



CDISC Nutrition Therapeutic Area User Guide

Public Review Webinar

Presented by John Owen
Nutrition TAUG Project Manager, Standards Development, CDISC

18 Oct 2018





Presenter and Q&A Panelists

Presenter

John Owen, Consultant Project Manager, CDISC

Q&A Panelists

Emilie Darcillon, Nestle

Simon Lebeau, Danone



Question and Answer

Examples:

- 1) John: When does the public review period start?
- 2) Emilie: When does the public review period end?



Content Disclaimer

All content in this presentation is for education and information only. References to any specific commercial product, process, service, or corporation are also for information only, and do not constitute endorsement, recommendation, or favoring by CDISC or the CDISC community.



CDISC Nutrition Therapeutic Area User Guide

Public Review Webinar

Presented by John Owen
Nutrition TAUG Project Manager, Standards Development, CDISC

18 Oct 2018



Nutrition

-- Public Review --

Nutrition Therapeutic Area User Guide v1.0

Comments due: 10 Dec 2018

Version 1.0 of the Therapeutic Area User Guide for Nutrition (TAUG-Nutrition) is being developed under the CDISC Standards Development Process and describes the most common biomedical concepts relevant to nutrition studies and the necessary metadata to represent such consistently with CDISC standards CDASH and SDTM.

TAUG-Nutrition v1.0 specifies how to structure the data as an extension of the CDISC Foundational Standards and includes examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submissions. TAUG-Nutrition v1.0 focuses on infant nutrition, food and fluid intake, stool sampling, and questionnaires (specific to clinical studies in nutrition), and includes concepts for adult and pediatric populations.

CDISC invites you to provide comments on TAUG-Nutrition v1.0 during the open Public Review period. Public review is a key quality step in our Standards Development Process. We rely on your input to ensure neutral, consensus-based standards are developed and adopted by a diverse global community interested in improving clinical research. Thank you for contributing your time and expertise.

View the user guide: [TAUG-Nutrition v1.0](#)

You will need to log in or register for the CDISC Wiki to review the Read Me and provide comments.

- To register for the Wiki: [Register](#). JIRA and Wiki use the same login, please create only one account.
- Instructions for providing comments: [Instructions for Reviewers](#)

CDISC Wiki is a different login from www.cdisc.org.

CDISC is holding a webinar 18 Oct 2018, 10:00 AM - 10:45 AM Central DaylightTime to introduce TAUG-Nutrition to the CDISC community for Public Review. [Join us!](#)

Public Review in Progress.

<https://www.cdisc.org/standards/therapeutic-areas/nutrition>

CURRENT PUBLIC REVIEWS

CGI and PGI Questionnaires Supplements to the SDTMIG
Comments Due by: 30 Oct 2018

Confirmed Data Endpoints for Exchange (CoDEx) for SENDIG v3.1 Data
Comments Due by: 30 Oct 2018

Traditional Chinese Medicine for Coronary Artery Disease - Angina v1.0
Comments Due by: 30 Oct 2018

ADaM Conformance Rules v2.0
Comments Due by: 12 Nov 2018

Nutrition Therapeutic Area User Guide v1.0
Comments Due by: 10 Dec 2018

DOWNLOADS

- **Public Review Start:**
10th October 2018

- **Public Review Comments Deadline:**
10th December 2018

Overview of Nutrition

- This Therapeutic Area Data Standards User Guide for Nutritional Research (TAUG-Nutrition) was led by Nutrition companies under the Clinical Data Interchange Standards Consortium (CDISC) umbrella.
 - Danone
 - Abbott
 - Nestle
 - Unilever
- The TAUG was developed using the CDISC Standards Development Process

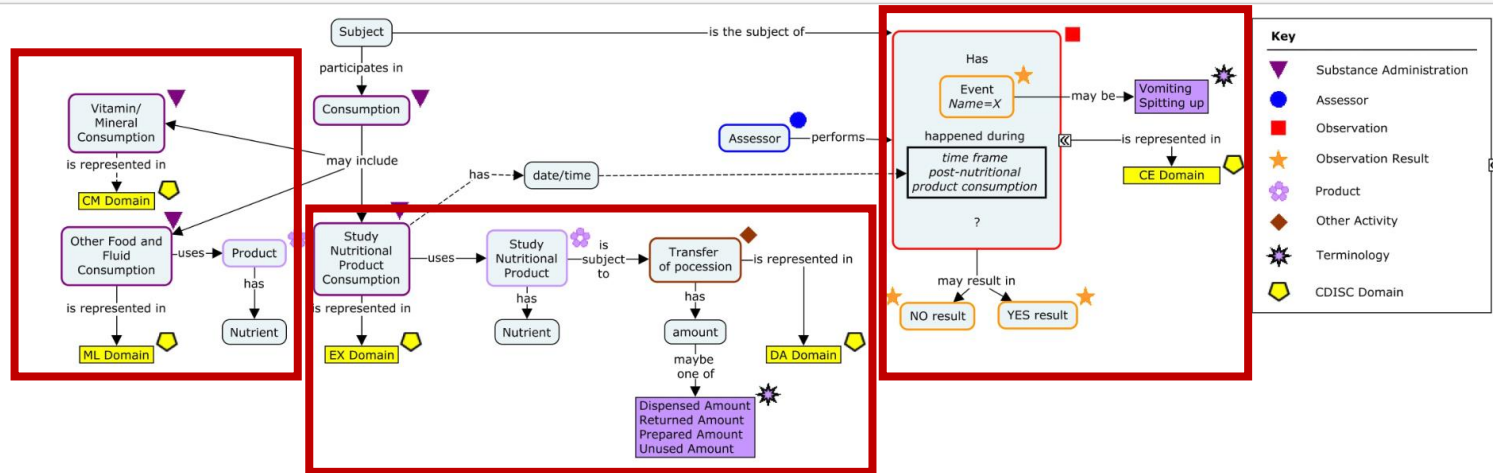


Overview of Nutrition

- Concepts were identified by one or more nutrition stakeholders as important concepts related to nutrition research.
- These concepts fall into 4 main categories:
 - Food & fluid Intake
 - Infant nutrition
 - Stool sampling and assessments
 - Questionnaires specific to clinical studies in nutrition
- The concepts were developed to include both adult and pediatric populations.

Overview of Nutrition

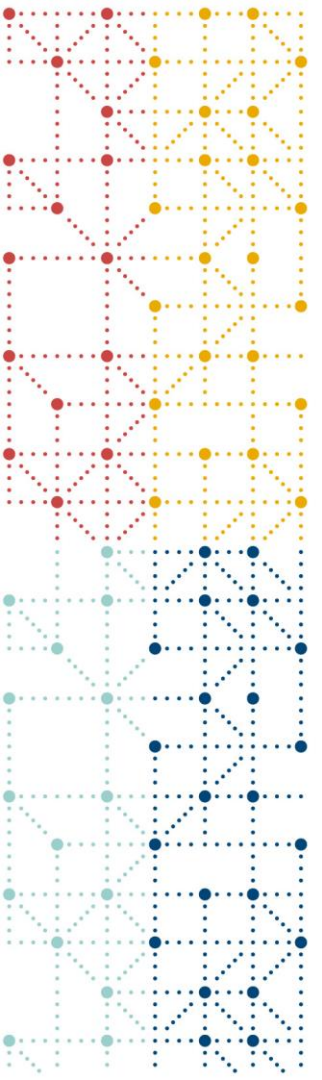
Concept Map: Overview of Nutrition



Overview of the TAUG Content

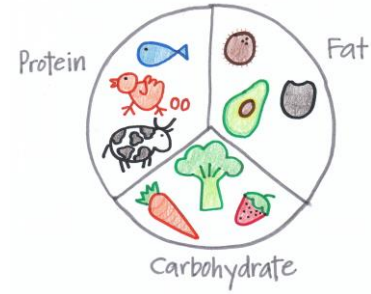
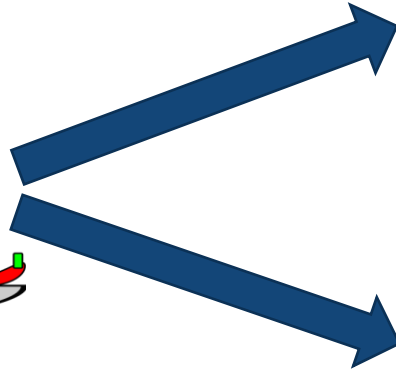
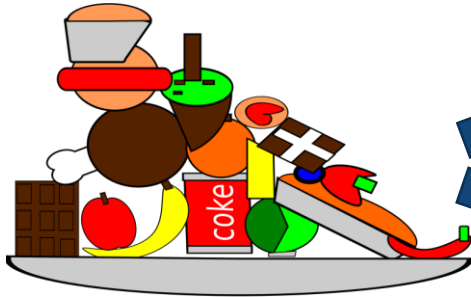
▼ TAUG-Nutrition sections

