Standard Procedure for Data Transfer

Version 1.0.0.20141021

Introduction

This document proposes a standard procedure for exchanging HIV cohort data within CCASANET. There are many benefits for using a standard format to transfer data within our region:

- We will remove ambiguity about the data in our cohort by standardizing the structure (syntax) of the data and the associated meaning (semantics) of the information represented by the data.
- On a practical level, we will be able to proceed faster in our analysis of pooled data. The experience over the last few years has shown that most of the time used in data management prior to analysis was spent (1) on converting the data to a common format from the individual site formats, and (2) on requests for clarifications from the sites about the data and local data conventions. The regional data coordination center will have *one process for all sites* for processing the received data.
- Convenience: If a submission standard is used for all the data elements relevant to our cohort, then the sites will only have to submit the data via one channel. The common data repository can then be used to generate data for most studies. In other words, the sites will have *one process* for submitting the data which will then be used by the data coordination center *for multiple concept sheets*. This will remove the need to issue a separate data call for every new concept sheet.

We have adopted many of the ideas and conventions that are described in the HIV Collaboration Data Exchange Protocol (HICDEP) and the derivative IeDEA Data Exchange Standard (IeDEA-DES). HICDEP is edited and maintained by the EuroCoord network. The IeDEA-DES is derived from HICDEP and maintained by the IeDEA Data Harmonization Working Group (DHWG).

The following statements apply to the data transfer protocol described in this document:

- The protocol is a *work in progress* and will evolve based on agreement and feedback from the participating sites in the CCASANET network. This document will evolve accordingly. Protocol version number will follow the following convention: '#.#.#.YYYYMMDD'. The first number is changed when the protocol undergoes significant change. If the first number is "0", then the protocol is still in draft phase. The second number will change if any variables are added, deleted, or modified. The third number will change if clarifications or procedural instructions about data submission are changed (minor changes, such as typos do not warrant a change in any version number). The fourth number will be appended to the name of electronic files that

contain the protocol and will indicate the date that such files were created. Data that is compatible with version 1.1.0 will remain compatible with version 1.1.13 because no variable will be modified between these two version numbers.

- Similar to HICDEP, the primary purpose of this protocol is to provide the network with *formats for data-exchange but not for an operational database* used for data-management on a day-to-day basis.
- This protocol *does not prescribe the use of specific data management software* such as DBASE, SQL-Server, Oracle, MySQL or any other tools developed or used by the local sites. It is based on a relational model that can be mirrored by most tools.
- Furthermore, the *format of the files that will be transferred is irrelevant*. Any file format (.xls, .dbf, .mdb, .csv, …) will work as long as the data conventions and structure suggested in this document are followed consistently.
- The regional data coordination center will *advise the sites that request assistance in developing tools for transforming their local data* into protocol-compliant format.

General Remarks about the Data Standard

From Flat Files to Normalized Structure

The main feature introduced in this protocol that differs from previous data calls in CCASANET is the *move from flat files towards a normalized structure*. A flat file looks like one spreadsheet in Excel. Patient records are stored in rows and the columns represent the different variables. Repeated measurements, such as medications administration or lab results and lab dates, are captured by assigning different variables for every new measurement (e.g. cd4_1_value, cd4_1_date, cd4_2_value, cd4_2_date, etc…). If the number of such repeated measurements is large or unknown then using a flat file structure is not flexible. The solution is to 'normalize' the data by breaking the flat file into multiple files: one file for the main patient record (demographics), and separate files for different types of measurements. A CD4 lab file can contain the following variables: patient id, CD4 date, and CD4 value. Patient records from the main file will then be tied to their lab results via the 'patient id' variable. Please see section the "Structure of the Data" section of the HICDEP website for further discussion of normalized vs. flat structures. The advantages of using a normalized structure include the flexibility to capture repetitive data, the ability to create separate specialized tables, and the ease of adding new data. New types of data such as disease information or medication can be added by adding new tables. New values of data such as newer lab results or newer medications can be added by adding rows to existing tables.

Not All the Variables are Required

Not all the tables and variables that are mentioned in this protocol are necessary for data transfer. The sites can submit a subset of the protocol variables that are needed for current studies and then submit additional variables as the need for them arises (or resubmit the entire data with the new variables added). When new concept sheets are approved, the Vanderbilt Data Coordination Center will provide information to the sites about the data that is currently available and will indicate whether new variables or data are needed.

Coded Values

The protocol specifies codes for certain categorical variables such as 'reason for ART stop'. Many sites collect this information and store it as free text rather than as coded values. It is encouraged to submit the data using coded values where indicated; however, this is not an absolute requirement. The protocol provides a way for submitting uncategorized values. For example, the variable that indicates the code for ART stop reason is "tblART.ART_RS". If a site wishes to submit the reason for ART stop as free text, then they can submit that data in the "tblART.ART_RS_OTH" variable. In other words, coded variables should only contain coded data; however, adding "_OTH" to the name of the variable allows the site to send un-encoded version of the same data. If the site is using categorical codes for that variable but the code key is not the same code key specified in this protocol, then they may submit the data using their own code and provide a translation table that maps their code onto the protocol code.

Combining Multiple Codes

If multiple codes apply to a given record, then the code field can be filled with a string containing all the applicable codes separated by the "+" character. When multiple codes are represented this way, the order of the codes can be used to represent the order of importance. For example if there is a primary and secondary reason for change represented by the codes "code1" and "code2" respectively, then the field tblART.ART_RS can be assigned the following string "code1+code2".

Variable Naming Convention

Variable name suffix conventions are described using "*_suffix", where "*" will be any set of alphanumeric characters followed by the character "_" then by the different types of suffixes such as "D" or "Y".

PATIENT

This is the primary key of the main patient table (tblBASIC). It is required in every table that contains patient data. There, it will be the foreign key indicating the patient for whom the row of data belongs. The patient id number should be unique for every patient and should only be used as an anonymous site-specific identifier of the patient within the CCASANET network. In other words, please do not store or encode any other information about the patient in the patient ID. It's preferable to use unique sequential integers as patient ids. This patient id will be the reference used when communicating with sites about specific patients. It does not need to be the internal patient identifier that the sites use for their own systems, however using the same id for both is easier for maintaining consistency. If the sites decide to use a different id for the CCASANET cohort, then please maintain a separate conversion table.

***_D (Date) and *_D_A (Date Annotation)**

Please use the suffix "_D" to end the names of all variables that report dates. The suffix "_D_A" is used for variables that describe the precision of the values in the corresponding "_D" variable. For example, the date of birth can be "DOB_D", or the date of initiation of a drug regimen can be "START_D". If you want to indicate more information regarding the regimen initiation date, then that information must be stored in the variable "START_D_A". The dates should be reported in a consistent syntax. For example if you choose to report dates in the 'yyyy-mm-dd' format, then the following strings are acceptable: '2001-03-01', '1999-04-17', however the data will be marked as inconsistent if any of the following strings appear in the date column: '2001-03', or 'xxxx-04-17', or '1999' or '01/03/2001' or '01/03/01'. Our preferred format is yyyy-mm-dd (always four digit for years and two digits for months and days, i.e. '03' not '3' for March). If you want to use a different format please explicitly indicate the format and use it consistently. If a table contains date columns that are not consistently formatted then that table will not be processed. Please see the discussion below on dates that are not completely known (such as when the day of the month, or the month are not known).

