

6 Domain Models Based on the General Observation Classes

6.3 Findings

Microbiology Domains: MB and MS

Microbiology Specimen (MB)

MB - Description/Overview for Microbiology Specimen Domain Model

The Microbiology Specimen findings (MB) domain is for representing non-host organisms identified including bacteria, viruses, parasites, protozoa and fungi.

MB - Specifications for Microbiology Specimen Domain Model

mb.xpt, Microbiology Specimen — Findings, Version 3.2. One record per microbiology specimen finding per time point per visit 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	MB	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
MBSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MBGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain to support relationships within the domain and between domains. In MB, used to link to findings about organisms which are stored in MS.	Exp
MBREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID	Perm
MBSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: ORGANISM IDENTIFIER. For organism identification, MBSPID would remain the same each time the same organism is identified in a new specimen.	Perm
MBLNKID	Link ID	Char		Identifier	Identifier used to link related records across domains.	Perm
MBLNKGRP	Link Group ID	Char		Identifier	Identifier used to link related, grouped records across domains.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MBTESTCD	Microbiology Test or Finding Short Name	Char	*	Topic	Short name of the measurement, test, or finding described in MBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. Examples : TRGMBEXM, ORGANISM.	Req
MBTEST	Microbiology Test or Finding Name	Char	*	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in MBTEST cannot be longer than 40 characters. Examples: Targeted Microbiology Exam, Organism Present	Req
MBEXMTRG	Microbiology Exam Target	Char		Variable Qualifier	Identifies the organism or group of organisms targeted by exams where MBTESTCD=TRGMBEXM	Perm
MBCAT	Category for Microbiology Finding	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
MBSCAT	Subcategory for Microbiology Finding	Char	*	Grouping Qualifier	Used to define a further categorization of MBCAT.	Perm
MBORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Microbiology measurement or finding as originally received or collected. Examples for TRGMBEXM findings: Present, Absent. Examples for ORGANISM findings: KLEBSIELLA PNEUMONIAE, MYCOBACTERIUM TUBERCULOSIS.	Exp
MBSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from MBORRES in a standard format or standard units. MBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in MBSTRESN. For example, if a test has results "+3 MODERATE", "MOD", and "MODERATE" in MBORRES and these results effectively have the same meaning, they could be represented in standard format in MBSTRESC as "MODERATE".	Exp
MBUSTRES	Unified Result in Std Format	Char		Result Qualifier	Used as a unifying result field when the dataset contains both solicited and non-solicited findings. Provides for a standard character value for pre-specified (Y/N) findings results that matches the standard character result for non-pre-specified findings. For non-pre-specified results, the value of --STRESC should be duplicated here.	Perm
MBRESCAT	Result Category	Char	*	Variable Qualifier	Used to categorize the result of a finding in a standard format. Example for ORGANISM finding: INFECTING, COLONIZER, CONTAMINANT, or NORMAL FLORA.	Exp
MBSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate Microbiology was not done, or a test was not done. Should be null or have a value of NOT DONE.	Perm
MBREASND	Reason Microbiology Not Performed	Char		Record Qualifier	Reason not done. Used in conjunction with MBSTAT when value is NOT DONE. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED.	Perm
MBNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provides the test results.	Perm
MBSPEC	Specimen Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SPUTUM, BLOOD, PUS.	Perm
MBSPECND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen. Example: CONTAMINATED.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MBLOC	Specimen Collection Location	Char	(LOC)	Record Qualifier	Location relevant to the collection of the measurement. Examples: LUNG, VEIN, ARM, FOOT	Perm
MBMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Example: GRAM STAIN, MACRO BROTH DILUTION, AGAR DILUTION	Exp
MBBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be “Y” or null.	Perm
MBDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records or some other derivation, and those that do not come from the CRF, are examples of records that would be derived for the submission datasets. If MBDRVFL=Y, then MBORRES may be null with MBSTRESC and (if numeric) MBSTRESN having the derived value.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
MBDTC	Date/Time of Specimen Collection	Char	ISO 8601	Timing		Exp
MBDY	Study Day of MB Specimen Collection	Num		Timing	1. Study day of the specimen collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm
MBTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when specimen should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See MBTPTNUM and MBTPTREF. Examples: Start, 5 min post.	Perm
MBTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of MBTPT to aid in sorting.	Perm
MBELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (MBTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by MBTPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by MBTPTREF.	Perm
MBTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by MBELTM, MBTPTNUM, and MBTPT. Example: PREVIOUS DOSE.	Perm
MBRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, MBTPTREF.	Perm

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

MB - Assumptions for Microbiology Specimen Domain Model

1. Definition: The Microbiology Specimen findings (MB) domain is for representing the identity and characteristics of non-host organisms that are found in subject samples including bacteria, viruses, parasites, and fungi. Representation of findings in the MB domain should be handled as follows:
 - a. For all identification tests, MBCAT should be set to "IDENTIFICATION".
 - i. In cases of non-prespecified tests, the result should be the name of the organism or group of organisms present (e.g., Influenza A H1N1; Acid Fast Bacilli, etc).
 - ii. In cases of pre-specified tests, MBTESTCD=TRGMBEXM (Targeted Microbiology Exam). MBEXMTRG (Exam Target) should be set equal to the name of the organism or group of organisms targeted by the exam, and the result should be PRESENT/ABSENT or POSITIVE/NEGATIVE.
 - b. Culture characteristics covers concepts such as growth/no growth, colony quantification measures, colony color, colony morphology, etc. MBCAT should be set to "CHARACTERISTIC" for these records. Note that this *does not include drug susceptibility testing*, which is represented in the Microbiology Susceptibility (MS) domain.
 - c. MBGRPID should be used to group characteristic records (MBCAT=CHARACTERISTIC) with the identification record (MBCAT=IDENTIFICATION) of the organism to which the characteristics apply.
2. MBDTC represents the date the specimen was collected.
3. If the specimen was cultured, the start and end date of culture would be represented in the BE domain in BESTDTC and BEENDTC respectively. The culture dates can be connected to the MB record via MBREFID and BEREVID; --REFID represents the sample ID.
4. --REFID represents the sample ID as originally assigned in the Biospecimen Events (BE) domain. See BE domain assumptions for guidelines on assigning --REFID values to samples and sub-samples.
5. The following variables would not generally be used in MB: NHOID, --MODIFY, --BODSYS, --FAST, --TOX, --TOXGR, --SEV, --ORRESU, --STRESU, --LOINC.

