incorrectly, not updated often, or reported using a different time zone. Sponsors must decide what dates and times to include in the SDTM/ADaM datasets.
- If dates and times are adjusted prior to the creation of the SDTM datasets, information on these derivations should be provided in any reviewer's guide. Health authorities may request that the device data be provided using the collected unadjusted dates and times.
- If SDTM datasets with unsynchronized dates are provided, the synchronized dates can be derived in intermediate ADaM datasets, ensuring traceability. The dates and times in SDTM are represented using ISO 8601 format. This format allows the offset from Coordinated Universal Time (UTC) to be represented. Sponsors would have to discuss with the appropriate vendor whether they have to ability to provide the date and time values with the appropriate UTC offset. Examples using this format are **not** currently provided in the SDTMIG at: <https://www.cdisc.org/standards/foundational/sdtmig>, or this TAUG.

2. Large Volume of Raw Data

- Typically, all collected data that support review, reporting, and analysis for the purpose of drug/device approvals should be submitted to health authorities. There are cases where a large volume of raw data is generated by a device. In this case, summary data that are received as an output from a device may be represented in an SDTM dataset instead of the full set of the raw data. Even though summary data are submitted, health authorities may request the submission of all of the raw data from the device. This TAUG presents examples of the representation of summary data/statistics from consumer wearable devices in SDTM-based domains. Representing these derived measures within an SDTM-based domain is under consideration by the Submission Data Standards (SDS) and Analysis Data Model (ADaM) Teams and is subject to change.

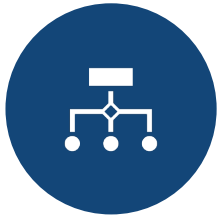
3. Non-Medical Devices

- Some of the devices mentioned in this TAUG may be considered consumer devices and not considered by regulatory authorities as medical devices. There has been a preference that Global Medical Device Nomenclature (GMDN) is used as controlled terminology for Device Type (DEVTYPE). However for non-medical devices, the sponsor may need to develop appropriate terminology for DEVTYPE. (SDTMIG-MD 1.1 at: <http://www.cdisc.org/>.



- Exercise and specific exercise activities were represented in the Procedures (PR) domain.
 - ✓ This is consistent with the representation of Physical Therapy, and Occupational Therapy in the PR domain.
- Medical/Consumer devices and Web applications were considered “devices”
- Findings about any exercise activity were represented in the appropriate SDTM Findings domain.

Protocol Defined- Exercise Session- Highlights



Administrative data on pre-defined protocol exercise sessions



Devices used during pre-defined protocol exercise sessions



Activities that occurred prior to pre-defined protocol exercise sessions.



Assessment during pre-defined protocol exercise sessions (e.g., heart rate, glucose)

Protocol-Defined Exercise Session- Administrative Data

Title: Part 2. In-clinic Exercise Session

This module collects administrative information about the in-clinic exercise sessions.

	Procedure Category <i>Hidden/pre-populated</i>	PROTOCOL DEFINED EXERCISE
	Environmental Setting <i>Hidden/pre-populated</i>	CLINIC
Record the identifier for this in-clinic exercise session.	What is the identifier for this in-clinic exercise session?	<input type="radio"/> CLINIC SESSION 1 <input type="radio"/> CLINIC SESSION 2 <input type="radio"/> CLINIC SESSION 3
Indicate if the subject attended the in-clinic exercise session.	Did the subject the attend the in-clinic exercise session?	<input type="radio"/> Yes <input type="radio"/> No
Record what type of exercise was assigned to the subject.	What was the type of exercise?	<input type="radio"/> Aerobic Exercise <input type="radio"/> Resistance Circuit Exercise <input type="radio"/> Intermittent Intensity Interval Exercise
Record the date the subject started the in-clinic exercise session using this format (DD-MON-YYYY).	Start Date	<input type="text"/>
Record the time the subject started the in-clinic exercise session using this format (HH:MM)	Start Time	<input type="text"/>
Record the date the subject ended the in-clinic exercise session using this format (DD-MON-YYYY).	End Date	<input type="text"/>
Record the time the subject ended the in-clinic exercise session using this format (HH:MM).	End Time	<input type="text"/>