- › Introduction
- Overview of Nutrition
- Food and Fluid Intake
- › Infant Nutrition
- › Stool Samples and Stool Assessments
- Questionnaires, Ratings, and Scales
- › Appendices



Food and Fluid Intake

Food and Fluid Intake

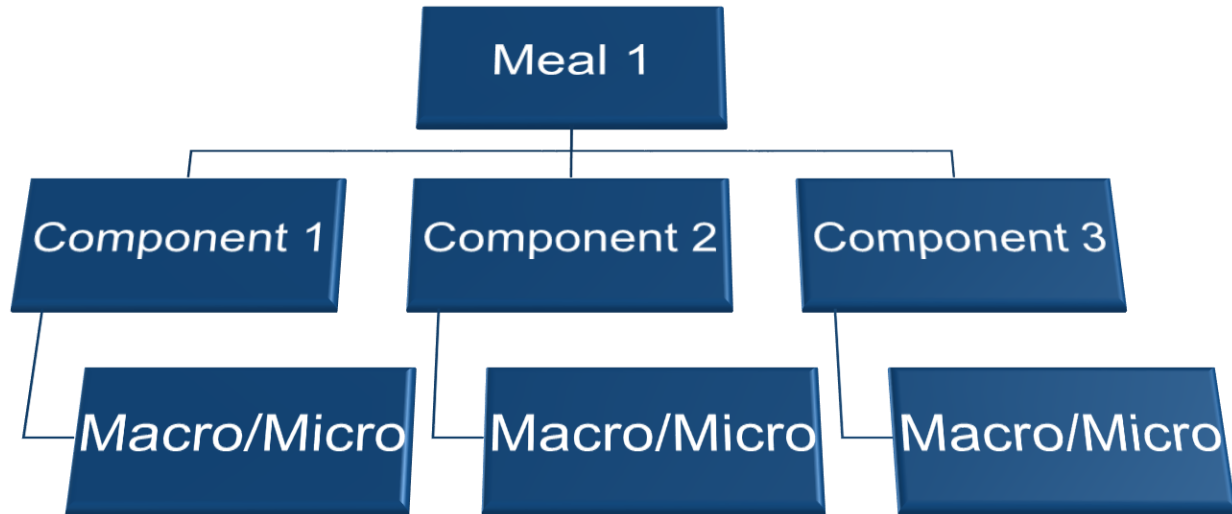


MACRO

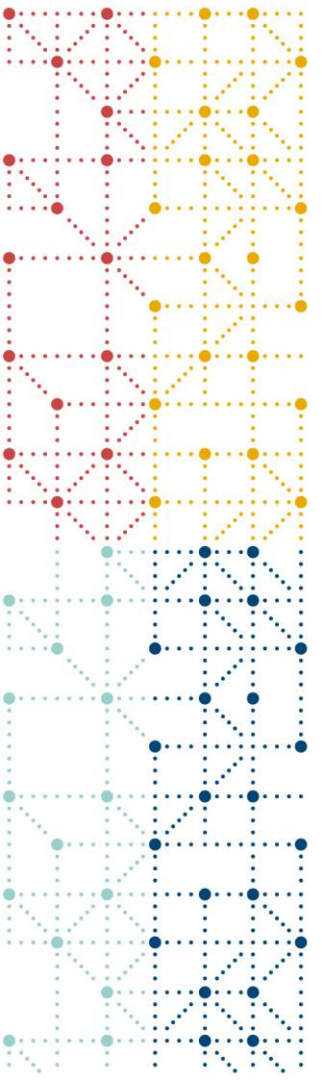


MICRO

Food and Fluid Intake



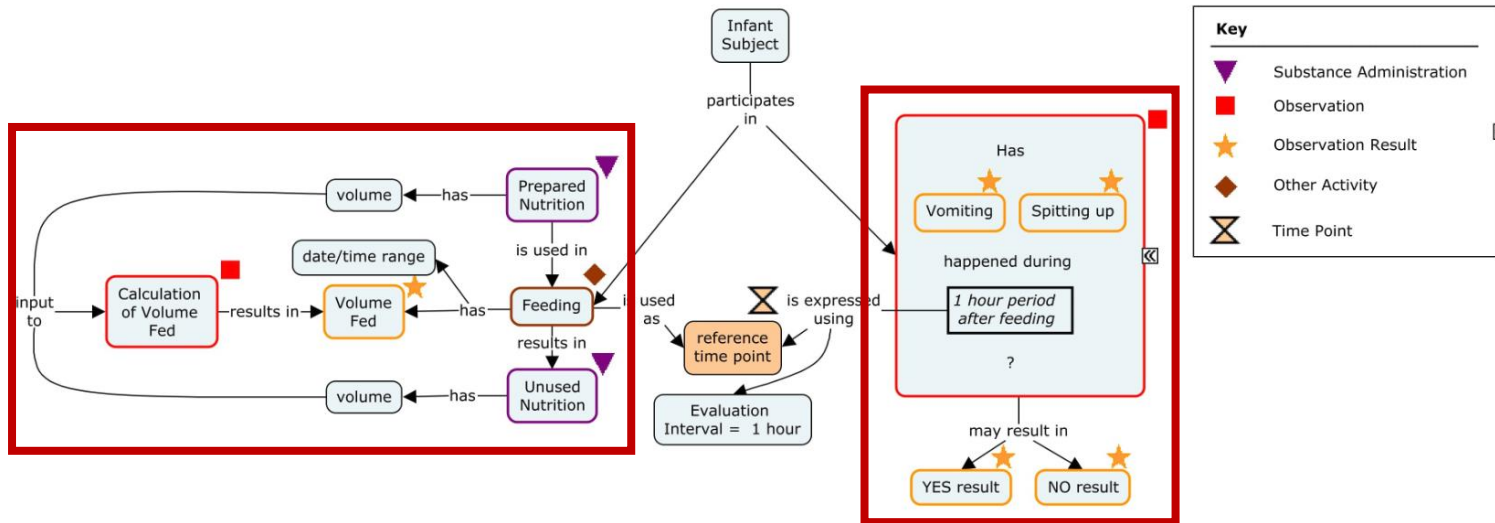
No food and fluid intake modelling is included in the TAUG-NUT



Infant Nutrition

Infant Nutrition

Concept Map: Infant Nutrition



Infant Nutrition – Product Accountability

In some nutritional studies, a supply of study product may be provided to the infant's caregiver, to be used between 2 scheduled visits. The data collected on this can be represented in the DA domain.

