INFECTIOUS DISEASES DATA OBSERVATORY

EDP Data Dictionary

Demographics (DM) Domain

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Demographics

"A special purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects. One record per subject."

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	DM	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
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. See Assumption 9 for additional detail on when **RFSTDTC** may be null.	Exp
RFICDTC	Date/Time of Informed Consent	Char	ISO 8601	Record Qualifier	Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.	Exp
DTHDTC	Date/Time of Death	Char	ISO 8601	Record Qualifier	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.	Exp
DTHFL	Subject Death Flag	Char	(NY)	Record Qualifier	Indicates the subject died. Should be "Y" or null. Should be populated even when the death date is unknown.	Exp
SITEID	Study Site Identifier	Char	*	Record Qualifier	Unique identifier for a site within a study.	Req
BRTHDTC	Date/Time of Birth	Char	ISO 8601	Record Qualifier	Date/time of birth of the subject.	Perm
AGE	Age	Num		Record Qualifier	Age expressed in **AGEU**. May be derived from **RFSTDTC** and **BRTHDTC**, but **BRTHDTC** may not be available in all cases (due to subject privacy concerns).	Exp
AGETXT	Age Text	Char		Record Qualifier	The age of the subject at study start, as planned, expressed as a range. If an age integer value is available, then populate the **AGE** variable instead. Either **AGE** or **AGETXT** variable should be populated, but not both.	Perm
AGEU	Age Units	Char	(AGEU)	Variable Qualifier	Units associated with **AGE**.	Exp
SEX	Sex	Char	(SEX)	Record Qualifier	Sex of the subject.	Req
RACE	Race	Char	(RACE)	Record Qualifier	Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, October, 2016) for guidance regarding the collection of race (https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf) See Assumption below regarding RACE.	Exp
ETHNIC	Ethnicity	Char	(ETHNIC)	Record Qualifier	The ethnicity of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, October, 2016) for guidance regarding the collection of ethnicity (https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf).	Perm
ARMCD	Planned Arm Code	Char	*	Record Qualifier	**ARMCD** is limited to 20 characters. It is not subject to the character restrictions that apply to TESTCD. The maximum length of **ARMCD** is longer than for other "short" variables to	Exp

					accommodate the kind of values that are likely to be needed for crossover trials. For example, if **ARMCD** values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of **ARMCD** values would be 20. If the subject was not assigned to an Arm, **ARMCD** is null and **ARMNRS** is populated. With the exception of studies which use multi-stage Arm assignments, must be a value of **ARMCD** in the Trial Arms Dataset.	
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name of the Arm to which the subject was assigned. If the subject was not assigned to an Arm, **ARM** is null and **ARMNRS** is populated. With the exception of studies which use multi-stage Arm assignments, must be a value of **ARM** in the Trial Arms Dataset.	Exp
COUNTRY	Country	Char	ISO 3166-1 Alpha-3	Record Qualifier	Country of the investigational site in which the subject participated in the trial.	Req
DMDTC	Date/Time of Collection	Char	ISO 8601	Timing	Date/time of demographic data collection.	Perm
DMDY	Study Day of Collection	Num		Timing	Study day of collection measured as integer days.	Perm

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN

DM

USUBJID – Unique Subject Identifier

- **DEFINITION**: This variable contains the unique subject identifier for a study. This is a secondary key/identifier for all subject-level domains in the IDDO Data Repository – every domain table containing subject-level information (i.e., all but the Trial Domains) will have the **USUBJID** identifier. This variable will identify unique subjects in the repository.
  - If data about the same subject is submitted as two separate submissions to IDDO, the same subjects in both submissions will have the same **USUBJID** to identify them as the same individual.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This value will be created by concatenating the values for **STUDYID_SITEID_SUBJID** for each subject. This created ID will be what is entered as the **USUBJID**.
- **CONTROLLED TERMINOLOGY**
  - None

SUBJID – Subject Identifier for the Study

- **DEFINITION**: This variable contains the unique subject identifier provided by the data contributor. This variable will identify unique subjects in the raw dataset.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.

    - This information will be either be 1) filled in verbatim from the raw dataset or 2) created and added to the dataset.
        - If the IDs in the raw dataset are unique across all subjects, it will be filled in verbatim from the raw datasets.
        - Studies that repeat subject IDs across sites will have a unique ID created by concatenating the values for **SITEID** with the value for the provided subject ID.
            - For example, Site A and Site B both identify subjects sequentially from 001 to 100. Unique IDs will be created for each subject, so "Site A_001" and "Site B_001" will be the identifiers for subjects 001 at Site A and Site B.
            - Datasets that require this creation of a unique **SUBJID** will not need to include **SITEID** a second time in the creation of the **USUBJID** variable (i.e., the **USUBJID** for these types of studies will only need the concatenation of **STUDYID_SUBJID**, and will not include **SITEID** a second time).

- **CONTROLLED TERMINOLOGY**
    - None

RFSTDTC – Subject Reference Start Date/Time

- **DEFINITION**: This variable describes the date and time of the start of the Subject Reference Period. The Subject Reference Period is defined by IDDO as starting with the subject's first study encounter and ending with the subject's final study encounter. **RFSTDTC** corresponds with the time and date of the subject's first study encounter (e.g., screening, enrollment, admission). This date will be used to calculate the relative days in the **--DY, --STDY, --ENDY** variables. This date and time will be provided in ISO 8601 format. This variable will be blank for submissions that do not provide this initial date. All of the derived variables will also be blank since they are all calculated based on **RFSTDTC**.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset that provide the actual date or time of the first study encounter. The date will not be derived from information about the study day (e.g., if no actual dates are included, this variable would be left blank and the information would be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables).
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided.
        - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
        - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
        - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.

- **CONTROLLED TERMINOLOGY**
    - ISO 8601 format

RFICDTC – Date/Time of Informed Consent

- **DEFINITION**: This variable describes the date and time the subject completed informed consent. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset that provide the actual date or time of the completion of informed consent. The date will not be derived from information about the study day (e.g., if no actual dates are included, this variable would be left blank).
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided.
        - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
        - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
        - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.

- **CONTROLLED TERMINOLOGY**
    - ISO 8601 format

DTHDTC – Date/Time of Death

- **DEFINITION**: This variable describes the date and time of death for a subject who has died during the study period. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset that provide the actual date or time of subject death. The date will not be derived from information about the study day (e.g., if no actual dates are included, this variable would be left blank).
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
        - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
        - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
        - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.

- **CONTROLLED TERMINOLOGY**
    - ISO 8601 format

DTHFL – Subject Death Flag

- **DEFINITION**: This variable contains information about whether the subject died during the study period. The variable is expected to be null if the choice is not "Yes". This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for subjects who have died.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided. Data will follow the terminology from the codelist ***No Yes Response (NY)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., information in text on an Adverse Event states the subject died – data would be Y), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

DTHFL	Description	Code
Y	Yes	C49488

SITEID – Study Site Identifier

- **DEFINITION**: This variable contains information about the study site.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded for clarity, or 3) created and added to the dataset, depending on the raw data provided.
    - If the raw data contains this information in a descriptive format, it will be filled in verbatim from the raw datasets (e.g., "Tororo").
    - If the raw data contains this information in a coded format, it will be re-coded into the descriptive format (e.g., variable "sitenum" with a value of "2" and a data dictionary description of "2 = Bihar" - the data entered would be "Bihar").
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states the study took place in Cochabamba - data would be "Cochabamba"), then a variable filled in with the information will be created.
- **CONTROLLED TERMINOLOGY**
  - None

BRTHDTC – Date/Time of Birth

- **DEFINITION**: This variable describes the date and time the subject's date of birth. This date and time will be provided in ISO 8601 format. This data will be excised from externally-shared datasets to ensure subject privacy and anonymity. It will only be available to IDDO staff.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset that provide the subject's actual date or time of birth. The date will not be derived from information about the study day (e.g., if no actual dates are included, this variable would be left blank).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided.
    - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
    - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
    - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

AGE – Age

- **DEFINITION**: This variable contains the age (expressed in the units described in **AGEU**) for the subject.
- **COMPLETION**:
  - This variable (or **AGETXT**, if age is not available) will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) created and added to the dataset.
    - If the raw data contains the age it will be filled in verbatim from the raw datasets.
    - If no age is provided and a birth date is available, then a variable filled with the calculated age will be created.
      - Age will be calculated per the methods described by CDISC:
        - **AGE** = **RFSTDTC - BRTHDTC**
      - The birth date cannot be used to calculate the **AGE** if the subject does not have a **RFSTDTC**. In this case the **AGETXT** variable would be populated instead. Ages can be calculated using imputed Date of Inclusions at the analysis stage.
  - For studies that provide two variables for age (i.e., both months and years for a single subject "4 years and 8 months old") a single age value will be created in the SMALLEST unit.

        - Years and months would be combined to give age in months
        - 4 years and 8 months = (4*12)+8 = **56** months

- **CONTROLLED TERMINOLOGY**
    - Integer

AGETXT – Age Text

- **DEFINITION**: This variable contains text describing the age of subjects, expressed as a range, at the start of the study. This is used when no actual age is available. It is a text description of the age ranges included in the study, per inclusion/exclusion criteria.
- **COMPLETION**:
    - This variable (or **AGE**, if the actual age is available) will be populated for every record in the dataset.
    - This will be created and added to the dataset.
        - If no age is provided and cannot be calculated, then a variable filled with the acceptable age range will be created (e.g., subjects with no age in a study that recruited children ages 6 months to 5 years would have "6 months - 5 years" populated in **AGETXT**).

- **CONTROLLED TERMINOLOGY**
    - None

AGEU – Age Units

- **DEFINITION**: This variable contains the unit describing the value in **AGE**. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a result for the subject's age (i.e., it will only be populated for records that have a value in **AGE**).
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided. Data will follow the terminology from the codelist ***Age Unit (AGEU)***.
        - If the raw data contains this result in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
        - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
        - If f the data is not in the raw dataset but available in another context (e.g., the CRF states all ages were recorded in years – data would be YEARS), then a variable filled in with the correct controlled terminology will be created.
    - For studies that provide two variables for age (i.e., both months and years for a single subject "4 years and 8 months old") a single age will be created in the SMALLEST unit.
        - Years and months would be combined to give age in months
            - 4 years and 8 months = (4*12)+8 = 56 **MONTHS**
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

AGEU	Code
DAYS	C25301
HOURS	C25529
MONTHS	C29846
WEEKS	C29844
YEARS	C29848

SEX – Sex

- **DEFINITION**: This variable describes the sex of the subject. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have information about the subject's sex.
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided. Data will follow the terminology from the codelist ***Sex (SEX)***.
        - If the raw data contains this result in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
        - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
        - If f the data is not in the raw dataset but available in another context (e.g., the study enrolled only pregnant women and all subjects are Female – data would be F), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

SEX	Description	Code
F	Female	C16576
M	Male	C20197
U	Unknown;	C17998

	UNK	
UNDIFFERENTIATED	Indeterminate	C45908

RACE – Race

- **DEFINITION**: This variable describes the race of the subject as provided by the Data Contributor.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have subject race provided in the raw datasets. There will be no attempt by IDDO Data Curators to standardize this data to match CDISC Controlled Terminology (i.e., reformatting the raw data to match the **Race (*RACE*)** Codelist will not be done).
  - This will be filled in verbatim from the raw datasets.

- **CONTROLLED TERMINOLOGY**
  - None

ETHNIC – Ethnicity

- **DEFINITION**: This variable describes the ethnicity of the subject as provided by the Data Contributor.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have subject ethnicity provided in the raw datasets. There will be no attempt by IDDO Data Curators to standardize this data to match CDISC Controlled Terminology (i.e., reformatting the raw data to match the **Ethnic Group (*ETHNIC*)** Codelist will not be done).
  - This will be filled in verbatim from the raw datasets.

- **CONTROLLED TERMINOLOGY**
  - None

ARMCD – Planned Arm Code

- **DEFINITION**: This variable is a code that identifies the treatment arm to which the subject was assigned. This is only populated in data submissions which included treatment arms (i.e., trials).
- **COMPLETION**:
  - This variable will only be populated for submissions that assigned subjects to a treatment arm.
  - This information will be created and added to the datasets.

- **CONTROLLED TERMINOLOGY**
  - None

ARM – Description of Planned Arm

- **DEFINITION**: This variable describes the treatment arm to which the subject was assigned. This is only populated in data submissions which included treatment arms (i.e., trials).
- **COMPLETION**:
  - This variable will only be populated for submissions that assigned subjects to a treatment arm.
  - This information will be created and added to the datasets.

- **CONTROLLED TERMINOLOGY**
  - This variable is populated with all of the agents included in the arm (i.e., all of the values from the *TRT - Investigational Therapy or Treatment* and *CMPTRT - Comparative Treatment Name* parameters from the TS Domain).
  - Each agent will use the UNII value with a space in between agents which are listed in alphabetical order (e.g., the arm "Artemether-Lumefantrine plus Primaquine" - data would be ARTEMETHER LUMEFANTRINE PRIMAQUINE).

COUNTRY – Country

- **DEFINITION**: This variable contains information about the country of the study site described in **SITEID**. This is defined by Controlled Terminology and will be populated with one of the codes described below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided. Data will follow the terminology from the ISO 3166-1 alpha-3 Country Codes codelist.
    - If the raw data contains this result in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.

        - If f the data is not in the raw dataset but available in another context (e.g., the study took place at one site in Thailand – data would be THA), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY**
    - The options for this are listed in the TS Domain page for the *FCNTRY - Planned Country of Investigational Sites* parameter and can be found here: Trial Summary (TS) Domain.aspx

DMDTC – Demographics Date/Time of Collection

- **DEFINITION**: This variable describes the date and time of the collection of the demographics data. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
    - This variable will only be populated for records that provide the actual date or time of the demographic data collection. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion will not happen. This variable would be left blank and the information on "Day 3" would be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables).
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created and added to the dataset, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
        - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
        - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
        - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.

- **CONTROLLED TERMINOLOGY**
    - ISO 8601 format

DMDY – Demographics Study Day of Collection

- **DEFINITION**: This variable describes the study day of the collection of the demographics data relative to the date in **RFSTDTC**. This will be blank for records with no value in in **DMDTC**. This will be blank for records with no value in **RFSTDTC**. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have both a value in **DMDTC** and **RFSTDTC**.
    - This information will be created and added to the dataset.
    - This will be calculated as per the methods described by CDISC
        - If **DMDTC** is on or after **RFSTDTC:**
            - **DMDY** = (date portion of **DMDTC**) – (date portion of **RFSTDTC**) +1
        - If **DMDTC** precedes **RFSTDTC**:
            - **DMDY** = (date portion of **DMDTC**) – (date portion of **RFSTDTC**)

- **CONTROLLED TERMINOLOGY**
    - Integer

Disposition (DS) Domain

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Disposition

"An events domain that contains information encompassing and representing data related to subject disposition. One record per disposition status per subject."

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	DS	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
DSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DSTERM	Reported Term for the Disposition Event	Char		Topic	Verbatim name of the event or protocol milestone. Some terms in **DSTERM** will match **DSDECOD**, but others, such as "Subject moved" will map to controlled terminology in **DSDECOD**, such as "LOST TO FOLLOW-UP".	Req
DSDECOD	Standardized Disposition Term	Char	(NCOMPLST) (PROTMLST)	Synonym Qualifier	Controlled terminology for the name of disposition event or protocol milestone. Examples of protocol milestones: "INFORMED CONSENT OBTAINED", "RANDOMIZED". There are separate codelists used for **DSDECOD** where the choice depends on the value of **DSCAT**. Codelist "NCOMPLT" is used for disposition events and codelist "PROTMLST" is used for protocol milestones. The variable may be subject to controlled terminology for other events.	Req
DSMODIFY	Modified Reported Term	Char		Synonym Qualifier	If **DSTERM** is modified to facilitate coding, then **DSMODIFY** will contain the modified text.	Perm
DSCAT	Category for Disposition Event	Char	(DSCAT)	Grouping Qualifier	Used to define a category of related records.	Exp
DSSCAT	Subcategory for Disposition Event	Char		Grouping Qualifier	A further categorization of **DSCAT** (e.g., "STUDY PARTICIPATION", "STUDY TREATMENT" when **DSCAT** = "DISPOSITION EVENT").	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the event.	Perm
DSDTC	Date/Time of Collection	Char	ISO 8601	Timing	Collection date and time of the disposition observation represented in ISO 8601 character format.	Perm
DSSTDTC	Start Date/Time of Disposition Event	Char	ISO 8601	Timing	Start date/time of the disposition event in ISO 8601 character format.	Exp
DSDY	Study Day of Collection	Num		Timing	Start date/time of the disposition event in ISO 8601 character format.	Exp
DSSTDY	Study Day of Start of Disposition Event	Num		Timing	Study day of start of event relative to the sponsor-defined **RFSTDTC**.	Perm

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN

DS

USUBJID – Unique Subject Identifier

- **DEFINITION**: This variable contains the unique subject identifier for a study. This is a secondary key/identifier for all subject-level domains in the IDDO Data Repository – every domain table containing subject-level information (i.e., all but the Trial Domains) will have the **USUBJID** identifier. This variable will identify unique subjects in the repository.
    - If data about the same subject is submitted as two separate submissions to IDDO, the same subjects in both submissions will have the same **USUBJID** to identify them as the same individual.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset.
    - This information will be created and added to the dataset.
        - This value will be created by concatenating the values for **STUDYID_SITEID_SUBJID** for each subject. This created ID will be what is entered as the **USUBJID**.
- **CONTROLLED TERMINOLOGY**
    - None

DSSEQ – Disposition Event Sequence Number

- **DEFINITION**: This variable is a sequence number to ensure uniqueness of subject records within the DS domain. Each disposition event (each recorded as a separate row in the table) will have a unique number within each subject. For example, a subject with 10 events will have 10 rows and each row is numbered sequentially from 1-10; a subject with 24 events will have 24 rows and each row is numbered sequentially from 1-24.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset.
    - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**
    - None

DSTERM - Reported Term for the Disposition Event

- **DEFINITION**: This variable contains the verbatim wording of the disposition or protocol milestone event as provided by the Data Contributor.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset.
    - This variable will be populated only with postive/actual occurrences of disposition or protocol milestone events.
        - If the raw dataset contains information about the disposition or protocol milestone event as a discrete variable with a value of occurrence/non-occurrence, an entry utilizing that verbatim variable name (or data dictionary description, if appropriate) will be created only when the event has occured.
    - This information will be filled in verbatim from the raw datasets with the spelling, phrasing, language, and terminology used by the Data Contributor.
        - If the raw data contains a line-listing of disposition events or protocol milestone events (e.g., variable "Outcome" and a value of "Discharged negative") this data it will be filled in verbatim from the raw datasets, i.e., "DISCHARGED NEGATIVE".
        - If the raw data contains the information about disposition events or protocol milestone events in another manner (e.g., as a variable name of "discharged" with a value about presence/absence; as a variable name of "outc01" and a data dictionary expansion of "Discharged" with a value of presence/absence) an entry utilizing that verbatim variable name or data dictionary description (as appropriate) will be created, i.e., "DISCHARGED".
        - If the raw data has the data in a non-English language as well as a translation provided in a data dictionary (e.g., variable named "Sorti negatif", data dictionary labelled "Discharged Negative"), the English translation will be used.
- **CONTROLLED TERMINOLOGY**
    - None

DSDECOD - Standardized Disposition Term

- **DEFINITION**: This variable contains a dictionary-derived text description of the disposition or protocol milestone event. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset.
    - This information will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Completion/Reason for Non-Completion (NCOMPLT)***.
        - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
        - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
        - If the data is not in the raw dataset but available in another context (e.g., the publication states all subjects completed the study and there were none lost to follow-up - data would be COMPLETED for all subjects)
            - Records for non-trial subjects should be restricted to the use of the NCOMPLT controlled terminology with care taken to ensure trial type disposition events (e.g. FAILURE TO MEET CONTINUATION CRITERIA) are avoided unless expressly synonymous with raw data disposition events.
            - RECOVERY, DEATH and OTHER are the primary terms to be utilised when curating EVD disease data from non-trial hospital/treatment centre records.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-12-20)*

DSDECOD	Description	Code
ADVERSE EVENT	Subject did not complete the study due to an adverse event.	C41331
COMPLETED	Subject completed the study (either to the end of follow-up or stopped due to treatment failure).	C25250
DEATH	Subject did not complete the study due to death.	C28554
LOST TO FOLLOW-UP	Subject did not complete the study and was lost to follow-up.	C48227
OTHER		C17649
PROTOCOL VIOLATION	Subject did not complete the study due to a significant departure from processes or procedures that were required by the protocol.	C142185
RECOVERY		C25746
SCREEN FAILURE	Subject did not meet eligibility criteria during the screening period.	C49628
WITHDRAWAL BY PARENT/GUARDIAN	Subject did not complete the study because s/he was removed by the parent or legal guardian.	C102355

WITHDRAWAL BY SUBJECT	Subject did not complete the study because s/he removed themself from the study.	C49634

DSMODIFY - Modified Reported Term for the Disposition Event

- **DEFINITION**: This variable contains a modification of the verbatim wording of the disposition or protocol milestone event as provided by the data contributor.
- **COMPLETION**:
  - This variable will be populated for records in the dataset that contain events of special interest. These events of special interest are defined by IDDO and will be populated with one of the codes listed below.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**

DSMODIFY	Description and Common Terms
TBD	To be defined

DSCAT - Category for Disposition Term

- **DEFINITION**: This variable contains a categorisation of the disposition or protocol milestone event. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - DSDECOD and DSCAT are dependent variables, the choice made in one will affect what terminology is available in the other (please see DS_Codetable_Mapping.xlsx).
    - Records for non-trial subjects should be restricted to the use of "DISPOSITION EVENT" and "OTHER EVENT".
- **CONTROLLED TERMINOLOGY**

DSCAT	Code
DISPOSITION EVENT	C74590
OTHER EVENT	C150824

DSSCAT - Subcategory for Disposition Term

- **DEFINITION**: This variable contains a sub-categorisation of the disposition or protocol milestone event.
- **COMPLETION**:
- **CONTROLLED TERMINOLOGY**

DSSCAT	Description and Common Terms
TBD	To be defined

EPOCH – Epoch of Disposition Event

- **DEFINITION**: This variable describes the Epoch period of the disposition event (e.g., Baseline, Treatment, Follow-up).
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. Data will follow the terminology from the codelist ***Epoch (EPOCH)***.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

EPOCH	Description	Code
BASELINE	A period in a clinical study after eligibility has been met and before the start of treatment, at which baseline measurements are collected.	C125938
FOLLOW-UP	A period in a clinical study during which information about the health status of an individual is obtained after study interventions have concluded.	C99158
SCREENING	A period in a clinical study during which subjects are evaluated for participation in a study. [An example would be when samples are taken prior to verification of disease-positive status - this is the Screening period and once verified disease-positive they move into the Baseline period].	C48262
TREATMENT	A period in a clinical study during which subjects receive investigational product. [We include all periods and types of treatments - no division into "Blinded Treatment" or "Continuation Treatment" etc.]	C101526

DSDTC - Date/Time of Collection

- **DEFINITION**: This variable describes the date and time of the collection of the disposition or protocol milestone event data. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for records that provide the actual date or time of the disposition or protocol milestone event data collection. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion), but will be left blank. Study day information may be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables, or other alternate CDISC timing variables.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
    - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
    - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
    - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.

- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

DSSTDTC - Start Date/Time of Disposition Event

- **DEFINITION**: This variable describes the date and time of the start of the disposition or protocol milestone event. Events in the DS domain do not have end dates.
- **COMPLETION**:
  - This variable will only be populated for records that provide the actual date or time of the disposition or protocol milestone event. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion), but will be left blank. Study day information may be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables, or other alternate CDISC timing variables.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
    - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
    - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
    - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

DSDY - Study Day of Collection

- **DEFINITION**: This variable describes the study day of the collection of the disposition and protocol milestone events data relative to the date in **RFSTDTC**. This will be blank for records with no value in **DSDTC**.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **DSDTC**.
  - This information will be created and added to the dataset.
  - This will be calculated as per the methods described by CDISC
    - If **DSDTC** is on or after **RFSTDTC:**
      - **DSDY** = (date portion of **DSDTC**) – (date portion of **RFSTDTC**) +1
    - If **DSDTC** precedes **RFSTDTC**:
      - **DSDY** = (date portion of **DSDTC**) – (date portion of **RFSTDTC**)
- **CONTROLLED TERMINOLOGY**
  - Non-zero integer

DSSTDY - Study Day of Start of Disposition Event

- **DEFINITION**: This variable describes the study day of the disposition and protocol milestone events data relative to the date in **RFSTDTC**. This will be blank for records with no value in **DSSTDTC**.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **DSSTDTC**.
  - This information will be created and added to the dataset.
  - This will be calculated as per the methods described by CDISC
    - If **DSSTDTC** is on or after **RFSTDTC:**
      - **DSSTDY** = (date portion of **DSSTDTC**) – (date portion of **RFSTDTC**) +1
    - If **DSSTDTC** precedes **RFSTDTC**:
      - **DSSTDY** = (date portion of **DSSTDTC**) – (date portion of **RFSTDTC**)
- **CONTROLLED TERMINOLOGY**
  - Non-zero integer

Examples for Completion of this Domain

CASE: Limited information in the raw data [MALARIA]

Sample of the raw data available [Treatment Arm *(1 = PQ, 2 = AS, 3 = CQ, 4 = SCREEN FAIL)*, Outcome *(0 = ACPR, 1 = Fail, 2 = LFU, 3 = Protocol Violation)*] :

PatientNo	Treatment Arm	Outcome
001	1	0
002	2	0
003	3	1
004	1	3
005	4	
006	2	0
007	3	2
008	1	0
009	2	1

The SDTM Mapping Strategy is as follows:

Treatment Arm = 4 [SCREEN FAIL] --> **DSDECOD** = SCREEN FAILURE

Outcome = 0 [ACPR] --> **DSDECOD** = COMPLETED
Outcome = 1 [Fail] --> **DSDECOD** = COMPLETED
Outcome = 2 [LFU] --> **DSDECOD** = LOST TO FOLLOW-UP
Outcome = 3 [Protocol Violation] --> **DSDECOD** = PROTOCOL VIOLATION

This data should be pulled out as follows:

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT
ABCDE	DS	ABCDE_Site_001	1	ACPR	COMPLETED	DISPOSITION EVENT
ABCDE	DS	ABCDE_Site_002	1	ACPR	COMPLETED	DISPOSITION EVENT
ABCDE	DS	ABCDE_Site_003	1	Fail	COMPLETED	DISPOSITION EVENT
ABCDE	DS	ABCDE_Site_004	1	Protocol Violation	PROTOCOL VIOLATION	DISPOSITION EVENT
ABCDE	DS	ABCDE_Site_005	1	SCREEN FAIL	SCREEN FAILURE	DISPOSITION EVENT
ABCDE	DS	ABCDE_Site_006	1	ACPR	COMPLETED	DISPOSITION EVENT
ABCDE	DS	ABCDE_Site_007	1	LFU	LOST TO FOLLOW-UP	DISPOSITION EVENT
ABCDE	DS	ABCDE_Site_008	1	ACPR	COMPLETED	DISPOSITION EVENT
ABCDE	DS	ABCDE_Site_009	1	Fail	COMPLETED	DISPOSITION EVENT

****** NOTE: See the Disease Response and Clinical Classification (RS) Domain to see an example of how this same data would be mapped in that domain. ******

Laboratory Test Results (LB) Domain

Navigation Links: Data Management / IDDO Repository Data Dictionary

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Laboratory+Test+Results

"A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains. One record per lab test per time point per visit per subject."