Microbiology Susceptibility (MS)

MS - Description/Overview for Microbiology Susceptibility Domain Model

The Microbiology Susceptibility (MS) domain is for representing drug susceptibility testing results only. This includes phenotypic testing (where drug is added directly to a culture of organisms) and genotypic tests that provide results in terms of susceptible or resistant. Drug susceptibility testing may occur on a wide variety of non-host organisms, including bacteria, viruses, fungi, protozoa and parasites.

MS - Specifications for Microbiology Susceptibility Domain Model

ms.xpt, Microbiology Susceptibility Test — Findings, Version 3.2. One record per microbiology susceptibility test (or other organism-related finding) per organism found in MB, 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	MS	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
MSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain to support relationships within the domain and between domains. In MS, used to link to organism in MB.	Req
MSREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm
NHOID	Non-host organism ID	Char		Identifier	Sponsor-defined identifier for a non-host organism which should only be used when the organism is the subject of the TEST. This variable should be populated with an intuitive name based on the identity of the non-host organism as reported by a lab (Example: "A/California/7/2009 (H1N1)"). It is not to be used as a qualifier of the result in the record on which it appears. Used when MSNSPCES is not sufficient to identify the non-host organism, such as when the identity contains multiple levels of taxonomy that aren't strictly "species."	Perm
MSNSPCES	Non-host Species	Char		Grouping Qualifier	Biological classification for a non-host organism that is used when the organism is the subject of the TEST. Used as a qualifier of TEST, not results. Unlike NHOID, which can accommodate any combination of taxonomic names, MSNSPCES is only used to represent valid species names when this level of identification is sufficient.	Perm
MSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
MSTESTCD	Microbiology Organism Finding Short Name	Char	*	Topic	Short name of the measurement, test, or finding described in MSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. MSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: MIC, DST	Req
MSTEST	Organism Test or Finding Name	Char	*	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. Examples: Minimum Inhibitory Concentration, Drug Susceptibility Testing	Req
MBEXMTRG	Microbiology Exam Target	Char		Variable Qualifier	Serves as a qualifier of MSTEST. Identifies the organism or group of organisms targeted by drug susceptibility testing. Example: MYCOBACTERIUM TUBERCULOSIS	Perm
MSDRUG	Drug Name	Char		Variable Qualifier	The name of the drug for which resistance is tested. The drug specified may be based on genetic markers or direct phenotypic drug sensitivity testing.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MSCONC	Drug Concentration	Num		Variable Qualifier	Numeric concentration of drug listed in --DRUG.	Perm
MSCONCU	Drug Concentration Units	Char	(UNIT)	Variable Qualifier	Units for value of the drug concentration listed in --CONC. Example: mg/L	Perm
MSCAT	Category for Organism Findings	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
MSSCAT	Subcategory for Organism Findings	Char	*	Grouping Qualifier	A further categorization of a test category	Perm
MSORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Microbiology Organism measurement or finding as originally received or collected	Exp
MSORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for MSORRES. Example: ng/mL	Perm
MSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from MSORRES in a standard format or standard units. MSSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in MSSTRESN.	Exp
MSSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from MSSTRESC. MSSTRESN should store all numeric test results or findings.	Perm
MSSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for MSSTRESC and MSSTRESN.	Perm
MSRESCAT	Result Category	Char	(MSRESCAT)	Variable Qualifier	Used to categorize the result of a finding in a standard format.	Perm
MSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a test on an organism was not done, or a test was not performed. Should be null if a result exists in MSORRES or have a value of NOT DONE.	Perm
MSREASND	Reason Test Not Done	Char		Record Qualifier	Reason not done. Describes why a measurement or test was not performed. Used in conjunction with MSSTAT when value is NOT DONE. Example: SAMPLE LOST	Perm
MSNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor that provided the test results.	Perm
MSLOINC	LOINC Code	Char	*	Synonym Qualifier	1. Dictionary-derived LOINC Code for MTEST. 2. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes	Perm
MSMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: ANTIBIOTIC AGAR SCREEN, NUCLEIC ACID AMPLIFICATION TEST	Perm
MSBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MSDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records or some other derivation, and those that do not come from the CRF, are examples of records that would be derived for the submission datasets. If MSDRVFL=Y, then MSORRES may be null, with MSSTRESC and (if numeric) MSSTRESN having the derived value.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
MSDTC	Date/Time of Test	Char	ISO 8601	Timing		Perm
MSDY	Study Day of Test	Num		Timing	1. Study day of the test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm
MSTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when test should be done. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See MSTPTNUM and MSTPTREF. Examples: Start, 5 min post.	Perm
MSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of MSTPT to aid in sorting.	Perm
MSELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Elapsed time (in ISO 8601) relative to a planned fixed reference (MSTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by MSTPTREF, or "P8H" to represent the period of 8 hours after the reference point indicated by MSTPTREF.	Perm
MSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by MSELTM, MSTPTNUM, and MSTPT. Example: PREVIOUS DOSE.	Perm
MSREPNUM						

