About HICDEP

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HIV cohort collaborations have made substantial contributions to the knowledge of HIV epidemiology and management over the last years. So far, most collaborations have incorporated slightly different protocols for data exchange causing unnecessary workload for the people in charge of data extraction.

We were therefore asked to put together this draft consensus protocol for discussion at the 7th International Workshop on HIV Observational Databases, March 29th-30th 2003, Fiuggi, Italy. It is based on our experience with data-exchange protocols for D:A:D, the ART Cohort-Collaboration, the PLATO Collaboration and several previous studies on the safety of stopping OI prophylaxis.

This protocol is based on a relational structure (with some very minor deviations) and currently incorporates 26 data tables and numerous lookup-tables for the codes. It is evident that - depending on the questions addressed - only subsets of tables and fields will have to be extracted for data exchange.

We have not elaborated on database systems (e.g. SQL-Server, Oracle, Access) and their respective file formats as there are excellent tools for transferring data between most of the popular packages (e.g. StatTransfer). The suggested data structure should work with most formats and software packages.

Please keep in mind that the primary purpose of this document is to provide you with formats for data-exchange but not for an operational database used for data-management on a day-to-day basis. Some considerations with that respect can be found in the appendices.

We plan to update this document on a regular basis and the most recent versions will be made available on the HICDEP website. HICDEP is a format under constant improvement (currently under the EuroCoord Project, Grant Agreement No. 260694) and additions are made almost every year. Please refer to the ChangeLog for the most current updates and always use the tables available on the HICDEP website for most current coding lists for ART and MED drugs.

Members of EuroCoord WP4, September 2011

ChangeLog

Draft Version 1.110

tblLAB_HCV

- Added table

tblVIS_SUBS

- Added table

tblART

- Added new options to ART_ID
  - J05AF13
  - J05AG06
  - J05AR20
  - J05AR21
  - J05AR22
  - J05AR24
  - J05AR25
- Added new options to ART_RS
  - 92.91 : Change to generic drug
  - 92.92 : Change to branded drug

tblBAS

- Redesigned codes for ETHNIC
  - 100 = White/Caucasian
  - 110 = White, European
  - 200 = Black
  - 204 = Other Black
  - 210 = Sub-Saharan African
  - 220 = Caribbean
  - 230 = African-American
  - 250 = Black, African
  - 300 = Hispanic/Latinx
  - 400 = Asian
  - 410 = East Asian (e.g. Chinese, Japanese)
  - 411 = Chinese
  - 412 = Japanese
  - 420 = Southeast Asia (e.g. Thai, Vietnamese, Philippino)
  - 421 = Indian Subcontinent (Indian, Pakistani, Bangladeshi)
  - 430 = South Asian (e.g. Indian, Pakistani)
  - 800 = Other ethnic groups
  - 810 = Maghrebian
  - 820 = Middle East/Arab
  - 830 = Turkish
  - 840 = Roma people/Gypsy (whichever is term is acceptable)

    - 850 = Indigenous people from Americas or Alaska Native
    - 860 = Indigenous people from other continents/locations
    - 900 = Mixed race/ethnicity
    - 910 = Do not want to disclose
    - 980 = Prohibited
    - 999 = Unknown
- Renamed GENDER to SEX

tblVIS

- Renamed GENDER_ID to GENDER_IDENT
- Added codes to GENDER_IDENT
    - 6 = Non-binary

tblCEP

- Added new codes to CEP_ID
    - CTAB
    - ARFI
- Added codes to CEP_SPEC, for CEP_ID = FRA
    - SKUL
    - FABO
    - COLB
    - SHOU
    - UPAR
    - LOAR
    - FING
    - RIB
    - TOSP
    - CESP
    - LUSP
    - FEM
    - HIP
    - LOLG
    - TOE
    - OTH
- Added codes to CEP_V, for CEP_ID = FRA
    - 1 = Traumatic
    - 2 = Osteoporotic/Fragility
    - 3 = Pathologic

tblLAB_RES

- Added new optional field TESTTYPE_M

tblLAB_VIRO

- Added new codes to VS_T
    - 10 = Rapid diagnostic test -3rd generation [HIV]

- 11 = Rapid diagnostic test -4th generation [HIV]
- 12 = Self-test-oral [HIV]
- 13 = Self-test-blood-based [HIV]
- 14 = Immunoassay (EIA, CLIA, ECL) - 3rd generation [HIV]
- 15 = Immunoassay (EIA,CLIA, ECL) plus p24 - 4th generation [HIV]
- 16 = WB: Western blot/immunoblot [HIV]
- 17 = NAT (Nucleic Acid Test) [HIV]

Previous versions

Version 1.100

tblART_MUM

- Added table

tblART

- Added new optional field ART_FORM
- Added new optional field ART_COMB
- Added new optional field ART_START_RS
- Added coding table with reasons for medication start ART_START_RS

tblBAS

- Removed field CENTER as it is available in

tblVIS

- Added new optional field PROPH_Y Extended coding table of field MODE
- Added Code 9 (sexual contact homo/hetero not specified)
- Added Code 10 (sexual abuse)

tblCENTER

- Added new optional field SURVEY_INTERNET
- Added new optional field SURVEY_PAPER
- Added new optional field LAST_REVIEWED_D tblDELIVERY_CHILD
- Added new optional field CHILD_ENROL tblDELIVERY_MUM
- Added new optional field ROM_DUR
- Added new optional field ROM_DUR_A
- Added new optional field DELIVERY_LOCATION
- Added new optional field PLANNED_HOME
- Added new optional field DELIV_ASSIST

tblDIS

- Added new optional field DIS_OUTCOME
- Added new optional field DIS_SITE
- Added various codes to coding table of field DIS_ID

tblLAB

- Added various codes to coding table of field LAB_ID
- Added new optional field LAB_R
- Added coding table for field LAB_ST

tblLAB_RES

- Added new optional field PATHOGENTYPE

tblLAB_RES_LVL_3

- Added new optional field RES_SCOR_ID

tblLAB_VIRO

- Added new optional field VS_ST

tblLTFU

- Added new optional field MOTHERDEATH_Y
- Added new optional field MOTHERDEATH_D
- Added new optional field FATHERDEATH_Y
- Added new optional field FATHERDEATH_D

tblMED

- Added new optional field MED_RS2
- Added new optional field MED_RS3
- Added new optional field MED_RS4
- Added new optional field MEDSTART_RS
- Added new optional field MED_DO
- Added new optional field MED_FR
- Added new optional field MED_DOT_Y

tblNEWBORN

- Added new optional field ENTRY_PMTCT
- Added new optional field BREASTFD_Y
- Added new optional field BREASTFD_DUR

tblNEWBORN_ABNORM

- Added IeDEA coding table for abnormalities
- Added field ABNORM_T_S to distinguish new coding of abnormalities from old Hicdep-coding

tblPREG

- Added new optional field EST_CONCEPT
- Added new optional field PREG_TEST_D
- Added new optional field NUM_FETUS
- Added new optional field ULTR_3
- Added new optional field ULTR_A_3

tblPREG_OUT

- Added new optional field CHILD_HIV
- Added new optional field CHILD_HIV_D
- Added codes to field OUTCOM:
  - 4 = Born alive
  - 22 = Termination: method unknown

tblVIS

- Added new optional field GENDER_ID
- Added new optional field SCHOOL
- Added new optional field SCHOOL_LVL

- Added new optional field FEEDOTH_Y
- Added new optional field CAREGIVER
- Added new optional field BROUGHT_PATIENT
- Added new optional field HIV_STATUS
- Added new optional field STATUS_KNOWN

Added date precision annotation variables for many date variables (both existing and new ones above):

- tblART: ART_SD_A, ART_ED_A
- tblBAS: BIRTH_D_A, ENROL_D_A, RECART_D_A, AIDS_D_A
- tblCANC: CANC_D_A
- tblCENTER: LAST_REVIEWED_D_A
- tbclDIS: DIS_D_A, DIS_ED_A
- tblLAB: LAB_D_A
- tblLAB_BP: BP_D_A
- tblLAB_CD4: CD4_D_A
- tblLAB_RES: SAMPLE_D_A, SEQ_DT_A
- tblLAB_RNA: RNA_D_A
- tblLTFU: DROP_D_A, DEATH_D_A, MOTHERDEATH_D_A, FATHERDEATH_D_A, L_ALIVE_D_A
- tblMED: MED_SD_A, MED_ED_A
- tblPREG: MENS_D_A, EST_CONCEPT_A, ANC_D_A, PREG_TEST_A
- tblPREG_OUT: OUTCOME_D_A, CHILD_HIV_D_A

Version 1.90

- tblART
  - added new optional field GENERIC
  - added new optional field ART_RS2
  - added new optional field ART_RS3
  - added new optional field ART_RS4
  - ART_ID
    - Added new single tablet formulations:
      - J05AR15 (Atazanavir and cobicistat)
      - J05AR16 (Lamivudine and raltegravir)
      - J05AR17 (Emtricitabine and tenofovir alafenamide)
      - J05AR18 (Emtricitabine, tenofovir alafenamide, elvitegravir and cobicistat)
      - J05AR19 (Emtricitabine, tenofovir alafenamide and rilpivirine)
    - Deleted (moved to tblMED):
      - J05AF08";"Adefovir (PREVEON)"
      - J05AF10";"Entecavir"
      - J05AF11";"Telbivudine"
  - ART_RS