Example 1

In this study, the sponsor dispensed a number of cans to the subject to use between the study visits. In this study, it was important to note the number of opened and unopened cans returned (i.e., the volume remaining in the unopened cans was not required to be collected); the variable DACAT was used to represent "Opened" and "Unopened" cans returned.

da.xpt

- Row 1:** Shows that at the first visit on Day 1, 30 cans of study product were dispensed to the subject.
- Row 2:** Shows that at the second visit on Day 21, 9 cans of unopened study product were returned by the subject.
- Row 3:** Shows that at the second visit on Day 21, 1 can of opened study product was returned by the subject.

da.xpt

Row	STUDYID	DOMAIN	USUBJID	DASEQ	DAREFID	DASPID	DATESTCD	DATEST	DACAT	DASCAT	DAORRES	DAORRESU	DASTRESC	DASTRESN	DASTRESU	DASTAT	DAREASND	DADTC	DADY
1	ABC	DA	101	1		1	DISPAMT	Dispensed Amount	Study Product		30	CAN	30	30	CAN			2017-05-01	1
2	ABC	DA	101	2		1	RETAMT	Returned Amount	Unopened Study Product		9	CAN	9	9	CAN			2017-05-21	21
3	ABC	DA	101	3		1	RETAMT	Returned Amount	Opened Study Product		1	CAN	1	1	CAN			2017-05-21	21

DA (Drug Accountability) >> DA (Product Accountability)

- Refer to <https://wiki.cdisc.org/display/PUB/Draft+Standards+of+Interest+to+TAUG-Nutrition>

Parent Standard	Section	Name	Notes
SDTM	6.1	Meal Data (ML)	Meal Data (ML) is a standard domain in the SDTMIG 3.3, however since this is not released at the time of public review of the TAUG Nutrition, a link to the ML domain has been provided here
SDTM	6.3	Product Accountability (DA)	

Submitting Comments

If you wish to provide feedback on any of the above draft standards:

- Comments on draft standards belonging to the SDTMIG should be made to the SDS team.

Infant Nutrition – Daily Feeding – Example 1

ec.xpt

Row 1: Shows the volume of blinded study Formula A consumed by the infant on the first feed of the diary (Day 1).

Row 2: Shows the volume of blinded study Formula B consumed by the infant on the second feed of the diary (Day 1).

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECLNKID	ECTRT	ECDOSE	ECDOSU	ECDOSFRM	ECROUTE	ECSTDTCT	ECENDTCT	ECSTDY	ECENDY
1	ABC	EC	101	1	D1-1	Feeding Formula A	50	mL	SUSPENSION	ORAL	2017-05-19T13:00	2017-05-19T13:00	1	1
2	ABC	EC	101	2	D1-2	Feeding Formula B	60	mL	SUSPENSION	ORAL	2017-05-19T19:00	2017-05-19T19:00	1	1

ce.xpt

Rows 1, 2: Show the response to the "spitting up" and "vomitting" questions on the first feed of the diary (Day 1).

Rows 3, 4: Show the response to the "spitting up" and "vomitting" questions on the second feed of the diary (Day 1).

ce.xpt

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CEGRPID	CELNKID	CETERM	CEPRES	CEOCCUR	CEDTCT	CEDY	CEEVINTX
1	ABC	CE	101	1	1	D1-1	Vomiting	Y	N	2017-05-19	1	Within 1 hour after feeding
2	ABC	CE	101	2	1	D1-1	Spitting up	Y	Y	2017-05-19	1	Within 1 hour after feeding
3	ABC	CE	101	3	2	D1-2	Vomiting	Y	N	2017-05-19	1	Within 1 hour after feeding
4	ABC	CE	101	4	2	D1-2	Spitting up	Y	Y	2017-05-19	1	Within 1 hour after feeding

ex.xpt

Row 1: Shows the volume of study formula consumed by the infant on the first feed of the diary (Day 1).

Row 2: Shows the volume of study formula consumed by the infant on the second feed of the diary (Day 1).

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXLNKID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXSTDTCT	EXENDTCT	EXSTDY	EXENDY
1	ABC	EX	101	1	D1-1	Nutra	50	mL	SUSPENSION	ORAL	2017-05-19T13:00	2017-05-19T13:00	1	1
2	ABC	EX	101	2	D1-2	Nutra-Plus	60	mL	SUSPENSION	ORAL	2017-05-19T19:00	2017-05-19T19:00	1	1

Infant Nutrition – Daily Feeding – Example 2

da.xpt

Row	STUDYID	DOMAIN	USUBJID	DASEQ	DAGRPID	DASPID	DATESTCD	DATEST	DACAT	DASCAT	DAORRES	DAORRESU	DASTRESC	DASTRESN	DASTRESU	DASTAT	DAREASND	DADTC	DADY
1	ABC	DA	101	1	1	1	PREPAMT	Prepared Amount	Study Product		100	mL	100	100	mL			2017-05-19	1
2	ABC	DA	101	2	1	1	REMAMT	Remaining Amount	Study Product		15	mL	15	15	mL			2017-05-19	1
3	ABC	DA	101	3	2	2	PREPAMT	Prepared Amount	Study Product		100	mL	100	100	mL			2017-05-19	1
4	ABC	DA	101	4	2	2	REMAMT	Remaining Amount	Study Product		25	mL	25	25	mL			2017-05-19	1
5	ABC	DA	101	5	3	1	PREPAMT	Prepared Amount	Study Product		100	mL	100	100	mL			2017-05-20	2
6	ABC	DA	101	6	3	1	REMAMT	Remaining Amount	Study Product		10	mL	10	10	mL			2017-05-20	2

ex.xpt

- Row 1:** Shows the weight of study formula consumed by the infant on the first feed of the diary (Day 1).
- Row 2:** Shows the weight of study formula consumed by the infant on the second feed of the diary (Day 1).
- Row 3:** Shows the weight of study formula consumed by the infant on the third feed of the diary (Day 2).

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXLNKID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1	ABC	EX	101	1	1	Nutra	25.5	g	POWDER, FOR SOLUTION	ORAL	2017-05-19	2017-05-19	1	1
2	ABC	EX	101	2	2	Nutra	22.5	g	POWDER, FOR SOLUTION	ORAL	2017-05-19	2017-05-19	1	1
3	ABC	EX	101	3	3	Nutra	27	g	POWDER, FOR SOLUTION	ORAL	2017-05-20	2017-05-20	2	2

The actual amount of unblinded study product exposed to the infant is represented in the EX domain. The sponsor chose to represent this as a weight (g) of study product actually consumed by the infant. This was calculated using the actual amount of feed consumed by the infant (total volume consumed minus total volume returned), and then converting the total number of spoons used to make up the product to the actual number of spoons consumed. Note that in this study each spoon used was 15 g of study product and 2 spoons of formula was always used to prepare the feed. It is generally accepted that this type of derived exposure information can be represented in SDTM in the EX domain. Please refer to Section 6.1 of SDTMIG v3.3, which describes the use of EC and EX domains and the requirements to document the derivations used to show data in EX in the define.xml

Infant Nutrition – Daily Feeding – Example 3

1) Breastfeeding with individual start and stop times per feed

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXSTDTC	EXENDTC
1	ABC	EX	101	1	Breast Milk				ORAL	2017-05-19T13:00	2017-05-19T13:20
2	ABC	EX	101	2	Breast Milk	50	mL		ORAL	2017-05-19T17:00	2017-05-19T17:15

2) Breastfeeding as a duration in minutes per feed

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXSTDTC	EXENDTC	EXDUR
1	ABC	EX	101	1	Breast Milk				ORAL	2017-05-19	2017-05-19	PT20M
2	ABC	EX	101	2	Breast Milk				ORAL	2017-05-19	2017-05-19	PT15M

EXDUR can only be used if this data was collected

3) Breastfeeding as a total number of feeds per day

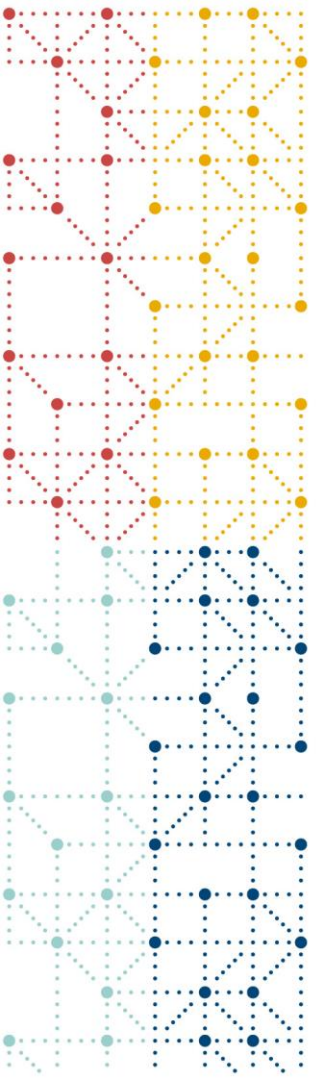
ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXSTDTC	EXENDTC	EXNADEVI
1	ABC	EX	101	1	Breast Milk				ORAL	2017-05-19	2017-05-19	4