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

MS - Assumptions for Microbiology Susceptibility Domain Model

1. Definition: The Microbiology Susceptibility (MS) domain is for representing drug susceptibility testing (DST) results only. This includes phenotypic testing (where drug is added directly to a culture of organisms) and genotypic tests that provide results in terms of susceptible or resistant based on the presence of mutations known to confer drug resistance.
 - a. Phenotypic DST may involve determining susceptibility/resistance (qualitative) at a pre-defined concentration of drug, or may involve determining a specific dose (quantitative) at which a drug inhibits organism growth or some other process associated with virulence. The MS domain is appropriate for both of these types of DST.
 - i. In the qualitative methods described in (a), MS DRUG, MS CONC and MS CONCU are used to represent the pre-defined drug, concentration, and units respectively. In these cases, the results are represented as “SUSCEPTIBLE” or “RESISTANT”.
 - ii. In the quantitative methods described in (a), MS DRUG is used to represent the drug being tested, but MS CONC and MS CONCU are not used. The concentration at which growth is inhibited is the result in these cases (MSORRES, MSSTRESC/N) with units being represented in MSORRESU/STRESU.
 - b. Genotypic tests that provide results in terms of specific changes to nucleotides, codons, or amino acids of genes/gene products associated with resistance should be represented in the Pharmacogenomics/genetics Findings (PF) domain as that domain structure contains the variables necessary to accommodate these types of data. Only genetic tests that provide results in terms of susceptible/resistant *only*—such as nucleic acid amplification tests (NAAT)—should be represented in MS. A test that provides both mutation data and susceptibility data should be represented in PF, with the susceptibility information being represented in PFRESCAT.
 - i. For genotypic tests that are appropriate for MS as described in (a), MS DRUG should be populated with the drug whose action would be affected by the genetic marker being assessed via the genotypic test. MS CONC and MS CONCU are null in these records.
2. MS DTC represents the date the specimen was collected.
3. If the specimen was cultured, the start and end date of culture would be represented in the BE domain in BESTDTC and BEENDTC respectively. The culture dates can be connected to the MS record via MSREFID and BEREFFID; --REFID represents the sample ID.
4. NHOID is a sponsor-defined, intuitive name of the non-host organism being tested. It should only be populated with values representing what is known about the identity of the organism before the results of the test are determined. It should therefore never be used as a qualifier of result.
5. --EXMTRG is used as a qualifier of --TEST when the test is designed specifically to target the organism populating this variable, regardless of whether this organism is present in the sample being tested (as opposed to NHOID, which is used to represent what is already known about the identity of an organism present in a sample being tested).
6. The following variables would not generally be used in MB: --MODIFY, --BODSYS, --SPEC, --SPCCND, --FAST, --TOX, --TOXGR --SEV.

MB-MS - Examples for Microbiology Specimen, and Microbiology Susceptibility Domain Models

Example 1

This example shows the microorganisms identified from a gastric aspirate specimen from a child with suspected TB. In this example, gastric lavage is only performed once. Three records in the Microbiology Specimen (MB) domain store identification records for two levels of identification: acid-fast bacilli, and Mycobacterium tuberculosis (Mtb). Characteristics from a culture on solid media that support the presumptive identification of Mtb are also represented in MB. The susceptibility results from both the NAAT and the solid culture are represented in the Microbiology Susceptibility (MS) domain. In both the MB and MS domains, --DTC will always be the date of sample collection.

The example table below shows specimen processing events including sample collection, preparation and culturing events. Sample processing events are represented in the Biospecimen Events (BE) domain. For TB studies, each sample needs a separate identifier to link it to further actions or characteristics of the sample. Therefore, each aliquot is assigned a unique BEREFD value that can be traced to the BEREFD value assigned to the collected “parent” sample. BEREFD is also used to connect the BE and BS domains (via BSREFID), as well as any results obtained from the sample that are in the MB or MS domains (via MBREFID and MSREFID). If the same sample is used in many tests, the use of --REFID may result in an undesirable MANY to MANY merge. Users may need to make use of additional linking variables, such as --LNKID.

- Row 1:** Shows the event of specimen collection. This is the genesis of the sample identified by BEREFD=100, therefore BEDTC and BESTDTC are the same. The collection method and specimen type are represented as non-standard variables.
- Rows 2-6:** Show that the sample was aliquoted (smaller subsamples were portioned out from the parent sample). Each separate aliquot is assigned a unique BEREFD. In these cases, BEREFD is an incremented decimal value with the original sample's BEREFD (when BECAT=COLLECTION) as the base number. This is not an explicit requirement, but makes tracking the samples easier. The definitive link between parent-child samples is defined by the PARENT variable shown in the RELSPEC dataset below.
- Rows 7-9:** Show that three of the aliquots (100.3, 100.4, and 100.5) were cultured for identification (Row 8; BECAT=IDENTIFICATION) and drug susceptibility testing (Rows 9 and 10; BECAT=DRUG SUSCEPTIBILITY). The inoculation and read dates of a culture should be represented in BESTDTC and BEENDTC, respectively. These dates can be linked to the culture results in MB and MS using BELNKID, MBLNKID, and MSLNKID.
- Row 10:** Shows that sample 100.1 was concentrated.