    - added new (sub-)codes for stopping medication
        - 11 (Bone toxicity)
        - 15 (Social contra-indication)
        - 16 (Contra-indication unspecified)
        - 16.8 (Contra-indication expired)
        - 16.9 (Contra-indication - other)
        - 17 (MTCT regimen completed)
        - 70 (Pregnancy - toxicity concerns (during pregnancy))
        - 75 (Pregnancy - switch to a more appropriate regimen for PMTCT)
        - 92.5 (Regular treatment termination (e.g. DAA's for HCV, antibiotics)
- tblBAS
    - Added field for Center CENTER
- tblCENTER
    - Added table
- tblLAB
    - LAB_U
        - Deleted 18 (µkat/L, was same as 11)
- tblLTFU
    - DEATH_R1
        - added new subcodes:
            - 03.1.3 (HCV with liver cancer)
            - 03.2.3 (HBV with liver cancer)
- tblMED
    - MED_ID
        - Added new drug codes:
            - A11CC (vitamin D)
            - G02CA (Tocolysis)
            - H02 (Corticosteroids)
            - J01 (Antibiotics)
            - J01GA01 (streptomycin)
            - J02AC05 (Isavuconazole)
            - J02AX04 (caspofungin)
            - J04AB05 (Rifapentine (Priftin))
            - J05AF12 (Clevudine)
            - J05AX GRAZ-ELB (Grazoprevir/Elbasvir)
            - J05AR-DAAS (Daclatasvir/Asunaprevir)
            - J07BM0 (HPV Vaccine)
            - J07BM01 (HPV Vaccine (types 6, 11, 16, 18))
            - J07BM02 (HPV Vaccine (types 16, 18))
            - J07BM03 (HPV Vaccine (types 6, 11, 16, 18, 31, 33, 45, 52, 58))
            - M05BA (bisphosphonate)

        - N05A (Antipsychotics)
        - N05CD (Benzodiazepine derivatives)
        - N05CF (Benzodiazepine related drugs)
        - N06A (Antidepressant)
        - N07BC (Other drugs used in opioid dependence)
        - N07BC01 (Buprenorphine)
        - N07BC02 (Methadone)
        - N07BC03 (Levacetylmethadol)
        - N07BC04 (Lofexidine)
        - N07BC51 (Buprenorphine, combinations)
        - V03AB15 (Naloxone)
    - Added new drug codes (moved from tblART):
        - J05AF08";"Adefovir (PREVEON)"
        - J05AF10";"Entecavir"
        - J05AF11";"Telbivudine"
    - Changed temporary drug names to ATC codes:
        - J05AR-A450OM (ABT-450/r/Ombitasvir) --> J05AX67 (Ombitasvir, paritaprevir(ABT-450) and ritonavir)
        - J05AR-LESO (Ledipasvir/Sofosbuvir) --> J05AX65 (Ledipasvir/Sofosbuvir)
        - J05AX-DBV (Dasabuvir) --> J05AX16 (Dasabuvir)
- MED_RS
    - added new (sub-)codes for stopping medication (to keep identical to ART_RS)
        - 11 (Bone toxicity)
        - 15 (Social contra-indication)
        - 16 (Contra-indication unspecified)
        - 16.8 (Contra-indication expired)
        - 16.9 (Contra-indication - other)
        - 17 (MTCT regimen completed)
        - 70 (Pregnancy - toxicity concerns (during pregnancy))
        - 75 (Pregnancy - switch to a more appropriate regimen for PMTCT)
        - 92.5 (Regular treatment termination (e.g. DAA's for HCV, antibiotics)
- tblPROGRAM
    - Added table
- tblVIS
    - Added field for Center CENTER
    - Added field for family history of CVD/Stroke FAM_Y
    - Added field for type of clinic/service CLIN_TYPE
    - Added field for speciality of physician SPEC_TYPE
    - Added field for stage of transition from adolescence to adulthood TRANS_STAGE

Version 1.80

- tblART

- ART_ID
  - Added:
    - J05AR11 (Lamivudine, tenofovir disoproxil and efavirenz)
    - J05AR12 (Lamivudine and tenofovir disoproxil)
    - J05AR13 (Lamivudine, abacavir and dolutegravir)
    - J05AR14 (Darunavir and cobicistat)
    - J05AX-CAB (Cabotegravir (GSK-744))
- tblBAS
  - ETHNIC
    - Revised and added codes for different ethnicities
    - Changed limitations
    - Changed description
  - ORIGIN
    - Changed description to be more specific
- tblCANC
  - Added table
- tblLTFU
  - DEATH_R1
    - Added sub-types for 22 and 23
    - Added additional codes table
- tblMED
  - MED_ID
    - Added:
      - J05AE11 (Telaprevir (INCIVEK, INCIVO))
      - J05AE13 (Faldaprevir)
      - J05AE14 (Simeprevir)
      - J05AE15 (Asunaprevir)
      - J05AX14 (Daclatasvir)
      - J05AX15 (Sofosbuvir)
      - J05AR-A450OM (ABT-450/r/Ombitasvir)
      - J05AR-DAAS (Daclatasvir/Asunaprevir)
      - J05AR-LESO (Ledipasvir/Sofosbuvir)
      - J05AX-DBV (Dasabuvir)
- tblLAB
  - LAB_U
    - Added:
      - 14 (mg/24h)
      - 15 (mg/mmol)
      - 16 (fl)
      - 17 (µg/mL = mg/L)
      - 18 (µkat/L)

- LAB_ID
  - Added:
    - ACRA (Albumin Creatinin Ratio)
    - PCRA (Protein Creatinin Ratio)
    - PROT (Protein)
    - PSA (Prostate-specific antigen)
    - PTH (Parathyroid Hormone)

Version 1.70

- tblAE has been renamed to tblCEP
- tblCEP
  - Added field CEP_V
  - CEP_ID
    - Added: HOSP, ICU, JAUN, LIVD, LIVT, USAB, ASP, BART, CHAG, NOCA, PCE, PMAR, REQU.
    - Added: BACT, ENDO, MENI, OSTI, PERI, PNEU, PYEL, LEIS, MCDI (Previously in tblDIS).
    - Removed: ANG, BYP, END as they are already in the field CEP_SPEC.
    - Removed COR as now specified with SUD_DEATH_Y and EXP_DEATH_Y in tblLTFU.
  - CEP_SPEC
    - Changed description of NADM - CERV to contain "grade 2 or higher"
    - Added values: LIVB - XX, HEP - XX, NADM - HENE, NADM - BRAIN
- tblBAS
  - Added field RECART_D (Date ART started)
  - Added field LTART_D (Date last assessed for ART)
  - ETHNIC: Added Limitations section in description
  - Added field EDU_LVL (Last completed education Level)
  - Added field HIV_POS_D (Date of first positive HIV test)
- tblDIS
  - DIS_ID: Removed HG, BACT, ENDO, MENI, OSTI, PERI, PNEU, PYEL, LEIS, MCDI (now in tblCEP).
- tblVIS
  - Added optional field EMPLOY (What is the patient's current situation regarding labour?)
  - Added optional field CONTRACT (If the patient is an employee, what is the type of the patient's employment contract?)
  - Added optional field SMOKING_Y (Is the patient currently a smoker?)
  - Added optional field PREG_Y (Is the patient currently pregnant?)
  - Added optional field CDC_STAGE
  - Added optional field WHO_STAGE
- tblLTFU
  - Added optional fields for ICD9 cause of death coding (ICD9_#)
  - Added optional field DEATH_SOURCE
  - Added optional fields SUD_DEATH_Y and EXP_DEATH_Y. Replacing COR

- CoDe
  - Typos in the coding table (HBF -> HBV)
  - New codes for cancer (04.XX)
  - New codes for AMI (08.XX)
  - New code: 92.1 - Unknown, competing risks
- tblART
  - ART_ID: Coding extended/updated to match current ATC codes.
    - Lopinavir / Ritonavir changed code from "J05AE06" to "J05AR10".
    - Elvitegravir changed code from "J05AX-EVG" to "J05AX11"
    - J05AR07 - Triomune
    - J05AR08 - Eviplera / Complera
    - J05AR09 - Stribild
    - J05AR10 - Kaletra / Aluvia
    - J05AX12 - Dolutegravir
    - V03AX03 - Cobicistat
  - ART_FR: Added 0.33 and 0.5. Added special value -1 for "frequency unknown".
  - ART_RS
    - Added new codes: 6.X, 92.31, 92.32, 92.33, 92.4, 92.9, 94.2, 96.1, 96.2, 97.1, 97.2, 97.6
- tblLAB
  - LAB_ID
    - Removed redundant "APT" code. Use code "ALP"
    - Removed "GLYCE" (synonymous to Glucose in blood)
    - Added "AFP" (Alfa Fetoprotein) and "DIPP" (Dipstick result for protein in Urine).
  - LAB_U
    - Removed WBC codes (WBC was already removed from LAB_ID)
    - Added generic "13 - µg/L" and "99 - No units" code
  - LAB_ST
    - Added codes U and U24.
- tblLAB_RES
  - SUBTYPEModified description to also include HCV
- tblLAB_RNA
  - RNA_T
    - New code: 42 - Abbott RealTime HIV-1 m2000
    - New code: 59 - Monitor unspecified
- tblMED
  - MED_ID
    - Changed description from "Other HIV-related drugs" to "Other medication"
    - Added codes for Boceprevir and Telaprevir
  - MED_RS
    - Same changes as in tblART ART_RS
- tblLAB_VIRO

- VS_TNew codes 6,7,8.