***_ID (Foreign Code Key)**

Please use the "_ID" suffix for variable names of foreign keys. For example if you are using a separate table to encode ART drugs, then the variable "ART_ID" will include the ART drug code in every row. Other suffixes such as "_R", "_RS" (reason), "_RC" (causal relation), "_DET" (method of determination), "_WD" (means of diagnosis), "_SPEC" (specialization) are also used throughout this protocol in the naming of code/key variables. Variables ending in these suffixes are essentially similar to those ending in "_ID" because they indicate the key or code in a different table, such as a table listing all the reasons for change.

*_Y (yes/no/unknown)

Please use suffix "_Y" while naming Boolean variables. For example the variable "tblFOLLOW.DEATH_Y" is a Boolean variable that indicates whether the patient passed away or not. This variable may contain empty values. The permitted values are "1" (yes), "2" (no), and "9" (unknown). There is a difference in meaning between "9" (unknown) value and "" (empty) value. See below for a discussion on unknown and incomplete data.

Note: some sites use: 0,1,9 (no, yes, unknown). At this point this will be accepted provided that the sites consistently follow all the convention for all the data, i.e. either the 0,1,9 or the 1,2,9 convention for all the Boolean variables in all the tables.

*_OTH (Other)

Variables whose names end with the "_OTH" suffix should be used to provide unstructured textual information. The "_OTH" suffix can be used instead of the "_ID" (or any other code variable). For example, if you do not represent your reasons for stopping an ART regimen in "tblART" using the codes in "tblART_CODE_RS" then do not use the "ART_RS" variable. Instead, include your text description of the reason for change in the "ART_OTH". Variables ending in "_OTH" can also be used to provide additional information that was not captured in the code variable. For example, the code '98' for regimen stop means 'other causes not specified above'. If a row has '98' as the value for "ART_RS", then "ART_OTH" can be used in this case to indicate the cause in free text. Please see the section below on using coding tables.

*_U (unit), *_V (value)

These suffixes are used for lab result values (_V) and lab result units (_U) in the various lab tables.

How to Treat Unknown Values

The general principle of reporting unknown values is the following:

Reporting something as "unknown" indicates that the value cannot be collected by the site. Leaving the value of a measurement empty indicates that the value has not been collected yet by the site.

For example the variable "tblBASIC.MODE" encodes the mode of transmission. If it is determined by reviewing the patient's record that the mode of transmission is not known, then the value "99" (unknown) should be used. If the site has not yet recorded the mode of transmission for that patient, then value "" (empty) should be used. The treatment of unknown date information is special, and will be discussed in the next section.

How to Treat Dates

As mentioned earlier, all the format of values in the date ("*_D") variables should be consistent for all data. The preferred format is 'yyyy-mm-dd'. The sites can choose other formats in which case all the dates in the transfer should adhere to the specified format.

The year, month, and day-of-the-month must all be present. When elements of the date cannot be known then please **provide a complete date (year, month, day) or leave the field empty** according to the following convention:

- Unknown year, month, and day: 1900-01-01
- Unknown month and day: 1958-07-15
- Unknown day of the month 1958-10-15
- Date not yet collected: "" (empty)

Strings like "2001-01", "2001", "xxxx-01-15", or "1998-??-??" are not accepted in date variables.

When there are missing or incomplete dates, please provide the annotation variables ("*_D_A") along with the date ("*_D") variables. This will further clarify the semantics of missing or incomplete dates and will help when checking the data for inconsistencies or when performing certain types of analyses. The possible values of the date annotation variables are the following:

Code	Precision of Date
<	Before this date
D or "" (empty)	Exact to the date (default)
M	Exact to the month
Y	Exact to the year
>	After this date
U	Unknown

Consider the following scenarios for the variable "tblBASIC.BIRTH_D" (date of birth) and the associated annotation variable, "tblBASIC.BIRTH_D_A".

tblBASIC.BIRTH_D	tblBASIC.BIRTH_D_A	Meaning
“” (empty)	“”(empty)	The birth date has not yet been collected.
1979-09-03	“”(empty)	“” has the same meaning as “D”, exact to the date. This patient was born on September 3rd, 1979.
1900-01-01	U	The date of birth cannot be found in the clinical records. The value of tblBASIC.BIRTH_D is completely ignored if “U” (unknown) is specified as the precision
1900-01-01	“”(empty)	1900 is an absurd year, most likely the date of birth is unknown and the _D_A value was mislabeled as “” (empty). Should be “U”
1975-10-15	D or “”(empty)	The patient was born on October 15, 1975
1975-10-15	M	The patient was born in October of 1975. Exact day is unknown.
1964-07-15	D or “”(empty)	The patient was born on July 15, 1964
1964-07-15	M	The patient was born in July of 1964. Exact day is unknown
1964-07-15	Y	The patient was born in 1964, exact month and day are unknown
1991-12-31	>	The patient was younger than 18 years in 2009

Note that the “” (empty) value for *_D_A is the same as “D” (exact to the date). This is for convenience. The sites can create *_D_A variables and leave most values empty except for the rows where some elements of the date are unknown in which case the values “M”, “Y”, “U”, “>”, or “<” can be used to describe the date precision.

Data Exchange Standard Tables Definitions

Tables can be submitted using any of the common file formats (.xls, .csv, .mdb, .dbf, …) It is acceptable to submit multiple files representing the same "protocol table". For example, visit data from multiple centers do not need to be merged into the same file and can be submitted separately. The date annotation variables (*_D_A) will not be explicitly mentioned in the table descriptions. They are implicitly assumed to accompany the date variables (*_D).

tblBASIC (Basic Data)

This is the main table and contains one row per patient. All patients in the cohort must be represented in this table. Note regarding the **PATIENT** "unique id" variable. It can be different than your local site id. In the latter case, please maintain (privately) a table with the correspondence between the two ids for consistent use in future data transfers.

Note on the Minimal Identifying Dataset

The **Minimal Identifying Dataset (MID)** contains the minimal set of variables needed to identify and reference all the potential patients that are in your cohort. The MID is composed of all potential patients in your cohort identified using the following variables from **tblBASIC**: **SITE**, **CENTER**, **PATIENT** (unique ID), **BIRTH_D**, and **MALE_Y**. These variables will serve (1) to establish the maximum number of records that can be used to characterize your cohort (a "denominator") as well as (2) to link to the clinical endpoints records in REDCap or to the other types of data that you have provided elsewhere.

Note on ENROL_D and FIRSTVIS_D

It is discourage to use this table to report the date of first visit (**FIRSTVIS_D**). Ideally, the first visit date would be computed as the earliest visit in **tblVISIT**. If your site is not providing **tblVISIT**, then the **FIRSTVIS_D** field should be used to capture the first visit.

Informed consent may not be required in some countries for collection of retrospective data. Therefore interpretation of **ENROL_D** variable is left to the site. If you choose to use ENROL_D, please provide a separate document with a brief summary of how patients are enrolled in the cohort. For sites where more than one visit is required to enroll, ENROL_D can be the date of the second visit; otherwise, ENROL_D will be assumed to equal FIRSTVISIT_D.