be.xpt

Row	STUDYID	DOMAIN	USUBJID	BESEQ	BEREFID	BELNKID	BETERM	BECAT	BEDTC	BESTDTC	BEENDTC
1	ABC	BE	ABC-01-101	1	100		Collecting	COLLECTION	2011-01-17T06:00	2011-01-17T06:00	
2	ABC	BE	ABC-01-101	2	100.1		Aliquoting	PREPARATION	2011-01-17T06:00	2011-01-17T09:00	
3	ABC	BE	ABC-01-101	3	100.2		Aliquoting	PREPARATION	2011-01-17T06:00	2011-01-17T09:00	
4	ABC	BE	ABC-01-101	4	100.3		Aliquoting	PREPARATION	2011-01-17T06:00	2011-01-17T09:00	
5	ABC	BE	ABC-01-101	5	100.4		Aliquoting	PREPARATION	2011-01-17T06:00	2011-01-17T09:00	

Row	STUDYID	DOMAIN	USUBJID	BESEQ	BEREFID	BELNKID	BETERM	BECAT	BEDTC	BESTDTC	BEENDTC
6	ABC	BE	ABC-01-101	6	100.5		Aliquoting	PREPARATION	2011-01-17T06:00	2011-01-17T09:00	
7	ABC	BE	ABC-01-101	7	100.3	1	Culturing	IDENTIFICATION	2011-01-17T06:00	2011-01-17T09:30	2011-02-02T09:00
8	ABC	BE	ABC-01-101	8	100.4	2	Culturing	DRUG SUSCEPTIBILITY	2011-01-17T06:00	2011-01-17T09:30	2011-02-05T09:00
9	ABC	BE	ABC-01-101	9	100.5	3	Culturing	DRUG SUSCEPTIBILITY	2011-01-17T06:00	2011-01-17T09:30	2011-02-06T09:00
10	ABC	BE	ABC-01-101	10	100.1		Concentrating	PREPARATION	2011-01-17T06:00	2011-01-17T09:15	

Row 1: Shows that the sample collection was done at a hospital.

Row 2: Shows the specimen collection method was gastric lavage.

Row 3: Shows that the specimen type was lavage fluid.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QEVAL
1	ABC	BE	ABC-01-101	BESEQ	1	COLLOC	Specimen Collection Location	Hospital	CRF
2	ABC	BE	ABC-01-101	BESEQ	1	CLMETH	Specimen Collection Method	GASTRIC LAVAGE	CRF
3	ABC	BE	ABC-01-101	BESEQ	1	BESPEC	Specimen Type	LAVAGE FLUID	CRF

Findings data captured about the specimen during collection, preparation, and handling are represented in the Biospecimen (BS) domain.

Row 1: Shows the total volume of lavage fluid collected during the gastric lavage by using the same values for BSREFID and BEREFID. This is the parent (collected) sample from which further aliquots were generated.

Rows 2-6: Show the volume of each aliquot created.

bs.xpt

Row	STUDYID	DOMAIN	USUBJID	BSSEQ	BSREFID	BSTESTCD	BSTEST	BSCAT	BSORRES	BSORRESU
1	ABC	BS	ABC-01-101	1	100	VOLUME	Volume	COLLECTION	20	mL
2	ABC	BS	ABC-01-101	2	100.1	VOLUME	Volume	PREPARATION	4	mL
3	ABC	BS	ABC-01-101	3	100.2	VOLUME	Volume	PREPARATION	4	mL
4	ABC	BS	ABC-01-101	4	100.3	VOLUME	Volume	PREPARATION	4	mL
5	ABC	BS	ABC-01-101	5	100.4	VOLUME	Volume	PREPARATION	4	mL
6	ABC	BS	ABC-01-101	6	100.5	VOLUME	Volume	PREPARATION	4	mL

Row	BSSTRESC	BSSTRESN	BSSTRESU	BSCOLMTH	BSSPEC	BSDTC
1 (cont)	20	20	mL	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
2 (cont)	4	4	mL	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
3 (cont)	4	4	mL	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
4 (cont)	4	4	mL	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
5 (cont)	4	4	mL	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
6 (cont)	4	4	mL	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00

The RELSPEC table shows the relationship of the "Parent" sample to its aliquots. The LEVEL variable indicates that the sample has been sub-sampled. The original "Parent" sample is always LEVEL=1. An aliquot of the sample would be LEVEL=2. If the aliquot was further split, that sub-sample would be LEVEL=3.

Row 1: Shows the original collected (parent) sample. The PARENT variable is left blank to indicate this is the highest level sample.

Rows 2-6: Show the relationship of each aliquot in the BE domain to the parent sample. PARENT is populated with the REFID value of the parent sample, indicating that the sample with REFID=100 is the parent of these samples. LEVEL=2 serves to indicate that these aliquots are sub-samples of the original (LEVEL=1) sample.

RELSPEC.xpt

Row	STUDYID	USUBJID	REFID	SPEC	PARENT	LEVEL
1	ABC	ABC-01-101	100	LAVAGE FLUID		1
2	ABC	ABC-01-101	100.1	LAVAGE FLUID	100	2
3	ABC	ABC-01-101	100.2	LAVAGE FLUID	100	2
4	ABC	ABC-01-101	100.3	LAVAGE FLUID	100	2
5	ABC	ABC-01-101	100.4	LAVAGE FLUID	100	2
6	ABC	ABC-01-101	100.5	LAVAGE FLUID	100	2

Results from identification tests performed on samples are represented in the MB domain. The sputum sample was aliquoted five times. Three of these aliquots underwent identification testing using three separate tests: one for Acid Fast Bacilli, one for *M. tuberculosis* Complex and one for *M. tuberculosis*. MBEXMTRG indicates the organism being investigated. MBMETHOD represents the testing method. MBREFID indicates which aliquot was tested. Identification records should have an MBCAT=IDENTIFICATION to facilitate dataset sub-setting. Culture characteristics should also be represented in the MB domain and can be distinguished from identification records using a MBCAT=CHARACTERISTIC. These can include testing quantifiable and semi-quantifiable results of the culture, as well as qualitative details about the culture such as colony color, morphology, etc.