Protocol-Defined Exercise Session- Administrative Data

Title: In-Clinic Exercise Pre-Session Data

	<i>Hidden/pre-populated</i>	PROTOCOL DEFINED EXERCISE
	<i>Hidden/pre-populated</i>	CLINIC
Indicate which in-clinic exercise session is being performed.	What is the the in-clinic session number?	<input type="radio"/> CLINIC SESSION 1 <input type="radio"/> CLINIC SESSION 2 <input type="radio"/> CLINIC SESSION 3
Record the date the subject started the in-clinic exercise session using this format (DD-MON-YYYY).	Date	<input type="text"/>
Record the time the subject started the in-clinic exercise session using this format (HHMM).	Time	<input type="text"/>
	<i>Hidden/pre-populated</i>	-PT24H
	<i>Hidden/pre-populated</i>	EXERCISE
	Was exercise performed in the 24 hours prior to the start of the in-clinic exercise session?	<input type="radio"/> Yes <input type="radio"/> No
Record the total duration (in minutes) of the exercise in the 24 hours prior to the start of the in-clinic exercise session.	What was the total duration (in minutes) of the exercise in the 24 hours prior to the start of the in-clinic exercise session?	<input type="text"/>
Record the estimated average intensity level of the exercise performed within 24 hours of the in-clinic session with the actual or subject-perceived intensity level.	What was the exercise intensity level of the exercise performed within 24 hours of the in-clinic session?	<input type="radio"/> Mild Intensity <input type="radio"/> Moderate Intensity <input type="radio"/> Vigorous intensity
Record the method used to determine exercise intensity.	What was the method used to determine exercise intensity?	<input type="radio"/> Actual <input type="radio"/> Self Assessment
	<i>Hidden/pre-populated</i>	FOOD
	<i>Hidden/pre-populated</i>	LAST FOOD
Indicate the date of the last food intake prior to the current in-clinical exercise session.	What was the date of the last food intake prior to this in-clinic exercise session?	<input type="text"/>
Indicate the time of the last food intake prior to the current in-clinical exercise session.	What was the time of the last food intake prior to this in-clinic exercise session?	<input type="text"/>

Protocol-Defined Exercise Session- Administrative Data

pr.xpt

Rows 1, 4, 7: Show the subject performed the 3 scheduled out-of-clinic exercise sessions.

Rows 2, 5: Show that this subject performed exercise in the 24 hours prior to the start of in-clinic exercise sessions 1 and 2. PROCUR was used to indicate if any pre-session exercise was performed. Because all subjects were asked if it was populated as "Y", PRDTC (the date of collection) was populated with the start date/time of the in-clinic exercise session to indicate that the pre-clinic information was collected at the start of the in-clinic exercise session of "-PT24H" to indicate that the interval of interest was the 24 hours prior to the date/time of collection (i.e., the start date/time of the in-clinic session).

Rows 3, 6: Show the subject attended in-clinic exercise sessions 1 and 2. The start date and end date/times of the sessions are shown in PRSTDTC and PRENDTC respectively.

Row 8: Shows the subject did not attend in-clinic session 3. Note that because the subject did not attend this session, the information about any pre-session exercise was not included.

