

RE6 Domain Models Based on the General Observation Classes

6.1 Interventions

Meal Data (ML)

ML - Definition/Overview for Meal Data Domain Model

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

ML – Specification for Meal Data Domain Model

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

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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					terms utilizing the define.xml external codelist attributes.	
MLCAT	Category for Meal	Char	*	Grouping Qualifier	Used to define a category of meal.	Perm
MLSCAT	Subcategory for Meal	Char	*	Grouping Qualifier	A further categorization of meal.	Perm
MLPRESP	ML Pre-Specified	Char	(NY)	Record Qualifier	Used to indicate whether (Y/null) information about the consumption of a specific meal was solicited on the CRF.	Perm
MLOCCUR	ML Occurrence	Char	(NY)	Record Qualifier	When the consumption of specific meal is solicited, MLOCCUR is used to indicate whether or not (Y/N) consumption of the meal occurred. Values are null for meals not specifically solicited.	Perm
MLSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question about a pre-specified meal was not answered. Should be null or have a value of NOT DONE.	Perm
MLREASND	Reason Meal Not Collected	Char		Record Qualifier	Describes the reason meal was not collected. Used in conjunction with MLSTAT when value is NOT DONE.	Perm
MLINDC	Indication	Char		Record Qualifier	Denotes why a meal was taken or administered.	Perm
MLDOSE	Meal Consumption	Num		Record Qualifier	Amount of MLTRT taken.	Perm
MLDOSTXT	Meal Consumption Text	Char		Record Qualifier	Dosing amounts or a range of dosing information collected in text form. Units may be stored in MLDOSU. Example: 200-400, 15-20.	Perm
MLDOSU	Consumption Units	Char	(UNIT)	Variable Qualifier	Units for MLDOSE, MLDOSTXT, and MLDOSTOT. Examples: ng, mg, or mg/kg.	Perm
MLDOSFRM	Meal Form	Char	(FRM)	Record Qualifier	Dose form for MLTRT. Examples: SOLID, LIQUID.	Perm
MLDOSFRQ	Meal Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of MLDOSE within a specific time period.	Perm
MLDOSTOT	Total Daily Consumption	Num		Record Qualifier	Total daily dose of MLTRT using the units in MLDOSU. Total dose over a period other than day could be recorded in a separate Supplemental Qualifier variable. MLDOSTOT should be used in addition to MLDOSE, and not in place of it.	Perm
MLDOSRGM	Intended Meal Regimen	Char		Variable Qualifier	Text description of the (intended) schedule or regimen for the Intervention. Examples: TWO WEEKS ON, TWO WEEKS OFF.	Perm
MLROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for MLTRT.	Perm
MLSTDTC	Start Date/Time of Meal	Char	ISO 8601	Timing		Perm
MLENDTC	End Date/Time of Meal	Char	ISO 8601	Timing		Perm
MLSTDY	Study Day of Start of Meal	Num		Timing	Study day of start of meal relative to the sponsor-defined RFSTDTC.	Perm
MLENDY	Study Day of End of Meal	Num		Timing	Study day of end of meal relative to the sponsor-defined RFSTDTC.	Perm
MLDUR	Duration of Meal	Char	ISO 8601	Timing	Collected duration for a meal. Used only if collected on the CRF and not derived from start and end date/times.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MLSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the meal relative to sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", ONGOING or "CONTINUING" was collected, this information may be translated into MLSTRF.	Perm
MLENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the meal relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into MLENRF.	Perm
MLSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the meal as being before or after the reference time point defined by variable MLSTTPT.	Perm
MLSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by MLSTRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
MLENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the meal as being before or after the reference time point defined by variable MLENTPT.	Perm
MLENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by MLENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

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

ML - Assumptions for Meal Data Domain Model

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

ML - Examples for Meal Data Domain Model

Example 1

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

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

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

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Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLTRT	MLTPT	MLTPTREF	MLRFTDTC
1	XYZ	ML	XYZ-001-001	1	EVENING MEAL	LAST DOSE PRIOR	HYPOGLYCEMIC EVENT 1	2013-09-01T11:00

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Row	STUDYID	DOMAIN	USUBJID	MLSEQ	MLTRT	MLTPT	MLPTREF	MLRFTDTC
2	XYZ	ML	XYZ-001-001	2	EVENING MEAL	LAST DOSE PRIOR	HYPOGLYCEMIC EVENT 2	2013-09-24T08:48
3	XYZ	ML	XYZ-001-001	3	EVENING SNACK	LAST DOSE PRIOR	HYPOGLYCEMIC EVENT 3	2012-11-01T07:00

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

Example 2

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

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

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

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Row	STUDYID	USUBJID	MLSEQ	MLTRT	MLSTDTC	RELMIDS	MIDS	MIDSDTC
1	XYZ	001-001	1	EVENING MEAL	2013-08-31T20:00	LAST MEAL PRIOR TO	HYPO 1	2013-09-01T11:00
2	XYZ	001-001	2	EVENING SNACK	2013-09-23T22:30	LAST MEAL PRIOR TO	HYPO 2	2013-09-24T08:48