- Row 1:** Shows a test targeting the presence or absence of Acid Fast Bacilli using a stain. The MBSPCCND shows that the sample used in the test was concentrated. MBGRPID can be used to connect the identification record with the corresponding AFB quantification results shown in Row 2.
- Row 2:** Shows a categorical result for an Acid Fast Bacilli test using a stain. MBORRES contains a result based on a CDC AFB rating scale. The name of the scale used is represented as a non-standard variable of MB (SUPPMB). MBEXMTRG indicates that this was a targeted exam testing for Acid Fast Bacilli. MBREFID indicates which aliquot the procedure was performed upon and MBGRPID is used to connect the AFB quantification record to the identification record in Row 1.
- Row 3:** Shows a test targeting the presence or absence of *M. tuberculosis* Complex using a genotyping method. Details about the assay can be found in the DI domain. The value in SPDEVID links the genotype result to the assay information in the DI domain.
- Row 4:** Shows a test targeting the presence or absence of *M. tuberculosis* performed on a solid culture. The medium type is represented as a non-standard variable of MB (SUPPMB). The culture start and stop dates are represented in BE and are connected to the culture results via BELNKID and MBLNKID. MBGRPID is used to connect the identification record in MB with the corresponding culture characteristics shown in Rows 5-7.
- Row 5:** Shows the result of a qualitative assessment of the color of the colonies growing on the culture plate. The medium type is represented as a non-standard variable of MB (SUPPMB).
- Row 6:** Shows a CFU count from a solid culture. The CFU count has been standardized using a categorical quantification scale. The quantification scale used and the medium type for the solid culture are represented as non-standard variables of MB (SUPPMB).
- Row 7:** Shows the result of a qualitative assessment of colony morphology under a microscope as indicated by MBMETHOD.

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MBSEQ	MBGRPID	MBLNKID	MBREFID	MBTESTCD	MBTEST	MBEXMTRG
1	ABC	MB	ABC-01-101		1	1		100.1	TRGMBEXM	Targeted Microbiology Exam	ACID FAST BACILLI
2	ABC	MB	ABC-01-101		2	1		100.1	QUANT	Quantification	ACID FAST BACILLI
3	ABC	MB	ABC-01-101		1	1		100.1	TRGMBEXM	Targeted Microbiology Exam	ACID FAST BACILLI
4	ABC	MB	ABC-01-101		4	2	1	100.3	TRGMBEXM	Targeted Microbiology Exam	MYCOBACTERIUM TUBERCULOSIS
5	ABC	MB	ABC-01-101		5	2	1	100.3	COLCOLOR	Colony Color	MYCOBACTERIUM TUBERCULOSIS
6	ABC	MB	ABC-01-101		6	2	1	100.3	QUANT	Quantification	MYCOBACTERIUM TUBERCULOSIS
7	ABC	MB	ABC-01-101		7	2	1	100.3	COLMORPH	Colony Morphology	MYCOBACTERIUM TUBERCULOSIS

Row	MBCAT	MBORRES	MBORRESU	MBSTRESC	MBSPEC	MBLOC	MBSPPCND	MBMETHOD
1 (cont)	IDENTIFICATION	PRESENT		PRESENT	LAVAGE FLUID	STOMACH	CONCENTRATED	ZIEHL NEELSEN ACID FAST STAIN
2 (cont)	CHARACTERISTIC	+3		+3	LAVAGE FLUID	STOMACH	CONCENTRATED	ZIEHL NEELSEN ACID FAST STAIN
3 (cont)	IDENTIFICATION	PRESENT		PRESENT	LAVAGE FLUID	STOMACH		NUCLEIC ACID AMPLIFICATION TEST
4 (cont)	IDENTIFICATION	PRESENT		PRESENT	LAVAGE FLUID	STOMACH		MICROBIAL CULTURE, SOLID
5 (cont)	CHARACTERISTIC	BUFF		BUFF	LAVAGE FLUID	STOMACH		MICROBIAL CULTURE, SOLID
6 (cont)	CHARACTERISTIC	147	CFU/mL	+2	LAVAGE FLUID	STOMACH		MICROBIAL CULTURE, SOLID
7 (cont)	CHARACTERISTIC	SERPENTINE CORD		SERPENTINE CORD	LAVAGE FLUID	STOMACH		MICROBIAL CULTURE, SOLID

Row	VISITNUM	VISIT	MBDTC
1 (cont)	1	WEEK 1	2011-01-17T06:00

Row	VISITNUM	VISIT	MBDTC
2 (cont)	1	WEEK 1	2011-01-17T06:00
3 (cont)	1	WEEK 1	2011-01-17T06:00
4 (cont)	1	WEEK 1	2011-01-17T06:00
5 (cont)	1	WEEK 1	2011-01-17T06:00
6 (cont)	1	WEEK 1	2011-01-17T06:00
7 (cont)	1	WEEK 1	2011-01-17T06:00