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	LB	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
LBSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
LBTESTCD	Lab Test or Examination Short Name.	Char	(LBTESTCD)	Topic	Short name of the measurement, test, or examination described in **LBTEST**. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in **LBTESTCD** cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). **LBTESTCD** cannot contain characters other than letters, numbers, or underscores. Examples: "ALT", "LDH".	Req
LBTEST	Lab Test or Examination Name	Char	(LBTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. Note any test normally performed by a clinical laboratory is considered a lab test. The value in **LBTEST** cannot be longer than 40 characters. Examples: "Alanine Aminotransferase", "Lactate Dehydrogenase".	Req
LBCAT	Category for Lab Test	Char	*	Grouping Qualifier	Used to define a category of related records across subjects. Examples: "HEMATOLOGY", "URINALYSIS", "CHEMISTRY".	Exp
LBSCAT	Subcategory for Lab Test	Char	*	Grouping Qualifier	A further categorization of a test category such as "DIFFERENTIAL", "COAGULATION", "LIVER FUNCTION", "ELECTROLYTES".	Perm
LBORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
LBORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for **LBORRES**. Example: "g/L".	Exp
LBORNRLO	Reference Range Lower Limit in Orig Unit	Char		Variable Qualifier	Lower end of reference range for continuous measurement in original units. Should be populated only for continuous results.	Exp
LBORNRHI	Reference Range Upper Limit in Orig Unit	Char		Variable Qualifier	Upper end of reference range for continuous measurement in original units. Should be populated only for continuous results.	Exp
LBSTRESC	Character Result/Finding in Std Format	Char	(LBSTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from **LBORRES** in a standard format or standard units. **LBSTRESC** should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in **LBSTRESN**. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in **LBORRES** and these results effectively have the same meaning, they could be represented in standard format in **LBSTRESC** as "NEGATIVE". For other examples, see general assumptions.	Exp
LBSTRESN	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 **LBSTRESC**. **LBSTRESN** should store all numeric test results or findings.	Exp
LBSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for **LBSTRESC** or **LBSTRESN**.	Exp
LBSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate exam not done. Should be null if a result exists in **LBORRES**.	Perm
LBREASND	Reason Test Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed, e.g., "BROKEN EQUIPMENT", "SUBJECT REFUSED", or "SPECIMEN LOST". Used in conjunction with **LBSTAT** when value is "NOT DONE".	Perm
LBSPEC	Specimen Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: "SERUM", "PLASMA", "URINE", "DNA", "RNA".	Perm
LBMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: "EIA" (Enzyme Immunoassay), "ELECTROPHORESIS", "DIPSTICK".	Perm
LBFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status such as "Y", "N", "U", or null if not relevant.	Perm
LBDRVFL	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 do not come from the CRF, or are not as originally received or collected are examples of records that might be derived for the submission datasets. If **LBDRVFL** = "Y", then **LBORRES** may be null, with **LBSTRESC** and (if numeric) **LBSTRESN** 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
LBDTC	Date/Time of Specimen Collection	Char	ISO 8601	Timing	Date/time of specimen collection represented in ISO 8601 character format.	Exp
LBDY	Study Day of Specimen Collection	Num		Timing	1. Study day of 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

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.

- **CONTROLLED TERMINOLOGY**

DOMAIN

LB

USUBJID – Unique Subject Identifier

- **DEFINITION**: This variable contains the unique subject identifier for a study. This is a secondary key/identifier for all subject-level domains in the IDDO Data Repository – every domain table containing subject-level information (i.e., all but the Trial Domains) will have the **USUBJID** identifier. This variable will identify unique subjects in the repository.
  - If data about the same subject is submitted as two separate submissions to IDDO, the same subjects in both submissions will have the same **USUBJID** to identify them as the same individual.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This value will be created by concatenating the values for **STUDYID_SITEID_SUBJID** for each subject. This created ID will be what is entered as the **USUBJID**.
- **CONTROLLED TERMINOLOGY**
  - None

LBSEQ – Laboratory Test or Examination Sequence Number

- **DEFINITION**: This variable is a sequence number to ensure uniqueness of subject records within the LB domain. Each laboratory test or exam (each recorded as a separate row in the table) will have a unique number within each subject. For example, a subject with 10 labs will have 10 rows and each row is numbered sequentially from 1-10; a subject with 24 labs will have 24 rows and each row is numbered sequentially from 1-24.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - **LBSEQ** data provided in raw datasets already in SDTM format will not be included in the repository, only the IDDO-supplied **LBSEQ** number.
- **CONTROLLED TERMINOLOGY**
  - None

LBTESTCD – Laboratory Test or Examination Short Name

- **DEFINITION**: This variable identifies the shortened code for the name of the laboratory test or examination performed. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology from the codelist ***Laboratory Test Code (LBTESTCD)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

LBTESTCD	LBTEST	Similar Names	Code
ALT	Alanine Aminotransferase	Alanine Aminotransferase; SGPT; ALAT	C64433
ALB	Albumin	Albumin; Microalbumin	C64431
ALBGLOB	Albumin/Globulin	Albumin/Globulin; Albumin to Globulin Ratio Measurement; A/G Ratio	C74894
ALP	Alkaline Phosphatase	Alkaline Phosphatase	C64432
ANIONG	Anion Gap	Anion Gap	C74685
AST	Aspartate Aminotransferase	Aspartate Aminotransferase; SGOT; ASAT	C64467
BASO	Basophils	Basophils; Total Basophil Count	C64470
BASOLE	Basophils/Leukocytes	Basophils/Leukocytes (reported as a percentage or ratio)	C64471
BILDIR	Direct Bilirubin	Direct Bilirubin	C64481
BILI	Bilirubin	Bilirubin; Total Bilirubin	C38037
BILIND	Indirect Bilirubin	Indirect Bilirubin	C64483
CA	Calcium	Calcium (no further details)	C64488
CAION	Calcium, Ionized	Calcium, Ionized	C81948
CL	Chloride	Chloride	C64495
CREAT	Creatinine	Creatinine	C64547
EOS	Eosinophils	Eosinophils; Eosinophil Count	C64550
EOSLE	Eosinophils/Leukocytes	Eosinophils/Leukocytes (reported as a percentage or ratio)	C64604
FERRITIN	Ferritin	Ferritin	C74737
G6PDA	Glucose-6-Phosphate Dehydrogenase Act	G6PD activity status (reported as normal or deficient)	C139065
GGT	Gamma Glutamyl Transferase	GGT; GamaGT; Gamma Glutamyl Transferase; Gamma Glutamyl Transpeptidase Measurement	C64847
GLOBUL	Globulin	Globulin; Globulin Protein	C74738
GLUC	Glucose	Glucose	C105585
GRAN	Granulocytes	Polymorphonuclear Leukocytes	C96654
GRANLE	Granulocytes/Leukocytes	Granulocytes/Leukocytes; Polymorphonuclear Leukocytes/Leukocytes (reported as a percentage or ratio)	C147351
HCT	Hematocrit	EVF; Erythrocyte Volume Fraction; Hematocrit; PCV; Packed Cell Volume	C64796
HGB	Hemoglobin	Hemoglobin; Hemoglobin Monomer	C64848
HGBMET	Methemoglobin	Methemoglobin	C96689
INR	Prothrombin Intl. Normalized Ratio	International Normalized Ratio of Prothrombin Time	C64805
K	Potassium	Potassium	C64853
LYMLE	Lymphocytes/Leukocytes	Lymphocytes/Leukocytes (reported as a percentage or ratio)	C64820
LYM	Lymphocytes	Lymphocytes; Total Lymphocyte Count	C51949
MCH	Ery. Mean Corpuscular Hemoglobin	Ery. Mean Corpuscular Hemoglobin	C64797
MCHC	Ery. Mean Corpuscular HGB Concentration	Ery. Mean Corpuscular HGB Concentration	C64798

MCV	Ery. Mean Corpuscular Volume	Ery. Mean Corpuscular Volume; Erythrocytes Mean Corpuscular Volume; RBC Mean Corpuscular Volume	C64799
MG	Magnesium	Magnesium; Serum magnesium	C64840
MONO	Monocytes	Monocytes; Total Monocyte Count	C64823
MONOLE	Monocytes/Leukocytes	Monocytes/Leukocytes (reported as a percentage or ratio)	C64824
MPV	Mean Platelet Volume	Mean Platelet Volume	C74730
NEUT	Neutrophils	Neutrophils; Absolute Neutrophil Count	C63321
NEUTLE	Neutrophils/Leukocytes	Neutrophils/Leukocytes (reported as a percentage or ratio)	C64827
PLAT	Platelets	Platelets	C51951
PROT	Protein	Protein; Total Protein	C64858
PT	Prothrombin Time	Prothrombin Time	C62656
RBC	Erythrocytes	Erythrocytes; Red Blood Cells	C51946
RDW	Erythrocytes Distribution Width	Erythrocytes Distribution Width; RDW-CV; Red Blood Cell Distribution Width; Red Cell Volume Distribution Width	C64800
RETIRBC	Reticulocytes/Erythrocytes	Reticulocytes/Erythrocytes (reported as a percentage or ratio)	C64828
SODIUM	Sodium	Sodium	C64809
UREA	Urea	Urea	C64815
UREAN	Urea Nitrogen	Urea Nitrogen; BUN	C125949
WBC	Leukocytes	Leukocytes; White Blood Cells	C51948

LBTEST – Laboratory Test or Examination Name

- **DEFINITION**: This variable identifies the name of the laboratory test or examination performed. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology from the codelist ***Laboratory Test Name (LBTEST)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

LBTESTCD	LBTEST	Similar Names	Code
ALT	**Alanine Aminotransferase**	Alanine Aminotransferase; SGPT; ALAT	C64433
ALB	**Albumin**	Albumin; Microalbumin	C64431
ALBGLOB	**Albumin/Globulin**	Albumin/Globulin; Albumin to Globulin Ratio Measurement; A/G Ratio	C74894
ALP	**Alkaline Phosphatase**	Alkaline Phosphatase	C64432
ANIONG	**Anion Gap**	Anion Gap	C74685
AST	**Aspartate Aminotransferase**	Aspartate Aminotransferase; SGOT; ASAT	C64467
BASO	**Basophils**	Basophils; Total Basophil Count	C64470
BASOLE	**Basophils/Leukocytes**	Basophils/Leukocytes (reported as a percentage or ratio)	C64471
BILDIR	**Direct Bilirubin**	Direct Bilirubin	C64481
BILI	**Bilirubin**	Bilirubin; Total Bilirubin	C38037
BILIND	**Indirect Bilirubin**	Indirect Bilirubin	C64483
CA	**Calcium**	Calcium (no further details)	C64488
CAION	**Calcium, Ionized**	Calcium, Ionized	C81948
CL	**Chloride**	Chloride	C64495
CREAT	**Creatinine**	Creatinine	C64547
EOS	**Eosinophils**	Eosinophils; Eosinophil Count	C64550
EOSLE	**Eosinophils/Leukocytes**	Eosinophils/Leukocytes (reported as a percentage or ratio)	C64604
FERRITIN	**Ferritin**	Ferritin	C74737
G6PDA	**Glucose-6-Phosphate Dehydrogenase Act**	G6PD activity status (reported as normal or deficient)	C139065
GGT	**Gamma Glutamyl Transferase**	GGT; GamaGT; Gamma Glutamyl Transferase; Gamma Glutamyl Transpeptidase Measurement	C64847
GLOBUL	**Globulin**	Globulin; Globulin Protein	C74738
GLUC	**Glucose**	Glucose	C105585
GRAN	**Granulocytes**	Polymorphonuclear Leukocytes	C96654
GRANLE	**Granulocytes/Leukocytes**	Granulocytes/Leukocytes; Polymorphonuclear Leukocytes/Leukocytes (reported as a percentage or ratio)	C147351
HCT	**Hematocrit**	EVF; Erythrocyte Volume Fraction; Hematocrit; PCV; Packed Cell Volume	C64796
HGB	**Hemoglobin**	Hemoglobin; Hemoglobin Monomer	C64848
HGBMET	**Methemoglobin**	Methemoglobin	C96689
INR	**Prothrombin Intl. Normalized Ratio**	International Normalized Ratio of Prothrombin Time	C64805
K	**Potassium**	Potassium	C64853
LYMLE	**Lymphocytes/Leukocytes**	Lymphocytes/Leukocytes (reported as a percentage or ratio)	C64820
LYM	**Lymphocytes**	Lymphocytes; Total Lymphocyte Count	C51949
MCH	**Ery. Mean Corpuscular Hemoglobin**	Ery. Mean Corpuscular Hemoglobin	C64797
MCHC	**Ery. Mean Corpuscular HGB Concentration**	Ery. Mean Corpuscular HGB Concentration	C64798
MCV	**Ery. Mean Corpuscular Volume**	Ery. Mean Corpuscular Volume; Erythrocytes Mean Corpuscular Volume; RBC Mean Corpuscular Volume	C64799
MG	**Magnesium**	Magnesium; Serum magnesium	C64840
MONO	**Monocytes**	Monocytes; Total Monocyte Count	C64823

MONOLE	**Monocytes/Leukocytes**	Monocytes/Leukocytes (reported as a percentage or ratio)	C64824
MPV	**Mean Platelet Volume**	Mean Platelet Volume	C74730
NEUT	**Neutrophils**	Neutrophils; Absolute Neutrophil Count	C63321
NEUTLE	**Neutrophils/Leukocytes**	Neutrophils/Leukocytes (reported as a percentage or ratio)	C64827
PLAT	**Platelets**	Platelets	C51951
PROT	**Protein**	Protein; Total Protein	C64858
PT	**Prothrombin Time**	Prothrombin Time	C62656
RBC	**Erythrocytes**	Erythrocytes; Red Blood Cells	C51946
RDW	**Erythrocytes Distribution Width**	Erythrocytes Distribution Width; RDW-CV; Red Blood Cell Distribution Width; Red Cell Volume Distribution Width	C64800
RETIRBC	**Reticulocytes/Erythrocytes**	Reticulocytes/Erythrocytes (reported as a percentage or ratio)	C64828
SODIUM	**Sodium**	Sodium	C64809
UREA	**Urea**	Urea	C64815
UREAN	**Urea Nitrogen**	Urea Nitrogen; BUN	C125949
WBC	**Leukocytes**	Leukocytes; White Blood Cells	C51948

LBCAT – Category for Laboratory Test or Examination

- **DEFINITION**: This variable is a categorization of the laboratory test or examination performed. These categories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that fit the categories of interest listed below.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

LBCAT	Description
TBD	To be defined

LBSCAT – SubCategory for Laboratory Test or Examination

- **DEFINITION**: This variable is a further categorization of the laboratory test or examination performed. These subcategories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that fit the subcategories of interest listed below.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

LBSCAT	Description
TBD	To be defined

LBORRES – Laboratory Test Result or Finding in Original Units

- **DEFINITION**: This variable contains the result of the laboratory test or examination performed as provided by the data contributor. The original data can be either numeric (e.g., "503") or string (e.g., "Positive").
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the laboratory test or exam (i.e., it will not be populated for records that have a result of "NOT DONE" for **LBSTAT**).
  - This information will be filled in verbatim from the raw datasets.
- **CONTROLLED TERMINOLOGY**
  - None

LBORRESU – Laboratory Test Original Units

- **DEFINITION**: This variable contains the unit for the result of the laboratory test or examination performed as provided by the data contributor. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the laboratory test or exam (i.e., it will not be populated for records that have a result of "NOT DONE" for **LBSTAT**).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Unit (UNIT)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all haemoglobin was recorded in grams/litre – data would be g/L), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

LBTESTCD	LBTEST	LBORRESU	Similar Names	Code
ALT	Alanine Aminotransferase	**U/L**	Unit per Liter; mU/mL	C67456
ALB	Albumin	**g/L**	Gram per Liter; Kilogram per Cubic Meter; Microgram per Microliter; Milligram per Milliliter; g/L; kg/m3; mg/mL; ug/uL	C42576
AST	Aspartate Aminotransferase	**U/L**	Unit per Liter; mU/mL	C67456
BASO	Basophils	**10^6/L**	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L *[Example range: 0-200]*	C67452
BASOLE	Basophils/Leukocytes	**%**	Percentage *[Example range: 0.3]*	C25613
BASOLE	Basophils/Leukocytes	**fraction of 1**	Fraction of 1; Proportion of 1 *[Example range: 0.003]*	C105484
BILI	Bilirubin	**mg/dL**	Milligram per Deciliter; mg% *[Example range: 0.3-1.2]*	C67015
CA	Calcium	**mg/L**	Gram per Cubic Meter; Microgram per Milliliter; Milligram per Liter; g/m3; mcg/mL; mg/L; ng/uL; ug/mL	C64572
CREAT	Creatinine	**mg/dL**	Milligram per Deciliter; mg% *[Example range: 0.1-0.4]*	C67015
CREAT	Creatinine	**mg/L**	Gram per Cubic Meter; Microgram per Milliliter; Milligram per Liter; g/m3; mcg/mL; mg/L; ng/uL; ug/mL	C64572
EOS	Eosinophils	**10^6/L**	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L *[Example range: 0-450]*	C67452
EOSLE	Eosinophils/Leukocytes	**%**	Percentage *[Example range: 2.7]*	C25613
EOSLE	Eosinophils/Leukocytes	**fraction of 1**	Fraction of 1; Proportion of 1 *[Example range: 0.027]*	C105484

FERRITIN	Ferritin	**ug/L**	Microgram per Liter; Milligram per Cubic Meter; Nanogram per Milliliter; mcg/L; mg/m3; ng/mL; ug/L	C67306
GLUC	Glucose	**mmol**	Millimole	C48513
GRANLE	Granulocytes/Leukocytes	**%**	Percentage	C25613
GRANLE	Granulocytes/Leukocytes	**fraction of 1**	Fraction of 1; Proportion of 1	C105484
HCT	Hematocrit	**%**	Percentage *[Example range: 10-50]*	C25613
HCT	Hematocrit	**fraction of 1**	Fraction of 1; Proportion of 1 *[Example range: 0.1-0.5]*	C105484
HGB	Hemoglobin	**g/L**	Gram per Liter; Kilogram per Cubic Meter; Microgram per Microliter; Milligram per Milliliter; g/L; kg/m3; mg/mL; ug/uL *[Example range: 140-175]*	C42576
HGB	Hemoglobin	**g/dL**	Gram per Deciliter; g% *[Example range: 14.0-17.5]*	C64783
LYM	Lymphocytes	**10^6/L**	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L *[Example range: 1,000-4,800]*	C67452
LYMLE	Lymphocytes/Leukocytes	**%**	Percentage *[Example range: 34]*	C25613
LYMLE	Lymphocytes/Leukocytes	**fraction of 1**	Fraction of 1; Proportion of 1 *[Example range: 0.34]*	C105484
MCH	Ery. Mean Corpuscular Hemoglobin	**pg**	Picogram *[Example range: 26-34]*	C64551
MCHC	Ery. Mean Corpuscular HGB Concentration	**%**	Percentage	C25613
MCHC	Ery. Mean Corpuscular HGB Concentration	**g/dL**	Gram per Deciliter; g% *[Example range: 33-37]*	C64783
MCHC	Ery. Mean Corpuscular HGB Concentration	**g/L**	Gram per Liter; Kilogram per Cubic Meter; Microgram per Microliter; Milligram per Milliliter; g/L; kg/m3; mg/mL; ug/uL *[Example range: 330-370]*	C42576
MCV	Ery. Mean Corpuscular Volume	**fL**	Cubic Micrometer; Cubic Micron; Femtoliter; um3 *[Example range: 80-100]*	C64780
MONO	Monocytes	**10^6/L**	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L *[Example range: 0-800]*	C67452
MONOLE	Monocytes/Leukocytes	**%**	Percentage *[Example range: 4]*	C25613
MONOLE	Monocytes/Leukocytes	**fraction of 1**	Fraction of 1; Proportion of 1 *[Example range: 0.04]*	C105484
NEUT	Neutrophils	**10^6/L**	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L	C67452
NEUTLE	Neutrophils/Leukocytes	**%**	Percentage	C25613
NEUTLE	Neutrophils/Leukocytes	**fraction of 1**	Fraction of 1; Proportion of 1	C105484
PLAT	Platelets	**10^9/L**	1/nL; 10^3/mm3; 10^3/uL; 10^6/mL; G/L; Gl/L; Giga per Liter; Billion per Liter *[Example range: 150-450]*	C67255
PLAT	Platelets	**10^6/L**	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L *[Example range: 150,000-450,000]*	C67452
PLAT	Platelets	**g/L**	Gram per Liter; Kilogram per Cubic Meter; Microgram per Microliter; Milligram per Milliliter; g/L; kg/m3; mg/mL; ug/uL	C42576
PT	Prothrombin Time	**sec**	Seconds *[Example range: 10-13]*	C42535
RBC	Erythrocytes	**10^9/L**	1/nL; 10^3/mm3; 10^3/uL; 10^6/mL; G/L; Gl/L; Giga per Liter; Billion per Liter	C67255
RBC	Erythrocytes	**10^12/L**	1/pL; 10^6/mm3; 10^6/uL; T/L; Tl/L; Tera/L; Million per Microliter *[Example range: 3.9-5.5]*	C67308
RETIRBC	Reticulocytes/Erythrocytes	**%**	Percentage	C25613
RETIRBC	Reticulocytes/Erythrocytes	**fraction of 1**	Fraction of 1; Proportion of 1	C105484
SODIUM	Sodium	**mmol/L**	Micromole per Milliliter; Millimole per Liter; Mole per Cubic Meter; mcmol/mL; mmol/L; mol/m3; nmol/uL; umol/mL *[Example range: 136-142]*	C64387
SODIUM	Sodium	**mEq/L**	Milliequivalent Per Liter; Millivalent per Liter; mval/L *[Example range: 136-142]*	C67474
UREA	Urea	**g/L**	Gram per Liter; Kilogram per Cubic Meter; Microgram per Microliter; Milligram per Milliliter; g/L; kg/m3; mg/mL; ug/uL	C42576
WBC	Leukocytes	**10^6/L**	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L *[Example range: 4,500-11,000]*	C67452
WBC	Leukocytes	**10^9/L**	1/nL; 10^3/mm3; 10^3/uL; 10^6/mL; G/L; Gl/L; Giga per Liter; Billion per Liter *[Example range: 4.5-11.0]*	C67255

LBORNRLO – Laboratory Test Reference Range Lower Limit in Original Units

- **DEFINITION**: This variable contains the lower limit of the reference range for the continuous results in the original units of the laboratory test or examination performed as provided by the data contributor.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a reference range provided in the raw datasets for the laboratory test or exam. There will be no attempt by IDDO Data Curators to derive this data for raw datasets that do not contain this information (i.e., gleaning of this data from protocols or CRFs will not be done).
  - This will be filled in verbatim from the raw datasets.
- **CONTROLLED TERMINOLOGY**
  - None

LBORNRHI – Laboratory Test Reference Range Upper Limit in Original Units

- **DEFINITION**: This variable contains the upper limit of the reference range for the result and units of the laboratory test or examination performed as provided by the data contributor.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a reference range provided in the raw datasets for the laboratory test or exam. There will be no attempt by IDDO Data Curators to derive this data for raw datasets that do not contain this information (i.e., gleaning of this data from protocols or CRFs will not be done).
  - This will be filled in verbatim from the raw datasets.
- **CONTROLLED TERMINOLOGY**
  - None

LBSTRESC – Laboratory Test Result or Finding in Standard Units, Character Format

- **DEFINITION**: This variable contains the IDDO-defined converted, standardized result of the laboratory test or examination performed. The data can be either numeric (e.g., "503") or string (e.g., "Positive") and is stored as a string in the repository. The standard units and conversion formulas are described in the section about the variable **LBSTRESU**. There is limited CDISC Controlled Terminology for tests with string/character-based results and is listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the laboratory test or exam (i.e., it will only be populated for records that have a value in **LBORRES**).
  - This will either be 1) filled in verbatim from the column **LBORRES** or 2) created, depending on the raw data provided.
    - If the raw data contains this result in the IDDO-Defined Standard Units for that laboratory test or exam, the value from **LBORRES** will be filled in verbatim.
    - If the result is not in the IDDO-Defined Standard Units for that laboratory test or exam, then a variable filled in with the converted value will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

LBSTRESC	Similar Names	Code
BORDERLINE	Borderline	C14157
INDETERMINATE	Indeterminate; Inconclusive; IND	C48658
INVALID	Invalid data; INV	C50913
NEGATIVE	Negative; Negative finding; Neg; -	C38757
POSITIVE	Positive; Positive finding; Pos; +	C38758

LBSTRESN – Laboratory Test Result or Finding in Standard Units, Numeric Format

- **DEFINITION**: This variable contains the converted, standardized result of the laboratory test or examination performed when the result is numeric. This column is a direct copy of the numeric values found in **LBSTRESC**. String/character-based results (e.g., "Positive") are not copied into this column.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a numeric result for the laboratory test or exam (i.e., it will only be populated for records that have a numeric value in **LBSTRESC**).
  - This will be a created variable.
    - A variable will be created and will be populated with the numeric results found in **LBSTRESC**.
- **CONTROLLED TERMINOLOGY**
  - None

LBSTRESU – Laboratory Test Standard Units

- **DEFINITION**: This variable contains the unit for the converted, standardized result of the laboratory test or examination performed. The IDDO-Defined Standard Units for each test or examination are listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the laboratory test or exam (i.e., it will only be populated for records that have a value in **LBORRES**).
  - This will either be 1) copied verbatim from the column **LBORRESU** or 2) created, depending on the raw data provided.
    - If the raw data contains this result in the IDDO-Defined Standard Units for that laboratory test or exam, the value from **LBORRESU** will be filled in verbatim.
    - If the result is not in the IDDO-Defined Standard Units for that laboratory test or exam, then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

LBTESTCD	LBTEST	LBORRESU	LBSTRESU	Code	Conversion Formula
GLUC	Glucose	mmol			
GRANLE	Granulocytes/Leukocytes	%	**%**	C25613	*n/a*
GRANLE	Granulocytes/Leukocytes	fraction of 1	**%**	C25613	value * 100
HCT	Hematocrit	%	**%**	C25613	*n/a*
HCT	Hematocrit	fraction of 1	**%**	C25613	value * 100
HGB	Hemoglobin	g/L	**g/dL**	C64783	value * 0.10
HGB	Hemoglobin	g/dL	**g/dL**	C64783	*n/a*
LYMLE	Lymphocytes/Leukocytes	%	**%**	C25613	*n/a*
LYMLE	Lymphocytes/Leukocytes	fraction of 1	**%**	C25613	value * 100
MONOLE	Monocytes/Leukocytes	%	**%**	C25613	*n/a*
MONOLE	Monocytes/Leukocytes	fraction of 1	**%**	C25613	value * 100
PLAT	Platelets	10^9/L			
RBC	Erythrocytes	10^12/L			
RETIRBC	Reticulocytes/Erythrocytes	%	**%**	C25613	*n/a*
RETIRBC	Reticulocytes/Erythrocytes	fraction of 1	**%**	C25613	value * 100
WBC	Leukocytes	10^9/L			

LBSTAT – Laboratory Test Completion Status

- **DEFINITION**: This variable contains information about the status of the laboratory test or examination – specifically that it was not completed when it was expected to have been. This column should be empty when there is a value in **LBORRES**. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have no value in **LBORRES**. This could be because 1) the test was not completed or 2) the data is missing/not provided in the raw dataset.
  - This will be a created variable. Data will follow the terminology from the codelist ***Not Done (ND)***.
    - A variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

LBSTRESC	Code
NOT DONE	C49484

LBREASND – Laboratory Test Reason Not Done

- **DEFINITION**: This variable contains information about the reason why the laboratory test or examination was not completed when it was expected to have been. This column should be empty when there is a value in **LBORRES**. This is defined by IDDO Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **LBSTAT**.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) be a created variable. Data will follow the terminology from the IDDO Codelist below.
    - If the raw data contains information as to why a laboratory test or exam was not completed, it will be filled in verbatim from the raw dataset.
    - If the raw data does not contain the reason why a laboratory test or exam was not competed, a variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

LBREASND
NOT PROVIDED IN THE CONTRIBUTED DATASET

LBSPEC – Laboratory Test Specimen Type

- **DEFINITION**: This variable contains information about the type of specimen used for the laboratory test or examination. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.

