Microbiology Domains: MB, MC and MS

This is a draft revision of the MB domain. Proposed new variables are marked with **New** in the left margin.

Microbiology Specimen (MB)

MB - Description/Overview for Microbiology Specimen Domain Model

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

MB - Specification for Microbiology Specimen Domain Model

mb.xpt, Microbiology Specimen — Findings, Version 3.3. 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
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 of MBTESTCD	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 of MBTESTCD and MBTEST	Identifies the organism or group of organisms targeted by exams where MBTESTCD=TRGMBEXM	Perm

New (MBEXMTRG row)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
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
New 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 of MBORRES	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
MBSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen. Example: CONTAMINATED.	Perm
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

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
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	Collection date and time of an observation represented in IS0 8601 character format.	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 non-host organisms that are identified; including bacteria, viruses, parasites, and fungi. Findings represented in the MB domain should be limited to names of organisms present or the presence/absence of pre-specified organisms (Note: this includes viruses even though they are not organisms in the strict sense of the term).

2. Controlled terminology for MB supports two TESTCDs: "ORGANISM" and "TRGMBEXM"

    a. "ORGANISM" should only be used when the test is non-selective and seeks to identify any and all organisms or group of organisms present in a sample. Results will be the name of the organism or group of organisms identified (e.g. MYCOBACTERIUM TUBERCULOSIS, ACID FAST BACILLI)

    b. "TRGMBEXM" should be used when the test is selective and seeks to identify a particular organism or group of organisms. Results will be "PRESENT" or "ABSENT", "POSITIVE" or "NEGATIVE" etc. MBEXMTRG will identify the organism/organism group targeted and is expected when MBTESTCD=TRGMBEXM.

3. MBDTC represents the date the specimen was collected.

4. 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 BEREFID; --REFID represents the sample ID.

5. --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.

6. The following variables would not generally be used in MB: NHOID, --MODIFY, --BODSYS, --FAST, --TOX, --TOXGR, --SEV, --ORRESU, --STRESU, --LOINC.

Microbiology Characteristics (MC)

> This is a proposed new domain. Variables proposed for addition to the SDTM are marked with **New** in the left margin.

MC - Description/Overview for Microbiology Characteristics Domain Model

The Microbiology Characteristics (MC) domain is for representing data on microbial characteristics other than drug susceptibility testing. This includes culture characteristics such as growth/no growth, colony quantification measures, colony color, colony morphology.

MC - Specification for Microbiology Characteristics Domain Model

mc.xpt, Microbiology Characteristics — Findings, Version 3.2. One record per microbiology characteristic test (or other organism-related finding), 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	MC	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
MCSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MCGRPID	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 MC, used to link to organism in MB.	Req
MCREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm
New 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.	Perm
New MCNSPCES	Non-host Species	Char		Grouping Qualifier	Biological classification for a non-host organism. Used to represent valid species names when they are known and when this level of identification is sufficient.	Perm
MCSPID	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
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
MCTESTCD	Microbiology Organism Finding Short Name	Char	*	Topic	Short name of the measurement, test, or finding described in MCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. MCTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: COLCOLOR, QUANT	Req
MCTEST	Organism Test or Finding Name	Char	*	Synonym Qualifier of MCTESTCD	Verbatim name of the test or examination used to obtain the measurement or finding. Examples: Colony Color, Quanitification	Req

	Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
New	MCEXMTRG	Microbiology Exam Target	Char		Variable Qualifier of MCTESTCD and MCTEST	Serves as a qualifier of MCTEST. Identifies the organism or group of organisms targeted by exams. Example: MYCOBACTERIUM TUBERCULOSIS	Perm
	MCCAT	Category for Organism Findings	Char	*	Grouping Qualifier	Used to define a category of related tests.	Req
	MCSCAT	Subcategory for Organism Findings	Char	*	Grouping Qualifier	A further categorization of a test category.	Perm
	MCORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Microbiology Organism measurement or finding as originally received or collected.	Exp
	MCORRESU	Original Units	Char	(UNIT)	Variable Qualifier of MCORRES	Original units in which the data were collected. The unit for MCORRES.	Exp
	MCSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from MCORRES in a standard format or standard units. MCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in MCSTRESN. For example, if a test has results "+3 MODERATE", "MOD", and "MODERATE", and in MCORRES and these results effectively have the same meaning, they could be represented in standard format in MCSTRESC as "MODERATE".	Exp
	MCSTRESN	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 MCSTRESC. MCSTRESN should store all numeric test results or findings.	Exp
	MCSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier of MCSTRESC and MCSTRESN	Standardized unit used for MCSTRESC and MCSTRESN.	Exp
	MCRESCAT	Result Category	Char	(MCRESCAT)	Variable Qualifier of MCORRES	Used to categorize the result of a finding in a standard format	Perm
	MCSTAT	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 MCORRES or have a value of NOT DONE.	Perm
	MCREASND	Reason Test Not Done	Char		Record Qualifier	Reason not done. Describes why a measurement or test was not performed. Used in conjunction with MCSTAT when value is NOT DONE. Example: SAMPLE LOST	Perm
	MCNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor that provided the test results.	Perm
	MCMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: MICROBIAL CULTURE, LIQUID; MICROBIAL CULTURE, SOLID; LIGHT MICROSCOPY	Exp
	MCBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Perm
	MCDRVFL	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 MCDRVFL=Y, then MCORRES may be null, with MCSTRESC and (if numeric) MCSTRESN having the derived value.	Perm
	VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
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
MCDTC	Date/Time of Test	Char	ISO 8601	Timing	Collection date and time of an observation represented in IS0 8601 character format.	Perm
MCDY	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
MCTPT	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 MCTPTNUM and MCTPTREF. Examples: Start, 5 min post.	Perm
MCTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of MCTPT to aid in sorting.	Perm
MCELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Elapsed time (in ISO 8601) relative to a planned fixed reference (MCTPTREF). 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 MCTPTREF, or "P8H" to represent the period of 8 hours after the reference point indicated by MCTPTREF.	Perm
MCTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by MCELTM, MCTPTNUM, and MCTPT. Example: PREVIOUS DOSE.	Perm

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

MC - Assumptions for Microbiology Characteristics Domain Model

1. Definition: The Microbiology Characteristics (MC) domain is for representing data on microbial characteristics other than drug susceptibility testing. This includes culture characteristics such as growth/no growth, colony quantification measures, colony color, colony morphology. The MC domain is designed to store any characteristics related to the organisms found and represented in MB. This domain can be used in conjunction with the MB domain described above, or it may be used to represent characteristics even when identification has not been made.

    a. This consists of organism-related findings such as growth, quantification measures, color, and colony morphology.

    b. This domain is not intended to store susceptibility testing results; these should be represented in the MS domain.

2. MCDTC 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 MC record via MCREFID and BEREFID; --REFID represents the sample ID.

4. MCLNKID may be used to link to findings related to that organism in the MB and MS domains.

5. NHOID is a sponsor-defined, intuitive name of the non-host organism being tested. It should only populated with values representing what is known about the identity of the organism before the results of the test are determined. It should therefor never be used as a qualifier of result.

6. –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).

7. The following Qualifiers would not generally be used in MB: --MODIFY, --BODSYS, --SPEC, --SPCCND, --FAST, --TOX, --TOXGR –SEV, --LOINC.

Microbiology Susceptibility (MS)

This is a draft revision of the MS domain. Proposed new variables are marked with **New** in the left margin.