- Row 1:** Shows the quantification scale used to assign the categorical result for the AFB test in Row 1 of the MB dataset above.
- Row 2:** Shows that the microbiological certainty for the test shown in Row 3 of the MB dataset above is definitive.
- Row 3:** Shows that the microbiological certainty for the test shown in Row 4 of the MB dataset above is presumptive.
- Row 4:** Shows the medium type used to perform the solid culture test in Rows 4-7 of the MB dataset.
- Row 5:** Shows the scale used to categorize the solid culture colony counts in Row 6 of the MB dataset above

supmb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QEVAL
1	ABC	MB	ABC-01-101	MBSEQ	2	AFBSCAL	AFB Quantification Scale	Smear Quantification: Centers for Disease Control Method for Carbol Fuchsin Staining (1000X)	MICROBIOLOGY LAB
2	ABC	MB	ABC-01-101	MBSEQ	3	MCIDCERT	Microbial Identification Certainty	DEFINITIVE	MICROBIOLOGY LAB
3	ABC	MB	ABC-01-101	MBSEQ	4	MCIDCERT	Microbial Identification Certainty	PRESUMPTIVE	MICROBIOLOGY LAB
4	ABC	MB	ABC-01-101	MBREFID	100.3	MEDTYPE	Medium Type	Middlebrook-7H10 Agar	MICROBIOLOGY LAB
5	ABC	MB	ABC-01-101	MBSEQ	6	COLSCAL	Colony Quantification Scale	Solid Media Result: Centers for Disease Control (CDC) Quantification Scale	MICROBIOLOGY LAB

Results from drug susceptibility tests performed on samples are represented in the MS domain. This includes all phenotypic tests (where drug is added directly to the culture medium) and genotypic tests when the result is given as susceptible or resistant. Genotypic tests that give results of specific genetic polymorphisms should be represented in the PF domain, even though such results may be categorized as susceptible or resistant (see Section 4.4 for examples of this type).

- Rows 1-2:** Show phenotypic testing results on two separate culture plates: one with medium containing rifampicin (Row 1) and one with medium containing isoniazid (Row 2). The variable MSTSTDTL=Phenotypic is used to distinguish it from a genotypic test as some labs do not report the method used. The culture start and stop dates are represented in BE and can be linked to MS by BELNKID and MSLNKID.
- Rows 3-4:** Show genotypic susceptibility testing results on the same aliquot from a nucleic acid amplification test (NAAT) that looks for mutations that confer resistance to two drugs. Even though no actual drug is present, MS DRUG should be populated with the name of the drug whose action is affected by the mutation being tested for. However, MSCONC and MSCONU should be null. These results are represented in MS because the only result given is in terms of resistant/susceptible; no genetic results are reported. The variable MSTSTDTL=Genotypic is used to distinguish it from a phenotypic test as some labs do not report the method used.
- All Rows:** The variable MSNSPCES should be populated with the name of the organism that is the subject of the test.

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Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MSNSPCES	MSSEQ	MSREFID	MSLNKID	MSTESTCD	MSTEST
1	ABC	MS	ABC-01-101		MYCOBACTERIUM TUBERCULOSIS	1	100.4	2	DS	Drug Susceptibility
2	ABC	MS	ABC-01-101		MYCOBACTERIUM TUBERCULOSIS	2	100.5	3	DS	Drug Susceptibility
3	ABC	MS	ABC-01-101	ABC765	MYCOBACTERIUM TUBERCULOSIS	3	100.2		DS	Drug Susceptibility
4	ABC	MS	ABC-01-101	ABC765	MYCOBACTERIUM TUBERCULOSIS	4	100.2		DS	Drug Susceptibility

Row	MSTSTDTL	MSDRUG	MSCONC	MSCONCU	MSORRES	MSSTRESC	MSSPEC	MSLOC	MSMETHOD	MSDTC
1 (cont)	Phenotypic	Rifampicin	1	ug/mL	RESISTANT	RESISTANT	LAVAGE FLUID	STOMACH	ANTIBIOTIC AGAR SCREEN	2011-01-17T06:00
2 (cont)	Phenotypic	Isoniazid	0.2	ug/mL	SUSCEPTIBLE	SUSCEPTIBLE	LAVAGE FLUID	STOMACH	ANTIBIOTIC AGAR SCREEN	2011-01-17T06:00
3 (cont)	Genotypic	Rifampicin			RESISTANT	RESISTANT	LAVAGE FLUID	STOMACH	NUCLEIC ACID AMPLIFICATION TEST	2011-01-17T06:00
4 (cont)	Genotypic	Isoniazid			SUSCEPTIBLE	SUSCEPTIBLE	LAVAGE FLUID	STOMACH	NUCLEIC ACID AMPLIFICATION TEST	2011-01-17T06:00

Rows 1-2: Show the medium type used to perform the phenotypic susceptibility tests in Rows 1 and 2 respectively of the MS dataset example above.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QEVAL
1	ABC	MS	ABC-01-101	MSREFID	100.4	MEDTYPE	Medium Type	Löwenstein-Jensen	MICROBIOLOGY LAB
2	ABC	MS	ABC-01-101	MSREFID	100.5	MEDTYPE	Medium Type	Löwenstein-Jensen	MICROBIOLOGY LAB

Data about the device used (Rows 3-4 of the MS dataset example above) are represented in the Device Identifier (DI) domain.

Row 1: Shows the device identified by SPDEVID=ABC765 is a nucleic acid amplification test (NAAT).