EX NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
EXNADEVI	Number of Administrations in Eval. Int.	integer	Non-Standard Record Qualifier		CRF

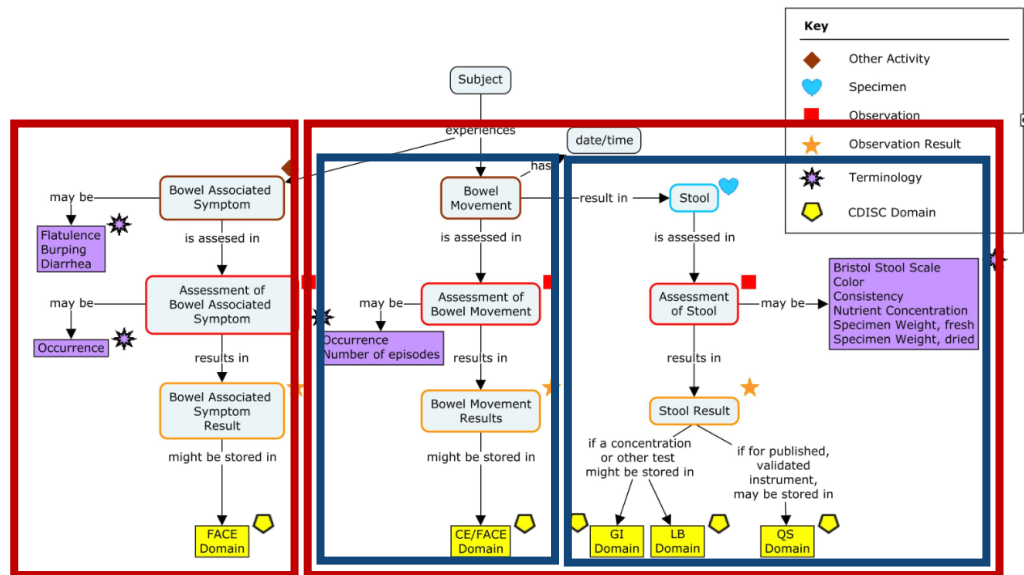
Note that EX was used in this example as breast milk was used as a direct comparator to a study product



Stool Assessments

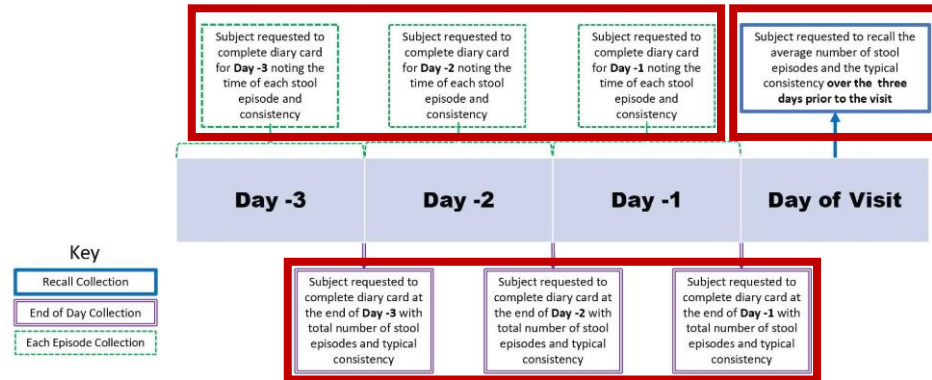
Stool Assessments

Concept Map: Stool Assessments



Stool Assessments – Types of Diary Data Collection

Types of Diary Collection



Stool Assessments – Recall Diary

At the baseline visit, the subject was asked:

- What was the average number of stool episodes per day over the 3 days prior to the visit?
- What was the typical consistency of the stools over the 3 days prior to the visit?

Record the the average number of stool episodes per day over the last 3 days that the subject recalls from memory.

Record the subject's assessment of the typical consistency of their stools over the last 3 days based on their recall from memory.

FAOBJ <i>Hidden/pre-populated</i>	BOWEL MOVEMENT
FAEVINTX FAEVINTX and LBEVINTX <i>Hidden/pre-populated</i>	PREVIOUS 3 CALENDAR DAYS
Over the last 3 days what was the average number of bowel movements per day?	
BMFREQ_FAORRES FAORRES where FATESTCD = "BMFREQ"	<input type="text"/>
BMFREQ_FACOLSRT NSV.FACOLSRT where FATESTCD = "BMFREQ" <i>Hidden/pre-populated</i>	RECALL AVERAGE
BMFREQ_FATEST FATEST where FATESTCD = "BMFREQ" <i>Hidden/pre-populated</i>	Bowel Movement Frequency
BMFREQ_FAORRESU FAORRESU where FATESTCD = "BMFREQ" <i>Hidden/pre-populated</i>	/day
Over the last 3 days what was the typical consistency of bowel movements?	
CONSIST_LBORRES LBORRES where LBTESTCD = "CONSIST"	<input type="radio"/> Watery <input type="radio"/> Loose <input type="radio"/> Soft <input type="radio"/> Formed <input type="radio"/> Hard
CONSIST_LBCOLSRT NSV.LBCOLSRT where LBTESTCD = "CONSIST" <i>Hidden/pre-populated</i>	RECALL TYPICAL
CONSIST_LBTEST LBTEST where LBTESTCD = "CONSIST" <i>Hidden/pre-populated</i>	Consistency

CDASH CRF Metadata

- Don't forget to review the CDASH Metadata tables
- These can be found underneath each CDASH CRF in an expandable section

▼ View CRF Metadata

Columns whose headers are shaded blue and rows whose Field ID are shaded blue contain metadata that were developed for this example annotated CRF, and are not part of the CDASH model or CDASHIG.

Observation Class	Order Number	Domain	TAUG Reference	CDASH Variable Name	CDASHIG Variable Label	Question Text	Prompt	Field Type	Case Report Form Completion Instructions	Information for Sponsors	TA Specific Usage Rules	SDTMIG Target	SDTM Variable Mapping	Controlled Terminology CodeList Name	Pre-Defined Values	Value that appears on the CRF but is not entered by the user
Findings	01	FA	TAUG-NUT v1.0- Baseline Information on bowel movements	FAEVLINT	Evaluation Interval	N/A	N/A	text	N/A			FAEVLINT		N/A		-P1D
Findings	02	FA	TAUG-NUT v1.0- Baseline Information on bowel movements	FATPT	Planned Time Point Name	What is the diary day?	Diary Day	text	Select the diary day being entered.			FATPT		N/A	DIARY DAY 1; DIARY DAY 2; DIARY DAY 3	
Findings	03	FA	TAUG-NUT v1.0- Baseline Information on bowel	FADAT	Date of Collection	What is the diary date?	Diary Date	text	Record the date the subject indicated the diary was			FADTC				

Stool Assessments – Recall Diary

face.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FASTRES	FASTRESN	FASTRESU	VISITNUM	VISIT	VISITDY	FADTC	FAEVINTX	FACOLSRT	FASOURCE
1	NUTR123	FA	NUTR123_001	1	EVENTFRQ	Event Frequency	BOWEL MOVEMENT	3	/day	3	3	/day	1	Baseline	-1	2017-01-05	PREVIOUS 3 CALENDAR DAYS	AVERAGE	RECALL

FACE NSV Metadata

Variable	Label	Type	Codelist	Role	Origin
FACOLSRT	Collected Summary Result Type	text		Non-Standard Variable Qualifier of --ORRES	CRF
FASOURCE	Source of Data	text		Non-Standard Record Qualifier	CRF

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBREFID	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRO	LBORNRI	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	LBSTREFC	LBNRIND	LBSPEC	LBEVAL	
2	NUTR123	LB	NUTR123_001		CONSIST	Consistency		Loose				Loose								STOOL	SUBJECT

VISITNUM	VISIT	VISITDY	LBDTC	LBEVINTX	LBCOLSRT	LBSOURCE
1	Baseline	-1	2017-01-05	PREVIOUS 3 CALENDAR DAYS	TYPICAL	RECALL

LB NSV Metadata

Variable	Label	Type	Codelist	Role	Origin
LBCOLSRT	Collected Summary Result Type	text		Non-Standard Variable Qualifier of --ORRES	CRF
LBSOURCE	Source of Data	text		Non-Standard Record Qualifier	CRF

Stool Assessments – End of Day

This example shows baseline stool information for actual daily number of bowel movements and typical stool consistency each day over a 3-day period prior to the baseline visit. Please note that it may be important for sponsors to provide additional instructions to the diary (e.g., how a subject should evaluate their consistency if they had 1 loose and 1 hard stool in a day).