Variable	Type	Description
PATIENT	Numeric	Unique patient ID per cohort. No identifying information. **Part of the MID**
BIRTH_D	Date	Birth date **Part of the MID**

Variable	Type	Description
SITE	Character	Name of the site (e.g. "Mexico") **Part of the MID**
CENTER	Character	Name of the center/clinic/hospital within the site **Part of the MID**
MALE_Y	Numeric	Gender at birth 0: Female - 1: Male - 9: Unknown **Part of the MID**
MODE	Code	Probable Mode of Infection See code table tblBAS_CODE_MODE
MODE_OTH	Character	Free text description if MODE was not coded or additional information for coded MODE
HIVDIAGNOSIS_D	Date	Date of first HIV positive test
FIRSTVIS_D*	Date	Date of first visit in your cohort. It is discouraged to use this variable since it can be computed from tblVISIT. Please provide a value only if you are not providing tblVISIT.
ENROL_D*	Date	Date of enrollment in your cohort. (see notes above)
RECART_Y*	Numeric	Has the patient received anti-retroviral treatment *prior to the first visit*? Similar to FIRSTVIS_D, this can be computed from another table – tblART. The use of this variable is discouraged if reliable ART data prior to the date of first visit is provided.
RECART_D*	Date	If RECART_Y is "1" (yes): the date that prior ART was started.
RECART_ID*	Character	If RECART_Y is "1" (yes): the regimen that was given prior to first visit.
AIDS_Y*	Boolean	Had the patient been given an AIDS diagnosis *prior to the first visit*? This value is a baseline observation and should not change as the patient status is changed after joining the cohort.
AIDS_D*	Date	If AIDS_Y is "1" (yes): date of AIDS diagnosis
EDUCATIONYEARS	Numeric	Number of years of education
EDUCATION_OTH		Info about levels and categorical preferably

Variable	Type	Description
		with a separate description of how to convert education categories to years
EMPLOYED_Y	Boolean	Was the patient employed at the time of enrollment?
MARITAL_STATUS	Category	Was the patient married at the time of enrollment? [The definition of marital status categories is still an open question.]
~~**MARRIED_Y**~~	~~Boolean~~	~~DEPRECATED~~

Additional variables for infants

Variable	Type	Description
BIRTH_MODE	Character	"Caesarian" or "Vaginal" delivery

tblBAS_CODE_MODE

Contains the code for probable mode of infection "tblBASIC.MODE". Note that this is a coding variable, so you can combine using "+" with the first code being primary, second being secondary, etc.

Code	Mode of Infection
1	Homosexual contact
2	Injecting drug user
~~**3**~~	~~(1+2) DEPRECATED – can use "+" notation now~~
4	Hemophiliac
5	Transfusion, non-hemophilia related
6	Heterosexual contact
~~**7**~~	~~(6+2) DEPRECATED – can use "+" notation now~~
8	Perinatal
9	Generic Sexual
10	Bisexual
90	Other (specify in mode_oth)
99	Unknown

tblFOLLOW

This table is used for death and loss-to-follow-up information. Patients have no more than one record in this table. It is acceptable for patients in tblBASIC not to have any entries in this table. This table is meant to record the following events:

- The patient is officially dropped from the cohort by the site.
- The patient is known to be dead (+ record reasons for death).

The definition of loss-to-follow-up will depend on the context and specific study analysis. Therefore, this table is **not** meant to record the calculated loss to follow up. Please use it to record whether **the patient was actively dropped from the cohort by the local CCASANET site**. For example, if the patient withdrew his/her consent, or moved to a different facility. Note that codes #1 (Patient lost to follow up) and #2 (patient has not had visit within required amount of time) are dependent on the policies by the site and not related to any working definition used for analysis: for example, if a local site has a policy of dropping patients if they had not had a visit in 2 years. Also note that if the patient was activated again (coming back after long absence), then the DROP_ variables may be cleared. The gap in follow-up will be calculated from other tables.

It is discouraged to use L_ALIVE_D variable to represent the last date that a patient was known to be alive. That information can be computed from other fields. However, if you would like to provide this date explicitly then L_ALIVE_D may be used.

Variable	Type	Description
PATIENT	Numeric	Patient ID from tblBASIC
DROP_Y	Numeric	Has the patient been dropped from the cohort?
DROP_D	Date	If yes, date of last visit
DROP_RS	Code	If dropped, reason for dropping See tblFOLLOW_DROP_CODE
DROP_OTH	Character	Free text description of reason for dropping
DEATH_Y	Numeric	Did the patient pass away?
DEATH_D	Date	Date of death
AUTOP_Y	Numeric	Was an autopsy performed?
DEATH_R1	Code	Cause of death See tblFOLLOW_CODE_DEATH
DEATH_OTH1	Character	Text cause of death if not coded or if more info is needed

Variable	Type	Description
DEATH_RC1	Code	Causal relation of reason to death See tblFOLLOW_CODE_DEATH_CAUSE
DEATH_R2	Code	Cause of death See tblFOLLOW_CODE_DEATH
DEATH_OTH2	Character	Text cause of death if not coded or if more info is needed
DEATH_RC2	Code	Causal relation of reason to death See tblFOLLOW_CODE_DEATH_CAUSE
DEATH_R3	Code	Cause of death See tblFOLLOW_CODE_DEATH
DEATH_OTH3	Character	Text cause of death if not coded or if more info is needed
DEATH_RC3	Code	Causal relation of reason to death See tblFOLLOW_CODE_DEATH_CAUSE
L_ALIVE_D	Date	Last date known to be alive DISCOURAGED – computed from other tables

Additional variables for children

Variable	Type	Description
DEATH_MOTHER_Y	Numeric	Did the mother pass away 1=Yes 2=No 9=Unknown
DEATH_MOTHER_D	Date	Date of mother's death
DEATH_FATHER_Y	Numeric	Did the father pass away 1=Yes 2=No 9=Unknown
DEATH_FATHER_D	Date	Date of father's death
OTHER_STORY	Character	If another caregiver for the child has passed away, please indicate the details here

tblFOLLOW_CODE_DROP

Code	Reason for Drop Out
1	Patient lost to follow-up/ not known to be dead
~~**2**~~	~~Patient has not had visit within required amount of time DEPRECATED~~
3	Patient moved away
4	Patient moved is followed by another center

5	Patient's decision
6	Consent withdrawn
7	Incarceration/jail
8	Institutionalization (drug treatment, psychological, … etc)
9	Other

tblFOLLOW_CODE_DEATH

Code	Cause of Death
1	Myocardial Infarction
2	Stroke
3	Other Cardiovascular Diseases
4	Symptoms caused by mitochondrial toxicity
4.1	Lactic acidosis
5	Complications due to diabetes mellitus
6	Pancreatitis
7	Complications due to liver failure
7.1	Hepatitis related
7.2	Liver failure not related to hepatitis or mitochondrial toxicity
8	HIV related
8.1	AIDS defining event
8.2	Invasive bacterial infection
9	Renal failure
10	Bleeding (hemophilia)
20	Non AIDS defining cancer
90	Other
91	Suicide
92	Drug overdose
93	Accident
99	Unknown, fatal case with no information

tblFOLLOW_CODE_DEATH_CAUSE

Code	Cause of Death
I	Immediate cause
U	Underlying cause/condition
C	Contributing cause
N	Not available

tblVISIT

This table documents all the clinical encounters (visits) with patient. Longitudinal clinical information is stored in this table. This table is essential for loss-to-follow up analysis. The absolutely necessary variables are PATIENT, LOCATION and VISIT_D. It is acceptable if PATIENT, LOCATION and VISIT_D are the only specified variables with all other variables being blank. The location can be the name of the clinic. It can be some other location than a clinic. For example, follow up data can be obtained from pharmacy pick up dates. In this case, LOCATION can be set as "pharmacy". This data may be collected from various sources such as the pharmacy pick up dates mentioned above. If such follow-up data is collected from more than one source, then it is acceptable and encouraged to provide more than one table using the format for tblVISIT.