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRREFID	PRLNKID	PRTRT	PRCAT	PRPESP	PROCCUR	PRDTC	PRSTDTC	PRENDTC	PREVLINT	PRSETTING	
1	EX008	PR	5001	1	NON-CLINIC SESSION 1	NC1	AEROBIC EXERCISE	P	OTOCOL DEFINED EXERCISE	Y	Y	2016-08-10	2016-08-10T09:30	2016-08-10T10:25		NON-CLINIC
2	EX008	PR	5001	2	CLINIC SESSION 1	C1P	EXERCISE	P	OTOCOL DEFINED EXERCISE	Y	Y	2016-08-23T08:00			-PT24H	
3	EX008	PR	5001	3	CLINIC SESSION 1	C1	AEROBIC EXERCISE	P	OTOCOL DEFINED EXERCISE	Y	Y	2016-08-23	2016-08-23T08:00	2016-08-23T09:10		CLINIC
4	EX008	PR	5001	4	NON-CLINIC SESSION 2	NC2	AEROBIC EXERCISE	P	OTOCOL DEFINED EXERCISE	Y	Y	2016-10-01	2016-10-01T09:45	2016-10-01T10:45		NON-CLINIC
5	EX008	PR	5001	5	CLINIC SESSION 2	C2P	EXERCISE	P	OTOCOL DEFINED EXERCISE	Y	Y	2016-10-23T08:00			-PT24H	
6	EX008	PR	5001	6	CLINIC SESSION 2	C2	AEROBIC EXERCISE	P	OTOCOL DEFINED EXERCISE	Y	Y	2016-10-23	2016-10-23T08:00	2016-10-23T08:57		CLINIC
7	EX008	PR	5001	7	NON-CLINIC SESSION 3	NC3	AEROBIC EXERCISE	P	OTOCOL DEFINED EXERCISE	Y	Y	2016-12-01	2016-12-01T09:30	2016-12-01T10:40		NON-CLINIC
8	EX008	PR	5001	8	CLINIC SESSION 3	C3	AEROBIC EXERCISE	P	OTOCOL DEFINED EXERCISE	Y	N	2016-12-23				CLINIC

PR NSV Metadata

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

Protocol-Defined Exercise Session- Activities Prior to the Exercise Session.

Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLREFID	MLLNKID	MLLNKGRP	MLTRT	MLCAT	MLPRESP	MLOCCUR	MLODOSE	MLODOSTXT	MLODOSU	MLDTC	MLSTDTC	MLENDTC	MLEVLINT	MLCRNORD	MLREAS	MLSETTNG
1	EX008	ML	5001	1	CLINIC SESSION 1P	MP1	C1	FOOD	PROTOCOL DEFINED EXERCISE	Y	Y				2016-08-23T08:00	2016-10-22T23:00		-PT24H	LAST FOOD		
2	EX008	ML	5001	2	CLINIC SESSION 1P	M11	C1	SNACK	PROTOCOL DEFINED EXERCISE						2016-08-23	2016-08-23T08:45				GLYCEMIC CONTROL	CLINIC
3	EX008	ML	5001	3	CLINIC SESSION 1 CLINIC	M12	C1	WATER	PROTOCOL DEFINED EXERCISE						2016-08-23	2016-08-23T09:05				HYDRATION	CLINIC
4	EX008	ML	5001	4	SESSION 2P	MP2	C2	FOOD	DEFINED EXERCISE	Y	Y				2016-10-23T08:00	2016-10-23T06:45		-PT24H	LAST FOOD		
5	EX008	ML	5001	5	CLINIC SESSION 2	M21	C2	SNACK	PROTOCOL DEFINED EXERCISE						2016-10-23	2016-10-23T08:15				HYDRATION	CLINIC
6	EX008	ML	5001	6	CLINIC SESSION 2	M22	C2	SPORTS DRINK	PROTOCOL DEFINED EXERCISE						2016-10-23	2016-10-23T08:45				GLYCEMIC CONTROL	CLINIC

ML NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
MLCRNORD	Chronological Order	text	Non-standard Timing Qualifier		CRF
MLREAS	Reason for the Intervention	text	Non-standard Record Qualifier		CRF
MLSETTNG	Environmental Setting	text	Non-standard Record Qualifier	(SETTING)	CRF

Protocol-Defined Exercise Session- Devices Used

Title: Part 1. Device Inventory for In-clinic Exercise


This module collects information about the device used by the subject for all in-clinic sessions. Sponsors might also collect device assignment for each session, or various device properties (e.g., manufacturer, serial number); for simplicity, in this example only the serial number was collected.