The sponsor chose to use a paper diary that was given to subject prior to the visit and then handed back at the visit where this was entered into the EDC system.

	FAOBJ <i>Hidden/pre-populated</i>	BOWEL MOVEMENT
	FAEVLINT FAEVLINT and LBEVLINT <i>Hidden/pre-populated</i>	-P1D
Select the diary day being entered.	What is the diary day? FATPT FATPT and LBTPPT	<input type="radio"/> END OF DIARY DAY -3 <input type="radio"/> END OF DIARY DAY -2 <input type="radio"/> END OF DIARY DAY -1
Record the date the subject indicated the diary was completed.	What is the diary date? FADAT FADTC and LBDTC	<input type="text"/>
Record the number of bowel movements that the subject had on this day.	What is the number of bowel movements reported by the subject? EPSDNUM_FAORRES FAORRES where FATESTCD = "EPSDNUM"	<input type="text"/>
Record the typical consistency of the subject's stools over this day.	LBSPEC <i>Hidden/pre-populated</i>	STOOL
	What is the typical consistency of bowel movements as reported by the subject? CONSIST_LBORRES LBORRES where LBTESCD = "CONSIST"	<input type="radio"/> Watery <input type="radio"/> Loose <input type="radio"/> Soft <input type="radio"/> Formed <input type="radio"/> Hard
	CONSIST_LBCOLSRT NSV.LBCOLSRT where LBTESCD = "CONSIST" <i>Hidden/pre-populated</i>	TYPICAL

Stool Assessments – End of Day

face.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FAREFID	FASPID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	FAEVAL	VISITNUM	FADTC	FATPT	FATPTNUM	FAEVLINT
1	NUTR123	FA	NUTR123_001	1	D-3_1	1	EVENTFRQ	Event Frequency	BOWEL MOVEMENT	2	/day	2	2	/day	SUBJECT		2017-01-02	END OF DIARY DAY -3	-3	-P1D
3	NUTR123	FA	NUTR123_001	2	D-2_1	2	EVENTFRQ	Event Frequency	BOWEL MOVEMENT	3	/day	3	3	/day	SUBJECT		2017-01-03	END OF DIARY DAY -2	-2	-P1D
5	NUTR123	FA	NUTR123_001	3	D-1_1	3	EVENTFRQ	Event Frequency	BOWEL MOVEMENT	2	/day	2	2	/day	SUBJECT		2017-01-04	END OF DIARY DAY -1	-1	-P1D

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBREFID	LBSPID	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRO	LBORNRI	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	LBSTREFC	LBNRIND	
1	NUTR123	GI	NUTR123_001	1	D-3_1	1	CONSIST	Consistency		Loose											
3	NUTR123	GI	NUTR123_001	2	D-2_1	2	CONSIST	Consistency		Hard											
5	NUTR123	GI	NUTR123_001	3	D-1_1	3	CONSIST	Consistency		Loose											

LBSPEC	LBEVAL	LBLOBXFL	VISITNUM	LBDTC	LBTPPT	LBTPPTNUM	LBEVLINT	LBCOLSRT
STOOL	SUBJECT			2017-01-02	END OF DIARY DAY -3	-3	-P1D	TYPICAL
STOOL	SUBJECT			2017-01-03	END OF DIARY DAY -3	-2	-P1D	TYPICAL
STOOL	SUBJECT			2017-01-04	END OF DIARY DAY -3	-1	-P1D	TYPICAL

LBCMV Metadata

Variable	Label	Type	Codelist	Role	Origin
LBCOLSRT	Collected Summary Result Type	text		Non-Standard Variable Qualifier if --ORRES	CRF

Stool Assessments – Each Episode

	CETERM <i>Hidden/pre-populated</i>	BOWEL MOVEMENT
Select the diary day being entered	What is the diary day? CETPT CETPT and LBPTT	<input type="radio"/> DIARY DAY -3 <input type="radio"/> DIARY DAY -2 <input type="radio"/> DIARY DAY -1
Record the date the subject indicated the diary was completed	What is the diary date? CESTDAT CESTDTC and CESTDTC and LBDTC	<input type="text"/>
Indicate if any bowel movements occurred, checking Yes or No.	CEPRES <i>Hidden/pre-populated</i>	Y
Record the bowel movement episode number. For each diary day, start the count at 1.	Did the subject have any bowel movements for this day? CEOCCUR	<input type="radio"/> Yes <input type="radio"/> No
Record the start time the subject indicated the bowel movement started	What is the clinical event identifier? CESPID CESPID and LBSPID	Select... ▼
Record the consistency of the subject's stool	What was the bowel movement start time? CESTTIM CESTDTC LBDTC	<input type="text"/>
	Specimen Type LBSPEC <i>Hidden/pre-populated</i>	STOOL
Record the consistency of the subject's stool	What is the consistency of bowel movement reported by the subject? CONSIST_LBORRES LBORRES where LBTESTCD = "CONSIST"	<input type="radio"/> Watery <input type="radio"/> Loose <input type="radio"/> Soft <input type="radio"/> Formed <input type="radio"/> Hard
Record the color of the subject's stool	What is the color of bowel movement reported by the subject? COLOR_LBORRES LBORRES where FATESTCD = "COLOR"	<input type="radio"/> Yellow <input type="radio"/> Green <input type="radio"/> Brown <input type="radio"/> Black

Stool Assessments – Each Episode

ce.xpt

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CEREFID	CESPID	CETERM	CEPRES	CEOCCUR	CESTAT	CEREASND	CEDTC	CESTDTC	CETPT	CETPTNUM
1	NUTR123	CE	NUTR123_001	1	D-3_1	1	BOWEL MOVEMENT	Y	Y			2017-01-02	2017-01-02 T09:45	DIARY DAY -3	-3
2	NUTR123	CE	NUTR123_001	2	D-3_2	2	BOWEL MOVEMENT	Y	Y			2017-01-02	2017-01-02 T12:45	DIARY DAY -3	-3
3	NUTR123	CE	NUTR123_001	3	D-3_3	3	BOWEL MOVEMENT	Y	Y			2017-01-02	2017-01-02 T19:45	DIARY DAY -3	-3
4	NUTR123	CE	NUTR123_001	4	D-2_1	1	BOWEL MOVEMENT	Y	Y			2017-01-03	2017-01-03 T08:30	DIARY DAY -2	-2
5	NUTR123	CE	NUTR123_001	5	D-2_2	2	BOWEL MOVEMENT	Y	Y			2017-01-03	2017-01-03 T20:00	DIARY DAY -2	-2
6	NUTR123	CE	NUTR123_001	6	D-1_1	1	BOWEL MOVEMENT	Y	Y			2017-01-04	2017-01-04 T09:00	DIARY DAY -1	-1
7	NUTR123	CE	NUTR123_001	7	D-1_2	2	BOWEL MOVEMENT	Y	Y			2017-01-04	2017-01-04 T21:00	DIARY DAY -1	-1
8	NUTR123	CE	NUTR123_002	1	D-3_1	1	BOWEL MOVEMENT	Y	N			2017-02-12		DIARY DAY -3	-3
9	NUTR123	CE	NUTR123_002	2	D-2_1	1	BOWEL MOVEMENT	Y		NOT DONE	FORGOT TO COMPLETE			DIARY DAY -2	-2