Variable	Type	Description
PATIENT	Numeric	Patient ID from tblBASIC
VISIT_D	Date	Date of encounter
LOCATION	Character	Name of clinic or location (e.g. lab or pharmacy) where the visit occurred.
~~**VISIT_ID**~~	~~Numeric~~	~~**DEPRECATED**~~
WEIGHT	Numeric	Weight
WEIGHT_U	Character	Weight unit (blank = kg)
HEIGHT	Numeric	Height
HEIGHT_U	Character	Height unit (blank = cm)
CDCSTAGE	Character	CDC Stage {A, A1, A2, A3, B, B1, B2, B3, C, C1, C2, C3}
WHOSTAGE	Character	WHO Stage {1, 2, 3, 4}

Additional variables for children

Variable	Type	Description
DISCLOSURE_STATUS	Character	Has the patient been or is being informed about his/her HIV status? "no", "ongoing", "yes"

tblCE

(previously tblDIS and tblAE)

This table is used to capture in one place all the patients' clinical endpoints (opportunistic infections or other co-morbid conditions including Non-AIDS Defining Events). This table now consolidates the two previously separate tables (tblAE and tblDIS used in HICDEP). The reason for using a new name that is unique to CCASANET is to highlight that the codes associated with this table are directly related to the clinical outcomes that are tracked by CCASANET.

Note on the procedures for submitting clinical endpoint data

The structure of this table is very similar to the structure of tblAE and tblDIS (so called "long skinny" tables) with the main difference residing in the codes used for CE_D. These codes maintain a 1:1 correspondence with the online Clinical Endpoints Case Report Forms (CE-CRF) in REDCap making it easy to interchange information without loss between the two modes of data submission. **In fact the sites have an option to submit their clinical endpoint data using either one (but not both) of the two modes:**

1. Submit the data directly into REDCap as described in the separate CE-CRF instructions document. REDCap will provide a means for you to enter, update, or view all the clinical endpoint data collected for your cohort. The VDCC will extract the data from REDCap and transform it to generate a copy in tblCE format that will be used for analysis. You may at any given point request that tblCE copy; however, updates can only be entered directly into REDCap.
2. Submit the data using the tblCE format or a format that closely resembles it (e.g. the previous tblAE and tblDIS).
    i. In the case of tblCE, use the table definition below and the exact corresponding codes provided.
    ii. If you capture your clinical endpoints in a similar format (i.e. a "long skinny table" which contains in every row the patient id, the date of clinical endpoint event, and a code or description of the event as was the case in the previous tblAE or tblDIS), then you may submit those tables along with a code translation table. The code translation table is a spreadsheet that will have as many rows as the number of unique codes that use (every possible code or description that you provide must be accounted for in this table). It will contain the following columns
        i. The first column contains all the codes that you use to refer to clinical endpoints (for example if you use HICDEP codes, then this column will contain the following codes like "TOX")
        ii. The second column contains the CCASANET codes that correspond to your local code (in the above example they would be "ade_toxoplasmosis"). This column

should always have a value. If you have a code that does not map to a CCASANET code, then enter "nade_other" in this column.

iii. In the third column will remain empty unless "nade_other" is entered, in which case you may enter your code or any description you want.

Note that using the "nade_other" will allow the VDCC to monitor all the clinical endpoints that the sites capture that do not exist in the common CCASANET list. This will guide the addition of new endpoints as the need arise.

Variable	Type	Description
~~**DISEASE_ID**~~	~~Numeric~~	~~DEPRECATED~~
PATIENT	Numeric	Patient ID from tblBASIC
CE_Y	Boolean	OPTIONAL: can be used to provide documentation of negative clinical outcome. If no CRF_ID is provided, then this will mean patient has no reportable clinical outcomes at all
CE_D	Date	Date of clinical outcome
CE_ID	Code	Code for clinical outcome from tblCRF_CODE
CE_OTH	Character	Free text description of the disease
CE_WD	Code	Means of Diagnosis From tblCRF_CODE_DIAG
STATUS_ID	Code	Disease status
STATUS_D	Date	Date of status observation
STATUS_OTH	Character	Free text description of status if not coded

tblCE_CODE

Code	Clinical Outcome
AIDS Defining Events	
ade_cancer	Cancer (AIDS-defining)
ade_candidiasis_pulm	Candidiasis of Bronchi, Trachea, or Lungs
ade_candidiasis_eso	Candidiasis, esophageal
ade_coccidioido	Coccidioidomycosis, disseminated or extrapulmonary
ade_cryptococcosis	Cryptococcosis, extrapulmonary
ade_cryptosporidiosis	Cryptosporidiosis, chronic intestinal
ade_cytomegalovirus	Cytomegalovirus disease (other than liver, spleen, or nodes)
ade_retinitis	Cytomegalovirus retinitis (with loss of vision)
ade_encephalopathy	Encephalopathy (HIV-related)

ade_herpes	Herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis
ade_histoplasmosis	Histoplasmosis, disseminated or extrapulmonary
ade_isosporiasis	Isosporiasis, chronic intestinal
ade_mycobacterium	Mycobacterium avium complex, M. kansasii, or M. bovis, disseminated or extrapulmonary
ade_pneumocystis	Pneumocystis jiroveci pneumonia
ade_pneumonia	Pneumonia, recurrent
ade_leukoenceph	Progressive multifocal leukoencephalopathy
ade_salmonella	Salmonella septicemia, recurrent
ade_toxoplasmosis	Toxoplasmosis of brain
ade_tuberculosis	Tuberculosis
ade_wasting	Wasting syndrome due to HIV

Non-AIDS Defining Events	
nade_cerebrovascular	Cerebrovascular Disease (stroke)
nade_coronary	Coronary Artery Disease
nade_renal **(1 occurance only)**	End-stage Renal Disease
nade_liver **(1 occurance only)**	Cirrhosis or End-Stage Liver Disease
nade_diabetes **(1 occurance only)**	Diabetes
nade_bone **(1 occurance only)**	Osteoporosis or Avascular Necrosis of Bone
nade_cancer	Cancer (Non-AIDS-Defining)
nade_chagas	Chagas Disease
nade_dengue	Dengue
nade_malaria	Malaria
nade_htlv **(1 occurance only)**	HTLV-1
nade_leishmaniasis	Leishmaniasis
nade_dyslipidemia **(1 occurance only)**	Dyslipidemia
nade_other	This is a placeholder used if you want to report any clinical outcome not captured by the codes above. Additional information will need to be provided via the CE_OTH field

The following codes are additional clinical endpoints for use by the pediatric cohorts. Please note that they are hierarchical. Pick the most specific endpoint that fits your case.