- **COMPLETION**:
  - This variable will **NEED GUIDANCE ON HOW WE ADDRESS THIS**

LBMETHOD – Laboratory Test Method

- **DEFINITION**: This variable contains information about the method used for the laboratory test or examination. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will **NEED GUIDANCE ON HOW WE ADDRESS THIS**

LBFAST – Laboratory Test Fasting Status

- **DEFINITION**: This variable contains information about the fasting status of the subject during the laboratory test or examination, if relevant. The variable is expected to be null if not relevant. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for laboratory tests or examinations that provide information about the subject's fasting status for the test.
  - This variable will only be mapped if explicitly detailed in the protocol/publication or if it is available in the raw dataset. There will be no effort by IDDO Data Curators to populate this with "Unknown" if the data is not available.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***No Yes Response (NY)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all glucose testing was done with the subject fasting – data would be Y), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

LBFAST	Description	Code
N	No	C49487
Y	Yes	C49488

LBDRVFL – Laboratory Test Value Derived Flag

- **DEFINITION**: This variable contains information about whether the result for the laboratory test or examination was derived. For example, this will be populated if the contributed dataset has the value comprised of an average of multiple lab tests. The variable is expected to be null if the choice is not "Yes". This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for derived laboratory test or examination results.
  - This variable will only be mapped if explicitly detailed in the protocol/publication or if it is available in the raw dataset.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***No Yes Response (NY)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the data dictionary states the haematocrit value is the average of two tests – data would be Y), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

LBDRVFL	Description	Code
Y	Yes	C49488

VISITNUM – Visit Number

- **DEFINITION**: This variable contains a number designating the planned clinical encounter number. This is a numeric version of the visit described in **VISIT** and it is used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The clinical encounter in the study will be numbered "1" and each subsequent visit given the next sequential number. These visits are not limited to days, but rather encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given a sequential number in **VISITNUM**. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISIT – Visit Name

- **DEFINITION**: This variable contains the protocol-defined text description of the planned clinical encounter number.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISITDY – Planned Study Day of Visit

- **DEFINITION**: This variable contains a number designating the Study Day of the planned clinical encounter. This is also a numeric version of the visit described in **VISIT** and can be used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The planned study day of the visit will be entered. These numbers are limited to days, not the encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given the same day in **VISITDY**. See the Example Section below for more details.
  - A note on malaria data: Historically in many antimalarial clinical trials, the day the subject is enrolled and receives the first antimalarial dose has been considered "Day 0" and the first day post-dose has been considered day 1. However, in the SDTM-based domains, a Study Day of 0 is not allowed. The Planned Study Day in these types of malaria trials will be shifted by 1 for **VISITDY** in order to accommodate this timing discrepancy (e.g., "Day 0" becomes **VISITDY**=1; "Day 28" becomes **VISITDY**=29).
- **CONTROLLED TERMINOLOGY**
  - None

LBDTC – Laboratory Test Date/Time of Specimen Collection

- **DEFINITION**: This variable describes the date and time of the collection of the laboratory test or examination specimen. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for laboratory tests or examinations that provide the actual date or time of the specimen collection. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion will not happen. This variable would be left blank and the information on "Day 3" would be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
    - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
    - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
    - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.

- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

LBDY – Laboratory Test Study Day of Specimen Collection

- **DEFINITION**: This variable describes the study day of the collection of the laboratory test or examination specimen relative to the date in **RFSTDTC**. This will be blank for records with no value in in **LBDTC**. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **LBDTC**.
  - This information will be created and added to the dataset.
  - This will be calculated as per the methods described by CDISC
    - If **LBDTC** is on or after **RFSTDTC:**
      - **LBDY** = (date portion of **LBDTC**) – (date portion of **RFSTDTC**) +1
    - If **LBDTC** precedes **RFSTDTC**:
      - **LBDY** = (date portion of **LBDTC**) – (date portion of **RFSTDTC**)

- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

Morphology and Physiology (MP) Domain

Navigation Links: **Data Management** / **IDDO Repository Data Dictionary**

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Generic+Morphology+Physiology+Specification

"A domain relevant to the science of the form and structure of an organism or of its parts. Macroscopic results (e.g., size, shape, color, and abnormalities of body parts or specimens) that are seen by the naked eye or observed via procedures such as imaging modalities, endoscopy, or other technologies. Many morphology results are obtained from a procedure, although information about the procedure may or may not be collected."

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	MO	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
MPSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MPTESTCD	Test or Examination Short Name	Char	*	Topic	Short name of the measurement, test, or examination described in **MPTEST**. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in **MPTESTCD** cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). **MPTESTCD** cannot contain characters other than letters, numbers, or underscores. Examples: "VOLUME", "INTP".	Req
MPTEST	Test or Examination Name	Char	*	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in **MPTEST** cannot be longer than 40 characters. Examples: "Volume", "Interpretation".	Req
MPCAT	Category for Test	Char	*	Grouping Qualifier	Used to categorize observations across subjects.	Perm
MPSCAT	Subcategory for Test	Char	*	Grouping Qualifier	A further categorization.	Perm
MPPOS	Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Perm
MPORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the procedure measurement or finding as originally received or collected.	Exp
MPORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for **MPORRES**.	Perm
MPSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from **MPORRES** in a standard format or standard units. **MPSTRESC** should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in **MPSTRESN**.	Exp
MPSTRESN	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 **MPSTRESC**. **MPSTRESN** should store all numeric test results or findings.	Perm
MPSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for **MPSTRESC** or **MPSTRESN**.	Perm
MPSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a test was not done, or a measurement was not taken. Should be null if a result exists in **MPORRES**.	Perm
MPREASND	Reason Test Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT" or "SUBJECT REFUSED". Used in conjunction with **MPSTAT** when value is "NOT DONE".	Perm
MPLOC	Location Used for Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of the measurement. Examples: "BRAIN", "KIDNEY", "LIVER", etc.	Perm
MPMETHOD	Method of Procedure Test	Char	(METHOD)	Record Qualifier	Method of the test or examination result.	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
MPDTC	Date/Time of Test	Char	ISO 8601	Timing	Date of test.	Exp
MPDY	Study Day of Test	Num		Timing	1. Study day of the procedure or test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined **RFSTDTC** variable in Demographics.	Perm

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN

MP

USUBJID – Unique Subject Identifier

- **DEFINITION**: This variable contains the unique subject identifier for a study. This is a secondary key/identifier for all subject-level domains in the IDDO Data Repository – every domain table containing subject-level information (i.e., all but the Trial Domains) will have the **USUBJID** identifier. This variable will identify unique subjects in the repository.

- If data about the same subject is submitted as two separate submissions to IDDO, the same subjects in both submissions will have the same **USUBJID** to identify them as the same individual.

- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This value will be created by concatenating the values for **STUDYID_SITEID_SUBJID** for each subject. This created ID will be what is entered as the **USUBJID**.

- **CONTROLLED TERMINOLOGY**
  - None

MPSEQ – Morphology/Physiology Finding Sequence Number

- **DEFINITION**: This variable is a sequence number to ensure uniqueness of subject records within the MP domain. Each morphological/physiological finding (each recorded as a separate row in the table) will have a unique number within each subject. For example, a subject with 10 findings will have 10 rows and each row is numbered sequentially from 1-10; a subject with 24 findings will have 24 rows and each row is numbered sequentially from 1-24.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - **MPSEQ** data provided in raw datasets already in SDTM format will not be included in the repository, only the IDDO-supplied **MPSEQ** number.

- **CONTROLLED TERMINOLOGY**
  - None

MPTESTCD – Morphology/Physiology Finding Short Name

- **DEFINITION**: This variable identifies the shortened code for the name of the morphological or physiological finding. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology from several of the Morphology Domains (see ***Cardiovascular Test Code (CVTESTCD)*** etc).
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-03-29)*

MPTESTCD	MPTEST	Code
INTP	Interpretation	C41255
LENGTH	Length	C25334

MPTEST – Morphology/Physiology Finding Name

- **DEFINITION**: This variable identifies the name of the morphological or physiological finding. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology from several of the Morphology Domains (see ***Cardiovascular Test Code (CVTESTCD)*** etc).
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-03-29)*

MPTESTCD	MPTEST	Code
INTP	**Interpretation**	C41255
LENGTH	**Length**	C25334

MPCAT – Category for Morphology/Physiology Finding

- **DEFINITION**: This variable is a categorization of the morphological or physiological finding. These categories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that fit the categories of interest listed below.
  - This information will be created and added to the dataset.

- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

MPCAT	Description
TBD	To be defined

MPSCAT – SubCategory for Morphology/Physiology Finding

- **DEFINITION**: This variable is a further categorization of the morphological or physiological finding. These subcategories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that fit the subcategories of interest listed below.
  - This information will be created and added to the dataset.

- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

MPSCAT	Description
TBD	To be defined

MPPOS – Morphology/Physiology Position of Subject

- **DEFINITION**: This variable contains information about the position of the subject during the morphological or physiological finding. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the morphological or physiological finding (i.e., it will not be populated for records that have a result of "NOT DONE" for **MPSTAT**) and have provided information on the position of the subject during the finding.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Position (POSITION)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all spleen size measurements were taken with the subject laying down – data would be SUPINE), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSPOS	Description	Code
SITTING	Sitting	C62122
STANDING	Standing	C62166
SUPINE	Supine; Lying on back	C62167

MPORRES – Morphology/Physiology Finding Result or Finding in Original Units

- **DEFINITION**: This variable contains the result of the morphological or physiological finding as provided by the data contributor. The original data can be either numeric (e.g., "503") or string (e.g., "Positive").
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the morphological or physiological finding (i.e., it will not be populated for records that have a result of "NOT DONE" for **MPSTAT**).
  - This information will be filled in verbatim from the raw datasets.
- **CONTROLLED TERMINOLOGY**
  - None

MPORRESU – Morphology/Physiology Finding Original Units

- **DEFINITION**: This variable contains the unit for the result of the morphological or physiological finding as provided by the data contributor. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the morphological or physiological finding (i.e., it will not be populated for records that have a result of "NOT DONE" for **MPSTAT**).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Unit (UNIT)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all spleen size findings was recorded in centimeters – data would be cm), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

MPTESTCD	MPTEST	MPORRESU	Similar Names	Code
LENGTH	Length	**cm**	Centimeter	C49668
LENGTH	Length	**in**	Inch	C48500
LENGTH	Length	**mm**	Millimeter	C28251

MPSTRESC – Morphology/Physiology Finding in Standard Units, Character Format

- **DEFINITION**: This variable contains the converted, standardized result of the morphological or physiological finding. The data can be either numeric (e.g., "503") or string (e.g., "Positive") and is stored as a string in the repository. The standard units and conversion formulas are described in the section about the variable **MPSTRESU**. There is limited CDISC Controlled Terminology for tests with string/character-based results and is listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the morphological or physiological finding (i.e., it will only be populated for records that have a value in **MPORRES**).
  - This will either be 1) filled in verbatim from the column **MPORRES** or 2) created, depending on the raw data provided.
    - If the raw data contains this result in the IDDO-Defined Standard Units for that morphological or physiological finding, the value from **MPORRES** will be filled in verbatim.
    - If the result is not in the IDDO-Defined Standard Units for that morphological or physiological finding, then a variable filled in with the converted value will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSSTRESC	Similar Names	Code
ABNORMAL	Abnormal	C25401
INDETERMINATE	Indeterminate; Inconclusive; IND	C48658
NORMAL	Normal	C14165
NOT EVALUABLE	Not Evaluable; Not assessable	C62222
UNKNOWN	Unknown; U; UNK	C17998

MPSTRESN – Morphology/Physiology Finding in Standard Units, Numeric Format

- **DEFINITION**: This variable contains the converted, standardized result of the morphological or physiological finding when the result is numeric. This column is a direct copy of the numeric values found in **MPSTRESC**. String/character-based results (e.g., "Positive") are not copied into this column.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a numeric result for the morphological or physiological finding (i.e., it will only be populated for records that have a numeric value in **MPSTRESC**).
  - This will be a created variable.
    - A variable will be created and will be populated with the numeric results found in **MPSTRESC**.
- **CONTROLLED TERMINOLOGY**
  - None

MPSTRESU – Morphology/Physiology Finding Standard Units

- **DEFINITION**: This variable contains the unit for the converted, standardized result of the morphological or physiological finding. The IDDO-Defined Standard Units for each finding are listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the morphological or physiological finding (i.e., it will only be populated for records that have a value in **MPORRES**).
  - This will either be 1) copied verbatim from the column **MPORRESU** or 2) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Unit (UNIT)***.
    - If the raw data contains this result in the IDDO-Defined Standard Units for that morphological or physiological finding, the value from **MPORRESU** will be filled in verbatim.
    - If the result is not in the IDDO-Defined Standard Units for that morphological or physiological finding, then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

MPTESTCD	MPTEST	MPORRESU	MPSTRESU	Code	Conversion Formula
LENGTH	Length	cm	**cm**	C49668	*n/a*
LENGTH	Length	in	**cm**	C49668	value * 2.54
LENGTH	Length	mm	**cm**	C49668	value * 0.1

MPSTAT – Morphology/Physiology Finding Completion Status

- **DEFINITION**: This variable contains information about the status of the morphological or physiological finding – specifically that it was not completed when it was expected to have been. This column should be empty when there is a value in **MPORRES**. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have no value in **MPORRES**. This could be because 1) the test was not completed or 2) the data is missing/not provided in the raw dataset.
  - This will be a created variable. Data will follow the terminology from the codelist ***Not Done (ND)***.

        - A variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

MPSTAT	Code
NOT DONE	C49484

MPREASND – Morphology/Physiology Finding Reason Not Done

- **DEFINITION**: This variable contains information about the reason why the morphological or physiological finding was not completed when it was expected to have been. This column should be empty when there is a value in **MPORRES**. This is defined by IDDO Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a value in **MPSTAT**.
    - This will either be 1) filled in verbatim from the raw datasets, or 2) be a created variable. Data will follow the terminology from the IDDO Codelist below.
        - If the raw data contains information as to why a morphological or physiological finding was not completed, it will be filled in verbatim from the raw dataset.
        - If the raw data does not contain the reason why a morphological or physiological finding was not competed, a variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

MPREASND
NOT PROVIDED IN THE CONTRIBUTED DATASET

MPLOC – Location of Morphology/Physiology Finding

- **DEFINITION**: This variable contains information about the location of the morphological or physiological finding. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have provided information on the location of the finding.
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Anatomical Location (LOC)***.
        - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
        - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
        - If the data is not in the raw dataset but available in another context, then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-03-29)*

MPLOC	Description	Code
LIVER	Liver	C12392
SPLEEN	Spleen	C12432

MPMETHOD – Morphology/Physiology Finding Method

- **DEFINITION**: This variable contains information about the method used for the morphological or physiological finding. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have provided information on the method of the finding.
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Method (METHOD)***.
        - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
        - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
        - If the data is not in the raw dataset but available in a nother context (e.g., the protocol states all liver measurements will be obtained by ultrasound - data would be ULTRASOUND), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-03-29)*

MPMETHOD	Description	Code
PALPATION	Feeling with the hands during a physical exam	C16950
ULTRASOUND	Ultrasound	C17230

VISITNUM – Visit Number

- **DEFINITION**: This variable contains a number designating the planned clinical encounter number. This is a numeric version of the visit described in **VISIT** and it is used for sorting.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset.
    - This information will be created and added to the dataset.
        - The clinical encounter in the study will be numbered "1" and each subsequent visit given the next sequential number. These visits are not limited to days, but rather encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given a sequential number in **VISITNUM**. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
    - None

VISIT – Visit Name

- **DEFINITION**: This variable contains the protocol-defined text description of the planned clinical encounter number.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset.
    - This information will be created and added to the dataset.
        - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
    - None

VISITDY – Planned Study Day of Visit

- **DEFINITION**: This variable contains a number designating the Study Day of the planned clinical encounter. This is also a numeric version of the visit described in **VISIT** and can be used for sorting.
- **COMPLETION**:
    - This variable will be populated for every record in the dataset.
    - This information will be created and added to the dataset.
        - The planned study day of the visit will be entered. These numbers are limited to days, not the encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given the same day in **VISITDY**. See the Example Section below for more details.
    - A note on malaria data: Historically in many antimalarial clinical trials, the day the subject is enrolled and receives the first antimalarial dose has been considered "Day 0" and the first day post-dose has been considered day 1. However, in the SDTM-based domains, a Study Day of 0 is not allowed. The Planned Study Day in these types of malaria trials will be shifted by 1 for **VISITDY** in order to accommodate this timing discrepancy (e.g., "Day 0" becomes **VISITDY**=1; "Day 28" becomes **VISITDY**=29).
- **CONTROLLED TERMINOLOGY**

- None

MPDTC – Date/Time of Morphology/Physiology Finding

- **DEFINITION**: This variable describes the date and time of the morphological or physiological finding. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for records that provide the actual date or time of the finding. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion will not happen. This variable would be left blank and the information on "Day 3" would be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
    - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
    - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
    - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

MPDY – Study Day of Morphology/Physiology Finding

- **DEFINITION**: This variable describes the study day of the morphological or physiological finding relative to the date in **RFSTDTC**. This will be blank for records with no value in in **MPDTC**. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **MPDTC**.
  - This information will be created and added to the dataset.
  - This will be calculated as per the methods described by CDISC
    - If **MPDTC** is on or after **RFSTDTC:**
      - **MPDY** = (date portion of **MPDTC**) – (date portion of **RFSTDTC**) +1
    - If **MPDTC** precedes **RFSTDTC**:
      - **MPDY** = (date portion of **MPDTC**) – (date portion of **RFSTDTC**)
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

Examples for Completion of this Domain

A study has collected spleen and liver measurements. The raw data variables are as follows:

Raw Variable	Label/Description
BASELINE_Spleen Measurement	Investigation: spleen measurement in cm
BASELINE_Liver Measure	Investigation: Liver measurement in cm
DAY 7_Spleen Measurement	Investigation: spleen measurement in cm
Day 7_Liver Measure	Investigation: Liver measurement in cm

The data would be collected as follows:

STUDYID	DOMAIN	USUBJID	MPSEQ	MPTESTCD	MPTEST	MPORRES	MPORRESU	MPSTAT	MPREASND	MPLOC	VISITNUM	VISIT	VISITDY
ABCDE	MP	ABCDE_Oxford_001	1	LENGTH	Length	4	cm			SPLEEN	1	Baseline	1
ABCDE	MP	ABCDE_Oxford_001	2	LENGTH	Length	0	cm			LIVER	1	Baseline	1
ABCDE	MP	ABCDE_Oxford_001	3	LENGTH	Length	5	cm			SPLEEN	5	Day 7	8
ABCDE	MP	ABCDE_Oxford_001	4	LENGTH	Length	0	cm			LIVER	5	Day 7	8
ABCDE	MP	ABCDE_Oxford_002	1	LENGTH	Length	2	cm			SPLEEN	1	Baseline	1
ABCDE	MP	ABCDE_Oxford_002	2	LENGTH	Length	4	cm			LIVER	1	Baseline	1
ABCDE	MP	ABCDE_Oxford_002	3	LENGTH	Length			NOT DONE	NOT PROVIDED IN CONTRIBUTED DATASET	SPLEEN	5	Day 7	8
ABCDE	MP	ABCDE_Oxford_002	4	LENGTH	Length			NOT DONE	NOT PROVIDED IN CONTRIBUTED DATASET	LIVER	5	Day 7	8
ABCDE	MP	ABCDE_Oxford_003	1	LENGTH	Length	3	cm			LIVER	1	Baseline	1
ABCDE	MP	ABCDE_Oxford_003	2	LENGTH	Length	4	cm			SPLEEN	1	Baseline	1
ABCDE	MP	ABCDE_Oxford_003	3	LENGTH	Length	4	cm			SPLEEN	5	Day 7	8
ABCDE	MP	ABCDE_Oxford_003	4	LENGTH	Length	3	cm			LIVER	5	Day 7	8

Pharmacokinetics Concentrations (PC) Domain

Navigation Links: **Data Management** / **IDDO Repository Data Dictionary**

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Pharmacokinetics+Concentrations

"A findings domain that contains concentrations of drugs or metabolites in fluids or tissues as a function of time. One record per sampe characteristic or time-point concentration per reference time point or per analyte per subject."

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	PC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier within the submission.	Req
PCSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PCTESTCD	Pharmacokinetic Test Short Name	Char		Topic	Short name of the analyte or specimen characteristic. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in **PCTESTCD** cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). **PCTESTCD** cannot contain characters other than letters, numbers, or underscores. Examples: "ASA", "VOL", "SPG".	Req
PCTEST	Pharmacokinetic Test Name	Char		Synonym Qualifier	Name of the analyte or specimen characteristic. Note any test normally performed by a clinical laboratory is considered a lab test. The value in **PCTEST** cannot be longer than 40 characters. Examples: "Acetylsalicylic Acid", "Volume", "Specific Gravity".	Req
PCCAT	Test Category	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: "ANALYTE", "SPECIMEN PROPERTY".	Perm
PCSCAT	Test Subcategory	Char	*	Grouping Qualifier	A further categorization of a test category.	Perm
PCORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
PCORRESU	Original Units	Char	(PKUNIT)	Variable Qualifier	Original units in which the data were collected. The unit for **PCORRES**. Example: "mg/L".	Exp
PCSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from **PCORRES** in a standard format or standard units. **PCSTRESC** should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in **PCSTRESN**. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in **PCORRES**, and these results effectively have the same meaning, they could be represented in standard format in **PCSTRESC** as "NEGATIVE". For other examples, see general assumptions.	Exp
PCSTRESN	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 **PCSTRESC**. **PCSTRESN** should store all numeric test results or findings.	Exp
PCSTRESU	Standard Units	Char	(PKUNIT)	Variable Qualifier	Standardized unit used for **PCSTRESC** and **PCSTRESN**.	Exp
PCSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a result was not obtained. Should be null if a result exists in **PCORRES**.	Perm
PCREASND	Reason Test Not Done	Char		Record Qualifier	Describes why a result was not obtained, such as "SPECIMEN LOST". Used in conjunction with **PCSTAT** when value is "NOT DONE".	Perm
PCSPEC	Specimen Material Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: "SERUM", "PLASMA", "URINE".	Exp
PCSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen, e.g., "HEMOLYZED", "ICTERIC", "LIPEMIC".	Perm
PCMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: "HPLC/MS", "ELISA". This should contain sufficient information and granularity to allow differentiation of various methods that might have been used within a study.	Perm
PCFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status.	Perm
PCDRVFL	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, which do not come from the CRF, are examples of records that would be derived for the submission datasets. If PCDRVFL = "Y", then **PCORRES** may be null with **PCSTRESC**, and **PCSTRESN** (if the result is numeric) having the derived value.	Perm
PCLLOQ	Lower Limit of Quantitation	Num		Variable Qualifier	Indicates the lower limit of quantitation for an assay. Units should be those used in **PCSTRESU**.	Exp
PCULOQ	Upper Limit of Quantitation	Num		Variable Qualifier	Indicates the upper limit of quantitation for an assay. Units should be those used in **PCSTRESU**.	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. Numeric version of **VISIT**, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	Protocol-defined description of clinical encounter. 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
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected.	Perm

PCDTC	Date/Time of Specimen Collection	Char	ISO 8601	Timing	Date/time of specimen collection represented in ISO 8601 character format. If there is no end time, then this will be the collection time.	Exp
PCENDTC	End Date/Time of Specimen Collection	Char	ISO 8601	Timing	End date/time of specimen collection represented in ISO 8601 character format. If there is no end time, the collection time should be stored in **PCDTC**, and **PCENDTC** should be null.	Perm
PCDY	Actual Study Day of Specimen Collection	Num		Timing	Study day of specimen collection, measured as integer days. Algorithm for calculations must be relative to the sponsor-defined **RFSTDTC** variable in Demographics.	Perm
PCENDY	Study Day of End of Observation	Num		Timing	Actual study day of end of observation expressed in integer days relative to the sponsor-defined **RFSTDTC** in Demographics.	Perm
PCTPT	Planned Time Point Name	Char		Timing	Text description of time when specimen should be taken. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See **PCTPTNUM** and **PCTPTREF**. Examples: "Start", "5 min post".	Perm
PCTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of **PCTPT** to aid in sorting.	Perm
PCELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (**PCTPTREF**) such as "PREVIOUS DOSE" or "PREVIOUS MEAL". This variable is useful where there are repetitive measures. Not a clock time or a date time variable.	Perm
PCTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point used as a basis for **PCTPT**, **PCTPTNUM**, and **PCELTM**. Example: "Most Recent Dose".	Perm
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601	Timing	Date/time of the reference time point described by **PCTPTREF**.	Perm
PCEVLINT	Evaluation Interval	Char	ISO 8601	Timing	Evaluation Interval associated with a **PCTEST** record represented in ISO 8601 character format. Example: "-PT2H" to represent an interval of 2 hours prior to a **PCTPT**.	Perm

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN

PC

USUBJID – Unique Subject Identifier

- **DEFINITION**: This variable contains the unique subject identifier for a study. This is a secondary key/identifier for all subject-level domains in the IDDO Data Repository – every domain table containing subject-level information (i.e., all but the Trial Domains) will have the **USUBJID** identifier. This variable will identify unique subjects in the repository.
  - If data about the same subject is submitted as two separate submissions to IDDO, the same subjects in both submissions will have the same **USUBJID** to identify them as the same individual.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This value will be created by concatenating the values for **STUDYID_SITEID_SUBJID** for each subject. This created ID will be what is entered as the **USUBJID**.
- **CONTROLLED TERMINOLOGY**
  - None

PCTESTCD – Pharmacokinetic Test Short Name

- **DEFINITION**: This variable identifies the shortened code for the name of the pharmacokinetic test. This is defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology according to the rules provided by CDISC.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

Raw Value	PCTESCTD	PCTEST
Amodiaquine	**AMODIQNE**	AMODIAQUINE
Artemether	**ARTEMTHR**	ARTEMETHER
Artesunate	**ARTESUNT**	ARTESUNATE
Carboxy-primaquine	**CRBPRIMQ**	CARBOXYPRIMAQUINE
Chloroquine	**CHLORQNE**	CHLOROQUINE

Desbutyl-lumefantrine	**DSBTLMFT**	DESBUTYLLUMEFANTRINE
Desethyl-amodiaquine	**DSTHAMDQ**	DESETHYLAMODIAQUINE
Desethyl-chloroquine	**DSTHCHLQ**	DESETHYLCHLOROQUINE
Dihydroartemisinin	**DHYARTMS**	DIHYDROARTEMISININ
Lumefantrine	**LUMEFTRN**	LUMEFANTRINE
Mefloquine	**MEFLOQNE**	MEFLOQUINE
Piperaquine	**PIPERQNE**	PIPERAQUINE
Primaquine	**PRIMAQNE**	PRIMAQUINE
Pyrimethamine; Pyremethamine	**PYRMTHMN**	PYRIMETHAMINE
Sulfadoxine; Sulphadoxine	**SULFADXN**	SULFADOXINE

PCTEST – Pharmacokinetic Test Name

- **DEFINITION**: This variable identifies the name of the pharmacokinetic test. This is defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology according to the rules provided by CDISC.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

Raw Value	PCTESCTD	PCTEST
Amodiaquine	AMODIQNE	**AMODIAQUINE**
Artemether	ARTEMTHR	**ARTEMETHER**
Artesunate	ARTESUNT	**ARTESUNATE**
Carboxy-primaquine	CRBPRIMQ	**CARBOXYPRIMAQUINE**
Chloroquine	CHLORQNE	**CHLOROQUINE**
Desbutyl-lumefantrine	DSBTLMFT	**DESBUTYLLUMEFANTRINE**
Desethyl-amodiaquine	DSTHAMDQ	**DESETHYLAMODIAQUINE**
Desethyl-chloroquine	DSTHCHLQ	**DESETHYLCHLOROQUINE**
Dihydroartemisinin	DHYARTMS	**DIHYDROARTEMISININ**
Lumefantrine	LUMEFTRN	**LUMEFANTRINE**
Mefloquine	MEFLOQNE	**MEFLOQUINE**
Piperaquine	PIPERQNE	**PIPERAQUINE**
Primaquine	PRIMAQNE	**PRIMAQUINE**
Pyrimethamine; Pyremethamine	PYRMTHMN	**PYRIMETHAMINE**
Sulfadoxine; Sulphadoxine	SULFADXN	**SULFADOXINE**

PCORRES – Pharmacokinetic Test Result in Original Units

- **DEFINITION**: This variable contains the result of the pharmacokinetic test as provided by the data contributor. The original data can be either numeric (e.g., "503") or string (e.g., "Positive").
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the pharmacokinetic test (i.e., it will not be populated for records that have a result of "NOT DONE" for **PCSTAT**).
  - This information will be filled in verbatim from the raw datasets.
- **CONTROLLED TERMINOLOGY**
  - None