Version 1.60

- tblBAS:
  - The ORIGIN field is now coded using UN region and country codes.
  - Added optional SEROHOW field indicating how the seroconversion date was determined.
  - Added optional CENS_D field holding the last date the database was updated for a patient.
- tblREFILLcreated to hold prescription refill data.
- tblLTFU: The DEATH_R# fields now use CoDe codes for coding cause of death.
- tblLAB:
  - Added codes for Gamma-glutamyltransferase and Prothrombin rate.
- tblLAB_VIRO:
  - Changed code for "Other" of field VS_T to value 9.
  - Added "HBVACIGM", "HBVACIGG", "HCVBD" and "HDVA" codes for VS_ID field.
- tblLAB_RES, tblLAB_RES_LVL_1, tblLAB_RES_LVL_2 and tblLAB_RES_LVL_3:
  - Renamed SAMP_ID to TEST_ID, as it gives a better description of what the values should encode.
- tblLAB_RES:
  - Added a VIRUSTYPE variable allowing to distinguish HIV- and HCV-resistance tests.
  - Added recommended HIV-1 subtype codes and HCV geno- and subtype codes.
- tblLAB_RES_LVL_3:
  - ATC_CODE replaces ART_ID as HCV medication in tblMED may be encoded.
- tblDIS:
  - Added optional DIS_ED field for the end date of the disease.
- tblMED:
  - Added MED_RS describing the reason for stopping the treatment; needed for HCV.
- tblAE:
  - Added a number of codes for AE_ID: ANG, ASCI, AVN, BYP, CERC, END, FIBS, FRA, HEP, HESY, LAC, LIVB, OESO, PAN and PERI.
- QA checks have been extended and updated where necessary.

Version 1.50

- Added the pediatric tables: tblPREG, tblPREG_OBS, tblPREG_OUT, tblDELIVERY_MUM, tblDELIVERY_CHILD, tblNEWBORN and tblNEWBORN_ABNORM.
- Added new table tblSAMPLES which holds information regarding sample storage.
- tblART: Updated list of drugs

Version 1.30

- tblART: Updated list of drugs
- tblAE:
  - added EVENT_ID as unique identifier and link to detailed tables for each event (see [1]) – this replaces the optional *AE_NO* field.
  - added AE_SPEC to further specify an event by coding
  - a series of basic verification fields have been added to allow for tracking of event status for source documentation availability, verification of documentation (through monitoring) and final

approval of the event.
  - in AE_R_Y - Relation to treatment: added more detailed codes.
- tblLAB: added several codes for various biomarker tests.
- tblLAB_CD4: added CD4_U as optional fields to discriminate between CD4% and CD4 cell count, so that the tblLAB_CD4 table can hold both types of measurements.
- tblLAB_VIRO: added several codes for various virology and serology tests.
- CaseDefinitionsupdated with end stage renal disease, chronic liver disease and non-AIDS defining malignancies

[1]:Detailed table definitions for the D:A:D events are available at http://www.cphiv.dk/HICDEP/Documents/tabid/159/Default.aspx

Version 1.25

- tblART: Updated list of drugs
- tblMED: Updated list of drugs
- tblDIS:
  - Changed wording for CANO to ‘Candidiasis, oesophageal, bronchi, trachea, or lungs’
  - Added COCC - Coccidioidomycosis, disseminated or extrapulmonary
- tblLAB: Added LAB_ST as additional field to code for type of specimen used for the measurement
- tblLAB_CD4: Added CD4_U as additional field so the table can hold both percentage and absolute CD4 measurements
- tblLAB_RNA: Added RNA_UL (upper limit of detection) to the list of additional fields.
- Added more viral assays to the list of RNA_T codes
- tblLAB_VIRO: Added unit field to tblLAB_VIRO into the general format and VS_LL (lower limit of detection), VS_UL (upper limit of detection) and VS_T (type of test) and list of tests to the list of additional fields.
- tblLTFU: Added DEATH_RC# to code for causal relation of the DEATH_R# code to the death in order to comply with CoDe and still maintain a format to be used for cohorts not using CoDe. ICD10_# fields have been moved to the list of additional fields.

Version 1.21

- Added reasons for stopping treatment to table tblART_CODE_RS:

Code	Coding for Reason of Stopping Treatment
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure – CD4 drop
1.4	Clinical progression
90	Side effects – any of the above but unspecified
90.1	Comorbidity
92.1	Simplified treatment available
92.2	Treatment to complex

92.3	Drug interaction
93.1	Structured Treatment Interruption (STI) – at high CD4
94.1	Non-compliance
96	Pregnancy
97	Study treatment

Version 1.2

- added CaseDefinitions

Version 1.1

- tblBAS:
  - The table was split into tblBAS and tblLTFU. tblLTFU holds data on death and drop-out
  - Renamed *LOS_Y* to *LOSS_Y*
  - Renamed *GAI_Y* to *GAIN_Y*
- *tblLAB_BLP*:
  - Renamed table to *tblLAB_BP*
  - Renamed *BLP_D* to *BP_D*
  - Renamed *BLP_SYS* to *BP_SYS*
  - Renamed *BLP_DIA* to *BP_DIA*
  - Renamed *BLP_U* to *BP_U*

Version 1.00

- *tblBas*:
  - Renamed *BIRTHDAY* to *BIRTH_D*
  - Renamed *FIRSTVIS* to *FRSVIS_D*
  - Renamed *REC_ART* to *RECART_Y*
- *tblLAB*:
  - *LAB_U*: has been dropped – please use the “unit codes/strings” as that is a safer way to code/represent the units – prefixing all “unit codes/strings” with a numeric value should however make analysis easier.
- *tblLAB_VIRO*:
  - New table added to capture mainly hepatitis measurements/tests
- *tblLAB_RES*:
  - *SEQ_DT* was added to capture the time of sequencing in order to facilitate quality assurance of the data for contamination that might have happened during the sequencing.
- *tblLAB_RES_LVL1*:
  - Renamed *SEQ_ST* to *SEQ_STAR*
  - *SEQ_STOP*: Added to the table to specify at which position in the sequence the sequencing was terminated
- *tblLAB_RES_LVL2*:
  - The table has been optimised for ease of analysis so that the mutation codes have been split into their components of amino acid position, sub position for insertions and 4 our more fields for mixtures of amino ac

Release Process

HICDEP Release Process

The HICDEP document is updated **at least annually** as part of the EuroCoord Work Package 4 deliverables.

You are encouraged to **use the most recent stable version** and **discuss changes to the draft version** at all times.

Before a new version is released (marked stable) formally, it runs through the following procedure:

1. Four weeks before a WP4 telephone conference, a WP4.1 member announces to the discussion board indicating that the current draft version is to be considered a release-candidate, highlighting the changes since the last stable version. The announcement is accompanied by a downloadable PDF of the release-candidate version.
2. All WP4 members forward this announcement to data managers and researchers who might have valuable feedback on the changes.
3. Within three weeks, everybody (including external parties) may comment and changes to the draft are still possible.
4. One week before the telephone conference, the draft is frozen and changes are no longer incorporated.
5. If the WP4 members accept the new version, a WP4.1 member performs the update and describes the differences from the last to the new stable version in the ChangeLog.

Table	Description
tblART	holds type of **antiretroviral drug**, start and stop dates and reason for stopping
tblART_MUM	Antiretroviral Medication of mother in cases where mother is not enrolled in cohort
tblBAS	holds **basic** information such as demographics, basic clinical information and date of AIDS diagnosis
tblCANC	holds type and date of **diagnosis of cancer**
tblCENTER	holds information about the **Center** (e.g. geographical localisation, type of clinic) where the patient is receiving HIV care
tblCEP	holds type and date of **clinical events and procedures** including serious non-AIDS conditions. Former known as tblAE (adverse event).
tblDELIVERY_CHILD	holds **delivery** information related to the child
tblDELIVERY_MUM	holds **delivery** information related to the mother
tblDIS	holds type and date of CDC-C **diseases** and malignancies.
tblLAB	holds type, date, value and unit of **laboratory tests**.
tblLAB_BP	holds date, diastolic and systolic values and unit of **blood pressure** measurements.
tblLAB_CD4	holds date and value of **CD4 measurements**.
tblLAB_HCV	holds information on HCV genotype and subtype
tblLAB_RES	holds **background information** on the resistance test, **laboratory**, library, kit, software and type of test
tblLAB_RES_LVL_1	holds nucleoside sequence for the PRO and RT sequences
tblLAB_RES_LVL_2	holds mutations and positions of these.
tblLAB_RES_LVL_3	holds resistance result in relation to antiretroviral drug.

tblLAB_RNA	holds date, value, detection limit and type of **viral assay**.
tblLAB_VIRO	holds test results for **viro-/serological tests** (hepatitis etc.)
tblLTFU	holds data on **death and drop-out**
tblMED	holds type, start and stop dates for **other medication/treatments**.
tblNEWBORN	holds information related to **newborns**
tblNEWBORN_ABNORM	holds information related to **abnormalities** of newborns
tblOVERLAP	holds information on the patient's **participation in other cohorts**
tblPREG	holds general **pregnancy**-related information
tblPREG_OBS	holds information on **obstetrical problems during pregnancy**
tblPREG_OUT	describes the **pregnancy outcome**
tblPROGRAM	holds information on the **program with which the center is associated**
tblREFILL	holds information on **prescription refills**
tblSAMPLES	holds information on the storage of blood, urine and other **biological samples**
tblVIS	holds **visit related information** such as weight, wasting, smoking, occupational status etc.
tblVIS_SUBS	holds information on patients **use of substances like alcohol, cigarettes and drugs**

Diagram

Diagram based on HICDEP 1.110

Structure of data

From flat files towards a normalized structure

The data collected in HIV collaborations is presented on the following pages in a set of data files/tables. Typically data would be put into one data file that would hold one line/record per patient where each field is represented as a separate column in that dataset. Often a dataset could contain more than 3000 columns of data.