For example if you want to report a specific neurologic disorder under "peds_neurologic" then please pick the most specific code that applies. E.g. epilepsy goes under "peds_epilepsy" and not "peds_neurologic". If you cannot find a specific code for the neurologic condition in this list, then simply code with "peds_neurologic".

Code	Parent	Clinical Outcome
peds_growth	**(none)**	Malnutrition, failure to thrive, low weight gain
peds_metabolic	**(none)**	Metabolic and Endocrine Disorders
peds_diabetic	**peds_metabolic**	Diabetes / hyperinsulinemia
peds_lipodystrophy	**peds_metabolic**	Lipodystrophy
peds_dislipidemia	**peds_metabolic**	Dyslipidemia
peds_osteopenia	**peds_matabolic, peds_musculoskeletal**	Osteopenia / Osteoporosis
peds_vitamindef	**peds_metabolic**	Vitamin deficiencies
peds_thyroid	**peds_metabolic**	Thyroid disorders
peds_obesity	**peds_metabolic**	Obesity
peds_neurologic	**(none)**	Neurologic disorders
peds_neuropathy	**peds_neurologic**	Neuropathy
peds_epilepsy	**peds_neurologic**	Epilepsy / Seizure disorder
peds_nonhivenceph	**peds_neurologic**	Non-HIV encephalopathy
peds_hivenceph	**peds_neurologic**	HIV encephalopathy
peds_cerebralpalsy	**peds_neurologic**	Cerebral palsy
peds_stroke	**peds_neurologic**	Stroke
peds_motordelay	**peds_neurologic**	Motor developmental delay
peds_verbaldelay	**peds_neurologic**	Verbal developmental delay
peds_hematologic	**(none)**	Hematologic disorders
peds_anemia	**peds_hematologic**	Anemia
peds_thrombocytopenia	**peds_hematologic**	Thrombocytopenia
peds_neutropenia	**peds_hematologic**	Neutropenia
peds_immunologic	**(none)**	Allergic / Immunologic disorders
peds_urticaria	**peds_immunologic**	Urticaria
peds_atopicderm	**peds_immunologic**	Atopic dermatitis

peds_eczema	**peds_immunologic**	Eczema
peds_allrhinitis	**peds_immunologic**	Allergic rhinitis
peds_oncologic	**(none)**	
peds_lymphoma	**peds_oncologic**	Lymphoma
peds_leukemia	**peds_oncologic**	Leukemia
peds_cardiovascular	**(none)**	Cardiovascular disorders
peds_cardiomyopathy	**peds_cardiovascular**	Cardiomyopathy
peds_cardiovalvular	**peds_cardiovascular**	Valvular heart disease
peds_chf	**peds_cardiovascular**	Congestive heart failure
peds_gastrointestinal	**(none)**	Gastro-intestinal disorders
peds_noninfhepatitis	**peds_gastrointestinal**	Non-infectious hepatitis
peds_pancreatitis	**peds_gastrointestinal**	Pancreatitis
peds_chronicdiarrhea	**peds_gastrointestinal**	Non-infectious chronic diarrhea
peds_pulmonary	**(none)**	Pulmonary disorders
peds_pulmhtn	**peds_pulmonary**	Pulmonary hypertension
peds_bronchiectasis	**peds_pulmonary**	Bronchiectasis
peds_lip	**peds_pulmonary**	Lymphoid interstitial pneumonitis (LIP)
peds_asthma	**peds_pulmonary**	Asthma
peds_musculoskeletal	**(none)**	
peds_osteopenia	**peds_matabolic, peds_musculoskeletal**	Osteopenia / Osteoporosis
peds_noninfarthritis	**peds_musculoskeletal**	Non-infectious arthritis
peds_fracture	**peds_musculoskeletal**	Fracture
peds_bonenecrosis	**peds_musculoskeletal**	Asceptic bone necrosis
peds_noninfmyositis	**peds_musculoskeletal**	Non-infectious myositis
peds_psychological	**(none)**	Behavioral and Psychological disorders
peds_conduct	**peds_psychological**	Personality / Conduct disorder
peds_substance	**peds_psychological**	Substance use disorder
peds_communication	**peds_psychological**	Communication disorder
peds_learning	**peds_psychological**	Learning disorder
peds_depressive	**peds_psychological**	Depressive disorder
peds_anxiety	**peds_psychological**	Anxiety disorder

peds_genitourinal	**(none)**	Renal / Genitourinal
peds_nephrolithiasis	**peds_genitourinal**	Nephrolithiasis
peds_hivnephropathy	**peds_genitourinal**	HIV nephropathy
peds_esrd	**peds_genitourinal**	End-stage renal disorder
peds_pregnancy	**(none)**	Pregnancy-related disorders
peds_preterm	**peds_pregnancy**	Pre-term delivery
peds_intrauterinedemise	**peds_pregnancy**	Intrauterine demise
peds_miscarriage	**peds_pregnancy**	Miscarriage
peds_ectopic	**peds_pregnancy**	Ectopic pregnancy
peds_chorioamnionitis	**peds_pregnancy**	Chorioamnionitis
peds_preeclampsia	**peds_pregnancy**	Pre-eclampsia
peds_iugr	**peds_pregnancy**	Intrauterine growth retardation

tblCE_CODE_DIAG

Coding of Means of Diagnosis field

Code	Means of Diagnosis
1	Definite diagnosis
2	Probable diagnosis

tblCE_CODE_STATUS

It provides code for disease status.

Code	Disease Status
1	Resolved
2	Inactive
3	Active

tblCE_TB

Filled for every case of TB that was recorded in tblCE. Maps 1:1 to the TB CRF that we have in REDCap. For every case that is recorded here, there needs to be a record of in tblCE with the CE_ID="ade_tuberculosis" and a CE_D= TBDIAGNOSIS_D value that matches the TBDIAGNOSIS_D in this table. If there is a recurrence, each recurrent case will need to be entered as a new record in this table for the same patient.

PATIENT	Patient ID (same one used in all other tables)
TBDIAGNOSIS_D (_A)	Date of TB Diagnosis for this particular case (Note that tblCE_TB.PATIENT and tblCE_TB.TBDIAGNOSIS need to match exactly with tblCE.PATIENT and tblCE.CE_D for every row that has tblCE.CE_ID='ade_tuberculosis')
CXPOS_Y	Culture-positive M. tuberculosis 1, yes | 2, no | 9, unknown | 8, culture not performed
AFBPOS_Y	AFB Smear-positive 1, yes | 2, no | 9, unknown | 8, smear not performed
PCRPOS_Y	PCR positive 1, yes | 2, no | 9, unknown | 8, PCR not performed
GENEXPERTPOS_Y	GeneXpert positive 1, yes | 2, no | 9, unknown | 8, GeneXpert not performed
MODSPOS_Y	MODS positive 1, yes | 2, no | 9, unknown | 8, MODS not performed
OTHERPOS_Y	Other diagnostic test results positive 1, yes | 2, no | 9, unknown
INHRESISTANCE_Y	INH Resistance 1, yes | 2, no | 9, unknown | 8, INH resistance testing not performed
RIFRESISTANCE_Y	Rifampin resistance 1, yes | 2, no | 9, unknown | 8, RIF resistance testing not performed
PYRRESISTANCE_Y	Pyrazinamide resistance 1, yes | 2, no | 9, unknown | 8, PYR resistance testing not performed
EMBRESISTANCE_Y	Ethambutol resistance 1, yes | 2, no | 9, unknown | 8, EMB resistance testing not