Stool Assessments – Each Episode

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEC	LBREFID	LBSPID	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRO	LBORNRI	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	LBSTREFC	LBNRIND	LBSPEC	LBEVAL	LBOBXFL	VISITNUM	LBDDTC	LBTPPT	LBTPNUM	
1	NUTR123	LB	NUTR123_001	1	D-3_1	1	CONSIST	Consistency		Loose				Loose														
2	NUTR123	LB	NUTR123_001	2	D-3_1	1	COLOR	Color		Brown				Brown								STOOL	CAREGIVER			2017-01-02 T09:45	DIARY DAY -3	-3
3	NUTR123	LB	NUTR123_001	3	D-3_2	2	CONSIST	Consistency		Hard				Hard								STOOL	CAREGIVER			2017-01-02 T09:45	DIARY DAY -3	-3
4	NUTR123	LB	NUTR123_001	4	D-3_2	2	COLOR	Color		Brown				Brown								STOOL	CAREGIVER			2017-01-02 T12:45	DIARY DAY -3	-3
5	NUTR123	LB	NUTR123_001	5	D-3_3	3	CONSIST	Consistency		Loose				Loose								STOOL	CAREGIVER			2017-01-02 T12:45	DIARY DAY -3	-3
6	NUTR123	LB	NUTR123_001	6	D-3_3	3	COLOR	Color		Brown				Brown								STOOL	CAREGIVER			2017-01-02 T19:45	DIARY DAY -3	-3
7	NUTR123	LB	NUTR123_001	7	D-2_1	1	CONSIST	Consistency		Hard				Hard								STOOL	CAREGIVER			2017-01-02 T19:45	DIARY DAY -3	-3
8	NUTR123	LB	NUTR123_001	8	D-2_1	1	COLOR	Color		Brown				Brown								STOOL	CAREGIVER			2017-01-03 T08:30	DIARY DAY -2	-2
9	NUTR123	LB	NUTR123_001	9	D-2_2	2	CONSIST	Consistency		Hard				Hard								STOOL	CAREGIVER			2017-01-03 T08:30	DIARY DAY -2	-2
10	NUTR123	LB	NUTR123_001	10	D-2_2	2	COLOR	Color		Brown				Brown								STOOL	CAREGIVER			2017-01-03 T20:00	DIARY DAY -2	-2
11	NUTR123	LB	NUTR123_001	11	D-1_1	1	CONSIST	Stool Consistency		Hard				Hard								STOOL	CAREGIVER			2017-01-03 T20:05	DIARY DAY -2	-2
12	NUTR123	LB	NUTR123_001	12	D-1_1	1	COLOR	Color		Brown				Brown								STOOL	CAREGIVER			2017-01-04 T09:00	DIARY DAY -1	-1
13	NUTR123	LB	NUTR123_001	13	D-1_2	2	CONSIST	Stool Consistency		Loose				Loose								STOOL	CAREGIVER			2017-01-04 T09:00	DIARY DAY -1	-1
14	NUTR123	LB	NUTR123_001	14	D-1_2	2	COLOR	Color		Brown				Brown								STOOL	CAREGIVER			2017-01-04 T21:00	DIARY DAY -1	-1
																						STOOL	CAREGIVER			2017-01-04 T21:00	DIARY DAY -1	-1



Stool Assessments

- Some sponsors may choose to use a stool scale to assess characteristics of the stool (e.g., The Bristol Stool Form Scale (BSFS))
 - Refer to the QRS section for the status of the BSFS supplement development
- The examples shown in this section assume that the stool characteristics are not being assessed using this type of scale

Symptom Assessments

In this example the subject was given a diary at Visit 1 to record their GI symptoms starting from the day after Visit 1 to the day before Visit 2. The diary was then collected at Visit 2 and a new diary given

Select the diary day being entered.	FAEVLINT <i>Hidden/pre-populated</i> What is the diary day? FATPT	-P1D <input type="radio"/> DIARY DAY 1 <input type="radio"/> DIARY DAY 2 <input type="radio"/> DIARY DAY 3
Record the date the subject indicated the diary was completed.	What is the diary date? FADAT FADTC	<input type="text"/>
Record whether the subject experienced nausea.	NAUSEA_FAOBJ FAOBJ <i>Hidden/pre-populated</i> Did the subject experience nausea? NAUSEA_OCCUR_FAOORES FAOORES where FAOBJ = "NAUSEA" and FATESTCD = "OCCUR"	NAUSEA <input type="radio"/> Yes <input type="radio"/> No
If the subject experienced nausea, complete the maximum severity over the day.	If "Yes," what was the maximum severity? NAUSEA_SEV_FAOORES FAOORES where FAOBJ = "NAUSEA" and FATESTCD = "SEV"	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
	NAUSEA_SEV_FACOLSRT NSV.FACOLSRT where FATESTCD = "SEV" and FAOBJ = "NAUSEA" <i>Hidden/pre-populated</i>	MAXIMUM
Record whether the subject experienced flatulence.	FLATULENCE_FAOBJ FAOBJ <i>Hidden/pre-populated</i> Did the subject experience flatulence? FLATULENCE_OCCUR_FAOORES FAOORES where FAOBJ = "FLATULENCE" and FATESTCD = "OCCUR"	FLATULENCE <input type="radio"/> Yes <input type="radio"/> No
If the subject experienced flatulence, complete the maximum severity over the day.	If "Yes," what was the maximum severity? FLATULENCE_SEV_FAOORES FAOORES where FAOBJ = "FLATULENCE" and FATESTCD = "SEV"	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
	FLATULENCE_SEV_FACOLSRT NSV.FACOLSRT where FATESTCD = "SEV" and FAOBJ = "FLATULENCE" <i>Hidden/pre-populated</i>	MAXIMUM
Record whether the subject experienced burping.	BURPING_FAOBJ FAOBJ <i>Hidden/pre-populated</i> Did the subject experience burping? BURPING_OCCUR_FAOORES FAOORES where FAOBJ = "BURPING" and FATESTCD = "OCCUR"	BURPING <input type="radio"/> Yes <input type="radio"/> No
If the subject experienced burping, complete the maximum severity over the day.	If "Yes," what was the maximum severity? BURPING_SEV_FAOORES FAOORES where FAOBJ = "BURPING" and FATESTCD = "SEV"	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
	BURPING_SEV_FACOLSRT NSV.FACOLSRT where FATESTCD = "SEV" and FAOBJ = "BURPING" <i>Hidden/pre-populated</i>	MAXIMUM

Symptom Assessments

face.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRES	VISITNUM	FADTC	FATPT	FATPTNUM	FAEVLINT	FACOLSRT
1	NUTR123	FA	NUTR123_001	1	1	OCCUR	Occurrence Indicator	DIARRHEA	GI SYMPTOMS	N	N		2017-01-05	END OF DIARY DAY 2	2	-P1D	
2	NUTR123	FA	NUTR123_001	2	2	OCCUR	Occurrence Indicator	FLATULENCE	GI SYMPTOMS	N	N		2017-01-05	END OF DIARY DAY 2	2	-P1D	
3	NUTR123	FA	NUTR123_001	3	3	OCCUR	Occurrence Indicator	BURPING	GI SYMPTOMS	Y	Y		2017-01-05	END OF DIARY DAY 2	2	-P1D	
4	NUTR123	FA	NUTR123_001	4	3	SEV	Severity/Intensity	BURPING	GI SYMPTOMS	Mild	MILD		2017-01-05	END OF DIARY DAY 2	2	-P1D	MAXIMUM
5	NUTR123	FA	NUTR123_001	5	1	OCCUR	Occurrence Indicator	DIARRHEA	GI SYMPTOMS	N	N		2017-01-06	END OF DIARY DAY 3	3	-P1D	
6	NUTR123	FA	NUTR123_001	6	2	OCCUR	Occurrence Indicator	FLATULENCE	GI SYMPTOMS	Y	Y		2017-01-06	END OF DIARY DAY 3	3	-P1D	
7	NUTR123	FA	NUTR123_001	7	2	SEV	Severity/Intensity	FLATULENCE	GI SYMPTOMS	Moderate	MODERATE		2017-01-06	END OF DIARY DAY 3	3	-P1D	MAXIMUM
8	NUTR123	FA	NUTR123_001	8	3	OCCUR	Occurrence Indicator	BURPING	GI SYMPTOMS	Y	Y		2017-01-06	END OF DIARY DAY 3	3	-P1D	
9	NUTR123	FA	NUTR123_001	9	3	SEV	Severity/Intensity	BURPING	GI SYMPTOMS	Severe	SEVERE		2017-01-06	END OF DIARY DAY 3	3	-P1D	MAXIMUM