The implication of going from thousands of fields to fewer fields means that data is in fact transposed from the flat format into the normalised format.

Example of a flat file structure:

PATIENT	ALAT_D	ALAT_V	ALAT_U	ASAT_D	ASAT_V	ASAT_U
999999	01-01-2000	15	U/l	01-01-2000	12	U/l

The normalised structure would then be like this:

PATIENT	TYPE_ID	LAB_DATE	LAB_VAL	LAB_UNIT
999999	1	01-01-2000	15	U/l
999999	2	01-01-2000	12	U/l

The type of measurement is identified through the TYPE_ID field. Here 1 codes for ALAT and 2 codes for ASAT:

Code	Description
1	ALAT - Alanin-Aminotransferase
2	ASAT - Aspartat aminotransferase

Technical considerations

To enable a normalised structure that minimises the number of columns dramatically, the one file solution must be broken into several minor tables. These breakdowns are driven by the different data characteristics.

Each table has a basic structure that includes the patient identifier, a code that represents e.g. drug, adverse event or laboratory test performed. Along with this combination values like date, result, unit etc are present for each record.

A record for a laboratory measurement would include:

- Patient identifier
- Measurement type identifier
- Measured value
- Unit of value
- Date of determination

A record for usage of an antiretroviral drug would include:

- Patient identifier
- Drug identifier
- Start date for usage
- End date for usage
- Reason for discontinuation

These issues imply that a set of distinct tables must be generated based on the “nature” of the data. Since laboratory, medication and event data both cannot and should not be mixed at least 3 tables must be designed. Additionally there are other types of information that need their own domains: background information on the patient (height, birth date etc.), visit related data (weight, blood pressure, wasting etc.), and resistance testing (the latter requires more consideration due to the diversity of data present).

In this protocol further separation of data into different tables are presented. These separations are not only based on the rules for the relational model and normalisation, but they are “culturally” related.

For example: antiretroviral treatment medication is kept in one table and other medication in another table; CD4 cell measurements and HIV-RNA measurements are put into separate tables, that are also different from the general laboratory table. These separations are done simply because data in these tables are of distinct importance in analysis and often are gathered more frequently and with more attention than other variables.

Coding Conventions Date codes

Although it is best to have precise dates in the format of YEAR-MONTH-DAY ISO standard, it might be that some cohorts are limited to representing date data at the level of the month only, or information kept on the patient in the charts only defines dates to the month and in some cases only to the year. To solve this a set of date codes are presented here.

Day unknown

In this case the date should be coded as the 15th of the month – so that 1999-12-?? becomes 1999-12-15. This enables the date to be no more than 15 days away from the actual date.

Month and day unknown

Best approach to this is to apply something similar, as with unknown dates, this would then mean that 1999-??-?? becomes 1999-07-01.

Year unknown

If the year is unknown but the presence of the date value is needed as in case of opportunistic infections or adverse events (see later in this document) a fictive date should be used that couldn’t be mistaken with an actual date. An unknown year should be coded as 1911-11-11.

Specification of precision

An alternative to the above is to apply an additional field to each date field for which it is known that there might be issues regarding the precision of the dates. The field is then used to specify at which degree of the day, month or year the date is precise:

Code	Precision of date
<	Before this date
D	Exact to the date
M	Exact to the month
Y	Exact to the year
>	After this date
U	Unknown

The Data Transfer Protocol for IeDEA Multi-regional Collaborations suggests that such a precision annotation variable should have the same name as the date variable with the additional Suffix _A. For example, the precision of BIRTH_D will be annotated using an optional variable with the name BIRTH_D_A.

ICD-10 codes

The coding system is the official standard for coding of diseases, however there is a wide set of “homebrew” codes used within the HIV field in data coding in general, often it’s a 3 or 4 letter code which is an abbreviation for the AIDS defining disease. ICD-10 doesn’t have single codes that represent all single CDC-C events and as a consequence of this a list of 3 to 4 letter codes is the recommended way of coding for all CDC stage C events

ICD-10 codes are however the recommended for codes AE’s since it would become impossible for this protocol to maintain a complete list of all possible AE’s. ICD-10 is also recommended for causes of death.

ATC codes

ATC is a hierarchical structure for coding medication. The structure and hierarchy are best explained with an example of how a drug code is defined. Here it is on Indinavir:
J - ANTIINFECTIVES FOR SYSTEMIC USE (1st level, anatomical main group) **J05** - ANTIVIRALS FOR SYSTEMIC USE (2nd level, therapeutic subgroup) **J05A** - DIRECT ACTING ANTIVIRALS (3rd level, pharmacological subgroup) **J05AE** - Protease inhibitors (4th level, chemical subgroup) **J05AE02** - Indinavir (5th level, chemical substance)

This hierarchy has some benefits as will be explained later, but one of its limitations is that it’s impossible to “read” the code compared to the widely used 3 letter mnemonic codes for antiretroviral drugs.

Example:

Drug	Code	ATC code
Indinavir	IDV	J05AE02

The difference is that the IDV code is easily readable, where the ATC code is not; going from a flat file structure to a normalised structure the human readable aspect becomes increasingly important. In the flat file format the column names and the possibility of labels makes data more or less readable; in the normalised format only the coding can help. Because of this the 3 letter codes are being presented in this document. However it must be stressed that usage of the ATC coding should be used to diminish the risk of several homebrew and non-compatible coding schemes.

Currently however, the ATC scheme does not provide sufficient detail on the specific drugs, there is e.g. no official way to code Saquinavir as hard or soft gel. Thus a slight alteration to the set of codes will be presented in the sections of the ART and MED tables. The alterations are designed to extend the existing structure of ATC.

One of the benefits is that the structure of ATC allows easier statistics on e.g. drug classes

- J05AE Protease inhibitors
  - J05AE01 Saquinavir
  - J05AE02 Indinavir
  - J05AE03 Ritonavir
  - J05AE04 Nelfinavir
  - J05AE05 Amprenavir
  - J05AE06 Lopinavir
- J05AF Nucleoside and nucleotide reverse transcriptase inhibitors
  - J05AF01 Zidovudine
  - J05AF02 Didanosine
  - J05AF03 Zalcitabine
  - J05AF04 Stavudine
  - J05AF05 Lamivudine
  - J05AF06 Abacavir
  - J05AF07 Tenofovir disoproxil
  - J05AF30 Combinations1
- J05AG Non-nucleoside reverse transcriptase inhibitors
  - J05AG01 Nevirapine
  - J05AG02 Delavirdine
  - J05AG03 Efavirenz

Although the codes might be harder to read they provide grouping mechanisms in the way they are coded. Interested readers should go to the ATC Website to learn about the structure of ATC. A fully updated database of ATC codes and DDD (Defined Daily Dosage) is available for querying.

Other codes

It is often necessary to code for values like “Yes”, “No” and “Unknown”, this document suggests that the following codes should be used:

Code	Description
0	No
1	Yes
9	Unknown

Unknown should be used to identify the difference between a value that has not yet been collected (Empty) and a value that cannot be collected (Unknown). Empty values should be required where Unknown values make little sense to keep querying for a value.

Example – weight:
Depending on the unit in which weight is measured, a different value for Unknown should be applied. In the case of kg the “Unknown” code should be 999 and not just 9 or 99, the last two could be actual values.

Blank values, for SAS users also known as "." and for database programmers known as NULL, should be used wherever specified in this protocol. However, sometimes it might be more correct just to omit the record if no value has been recorded, test has not been performed etc.

Quality Assurance
In order to verify the consistency and correctness of the data, QA checks are made before the data is used. The QA checks applying to a given table are listed at the bottom of its article. Additionally, a list of all QA checks, including checks which do not directly apply to the HICDEP tables themselves, is available here.

HICDEP 1.110

This article describes the current draft version HICDEP 1.110. For a more detailed version history, please refer to the ChangeLog.

General data format

The table pages referenced in the overview describe the specific tables' structure in detail and present a list of suggested codes, both standard and human readable.

All codes apart from trivial no, yes or unknown codes are presented as lookup tables, the usage of these are described in the the article Considerations for using the format to create a database.

Along with the basic structure described in each “Core fields” section, additional fields containing additional or more specific data are described in the “Additional fields” sections. These fields were taken from several cohort collaborations but with the required changes that were needed for the specific data structures. This is presented to the reader to show that the core structure is not a fixed proposal but rather a basic structure, which can be altered by adding fields.
Issues regarding duplicates are discussed in Considerations For Data Management.