	performed
TBSITE	Site of disease 0, pulmonary | 1, extrapulmonary | 2, both | 9, unknown
TUBERCULINPOS_Y	Did the patient have a positive tuberculin skin test before TB diagnosis? 1, Yes | 2, No | 9, Unknown
TBPREVENTIVE_Y	Did the patient receive TB preventive therapy before TB diagnosis? 1, Yes | 2, No | 9, Unknown
TBTX_INIT	First 2 months (initiation phase). If there are multiple then use the "+" symbol to separate INH, Isoniazid RMP (RIF), Rifampin RFB (RBT), Rifabutin PZA, Pyrazinamide EMB, Ethambutol STM, Streptomycin OTH, Other
TBTX_INIT_OTH	Other treatment in first 2 months
TBTX_INIT_STOP_D (_A)	Initiation phase stop date
TBTX_CONT	After first 2 months (continuation phase) If there are multiple then use the "+" symbol to separate INH, Isoniazid RMP (RIF), Rifampin RFB (RBT), Rifabutin PZA, Pyrazinamide EMB, Ethambutol STM, Streptomycin OTH, Other
TBTX_CONT_OTH	Other treatment after first 2 months
TBTX_CONT_STOP_D (_A)	Continuation phase (all treatment) stop date
TBTX_INTERMITTENCY	Intermittency of dosing that the patient received in continuation phase 0, 2x per week | 1, 3x per week | 2, 5x per week | 3, 7x per week
RECEIVEINH_Y	Did the patient receive INH preventive therapy after TB treatment completion? 1, Yes | 2, No | 9, Unknown

tblCE_CANCER

Filled for every case of “ade_cancer” or “nade_cancer” that was recorded in tblCE. Maps 1:1 to the Cancer CRF that we have in REDCap. For every case that is recorded here, there needs to be a record of in tblCE with the CE_ID=“ade_cancer” or CE_ID=”nade_cancer” and a CE_D= CANCER_D value that matches the CANCER_D in this table. If there is more than one cancer case per patient, each case will need to be entered as a new record in this table for the same patient.

PATIENT	Patient ID
CANCER_TYPE	Cancer type “KS”, Kaposi's Sarcoma “NHL”, Non-Hodgkin lymphoma “ICC”, Invasive cervical “LUNG”, Lung “BREAST”, Breast “ANAL”, Anal “COLON”, Colon “PROSTATE”, Prostate “SKIN”, Skin “OTH”, Other
CANCER_OTH	Please specify:
CANCER_D (_A)	Date of diagnosis
CANCER_CERTAINTY	Certainty of diagnosis 1, Definite | 2, Probable
CANCER_EXTENT	Extent 1, Local | 2, Distant Metastases | 3, Unknown
CANCER_TREATMENT	Cancer treatment 1, HAART | 2, Chemotherapy | 3, Radiation Therapy | 4, Surgery | 5, Unknown

tblHPV_CERVICAL

This table is to collect all the Cervical HPV information. Negative PAPs or normal scope results will need to be entered here as well. As many examinations (with positive or negative results) per patient as needed can be entered as multiple rows in this table.

If cervical carcinoma is present then appropriate entries in both tblCE and tblCE_CANCER will need to exist to reflect this case (with matching dates).

PATIENT	Patient ID
CERV_DX_D	Date of diagnostic test(s)
CERV_TEST_TYPE	What type of test was performed on this date? "pap" = Pap smear | "colpo" = Colposcopy/Biopsy | "both" = Both (Pap smear and Colposcopy/Biopsy) "hpv" = HPV test done only (no pap, scope or biopsy)
CERV_RESULTS_PAP	Pap results "ascus" = ASCUS (atypical squamous cells of unknown significance) "lgsil" = LGSIL (low grade (mild dysplasia) squamous intraepithelial lesion) "hgsil" = HGSIL (high grade squamous intraepithelial "lesion" = (moderate or severe dysplasia)) "cis" = CIS (carcinoma in situ) "carcinoma" = Invasive carcinoma (please complete cancer CRF also) "negative" = negative result "other" = Other
CERV_RESULTS_PAP_OTH	Other Pap smear result
CERV_RESULTS_COLPO *if desired, biopsy results can be stored in a separate variable* **CERV_RESULTS_BIOPSY**	Colposcopy/biopsy results. Note: If multiple biopsies done on this date, enter highest grade lesion. normal = Normal ascus = ASCUS (atypical squamous cells of unknown significance) lgsil = LGSIL (low grade (mild dysplasia) squamous intraepithelial lesion) hgsil = HGSIL (high grade squamous intraepithelial lesion (moderate or severe dysplasia)) cis = CIS (carcinoma in situ) carcinoma = Invasive carcinoma (please complete cancer CRF also) leukoplakia = Leukoplakia other = Other

CERV_RESULTS_COLPO_OTH *if desired, biopsy results can be stored in a separate variable* ***CERV_RESULTS_BIOPSY_OTH***	Other colposcopy/biopsy result
CERV_HPV_STATUS	HPV testing done? 1, Yes | 2, No | 9, Unknown
CERV_HPV_RESULTS	HPV status results negative = Negative low = Low Risk high = High Risk mixed = Mixed (Low and High Risk) inconclusive = Inconclusive positive = Positive HPV (risk designation unknown) [discouraged if you have the subtype and risk level]
CERV_HPV_SUBTYPES	Specific subtyping results (if done)
CERV_TX	Treatment "none", None (expectant management) "chemical", Topical chemical (TCA) therapy "leep", LEEP (loop electrosurgical excision) "conization", Conization "hysterectomy", Hysterectomy "cryotherapy", Cryotherapy "other", Other
CERV_TX_OTH	Other treatment
CERV_TX_D	Treatment date
CERV_CONDY	Condylomas present? [in genital tract – not just cervix] 1, Yes | 2, No | 9, Unknown
CERV_CONDY_TX	Specific condyloma treatment. Includes one-time or repeated treatment. "none", None (expectant management) "chemical", Topical chemical (TCA) therapy "cryotherapy", Cryotherapy "modulation", Topical immune modulation (imiquimod) "ablation", Laser ablation "surgery", Surgical removal

	“other”, Other
CERV_CONDY_TX_OTH	Other
CERV_CONDY_TX_D	Condyloma treatment date

tblHPV_ANAL

This table is to collect all the Anal HPV information. Negative PAPs or normal scope results will need to be entered here as well. As many examinations (with positive or negative results) per patient as needed can be entered as multiple rows in this table.

If anal carcinoma is present then appropriate entries in both tblCE and tblCE_CANCER will need to exist to reflect this case (with matching dates).