Row 2: Shows the trade name for the NAAT device.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC	DI	ABC765	1	TYPE	Device Type	NUCLEIC ACID AMPLIFICATION TEST
2	ABC	DI	ABC765	2	TRADENAM	Trade Name	HAIN GENOTYPE MTBDRplus

The below RELREC table shows how to link culture start and end dates from BE to the culture results in MB and MS.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	BE		BELNKID		ONE	A
2	ABC	MB		MBLNKID		MANY	A
3	ABC	BE		BELNKID		ONE	B
4	ABC	MS		MSLNKID		MANY	B

Example 2

The following is an example from Study P7081-5102 that describes genotyping of the HCV virus in two subjects using a line probe assay (LPA). Some Required and Expected variables have been omitted in consideration of space and clarity. Controlled terminology is still under development, so some values in the examples are not CDISC controlled terms. Check terminology shown against current standards before adopting it.

Row 1: The HCV for this subject has a genotype of 1a.

Row 2: The HCV for this subject has a genotype of 2b.

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBREFID	MBTESTCD	MBTEST	MBORRES	MBSTRESC	MBNAM	MBSPEC
1	P7081-5102	MB	P7081-5102-01402	1	DEF-002	ORGANISM	Organism Present	HCV 1a	HCV 1a	Acme Genetics	RNA
2	P7081-5102	MB	P7081-5102-01403	1	DEF-002	ORGANISM	Organism Present	HCV 2b	HCV 2b	Acme Genetics	RNA

Row	MBMETHOD	MBBLFL	VISITNUM	VISIT	VISITDY	MBDTC
1 (cont)	LINE PROBE ASSAY	Y	1	Baseline	1	2014-01-30
2 (cont)	LINE PROBE ASSAY	Y	1	Baseline	1	2014-01-30

Example 3

This example shows how to represent data from an NA inhibition assay assessing influenza susceptibility to a neuraminidase inhibitor during an antiviral treatment trial. This assessment was done at three time points over a five-day period. Each time point compares a known reference strain to a subject-derived sample strain that has previously been identified as being of the same lineage based on genetic markers (thus the strain name ending in “-like”). The taxonomy information for each sample is captured in the OI domain and can be linked to the results in the MS domain using the variable NHOID. In this example, information about the analysis software and software version used to calculate the IC50 values is represented in non-standard variables for MS, but it could also be represented as changeable properties of the workstation, in the Device-In-Use (DU) domain. SPDEVID holds the commercial kits used; the full set of information necessary to identify these is represented in the Device Identifiers domain (DI).

Some Required and Expected variables have been omitted in consideration of space and clarity. Controlled terminology is still under development, thus some values in the examples are not CDISC controlled terms. Check terminology shown against current standards before adopting it.

- Rows 1-3:** Show the drug concentration required to produce 50% inhibition of the virus growth (IC50) for both the influenza virus extracted from subject INF01-01 (Row 1) and the reference influenza strain (Row 2). In both cases, NHOID represents the organism being tested (subject sample virus and reference virus, respectively). This value serves as both an intuitive representation of the as-reported name of the virus, and a link to the OI domain where there fully parsed taxonomic nomenclature is represented. Row 3 shows the fold change in the IC50 of the virus extracted from the subject compared to the reference virus. This fold change value is the subject sample result (Row 1) divided by the reference result (Row 2). Because this record is derived, MSDRVFL=Y. These 3 records comprise the baseline visit for this subject.
- Rows 4-6:** Show the IC50 values for the same subject and reference strain (Rows 4 and 5 respectively), and the fold change in resistance (Row 6) for the “Day 2” visit.
- Row 7:** Shows the fold change in resistance of the subject virus sample at the Day 2 visit from the *baseline* visit. Not to be confused with fold change in resistance as in Rows 3 and 6, fold change from baseline is calculated by dividing the current IC50 Subject Result (Row 4) by the IC50 Subject Result from the baseline visit (Row 1).
- Rows 8-10:** Show the IC50 values for the same subject and reference strain (Rows 8 and 9 respectively), and the fold change in resistance (Row 10) for the “Day 5” visit.
- Row 11:** Shows the fold change in resistance of the subject virus sample at the Day 5 visit from the baseline visit. Fold change from baseline is calculated by dividing the current IC50 Subject Result (Row 8) by the IC50 Subject Result from the baseline visit (Row 1).
- Row 12:** Shows the qualitative net assessment of the overall change in susceptibility of subject sample virus over the 3 visits. MSORRES/MSSTRESC shows “Reduced Susceptibility”. The variable MSGRPID is used to show all of the results that were used in the “Inhibitory Net Concentration Assessment”.

ms.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MSSEQ	MSGRPID	NHOID	MSTESTCD	MSTEST	MSDRUG
1	INFL123	MS	INF01-01	10	1	1	A/California/7/2009 (H1N1)	IC50S	IC50 Subject Result	Investigamavir
2	INFL123	MS	INF01-01	10	2	1	A/California/7/2009 (H1N1)-like	IC50R	IC50 Reference Control Result	Investigamavir
3	INFL123	MS	INF01-01		3	1		IC50FCR	IC50 Fold Change from Reference	Investigamavir
4	INFL123	MS	INF01-01	12	4	1	A/California/7/2009 (H1N1)	IC50S	IC50 Subject Result	Investigamavir
5	INFL123	MS	INF01-01	12	5	1	A/California/7/2009 (H1N1)-like	IC50R	IC50 Reference Control Result	Investigamavir
6	INFL123	MS	INF01-01		6	1		IC50FCR	IC50 Fold Change from Reference	Investigamavir
7	INFL123	MS	INF01-01		7	1		IC50FCB	IC50 Fold Change from Baseline	Investigamavir
8	INFL123	MS	INF01-01	12	8	1	A/California/7/2009 (H1N1)	IC50S	IC50 Subject Result	Investigamavir
9	INFL123	MS	INF01-01	12	9	1	A/California/7/2009 (H1N1)-like	IC50R	IC50 Reference Control Result	Investigamavir
10	INFL123	MS	INF01-01		10	1		IC50FCR	IC50 Fold Change from Reference	Investigamavir
11	INFL123	MS	INF01-01		11	1		IC50FCB	IC50 Fold Change from Baseline	Investigamavir
12	INFL123	MS	INF01-01		12	1		ICNETAS	Inhibitory Concentration Net Assessment	Investigamavir