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 - Specification 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
New 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.	Perm
New MSNSPCES	Non-Host Species	Char		Grouping Qualifier	Biological classification for a non-host organism. Used to represent valid species names when they are known and 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 of MSTESTCD	Verbatim name of the test or examination used to obtain the measurement or finding. Examples: Minimum Inhibitory Concentration, Drug Susceptibility Testing	Req

	Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
New	MBEXMTRG	Microbiology Exam Target	Char		Variable Qualifier of MBTESTCD and MBTEST	Serves as a qualifier of MSTEST. Identifies the organism or group of organisms targeted by drug susceptibility testing. Example: MYCOBACTERIUM TUBERCULOSIS	Perm
New	MSDRUG	Drug Name	Char		Variable Qualifier of MBTESTCD and MBTEST	The name of the drug for which resistance is based on genetic biological markers.	Perm
New	MSCONC	Drug Concentration	Num		Variable Qualifier of MSDRUG	Numeric concentration of drug listed in --DRUG.	Perm
New	MSCONCU	Drug Concentration Units	Char	(UNIT)	Variable Qualifier of MSCONC	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 of MSORRES	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 of MSSTRESC and MSSTRESN	Standardized unit used for MSSTRESC and MSSTRESN.	Perm
	MSRESCAT	Result Category	Char	(MSRESCAT)	Variable Qualifier of MSORRES	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 of MSTESTCD	1. Dictionary-derived LOINC Code for MSTEST. 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

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MSBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Perm
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	Collection date and time of an observation represented in IS0 8601 character format.	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

* 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), MSDRUG, MSCONC and MSCONCU 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), MSDRUG is used to represent the drug being tested, but MSCONC and MSCONCU 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.

2. MSDTC 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 BEREFID; --REFID represents the sample ID.

4. NHOID is a sponsor-defined, intuitive name of the non-host organism being tested. It should only populated with values representing what is known about the identity of the organism before the results of the test are determined. It should therefor 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-MC-MS - Examples for Microbiology Specimen, Microbiology Characteristics, 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). Related records in the Microbiology Characteristics (MC) domain store the findings of a culture on solid media leading to the presumptive Mtb identification. The susceptibility results from both the NAAT and the solid culture are represented in the Microbiology Susceptibility (MS) domain. In all three domains (MB, MC, and MS), --DTC will always be the date of sample collection.

The 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 BEREFID value that can be traced to the BEREFID assigned for the collected "parent" sample. BEREFID is used to connect the BE and BS (BSREFID) domains, as well as to any results in the MB, MC, or MS domains (MBREFID, MCREFID, MSREFID) obtained from the sample.

Row 1:   Shows the origin of the specimen is gastric lavage (BETERM when BECAT=COLLECTION).

Rows 2-7:   Show that the sample was aliquoted (smaller subsamples were portioned out from the parent sample). Each separate aliquot is assigned a unique BEREFID. In these cases, BEREFID is an incremented decimal value based on the original sample's BEREFID (when BECAT=COLLECTION) as a 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 8-10: Show that three of the aliquots (100.1, 100.2, 100.3) were cultured for identification (Row 8; BECAT=IDENTIFICATION) and drug susceptibility testing (Rows 9 and 10; BECAT=DRUG SUSCEPTIBILITY). When a sample is cultured, it is important to record the inoculation and culture read dates which should be represented in BESTDTC and BEENDTC respectively.

Row 11:   Shows that sample 100.1 was concentrated.