PCORRESU – Pharmacokinetic Test Original Units

- **DEFINITION**: This variable contains the unit for the result of the microbiology test or finding as provided by the data contributor. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the pharmacokinetic test (i.e., it will not be populated for records that have a result of "NOT DONE" for **PCSTAT**).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***PK Units of Measure (PKUNIT)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all parasite counts were recorded as per microliter – data would be uL), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

PCTESTCD	PCTEST	PCORRESU	Similar Names	Code
all	*all*	**ng/mL**	Microgram per Liter; Milligram per Cubic Meter; Nanogram per Milliliter; mcg/L; mg/m3; ng/mL; ug/L	C67306
all	*all*	**ug/mL**	Gram per Cubic Meter; Microgram per Milliliter; Milligram per Liter; g/m3;	C64572

mcg/mL; mg/L; ng/uL; ug/mL

PCCAT – Pharmacokinetic Test Category

- **DEFINITION**: This variable is a categorization of the pharmacokinetic test. These categories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**

PCTESTCD	PCTEST	PCCAT
		TBD

PCSTAT – Pharmacokinetic Test Completion Status

- **DEFINITION**: This variable contains information about the status of the pharmacokinetic test – specifically that it was not completed when it was expected to have been. This column should be empty when there is a value in **PCORRES**. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have no value in **PCORRES**. This could be because 1) the test was not completed or 2) the data is missing/not provided in the raw dataset.
  - This will be a created variable. Data will follow the terminology from the codelist ***Not Done (ND)***.
    - A variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

PCSTAT	Code
NOT DONE	C49484

PCREASND – Pharmacokinetic Test Reason Not Done

- **DEFINITION**: This variable contains information about the reason why the pharmacokinetic test was not completed when it was expected to have been. This column should be empty when there is a value in **PCORRES**. This is defined by IDDO Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **PCSTAT**.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) be a created variable. Data will follow the terminology from the IDDO Codelist below.
    - If the raw data contains information as to why a test or finding was not completed, it will be filled in verbatim from the raw dataset.
    - If the raw data does not contain the reason why a test or finding was not competed, a variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

PCREASND
NOT PROVIDED IN THE CONTRIBUTED DATASET

PCSPEC – Pharmacokinetic Test Speciment Material Type

- **DEFINITION**: This variable contains information about the type of speciment used for the pharmacokinetic test. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for all records in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Specimen Type (SPECTYPE)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all samples were taken from Capillary Blood – data would be CAPILLARY BLOOD), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

PCSPEC	Similar Names	Code
BLOOD	Peripheral Blood; Whole Blood	C12434
CAPILLARY BLOOD	Capillary Blood	C112235
CAPILLARY PLASMA	Capillary Plasma	C132461
MIXED VENOUS BLOOD	Mixed Venous Blood	C158281
PLASMA	Plasma	C13356
URINE	Urine	C13283
VENOUS BLOOD	Venous Blood	C78730
VENOUS PLASMA	Venous Plasma	C132462

VISITNUM – Visit Number

- **DEFINITION**: This variable contains a number designating the planned clinical encounter number. This is a numeric version of the visit described in **VISIT** and it is used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The clinical encounter in the study will be numbered "1" and each subsequent visit given the next sequential number. These visits are not limited to days, but rather encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given a sequential number in **VISITNUM**. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**

- None

VISIT – Visit Name

- **DEFINITION**: This variable contains the protocol-defined text description of the planned clinical encounter number.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISITDY – Planned Study Day of Visit

- **DEFINITION**: This variable contains a number designating the Study Day of the planned clinical encounter. This is also a numeric version of the visit described in **VISIT** and can be used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The planned study day of the visit will be entered. These numbers are limited to days, not the encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given the same day in **VISITDY**. See the Example Section below for more details.
  - A note on malaria data: Historically in many antimalarial clinical trials, the day the subject is enrolled and receives the first antimalarial dose has been considered "Day 0" and the first day post-dose has been considered day 1. However, in the SDTM-based domains, a Study Day of 0 is not allowed. The Planned Study Day in these types of malaria trials will be shifted by 1 for **VISITDY** in order to accommodate this timing discrepancy (e.g., "Day 0" becomes **VISITDY**=1; "Day 28" becomes **VISITDY**=29).
- **CONTROLLED TERMINOLOGY**
  - None

EPOCH – Epoch of Pharmacokinetic Test

- **DEFINITION**: This variable describes the Epoch period of the pharmacokinetic test (e.g., Baseline, Treatment, Follow-up).
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. Data will follow the terminology from the codelist ***Epoch (EPOCH)***.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

EPOCH	Description	Code
BASELINE	A period in a clinical study after eligibility has been met and before the start of treatment, at which baseline measurements are collected.	C125938
FOLLOW-UP	A period in a clinical study during which information about the health status of an individual is obtained after study interventions have concluded.	C99158
SCREENING	A period in a clinical study during which subjects are evaluated for participation in a study. [An example would be when samples are taken prior to verification of disease-positive status - this is the Screening period and once verified disease-positive they move into the Baseline period].	C48262
TREATMENT	A period in a clinical study during which subjects receive investigational product. [We include all periods and types of treatments - no division into "Blinded Treatment" or "Continuation Treatment" etc.]	C101526

PCDTC – Pharmacokinetic Test Date/Time of Collection

- **DEFINITION**: This variable describes the date and time of the collection of the sample for the pharmacokinetic test. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for pharmacokinetic tests that provide the actual date or time of the collection of the sample. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion will not happen. This variable would be left blank and the information on "Day 3" would be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
    - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
    - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
    - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

PCDY – Pharmacokinetic Test Study Day of Measurements

- **DEFINITION**: This variable describes the study of the collection of the sample for the pharmacokinetic test relative to the date in **RFSTDTC**. This will be blank for records with no value in in **PCDTC**. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **PCDTC**.
  - This information will be created and added to the dataset.
  - This will be calculated as per the methods described by CDISC
    - If **PCDTC** is on or after **RFSTDTC:**
      - **PCDY** = (date portion of **PCDTC**) – (date portion of **RFSTDTC**) +1
    - If **PCDTC** precedes **RFSTDTC**:
      - **PCDY** = (date portion of **PCDTC**) – (date portion of **RFSTDTC**)
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

Examples for Completion of this Domain

CASE: Limited information in the raw data and details gleaned from the publication

Sample of the raw data available:

Patient ID	PQ ng/ml D0	PQ ng/ml D1	PQ ng/ml D3
01-OPQ	Not Detected	145	132
02-OPQ	Not Detected	165	99
03-OPQ	Not Detected	147	32
04-OPQ	Not Detected	69	69
05-OPQ	Not Detected	118	119

Information from the publication:

> *"For the dosage of the antimalarials, venous blood samples were collected in EDTA anticoagulant."* **--> This supplies the value for the Specimen Material Type - PCSPEC = VENOUS BLOOD**
>
> *"For primaquine, the limit of detection was 5 ng/mL and the limit of quantification was 10 ng/mL."* **--> This supplies the value for the Lower Limit of Quantitation - PCLLOQ = 10 as well as the "translation" for the values of "Not Detected" on Day 0 which will = <5 (because the limit of detection was 5 ng/mL, so if it was not detected it was below 5)**

This data can be combined to describe the raw data and is illustrated in the table below:

STUDYID	DOMAIN	USUBJID	PCSEQ	PCTESTCD	PCTEST	PCORRES	PCORRESU	PCSPEC	PCLLOQ	VISIT
ABCDE	PC	ABCDE_Site_01-OPQ	1	PRIMAQNE	PRIMAQUINE	<5	ng/mL	VENOUS BLOOD	10	Day 0
ABCDE	PC	ABCDE_Site_01-OPQ	2	PRIMAQNE	PRIMAQUINE	145	ng/mL	VENOUS BLOOD	10	Day 1
ABCDE	PC	ABCDE_Site_01-OPQ	3	PRIMAQNE	PRIMAQUINE	132	ng/mL	VENOUS BLOOD	10	Day 3
ABCDE	PC	ABCDE_Site_02-OPQ	1	PRIMAQNE	PRIMAQUINE	<5	ng/mL	VENOUS BLOOD	10	Day 0
ABCDE	PC	ABCDE_Site_02-OPQ	2	PRIMAQNE	PRIMAQUINE	165	ng/mL	VENOUS BLOOD	10	Day 1
ABCDE	PC	ABCDE_Site_02-OPQ	3	PRIMAQNE	PRIMAQUINE	99	ng/mL	VENOUS BLOOD	10	Day 3
ABCDE	PC	ABCDE_Site_03-OPQ	1	PRIMAQNE	PRIMAQUINE	<5	ng/mL	VENOUS BLOOD	10	Day 0
ABCDE	PC	ABCDE_Site_03-OPQ	2	PRIMAQNE	PRIMAQUINE	147	ng/mL	VENOUS BLOOD	10	Day 1
ABCDE	PC	ABCDE_Site_03-OPQ	3	PRIMAQNE	PRIMAQUINE	32	ng/mL	VENOUS BLOOD	10	Day 3

Questionnaires (QS) Domain

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Questionnaires

"A findings domain that contains data for named, stand-alone insturements designed to provide an assessment of a concept. Questionnaires have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and have documented methods for adminstration and analysis. One record per questionnaire per question per time point per visit per subject."

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	QS	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
QSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
QSTESTCD	Question Short Name	Char	*	Topic	Topic variable for QS. Short name for the value in **QSTEST**, which can be used as a column name when converting the dataset from a vertical format to a horizontal format. The value in **QSTESTCD** cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). **QSTESTCD** cannot contain characters other than letters, numbers, or underscores. Controlled terminology for **QSTESTCD** is published in separate codelists for each questionnaire. See https://www.cdisc.org/standards/semantics/terminology for values for **QSTESTCD**. Examples: "ADCCMD01", "BPR0103".	Req
QSTEST	Question Name	Char	*	Synonym Qualifier	Verbatim name of the question or group of questions used to obtain the measurement or finding. The value in **QSTEST** cannot be longer than 40 characters. Controlled terminology for **QSTEST** is published in separate codelists for each questionnaire. See https://www.cdisc.org/standards/semantics/terminology for vaues for **QSTEST**. Example: "BPR01 - Emotional Withdrawal".	Req
QSCAT	Category of Question	Char	(QSCAT)	Grouping Qualifier	Used to specify the questionnaire in which the question identified by **QSTEST** and **QSTESTCD** was included. Examples: "ADAS-COG", "MDS-UPDRS".	Req
QSSCAT	Subcategory for Question	Char	*	Grouping Qualifier	A further categorization of the questions within the category. Examples: "MENTAL HEALTH" , "DEPRESSION", "WORD RECALL".	Perm
QSORRES	Finding in Original Units	Char		Result Qualifier	Finding as originally received or collected (e.g., "RARELY", "SOMETIMES"). When sponsors apply codelist to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, **QSORRES** will contain the decode format, and **QSSTRESC** and **QSSTRESN** may contain the standardized code values or scores.	Exp
QSORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for **QSORRES**, such as minutes or seconds or the units associated with a visual analog scale.	Perm
QSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the finding for all questions or sub-scores, copied or derived from **QSORRES** in a standard format or standard units. **QSSTRESC** should store all findings in character format; if findings are numeric, they should also be stored in numeric format in **QSSTRESN**. If question scores are derived from the original finding, then the standard format is the score. Examples: "0", "1". When sponsors apply codelist to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, **QSORRES** will contain the decode format, and **QSSTRESC** and **QSSTRESN** may contain the standardized code values or scores.	Exp
QSSTRESN	Numeric Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric findings in standard format; copied in numeric format from **QSSTRESC**. **QSSTRESN** should store all numeric results or findings.	Perm
QSSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for **QSSTRESC** or **QSSTRESN**.	Perm
QSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question was not done or was not answered. Should be null if a result exists in **QSORRES**.	Perm
QSREASND	Reason Not Performed	Char		Record Qualifier	Describes why a question was not answered. Used in conjunction with **QSSTAT** when value is "NOT DONE". Example: "SUBJECT REFUSED".	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. Numeric version of **VISIT**, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	Protocol-defined description of clinical encounter. 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
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the observation date/time of the physical exam finding.	Perm
QSDTC	Date/Time of Finding	Char	ISO 8601	Timing	Date of questionnaire.	Exp
QSDY	Study Day of Finding	Num		Timing	Study day of finding collection, measured as integer days. Algorithm for calculations must be relative to the sponsor-defined **RFSTDTC** variable in Demographics.	Perm

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN
QS

USUBJID – Unique Subject Identifier

- **DEFINITION**: This variable contains the unique subject identifier for a study. This is a secondary key/identifier for all subject-level domains in the IDDO Data Repository – every domain table containing subject-level information (i.e., all but the Trial Domains) will have the **USUBJID** identifier. This variable will identify unique subjects in the repository.
  - If data about the same subject is submitted as two separate submissions to IDDO, the same subjects in both submissions will have the same **USUBJID** to identify them as the same individual.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This value will be created by concatenating the values for **STUDYID_SITEID_SUBJID** for each subject. This created ID will be what is entered as the **USUBJID**.
- **CONTROLLED TERMINOLOGY**
  - None

QSSEQ – Questionnaire Sequence Number

- **DEFINITION**: This variable is a sequence number to ensure uniqueness of subject records within the QS domain. Each questionnaire finding (each recorded as a separate row in the table) will have a unique number within each subject. For example, a subject with 10 QS tests will have 10 rows and each row is numbered sequentially from 1-10; a subject with 24 QS tests will have 24 rows and each row is numbered sequentially from 1-24.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
  - **QSSEQ** data provided in raw datasets already in SDTM format will not be included in the repository, only the IDDO-supplied **QSSEQ**number.
- **CONTROLLED TERMINOLOGY**
  - None

QSTESTCD – Questionnaire Test Short Name

- **DEFINITION**: This variable identifies the shortened code for the name of the questionnaire performed. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology from the codelist(s): ***Karnofsky Performance Status Scale Questionnaire Test Code (KPSSTC)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-12-20)*

QSTESTCD	QSTEST	Similar Names	Code
KPSS01	KPSS-Karnofsky Performance Status	KPS Scale - Karnofsky Performance Status	C100417

QSTEST – Questionnaire Test Name

- **DEFINITION**: This variable identifies the name of the questionniare performed. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology from the codelist(s): ***Karnofsky Performance Status Scale Questionnaire Test Name***

(KPSSTN).
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-12-20)*

QSTESTCD	QSTEST	Similar Names	Code
KPSS01	**KPSS-Karnofsky Performance Status**	KPS Scale - Karnofsky Performance Status	C100417

QSCAT – Category for Questionnaire

- **DEFINITION**: This variable is a categorization of the questionniare performed. This defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that fit the categories of interest listed below.
    - This information will be created and added to the dataset. Data will follow the terminology from the codelist ***Category of Questionnaire (QSCAT)***.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

QSCAT	Description	Code
KPS SCALE	Karnofsky Performance Status Scale Questionnaire	C100768

QSSCAT – SubCategory for Questionnaire

- **DEFINITION**: This variable is a further categorization of the questionniare performed. These subcategories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that fit the subcategories of interest listed below.
    - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

QSSCAT	Description
TBD	To be defined

QSORRES – Questionnaire Finding in Original Units

- **DEFINITION**: This variable contains the result of the questionniare performed as provided by the data contributor. The original data can be either numeric (e.g., "503") or string (e.g., "Positive").
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a result for the questionniare (i.e., it will not be populated for records that have a result of "NOT DONE" for **QSSTAT**).
    - This information will be filled in verbatim from the raw datasets.
- **CONTROLLED TERMINOLOGY**
    - None

QSORRESU – Questionnaire Original Units

- **DEFINITION**: This variable contains the unit for the result of the questionniare performed as provided by the data contributor. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a result for the questionniare finding that requires a unit (i.e., 1) it will not be populated for records that have a result of "NOT DONE" for **QSSTAT** or 2) for results that have no unit, like "Positive").
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Unit (UNIT)***.
        - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
        - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
        - If the data is not in the raw dataset but available in another context (e.g., the a table for the questionnaire states all results are recorded as a percentage – data would be %), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

QSORRES	QSTESTCD	QSTEST	QSORRESU	Similar Names	Code
80	KPSS01	KPSS-Karnofsky Performance Status	**%**	Percentage	C25613
0.80	KPSS01	KPSS-Karnofsky Performance Status	**fraction of 1**	Fraction of 1; Proportion of 1	C105484
Normal no complaints; no evidence of disease	KPSS01	KPSS-Karnofsky Performance Status		*NO UNIT for this response*	*n/a*

QSSTRESC – Questionnaire Finding in Standard Units, Character Format

- **DEFINITION**: This variable contains the IDDO-defined converted, standardized result of the questionnaire performed. The data can be either numeric (e.g., "503") or string (e.g., "Positive") and is stored as a string in the repository. The standard units and conversion formulas are described in the section about the variable **QSSTRESU**.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a result for the questionnaire performed (i.e., it will only be populated for records that have a value in **QSORRES**).

    - This will either be 1) filled in verbatim from the column **QSORRES** or 2) created, depending on the raw data provided.
        - If the raw data contains this result in the IDDO-Defined Standard Units for that questionnaire performed, the value from **QSORRES** will be filled in verbatim.
        - If the result is not in the IDDO-Defined Standard Units for that questionnaire performed, then a variable filled in with the converted value will be created.
            - Any Karnofsky Performancy Status results that are character based (e.g., "Normal no complaints") will be converted to the corresponding numeric percentage result. See the Appendix at the end of this section for details.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*
    - None

QSSTRESN – Questionnaire Finding in Standard Units, Numeric Format

- **DEFINITION**: This variable contains the converted, standardized result of the questionnaire performed when the result is numeric. This column is a direct copy of the numeric values found in **QSSTRESC**. String/character-based results (e.g., "Positive") are not copied into this column.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a numeric result for the questionnaire performed (i.e., it will only be populated for records that have a numeric value in **QSSTRESC**).
    - This will be a created variable.
        - A variable will be created and will be populated with the numeric results found in **QSSTRESC**.
- **CONTROLLED TERMINOLOGY**
    - None

QSSTRESU – Questionnaire Standard Units

- **DEFINITION**: This variable contains the unit for the converted, standardized result of the questionnaire performed. The IDDO-Defined Standard Units for each questionnaire are listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a result for the questionnaire finding (i.e., it will only be populated for records that have a value in **QSORRES**).
    - This will either be 1) copied verbatim from the column **QSORRESU** or 2) created, depending on the raw data provided.
        - If the raw data contains this result in the IDDO-Defined Standard Units for that questionnaire , the value from **QSORRESU** will be filled in verbatim.
        - If the result is not in the IDDO-Defined Standard Units for that questionnaire, then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

QSORRES	QSTESTCD	QSTEST	QSORRESU	QSSTRESU	Similar Names	Code	Conversion Formula
80	KPSS01	KPSS-Karnofsky Performance Status	%	**%**	Percentage	C25613	*n/a*
0.80	KPSS01	KPSS-Karnofsky Performance Status	fraction of 1	**%**	Percentage	C25613	value * 100
Normal no complaints; no evidence of disease	KPSS01	KPSS-Karnofsky Performance Status		**%**	Percentage	C25613	Character-based responses will be converted to corresponding numeric percentage.

QSSTAT – Questionnaire Completion Status

- **DEFINITION**: This variable contains information about the status of the questionnaire finding – specifically that it was not given when it was expected to have been. This column should be empty when there is a value in **QSORRES**. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have no value in **QSORRES**. This could be because 1) the questionnaire finding was not completed or 2) the data is missing/not provided in the raw dataset.
    - This will be a created variable. Data will follow the terminology from the codelist ***Not Done (ND)***.
        - A variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

QSSTAT	Code
NOT DONE	C49484

QSNREASND – Questionnaire Reason Not Done

- **DEFINITION**: This variable contains information about the reason why the questionnaire finding was not completed when it was expected to have been. This column should be empty when there is a value in **QSORRES**. This is defined by IDDO Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a value in **QSSTAT**.
    - This will either be 1) filled in verbatim from the raw datasets, or 2) be a created variable. Data will follow the terminology from the IDDO Codelist below.
        - If the raw data contains information as to why the questionnaire finding was not completed, it will be filled in verbatim from the raw dataset.
        - If the raw data does not contain the reason why the questionnaire finding was not completed, a variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

QSREASND
NOT PROVIDED IN THE CONTRIBUTED DATASET

VISITNUM – Visit Number

- **DEFINITION**: This variable contains a number designating the planned clinical encounter number. This is a numeric version of the visit described in **VISIT** and it is used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The clinical encounter in the study will be numbered "1" and each subsequent visit given the next sequential number. These visits are not limited to days, but rather encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given a sequential number in **VISITNUM**. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISIT – Visit Name

- **DEFINITION**: This variable contains the protocol-defined text description of the planned clinical encounter number.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISITDY – Planned Study Day of Visit

- **DEFINITION**: This variable contains a number designating the Study Day of the planned clinical encounter. This is also a numeric version of the visit described in **VISIT** and can be used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The planned study day of the visit will be entered. These numbers are limited to days, not the encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given the same day in **VISITDY**. See the Example Section below for more details.
  - A note on malaria data: Historically in many antimalarial clinical trials, the day the subject is enrolled and receives the first antimalarial dose has been considered "Day 0" and the first day post-dose has been considered day 1. However, in the SDTM-based domains, a Study Day of 0 is not allowed. The Planned Study Day in these types of malaria trials will be shifted by 1 for **VISITDY** in order to accommodate this timing discrepancy (e.g., "Day 0" becomes **VISITDY**=1; "Day 28" becomes **VISITDY**=29).
- **CONTROLLED TERMINOLOGY**
  - None

EPOCH – Epoch of Treatment or Intervention

- **DEFINITION**: This variable describes the Epoch period of the questionnaire finding (e.g., Baseline, Treatment, Follow-up).
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. Data will follow the terminology from the codelist ***Epoch (EPOCH)***.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

EPOCH	Description	Code
BASELINE	A period in a clinical study after eligibility has been met and before the start of treatment, at which baseline measurements are collected.	C125938
FOLLOW-UP	A period in a clinical study during which information about the health status of an individual is obtained after study interventions have concluded.	C99158
SCREENING	A period in a clinical study during which subjects are evaluated for participation in a study. [An example would be when samples are taken prior to verification of disease-positive status - this is the Screening period and once verified disease-positive they move into the Baseline period].	C48262
TREATMENT	A period in a clinical study during which subjects receive investigational product. [We include all periods and types of treatments - no division into "Blinded Treatment" or "Continuation Treatment" etc.]	C101526

QSDTC – Date/Time of Questionnaire

- **DEFINITION**: This variable describes the date and time of the collection of the questionnaire finding. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for questionnaire findings that provide the actual date or time of the measurement. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion will not happen. This variable would be left blank and the information on "Day 3" would be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
    - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
    - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
    - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

QSDY – Study Day of Questionnaire

- **DEFINITION**: This variable describes the study of the collection of the questionnaire finding relative to the date in **RFSTDTC**. This will be blank for records with no value in in **QSDTC**. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **QSDTC**.
  - This information will be created and added to the dataset.
  - This will be calculated as per the methods described by CDISC
    - If **QSDTC** is on or after **RFSTDTC:**
      - **QSDY** = (date portion of **QSDTC**) – (date portion of **RFSTDTC**) +1
    - If **QSDTC** precedes **RFSTDTC**:
      - **QSDY** = (date portion of **QSDTC**) – (date portion of **RFSTDTC**)

- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

Appendix of Included Questionnaires

- **Karnofsky Performance Status Scale Definitions Rating (%) Criteria**

[http://www.npcrc.org/files/news/karnofsky_performance_scale.pdf]

Description	QSORRES *(number)*	QSORRES *(character)*	QSSTRESC	QSSTRESN	QSSTRESU
Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.	100	100	%
	90	Able to carry on normal activity; minor signs or symptoms of disease.	90	90	%
	80	Normal activity with effort; some signs or symptoms of disease.	80	80	%
Unable to work; able to live at home and care for most personal needs; varying amount of assisstance needed.	70	Cares for self; unable to carry on normal activity or to do active work.	70	70	%
	60	Requires occassional assistance, but is able to care for most of his personal needs.	60	60	%
	50	Requires considerable assistance and frequent medical care.	50	50	%
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.	40	40	%
	30	Severely disabled; hospital admission is indicated although death is not imminent.	30	30	%
	20	Very sick; hospital admission necessary; active support team necessary.	20	20	%
	10	Moribund; fatal processes progressing rapidly.	10	10	%
	0	Dead	11	11	%

Reproductive System Findings (RP) Domain

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Reproductive+System+Findings

"A findings domain that contains physiological and morphological findings related to the male and female reproductive systems. One record per finding or result per time point per visit per subject."