Legend: Variable in the SDTM-based submission dataset CDASH variable that differs from the SDTM variable

	Collected Device Identifier <i>Hidden/pre-populated</i>	Sponsor-defined
Indicate what chest strap band was assigned to the subject.	What chest strap band device was assigned to the subject?	<input type="radio"/> Chest Strap 1 <input type="radio"/> Chest Strap 2 <input type="radio"/> Chest Strap 3
Record the serial number of the device.	What is the serial number of the device?	<input type="text"/>

Protocol-Defined Exercise Session- Devices Used

Row	STUDYID	SPDEVID	DIPARMCD	DIPARM	DIVAL
1	EX-001	IP	DEVTYPE	Device Type	Ambulatory insulin infusion pump, electronic
2	EX-001	IP	MANUF	Manufacturer	Generic Infusions
3	EX-001	CGM	DEVTYPE	Device Type	Implantable glucose monitoring system
4	EX-001	CGM	MANUF	Manufacturer	Generic CGM
5	EX-001	STUDY CSTRAP	DEVTYPE	Device Type	Heart Rate Strap and Transmitter
6	EX-001	STUDY CSTRAP	MANUF	Manufacturer	Generic Straps
7	EX-001	STUDY CSTRAP	SERIAL	Serial Number	xxw6789yqs
8	EX-001	STUDY WATCH	DEVTYPE	Device Type	Consumer Wearable Activity Watch
9	EX-001	STUDY WATCH	MANUF	Manufacturer	Manufacture X
10	EX-001	STUDY WATCH	SOFTVERS	Software Version	2.3

- 
- Assessment Data from devices used to track exercise information may be represented in several different SDTM domains:
 - Vital Signs (VS) - heart rate)
 - Respiratory System Findings (RE) - Estimated maximal oxygen consumption (VO2) max
 - Laboratory Test Results (LB)- Glucose levels from a continuous glucose monitor (CGM)
 - Concomitant Medications (CM) or Exposure (EX)- Insulin levels from an insulin pump)
 - Findings About (FA) - Findings data not specific to a body system domain

Protocol-Defined Exercise Session-Assessments

vs.xpt

Rows 1-3: Show summary heart rate measurements for the WARM-UP, TRAINING, and COOL DOWN time periods (VSTPT). The NSV VSCOLSRT indicates what type of result was reported. Results reported were the average heart rate for the warm-up period, the maximum heart rate for the training period, and the minimum heart rate for the cool-down period. Note that because these are summary values over an interval of time, VSENDTC is provided.

Rows 4-7: Show the actual heart rate measured every 5 minutes during the TRAINING period. Note that each of these is a single measurement, so VSENDTC is not provided.

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	VSEID	VSRFID	VSLNKID	VSTESTCD	VSTEST	VSCAT	VSORRES	VSORRESU	VSTRESC	VSTRESN	VSTRESU	VISITNUM	VSDTC	VSENDTC	VSTPT	VSTPTNUM	VSCOLSRT	VSRRECFL	VSRRECVF	VSSSETTING
1	EX-001	VS	007	STUDY CSTRAP	1	CLINIC SESSION 1	C1	HR	Heart Rate	PROTOCOL DEFINED EXERCISE	80	beats/min	80	80	beats/min		2016-08-23T08:00	2016-08-23T08:10	WARM-UP	1	AVERAGE	Y		CLINIC
2	EX-001	VS	007	STUDY CSTRAP	2	CLINIC SESSION 1	C1	HR	Heart Rate	PROTOCOL DEFINED EXERCISE	165	beats/min	165	165	beats/min		2016-08-23T08:10	2016-08-23T09:00	TRAINING	2	MAXIMUM	Y		CLINIC
3	EX-001	VS	007	STUDY CSTRAP	3	CLINIC SESSION 1	C1	HR	Heart Rate	PROTOCOL DEFINED EXERCISE	85	beats/min	85	85	beats/min		2016-08-23T09:00	2016-08-23T09:05	COOL DOWN	3	MINIMUM	Y		CLINIC
4	EX-001	VS	007	STUDY CSTRAP	4	CLINIC SESSION 1	C1	HR	Heart Rate	PROTOCOL DEFINED EXERCISE	130	beats/min	130	130	beats/min		2016-08-23T08:10		TRAINING	2		Y		CLINIC
5	EX-001	VS	007	STUDY CSTRAP	5	CLINIC SESSION 1	C1	HR	Heart Rate	PROTOCOL DEFINED EXERCISE	140	beats/min	140	140	beats/min		2016-08-23T08:15		TRAINING	2		N	Technical Error	CLINIC
6	EX-001	VS	007	STUDY CSTRAP	6	CLINIC SESSION 1	C1	HR	Heart Rate	PROTOCOL DEFINED EXERCISE	137	beats/min	137	137	beats/min		2016-08-23T08:20		TRAINING	2		Y		CLINIC
7	EX-001	VS	007	STUDY CSTRAP	7	CLINIC SESSION 1	C1	HR	Heart Rate	PROTOCOL DEFINED EXERCISE	165	beats/min	165	165	beats/min		2016-08-23T08:25		TRAINING	2		Y		CLINIC