be.xpt

Row	STUDYID	DOMAIN	USUBJID	BESEQ	BEREFID	BETERM	BECAT	BEDTC	BESTDTC	BEENDTC
1	ABC	BE	ABC-01-101	1	100	Gastric Lavage	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	100.3	Aliquoting	PREPARATION	2011-01-17T06:00	2011-01-17T09:00	
6	ABC	BE	ABC-01-101	6	100.4	Aliquoting	PREPARATION	2011-01-17T06:00	2011-01-17T09:00	
7	ABC	BE	ABC-01-101	7	100.5	Aliquoting	PREPARATION	2011-01-17T06:00	2011-01-17T09:00	
8	ABC	BE	ABC-01-101	8	100.3	Culturing	IDENTIFICATION	2011-01-17T06:00	2011-01-17T09:30	2011-02-02T09:00
9	ABC	BE	ABC-01-101	9	100.4	Culturing	DRUG SUSCEPTIBILITY	2011-01-17T06:00	2011-01-17T09:30	2011-02-05T09:00
10	ABC	BE	ABC-01-101	10	100.5	Culturing	DRUG SUSCEPTIBILITY	2011-01-17T06:00	2011-01-17T09:30	2011-02-06T09:00
11	ABC	BE	ABC-01-101	11	100.1	Concentration	PREPARATION	2011-01-17T06:00	2011-01-17T09:15	

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	BSSTRESC	BSSTRESN	BSSTRESU
1	ABC	BS	ABC-01-101	1	100	VOLUME	Volume	COLLECTION	20	mL	20	20	mL
2	ABC	BS	ABC-01-101	2	100.1	VOLUME	Volume	PREPARATION	4	mL	4	4	mL
3	ABC	BS	ABC-01-101	3	100.2	VOLUME	Volume	PREPARATION	4	mL	4	4	mL
4	ABC	BS	ABC-01-101	4	100.3	VOLUME	Volume	PREPARATION	4	mL	4	4	mL
5	ABC	BS	ABC-01-101	5	100.4	VOLUME	Volume	PREPARATION	4	mL	4	4	mL
6	ABC	BS	ABC-01-101	6	100.5	VOLUME	Volume	PREPARATION	4	mL	4	4	mL

Row	BSCOLMTH	BSSPEC	BSDTC
1 (cont)	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
2 (cont)	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
3 (cont)	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
4 (cont)	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
5 (cont)	GASTRIC LAVAGE	LAVAGE FLUID	2011-01-17T06:00
6 (cont)	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. MBCOLMTH

indicates that the sample was collected using gastric lavage. MBEXMTRG indicates the organism being investigated. MBMETHOD represents the testing method. MBREFID indicates which aliquot was tested.

Row 1:   Shows a test targeting the presence of absence of Acid Fast Bacilli using a stain. The MBSPCCND shows that the sample used in the test was concentrated. MBREFID can be used to connect the identification record with the corresponding AFB quantification results in MC via MCREFID.

Row 2:   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 3:   Shows a test targeting the presence or absence of M.tuberculosis performed on a solid culture. The particular media type used is stored in SUPPMB. MCREFID is used to connect the identification record in MB with the corresponding culture results in MC via MCREFID. The culture start and stop dates are represented in BE and could be merged to MB by BEREFID and MBREFID where BETERM=Culturing and BECAT=IDENTIFICATION.

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	SPDEVID	MBREFID	MBTESTCD	MBTEST	MBEXMTRG	MBORRES	MBORRESU	MBSTRESC
1	ABC	MB	ABC-01-101	1		100.1	TRGMBEXM	Targeted Microbiology Exam	ACID FAST BACILLI	PRESENT		PRESENT
2	ABC	MB	ABC-01-101	2	ABC765	100.2	TRGMBEXM	Targeted Microbiology Exam	MYCOBACTERIUM TUBERCULOSIS COMPLEX	PRESENT		PRESENT
3	ABC	MB	ABC-01-101	3		100.3	TRGMBEXM	Targeted Microbiology Exam	MYCOBACTERIUM TUBERCULOSIS	PRESENT		PRESENT

Row	MBSTRESU	MBSPEC	MBSPCCND	MBCOLMTH	MBMETHOD	VISITNUM	VISIT	MBDTC
1 (cont)		LAVAGE FLUID	CONCENTRATED	GASTRIC LAVAGE	ZIEHL NEELSEN ACID FAST STAIN	1	WEEK 1	2011-01-17T06:00
2 (cont)		LAVAGE FLUID		GASTRIC LAVAGE	LINE PROBE ASSAY	1	WEEK 1	2011-01-17T06:00
3 (cont)		LAVAGE FLUID		GASTRIC LAVAGE	MICROBIAL CULTURE, SOLID	1	WEEK 1	2011-01-17T06:00

Culture characteristics are represented in the MC domain. These can include testing quantifiable and semi-quantifiable results of the culture, as well qualitative details about the culture such as colony color, morphology, etc.