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	RP	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
RPSEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.	Req
RPGRPID	Group ID	Char		Identifier	Optional group identifier, used to link together a block of related records within a subject in a domain. Also used to link together a block of related records in the Trial Summary dataset.	Perm
RPTESTCD	Short Name of Reproductive Test	Char	(RPTESTCD)	Topic	Short character value for **RPTEST** used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: "CHILDPOT", "BCMETHOD", "MENARAGE".	Req
RPTEST	Name of Reproductive Test	Char	(RPTEST)	Synonym Qualifier	Long name For **RPTESTCD**. Examples: "Childbearing Potential", "Birth Control Method", "Menarche Age".	Req
RPCAT	Category for Reproductive Test	Char		Grouping Qualifier	Used to define a category of topic-variable values. Examples: "No use case to date, but values would be relative to reproduction tests grouping".	Perm
RPSCAT	Subcategory for Reproductive Test	Char		Grouping Qualifier	Used to define a further categorization of **RPCAT** values. Example: "No use case to date, but values would be relative to reproduction tests grouping".	Perm
RPORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: "120", "<1", "POS".	Exp
RPORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Unit for **RPORRES**. Examples: "in", "LB", "kg/L".	Perm
RPSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from **RPORRES** in a standard format or in standard units. **RPSTRESC** should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in **RPSTRESN**. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in **RPORRES**, and these results effectively have the same meaning, they could be represented in standard format in **RPSTRESC** as "NEGATIVE".	Exp
RPSTRESN	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 **RPSTRESC**. **RPSTRESN** should store all numeric test results or findings.	Perm
RPSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized units used for **RPSTRESC** and **RPSTRESN**. Example: "mol/L".	Perm
RPSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question was not asked or a test was not done, or a test was attempted but did not generate a result. Should be null or have a value of "NOT DONE".	Perm
RPREASND	Reason Not Done	Char		Record Qualifier	Reason not done. Used in conjunction with **RPSTAT** when value is "NOT DONE".	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. Numeric version of **VISIT**, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	Protocol-defined description of a clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of **VISIT**. Should be an integer.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the date/time at which the assessment was made.	Perm
RPDTC	Date/Time of Collection	Char	ISO 8601	Timing	Collection date and time of an observation.	Exp
RPDY	Study Day of Visit/Collection/Exam	Num		Timing	Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined **RFSTDTC** in Demographics.	Perm
RPDUR	Duration	Char	ISO 8601	Timing	Collected duration of an event, intervention, or finding represented in ISO 8601 character format. Used only if collected on the CRF and not derived.	Perm
RPTPT	Planned Time Point Name	Char		Timing	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose.	Perm
RPTPTNUM	Planned Time Point Number	Num		Timing	Numeric version of planned time point used in sorting.	Perm
RPELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time in ISO 8601 character format relative to a planned fixed reference (**RPTPTREF**) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval, represented as ISO duration.	Perm
RPTPTREF	Time Point Reference	Char		Timing	Description of the fixed reference point referred to by **RPELTM**, **RPTPTNUM**, and **RPTPT**. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".	Perm
RPRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time for a fixed reference time point defined by **RPTPTREF** in ISO 8601 character format.	Perm

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN

RP

USUBJID – Unique Subject Identifier

- **DEFINITION**: This variable contains the unique subject identifier for a study. This is a secondary key/identifier for all subject-level domains in the IDDO Data Repository – every domain table containing subject-level information (i.e., all but the Trial Domains) will have the **USUBJID** identifier. This variable will identify unique subjects in the repository.
  - If data about the same subject is submitted as two separate submissions to IDDO, the same subjects in both submissions will have the same **USUBJID** to identify them as the same individual.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This value will be created by concatenating the values for **STUDYID_SITEID_SUBJID** for each subject. This created ID will be what is entered as the **USUBJID**.
- **CONTROLLED TERMINOLOGY**
  - None

RPSEQ – Reproductive System Finding Sequence Number

- **DEFINITION**: This variable is a sequence number to ensure uniqueness of subject records within the RP domain. Each reproductive system finding (each recorded as a separate row in the table) will have a unique number within each subject. For example, a subject with 10 RP findings will have 10 rows and each row is numbered sequentially from 1-10; a subject with 24 RP findings will have 24 rows and each row is numbered sequentially from 1-24.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
  - **RPSEQ** data provided in raw datasets already in SDTM format will not be included in the repository, only the IDDO-supplied **RPSEQ** number.
- **CONTROLLED TERMINOLOGY**
  - None

RPTESTCD – Reproductive System Findings Short Name

- **DEFINITION**: This variable identifies the shortened code for the name of the reproductive system finding. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created,depending on the raw data provided. Data will follow the terminology from the codelist ***Reproductive System Findings Test Code (RPTESTCD)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all eligible patients must be pregant - data would be PREGIND, PREGST), then a variable fille din with the correct terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-12-20)*

RPTESTCD	RPTEST	Similar Names	Code
EGESTAGE	Estimated Gestational Age	EGA	C122188
PREGIND	Pregnant Indicator	This finding is used when a question like pregnant/not pregnant is asked. This should be populated for ALL pregnant women (i.e., both PREGIND and PREGST should be populated for studies focusing on pregnant women). PREGIND will be used to easily search and identify pregnant women - even in studies that did not focus on pregnant women.	C139264
PREGNN	Number of Pregnancies	Gravidity; Total number of pregnancies, regardless of outcome.	C106551
PREGST	Pregnant During the Study	This finding is used when the study is recruiting pregnant women.	C106561

RPTEST – Reproductive System Findings Name

- **DEFINITION**: This variable identifies the name of the reproductive system finding. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Reproductive System Findings Test Name (RPTEST)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all eligible patients must be pregant - data would be Pregnant Indicator, Pregnant During the Study), then a variable fille din with the correct terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-12-20)*

RPTESTCD	RPTEST	Similar Names	Code
EGESTAGE	**Estimated Gestational Age**	EGA	C122188
PREGIND	**Pregnant Indicator**	This finding is used when a question like pregnant/not pregnant is asked. This should be populated for ALL pregnant women (i.e., both PREGIND and PREGST should be populated for studies focusing on pregnant women). PREGIND will be used to easily search and identify pregnant women - even in studies that did not focus on pregnant women.	C139264
PREGNN	**Number of Pregnancies**	Number of Pregnancies; Gravidity; Total number of pregnancies, regardless of outcome	C106551
PREGST	**Pregnant During the Study**	This finding is used when the study is recruiting pregnant women.	C106561

RPCAT – Category for Reproductive System Findings

- **DEFINITION**: This variable is a categorization of the reproductive system finding. These categories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that fit the categories of interest listed below.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

RPCAT	Description

TBD	To be defined

RPSCAT – SubCategory for Reproductive System Findings

- **DEFINITION**: This variable is a further categorization of the reproductive system finding. These subcategories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that fit the subcategories of interest listed below.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

RPSCAT	Description
TBD	To be defined

RPORRES – Reproductive System Finding in Original Units

- **DEFINITION**: This variable contains the result of the reproductive system finding as provided by the data contributor. The original data can be either numeric (e.g., "503") or string (e.g., "Positive"). There is limited CDISC Controlled Terminology for tests that have a Yes/No response and are listed below. These should be used when the data is created and added to the dataset.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the reproductive system finding (i.e., it will not be populated for records that have a result of "NOT DONE" for **RPSTAT**).
  - This information will either be 1) filled in verbatim from the raw datasets or 2) created, depending on the raw data provided.
    - If the raw data contains the information it will be filled in verbatim.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all eligible patients must be pregant - data would be Pregnant Indicator = Y, Pregnant During the Study = Y), then a variable fille din with the correct terminology will be created.
- **CONTROLLED TERMINOLOGY**
  - Limited

RPTESTCD	RPTEST	RPORRES	Similar Names	Code
PREGIND	Pregnant Indicator	**Y / N / U**	Yes - subject is pregnant (self-report or test-confirmed) / No - subject is not pregnant (self-report or test-confirmed) / Unknown - Subject pregnancy status is unknown	C49488 / C49487 / C17998
PREGST	Pregnant During the Study	**Y / N / U**	Yes - subject is pregnant (self-report or test-confirmed) / No - subject is not pregnant (self-report or test-confirmed) / Unknown - Subject pregnancy status is unknown	C49488 / C49487 / C17998

RPORRESU – Reproductive System Finding Original Units

- **DEFINITION**: This variable contains the unit for the result of the reproductive system finding as provided by the data contributor. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the reproductive system finding (i.e., it will not be populated for records that have a result of "NOT DONE" for **RPSTAT**).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Unit (UNIT)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all EGA measurements were recorded in weeks – data would be WEEKS), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-12-20)*

RPTESTCD	RPTEST	RPORRESU	Similar Names	Code
EGA	Estimated Gestational Age	**DAYS**		C25301
EGA	Estimated Gestational Age	**MONTHS**		C29846
EGA	Estimated Gestational Age	**WEEKS**		C29844

RPSTRESC – Reproductive System Finding in Standard Units, Character Format

- **DEFINITION**: This variable contains the converted, standardized result of the reproductive system finding. The data can be either numeric (e.g., "503") or string (e.g., "Positive") and is stored as a string in the repository. The standard units and conversion formulas are described in the section about the variable **RPSTRESU**. There is limited CDISC Controlled Terminology for tests with string/character-based results and is listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the reproductive system finding (i.e., it will only be populated for records that have a value in **RPORRES**).
  - This will either be 1) filled in verbatim from the column **RPORRES** or 2) created, depending on the raw data provided.
    - If the raw data contains this result in the IDDO-Defined Standard Units for that reproductive system finding, the value from **RPORRES** will be filled in verbatim.
    - If the result is not in the IDDO-Defined Standard Units for that reproductive system finding, then a variable filled in with the converted value will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

RPTESTCD	RPTEST	RPSTRESC	Similar Names	Code
PREGIND	Pregnant Indicator	**Y / N / U**	Yes - subject is pregnant (self-report or test-confirmed) / No - subject is not pregnant (self-report or test-confirmed) / Unknown - Subject pregnancy status is unknown	C49488 / C49487 / C17998
PREGST	Pregnant During the Study	**Y / N / U**	Yes - subject is pregnant (self-report or test-confirmed) / No - subject is not pregnant (self-report or test-confirmed) / Unknown - Subject pregnancy status is unknown	C49488 / C49487 / C17998

RPSTRESN – Reproductive System Finding in Standard Units, Numeric Format

- **DEFINITION**: This variable contains the converted, standardized result of the reproductive system finding when the result is numeric. This column is a direct copy of the numeric values found in **RPSTRESC**. String/character-based results (e.g., "Positive") are not copied into this column.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a numeric result for the reproductive system finding (i.e., it will only be populated for records that have a numeric value in **RPSTRESC**).
  - This will be a created variable.
    - A variable will be created and will be populated with the numeric results found in **RPSTRESC**.
- **CONTROLLED TERMINOLOGY**
  - None

RPSTRESU – Reproductive System Finding Standard Units

- **DEFINITION**: This variable contains the unit for the converted, standardized result of the reproductive system finding. The IDDO-Defined Standard Units for each finding are listed below.
- **COMPLETION**:

- This variable will only be populated for records in the dataset that have a result for the reproductive system finding (i.e., it will only be populated for records that have a value in **RPORRES**).
- This will either be 1) copied verbatim from the column **RPORRESU** or 2) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Unit (UNIT)***.
  - If the raw data contains this result in the IDDO-Defined Standard Units for that reproductive system finding, the value from **RPORRESU** will be filled in verbatim.
  - If the result is not in the IDDO-Defined Standard Units for that reproductive system finding, then a variable filled in with the correct controlled terminology will be created.

- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

RPTESTCD	RPTEST	RPORRESU	RPSTRESU	Code	Conversion Formula
EGA	Estimated Gestational Age	DAYS	**WEEKS**	C29844	
EGA	Estimated Gestational Age	MONTHS	**WEEKS**	C29844	1 month = 7 weeks; 2 = 11, 3 = 15, 4 = 20, 5 = 24, 6 = 28, 7 = 33, 8 = 37, 9 = 41 ***[TO BE VERIFIED - THIS WAS USED FOR THE MiP STUDY GROUP, PER MAKOTO]***
EGA	Estimated Gestational Age	WEEKS	**WEEKS**	C29844	*n/a*

RPSTAT – Reproductive System Finding Completion Status

- **DEFINITION**: This variable contains information about the status of the reproductive system finding – specifically that it was not completed when it was expected to have been. This column should be empty when there is a value in **RPORRES**. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have no value in **RPORRES**. This could be because 1) the test was not completed or 2) the data is missing/not provided in the raw dataset.
  - This will be a created variable. Data will follow the terminology from the codelist ***Not Done (ND)***.
    - A variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

RPSTAT	Code
NOT DONE	C49484

RPREASND – Reproductive System Finding Reason Not Done

- **DEFINITION**: This variable contains information about the reason why the reproductive system finding was not completed when it was expected to have been. This column should be empty when there is a value in **RPORRES**. This is defined by IDDO Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **RPSTAT**.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) be a created variable. Data will follow the terminology from the IDDO Codelist below.
    - If the raw data contains information as to why a reproductive system finding was not completed, it will be filled in verbatim from the raw dataset.
    - If the raw data does not contain the reason why a reproductive system finding was not competed, a variable will be created and will be populated with the correct controlled terminology.

- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

RPREASND
NOT PROVIDED IN THE CONTRIBUTED DATASET

RPMETHOD – Reproductive System Finding Method of Test or Examination

- **DEFINITION**: This variable contains the method used to obtain the result of the reproductive system finding. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the applicable reproductive system findings listed below.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Method (METHOD)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all EGA measurements were recorded using last menstrual period (LMP) – data would be MENSTRUAL HISTORY), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-12-20)*

RPTESTCD	RPTEST	RPMETHOD	Similar Names	Code
EGA	Estimated Gestational Age	**BALLARD**	Ballard Score; Ballard Scale; Ballard Maturational Assessment	
EGA	Estimated Gestational Age	**DUBOWITZ**	Dubowitz Score	
EGA	Estimated Gestational Age	**FUNDAL HEIGHT**	Fundal height	
EGA	Estimated Gestational Age	**MENSTRUAL HISTORY**	Last Menstrual Period; LMP	
EGA	Estimated Gestational Age	**ULTRASOUND**	Ultrasound	C17230

VISITNUM – Visit Number

- **DEFINITION**: This variable contains a number designating the planned clinical encounter number. This is a numeric version of the visit described in **VISIT** and it is used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The clinical encounter in the study will be numbered "1" and each subsequent visit given the next sequential number. These visits are not limited to days, but rather encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given a sequential number in **VISITNUM**. See the Example Section below for more details.

- **CONTROLLED TERMINOLOGY**
  - None

VISIT – Visit Name

- **DEFINITION**: This variable contains the protocol-defined text description of the planned clinical encounter number.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. See the Example Section below for more details.

- **CONTROLLED TERMINOLOGY**
  - None

VISITDY – Planned Study Day of Visit

- **DEFINITION**: This variable contains a number designating the Study Day of the planned clinical encounter. This is also a numeric version of the visit described in **VISIT** and can be used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The planned study day of the visit will be entered. These numbers are limited to days, not the encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given the same day in **VISITDY**. See the Example Section below for more details.
  - A note on malaria data: Historically in many antimalarial clinical trials, the day the subject is enrolled and receives the first antimalarial dose has been considered "Day 0" and the first day post-dose has been considered day 1. However, in the SDTM-based domains, a Study Day of 0 is not allowed. The Planned Study Day in these types of malaria trials will be shifted by 1 for **VISITDY** in order to accommodate this timing discrepancy (e.g., "Day 0" becomes **VISITDY**=1; "Day 28" becomes **VISITDY**=29).
- **CONTROLLED TERMINOLOGY**
  - None

EPOCH – Epoch of Reproductive System Finding

- **DEFINITION**: This variable describes the Epoch period of the reproductive system finding (e.g., Baseline, Treatment, Follow-up).
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. Data will follow the terminology from the codelist ***Epoch (EPOCH)***.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

EPOCH	Description	Code
BASELINE	A period in a clinical study after eligibility has been met and before the start of treatment, at which baseline measurements are collected.	C125938
FOLLOW-UP	A period in a clinical study during which information about the health status of an individual is obtained after study interventions have concluded.	C99158
SCREENING	A period in a clinical study during which subjects are evaluated for participation in a study. [An example would be when samples are taken prior to verification of disease-positive status - this is the Screening period and once verified disease-positive they move into the Baseline period].	C48262
TREATMENT	A period in a clinical study during which subjects receive investigational product. [We include all periods and types of treatments - no division into "Blinded Treatment" or "Continuation Treatment" etc.]	C101526

RPDTC – Reproductive System Finding Date/Time of Collection

- **DEFINITION**: This variable describes the date and time of the collection of the reproductive system finding. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for reproductive system finding that provide the actual date or time of the collection. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion will not happen. This variable would be left blank and the information on "Day 3" would be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables).
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
    - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
    - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
    - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

RPDY – Reproductive System Finding Study Day of Collection

- **DEFINITION**: This variable describes the study of the collection of the reproductive system finding collection relative to the date in **RFSTDTC**. This will be blank for records with no value in in **RPDTC**. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **RPDTC**.
  - This information will be created and added to the dataset.
  - This will be calculated as per the methods described by CDISC
    - If **RPDTC** is on or after **RFSTDTC:**
      - **RPDY** = (date portion of **RPDTC**) – (date portion of **RFSTDTC**) +1
    - If **RPDTC** precedes **RFSTDTC**:
      - **RPDY** = (date portion of **RPDTC**) – (date portion of **RFSTDTC**)
- **CONTROLLED TERMINOLOGY**
  - ISO 8601 format

RPSTRTPT – Start of Reproductive System Finding Collection Relative to Reference Time Point

- **DEFINITION**: This variable describes *when* the reproductive system finding occured in reference to the point described in **RPSTTPT**.
- **COMPLETION**:
  - This variable will be populated for records in the dataset that have no value in **RPDTC** or the **VISIT** variables (i.e., there is no useable timing information and we can only represent the time of the collection in relation to a fixed point during the study).
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. Data will follow the terminology from the codelist ***Relation to Reference Period (STENRF)***.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

RPSTRTPT	Description	Code
AFTER	The reproductive system finding collection occured AFTER the period described in **RPSTTPT**.	C38008
BEFORE	The reproductive system finding collection occurred BEFORE the period described in **RPSTTPT**.	C25629

RPSTTPT – Start Reference Time Point

- **DEFINITION**: This variable describes the time point to which the *when* of the occurrence of the collection of the reproductive system finding is compared.
- **COMPLETION**:
  - This variable will be populated for records in the dataset that have no value in **RPDTC** or the **VISIT** variables (i.e., there is no useable timing information and we can only represent the time of the collection in relation to a fixed point during the study).
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available.

- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*
  - none

Trial Inclusion Exclusion Criteria (TI) Domain

Navigation Links: **Data Management** / **IDDO Repository Data Dictionary**

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Trial+Inclusion+Exclusion+Criteria

"A trial design domain that contains one record for each of the inclusion and exclusion criteria for the trial. This domain is not subject oriented. It contains all the inclusion and exclusion criteria for the trial, and thus provides information that may not be present in the subject-level data on inclusion and exclusion criteria. One record per inclusion/exclusion criterion."

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	TI	Identifier	Two-character abbreviation for the domain.	Req
IETESTCD	Incl/Excl Criterion Short Name	Char	*	Topic	Short name **IETEST**. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in **IETESTCD** cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). **IETESTCD** cannot contain characters other than letters, numbers, or underscores. The prefix "IE" is used to ensure consistency with the IE domain.	Req
IETEST	Inclusion/Exclusion Criterion	Char	*	Synonym Qualifier	Full text of the inclusion or exclusion criterion. The prefix "IE" is used to ensure consistency with the IE domain.	Req
IECAT	Inclusion/Exclusion Category	Char	(IECAT)	Grouping Qualifier	Used for categorization of the inclusion or exclusion criteria.	Req

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table. This is defined by CDISC Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**

DOMAIN

TI

IETESTCD – Incl/Excl Criterion Short Name

- **DEFINITION**: This variable contains the short name for each unique criterion of inclusion and exclusion for the study. This is defined by CDISC Terminology and will be populated according to the rules described below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - Each record will be identified as either "INCL--" or "EXCL--" as appropriate, with each record given a sequential number (e.g., a study's three inclusion criteria will be numbered "INCL01", "INCL02", and "INCL03", and its 5 exclusion criteria will be "EXCL01", "EXCL02", "EXCL03", "EXCL04", and "EXCL05").
- **CONTROLLED TERMINOLOGY**
  - INCL-- or EXCL-- as appropriate, with the -- populated with sequential two-digit numbers.

IETEST – Inclusion/Exclusion Criterion

- **DEFINITION**: This variable contains the description of each unique criterion of inclusion and exclusion for the study as provided in the protocol, publication, or other study documentation.

- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This information is pulled from study documentation (e.g., Publication, Protocol, CRF, Trial Registration).
    - There will be no effort taken to standardize this data across submissions (e.g., no effort will be made to standardize different exclusionary records of "Pregnancy", "Pregnant or breastfeeding", "Positive pregnancy test" to a single code of "PREGNANT").
- **CONTROLLED TERMINOLOGY**
  - None

IECAT – Inclusion/Exclusion Category

- **DEFINITION**: This variable contains a categorization of each unique criterion as being either inclusionary or exclusionary. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**

IECAT	Code
EXCLUSION	C25370
INCLUSION	C25532

Examples for Completion of this Domain

When data is available from the **publication**:

Study population
The study considered patients at least two years old suffering from acute, uncomplicated *Plasmodium falciparum* malaria with fever (axillary temperature ≥37.5°C) and a parasitaemia of between 1,000 and 100,000 trophozoites/µl in Senegal and 2,000 to 200,000 trophozoites/µl in Cameroon and Ivory Coast. Patients with signs of complicated malaria, severe malnutrition, repeated vomiting, intercurrent infectious disease, known allergy to the study drugs, past cardiac, hepatic or renal history or who were pregnant (positive test) or breast-feeding, were excluded.

The data described in the publication should be pulled out as discrete instances of inclusionary and exclusionary criteria and populated as illustrated in the table below.

STUDYID	DOMAIN	IETESTCD	IETEST	IECAT
ABCDE	TI	INCL01	At least 2 years old	INCLUSION
ABCDE	TI	INCL02	Parasitaemia of between 1,000 and 100,000 trophozoites/uL in Senegal and 2,000 to 200,000 trophozoites/uL in Cameroon and Ivory Coast	INCLUSION
ABCDE	TI	INCL03	Acute, uncomplicated *Plasmodium falciparum* malaria with fever (axillary temperature ≥ 37.5 C)	INCLUSION
ABCDE	TI	EXCL01	Signs of complicated malaria	EXCLUSION
ABCDE	TI	EXCL02	Severe malnutrition	EXCLUSION
ABCDE	TI	EXCL03	Repeated vomiting	EXCLUSION
ABCDE	TI	EXCL04	Intercurrent infectious disease	EXCLUSION
ABCDE	TI	EXCL05	Known allergy to the study drugs	EXCLUSION
ABCDE	TI	EXCL06	Past cardiac, hepatic or renal history	EXCLUSION
ABCDE	TI	EXCL07	Pregnant (positive test) or breast-feeding	EXCLUSION

When data is available from the **protocol**:

Inclusion Criteria	• Adults and children ≥ 6 months • Weight ≥ 7 kg for children • Participant (or parent/guardian if <18 years old) is willing and able to give written informed consent • Microscopic diagnosis of Plasmodium vivax mono-infection • Ability (in the investigators opinion) and willingness of patient or parent/guardian to comply with all study requirements
Exclusion Criteria	• Allergy to artesunate, chloroquine or primaquine • Severe malaria • Patients with microscopic diagnosis of co-infection with Plasmodium falciparum • Presence of any condition which in the judgement of the investigator would place the subject at undue risk or interfere with the results of the study • Inability to tolerate oral medication • Pregnancy • Blood transfusion in the last 3 months • Hematocrit ≤ 25%

The data listed in the protocol should be pulled out as discrete instances of inclusionary and exclusionary criteria and populated as illustrated in the table below.

STUDYID	DOMAIN	IETESTCD	IETEST	IECAT
ABCDE	TI	INCL01	Adults and children ≥ 6 months	INCLUSION
ABCDE	TI	INCL02	Weight ≥ 7 kg for children	INCLUSION
ABCDE	TI	INCL03	Participant (or parent/guardian if <18 years old) is willing and able to give written informed consent	INCLUSION
ABCDE	TI	INCL04	Microscopic diagnosis of Plasmodium vivax mono-infection	INCLUSION
ABCDE	TI	INCL05	Ability (in the investigators opinion) and willingness of patient or parent/guardian to comply with all study requirements	INCLUSION
ABCDE	TI	EXCL01	Allergy to artesunate, chloroquine or primaquine	EXCLUSION
ABCDE	TI	EXCL02	Severe malaria	EXCLUSION
ABCDE	TI	EXCL03	Patients with microscopic diagnosis of co-infection with Plasmodium falciparum	EXCLUSION
ABCDE	TI	EXCL04	Presence of any condition which in the judgement of the investigator would place the subject at undue risk or interfere with the results of the study	EXCLUSION
ABCDE	TI	EXCL05	Inability to tolerate oral medication	EXCLUSION
ABCDE	TI	EXCL06	Pregnancy	EXCLUSION
ABCDE	TI	EXCL07	Blood transfusion in the last 3 months	EXCLUSION
ABCDE	TI	EXCL08	Hematocrit ≤ 25%	EXCLUSION

When **CONFLICTING** data is available from multiple sources (Publication, Protocol, Trial Registration):

Eligibility

Key inclusion criteria	Children with an axillary temperature >37.5 degrees Centigrade or fever during the previous 24 hours with either P. falciparum (>1000 asexual parasites per microlitre whole blood) or P. vivax (>250 per microlitre) on blood smear microscopy
Minimum age	0 Years
Maximum age	5 Years
Gender	Both males and females
Can healthy volunteers participate?	No
Key exclusion criteria	Features of severity, treatment with a study drug or other antimalarial in the previous 28 days, clinical or laboratory evidence of another infection or co-morbidity including malnutrition

Patients

Children aged 0.5–5 y presenting with an axillary temperature >37.5°C or a history of fever during the previous 24 h were screened using on-site blood film microscopy. Those with *P. falciparum* (>1,000 asexual parasites/μl whole blood) or *P. vivax* (>250/μl) were eligible if (i) there were no features of severity [18], (ii) they had not taken a study drug in the previous 14 d, (iii) there was no history of allergy to study drugs, and (iv) there was no evidence of another infection or co-morbidity.

Both the conflicting criteria should be included with an indication of their origin as illustrated in the table below (INCL01 and INCL02; EXCL02 and EXCL03).

STUDYID	DOMAIN	IETESTCD	IETEST	IECAT
ABCDE	TI	INCL01	**Children 0.5-5 years (PROTOCOL & PUBLICATION)**	INCLUSION
ABCDE	TI	INCL02	**Children 0-5 years (TRIAL REGISTRATION)**	INCLUSION
ABCDE	TI	INCL03	Axillary temperature > 37.5C or fever during the previous 24 hours	INCLUSION
ABCDE	TI	INCL04	P falciparum (>1000 asexual parasites /uL whole blood) or P vivax (>250/uL)	INCLUISION
ABCDE	TI	EXCL01	Features of severity	EXCLUSION
ABCDE	TI	EXCL02	**Taken a study drug in the previous 28 days (PROTOCOL & TRIAL REGISTRATION)**	EXCLUSION
ABCDE	TI	EXCL03	**Taken a study drug in the previous 14 days (PUBLICATION)**	EXCLUSION
ABCDE	TI	EXCL04	Clinical (including anthropometric) or laboratory evidence of another infection or comorbidity including malnutrition	EXCLUSION

Trial Summary (TS) Domain

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Trial+Summary

"A trial design domain that contains one record for each trial summary characteristic. This domain is not subject oriented. The Trial Summary (TS) dataset allows the sponsor to submit a summary of the trial in a structured format. Each record in the Trial Summary dataset contains the value of a parameter, a characteristic of the trial. For example, Trial Summary is used to record basic information about the study such as trial phase, protocol title, and trial objectives. The Trial Summary dataset contains information about the planned and actual trial characteristics. One record per trial summary parameter value."