VS NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
VSCOLSRT	Collected Summary Result Type	text	Non-standard Record Qualifier		CRF
VSRRECFL	Record Validity Flag	text	Non-standard Record Qualifier (NY)		CRF
VSRRECVF	Reason for Record Validity Flag	text	Non-standard Record Qualifier		CRF
VSSSETTING	Environmental Setting	text	Non-standard Record Qualifier (SETTING)		CRF

Protocol-Defined Exercise Session-Assessments

fapr.xpt

Rows 1-4: Show the physical activities parameters collected during a 24-hour period prior to the baseline visit. These parameters were directly reported by the wearable device identified in the DI domain. The method of deriving the parameters was included in the device manual.

Rows 5-8: Show the physical activity parameters as reported by the wearable device for a 24-hour period prior to the week 12 visit.

fapr.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	FASEQ	FAREFID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	VISITNUM	VISIT	FADTC	FAENDTC
1	EX010	FA	EX010-007	STUDY WATCH	1	PHYSICAL ACTIVITY SESSION 1	STEPSTN	Number of Steps Taken	24-HOUR PHYSICAL ACTIVITY MONITORING	GENERAL PHYSICAL ACTIVITY	13768		13768	13768		2	BASELINE	2016-09-23T00:00:00	2016-09-23T23:59:59
2	EX010	FA	EX010-007	STUDY WATCH	2	PHYSICAL ACTIVITY SESSION 1	DISTANCE	Distance	24-HOUR PHYSICAL ACTIVITY MONITORING	GENERAL PHYSICAL ACTIVITY	10.45	km	10.45	10.45	km	2	BASELINE	2016-09-23T00:00:00	2016-09-23T23:59:59
3	EX010	FA	EX010-007	STUDY WATCH	3	PHYSICAL ACTIVITY SESSION 1	CALBURNT	Calories Burned	24-HOUR PHYSICAL ACTIVITY MONITORING	GENERAL PHYSICAL ACTIVITY	2079	kcal	2079	2079	kcal	2	BASELINE	2016-09-23T00:00:00	2016-09-23T23:59:59
4	EX010	FA	EX010-007	STUDY WATCH	4	PHYSICAL ACTIVITY SESSION 1	TTIMPHAC	Total Time Physically Active	24-HOUR PHYSICAL ACTIVITY MONITORING	GENERAL PHYSICAL ACTIVITY	308	min	308	308	min	2	BASELINE	2016-09-23T00:00:00	2016-09-23T23:59:59
5	EX010	FA	EX010-007	STUDY WATCH	5	PHYSICAL ACTIVITY SESSION 2	STEPSTN	Number of Steps Taken	24-HOUR PHYSICAL ACTIVITY MONITORING	GENERAL PHYSICAL ACTIVITY	14356		14356	14356		12	WEEK 12	2016-12-16T00:00:00	2016-12-16T23:59:59
6	EX010	FA	EX010-007	STUDY WATCH	6	PHYSICAL ACTIVITY SESSION 2	DISTANCE	Distance	24-HOUR PHYSICAL ACTIVITY MONITORING	GENERAL PHYSICAL ACTIVITY	11.45	km	11.45	11.45	km	12	WEEK 12	2016-12-16T00:00:00	2016-12-16T23:59:59
7	EX010	FA	EX010-007	STUDY WATCH	7	PHYSICAL ACTIVITY SESSION 2	CALBURNT	Calories Burned	24-HOUR PHYSICAL ACTIVITY MONITORING	GENERAL PHYSICAL ACTIVITY	2345	kcal	2345	2345	kcal	12	WEEK 12	2016-12-16T00:00:00	2016-12-16T23:59:59
8	EX010	FA	EX010-007	STUDY WATCH	8	PHYSICAL ACTIVITY SESSION 2	TTIMPHAC	Total Time Physically Active	24-HOUR PHYSICAL ACTIVITY MONITORING	GENERAL PHYSICAL ACTIVITY	345	min	345	345	min	12	WEEK 12	2016-12-16T00:00:00	2016-12-16T23:59:59