Overview of data tables

Table: tblART - Antiretroviral treatment

Description: holds type of **antiretroviral drug**, start and stop dates and reason for stopping

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	identifies patient
ART_ID	character. see coding table for valid codings.	represents the antiretroviral treatment
ART_SD	yyyy-mm-dd	date of initiation of treatment
ART_SD_A	character: see coding of date precision	precision of date "Initiation of Treatment"

ART_ED	yyyy-mm-dd	date of stopping treatment
ART_ED_A	character: see coding of date precision	precision of date "Stopping of Treatment"
ART_RS	character. see coding table for valid codings.	reason for stopping treatment

Additional Fields

Depending on the aim of the study it might be needed to gather both the dosage and the frequency of the dosage taken. However many cohorts do not collect this date and thus these fields are optional.

Field name	**Format**	**Description**
ART_RS2	character. see coding table for valid codings.	Second reason for stopping treatment
ART_RS3	character. see coding table for valid codings.	Third reason for stopping treatment
ART_RS4	character. see coding table for valid codings.	Fourth reason for stopping treatment
ART_DO	numeric	Dosage (mg or mL) per intake unless ART_FR=-1
ART_FR	numeric: • -1 = Frequency not known. ART_DO contains dosage per day • 0.33 = 1 dose every third day • 0.5 = 1 dose every second day • 1 = 1 daily dose/qd • 2 = 2 daily doses/bid • 3 = 3 daily doses/tid • 4... = code gives number of daily doses	Frequency
GENERIC	numeric: • 1 = Branded • 2 = Generic • 9 = Unknown	Was this a branded or generic drug?

ART_FORM	numeric: • 1 = Tablet/capsule • 2 = Syrup/Suspension • 3 = Combination of 1 and 2 • 4 = Powder • 5 = Subcutaneous • 6 = Intravenous • 7 = Intramuscular • 9 = Unknown	What formulations of the drug was given?
ART_COMB	numeric: • 0 = Individual drug • 1 = Part of a fixed-dose combination • 9 = Unknown	Was the drug given as part of a fixed-dose combination?
ART_START_RS	numeric: see coding table for valid codings	Reason for starting/receiving ART

It may also be necessary to record the start and end time:

ART_ST	hh:mm	Start hour and minute of the day
ART_ET	hh:mm	Stop hour and minute of the day

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes

AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblART	WithinTable	AW001	ART_RS not null, but end date NULL		Yes
tblART	WithinTable	AW002	ART_RS null but end-date non NULL		Yes
tblART	WithinTable	AW003	ART_RS=98 yet ART_OTH is null	EPPICC	No
tblART	WithinTable	AW004	Duplicate records for same cohort, patient, art_id and art_sd		Yes
tblART	WithinTable	AW005	Dose out of range for those dose units and frequency	PaediatricOnly	Yes
tblART	WithinTable	AW006	Missing art_fr	PaediatricOnly	Yes
tblART	WithinTable	AW007	Missing art_do	PaediatricOnly	Yes
tblART	WithinTable	AW008	Missing patient		Yes

tblART	WithinTable	AW009	Missing art_id		Yes
tblART	WithinTable	AW010	Missing art_sd		Yes
tblART	WithinTable	AW011	Overlapping periods of same drug		Yes
tblART	WithinTable	AW012	Double reporting - records reported for both combination drugs and their components		Yes
tblART	WithinTable	AW013	Periods of overlap of contra-indicated drugs		Yes
tblART	WithinTable	AW014	Restart of same drug without a stop		Yes
tblART	WithinTable	AW015	ART_SD greater than or equal to ART_ED		Yes
tblART	CrossTable	AC001	Patient has no record in table BAS		Yes
tblART	CrossTable	AC002	Records exist in tblART yet RECART_Y=0 in tblBAS		Yes

ART_ID - Coding Table

A set of extended ATC codes are being presented here in order to code both more specific on subtypes of the drugs, e.g. saquinavir hard and soft gel, but also to enable coding of drugs that are at their trial stage and have not yet been assigned an ATC code. To do this the drug will be assigned the code elements as far down the levels as possible. Given two examples to illustrate this:

Saquinavir - Hard Gel J05AE01-SQH Saquinavir - Soft Gel J05AE01-SQS Saquinavir - not specified J05AE01

This will ensure the fidelity needed to distinguish between hard and soft gel and not specified, but also for analysis easily include all records which coding starts with J05AE01, regardless if the drug is hard or soft gel.

See the ATC Index for the individual codes. The extended ATC codes are listed below along with a subset of ATC codes relevant to ART.

Code (Extended ATC Codes)	Anti-Retroviral Drugs
J05A	ART unspecified
J05A-BEV	Bevirimat
J05A-PBT	Participant in Blinded Trial
J05AE	PI unspecified
J05AE-MOZ	Mozenavir (DMP-450)
J05AE01	Saquinavir (gel, not specified)
J05AE01-SQH	Saquinavir hard gel (INVIRASE)
J05AE01-SQS	Saquinavir soft gel (FORTOVASE)
J05AE02	Indinavir (CRIXIVAN)
J05AE03	Ritonavir (NORVIR)
J05AE03-H	Ritonavir high dose (NORVIR)
J05AE03-L	Ritonavir low dose (NORVIR)
J05AE04	Nelfinavir (VIRACEPT)
J05AE05	Amprenavir (AGENERASE)
J05AR10	Lopinavir/Ritonavir (Kaletra). Former code: J05AE06
J05AE07	Fos-amprenavir (Telzir, Lexiva)
J05AE08	Atazanavir (Reyataz)
J05AE09	Tipranavir (Aptivus)

J05AE10	Darunavir (TMC-114, Prezista)
J05AF	NRTI unspecified
J05AF-ALO	Alovudine
J05AF-AMD	Amdoxovir (DADP)
J05AF-FOZ	Fozivudine tidoxi
J05AF-LDN	Lodenosine (trialdrug)
J05AF-RVT	Reverset
J05AF01	Zidovudine (AZT, RETROVIR)
J05AF02	Didanosine (ddI) (VIDEX)
J05AF03	Zalcitabine (ddC) (HIVID)
J05AF04	Stavudine (d4T) (ZERIT)
J05AF05	Lamivudine (3TC, EPIVIR)
J05AF06	Abacavir (1592U89) (ZIAGEN)
J05AF07	Tenofovir (VIREAD)
J05AF09	Emtricitabine
J05AG	NNRTI unspecified
J05AG04	Etravirine (TMC 125)
J05AG05	Rilpivirine (TMC-278)
J05AG-CPV	Capravirine
J05AG-DPC083	DPC 083
J05AG-DPC961	DPC 961
J05AG-EMV	Emivirine (MKC442)
J05AG-LOV	Loviride
J05AG01	Nevirapine (VIRAMUN)
J05AG02	Delavirdine (U-90152) (RESCRIPTOR)
J05AG03	Efavirenz (DMP-266) (STOCRIN, SUSTIVA)
J05AR01	Combivir (Zidovudine/Lamivudine)
J05AR02	Kivexa (Lamivudine/Abacavir)
J05AR03	Truvada (Tenofovir/Emtricabine)
J05AR04	Trizivir (Zidovudine/Lamivudine/Abacavir)
J05AR05	Douvir-N (Zidovudine/Lamivudine/Nevirapine)

J05AR06	Atripla (Emtricitabine/Tenofovir/Efavirenz)
J05AR07	Triomune (Stavudine/Lamivudine/Nevirapine)
J05AR08	Eviplera/Complera (Emtricitabine/Tenofovir/Rilpivirine)
J05AR09	Stribild (Emtricitabine/Tenofovir/Elvitegravir/Cobicistat)
J05AR10	Kaletra/Aluvia (Lopinavir/Ritonavir)
J05AR11	Lamivudine, tenofovir disoproxil and efavirenz
J05AR12	Lamivudine and tenofovir disoproxil
J05AR13	Triumeq (Lamivudine, abacavir and dolutegravir)
J05AR14	Darunavir and cobicistat
J05AR15	Atazanavir and cobicistat
J05AR16	Lamivudine and raltegravir
J05AR17	Emtricitabine and tenofovir alafenamide
J05AR18	Emtricitabine, tenofovir alafenamide, elvitegravir and cobicistat
J05AR19	Emtricitabine, tenofovir alafenamide and rilpivirine
J05AX-VIC	Vicriviroc (Schering)
J05AX07	Enfuvirtide (Fuzeon, T-20)
J05AX08	Raltegravir (Merck)
J05AX09	Maraviroc (Pfizer)
J05AX11	Elvitegravir
J05AX12	Dolutegravir
J05AX-CAB	Cabotegravir (GSK-744)
L01XX05	Hydroxyurea/Hydroxycarbamid (Litalir)
V03AX03	Cobicistat
J05AF13	TAF: Tenofoviralafenamid (TAF)
J05AG06	Doravirine
J05AR20	Emtricitabine, Tenofovir Alafenamide and Bictegravir
J05AR21	JLC: Juluca (DTG/RPV)

J05AR22	Symtuza (Emtricitabine, Tenofovir, Alafenamide, Darunavir and Cobicistat)
J05AR24	Lamivudine, Tenofovir, Disoproxil and Doravirine
J05AR25	Lamivudine and Dolutegravir

ART_RS - Coding Table

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired

16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance

94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown
92.91	Change to generic drug
92.92	Change to branded drug

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This coding list is identical to MED_RS used for non-ART medication recorded in tblMED

ART_RS2 - Coding Table

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired

16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance

94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This coding list is identical to MED_RS used for non-ART medication recorded in tblMED

ART_RS3 - Coding Table

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired

16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance

94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This coding list is identical to MED_RS used for non-ART medication recorded in tblMED