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	TS	Identifier	Two-character abbreviation for the domain.	Req
TSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset. Allows inclusion of multiple records for the same **TSPARMCD**.	Req
TSGRPID	Group ID	Char		Identifier	Used to tie together a group of related records.	Perm
TSPARMCD	Trial Summary Parameter Short Name	Char	(TSPARMCD)	Topic	**TSPARMCD** (the companion to **TSPARM**) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that **TSPARMCD** will need to serve as variable names. Examples: "AGEMIN", "AGEMAX".	Req
TSPARM	Trial Summary Parameter	Char	(TSPARM)	Synonym Qualifier	Term for the Trial Summary Parameter. The value in **TSPARM** cannot be longer than 40 characters. Examples: "Planned Minimum Age of Subjects", "Planned Maximum Age of Subjects".	Req
TSVAL	Parameter Value	Char	*	Result Qualifier	Value of **TSPARM**. Example: "ASTHMA" when **TSPARM** value is "Trial Indication". **TSVAL** can only be null when **TSVALNF** is populated. Text over 200 characters can be added to additional columns TSVAL1-TSVALn. See Assumption 8.	Exp
TSVALNF	Parameter Null Flavor	Char	ISO 21090 NullFlavor enumeration	Result Qualifier	Null flavor for the value of **TSPARM**, to be populated if and only if **TSVAL** is null.	Perm
TSVALCD	Parameter Value Code	Char	*	Result Qualifier	This is the code of the term in **TSVAL**. For example, "6CW7F3G59X" is the code for Gabapentin; "C49488" is the code for Y. The length of this variable can be longer than 8 to accommodate the length of the external terminology.	Exp
TSVCDREF	Name of the Reference Terminology	Char		Result Qualifier	The name of the Reference Terminology from which **TSVALCD** is taken. For example; CDISC, SNOMED, ISO 8601.	Exp
TSVCDVER	Version of the Reference Terminology	Char		Result Qualifier	The version number of the Reference Terminology, if applicable.	Exp

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN

TS

TSSEQ – Trial Summary Sequence Number

- **DEFINITION**: This variable is a sequence number to ensure uniqueness of trial parameters within the TS domain. Multiple instances of the same parameter (each recorded as a separate row in the table) will have a unique number. Parameters with just a single entry will all be numbered 1. If there is a parameter that has more than one value, those will be numbered sequentially (e.g., the study took place in three different countries - there would be three rows of the parameter *FCNTRY - Planned Country of Investigational Sites* and these three rows will be numbered 1-3.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - **TSSEQ** data provided in raw datasets already in SDTM format will not be included in the repository, only the IDDO-supplied **TSSEQ** number.
- **CONTROLLED TERMINOLOGY**
  - None

TSGRPID – Trial Summary Group ID

- **DEFINITION**: This variable contains an identifier that ties together a group of trial parameters records within the TS domain. These group definitions are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will only be populated for records that are part of a group of interest in the domain.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**

TSGRPID	Description
TBD	To be defined

TSPARMCD – Trial Summary Parameter Short Name

- **DEFINITION**: This variable identifies the shortened code for the name of the trial summary parameter. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-06-28)*

TSPARMCD	TSPARM	Description	Code
ACTSUB	Actual Number of Subjects	Actual number of subjects enrolled; may include subjects who were not randomized.	C98703
AEMETHD	Adverse Event Method Description	*IDDO ADDED:* A text description of the AE methodology employed for AE/symptoms in the study.	
AGEMAX	Planned Maximum Age of Subjects	The anticipated maximum age of the subjects to be entered in a clinical trial. (NCI)	C49694
AGEMIN	Planned Minimum Age of Subjects	The anticipated minimum age of the subjects to be entered in a clinical trial. (NCI)	C49693
ARMDESC	Arm Description	*IDDO ADDED:* A text description of the arm to clearly explain the treatment, regimen, frequency, etc.	
COMPTRT	Comparative Treatment Name	A therapeutically active agent that is intended to provide reference measurements for the experimental protocol of a clinical trial.	C68612
CURTRT	Current Therapy or Treatment	The literal identifier of the therapy or medication that is currently being given per protocol.	C85582
~~DOSE~~	~~Dose per Administration~~	~~The amount of drug administered to a patient or test subject at one time or the total quantity administered. [AMA Manual of Style] (CDISC Glossary)~~	~~C25488~~
~~DOSFRM~~	~~Dose Form~~	~~The pharmaceutical dosage form of the drug administered.~~	~~C42636~~
~~DOSFRQ~~	~~Dosing Frequency~~	~~The number of doses administered per a specific interval.~~	~~C89081~~
~~DOSRGM~~	~~Dose Regimen~~	~~The planned schedule for the administration of an agent (such as a drug, substance or radiation).~~	~~C71137~~
~~DOSU~~	~~Dose Units~~	~~The unit of measure for the dosage form.~~	~~C73558~~
FCNTRY	Planned Country of Investigational Sites	The country name of planned study facility which has received IRB approval.	C98770
HLTSUBJI	Healthy Subject Indicator	Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study.	C98737
INDIC	Trial Disease/Condition Indication	The condition, disease or disorder that the clinical trial is intended to investigate or address.	C112038
INTMODEL	Intervention Model	The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov)	C98746
INTTYPE	Intervention Type	The kind of product or procedure studied in a trial.	C98747
MNFCNTRY	Country of Manufacture	The name of the country within which the final product under study is produced.	C124455
MNFNAM	Manufacturer Name	*IDDO ADDED:* The name of the manufacturer of the product named in either **CMPTRT**, **CURTRT**, or **TRT**.	
MNFBRND	Manufacturer Brand Name	*IDDO ADDED:* The product name of the product named in either **CMPTRT**, **CURTRT**, or **TRT.**	
NARMS	Planned Number of Arms	The planned number of intervention groups.	C98771
NCOHORT	Number of Groups/Cohorts	The number of groups or cohorts that are part of the study.	C126063
COHODESC	Description of Groups/Cohorts	*IDDO ADDED:* A text description of the groups or cohorts to clearly explain what they contain and how they were selected	
OBSMODEL	Observational Model	The trial design developed to compare biomedical and/or health outcomes in pre-defined and non-assigned groups of individuals.	C126064
OBSTIMP	Observational Time Perspective	The temporal relationship between the observation period and time of subject enrollment. (ClinicalTrials.gov)	C126065
OBSTPOPD	Obs Study Population Description	A description of the population from which the groups or cohorts will be selected within an observational study.	C126066
OBSTSMM	Observational Study Sampling Method	The sampling method used to assign study participants into groups or cohorts within an observational study.	C126067
OBSTSMMD	Obs Study Sampling Method Description	A textual description of the sampling method used to assign study participants into groups or cohorts within an observational study.	C126068
PLANSUB	Planned Number of Subjects	The planned number of subjects to be entered in a clinical trial. (NCI)	C49692
PLNTRDUR	Planned Trial Duration	The approximate period of time over which the clinical trial is expected to occur.	C127796
PTRTDUR	Planned Treatment Duration	The period of time during which the treatment is intended to be given.	C139276
PUBMEDID	PubMed ID for Citation Used in Study	A globally unique identifier for a biomedical article, as assigned by PubMed.	C127797
RANDOM	Trial is Randomized	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. NOTE: Unequal randomization is used to allocate subjects into groups at a differential rate; for example, three subjects may be assigned to a treatment group for every one assigned to the control group. [ICH E6 1.48] See also balanced study. (CDISC glossary)	C25196
RANDDESC	Randomization Description	*IDDO ADDED:* A text description of the method used to randomize subjects in the study	
RANDQT	Randomization Quotient	The randomization quotient is the number of planned subjects to be exposed to investigational therapy, independent of dose or other factors, divided by the total number of planned subjects.	C98775
REGID	Registry Identifier	Identification numbers assigned to the protocol by clinicaltrials.gov, EudraCT, or other registries.	C98714
ROUTE	Route of Administration	The course by which a substance is administered in order to reach the site of action in the body.	C38114
SENDTC	Study End Date	The date on which the final data item for a clinical study was collected from the last study participant (that is, last subject, last visit, or as otherwise defined in the study protocol). (CDISC Glossary)	C90462
SEXPOP	Sex of Participants	The specific sex, either male, female, or mixed of the subject group being studied. (NCI)	C49696
SSTDTC	Study Start Date	The earliest date of informed consent among any subject (Date/Time of Informed Consent, **RFICDTC**) that enrolled in the study. For studies conducted without informed consent (ie. emergency use) use the date of treatment. Dates for subjects who were screen failures are not included.	C69208
STRATFCT	Stratification Factor	Selected factors that are used during randomization to ensure there is balance of these factors across all subjects within each arm of a study. The subject level values of these factors may be used as fixed effects in statistical models and for sensitivity analyses.	C16153
STRADESC	Stratification Description	*IDDO ADDED:* A text description of the methods used to stratify subjects in arms	
STYPE	Study Type	Describes the role the study plays in determining the interventions a subject receives.	C142175
TBLIND	Trial Blinding Schema	The type of experimental design used to describe the level of awareness of the clinical trial subjects and/or investigators of the intervention(s) that they are receiving and/or administering.	C49658
TBLNDESC	Trial Blinding Description	*IDDO ADDED:* A text description of any further blinding that occured in the study (beyond what is described in **TBLIND**).	
TCNTRL	Control Type	Comparator against which the study treatment is evaluated.	C49647
TDIGRP	Diagnosis Group	A grouping of individuals on the basis of a shared procedure or disease, or lack thereof.	C49650
TINDTP	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	C49652

TITLE	Trial Title	The name of a clinical trial. (NCI)	C49802
TPHASE	Trial Phase Classification	Any defined stage in the lifecycle of a clinical trial.	C48281
TRGFUDUR	Target Follow-Up Duration	The anticipated time period over which each study participant is to be followed. (ClinicalTrials.gov)	C126077
TRT	Investigational Therapy or Treatment	The investigational product under study.	C41161
TTYPE	Trial Type	The type of primary outcome or endpoint that the protocol is designed to evaluate. (clinicaltrials.gov)	C49660

TSPARM – Trial Summary Parameter Name

- **DEFINITION**: This variable identifies the name of the trial summary parameter. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2019-06-28)*

TSPARMCD	TSPARM	Description	Code
ACTSUB	**Actual Number of Subjects**	Actual number of subjects enrolled; may include subjects who were not randomized.	C98703
AEMETHD	**Adverse Event Method Description**	*IDDO ADDED:* A text description of the AE methodology employed for the collection of AE/symptom data in the study.	
AGEMAX	**Planned Maximum Age of Subjects**	The anticipated maximum age of the subjects to be entered in a clinical trial. (NCI)	C49694
AGEMIN	**Planned Minimum Age of Subjects**	The anticipated minimum age of the subjects to be entered in a clinical trial. (NCI)	C49693
ARMDESC	**Arm Description**	*IDDO ADDED:* A text description of the arm to clearly explain the treatment, regimen, frequency, etc.	
COMPTRT	**Comparative Treatment Name**	A therapeutically active agent that is intended to provide reference measurements for the experimental protocol of a clinical trial.	C68612
CURTRT	**Current Therapy or Treatment**	The literal identifier of the therapy or medication that is currently being given per protocol.	C85582
~~DOSE~~	~~Dose per Administration~~	~~The amount of drug administered to a patient or test subject at one time or the total quantity administered. [AMA Manual of Style] (CDISC Glossary)~~	~~C25488~~
~~DOSFRM~~	~~Dose Form~~	~~The pharmaceutical dosage form of the drug administered.~~	~~C42636~~
~~DOSFRQ~~	~~Dosing Frequency~~	~~The number of doses administered per a specific interval.~~	~~C89081~~
~~DOSRGM~~	~~Dose Regimen~~	~~The planned schedule for the administration of an agent (such as a drug, substance or radiation).~~	~~C71137~~
~~DOSU~~	~~Dose Units~~	~~The unit of measure for the dosage form.~~	~~C73558~~
FCNTRY	**Planned Country of Investigational Sites**	The country name of planned study facility which has received IRB approval.	C98770
HLTSUBJI	**Healthy Subject Indicator**	Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study.	C98737
INDIC	**Trial Disease/Condition Indication**	The condition, disease or disorder that the clinical trial is intended to investigate or address.	C112038
INTMODEL	**Intervention Model**	The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov)	C98746
INTTYPE	**Intervention Type**	The kind of product or procedure studied in a trial.	C98747
MNFCNTRY	**Country of Manufacture**	The name of the country within which the final product under study is produced.	C124455
MNFNAM	**Manufacturer Name**	*IDDO ADDED:* The name of the manufacturer of the product named in either **CMPTRT**, **CURTRT**, or **TRT**.	
MNFBRND	**Manufacturer Brand Name**	*IDDO ADDED:* The product name of the product named in either **CMPTRT**, **CURTRT**, or **TRT**.	
NARMS	**Planned Number of Arms**	The planned number of intervention groups.	C98771
NCOHORT	**Number of Groups/Cohorts**	The number of groups or cohorts that are part of the study.	C126063
COHODESC	**Description of Groups/Cohorts**	*IDDO ADDED:* A text description of the groups or cohorts to clearly explain what they contain and how they were selected	
OBSMODEL	**Observational Model**	The trial design developed to compare biomedical and/or health outcomes in pre-defined and non-assigned groups of individuals.	C126064
OBSTIMP	**Observational Time Perspective**	The temporal relationship between the observation period and time of subject enrollment. (ClinicalTrials.gov)	C126065
OBSTPOPD	**Obs Study Population Description**	A description of the population from which the groups or cohorts will be selected within an observational study.	C126066
OBSTSMM	**Observational Study Sampling Method**	The sampling method used to assign study participants into groups or cohorts within an observational study.	C126067
OBSTSMMD	**Obs Study Sampling Method Description**	A textual description of the sampling method used to assign study participants into groups or cohorts within an observational study.	C126068
PLANSUB	**Planned Number of Subjects**	The planned number of subjects to be entered in a clinical trial. (NCI)	C49692
PLNTRDUR	**Planned Trial Duration**	The approximate period of time over which the clinical trial is expected to occur.	C127796
PTRTDUR	**Planned Treatment Duration**	The period of time during which the treatment is intended to be given.	C139276
PUBMEDID	**PubMed ID for Citation Used in Study**	A globally unique identifier for a biomedical article, as assigned by PubMed.	C127797
RANDOM	**Trial is Randomized**	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. NOTE: Unequal randomization is used to allocate subjects into groups at a differential rate; for example, three subjects may be assigned to a treatment group for every one assigned to the control group. [ICH E6 1.48] See also balanced study. (CDISC glossary)	C25196
RANDDESC	**Randomization Description**	*IDDO ADDED:* A text description of the method used to randomize subjects in the study	
RANDQT	**Randomization Quotient**	The randomization quotient is the number of planned subjects to be exposed to investigational therapy, independent of dose or other factors, divided by the total number of planned subjects.	C98775
REGID	**Registry Identifier**	Identification numbers assigned to the protocol by clinicaltrials.gov, EudraCT, or other registries.	C98714
ROUTE	**Route of Administration**	The course by which a substance is administered in order to reach the site of action in the body.	C38114
SENDTC	**Study End Date**	The date on which the final data item for a clinical study was collected from the last study participant (that is, last subject, last visit, or as otherwise defined in the study protocol). (CDISC Glossary)	C90462
SEXPOP	**Sex of Participants**	The specific sex, either male, female, or mixed of the subject group being studied. (NCI)	C49696
SSTDTC	**Study Start Date**	The earliest date of informed consent among any subject (Date/Time of Informed Consent, **RFICDTC**) that enrolled in the study. For studies conducted without informed consent (ie. emergency use) use the date of treatment. Dates for subjects who were screen failures are not included.	C69208
STRATFCT	**Stratification Factor**	Selected factors that are used during randomization to ensure there is balance of these factors across all subjects within each arm of a study. The subject level values of these factors may be used as fixed effects in statistical models and for sensitivity analyses.	C16153
STRDESC	**Stratification Description**	IDDO ADDED: A text description of the methods used to stratify subjects in arms	
STYPE	**Study Type**	Describes the role the study plays in determining the interventions a subject receives.	C142175
TBLIND	**Trial Blinding Schema**	The type of experimental design used to describe the level of awareness of the clinical trial subjects and/or investigators of the intervention(s) that they are receiving and/or administering.	C49658

TCNTRL	**Control Type**	Comparator against which the study treatment is evaluated.	C49647
TDIGRP	**Diagnosis Group**	A grouping of individuals on the basis of a shared procedure or disease, or lack thereof.	C49650
TINDTP	**Trial Intent Type**	The planned purpose of the therapy, device, or agent under study in the clinical trial.	C49652
TITLE	**Trial Title**	The name of a clinical trial. (NCI)	C49802
TPHASE	**Trial Phase Classification**	Any defined stage in the lifecycle of a clinical trial.	C48281
TRGFUDUR	**Target Follow-Up Duration**	The anticipated time period over which each study participant is to be followed. (ClinicalTrials.gov)	C126077
TRT	**Investigational Therapy or Treatment**	The investigational product under study.	C41161
TTYPE	**Trial Type**	The type of primary outcome or endpoint that the protocol is designed to evaluate. (clinicaltrials.gov)	C49660

TSVAL – Trial Summary Parameter Value

- **DEFINITION**: This variable contains the value for the trial summary parameter. The data can be either numeric (e.g., "503") or string (e.g., "Positive") and is stored as a string in the repository. There is limited CDISC Controlled Terminology for some parameters and this is listed in the detailed TS Parameter Completion Examples section below.
- **COMPLETION**:
  - This variable will be populated for all records that have a non-null flavor result (i.e., it will only be NULL for records that have a value in **TSVALNF**).
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**
  - See the TS Parameter Completion Examples section

TSVALNF - Trial Summary Parameter Null Flavor

- **DEFINITION**: This variable contains the null flavor result for the value for the trial summary parameter (a value that provides additional coded information when **TSVAL** is null). This is defined by ISO 21090 NullFlavor Enumeration terminology.
- **COMPLETION**:
  - This variable will be populated for all records that have no result for **TSVAL**.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(ISO 21090 NullFlavor Enumeration)*

TSVALNF	Name	Description
PINF	Positive Infinity	Positive Infinity of Numbers
NINF	Negative Infinity	Negative Infinity of Numbers
UNK	Unknown	A proper value is applicable, but not known.
NA	Not Applicable	No proper value is applicable in this context (e.g., last menstrual period for a male).

TSVALCD - Trial Summary Parameter Value Code

- **DEFINITION**: This variable contains the code (if applicable) for the term found in **TSVAL**. This value can be found in the appropriate code list, be it SNOMED or CDISC Controlled Terminology. The codes for controlled terminology for the applicable parameters is listed in the detailed TS Parameter Completion Examples section below.
- **COMPLETION**:
  - This variable will be populated for all records that have a code for the controlled terminology applied to **TSVAL**.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**
  - See the TS Parameter Completion Examples section

TSVCDREF - Trial Summary Parameter Code Name of Reference Terminology

- **DEFINITION**: This variable contains the name of the Reference Terminology from which **TSVALCD** is taken. Examples include CDISC, SNOMED, ISO 8601, etc. The names of the reference terminology for the values of **TSVALCD** are included in the detailed TS Parameter Completion Examples section below.
- **COMPLETION**:
  - This variable will be populated for all records with a value in **TSVALCD.**
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**
  - See the TS Parameter Completion Examples section

TSVCDVER - Trial Summary Parameter Code Version of Reference Terminology

- **DEFINITION:** This variable contains the version of the Reference Terminology named in **TSVCDREF** (if applicable). The versions of the reference terminology for the values of **TSVALCD** are included in the detailed TS Parameter Completion Examples section below.
- **COMPLETION**
  - This variable will be populated for all applicable records with a value in **TSVCDREF**.
  - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY**
  - See the TS Parameter Completion Examples section

Examples for Completion of this Domain

NOTE: Some tables are truncated for space and do not contain all the required variables for the domain.

- Completion of the **TSSEQ** variable
  - When there is a single value for each parameter. Note that every row is numbered "1" in **TSSEQ**:

TSSEQ	TSPARMCD	TSPARM	TSVAL
1	AGEMAX	Planned Maximum Age of Participants	P65Y
1	AGEMIN	Planned Minimum Age of Participants	P2Y
1	HLTSUBJI	Healthy Subject Indicator	N
1	INDIC	Trial Disease/Condition Indication	MALARIA

1	INTMODEL	Intervention Model	SINGLE GROUP

- Completion of the **TSSEQ** variable
  - When there are multiple values for some parameters. Note that every parameter with a single value is numbered "1" in **TSSEQ**. Parameters with multiple values (e.g., TRT) are numbered sequentially:

TSSEQ	TSPARMCD	TSPARM	TSVAL
1	STYPE	Study Type	INTERVENTIONAL
1	TTYPE	Trial Type	EFFICACY
2	TTYPE	Trial Type	TOLERABILITY
1	PLANSUB	Planned Number of Subjects	400
1	TRT	Investigational Therapy or Treatment	AL
2	TRT	Investigational Therapy or Treatment	DPT
3	TRT	Investigational Therapy or Treatment	PQ

TS Parameter Completion Examples

NOTE: Multiple examples of how to complete the parameter may be contained in the same table for space and is not indicative of a "real" TS Domain table.

AGEMAX - Planned Maximum Age of Subjects: This is the planned maximum age of subjects to be enrolled in the trial.

This parameter should be included in all TS datasets.

This should only be completed with the planned age of subjects, as defined in a protocol or trial registration.

This should not be populated with the actual maximum age of the subjects found in the contributed dataset.

This information is recorded in ISO 8601 format - following the form "P+number+unit". Units are as follows: Years = Y, Months = M, Weeks = W, Days = D.

For example, a maximum age of 18 months would be "P18M" and a maximum age of 65 years would be "P65Y".

Studies with no defined maximum age (e.g., "participants had to be at least 18 years old") will have no value under **TSVAL** and will have **TSVALNF** populated with "PINF" to indicate there is no upper limit. Since there is no value in **TSVAL**, there is no value needed for **TSVALCD**, **TSVCDREF**, or **TSVCDVER**.

Studies with no information available about planned maximum age will have **TSVALNF** populated with "UNK" to indicate the value is unknown.

Studies with vague age ranges (e.g., "Adult males") will also have **TSVALNF** populated with "UNK" since we don't know what the study's definiton of "adult" was.

Raw Value	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
18 months	AGEMAX	Planned Maximum Age of Subjects	P18M			ISO 8601	
65 years	AGEMAX	Planned Maximum Age of Subjects	P65Y			ISO 8601	
no max age limit	AGEMAX	Planned Maximum Age of Subjects		PINF			
max age unknown; unclear maximum like "adults"	AGEMAX	Planned Maximum Age of Subjects		UNK			

AGEMIN - Planned Minimum Age of Subjects: This is the planned minimum age of subjects to be enrolled in the trial.

This parameter should be included in all TS datasets.

This should only be completed with the planned age of subjects, as defined in a protocol or trial registration.

This should not be populated with the actual minimum age of the subjects found in the contributed dataset.

This information is recorded in ISO 8601 format - following the form "P+number+unit". Units are as follows: Years = Y, Months = M, Weeks = W, Days = D.

For example, a minimum age of 6 months would be "P6M" and a minimum age of 18 years would be "P18Y".

Studies with no defined minimum age (e.g., "participants had to be under 6 years old") will have "P0Y" populated into **TSVAL.**

Studies with no information available about planned minimum age will have **TSVALNF** populated with "UNK" to indicate the value is unknown.

Studies with vague age ranges (e.g., "Adult males") will also have **TSVALNF** populated with "UNK" since we don't know what the study's definiton of "adult" was.

Raw Value	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
6 months	AGEMIN	Planned Minimum Age of Subjects	P6M			ISO 8601	
18 years	AGEMIN	Planned Minimum Age of Subjects	P18Y			ISO 8601	
no min age limit	AGEMIN	Planned Minimum Age of Subjects	P0Y			ISO 8601	
min age unknown; unclear minimum like "adults"	AGEMIN	Planned Minimum Age of Subjects		UNK			

COMPTRT - Comparative Treatment Name: This is the therapeutically active agent that is intended to provide reference measurements for the experimental protocol of a clinical trial.

This parameter should be included only for submissions which included active comparators (i.e., those with a value of "ACTIVE" for the *TCNTRL - Control Type* parameter).

There should be a row for each applicable drug/agent.

This information is recorded using the Unique Ingredient Identifier (UNII) codelist, which can be found here: https://fdasis.nlm.nih.gov/srs/

Commonly encountered agents are recorded below for ease of reference:

Raw Value	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
Common Malaria Drugs							
Amodiaquine; AQ; ASAQ [(Artesunate)+Amodiaquine]	COMPTRT	Comparative Treatment Name	AMODIAQUINE		220236ED28	UNII	
Artemether; AL [Artemether+(Lumefantrine)]; Coartem	COMPTRT	Comparative Treatment Name	ARTEMETHER		C7D6T3H22J	UNII	
Artemisinin	COMPTRT	Comparative Treatment Name	ARTEMISININ		9RMU91N5K2	UNII	
Dihydroartemisinin; DHA; DHAPPQ [Dihydroartemisinin+(Piperaquine)]; Eurartesim	COMPTRT	Comparative Treatment Name	ARTENIMOL		6A9O50735X	UNII	

Artesunate; ASAQ [Artesunate+(Amodiaquine)]; ASMQ [Artesunate+(Mefloquine)]; Pyramax [Artesunate+(Pyronaridine)]	COMPTRT	Comparative Treatment Name	ARTESUNATE		60W3249T9M	UNII	
Atovaquone	COMPTRT	Comparative Treatment Name	ATOVAQUONE		Y883P1Z2LT	UNII	
Azithromycin	COMPTRT	Comparative Treatment Name	AZITHROMYCIN, UNSPECIFIED FORM		F94OW58Y8V	UNII	
Chloroquine	COMPTRT	Comparative Treatment Name	CHLOROQUINE		886U3H6UFF	UNII	
Chlorproguanil	COMPTRT	Comparative Treatment Name	CHLORPROGUANIL		8O3249M729	UNII	
Clindamycin	COMPTRT	Comparative Treatment Name	CLINDAMYCIN		3U02EL437C	UNII	
Dapsone	COMPTRT	Comparative Treatment Name	DAPSONE		8W5C518302	UNII	
Doxycycline	COMPTRT	Comparative Treatment Name	DOXYCYCLINE		N12000U13O	UNII	
Halofantrine	COMPTRT	Comparative Treatment Name	HALOFANTRINE		Q2OS4303HZ	UNII	
Ivermectin	COMPTRT	Comparative Treatment Name	IVERMECTIN		8883YP2R6D	UNII	
Lumefantrine; AL [(Artemether)+Lumefantrine]; Coartem	COMPTRT	Comparative Treatment Name	LUMEFANTRINE		F38R0JR742	UNII	
Mefloquine; MQ; ASMQ [(Artesunate)+Mefloquine]	COMPTRT	Comparative Treatment Name	MEFLOQUINE		TML814419R	UNII	
Methylene Blue	COMPTRT	Comparative Treatment Name	METHYLENE BLUE		T42P99266K	UNII	
Naphthoquine	COMPTRT	Comparative Treatment Name	NAPHTHOQUINE		TRY8UD4E2H	UNII	
Piperaquine; PPQ; DHAPPQ [(Dihydroartemisinin)+Piperaquine]; Eurartesim	COMPTRT	Comparative Treatment Name	PIPERAQUINE		A0HV2Q956Y	UNII	
Primaquine; PQ	COMPTRT	Comparative Treatment Name	PRIMAQUINE		MVR3634GX1	UNII	
Proguanil	COMPTRT	Comparative Treatment Name	PROGUANIL		S61K3P7B2V	UNII	
Pyrimethamine; SP [(Sulfadoxine)+Pyrimethamine]	COMPTRT	Comparative Treatment Name	PYRIMETHAMINE		Z3614QOX8W	UNII	
Pyronaridine; Pyramax [(Artesunate)+Pyronaridine]	COMPTRT	Comparative Treatment Name	PYRONARIDINE		TD3P7Q3SG6	UNII	
Quinine	COMPTRT	Comparative Treatment Name	QUININE		A7V27PHC7A	UNII	
Sufadoxine; Sulphadoxine; SP [Sulfadoxine+(Pyrimethamine)]	COMPTRT	Comparative Treatment Name	SULFADOXINE		88463U4SM5	UNII	
Sulfamethoxypyrazine	COMPTRT	Comparative Treatment Name	SULFALENE		T6BL4ZC15G	UNII	
Tafenoquine	COMPTRT	Comparative Treatment Name	TAFENOQUINE		262P8GS9L9	UNII	
Tetracycline	COMPTRT	Comparative Treatment Name	TETRACYCLINE		F8VB5M810T	UNII	
Trimethoprim	COMPTRT	Comparative Treatment Name	TRIMETHOPRIM		AN164J8Y0X	UNII	
Common VL Drugs							
Allopurinol	COMPTRT	Comparative Treatment Name	ALLOPURINOL		63CZ7GJN5I	UNII	
AmBisome; Amphotericin B deoxycholate; Amphotericin B colloidal dispersion; Amphotericin B lipid emulsion; Amphotericin B lipid complex; Liposomal Amphotericin B	COMPTRT	Comparative Treatment Name	AMPHOTERICIN B		7XU7A7DROE	UNII	
Fluconazole	COMPTRT	Comparative Treatment Name	FLUCONAZOLE		8VZV102JFY	UNII	
Ketoconazole	COMPTRT	Comparative Treatment Name	KETOCONAZOLE		R9400W927I	UNII	
Meglumine antimoniate	COMPTRT	Comparative Treatment Name	MEGLUMINE ANTIMONIATE		75G4TW236W	UNII	
Miltefosine	COMPTRT	Comparative Treatment Name	MILTEFOSINE		53EY29W7EC	UNII	
Paromycin; Aminosidine	COMPTRT	Comparative Treatment Name	PAROMOMYCIN		61JJC8N5ZK	UNII	
Paromycin sulphate	COMPTRT	Comparative Treatment Name	PAROMOMYCIN SULFATE		845NU6GJPS	UNII	
Pentamidine	COMPTRT	Comparative Treatment Name	PENTAMIDINE		673LC5J4LQ	UNII	
Pentamidine isethionate	COMPTRT	Comparative Treatment Name	PENTAMIDINE ISETHIONATE		V2P3K60DA2	UNII	
Roxithromycin	COMPTRT	Comparative Treatment Name	ROXITHROMYCIN		21KOF230FA	UNII	
Sitamaquine	COMPTRT	Comparative Treatment Name	SITAMAQUINE		5AIJ4TGC6B	UNII	
Sodium stibogluconate	COMPTRT	Comparative Treatment Name	SODIUM STIBOGLUCONATE ANHYDROUS		V083S0159D	UNII	
Common SCH/STH Drugs							
Albendazole	COMPTRT	Comparative Treatment Name	ALBENDAZOLE		F4216019LN	UNII	
Praziquantel	COMPTRT	Comparative Treatment Name	PRAZIQUANTEL		6490C9U457	UNII	

FCNTRY - Planned Country of Investigational Sites: This is the name of all countries containing study sites for the contributed dataset.

This parameter should be included in all TS datasets.

This parameter will have as many rows as needed to encompass all unique countries.

This information is recorded using the ISO 3166-1 alpha-3 codelist, which can be found here: https://www.iso.org/iso-3166-country-codes.html (click on Online Browsing Platform under the question "How can I access ISO 3166?")