Summary: Types of Activity and Activity Devices

- **PR domain was used to represent when**
 - Participants exercised
 - Periods of time when physical activity was monitored.
- **Medical Devices domains were used to describe wearable devices used by participants.**
- **Findings domains were used to represent assessments of exercise/physical activity.**
 - Vital Signs (VS) - Heart Rate
 - Respiratory System Findings (RE) - Estimated maximal oxygen consumption (VO₂ max))
 - Laboratory Test Results (LB) - Data from a continuous glucose monitor (CGM))
- **Interventions domains were used to represent information on food/insulin evaluated during exercise/physical activity.**
 - ML is used to record food consumption
 - CM is used to record any information on insulin consumption, .



Exercise Questionnaires, Ratings, & Scales —QRS Supplements

John Owen

Prevention QRS Instruments

Table 1. Identified QRS Measures of Interest to Type 1 Diabetes - Exercise

Full Name and Abbreviation	Subtitle (Where Applicable)	Copyright Permission Status	Supplement Status
Clarke's Hypoglycemia Awareness Questionnaire		Requested	
International Physical Activity Questionnaire (IPAQ)	IPAQ Long Last 7 Days Self-Administered Format	Public domain	Supplement in progress
	IPAQ Short Last 7 Days Self-Administered Format	Public domain	Supplement in progress
	IPAQ Long Last 7 Days Telephone Format	Public domain	Supplement in progress
	IPAQ Short Last 7 Days Telephone Format	Public domain	Supplement in progress
Physical Activity Readiness Questionnaire for Everyone		Requested	
Rockport One-Mile Walk Test		Public domain	Supplement in progress



Thank You!



Audience Questions



Why did you choose the handgrip strength test as an example for the baseline fitness & strength status module?

Audience Questions

Rebecca:

Does the nutrition modelling just apply to T1D Exercise studies or can this be used for any nutrition data?



Audience Questions



John:

There only appear to be 5 QRS instruments identified – aren't there many more that are used in diabetes research?

Audience Questions

How do I get involved in the public review?



Audience Questions



Where/how can I leave a public comment on the guide?

Audience Questions

I did not see a field for time zone for any of the fields?



Audience Questions



While food photographs were mentioned in the talk, I did not see the fields where those photos might be stored in the nutrition module?



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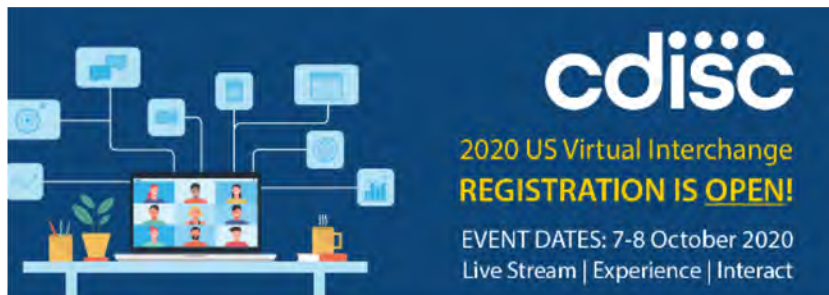
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1 OCT	Public Review: TAUG for Crohn's Disease
13 OCT	Controlled Terminology Updates for Q4
20 OCT	Linking Data in SDTM
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