Row 1:   Shows a categorical result for an Acid Fast Bacilli test using a stain. MCORRES contains a result based on a CDC AFB rating scale. The scale is contained in SUPPMC. MCREFID indicates that which aliquot the procedure was performed upon. MCEXMTRG indicates that this was a targeted exam testing for Acid Fast Bacilli. MCREFID is used to connect the AFB quantification record to the identification record in MB via MBREFID.

Row 2:   Shows a test targeting the presence or absence of M. tuberculosis from a solid culture. The medium type is stored in SUPPMC.

Row 3:   Shows the result of a qualitative assessment of the color of the colonies growing on the culture plate. The medium type is stored in SUPPMC.

Row 4:   Shows a CFU count from a solid culture. The CFU count has been standardized using a categorical quantitation scale. The name of the quantification scale used is represented in SUPPMC. The medium type for the solid culture is also represented in SUPPMC.

Row 5:   Shows the result of a qualitative assessment of colony morphology under a microscope as indicated by MCMETHOD.

Rows 2-5:   The culture start and stop dates are represented in BE and could be merged to MC by BEREFID and MCREFID where BETERM=Culturing and BECAT=IDENTIFICATION.

mc.xpt

Row	STUDYID	DOMAIN	USUBJID	MCSEQ	MCREFID	MCTESTCD	MCTEST	MCEXMTRG	MCORRES	MCORRESU
1	ABC	MC	ABC-01-101	1	100.1	QUANT	Quantification	ACID FAST BACILLI	3+	
2	ABC	MC	ABC-01-101	2	100.3	GROWTH	Growth	MYCOBACTERIUM TUBERCULOSIS	POSITIVE	
3	ABC	MC	ABC-01-101	3	100.3	COLCOLOR	Colony Color	MYCOBACTERIUM TUBERCULOSIS	BUFF	
4	ABC	MC	ABC-01-101	4	100.3	QUANT	Quantification	MYCOBACTERIUM TUBERCULOSIS	147	CFU/mL
5	ABC	MC	ABC-01-101	5	100.3	COLMMIC	Colony Morphology, Microscopic	MYCOBACTERIUM TUBERCULOSIS	SERPENTINE CORD	

Row	MCSTRESC	MCSTRESN	MCSTRESU	MCSPEC	MCSPCCND	MCCOLMETH	MCMETHOD	MCDTC
1 (cont)	3+			LAVAGE FLUID	CONCENTRATED	GASTRIC LAVAGE	ZIEHL NEELSEN ACID FAST STAIN	2011-01-17T06:00
2 (cont)	POSITIVE			LAVAGE FLUID		GASTRIC LAVAGE	MICROBIAL CULTURE, SOLID	2011-01-17T06:00
3 (cont)	BUFF			LAVAGE FLUID		GASTRIC LAVAGE	MICROBIAL CULTURE, SOLID	2011-01-17T06:00
4 (cont)	2+			LAVAGE FLUID		GASTRIC LAVAGE	MICROBIAL CULTURE, SOLID	2011-01-17T06:00
5 (cont)	SERPENTINE CORD			LAVAGE FLUID		GASTRIC LAVAGE	LIGHT MICROSCOPY	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 MC dataset above.
Row 2: Shows the medium type used to perform the solid culture test in Rows 2-4 of the MC dataset above.
Row 3: Shows how to identify the scale used to categorize for the solid culture colony counts.

suppmc.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QEVAL
1	ABC	MC	ABC-01-101	MCSEQ	1	AFBSCAL	AFB Quantitation Scale	Smear Quantitation: Centers for Disease Control Method for Carbol fuchsin Staining (1000X)	MICROBIOLOGY LAB
2	ABC	MC	ABC-01-101	MCREFID	100.3	MEDTYPE	Medium Type	Middlebrook-7H10 Agar	MICROBIOLOGY LAB
3	ABC	MC	ABC-01-101	MCSEQ	4	COLSCAL	Colony Quantitation 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 4.3 for examples of this type).