ART_RS4 - Coding Table

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired

16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance

94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This coding list is identical to MED_RS used for non-ART medication recorded in tblMED

ART_START_RS - Coding Table

Code	Reason for starting/receiving ART
1	PMTCT
30	ARV as treatment
40	PEP - Post Exposure Prophylaxis
50	PREP
95	Not ascertained
99	Unknown despite attempting ascertainment

Table: tblART_MUM - Antiretroviral Treatment of non-cohort mother

Description: Antiretroviral Medication of mother in cases where mother is not enrolled in cohort

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
CHILD_ID	character (or numeric if possible)	Patient ID of the child (If child is not enrolled into care at an IeDEA site, enter mother's ID with dashed numeric Suffix such as [MOTHER_ID]-1, [MOTHER_ID]-2, etc. here)
ART_ID	character. see coding table for valid codings.	represents the antiretroviral treatment
ART_SD	yyyy-mm-dd	date of initiation of treatment
ART_SD_A	character: see coding of date precision	Optional precision for date of initiation of treatment
ART_ED	yyyy-mm-dd	date of stopping treatment
ART_ED_A	character: see coding of date precision	Optional precision for date of stopping treatment
ART_RS	character. see coding table for valid codings.	reason for stopping treatment

Additional Fields

Depending on the aim of the study it might be needed to gather both the dosage and the frequency of the dosage taken. However many cohorts do not collect this date and thus these fields are optional.

Field name	Format	Description
ART_RS2	character. see coding table for valid codings.	Additional reason for stopping treatment
ART_RS3	character. see coding table for valid codings.	Additional reason for stopping treatment
ART_RS4	character. see coding table for valid codings.	Additional reason for stopping treatment
ART_FORM	numeric: • 1 = Tablet/capsule • 2 = Syrup/Suspension • 3 = Combination of 1 and 2 • 4 = Powder • 5 = Subcutaneous • 6 = Intravenous • 7 = Intramuscular • 9 = Unknown	What formulations of the drug was given?
ART_COMB	numeric: • 0 = Individual drug • 1 = Part of a fixed-dose combination • 9 = Unknown	Was the drug given as part of a fixed-dose combination?
ART_START_RS	numeric: see coding table for valid codings	Reason for starting/receiving ART

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes

AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

ART_ID - Coding Table

A set of extended ATC codes are being presented here in order to code both more specific on subtypes of the drugs, e.g. saquinavir hard and soft gel, but also to enable coding of drugs that are at their trial stage and have not yet been assigned an ATC code. To do this the drug will be assigned the code elements as far down the levels as possible. Given two examples to illustrate this:

Saquinavir - Hard Gel J05AE01-SQH Saquinavir - Soft Gel J05AE01-SQS Saquinavir - not specified J05AE01

This will ensure the fidelity needed to distinguish between hard and soft gel and not specified, but also for analysis easily include all records which coding starts with J05AE01, regardless if the drug is hard or soft gel.

See the ATC Index for the individual codes. The extended ATC codes are listed below along with a subset of ATC codes relevant to ART.

Code (Extended ATC Codes)	Anti-Retroviral Drugs
J05A	ART unspecified
J05A-BEV	Bevirimat
J05A-PBT	Participant in Blinded Trial
J05AE	PI unspecified
J05AE-MOZ	Mozenavir (DMP-450)
J05AE01	Saquinavir (gel, not specified)
J05AE01-SQH	Saquinavir hard gel (INVIRASE)
J05AE01-SQS	Saquinavir soft gel (FORTOVASE)
J05AE02	Indinavir (CRIXIVAN)
J05AE03	Ritonavir (NORVIR)
J05AE03-H	Ritonavir high dose (NORVIR)
J05AE03-L	Ritonavir low dose (NORVIR)
J05AE04	Nelfinavir (VIRACEPT)
J05AE05	Amprenavir (AGENERASE)
J05AR10	Lopinavir/Ritonavir (Kaletra). Former code: J05AE06
J05AE07	Fos-amprenavir (Telzir, Lexiva)
J05AE08	Atazanavir (Reyataz)
J05AE09	Tipranavir (Aptivus)

J05AE10	Darunavir (TMC-114, Prezista)
J05AF	NRTI unspecified
J05AF-ALO	Alovudine
J05AF-AMD	Amdoxovir (DADP)
J05AF-FOZ	Fozivudine tidoxi
J05AF-LDN	Lodenosine (trialdrug)
J05AF-RVT	Reverset
J05AF01	Zidovudine (AZT, RETROVIR)
J05AF02	Didanosine (ddI) (VIDEX)
J05AF03	Zalcitabine (ddC) (HIVID)
J05AF04	Stavudine (d4T) (ZERIT)
J05AF05	Lamivudine (3TC, EPIVIR)
J05AF06	Abacavir (1592U89) (ZIAGEN)
J05AF07	Tenofovir (VIREAD)
J05AF09	Emtricitabine
J05AG	NNRTI unspecified
J05AG04	Etravirine (TMC 125)
J05AG05	Rilpivirine (TMC-278)
J05AG-CPV	Capravirine
J05AG-DPC083	DPC 083
J05AG-DPC961	DPC 961
J05AG-EMV	Emivirine (MKC442)
J05AG-LOV	Loviride
J05AG01	Nevirapine (VIRAMUN)
J05AG02	Delavirdine (U-90152) (RESCRIPTOR)
J05AG03	Efavirenz (DMP-266) (STOCRIN, SUSTIVA)
J05AR01	Combivir (Zidovudine/Lamivudine)
J05AR02	Kivexa (Lamivudine/Abacavir)
J05AR03	Truvada (Tenofovir/Emtricabine)
J05AR04	Trizivir (Zidovudine/Lamivudine/Abacavir)
J05AR05	Douvir-N (Zidovudine/Lamivudine/Nevirapine)

J05AR06	Atripla (Emtricitabine/Tenofovir/Efavirenz)
J05AR07	Triomune (Stavudine/Lamivudine/Nevirapine)
J05AR08	Eviplera/Complera (Emtricitabine/Tenofovir/Rilpivirine)
J05AR09	Stribild (Emtricitabine/Tenofovir/Elvitegravir/Cobicistat)
J05AR10	Kaletra/Aluvia (Lopinavir/Ritonavir)
J05AR11	Lamivudine, tenofovir disoproxil and efavirenz
J05AR12	Lamivudine and tenofovir disoproxil
J05AR13	Triumeq (Lamivudine, abacavir and dolutegravir)
J05AR14	Darunavir and cobicistat
J05AR15	Atazanavir and cobicistat
J05AR16	Lamivudine and raltegravir
J05AR17	Emtricitabine and tenofovir alafenamide
J05AR18	Emtricitabine, tenofovir alafenamide, elvitegravir and cobicistat
J05AR19	Emtricitabine, tenofovir alafenamide and rilpivirine
J05AX-VIC	Vicriviroc (Schering)
J05AX07	Enfuvirtide (Fuzeon, T-20)
J05AX08	Raltegravir (Merck)
J05AX09	Maraviroc (Pfizer)
J05AX11	Elvitegravir
J05AX12	Dolutegravir
J05AX-CAB	Cabotegravir (GSK-744)
L01XX05	Hydroxyurea/Hydroxycarbamid (Litalir)
V03AX03	Cobicistat

ART_RS - Coding Table

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired

16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance

94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This coding list is identical to MED_RS used for non-ART medication recorded in tblMED

ART_RS2 - Coding Table

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired

16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance

94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This coding list is identical to MED_RS used for non-ART medication recorded in tblMED

ART_RS3 - Coding Table

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired

16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance

94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This coding list is identical to MED_RS used for non-ART medication recorded in tblMED

ART_RS4 - Coding Table

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired

16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance

94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

Although most reasons mentioned above could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This coding list is identical to MED_RS used for non-ART medication recorded in tblMED

ART_START_RS - Coding Table

Code	Reason for starting/receiving ART
1	PMTCT
30	ARV as treatment
40	PEP - Post Exposure Prophylaxis
50	PREP
95	Not ascertained
99	Unknown despite attempting ascertainment

Table: tblBAS - Basic clinical, background and demographic information

Description: holds **basic** information such as demographics, basic clinical information and date of AIDS diagnosis

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
BIRTH_D	yyyy-mm-dd	Birth date
BIRTH_D_A	character: see coding of date precision	optional precision annotation for birth date
FRSVIS_D	yyyy-mm-dd	First seen at clinic
ENROL_D	yyyy-mm-dd	Date of enrolment into the cohort
ENROL_D_A	character: see coding of date precision	optional precision annotation for date of enrolment into the cohort
SEX	numeric: • 1 = Male • 2 = Female • 9 = Unknown	Patient's gender/sex at birth
HEIGH	numeric (metric): 999 = Unknown	Height of patient at visit/most current
MODE	numeric. see coding table for valid codings.	Mode of infection

ORIGIN	character (1-3 letter/numeric codes). see coding table for valid codings.	Country or region of birth
ETHNIC	numeric. see coding table for valid codings.	Ethnicity of patient. Please take the additional notes into consideration when using this field.
EDU_LVL	numeric. see coding table for valid codings.	Last completed education Level. ISCED97 refers to the 1997 International Standard Classification of Education
HIV_POS_D	yyyy-mm-dd	Date of first positive HIV test
SEROCO_D	yyyy-mm-dd	Date of seroconversion
RECART_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Has the patient ever received antiretroviral treatment? This includes all antiretroviral therapy given as Treatment even if given by another Center or program but excludes antiretroviral drugs given only for PMTCT or other prophylaxis.
RECART_D	yyyy-mm-dd	Date of first antiretroviral Treatment Initiation. Leave blank if ART not yet initiated. This should be the first date at which antiretroviral therapy, regardless of Regimen, was given as Treatment irrespective of whether it was given at this center/program or not. It excludes antiretroviral regimens given only for PMTCT or other prophylaxis.
RECART_D_A	character: see coding of date precision	optional date precision annotation for date RECART_D.