Row	MSORRES	MSORRESU	MSSTRESC	MSTRESN	MSSTRESU	MSSPEC	MSMETHOD
1 (cont)	0.20	nM	0.20	0.20	nM	MUCUS	NEURAMINIDASE INHIBITION ASSAY
2 (cont)	0.21	nM	0.21	0.21	nM		NEURAMINIDASE INHIBITION ASSAY
3 (cont)			0.95	0.95			
4 (cont)	0.21	nM	0.21	0.21	nM	MUCUS	NEURAMINIDASE INHIBITION ASSAY
5 (cont)	0.22	nM	0.22	0.22	nM		NEURAMINIDASE INHIBITION ASSAY
6 (cont)			0.95	0.95			
7 (cont)			1.05	1.05			
8 (cont)	4.18	nM	4.18	4.18	nM	MUCUS	NEURAMINIDASE INHIBITION ASSAY
9 (cont)	0.20	nM	0.20	0.20	nM		NEURAMINIDASE INHIBITION ASSAY

Row	MSORRES	MSORRESU	MSSTRESC	MSTRESN	MSSTRESU	MSSPEC	MSMETHOD
10 (cont)			21	21			
11 (cont)			21	21			
12 (cont)	REDUCED SUSCEPTIBILITY		REDUCED SUSCEPTIBILITY				

Row	MSCLMETH	MSANMETH	MSDRVFL	VISITNUM	VISIT	MSDTC	SFTWR	SFTWRVER
1 (cont)	NASAL SWAB	SOFTWARE ANALYSIS		1	BASELINE	2011-08-01	JASPR	1.3
2 (cont)		SOFTWARE ANALYSIS		1	BASELINE	2011-08-01	JASPR	1.3
3 (cont)			Y	1	BASELINE	2011-08-01	JASPR	1.3
4 (cont)	NASAL SWAB	SOFTWARE ANALYSIS		2	DAY 2	2011-08-02	JASPR	1.3
5 (cont)		SOFTWARE ANALYSIS		2	DAY 2	2011-08-02	JASPR	1.3
6 (cont)			Y	2	DAY 2	2011-08-02	JASPR	1.3
7 (cont)			Y	2	DAY 2	2011-08-02	JASPR	1.3
8 (cont)	NASAL SWAB	SOFTWARE ANALYSIS		3	DAY 5	2011-08-05	JASPR	1.3
9 (cont)		SOFTWARE ANALYSIS		3	DAY 5	2011-08-05	JASPR	1.3
10 (cont)			Y	3	DAY 5	2011-08-05		
11 (cont)			Y	3	DAY 5	2011-08-05		
12 (cont)				3	DAY 5	2011-08-05		

Metadata for non-standard variables:

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Origin	Role	Evaluator	Sponsor Comments
SFTWR	Analysis Software	Char		CRF	Non-Standard Qualifier		
SFTWRVER	Software Version	Num		CRF	Non-Standard Qualifier		

The table below shows how influenza species, subtype, and strain are represented in the OI domain. The variable NHOID is used to link this information to NA inhibition assay results in the MS domain.

- Rows 1-3:** Show the taxonomy for the influenza organism extracted from the subject. This virus has been identified as A/California/7/2009 (H1N1) and has been given the NHOID A/California/7/2009 (H1N1).
- Rows 4-6:** Show the taxonomy for the influenza laboratory reference sample. This virus has been identified as A/California/7/2009 (H1N1)-like and has been given the NHOID A/California/7/2009 (H1N1)-like.

oi.xpt

Row	STUDYID	DOMAIN	NHOID	OISEQ	OIPARMCD	OIPARM	OIVAL
1	INFL123	OI	A/California/7/2009 (H1N1)	1	SPCIES	Species	Influenza A
2	INFL123	OI	A/California/7/2009 (H1N1)	2	SUBTYP	Subtype	H1N1
3	INFL123	OI	A/California/7/2009 (H1N1)	3	STRAIN	Strain	A/California/7/2009 (H1N1)
4	INFL123	OI	A/California/7/2009 (H1N1)-like	1	SPCIES	Species	Influenza A
5	INFL123	OI	A/California/7/2009 (H1N1)-like	2	SUBTYP	Subtype	H1N1
6	INFL123	OI	A/California/7/2009 (H1N1)-like	3	STRAIN	Strain	A/California/7/2009 (H1N1)-like

The table below shows how to represent the type of assay and the commercial kit name in the DI domain.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	INFL123	DI	10	1	DEVTYPE	Device Type	NA Inhibition Assay
2	INFL123	DI	10	2	TRADENAM	Trade Name	NA-XTD KIT
3	INFL123	DI	12	1	DEVTYPE	Device Type	NA Inhibition Assay
4	INFL123	DI	12	2	TRADENAM	Trade Name	NA-STAR KIT

DRAFT