FACE NSV Metadata

Variable	Label	Type	Code list	Role	Origin
FACOLSRT	Collected Summary Result Type	text		Non-Standard Variable Qualifier of --ORRES	CRF

General Diary Guidance

When providing diaries for a subject to complete, it is important to provide the subject with instructions on how and when to complete the diary; those instructions must be understood by all functions within the study team. Although this may differ from protocol to protocol, detailed, unambiguous instructions will help ensure that data are collected in a consistent format across all subjects. This may be particularly important when analyzing the data. Some diary completion instructions may be as simple as "Please record all bowel movements that occurred between 00:00 and 23:59 on this day." It may also be important to provide additional information on how subjects should record data if, for example, they retire to bed before or after midnight and then they have a bowel movement prior to or after midnight. Providing instructions on which diary day to record these episodes will help ensure that data are recorded consistently across all subjects.

Stool Sample Collection and Characteristics

be.xpt

Rows 1, 3: Show the date and time of the stool sample collection.

Row 2: Shows the date and time of drying the stool sample.

Row 4: Shows the date and time of freezing the stool sample. The container number was represented in BEREFIG to identify the sample.

be.xpt

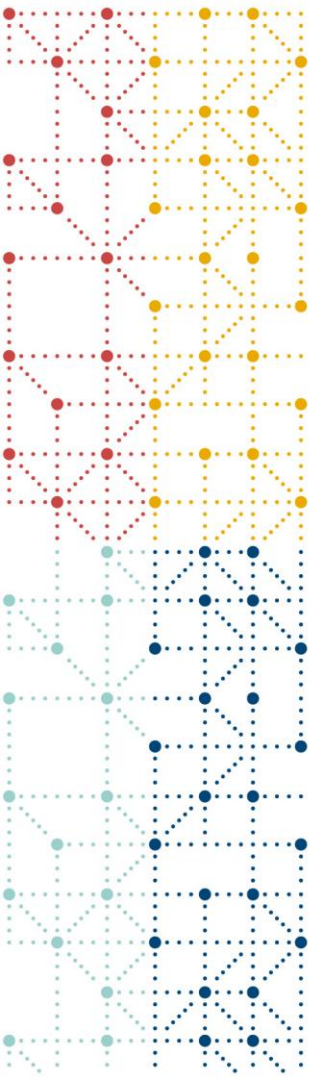
Row	STUDYID	DOMAIN	USUBJID	BESEQ	BEREFID	BETERM	BEDECOD	VISITNUM	VISIT	VISITDY	BEDTC	BESTDTC	BEENDTC	BESTDY	BESPEC
1	NUTR123	BE	NUTR123_001	1	ST123	Collected	COLLECTING	1	BASELINE	-1	2017-01-03T13:05	2017-01-03T13:05		-1	STOOL
2	NUTR123	BE	NUTR123_001	2	ST123	Drying	DRYING	2	BASELINE	-1	2017-01-03T13:05	2017-01-03T14:45		-1	STOOL
3	NUTR123	BE	NUTR123_002	1	ST124	Collected	COLLECTING	1	BASELINE	-1	2017-01-23T15:00	2017-01-03T15:00		-1	STOOL
4	NUTR123	BE	NUTR123_002	2	ST124	Frozen	FREEZING	1	BASELINE	-1	2017-01-23T15:00	2017-01-23T17:00		-1	STOOL

BE NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
BESPEC	Specimen Type	text	Non-Standard Record Qualifier	SPECTYPE	CRF

lb.xpt

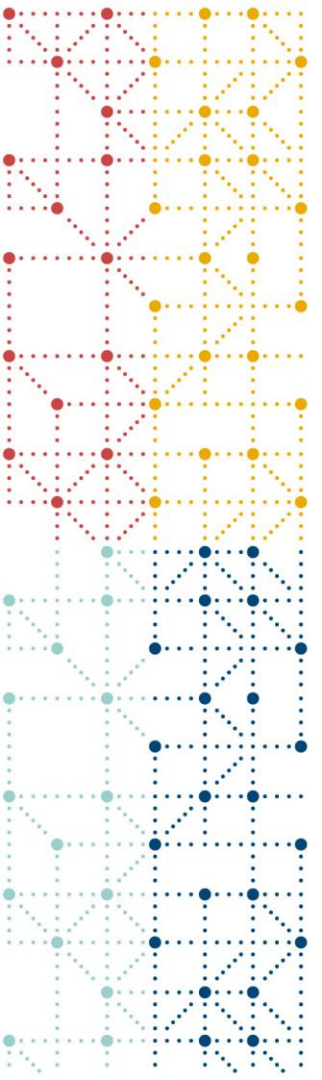
Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBREFID	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBSPCEND	LBOBFL	VISITNUM	VISIT	VISITDY	LB DTC
1	NUTR123	LB	NUTR123_001	1	ST123	SPWEIGHT	Specimen Weight	SPECIMEN ASSESSMENT	95	g	95	95	g	STOOL	FRESH	Y	-1	Baseline	-1	2017-01-03T13:10
2	NUTR123	LB	NUTR123_001	2	ST123	COLOR	Color	SPECIMEN ASSESSMENT	Brown		BROWN			STOOL	FRESH	Y	-1	Baseline	-1	2017-01-03T13:10
3	NUTR123	LB	NUTR123_001	3	ST123	CONSIST	Consistency	SPECIMEN ASSESSMENT	Soft		SOFT			STOOL	FRESH	Y	-1	Baseline	-1	2017-01-03T13:10
4	NUTR123	LB	NUTR123_001	4	ST123	SPWEIGHT	Specimen Weight	SPECIMEN ASSESSMENT	20	g	20	20	g	STOOL	DRIED	Y	-1	Baseline	-1	2017-01-03T13:10



QRS (Questionnaires, Ratings, and Scales)

QRS

Full Name and Abbreviation	Copyright Permission Status	Supplement Status
"Amsterdam" Stool Scale	To be requested	
King's Stool Chart	To be requested	
Baby Eating Behaviour Questionnaire - Concurrent (BEBQ CONCURRENT)	Public domain	Supplement in progress
Baby Eating Behaviour Questionnaire - Retrospective (BEBQ RETROSPECTIVE)	Public domain	Supplement in progress
Bristol Stool Form Scale (BSFS)	No response received	
International Physical Activity Questionnaire - Short Last 7 Days Telephone Format (IPAQ SF PHONE VERSION)	Public domain	Supplement in progress
International Physical Activity Questionnaire - Long Last 7 Days Telephone Format (IPAQ LF PHONE VERSION)	Public domain	Supplement in progress
International Physical Activity Questionnaire - Short Last 7 Days Self-Administered Format (IPAQ SF SELF-ADMINISTERED VERSION)	Public domain	Supplement in progress
International Physical Activity Questionnaire - Long Last 7 Days Self-Administered Format (IPAQ LF SELF-ADMINISTERED VERSION)	Public domain	Supplement in progress



Known Issues



Known Issues

• Timing Variables

- The time when a subject completes diary information may not be defined precisely by the sponsor.
- Instructions to subjects filling out a diary card might refer to calendar days (e.g., "Complete this diary with any relevant information from 00:00 on Day 1 to 11:59 on Day 1")
- or might ask the subject to complete the diary card at the end of the day before retiring for the night (in which case any diary information after they retired for the night would be captured on the next day's diary).
- In the examples in this document, the --TPT value "END OF DIARY DAY X" is used to represent imprecise timing of diary data collection.
- The variables --EVLINT and --EVINTX are used to capture the evaluation interval.
- However, values such as -P1D are not intended to imply that data are collected in strict 24-hour intervals based on the time of (e.g., 21:30 on one day to 21:30 on the next day).