LTART_D	yyyy-mm-dd	Date last assessed for ART. If started ART, last date known to be on ART, or if not on ART, last date ART free.
AIDS_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Has the patient ever been given an AIDS diagnosis? (i.e. WHO stage 3 or 4 or CDC category C diagnosis)
AIDS_D	yyyy-mm-dd	If yes, date of AIDS diagnosis
AIDS_D_A	character: see coding of date precision	optional precision annotation for date AIDS_D

Additional Fields

For mode of infection and origin a set of other fields are often used to capture what cannot be coded. These fields are represented here as optional fields as it is the intention that the suggested codes applied to the MODE and ORIGIN should be able to cover all possible values.

Field name	**Format**	**Description**
MODE_OTH	character	Mode of infection OTHER
ORI_OTH	character	Origin of patient OTHER
CENS_D	yyyy-mm-dd	The last date the database has been updated for this patient
SEROHOW	numeric: • 1 = Midpoint between last neg/first pos test • 2 = Lab evidence of seroconversion • 3 = Seroconversion illness • 4 = Other • 9 = Unknown	For Seroconverters only: How was the seroconversion date determined?
NAIVE_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is the patient ART-naïve upon enrollment?

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblBAS	WithinTable	BW001	AIDS date < SEROCO_D		Yes
tblBAS	WithinTable	BW002	Duplicate patients		Yes
tblBAS	WithinTable	BW003	First 3 chars of PATIENT don't form valid cohort code	CascadeOnly	Yes
tblBAS	WithinTable	BW004	Missing PATIENT		Yes

tblBAS	WithinTable	BW005	Missing CENTER		Yes
tblBAS	WithinTable	BW006	Missing BIRTH_D		Yes
tblBAS	WithinTable	BW007	Missing FRSVIS_D		Yes
tblBAS	WithinTable	BW008	Missing ENROL_D		Yes
tblBAS	WithinTable	BW009	Missing GENDER		Yes
tblBAS	WithinTable	BW010	Missing HEIGH		Yes
tblBAS	WithinTable	BW011	Missing MODE		Yes
tblBAS	WithinTable	BW012	Missing MODE_OTH if MODE=90		Yes
tblBAS	WithinTable	BW013	Missing ORIGIN		Yes
tblBAS	WithinTable	BW014	Missing ETHNIC		Yes
tblBAS	WithinTable	BW015	Missing SEROCO_D		Yes
tblBAS	WithinTable	BW016	Missing RECART_Y		Yes
tblBAS	WithinTable	BW017	Missing AIDS_Y		Yes
tblBAS	WithinTable	BW018	Missing AIDS_D if AIDS_Y=1		Yes
tblBAS	WithinTable	BW019	BIRTH_D out of range (15-85 yrs)	CascadeOnly	Yes
tblBAS	WithinTable	BW020	BIRTH_D out of range (<18)	PENTA	Yes
tblBAS	CrossTable	BC001	RECART_Y=1 but no records in tblART		Yes

tblBAS	CrossTable	BC002	AIDS_Y=0, but AIDS-defining records in tblDIS		Yes
tblBAS	CrossTable	BC003	AIDS_Y=1 but no AIDS-defining records in tblDIS table		Yes

MODE - Coding Table

Code	Mode of infection
1	homo/bisexual
2	injecting drug user
3	(1+2)
4	haemophiliac
5	transfusion, non-haemophilia related
6	heterosexual contact
7	(6+2)
8	Perinatal
9	Sexual contact (homo/hetero not specified)
10	Sexual abuse
90	other, (specify)
99	unknown

ORIGIN - Coding Table

Region codes & country codes

Region Codes

UN Region Codes - Composition of macro geographical (continental) regions, geographical sub-regions, and selected economic and other groupings

Code	Region
001	World
002	Africa
014	- Eastern Africa
017	- Middle Africa
015	- Northern Africa
018	- Southern Africa
011	- Western Africa
019	Americas
419	- Latin America and the Caribbean
029	- - Caribbean
013	- - Central America
005	- - South America
021	- Northern America
142	Asia
143	- Central Asia
030	- Eastern Asia
034	- Southern Asia
035	- South-Eastern Asia
145	- Western Asia
150	Europe
151	- Eastern Europe
154	- Northern Europe
039	- Southern Europe
155	- Western Europe
009	Oceania

053	- Australia and New Zealand
054	- Melanesia
057	- Micronesia
061	- Polynesia

Country Codes

UN Country Codes - Countries or areas, codes and abbreviations, including translation from ISO ALPHA-3 codes.

Code	Country	ISO ALPHA-3 code
4	Afghanistan	AFG
248	Åland Islands	ALA
8	Albania	ALB
12	Algeria	DZA
16	American Samoa	ASM
20	Andorra	AND
24	Angola	AGO
660	Anguilla	AIA
28	Antigua and Barbuda	ATG
32	Argentina	ARG
51	Armenia	ARM
533	Aruba	ABW
36	Australia	AUS
40	Austria	AUT
31	Azerbaijan	AZE
44	Bahamas	BHS
48	Bahrain	BHR
50	Bangladesh	BGD
52	Barbados	BRB
112	Belarus	BLR
56	Belgium	BEL
84	Belize	BLZ

204	Benin	BEN
60	Bermuda	BMU
64	Bhutan	BTN
68	Bolivia (Plurinational State of)	BOL
535	Bonaire, Saint Eustatius and Saba	BES
70	Bosnia and Herzegovina	BIH
72	Botswana	BWA
76	Brazil	BRA
92	British Virgin Islands	VGB
96	Brunei Darussalam	BRN
100	Bulgaria	BGR
854	Burkina Faso	BFA
108	Burundi	BDI
116	Cambodia	KHM
120	Cameroon	CMR
124	Canada	CAN
132	Cape Verde	CPV
136	Cayman Islands	CYM
140	Central African Republic	CAF
148	Chad	TCD
830	Channel Islands	
152	Chile	CHL
156	China	CHN
344	China, Hong Kong Special Administrative Region	HKG
446	China, Macao Special Administrative Region	MAC
170	Colombia	COL
174	Comoros	COM
178	Congo	COG
184	Cook Islands	COK

188	Costa Rica	CRI
384	Côte d'Ivoire	CIV
191	Croatia	HRV
192	Cuba	CUB
531	Curaçao	CUW
196	Cyprus	CYP
203	Czech Republic	CZE
408	Democratic People's Republic of Korea	PRK
180	Democratic Republic of the Congo	COD
208	Denmark	DNK
262	Djibouti	DJI
212	Dominica	DMA
214	Dominican Republic	DOM
218	Ecuador	ECU
818	Egypt	EGY
222	El Salvador	SLV
226	Equatorial Guinea	GNQ
232	Eritrea	ERI
233	Estonia	EST
231	Ethiopia	ETH
234	Faeroe Islands	FRO
238	Falkland Islands (Malvinas)	FLK
242	Fiji	FJI
246	Finland	FIN
250	France	FRA
254	French Guiana	GUF
258	French Polynesia	PYF
266	Gabon	GAB
270	Gambia	GMB
268	Georgia	GEO

276	Germany	DEU
288	Ghana	GHA
292	Gibraltar	GIB
300	Greece	GRC
304	Greenland	GRL
308	Grenada	GRD
312	Guadeloupe	GLP
316	Guam	GUM
320	Guatemala	GTM
831	Guernsey	GGY
324	Guinea	GIN
624	Guinea-Bissau	GNB
328	Guyana	GUY
332	Haiti	HTI
336	Holy See	VAT
340	Honduras	HND
348	Hungary	HUN
352	Iceland	ISL
356	India	IND
360	Indonesia	IDN
364	Iran (Islamic Republic of)	IRN
368	Iraq	IRQ
372	Ireland	IRL
833	Isle of Man	IMN
376	Israel	ISR
380	Italy	ITA
388	Jamaica	JAM
392	Japan	JPN
832	Jersey	JEY
400	Jordan	JOR
398	Kazakhstan	KAZ

404	Kenya	KEN
296	Kiribati	KIR
414	Kuwait	KWT
417	Kyrgyzstan	KGZ
418	Lao People's Democratic Republic	LAO
428	Latvia	LVA
422	Lebanon	LBN
426	Lesotho	LSO
430	Liberia	LBR
434	Libya	LBY
438	Liechtenstein	LIE
440	Lithuania	LTU
442	Luxembourg	LUX
450	Madagascar	MDG
454	Malawi	MWI
458	Malaysia	MYS
462	Maldives	MDV
466	Mali	MLI
470	Malta	MLT
584	Marshall Islands	MHL
474	Martinique	MTQ
478	Mauritania	MRT
480	Mauritius	MUS
175	Mayotte	MYT
484	Mexico	MEX
583	Micronesia (Federated States of)	FSM
492	Monaco	MCO
496	Mongolia	MNG
499	Montenegro	MNE
500	Montserrat	MSR