ANAL_DX_D	Date of diagnostic test(s)
ANAL_TEST_TYPE	What type of test was performed on this date? analpap, Anal Pap smear anoscopy, Anoscopy/Biopsy both, Both (Anal Pap smear and Anoscopy/Biopsy) hpv, HPV test done only (no pap, scope or biopsy)
ANAL_RESULTS_PAP	Anal Pap results "ascus", ASCUS (atypical squamous cells of unknown significance) "lgain", LG-AIN (low grade anal intraepithelial neoplasia or mild dysplasia) "hgain", HG-AIN (high grade anal intraepithelial neoplasia; moderate or severe dysplasia) "cis", CIS (carcinoma in situ) "carcinoma", Invasive carcinoma (please complete cancer CRF also) "negative", Negative "other", Other
ANAL_RESULTS_PAP_OTH	Other Anal Pap smear result
ANAL_RESULTS_SCOPE *if desired, biopsy results can be stored in a separate variable* **ANAL_RESULTS_BIOPSY**	Anoscopy/biopsy results. Note: If multiple biopsies done on this date, enter highest grade lesion. "normal", Normal "ascus", ASCUS (atypical squamous cells of unknown significance) "lgain", LG-AIN (low grade anal intraepithelial neoplasia or mild dysplasia) "hgain", HG-AIN (high grade anal intraepithelial neoplasia; moderate or severe dysplasia) "cis", CIS (carcinoma in situ) "carcinoma", Invasive carcinoma (please complete cancer CRF also) "other", Other
ANAL_RESULTS_SCOPE_OTH *if desired, biopsy results can*	Other anoscopy/biopsy result

be stored in a separate variable **ANAL_RESULTS_BIOPSY_OTH**	
ANAL_HPV_STATUS	HPV testing done? 1, Yes | 2, No | 9, Unknown
ANAL_HPV_RESULTS	HPV status results “negative”, Negative “low”, Low Risk “high”, High Risk “mixed”, Mixed (Low and High Risk) “inconclusive”, Inconclusive “positive” = Positive HPV (risk designation unknown) [discouraged if you have the subtype and risk level]
ANAL_HPV_SUBTYPES	Specific subtyping results (if done)
ANAL_TX	Treatment “none”, None (expectant management) “chemical”, Topical chemical (TCA) therapy “cryotherapy”, Cryotherapy “modulation”, Topical immune modulation (imiquimod) “ablation”, Laser ablation “surgery”, Surgical removal “other”, Other
ANAL_TX_OTH	Other treatment
ANAL_TX_D (_A)	Treatment date
ANAL_CONDY	Condylomas present? 1, Yes | 2, No | 9, Unknown
ANAL_CONDY_TX	Specific condyloma treatment. Includes one-time or repeated treatment. “none”, None (expectant management) “chemical”, Topical chemical (TCA) therapy “cryotherapy”, Cryotherapy “modulation”, Topical immune modulation (imiquimod) “ablation”, Laser ablation “surgery”, Surgical removal “other”, Other
ANAL_CONDY_TX_OTH	Other
ANAL_CONDY_TX_D (_A)	Condyloma treatment date

tblART

This table captures ARV Therapy. The ART_ID can refer to a single drug, or a multi-drug regimen, depending on the site's coding scheme. Please provide a list that maps any drug string/code used in this table to the generic name of the drug or drugs. There is no need for this list if you are using unambiguous generic drug names or abbreviations. When you provide a combination of drugs in a single row, please separate the drug symbols with a "+". When discontinuing or switching drugs, then the ART_ED (end date) and the ART_RS_STOP (reason for stop or switch) need to be provided. Sometimes a drug is added to the regimen for reasons that are *not related to a previously discontinued drug* (for example, starting PMTCT prophylaxis). This independent reason for starting can now be captured using the ART_RS_START (_OTH) variables. Whenever possible please use the reason for stopping instead of reason for starting, and please avoid duplicating information by adding in twice in those two variables.

Variable	Type	Description
PATIENT	Numeric	Patient ID from tblBASIC
ART_ID	Code	Code representing the ART Use ART code for single drugs or multidrug regimen. If choosing to include multiple drugs per row, separate the drug code by "+". Whitespace will be ignored.
ART_SD	Date	Date of starting treatment
ART_ED	Date	Date of stopping treatment If the drug is still being taken, then you can leave this blank. It is also possible to fill with the date of submission and add the value ">" to ART_ED_D_A
ART_RS_START	Code	OPTIONAL: Reason why this drug is added (if not explained by the reason for stop for a different drug) Use applicable codes from tblART_CODE_RS
ART_RS_START_OTH	Character	OPTIONAL: Free text (non-code) for reason to start or additional information
ART_RS_STOP	Code	Reason for stop code (previously ART_RS). See tblART_CODE_RS
ART_RS_STOP_OTH	Character	Free text (non-code) for reason to stop or additional information
ART_DO	Numeric	Dosage (mg or mL)
ART_FR	Numeric	Frequency: 1=Once daily (qd), 2=Twice daily (bid), 3=Thrice daily (tid), … and so on

tblART_CODE_RS

Code	Reason
1	Treatment Failure (i.e. virological, immunological, and/or clinical failure)
1.1	Virological failure
~~**1.2**~~	~~Partial virological failure - **DEPRECATED**~~
1.3	Immunological failure – CD4 drop
1.4	Clinical Progression
1.5	Drug resistance based on HIV-1 Genotype **- NEW**
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (HSR to abacavir)
5	Toxicity – Predominantly from abdomen/GI tract
5.1	Toxicity – GI tract
5.2	Toxicity – Liver
5.3	Toxicity – Pancreas
6	Toxicity – Predominantly from nervous system
6.1	Toxicity – peripheral neuropathy **– NEW**
6.2	Toxicity – Central Nervous System **– NEW**
7	Toxicity – Predominantly from kidneys
8	Toxicity – Predominantly from endocrine system
8.1	Diabetes
9	Hematological toxicity (anemia… etc)
10	Hyperlactataemia/lactic acidosis
11	Toxicity – Dermatologic **– NEW**
88	Death
89	Loss to follow-up **– NEW**
89.1	Transfer to another center **– NEW**
90	Side effects – Any of the above, but unspecified
90.1	Comorbidity
90.2	Comorbidity resolved **– NEW**
91	Toxicity, not mentioned above
92	Availability of more effective treatment (not specifically failure or side effect related)

Code	Reason
92.1	Simplified treatment available
~~**92.2**~~	~~Treatment too complex - **DEPRECATED**~~
92.3	Drug interaction
92.31	Drug interaction - commencing TB treatment
92.32	Drug interaction - ended TB treatment
92.4	Protocol change **– NEW**
92.5	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available) **– NEW**
92.6	Preferred drug now available **– NEW**
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication **– NEW**
93	Structured Treatment Interruption (STI)
93.1	Structured Treatment Interruption (STI) – at high CD4
94	Patient's wish/decision, not specified above
94.1	Non-adherence
~~**94.2**~~	~~Defaulter **– DEPRECATED**~~
95	Physician's decision, not specified above
96	Pregnancy
96.1	Pregnancy intended or possible **– NEW**
96.2	Pregnancy ended **– NEW**
96.3	Preconceptual concerns counseling **– NEW**
~~**97**~~	~~**DEPRECATED**~~
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

tblART_MOTHER

This table will be used to capture the ART regimens that are received by a child's *mother*. The structure will be very similar to tblART. The only difference will be that the PATIENT variable will refer to the child's rather than the mother's PATIENT id (whereas the regimens are those given to the mother). This will include pre-birth PMTCT prophylaxis ART regimens given to the mother.