Known Issues

- **Representing Total Number of Breastfeeding Feeds per Day:**
 - This example uses the NSV EXNADEVI to represent the number of breastfeeding feeds per day.
 - The modeling of this example is still under discussion and users are warned that this modeling may be subject to change.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXSTDTC	EXENDTC
1	ABC	EX	101	1	Breast Milk				ORAL	2017-05-19	2017-05-19

EXNADEVI
4

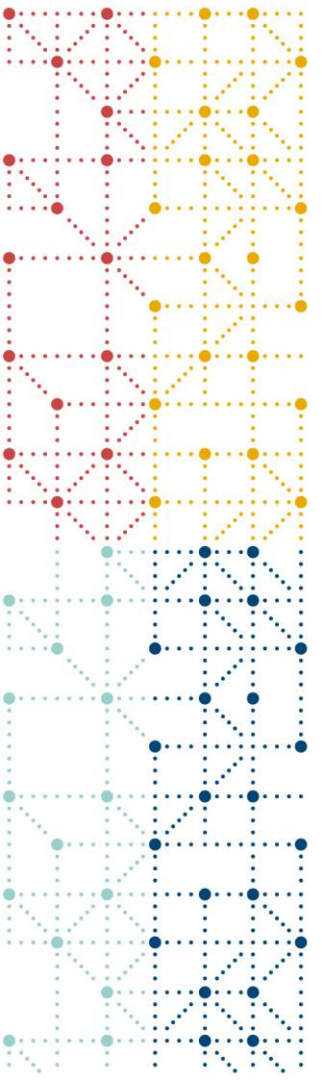
EX NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
EXNADEVI	Number of Administrations in Eval. Int.	integer	Non-Standard Record Qualifier		CRF

Known Issues

- **Modeling of stool color and consistency in the LB domain :**

- Guidance on where to model this data was provided by the CDISC Technical Team and Presented to the GGG. This is still under discussion and therefore users are wa are warned that this modeling may be subject to change.
 - LB: specimens that are removed from the body and undergo an observation or test that tell you something about the state of the subject
 - Color
 - Volume
 - pH
 - Measurement of an analyte
 - Morphology/Physiology domains
 - All imaging - including measurements of volume, structure, or abnormalities (lesions, masses, etc.)
 - EEG measurements
 - Results from eye exams
 - BS: Information about the sample that is not meant to inform you about the health of the subject
 - Tracking
 - Sample condition
 - Amount of specimen available for testing. when that information is used to keep track for testing
 - Test run dates



Public Review Process

Public Review Information

❑ **Public Review Start:** 10th October 2018

❑ **Public Review Comments Deadline:** 10th December 2018

❑ **CDISC Website Announcement:** <https://www.cdisc.org/standards/therapeutic-areas/nutrition>

❑ **Link to WIKI Version of the TAUG:** <https://wiki.cdisc.org/display/TANUTRI/Therapeutic+Area+User+Guide+for+Nutrition>

- ❑ This landing page provides detailed instructions on how to navigate the document and how to provide comments in JIRA
- ❑ Please also read the [Instructions for Reviewers](#) for additional information

❑ **Any questions** can be directed to jowen.external@cdisc.org

The screenshot shows the CDISC website header with navigation links: Home, Standards, Therapeutic Areas, Nutrition. The main content area is titled "Nutrition" and features a yellow banner for the "Nutrition Therapeutic Area User Guide v1.0". The banner includes a "Comments due 10 Dec 2018" notice and a "CURRENT PUBLIC REVIEWS" section with a list of review items and a "DOWNLOADS" button. Below the banner, there is a "Notes to Readers" section and a "Revision History" table.

The screenshot shows the CDISC website header with navigation links: Home, Standards, Therapeutic Areas, Nutrition. The main content area is titled "Therapeutic Area Data Standards User Guide for Nutritional Research" and features a yellow banner for the "Therapeutic Area Data Standards User Guide for Nutritional Research". The banner includes a "Notes to Readers" section and a "Revision History" table.





CDISC Education: Upcoming Learning Opportunities

Saad Yousef








2019 NORTH AMERICA PUBLIC TRAINING OPPORTUNITIES

Location	Dates	Courses Offered	Discount Period Ends	Host
Chicago, IL	TBD	SDTM, CDASH, ADaM, Define-XML	TBD	TBD
Bay Area (California)	TBD	SDTM, SEND, CDASH, ADaM, Define-XML	TBD	TBD
Durham, NC	TBD	SDTM, CDASH, ADaM, Define-XML	TBD	TBD
Boston, MA	March 2019	SDTM, CDASH, ADaM, Define-XML	Dec 2018	
Bridgewater, NJ	May 2019	SDTM, CDASH, ADaM, Define-XML	Feb 2019	
Gaithersburg, MD	Sep 2019	SDTM, CDASH, ADaM, Define-XML	Jun 2019	
San Diego, CA (US Interchange)	Oct 2019	SDTM, SEND, SDTM-MD, CDASH, ADaM, Define-XML, CDISC for Newcomers, and more!	Jul 2019	

To learn more about CDISC training opportunities, please visit our website: <https://www.cdisc.org/education/public-training>




UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Host
Copenhagen, Denmark	8-16 Nov 2018	SDTM, SEND, ADaM, Define-XML	8 Aug 2018	
Reading, UK	21-25 Jan 2019	SDTM, CDASH, ADaM, Define-XML	22 Oct 2018	
Madrid, Spain	11-15 Feb 2019	SDTM, CDASH, ADaM, Define-XML	12 Nov 2018	
Amsterdam, Netherlands (Europe Interchange)	6-10 May 2019	SDTM, SDTM-MD, SEND, ADaM, Define-XML, ODM, Controlled Terminology, CDASH, CDISC for Newcomers	TBD	
Frankfurt, Germany	3-7 Jun 2019	SDTM, CDASH, ADaM, Define-XML	4 Mar 2019	

To learn more about CDISC training opportunities, please visit our website: <https://www.cdisc.org/education/public-training>



UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Host
Tokyo, Japan	21-25 Jan 2019	SDTM, CDASH, ADaM, Define-XML	21 Oct 2018	
Osaka, Japan	3-7 Jun 2019	SDTM, CDASH, ADaM, Define-XML	3 Mar 2019	
Tokyo, Japan	2-6 Sep 2019	SDTM, CDASH, ADaM, Define-XML	2 Jun 2019	

To learn more about CDISC training opportunities, please visit our website: <https://www.cdisc.org/education/public-training>

Upcoming Webinars

Date	Webinar Title
18 Oct	<u>CDISC Public Webinar: ADaM Implementation - New Parameter vs. New Analysis Timepoint (Language: Chinese)</u>
25 Oct	<u>CDISC Members-Only Mini-Training Series - ODM v2 Overview</u>
30 Oct	<u>CDISC Standards Public Webinar: New CDISC TA Projects Starting - Psoriasis, Congestive Heart Failure, Acute Kidney Injury</u>
13 Dec	<u>CDISC Members Only Mini-Training Series: Disease Milestones</u>
8 Jan 2019	<u>Controlled Terminology Mapping/Alignment Across Codelists</u>

Last call for Q&A





Thank you for attending

- Recording of the presentation and the PDF slide deck will be available on the CDISC website soon.