Commonly encountered countries are recorded below for ease of reference:

Other Names	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
	FCNTRY	Planned Country of Investigational Sites	Brazil		BRA	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Burkina Faso		BFA	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Cambodia		KHM	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Canada		CAN	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	China		CHN	ISO 3166	
Ivory Coast	FCNTRY	Planned Country of Investigational Sites	Côte d'Ivoire		CIV	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Egypt		EGY	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	France		FRA	ISO 3166	

	FCNTRY	Planned Country of Investigational Sites	Guadeloupe		GLP	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Guinea		GIN	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	India		IND	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Indonesia		IDN	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Italy		ITA	ISO 3166	
South Korea	FCNTRY	Planned Country of Investigational Sites	Korea (the Republic of)		KOR	ISO 3166	
Laos	FCNTRY	Planned Country of Investigational Sites	Lao People's Democratic Republic (the)		LAO	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Liberia		LBR	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Mexico		MEX	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Niger (the)		NER	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Nigeria		NGA	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Pakistan		PAK	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Papua New Guinea		PNG	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Peru		PER	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Sierra Leone		SLE	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Solomon Islands		SLB	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	South Africa		ZAF	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Sudan (the)		SDN	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Switzerland		CHE	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Thailand		THA	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Uganda		UGA	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Vanuatu		VUT	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Venezuela (Bolivarian Republic of)		VEN	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Viet Nam		VNM	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Zambia		ZMB	ISO 3166	
	FCNTRY	Planned Country of Investigational Sites	Zimbabwe		ZWE	ISO 3166	

HLTSUBJI - Healthy Subject Indicator: This identifies if healthy subjects (i.e., those who do not have the condition being studied) may participate in the study.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *No Yes Response (NY)* Codelist.

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
Healthy subjects are NOT permitted	HLTSUBJI	Healthy Subject Indicator	N		C49487	CDISC	2019-06-28
Healthy subjects status unknown	HLTSUBJI	Healthy Subject Indicator	U		C17998	CDISC	2019-06-28
Healthy subjects may participate	HLTSUBJI	Healthy Subject Indicator	Y		C49488	CDISC	2019-06-28

INDIC - Trial Disease/Condition Indication: This is condition, disease, or disorder the clinical trial is intended to investigate in the study population in the contributed dataset.

This parameter should be included in all TS datasets with the exception of those focusing only on Healthy Subjects (i.e., those containing a "Y" in the parameter *HLTSUBJI - Healthy Subject Indicator* and not having any other groups).

This parameter will have as many rows as needed to encompass all the unique conditions.

This information is recorded using the Systematized Nomenclature of Medicine (SNOMED) codelist, which can be found here: https://ncit.nci.nih.gov/ncitbrowser/pages/multiple_search.jsf?nav_type=terminologies

Commonly encountered diagnosis groups are recorded below for ease of reference:

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
Ebola Virus Disease							
Ebola; EVD; Ebola hemorrhagic fever; Viral hemorrhagic fever, Ebola	INDIC	Trial Disease/Condition Indication	Ebola virus disease		37109004	SNOMED	2018_09_01
Malaria							
malaria (no more details available)	INDIC	Trial Disease/Condition Indication	Malaria		61462000	SNOMED	2018_09_01
pf malaria; falciparum	INDIC	Trial Disease/Condition Indication	Falciparum malaria		62676009	SNOMED	2018_09_01
pv malaria; vivax	INDIC	Trial Disease/Condition Indication	Vivax malaria		27052006	SNOMED	2018_09_01
po malaria; ovale	INDIC	Trial Disease/Condition Indication	Ovale malaria		19341001	SNOMED	2018_09_01
pm malaria; malariae	INDIC	Trial Disease/Condition Indication	Quartan malaria		27618009	SNOMED	2018_09_01
pk malaria; knowlesi	INDIC	Trial Disease/Condition Indication	Malaria due to simian plasmodia		186795000	SNOMED	2018_09_01
mixed malaria; mixed infection	INDIC	Trial Disease/Condition Indication	Mixed malaria		21070001	SNOMED	2018_09_01
human challenge malaria; healthy volunteer malaria infection	INDIC	Trial Disease/Condition Indication	Therapeutically induced malaria		69668008	SNOMED	2018_09_01
malaria in pregnancy; MiP	INDIC	Trial Disease/Condition Indication	Maternal malaria during pregnancy, childbirth and the puerperium		199183007	SNOMED	2018_09_01
Leishmaniasis							
leishmaniasis (no more details available)	INDIC	Trial Disease/Condition Indication	Leishmaniasis		80612004	SNOMED	2018_09_01

visceral leishmaniasis, kala-azar	INDIC	Trial Disease/Condition Indication	Visceral leishmaniasis		186803007	SNOMED	2018_09_01
PKDL	INDIC	Trial Disease/Condition Indication	Post-kala-azar dermal leishmaniasis		67896006	SNOMED	2018_09_01
Soilt-trasmitted Helminthiasis and Schistosomiasis							
Schistosoma mansoni, s. mansoni	INDIC	Trial Disease/Condition Indication	Schistosoma mansoni infection		750009	SNOMED	2018_09_01
Schistosoma haematobium, s. haematobium	INDIC	Trial Disease/Condition Indication	Schistosoma haematobium infection		60979006	SNOMED	2018_09_01
Schistosomiasis (no more details available)	INDIC	Trial Disease/Condition Indication	Infection by Schistosoma		10087007	SNOMED	2018_09_01
Strongyloides stercoralis, s. stercoralis	INDIC	Trial Disease/Condition Indication	Infection by Strongyloides stercoralis		17425008	SNOMED	2019_03_01
Strongyloides (no more details available)	INDIC	Trial Disease/Condition Indication	Infection by Strongyloides		1214006	SNOMED	2019_03_01
Hookworm infection	INDIC	Trial Disease/Condition Indication	Disease due to superfamily Ancylostomatoidea		105694003	SNOMED	2019_03_01
Infection by Trichuris; Trichuriasis - Whipworm; Whipworm infection (no more details available)	INDIC	Trial Disease/Condition Indication	Trichuriasis		3752003	SNOMED	2019_03_01
Infection by Trichuris trichiura	INDIC	Trial Disease/Condition Indication	Infection by Trichuris trichiura		60570001	SNOMED	2019_03_01
Ascariasis - roundworms; Ascaridiasis; Ascriosis; Roundworm infection (no more details available)	INDIC	Trial Disease/Condition Indication	Ascariasis		2435008	SNOMED	2019_03_01
Infection by Ascaris lumbricoides	INDIC	Trial Disease/Condition Indication	Infection by Ascaris lumbricoides		50982003	SNOMED	2019_03_01
Others							
Scabies	INDIC	Trial Disease/Condition Indication	Infestation by Sarcoptes scabiei var hominis		128869009	SNOMED	2019_03_01
Phthiriasis palpebrarum; pubic lice; Phtirus pubis	INDIC	Trial Disease/Condition Indication	Infestation by Phthirus pubis		71011005	SNOMED	2019_03_01
Tapeworms; Taeniasis; Teniasis; Taeniosis	INDIC	Trial Disease/Condition Indication	Infection by Taenia		76172008	SNOMED	2019_03_01
Cutaneous larva migrans; CLM	INDIC	Trial Disease/Condition Indication	Cutaneous larva migrans		19362000	SNOMED	2019_03_01

INTMODEL - Intervention Model: This describes the strategy for assigning interventions to participants in the study.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Intervention Model Response (INTMODEL)* Codelist.

Commonly encountered models are recorded below for ease of reference:

Raw Value	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
Participants are assigned to 1 of two or more treatment groups	INTMODEL	Intervention Model	PARALLEL		C82639	CDISC	2019-06-28
All participants are assigned to a single treatment group	INTMODEL	Intervention Model	SINGLE GROUP		C82640	CDISC	2019-06-28
Intervention model is unknown	INTMODEL	Intervention Model		UNK			
The study is not interventional, so this parameter is not applicable	INTMODEL	Intervention Model		NA			

INTTYPE - Intervention Type: This describes the kind of product or procedure being studied in the trial.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Intervention Type Response (INTTYPE)* Codelist.

Commonly encountered types are recorded below for ease of reference:

Raw Value	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
A pharmacological substance (drug) for the treatment of disease	INTTYPE	Intervention Type	DRUG		C1909	CDISC	2019-06-28
The intervention type is applicable, but unknown	INTTYPE	Intervention Type		UNK			
The study is not interventional, so this parameter is not applicable	INTTYPE	Intervention Type		NA			

OBSMODEL - Observational Model: This describes the trial design developed to compare biomedical and/or health outcomes in pre-defined and non-assigned groups of individuals.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Observational Study Model (OBSSMO)* Codelist.

Commonly encountered types are recorded below for ease of reference:

Raw Value	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
A study that compares groups of people with generally similar characteristics, those with the condition under study (case) and those without the condition under study (control).	OBSMODEL	Observational Model	CASE CONTROL		C15197	CDISC	2019_12_20
A study in which subjects are grouped based on a predefined personal or administrative characteristic.	OBSMODEL	Observational Model	COHORT		C15208	CDISC	2019_12_20
The observational model type is applicable, but unknown	OBSMODEL	Observational Model		UNK			
The study is not observational, so this parameter is not applicable	OBSMODEL	Observational Model		NA			

OBSTIMP - Observational Time Perspective: This describes the relationship between the observation period of the trial and the time of subject enrollment in the trial.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Observational Study Time Perspective (OBSSTP)* Codelist.

Commonly encountered types are recorded below for ease of reference:

Raw Value	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
Studies in which observations or measurements made at a single point in time, usually at subject enrollment.	OBSTIMP	Observational Time Perspective	CROSS SECTIONAL		C53310	CDISC	2019_12_20

Studies that look forward using periodic observations collected predominantly following subject enrollment.	OBSTIMP	Observational Time Perspective	PROSPECTIVE		C15273	CDISC	2019_12_20
Studies that look back using observations collected predominantly prior to subject selection and enrollment.	OBSTIMP	Observational Time Perspective	RETROSPECTIVE		C53312	CDISC	2019_12_20
The observational time perspective is applicable, but unknown	OBSTIMP	Observational Time Perspective		UNK			
The study is not observational, so this parameter is not applicable	OBSTIMP	Observational Time Perspective		NA			

OBSTSMM - Observational Study Sampling Method: This describes the sampling method used to assign study participants into groups or cohorts within an observational study.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Observational Study Sampling Method (OBSSSM)* Codelist.

Commonly encountered types are recorded below for ease of reference:

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
A non-random process used to select a study population in which the participants have been selected based on convenience or with a particular purpose in mind.	OBSTSMM	Observational Study Sampling Method	NON-PROBABILITY SAMPLE		C127781	CDISC	2019_12_20
An exclusively random process to guarantee that each participant or population has specified chance of selection, such as simple random sampling, systematic sampling, stratified random sampling, cluster sampling, and consecutive patient sampling.	OBSTSMM	Observational Study Sampling Method	PROBABILITY SAMPLE		C71517	CDISC	2019_12_20
The observational sampling method is applicable, but unknown	OBSTSMM	Observational Study Sampling Method		UNK			
The study is not observational, so this parameter is not applicable	OBSTSMM	Observational Study Sampling Method		NA			

RANDOM - Trial is Randomized: This describes the whether or not a process of assigning individuals to the treatment or control groups was used within the contributed dataset.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *No Yes Response (NY)* Codelist.

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
No part of the trial has been randomized. Non-randomized. The study was not interventional. There was only a single arm in the study.	RANDOM	Trial is Randomized	N		C49487	CDISC	2019-06-28
Randomization status is unknown.	RANDOM	Trial is Randomized	U		C17998	CDISC	2019-06-28
Assignment to trial arms was randomized.	RANDOM	Trial is Randomized	Y		C49488	CDISC	2019-06-28

REGID - Registry Identifier: This is the identification number assigned by a clinical trial registry.

This parameter should be included in all TS datasets.

This parameter will have as many rows as needed to encompass all unique registration numbers (i.e., a single trial may be registered with more than one provider and so have more than one registry ID).

The registry identifier populates both the **TSVAL** and the **TSVALCD** variables.

The name of the registry is captured in the **TSVCDREF** variable. Please follow the naming conventions shown in the example table below.

TSPARMCD	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
REGID	Registry Identifier	ACTRN12610000913077		ACTRN12610000913077	ANZCTR	
REGID	Registry Identifier	2012-001333-14		2012-001333-14	EudraCT	
REGID	Registry Identifier	NCT02662855		NCT02662855	ClinicalTrials.gov	
REGID	Registry Identifier	PACTR201804003343404		PACTR201804003343404	PACTR	
REGID	Registry Identifier	RBR-79s56s		RBR-79s56s	ReBEC	
REGID	Registry Identifier	ISRCTN15871729		ISRCTN15871729	ISRCTN	
REGID	Registry Identifier		UNK			

ROUTE - Route of Administration: This is the route of administration of the drug named in *TRT - Investigational Therapy or Treatment* or *COMPTRT - Comparative Treatment Name* for the regimen associated with the Regimen/Arm listed in **TSGRPID**.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Route of Administration (ROUTE)* Codelist.

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
Intravenous, IV	ROUTE	Route of Administration	INTRAVENOUS		C38276	CDISC	2019-06-28
Oral, by mouth, swallowed	ROUTE	Route of Administration	ORAL		C38288	CDISC	2019-06-28
Route is not known	ROUTE	Route of Administration	UNKNOWN		C38311	CDISC	2019-06-28

SENDTC - Study End Date: This is the reported completion date of the study that generated the data in the contributed dataset.

This parameter should be included in all TS datasets.

This information is recorded in ISO 8601 format - see below for completion rules and examples.

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
A full date is provided - 16th June 2007	SENDTC	Study End Date	2007-06-16			ISO 8601	

A partial date is provided - June 2007	SENDTC	Study End Date	2007-06			ISO 8601	
A partial date is provided - 2007	SENDTC	Study End Date	2007			ISO 8601	
End of the study is unknown	SENDTC	Study End Date		UNK			

SEXPOP - Sex of Participants: This is the sex of participants included in the group being studied in the contributed dataset.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Sex of Participants Response (SEXPOP)* Codelist.

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
Trial includes both male and female participants	SEXPOP	Sex of Participants	BOTH		C49636	CDISC	2019-06-28
Trial includes ONLY female participants	SEXPOP	Sex of Participants	F		C16576	CDISC	2019-06-28
Trial includes ONLY male participants	SEXPOP	Sex of Participants	M		C20197	CDISC	2019-06-28

SSTDTC - Study Start Date: This is the reported start date of enrollment of the study that generated the data in the contributed dataset.

This parameter should be included in all TS datasets.

This information is recorded in ISO 8601 format - see below for completion rules and examples.

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
A full date is provided - 16th June 2007	SSTDTC	Study Start Date	2007-06-16			ISO 8601	
A partial date is provided - June 2007	SSTDTC	Study Start Date	2007-06			ISO 8601	
A partial date is provided - 2007	SSTDTC	Study Start Date	2007			ISO 8601	
Start of the study is unknown	SSTDTC	Study Start Date		UNK			

STYPE - Study Type: This is the role the study plays in determining the interventions a subject receives in the contributed dataset.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Study Type Response (STYPE)* Codelist.

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
Studies where individuals are assigned by an investigator based on a protocol to receive specific interventions. Assignment may or may not be random. Individuals are then followed and outcomes are assessed.	STYPE	Study Type	INTERVENTIONAL		C98388	CDISC	2019-06-28
Outcomes are assessed in pre-defined groups of individuals. They may receive interventions but the investigator does not assign specific interventions to the subjects.	STYPE	Study Type	OBSERVATIONAL		C16084	CDISC	2019-06-28
Observational studies which include an organized system that uses observational methods to collect uniform data prospectively for a population defined by a particular disorder/disease and serves a predetermined purpose.	STYPE	Study Type	PATIENT REGISTRY		C129000	CDISC	2019-06-28
The study type is unknown.	STYPE	Study Type		UNK			

TBLIND - Trial Blinding Schema: This describes the level of awareness by the subjects and/or investigators to the interventions received by individuals in the contributed dataset.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Trial Blinding Schema Response (TBLIND)* Codelist.

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
Neither the subject or the investigators know which treatment the subject is receiving.	TBLIND	Trial Blinding Schema	DOUBLE BLIND		C15228	CDISC	2019-06-28
Both the subjects and the investigators know which treatment the subject is receiving. No blinding performed. Unmasked study.	TBLIND	Trial Blinding Schema	OPEN LABEL		C49659	CDISC	2019-06-28
The treatment received is known, but the *dose of that treatment* is not known to either investigators or subject.	TBLIND	Trial Blinding Schema	OPEN LABEL TO TREATMENT AND DOUBLE BLIND TO IMP DOSE		C156592	CDISC	2019-06-28
One party (either investigators or subject) does not know which treatment the subject is receiving. Singlemasked study.	TBLIND	Trial Blinding Schema	SINGLE BLIND		C28233	CDISC	2019-06-28
Blinding status unknown	TBLIND	Trial Blinding Schema		UNK			
The study was not interventional	TBLIND	Trial Blinding Schema		NA			

TCNTRL - Control Type: This is the type of comparator against which the experimental protocol (study treatment) is designed to evaluate.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Control Type Response (TCNTRL)* Codelist.

Commonly encountered control types are recorded below for ease of reference:

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
A different therapeutic agent to the experimental protocol	TCNTRL	Control Type	ACTIVE		C49649	CDISC	2019-06-28
The same agent, but a different dose or regimen to the experimental protocol	TCNTRL	Control Type	DOSE RESPONSE		C120841	CDISC	2019-06-28

There is no control arm	TCNTRL	Control Type	NONE		C41132	CDISC	2019-06-28
An inactive compound identical in appearance to the experimental protocol	TCNTRL	Control Type	PLACEBO		C49648	CDISC	2019-06-28
The study was not interventional	TCNTRL	Control Type		NA			
Control type status unknown	TCNTRL	Control Type		UNK			

TDIGRP - Diagnosis Group: This is the grouping of individuals on the basis of a shared disease, i.e., the disease/medical problem of the study population in the contributed dataset.

This parameter should be included in all TS datasets.

This is the "high level" disease description of the study population (in line with the IDDO Research Themes). Specifics about species, complications, co-morbidities, etc. will be captured in the *INDIC - Trial Disease/Condition Indication* parameter.

Studies focusing only on Healthy Subjects (i.e., those containing a "Y" in the parameter *HLTSUBJI - Healthy Subject Indicator* and not having any other groups) will be populated with NA - see below for details.

This information is recorded using the Systematized Nomenclature of Medicine (SNOMED) codelist, which can be found here: https://ncit.nci.nih.gov/ncitbrowser/pages/multiple_search.jsf?nav_type=terminologies

Commonly encountered diagnosis groups are recorded below for ease of reference:

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
Ebola; EVD; Ebola hemorrhagic fever; Viral hemorrhagic fever, Ebola	TDIGRP	Diagnosis Group	Ebola virus disease		37109004	SNOMED	2018-09-01
malaria	TDIGRP	Diagnosis Group	Malaria		61462000	SNOMED	2018-09-01
schistosomiasis	TDIGRP	Diagnosis Group	Infection by Schistosoma		10087007	SNOMED	2018-09-01
visceral leishmaniasis; kala-azar	TDIGRP	Diagnosis Group	Visceral leishmaniasis		186803007	SNOMED	2018-09-01
soil-transmitted helminthiasis; STH	TDIGRP	Diagnosis Group	Helminth infection		27601005	SNOMED	2018-09-01
tapeworms	TDIGRP	Diagnosis Group	Infection by Taenia		76172008	SNOMED	2019-03-01
scabies	TDIGRP	Diagnosis Group	Infestation by Sarcoptes scabiei var hominis		128869009	SNOMED	2019-03-01
Phthiriasis palpebrarum; pubic lice; Phtirus pubis	TDIGRP	Diagnosis Group	Infestation by Phthirus pubis		71011005	SNOMED	2019-03-01
the study included healthy volunteers ONLY	TDIGRP	Diagnosis Group		NA			

TINDTP - Trial Intent Type: This is the planned purpose of the therapy, device, or agent the trial is designed to evaluate.

This parameter should be included in all TS datasets.

This information is recorded using the CDISC *Trial Intent Type Response (TINDTP)* Codelist.

Commonly encountered trial intent types are recorded below for ease of reference:

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
A study designed to identify actions necessary to permanently eliminate or reduce the risk to human life.	TINDTP	Trial Intent Type	PREVENTION		C49657	CDISC	2019-06-28
A study designed to evaluate intervention(s) for treatment of a disease, syndrome, or condition.	TINDTP	Trial Intent Type	TREATMENT		C49656	CDISC	2019-06-28
A study with only healthy volunteers	TINDTP	Trial Intent Type		NA			

TITLE - Trial Title: This is the title of the clinical trial or study that provided the contributed dataset.

This parameter should be included in all TS datasets.

If you are unable to locate an official Trial Title from the protocol or registration then use the title of the associated publication.

TPHASE - Trial Phase Classification: This is the defined stage in the lifecycle of the clinical trial or study that provided the contributed dataset..

This parameter should be included in all TS datasets.

Completion should be based on explicit Trial Phase information in the protocol, registration, or publication. Do not try to determine the phase based on other information - mark it "UNK".

This information is recorded using the CDISC *Trial Phase Response (TPHASE)* Codelist.

Commonly encountered trial phases are recorded below for ease of reference:

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**
Trial Phase 3; Phase 3 Trial	TPHASE	Trial Phase Classification	PHASE III TRIAL		C15602	CDISC	2019-06-28
The trial phase is applicable, but unknown.	TPHASE	Trial Phase Classification		UNK			
The submission is not from a clinical trial.	TPHASE	Trial Phase Classification	NOT APPLICABLE		C48660	CDISC	2019-06-28

TTYPE - Trial Type: This is the type of ***primary*** outcome or endpoint the trial is designed to evaluate.

This parameter should be included in all TS datasets.

This parameter will have as many rows as needed to encompass all applicable values.

This information is recorded using the CDISC *Trial Type Response (TTYPE)* Codelist.

Commonly encountered trial types are recorded below for ease of reference:

Raw Value	**TSPARMCD**	**TSPARM**	**TSVAL**	**TSVALNF**	**TSVALCD**	**TSVCDREF**	**TSVCDVER**

Primary outcome is looking at the relative therapeutic efficacy of treatment of a disease.	TTYPE	Trial Type	EFFICACY		C49666	CDISC	2019-06-28
Primary outcome is looking at the process by which a drug is absorbed, distributed, metabolized, and eliminated by the body.	TTYPE	Trial Type	PHARMACOKINETIC		C49663	CDISC	2019-06-28
Primary outcome is looking at the medical risks to a subject (usually assessed by examining a wide range of clinical parameters, including adverse events, vital signs, physical exam, laboratory tests).	TTYPE	Trial Type	SAFETY		C49667	CDISC	2019-06-28
Primary outcome is looking at the degree to which overt adverse effects can be tolerated by the subject.	TTYPE	Trial Type	TOLERABILITY		C98791	CDISC	2019-06-28
Primary outcome is looking to evaluate intervention(s) for treatment of disease, syndrome or condition.	TTYPE	Trial Type	TREATMENT		C49656	CDISC	2019-06-28
The trial type is applicable, but unknown.	TTYPE	Trial Type		UNK			
The submission is not from a trial with any pre-determined outcome measures.	TTYPE	Trial Type		NA			

Trial Visits (TV) Domain

Navigation Links: Data Management / IDDO Repository Data Dictionary

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Trial+Visits

*"A trial design domain that contains the **planned** order and number of visits in the study within each arm. Visits are defined as "clinical encounters" and are described using the timing variables VISIT, VISITNUM, and VISITDY. Protocols define Visits in order to describe assessments and procedures that are to be performed at the Visits. One record per planned Visit per Arm."*

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 Abbr eviation	Char	TV	Identifier	Two-character abbreviation for the domain.	Req
VISITNUM	Visit Number	Num		Topic	1. Clinical encounter number. 2. Numeric version of **VISIT**, used for sorting	Req
VISIT	Visit Name	Char		Synonym Qualifier	1. Protocol-defined description of clinical encounter. 2. May be used in addition to **VISITNUM** and/or **VISITDY** as a text description of the clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	1. Planned study day of **VISIT**. 2. Due to its sequential nature, used for sorting.	Perm
ARMCD	Planned Arm Code	Char	*	Record Qualifier	1. **ARMCD** is limited to 20 characters and does not have special character restrictions. The maximum length of **ARMCD** is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if **ARMCD** values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of **ARMCD** values would be 20. 2. If the timing of Visits for a trial does not depend on which Arm a subject is in, then **ARMCD** should be null.	Exp
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	1. Name given to an Arm or Treatment Group. 2. If the timing of Visits for a trial does not depend on which Arm a subject is in, then **ARM** should be left blank.	Perm
TVSTRL	Visit Start Rule	Char		Rule	Rule describing when the Visit starts, in relation to the sequence of Elements.	Req

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN

TV

VISITNUM – Visit Number

- **DEFINITION**: This variable contains a number designating the planned clinical encounter number. This is a numeric version of the visit described in **VISIT** and it is used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The first clinical encounter in the study will be numbered "1" and each subsequent visit given the next sequential number. These visits are not limited to days, but rather encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given a sequential number in **VISITNUM**. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISIT – Visit Name

- **DEFINITION**: This variable contains the protocol-defined text description of the planned clinical encounter number.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISITDY – Planned Study Day of Visit

- **DEFINITION**: This variable contains a number designating the Study Day of the planned clinical encounter. This is also a numeric version of the visit described in **VISIT** and can be used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The planned study day of the visit will be entered. These numbers are limited to days, not the encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given the same day in **VISITDY**. See the Example Section below for more details.
  - A note on malaria data: Historically in many antimalarial clinical trials, the day the subject is enrolled and receives the first antimalarial dose has been considered "Day 0" and the first day post-dose has been considered day 1. However, in the SDTM-based domains, a Study Day of 0 is not allowed. The Planned Study Day in these types of malaria trials will be shifted by 1 for **VISITDY** in order to accommodate this timing discrepancy (e.g., "Day 0" becomes **VISITDY**=1; "Day 28" becomes **VISITDY**=29).
- **CONTROLLED TERMINOLOGY**
  - None

ARMCD – Planned Arm Code

- **DEFINITION**: This variable contains a shortened version of the name of the Planned Arm or Treatment Group. This only needs to be populated if the timing of the Visits for a trial are dependent on which Arm the subject is in - see the Example Section below for more details.
- **COMPLETION**:
  - This variable will only be populated for visits that are dependent on which Arm a subject is in. This variable will be blank for visits that are not dependent on Arms.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication.
- **CONTROLLED TERMINOLOGY**
  - This will be the same value found in the Demographics (DM) domain variable **ARMCD**. See completion rules from the DM domain for more details.

ARM – Description of Planned Arm

- **DEFINITION**: This variable contains a description of the name of the Planned Arm or Treatment Group. This only needs to be populated if the timing of the Visits for a trial are dependent on which Arm the subject is in - see the Example Section below for more details.
- **COMPLETION**:
  - This variable will only be populated for visits that are dependent on which Arm a subject is in. This variable will be blank for visits that are not dependent on Arms.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication.

- **CONTROLLED TERMINOLOGY**
  - This will be the exact same value found in the Demographics (DM) domain variable **ARM**. See completion rules from the DM domain for more details.

TVSTRL – Visit Start Rule

- **DEFINITION**: This variable contains the text description of the planned clinical encounter and when it starts. This should contain details of what happened during the visit described in **VISIT**. It should have enough detail that someone referring to this table would understand what happened and when, without having to refer back to the protocol or publication.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. See the Example Section below for more details.