PMTCT prophylaxis given to the infant will need to be included in tblART.

Variable definitions: exact same as tblART, except that PATIENT refers to the child's ID and the other fields refer to the maternal medication.

tblMED

Non ARV medication

Variable	Type	Description
PATIENT	Numeric	Patient ID from tblBASIC
MED_ID	Code	Code representing the MED Same convention as tblART.ART_ID
MED_OTH	Character	Required if no medication code is given
MED_SD	Date	Date of starting treatment
MED_ED	Date	Date of stopping treatment If the drug is still being taken, then fill with the date of submission and add the value ">" to MED_ED_D_A
MED_RS_START_OTH	Character	Reason for starting the medication e.g. PCP prophylaxis for children (no coded)
MED_RS_STOP_OTH	Character	Reason for stopping the medication (not coded)
MED_DO	Numeric	Dosage (mg or mL)
MED_FR	Code/Numeric	Frequency: 1=Once daily (qd), 2=Twice daily (bid), 3=Thrice daily (tid), … and so on

tblLAB

Use this table for generic laboratory values. Blood Pressure, Hemoglobin, Virology tests, Viral Load, and CD4 count have their own specialized tables.

Variable	Type	Description
PATIENT	Numeric	Patient ID
LAB_D	Date	Date of lab result
LAB_ID	Code	Lab test ID See tblLAB_CODE
LAB_V	Numeric	-1 = undetectable (Can use detection limit as negative value, e.g. -80 means that the lowest detection limit is 80, and the result was undecetable)
LAB_U	Code	Unit code See tblLAB_CODE_UNITS
LAB_F	Numeric	Fasting? Use boolean convention, "1" (yes) "2" (no) and "9" (unknown)
LAB_ST	Character	Specimen type WB=Whole blood P=Plasma S=Serum

tblLAB_CODE

(see HICDEP or you can use common strings like "gluc" or "MCV" or "NA+" or "TRIG" …)

tblLAB_CODE_UNITS

(see HICDEP or you can use the units as string like "mmol/L" or "gm/L" …)

tblLAB_BP

Blood Pressure Table

Variable	Type	Description
PATIENT	Numeric	Patient ID
BP_D	Date	Date of lab
BP_SYS	Numeric	Systolic Blood Pressure if taken
BP_DIA	Numeric	Diastolic Blood Pressure if taken
BP_U	Code	Unit code 1=mmHg 2=cmHg 3=Kpa

tblLAB_VIRO

Virology and Serology Labs Table

Variable	Type	Description
PATIENT	Numeric	Patient ID
VS_D	Date	Date of lab
VS_ID	Code	Lab test ID See tblLAB_VIRO_CODE
VS_R	Numeric	Result Use Boolean convention "1" (positive) "2" (negative) and "9" (unknown/borderline)
VS_V	Numeric	Result value e.g. copies/ml when applicable (RNA/DNA)
VS_U	Code	Unit code 1=copies/mL 2=IU/mL 3=Geq(millions of genome equivalent)
VS_LL	Numeric	Lower limit of assay if available
VS_UL	Numeric	Upper limit of assay if available
VS_T	Code	Type of Assay if available See tblLAB_VIRO_CODE_TYPE

tblLAB_VIRO_CODE

(See tblLAB_VIRO_CODE in HICDEP or use clear abbreviations "HBV", "HCV", "HIV-1", "HIV-2" …)

tblLAB_VIRO_CODE_TYPE

This table is subject to change based on feedback from the network

Code	Type of Assay Used
1	Roche qualitative (Amplicor) [HCV,HBV]
2	Roche quantitative test for HBV (Cobas Amplicor HBV monitor)
3	Bayer Bdna quantitative [HCV]
4	Bayer Bdna quantitative [HBV]
5	Roche Taqman
6	Other

tblLAB_RNA

Viral Load

Variable	Type	Description
PATIENT	Numeric	Patient ID
RNA_D	Date	Date of lab
RNA_V	Numeric	-1 = undetectable (Can use detection limit as negative value, e.g. -80 means that the lowest detection limit is 80, and the result was undetectable)
RNA_L	Numeric	Lower limit of HIV-RNA Assay
RNA_U	Numeric	If available, upper limit of HIV-RNA Assay
RNA_T	Code	If available, what type of assay was used See tblLAB_RNA_CODE_ASSAY

tblLAB_RNA_CODE_ASSAY

This table is subject to change based on feedback from the network.

Code	Viral Assay Used
5	Roche TaqMan
10	Roche 1.0
15	Roche 1.5 ultra-sensitive
19	Any Roche (unspecified)
20	NASBA
21	NASBA ultra-sensitive
29	Any NASBA (unspecified)
31	Chiron b-DNA 1.0
32	Chiron b-DNA 2.0
33	Chiron b-DNA 3.0
39	Any Chiron (unspecified)
40	Abbott ultra-sensitive
41	Abbott LCx
50	Monitor 1.0
51	Monitor 1.0 ultra-sensitive
55	Monitor 1.5
56	Monitor 1.5 ultra-sensitive
65	Cobas 1.5
66	Cobas 1.5 ultra-sensitive

Code	Viral Assay Used
90	Other
99	Unknown

tblLAB_CD4

CD4 count, could be replicated for CD8. Note that either the CD4 count value or the percent value is required in every row. If both are present for the same lab sample, then please submit both results in the same row. This will keep the 1:1 correspondence between the two measurements.

Variable	Type	Description
PATIENT	Numeric	Patient ID
CD4_D	Date	Date of lab
CD4_V	Numeric	CD4 count value
CD4_PER	Numeric	CD4 %

tblLAB_HB

Hemoglobin values table

Variable	Type	Description
PATIENT	Numeric	Patient ID
HB_D	Date	Date of hemoglobin measurement
HB_V	Numeric	Value

tblLAB_HEB

This is a specialized table for Hepatitis. It is preferred to tblLAB_VIRO for sending hepatitis-related virology data.

Variable	Type	Description
PATIENT	Numeric	Patient ID
HEB_R	Numeric	Result 1=yes, 2=no, 9=unknown
HEB_VIRAL_TYP	Character	B or C
HEB_T	Character	Type of HBV/HCV test
HEB_D	Date	Date of the test result

tblClinicalTrial

This table includes information about your patients regarding their participation in clinical trials. For patients that are enrolled in clinical trials, this table documents all their encounters in those trials.

Variable	Type	Description
PATIENT	Numeric	Patient ID
CLINICAL_TRIAL	Numeric	Is this patient enrolled in a clinical trial 1=yes, 2=no, 9=unknown. If 2 (not enrolled) then all the subsequent fields should be empty.
CLINICAL_TRIAL_VISIT_D	Date	Visit date associated with this specific trial
CLINICAL_TRIAL_REASON	Character	Reason for stopping the clinical trial. Empty for all visits except the last visit.
CLINICAL_TRIAL_ID	Character	The name of the clinical trial

Change log from Versions 0.9.7

tblCE

- Added pediatric hierarchical codes
- Added a limit on the number of occurrences for some of the reported CE

tblHPV_CERVICAL

- New table

tblHPV_ANAL

- New table