Rows 1-2: Show phenotypic testing results on two separate culture plates: one with medium containing rifampicin (Row 3) and one with medium containing isoniazid (Row 4). The culture start and stop dates are represented in BE and could be merged to MS by BEREFID and MSREFID where BETERM=Culturing and BECAT=DRUG SUSCEPTIBILITY.
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. No actual drug is present, so MSDRUG and MSCONC are left blank. These results are represented in MS because the only result given is in terms of resistant/susceptible; no genetic results are reported. MSMETHOD is populated as "LINE PROBE ASSAY" as opposed to "NAAT" since there are multiple methods of NAA testing.

ms.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MSSEQ	MSREFID	MSTESTCD	MSTEST	MSEXMTRG	MSDRUG
1	ABC	MS	ABC-01-101		1	100.4	DST	Drug Susceptibility Testing	MYCOBACTERIUM TUBERCULOSIS	Rifampicin
2	ABC	MS	ABC-01-101		2	100.5	DST	Drug Susceptibility Testing	MYCOBACTERIUM TUBERCULOSIS	Isoniazid
3	ABC	MS	ABC-01-101	ABC765	3	100.2	DST	Drug Susceptibility Testing	MYCOBACTERIUM TUBERCULOSIS	
4	ABC	MS	ABC-01-101	ABC765	4	100.2	DST	Drug Susceptibility Testing	MYCOBACTERIUM TUBERCULOSIS	

Row	MSCONC	MSCONCU	MSORRES	MSSTRESC	MSSPEC	MSLOC	MSMETHOD	MSDTC
1 (cont)	1	ug/mL	RESISTANT	RESISTANT	LAVAGE FLUID	STOMACH	ANTIBIOTIC AGAR SCREEN	2011-01-17T06:00
2 (cont)	0.2	ug/mL	SUSCEPTIBLE	SUSCEPTIBLE	LAVAGE FLUID	STOMACH	ANTIBIOTIC AGAR SCREEN	2011-01-17T06:00
3 (cont)			RIFAMPICIN RESISTANT	RIFAMPICIN RESISTANT	LAVAGE FLUID	STOMACH	LINE PROBE ASSAY	2011-01-17T06:00
4 (cont)			ISONIAZID SUSCEPTIBLE	ISONIAZID SUSCEPTIBLE	LAVAGE FLUID	STOMACH	LINE PROBE ASSAY	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 table shows how to link BE and BS, MB and MC, BE and MB, BE and MC, and BE and MS via a RELREC dataset.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	BE		BEREFID		MANY	A
2	ABC	BS		BSREFID		MANY	A
3	ABC	BE		MBREFID		ONE	B
4	ABC	MB		MCREFID		MANY	B
5	ABC	BE		BEREFID		MANY	C
6	ABC	MB		MBREFID		ONE	C
7	ABC	BE		BEREFID		MANY	D
8	ABC	MC		MCREFID		MANY	D
9	ABC	BE		BEREFID		MANY	E

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
10	ABC	MS		MSREFID		ONE	E

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 Expected variables have been omitted in consideration of space and clarity; their place is marked in the table with an ellipsis (…). 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).

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
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

Row	MSCLMETH	MSANMETH	MSDRVFL	VISITNUM	VISIT	MSDTC	SFTWR	SFTWRVER
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
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