- **CONTROLLED TERMINOLOGY**
  - None

Examples for Completion of this Domain

CASE: Detailed visit data available from the publication

> *"Axillary temperature and both thin and thick smears obtained by finger capillary puncture were collected on days 0, 2, 3, 7, 14, 21, and 28"*
>
> *"CQ phospahte (1500mg over 3 days, total 10 tablets, each having 150mg CQ base: four each on days 'zero' and 'one', plus two on day 'two') and PQ phosphate (210 mg over 14 days, total 28 tablets, each of 7.5 mg PQ: two daily) standard antimalarial regimen for P. vivax was given."*

The data described in the publication should be pulled out as each protocol-defined, PLANNED study visit and populated as illustrated in the table below (notice the variables **ARM** and **ARMCD** are not populated because visits for this study do not differ based on treatment arm):

STUDYID	DOMAIN	VISITNUM	VISIT	VISITDY	ARM	ARMCD	TVSTRL
ABCDE	TV	1	Day 0	1			Collection of baseline, clinical, hematological, and parasitological data and administration of CQ [dose 1] and PQ [dose1]
ABCDE	TV	2	Day 1	2			Administration of CQ [dose 2] and PQ [dose 2]
ABCDE	TV	3	Day 2	3			Collection of clinical and parasitological data and administration of CQ [dose 3] and PQ [dose 3]
ABCDE	TV	4	Day 3	4			Collection of clinical and parasitological data and administration of PQ [dose 4]
ABCDE	TV	5	Day 4	5			Administration of PQ [dose 5]
ABCDE	TV	6	Day 5	6			Administration of PQ [dose 6]
ABCDE	TV	7	Day 6	7			Administration of PQ [dose 7]
ABCDE	TV	8	Day 7	8			Collection of clinical and parasitological data and administration of PQ [dose 8]
ABCDE	TV	9	Day 8	9			Administration of PQ [dose 9]
ABCDE	TV	10	Day 9	10			Administration of PQ [dose 10]
ABCDE	TV	11	Day 10	11			Administration of PQ [dose 11]
ABCDE	TV	12	Day 11	12			Administration of PQ [dose 12]
ABCDE	TV	13	Day 12	13			Administration of PQ [dose 13]
ABCDE	TV	14	Day 13	14			Administration of PQ [dose 14]

ABCDE	TV	15	Day 14	15			Collection of clinical and parasitological data
ABCDE	TV	16	Day 21	22			Collection of clinical and parasitological data
ABCDE	TV	17	Day 28	29			Collection of clinical and parasitological data

CASE: Less-detailed visit data available from the publication

> "*Children provided three urine samples over consecutive days. Three stool samples were collected over consecutive days at baseline and for the two follow-ups.*"
>
> "*Children were treated with a single dose of praziquantel syrup. They remained under medical supervision for 4h and adverse events were recorded. Additionally, a questionnaire was administered to mothers/guardians 24h post-treatment for further probing of adverse events. Treatment was evaluated 3 and 6 weeks post-treatment using multiple stool and urine samples.*"

The data described in the publication should be pulled out as each protocol-defined, PLANNED study visit and populated as illustrated in the table below (notice the variables **ARM** and **ARMCD** are not populated because visits for this study do not differ based on treatment arm; notice the variable **VISITDY** is not populated because the planned study days are not available):

STUDYID	DOMAIN	VISITNUM	VISIT	VISITDY	ARM	ARMCD	TVSTRL
ABCDE	TV	1	Screening				Collection of three urine and stool samples over consecutive days to screen for eligibility
ABCDE	TV	2	Day 1				Collection of baseline data and administration of treatment
ABCDE	TV	3	4 Hours Post Treatment				Direct surveillance period of 4 hours directly after treatment administration to monitor for adverse events
ABCDE	TV	4	24 Hours Post Treatment				Parental report of additional adverse events that occurred within 24h of treatment administration
ABCDE	TV	5	3 Weeks Post Treatment				Collection of three urine and stool samples over consecutive days 3 weeks post treatment
ABCDE	TV	6	6 Weeks Post Treatment				Collection of three urine and stool samples over consecutive days 6 weeks post treatment

Vital Signs (VS) Domain

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3#Vital+Signs

"A findings domain that contains measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index, height and weight. One record per vital sign measurement per time point per visit per subject."

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	VS	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
VSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTCD)	Topic	Short name of the measurement, test, or examination described in **VSTEST**. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in **VSTESTCD** cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). **VSTESTCD** cannot contain characters other than letters, numbers, or underscores. Examples: "SYSBP", "DIABP", "BMI".	Req
VSTEST	Vital Signs Test Name	Char	(VSTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in **VSTEST** cannot be longer than 40 characters. Examples: "Systolic Blood Pressure", "Diastolic Blood Pressure", "Body Mass Index".	Req
VSCAT	Category for Vital Signs	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
VSSCAT	Subcategory for Vital Signs	Char	*	Grouping Qualifier	A further categorization of a measurement or examination.	Perm
VSPOS	Vital Signs Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Perm
VSORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the vital signs measurement as originally received or collected.	Exp
VSORRESU	Original Units	Char	(VSRESU)	Variable Qualifier	Original units in which the data were collected. The unit for **VSORRES**. Examples: "in", "LB", "beats/min".	Exp
VSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from **VSORRES** in a standard format or standard units. **VSSTRESC** should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in **VSSTRESN**. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in **VSORRES**, and these results effectively have the same meaning, they could be represented in standard format in **VSSTRESC** as "NEGATIVE".	Exp
VSSTRESN	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 **VSSTRESC**. **VSSTRESN** should store all numeric test results or findings.	Exp
VSSTRESU	Standard Units	Char	(VSRESU)	Variable Qualifier	Standardized unit used for **VSSTRESC** and **VSSTRESN**.	Exp
VSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a vital sign measurement was not done. Should be null if a result exists in **VSORRES**.	Perm
VSREASND	Reason Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT" or "SUBJECT REFUSED". Used in conjunction with **VSSTAT** when value is "NOT DONE".	Perm

VSLOC	Location of Vital Signs Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of Vital Signs measurement. Example: "ARM" for blood pressure.	Perm
VSDRVFL	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 that do not come from the CRF are examples of records that would be derived for the submission datasets. If **VSDRVFL** = "Y," then **VSORRES** may be null, with **VSSTRESC** and (if numeric) **VSSTRESN** 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
EPOCH	Epoch	Char		Timing	Epoch associated with the start date or start date and time of the observation, or the date/time of collection if start date/time is not collected.	Perm
VSDTC	Date/Time of Measurements	Char	ISO 8601	Timing	Date and time of the vital signs assessment represented in ISO 8601 character format.	Exp
VSDY	Study Day of Vital Signs	Num		Timing	1. Study day of vital signs measurements, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined **RFSTDTC** variable in Demographics.	Perm
VSSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the observation as being before or after the sponsor-defined reference time point defined by variable **VSSTTPT.**	Perm
VSSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 or other character format of the sponsor-defined reference point referred to by **VSSTRTPT**. Exampes: "2003-12-15" or "VISIT 1".	Perm

STUDYID – Study Identifier

- **DEFINITION**: This variable contains the unique identifier for a study. This is the main key/identifier for all domains in the IDDO Data Repository – every domain table will have the **STUDYID** identifier.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The IDDO system creates a submission ID when datasets are shared. This submission ID will be what is entered as the **STUDYID**.
- **CONTROLLED TERMINOLOGY**
  - None

DOMAIN – Domain Abbreviation

- **DEFINITION**: This variable contains the two-character domain abbreviation for this table.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset. Data will follow the terminology according to the rules provided by CDISC.
- **CONTROLLED TERMINOLOGY**

DOMAIN

VS

USUBJID – Unique Subject Identifier

- **DEFINITION**: This variable contains the unique subject identifier for a study. This is a secondary key/identifier for all subject-level domains in the IDDO Data Repository – every domain table containing subject-level information (i.e., all but the Trial Domains) will have the **USUBJID** identifier. This variable will identify unique subjects in the repository.
  - If data about the same subject is submitted as two separate submissions to IDDO, the same subjects in both submissions will have the same **USUBJID** to identify them as the same individual.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This value will be created by concatenating the values for **STUDYID_SITEID_SUBJID** for each subject. This created ID will be what is entered as the **USUBJID**.

- **CONTROLLED TERMINOLOGY**
  - None

VSSEQ – Vital Signs Sequence Number

- **DEFINITION**: This variable is a sequence number to ensure uniqueness of subject records within the VS domain. Each vital signs test (each recorded as a separate row in the table) will have a unique number within each subject. For example, a subject with 10 VS tests will have 10 rows and each row is numbered sequentially from 1-10; a subject with 24 VS tests will have 24 rows and each row is numbered sequentially from 1-24.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
  - **VSSEQ** data provided in raw datasets already in SDTM format will not be included in the repository, only the IDDO-supplied **VSSEQ** number.
- **CONTROLLED TERMINOLOGY**
  - None

VSTESTCD – Vital Signs Test Short Name

- **DEFINITION**: This variable identifies the shortened code for the name of the vital signs test or examination performed. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology from the codelist ***Vital Signs Test Code (VSTESTCD)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSTESTCD	VSTEST	Similar Names	Code
BMI	Body Mass Index		C16358
DIABP	Diastolic Blood Pressure	the bottom number/second number in a BP reading (e.g., 140/90 - DIABP = 90)	C25299
HDCIRC	Head Circumference		C81255
HEIGHT	Height		C25347
HR	Heart Rate		C49677
MUARMCIR	Mid-Upper Arm Circumference	MUAC	C124475
OXYSAT	Oxygen Saturation		C60832
PULSE	Pulse Rate		C49676
RESP	Respiratory Rate		C49678
SSSKNF	Subscapular Skinfold Thickness		C98785
SYSBP	Systolic Blood Pressure	the top number/first number in a BP reading (e.g., 140/90 - SYSBP = 140)	C25298
TEMP	Temperature		C25206
TRSKNF	Triceps Skinfold Thickness		C98793
WEIGHT	Weight		C25208

VSTEST – Vital Signs Test Name

- **DEFINITION**: This variable identifies the name of the vital signs test or examination performed. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) re-coded to match the Controlled Terminology, depending on the raw data provided. Data will follow the terminology from the codelist ***Vital Signs Test Name (VSTEST)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.

        - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSTESTCD	VSTEST	Similar Names	Code
BMI	**Body Mass Index**		C16358
DIABP	**Diastolic Blood Pressure**	the bottom number/second number in a BP reading (e.g., 140/90 - DIABP = 90)	C25299
HDCIRC	**Head Circumference**		C81255
HEIGHT	**Height**		C25347
HR	**Heart Rate**		C49677
MUARMCIR	**Mid-Upper Arm Circumference**	MUAC	C124475
OXYSAT	**Oxygen Saturation**		C60832
PULSE	**Pulse Rate**		C49676
RESP	**Respiratory Rate**		C49678
SSSKNF	**Subscapular Skinfold Thickness**		C98785
SYSBP	**Systolic Blood Pressure**	the top number/first number in a BP reading (e.g., 140/90 - SYSBP = 140)	C25298
TEMP	**Temperature**		C25206
TRSKNF	**Triceps Skinfold Thickness**		C98793
WEIGHT	**Weight**		C25208

VSCAT – Category for Vital Signs Test or Examination

- **DEFINITION**: This variable is a categorization of the vital signs test or examination performed. These categories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that fit the categories of interest listed below.
    - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

VSCAT	Description
TBD	To be defined

VSSCAT – SubCategory for Vital Signs Test or Examination

- **DEFINITION**: This variable is a further categorization of the vital signs test or examination performed. These subcategories are defined by IDDO and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that fit the subcategories of interest listed below.
    - This information will be created and added to the dataset.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

VSSCAT	Description
TBD	To be defined

VSPOS – Vital Signs Position of Subject

- **DEFINITION**: This variable contains information about the position of the subject during the vital signs test or examination. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a result for the vital signs test or exam (i.e., it will not be populated for records that have a result of "NOT DONE" for **VSSTAT**) and have provided information on the position of the subject during the exam.

- This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Position (POSITION)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all blood pressure measurements were taken with the subject laying down – data would be SUPINE), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSPOS	Description	Code
SITTING	Sitting	C62122
STANDING	Standing	C62166
SUPINE	Supine; Lying on back	C62167

VSORRES – Vital Signs Test Result or Finding in Original Units

- **DEFINITION**: This variable contains the result of the vital signs test or examination performed as provided by the data contributor. The original data can be either numeric (e.g., "503") or string (e.g., "Positive").
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a result for the vital signs test or exam (i.e., it will not be populated for records that have a result of "NOT DONE" for **VSSTAT**).
    - This information will be filled in verbatim from the raw datasets.
- **CONTROLLED TERMINOLOGY**
    - None

VSORRESU – Vital Signs Test Original Units

- **DEFINITION**: This variable contains the unit for the result of the vital signs test or examination performed as provided by the data contributor. This is defined by CDISC Controlled Terminology and will be populated with one of the codes listed below.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a result for the vital signs test or exam (i.e., it will not be populated for records that have a result of "NOT DONE" for **VSSTAT**).
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Units for Vital Signs Results (VSRESU)***.
        - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
        - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
        - If the data is not in the raw dataset but available in another context (e.g., the protocol states all temperature was recorded in degrees Celsius – data would be C), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSTESTCD	VSTEST	VSORRESU	Similar Names	Code
BMI	Body Mass Index	**kg/m2**	Kilograms per Square Meter	C49671
DIABP	Diastolic Blood Pressure	**mmHg**	Millimeter of Mercury	C49670
DIABP	Diastolic Blood Pressure	**cmHg**	Centimeter of Mercury	C147129
HDCIRC	Head Circumference	**cm**	Centimeter	C49668
HDCIRC	Head Circumference	**in**	Inch	C48500
HDCIRC	Head Circumference	**mm**	Millimeter	C28251
HEIGHT	Height	**cm**	Centimeter	C49668
HEIGHT	Height	**in**	Inch	C48500
HEIGHT	Height	**m**	Meter	C41139
HEIGHT	Height	**mm**	Millimeter	C28251
HR	Heart Rate	**beats/min**	Beats per Minute	C49673
MUARMCIR	Mid-Upper Arm Circumference	**cm**	Centimeter	C49668
MUARMCIR	Mid-Upper Arm Circumference	**in**	Inch	C48500
MUARMCIR	Mid-Upper Arm Circumference	**mm**	Millimeter	C28251

OXYSAT	Oxygen Saturation	**%**	Percentage	C25613
PULSE	Pulse Rate	**beats/min**	Beats per Minute	C49673
RESP	Respiratory Rate	**breaths/min**	Breaths per Minute	C49674
SSSKNF	Subscapular Skinfold Thickness	**cm**	Centimeter	C49668
SSSKNF	Subscapular Skinfold Thickness	**in**	Inch	C48500
SSSKNF	Subscapular Skinfold Thickness	**mm**	Millimeter	C28251
SYSBP	Systolic Blood Pressure	**mmHg**	Millimeter of Mercury	C49670
SYSBP	Systolic Blood Pressure	**cmHg**	Centimeter of Mercury	C147129
TEMP	Temperature	**C**	Degree Celsius	C42559
TEMP	Temperature	**F**	Degree Fahrenheit	C44277
TRSKNF	Triceps Skinfold Thickness	**cm**	Centimeter	C49668
TRSKNF	Triceps Skinfold Thickness	**in**	Inch	C48500
TRSKNF	Triceps Skinfold Thickness	**mm**	Millimeter	C28251
WEIGHT	Weight	**g**	Gram	C48155
WEIGHT	Weight	**kg**	Kilogram	C28252
WEIGHT	Weight	**LB**	Pound	C48531

VSSTRESC – Vital Signs Test Result or Finding in Standard Units, Character Format

- **DEFINITION**: This variable contains the converted, standardized result of the vital signs test or examination performed. The data can be either numeric (e.g., "503") or string (e.g., "Positive") and is stored as a string in the repository. The standard units and conversion formulas are described in the section about the variable **VSSTRESU**. There is limited CDISC Controlled Terminology for tests with string/character-based results and is listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the vital signs test or exam (i.e., it will only be populated for records that have a value in **VSORRES**).
  - This will either be 1) filled in verbatim from the column **VSORRES** or 2) created, depending on the raw data provided.
    - If the raw data contains this result in the IDDO-Defined Standard Units for that vital signs test or exam, the value from **VSORRES** will be filled in verbatim.
    - If the result is not in the IDDO-Defined Standard Units for that vital signs test or exam, then a variable filled in with the converted value will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSSTRESC	Similar Names	Code
BORDERLINE	Borderline	C14157
INDETERMINATE	Indeterminate; Inconclusive; IND	C48658
INVALID	Invalid data; INV	C50913
NEGATIVE	Negative; Negative finding; Neg; - ; -ve	C38757
POSITIVE	Positive; Positive finding; Pos; + ; +ve	C38758

VSSTRESN – Vital Signs Test Result or Finding in Standard Units, Numeric Format

- **DEFINITION**: This variable contains the converted, standardized result of the vital signs test or examination performed when the result is numeric. This column is a direct copy of the numeric values found in **VSSTRESC**. String/character-based results (e.g., "Positive") are not copied into this column.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a numeric result for the vital signs test or exam (i.e., it will only be populated for records that have a numeric value in **VSSTRESC**).
  - This will be a created variable.
    - A variable will be created and will be populated with the numeric results found in **VSSTRESC**.
- **CONTROLLED TERMINOLOGY**
  - None

VSSTRESU – Vital Signs Test Standard Units

- **DEFINITION**: This variable contains the unit for the converted, standardized result of the vital signs test or examination performed. The IDDO-Defined Standard Units for each test or examination are listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the vital signs test or exam (i.e., it will only be populated for records that have a value in **VSORRES**).
  - This will either be 1) copied verbatim from the column **VSORRESU** or 2) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Units for Vital Signs Results (VSRESU)***.
    - If the raw data contains this result in the IDDO-Defined Standard Units for that vital signs test or exam, the value from **VSORRESU** will be filled in verbatim.
    - If the result is not in the IDDO-Defined Standard Units for that vital signs test or exam, then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSTESTCD	VSTEST	VSORRESU	VSSTRESU	Code	Conversion Formula
BMI	Body Mass Index	kg/m2	**kg/m2**	C49671	*n/a*
DIABP	Diastolic Blood Pressure	mmHg	**mmHg**	C49670	*n/a*
DIABP	Diastolic Blood Pressure	cmHg	**mmHg**	C49670	value * 10
HDCIRC	Head Circumference	cm	**cm**	C49668	*n/a*
HDCIRC	Head Circumference	in	**cm**	C49668	value * 2.54
HDCIRC	Head Circumference	mm	**cm**	C49668	value * 0.1
HEIGHT	Height	cm	**cm**	C49668	*n/a*
HEIGHT	Height	in	**cm**	C49668	value * 2.54
HEIGHT	Height	m	**cm**	C49668	value * 100
HEIGHT	Height	mm	**cm**	C49668	value * 0.1
HR	Heart Rate	beats/min	**beats/min**	C49673	*n/a*
MUARMCIR	Mid-Upper Arm Circumference	cm	**cm**	C49668	*n/a*
MUARMCIR	Mid-Upper Arm Circumference	in	**cm**	C49668	value * 2.54
MUARMCIR	Mid-Upper Arm Circumference	mm	**cm**	C49668	value * 0.1
OXYSAT	Oxygen Saturation	%	**%**	C25613	*n/a*
PULSE	Pulse Rate	beats/min	**beats/min**	C49673	*n/a*
RESP	Respiratory Rate	breaths/min	**breaths/min**	C49674	*n/a*
SSSKNF	Subscapular Skinfold Thickness	cm	**cm**	C49668	*n/a*
SSSKNF	Subscapular Skinfold Thickness	in	**cm**	C49668	value * 2.54
SSSKNF	Subscapular Skinfold Thickness	mm	**cm**	C49668	value * 0.1
SYSBP	Systolic Blood Pressure	mmHg	**mmHg**	C49670	*n/a*
SYSBP	Systolic Blood Pressure	cmHg	**mmHg**	C49670	value * 10
TEMP	Temperature	C	**C**	C42559	*n/a*
TEMP	Temperature	F	**C**	C42559	(value – 32) * 5/9
TRSKNF	Triceps Skinfold Thickness	cm	**cm**	C49668	*n/a*
TRSKNF	Triceps Skinfold Thickness	in	**cm**	C49668	value * 2.54
TRSKNF	Triceps Skinfold Thickness	mm	**cm**	C49668	value * 0.1
WEIGHT	Weight	g	**kg**	C28252	value * 0.001
WEIGHT	Weight	kg	**kg**	C28252	*n/a*
WEIGHT	Weight	LB	**kg**	C28252	value/0.45359237

VSSTAT – Vital Signs Test Completion Status

- **DEFINITION**: This variable contains information about the status of the vital signs test or examination – specifically that it was not completed when it was expected to have been. This column should be empty when there is a value in **VSORRES**. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have no value in **VSORRES**. This could be because 1) the test was not completed or 2) the data is missing/not provided in the raw dataset.
  - This will be a created variable. Data will follow the terminology from the codelist ***Not Done (ND)***.
    - A variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSSTAT	Code
NOT DONE	C49484

VSREASND – Vital Signs Test Reason Not Done

- **DEFINITION**: This variable contains information about the reason why the vital signs test or examination was not completed when it was expected to have been. This column should be empty when there is a value in **VSORRES**. This is defined by IDDO Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a value in **VSSTAT**.
  - This will either be 1) filled in verbatim from the raw datasets, or 2) be a created variable. Data will follow the terminology from the IDDO Codelist below.
    - If the raw data contains information as to why a vital signs test or exam was not completed, it will be filled in verbatim from the raw dataset.
    - If the raw data does not contain the reason why a vital signs test or exam was not competed, a variable will be created and will be populated with the correct controlled terminology.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*

VSREASND
NOT PROVIDED IN THE CONTRIBUTED DATASET

VSLOC – Location of Vital Signs Measurement

- **DEFINITION**: This variable contains information about the location of the vital signs test or examination. This is defined by CDISC Controlled Terminology and will be populated with the code listed below.
- **COMPLETION**:
  - This variable will only be populated for records in the dataset that have a result for the vital signs test or exam (i.e., it will not be populated for records that have a result of "NOT DONE" for **VSSTAT**) and have provided information on the location of the exam.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***Anatomical Location (LOC)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the protocol states all temperature measurements were orally – data would be ORAL CAVITY), then a variable filled in with the correct controlled terminology will be created.
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSLOC	Description	Code
ARM	Arm; Brachium; Upper Arm	C32141
AXILLA	Axilla; Axillary; Armpit	C12674
EAR	Ear	C12394
ORAL CAVITY	Mouth; Oral Cavity	C12421

VSDRVFL – Vital Signs Test Value Derived Flag

- **DEFINITION**: This variable contains information about whether the result for the vital signs test or examination was derived. For example, this will be populated if the contributed dataset has a value comprised of an average of multiple vital signs results. The variable is expected to be null if the choice

is not "Yes". This is defined by CDISC Controlled Terminology and will be populated with the code listed below.

- **COMPLETION**:
  - This variable will only be populated for derived vital signs tests or examinations.
  - This variable will only be mapped if explicitly detailed in the protocol/publication or if it is available in the raw dataset.
  - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the terminology from the codelist ***No Yes Response (NY)***.
    - If the raw data contains this information in the correct controlled terminology, it will be filled in verbatim from the raw datasets.
    - If the data is not in the correct controlled terminology, it will be re-coded into the correct terminology.
    - If the data is not in the raw dataset but available in another context (e.g., the data dictionary states the blood pressure value is the average of two tests – data would be Y), then a variable filled in with the correct controlled terminology will be created.
  -
- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSDRVFL	Description	Code
Y	Yes	C49488

VISITNUM – Visit Number

- **DEFINITION**: This variable contains a number designating the planned clinical encounter number. This is a numeric version of the visit described in **VISIT** and it is used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The clinical encounter in the study will be numbered "1" and each subsequent visit given the next sequential number. These visits are not limited to days, but rather encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given a sequential number in **VISITNUM**. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISIT – Visit Name

- **DEFINITION**: This variable contains the protocol-defined text description of the planned clinical encounter number.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. See the Example Section below for more details.
- **CONTROLLED TERMINOLOGY**
  - None

VISITDY – Planned Study Day of Visit

- **DEFINITION**: This variable contains a number designating the Study Day of the planned clinical encounter. This is also a numeric version of the visit described in **VISIT** and can be used for sorting.
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.
  - This information will be created and added to the dataset.
    - The planned study day of the visit will be entered. These numbers are limited to days, not the encounters. If a subject has several clinical encounters in a single day, each encounter for that day is given the same day in **VISITDY**. See the Example Section below for more details.
  - A note on malaria data: Historically in many antimalarial clinical trials, the day the subject is enrolled and receives the first antimalarial dose has been considered "Day 0" and the first day post-dose has been considered day 1. However, in the SDTM-based domains, a Study Day of 0 is not allowed. The Planned Study Day in these types of malaria trials will be shifted by 1 for **VISITDY** in order to accommodate this timing discrepancy (e.g., "Day 0" becomes **VISITDY**=1; "Day 28" becomes **VISITDY**=29).
- **CONTROLLED TERMINOLOGY**
  - None

EPOCH – Epoch of Vital Signs Test Measurement

- **DEFINITION**: This variable describes the Epoch period of the vital signs test or examination (e.g., Baseline, Treatment, Follow-up).
- **COMPLETION**:
  - This variable will be populated for every record in the dataset.

- This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. Data will follow the terminology from the codelist ***Epoch (EPOCH)***.

- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

EPOCH	Description	Code
BASELINE	A period in a clinical study after eligibility has been met and before the start of treatment, at which baseline measurements are collected.	C125938
FOLLOW-UP	A period in a clinical study during which information about the health status of an individual is obtained after study interventions have concluded.	C99158
SCREENING	A period in a clinical study during which subjects are evaluated for participation in a study. [An example would be when samples are taken prior to verification of disease-positive status - this is the Screening period and once verified disease-positive they move into the Baseline period].	C48262
TREATMENT	A period in a clinical study during which subjects receive investigational product. [We include all periods and types of treatments - no division into "Blinded Treatment" or "Continuation Treatment" etc.]	C101526

VSDTC – Vital Signs Test Date/Time of Measurements

- **DEFINITION**: This variable describes the date and time of the collection of the vital signs test or examination measurement. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
    - This variable will only be populated for vital signs tests or examinations that provide the actual date or time of the measurement. The date will not be derived from information about the study day (e.g., calculation of the date of "Day 3" based on the date of inclusion will not happen. This variable would be left blank and the information on "Day 3" would be captured in the **VISITNUM**, **VISIT**, and **VISITDY** variables).
    - This will either be 1) filled in verbatim from the raw datasets, 2) re-coded to match the Controlled Terminology, or 3) created, depending on the raw data provided. Data will follow the formatting required for ISO 8601 format.
        - If the raw data contains both the date and time in a single variable in IS0 8601 format, it will be filled in verbatim from the raw datasets.
        - If the date and time are in the same column but not in ISO 8601 format, it will be re-coded into the correct format.
        - If the time and date are in two separate variables, then a variable composed of a concatenation of the date and time in ISO 8601 format will be created.

- **CONTROLLED TERMINOLOGY**
    - ISO 8601 format

VSDY – Vital Signs Test Study Day of Measurements

- **DEFINITION**: This variable describes the study of the collection of the vital signs test or examination measurement relative to the date in **RFSTDTC**. This will be blank for records with no value in in **VSDTC**. This date and time will be provided in ISO 8601 format.
- **COMPLETION**:
    - This variable will only be populated for records in the dataset that have a value in **VSDTC**.
    - This information will be created and added to the dataset.
    - This will be calculated as per the methods described by CDISC
        - If **VSDTC** is on or after **RFSTDTC:**
            - **VSDY** = (date portion of **VSDTC**) – (date portion of **RFSTDTC**) +1
        - If **VSDTC** precedes **RFSTDTC**:
            - **VSDY** = (date portion of **VSDTC**) – (date portion of **RFSTDTC**)

- **CONTROLLED TERMINOLOGY**
    - ISO 8601 format

VSSTRTPT – Start of Vital Signs Test Measurement Relative to Reference Time Point

- **DEFINITION**: This variable describes *when* the vital signs test or examination occured in reference to the point described in **VSSTTPT**.
- **COMPLETION**:
    - This variable will be populated for records in the dataset that have no value in **VSDTC** or the **VISIT** variables (i.e., there is no useable timing information and we can only represent the time of the test or exam in relation to a fixed point during the study).
    - This information will be created and added to the dataset.
        - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available. Data will follow the terminology from the codelist ***Relation to Reference Period (STENRF)***.

- **CONTROLLED TERMINOLOGY** *(CDISC SDTM Controlled Terminology, 2018-12-21)*

VSSTRTPT	Description	Code
AFTER	The vital signs test or measurment occured AFTER the period described in **VSSTTPT**.	C38008
BEFORE	The vital signs test or measurement occurred BEFORE the period described in **VSSTTPT**.	C25629

VSSTTPT – Start Reference Time Point

- **DEFINITION**: This variable describes the time point to which the *when* of the occurrence of the vital signs test or examination is compared.
- **COMPLETION**:
  - This variable will be populated for records in the dataset that have no value in **VSDTC** or the **VISIT** variables (i.e., there is no useable timing information and we can only represent the time of the test or exam in relation to a fixed point during the study).
  - This information will be created and added to the dataset.
    - This data will be pulled from the protocol or the publication. In rare instances it will be pulled from the data dictionary or dataset itself if there is not other documentation available.
- **CONTROLLED TERMINOLOGY** *(IDDO Controlled Terminology, date of this document)*
  - none