504	Morocco	MAR
508	Mozambique	MOZ
104	Myanmar	MMR
516	Namibia	NAM
520	Nauru	NRU
524	Nepal	NPL
528	Netherlands	NLD
540	New Caledonia	NCL
554	New Zealand	NZL
558	Nicaragua	NIC
562	Niger	NER
566	Nigeria	NGA
570	Niue	NIU
574	Norfolk Island	NFK
580	Northern Mariana Islands	MNP
578	Norway	NOR
275	Occupied Palestinian Territory	PSE
512	Oman	OMN
586	Pakistan	PAK
585	Palau	PLW
591	Panama	PAN
598	Papua New Guinea	PNG
600	Paraguay	PRY
604	Peru	PER
608	Philippines	PHL
612	Pitcairn	PCN
616	Poland	POL
620	Portugal	PRT
630	Puerto Rico	PRI
634	Qatar	QAT
410	Republic of Korea	KOR

	Republic of Kosovo	
498	Republic of Moldova	MDA
638	Réunion	REU
642	Romania	ROU
643	Russian Federation	RUS
646	Rwanda	RWA
652	Saint-Barthélemy	BLM
654	Saint Helena	SHN
659	Saint Kitts and Nevis	KNA
662	Saint Lucia	LCA
663	Saint-Martin (French part)	MAF
666	Saint Pierre and Miquelon	SPM
670	Saint Vincent and the Grenadines	VCT
882	Samoa	WSM
674	San Marino	SMR
678	Sao Tome and Principe	STP
680	Sark	
682	Saudi Arabia	SAU
686	Senegal	SEN
688	Serbia	SRB
690	Seychelles	SYC
694	Sierra Leone	SLE
702	Singapore	SGP
534	Sint Maarten (Dutch part)	SXM
703	Slovakia	SVK
705	Slovenia	SVN
90	Solomon Islands	SLB
706	Somalia	SOM
710	South Africa	ZAF
728	South Sudan	SSD

724	Spain	ESP
144	Sri Lanka	LKA
729	Sudan	SDN
740	Suriname	SUR
744	Svalbard and Jan Mayen Islands	SJM
748	Swaziland	SWZ
752	Sweden	SWE
756	Switzerland	CHE
760	Syrian Arab Republic	SYR
762	Tajikistan	TJK
764	Thailand	THA
807	The former Yugoslav Republic of Macedonia	MKD
626	Timor-Leste	TLS
768	Togo	TGO
772	Tokelau	TKL
776	Tonga	TON
780	Trinidad and Tobago	TTO
788	Tunisia	TUN
792	Turkey	TUR
795	Turkmenistan	TKM
796	Turks and Caicos Islands	TCA
798	Tuvalu	TUV
800	Uganda	UGA
804	Ukraine	UKR
784	United Arab Emirates	ARE
826	United Kingdom of Great Britain and Northern Ireland	GBR
834	United Republic of Tanzania	TZA
840	United States of America	USA
850	United States Virgin Islands	VIR

858	Uruguay	URY
860	Uzbekistan	UZB
548	Vanuatu	VUT
862	Venezuela (Bolivarian Republic of)	VEN
704	Viet Nam	VNM
876	Wallis and Futuna Islands	WLF
732	Western Sahara	ESH
887	Yemen	YEM
894	Zambia	ZMB
716	Zimbabwe	ZWE

ETHNIC - Coding Table

Codes are hierarchically structured, therefore please indicate most detailed code as possible.

Code	Ethnicity of patient
100	White/Caucasian
110	> White, European
200	Black
204	> Other Black
210	> Sub-Saharan African
220	> Caribbean
230	> African-American
250	> Black, African
300	Hispanic/Latinx
400	Asian
405	> Other asian
410	> East Asian (e.g. Chinese, Japanese)
411	> > Chinese
412	> > Japanese
420	> Southeast Asia (e.g. Thai, Vietnamese, Philippino)
421	> > Indian Subcontinent (Indian, Pakistani, Bangladeshi)
430	> South Asian (e.g. Indian, Pakistani)
800	Other ethnic groups
810	> Maghrebian
820	> Middle East/Arab
830	> Turkish
840	> Roma people/Gypsy (whichever is term is acceptable)
850	> Indigenous people from Americas or Alaska Native
860	> Indigenous people from other continents/locations

900	Mixed race/ethnicity
910	Do not want to disclose
980	Prohibited
999	Unknown

Limitations

The definition of ethnicity is complex and there is no ideal definition for all countries and for all times. Likewise is the definition of race and though conceptually different from ethnicity, they are often used interchangeably. As described by many authors, ethnicity is a fluid and imprecise concept heavily influenced by societal views. If definition of ethnicity is complex, inevitably its categorization will be complex too. The definition and categorization used in HICDEP acknowledges these limitations and aims by no means to solve the intense international debate of this issue but to provide a homogeneous and practical approach for HIV research. We have partially used existing administrative classifications as they provide the advantage to have, in some instances, census population denominators but are invariably too detailed for practical use in the context of HICDEP.

We suggest users to ask themselves "why is this variable necessary to answer my research question?" to avoid some of the common mistakes highlighted in the publications below which have attributed to exclusively biological and/or genetic traits differences heavily influenced by the profound social, cultural and political differences inherent to those categories. We aim to provide a standardized definition that, in addition to the information on country or region of birth already collected within HICDEP, can be used by cohort studies of HIV infected people from different countries. Therefore, in order to encompass these different scenarios, some terms may have little meaning for some settings. Finally, this classification allows for multiple options and whenever possible, should be based on the patients' self-identification.

1. Ahdieh L, Hahn RA. Use of the terms 'race', 'ethnicity', and 'national origins': a review of articles in the American Journal of Public Health, 1980–1989. Ethnicity and Health 1996; 1:95–8

2. Bhopal R. Glossary of terms relating to ethnicity and race: for reflection and debate. J. Epidemiol. Community Health 2004; 58:441–445
3. Cooper RS, Kaufman JS, Ward R. Race and Genomics. N Engl J Med 2003; 348; 12: 1166-1170
4. European Centre for Disease Prevention and Control. Improving HIV data comparability in migrant populations and ethnic minorities in EU/EEA/EFTA countries: findings from a literature review and expert panel. Stockholm: ECDC; 2011.www.ecdc.europa.eu

EDU_LVL - Coding Table

Code	Description
1	primary education (ISCED97-1)
2	lower secondary (ISCED97-2) OR end of basic education
3	upper secondary or post-secondary non-tertiary (ISCED97 3 and 4)
4	university or post-graduate (ISCED97 5A and 5B)
8	other, only if none of the codes 0 to 4 applies
9	Unknown

Table: tblCANC - Diagnosis of Cancer

Description: holds type and date of **diagnosis of cancer**

There is a large heterogeneity across cohorts regarding the documentation of cancer diagnoses. Some use ICD9 or ICD10 for cancer location and have no information on histology. Others have cross-linked with cancer registries and are able to provide very granular ICD-O-3 histology codes. There are also proprietary systems such as the NA-ACCORD short list (instructions, list_1 & list_2). In tblCANC we suggest to not restrict to a single coding system but to allow cohorts to provide the data in different systems as long as definitions and mapping tables are submitted alongside the data.

For new cohorts we propose to use ICD9/10 coding schemes for cancer location and ICD-O-3 for histology if these results can be obtained from cancer registries.
Each row of tblCANC consists of a diagnosis of one cancer type.
If AIDS defining cancers are reported in tblCANC they should NOT be deleted from tblDIS.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Patient id
CANC_D	yyyy-mm-dd	Date of diagnosis
CANC_D_A	character: see coding of date precision	optional precision annotation for date of diagnosis
LOC_CODE	character	Location code according to diagnosis
LOC_CODE_SYS	character	Location coding System: ICD10, ICD9, other systems, e.g. NA-ACCORD-short list
HIST_CODE	character	Histology code according to diagnosis

HIST_CODE_SYS	character	Histology coding system: ICD-O-3, other systems, e.g. NA-ACCORD-short list, None

Additional Fields

Field name	Format	Description
DIAG_ADJUD_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Diagnosis centrally adjudicated
DIAG_VALID_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Diagnosis histologically confirmed
REGISTRY_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Coding and Diagnosis taken from cancer registry
HIST_AVAILABLE_Y	numeric: • 0 = No • 1 = Yes • 2 = Summary available • 9 = Unknown	Histology available
HIST_SUMMARY	character	If HIST_AVAILABLE_Y = 1 or 2, please store a copy of the full report and provide a short free text histology summary here.
CANC_HISTORY_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Has the patient previously received radiotherapy, chemotherapy or surgery for a malignant disease
CANC_HISTORY_D	yyyy	If yes, provide first year of treatment

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

Table: tblCENTER - Center information

Description: holds information about the **Center** (e.g. geographical localisation, type of clinic) where the patient is receiving HIV care

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
CENTER	character	Code for Clinic/Center/Hospital where patient is seen. Needs to be unique within each Region.
PROGRAM	character	Program or region with which the center is associated. Links to tblPROGRAM.
NAME	character	Proper name to identify center
COUNTRY	character	3-letter ISO code
PROVINCE	character	(Optional) Proper name to identify province
DISTRICT	character	(Optional) Proper name to identify disctrict
CITY	character	(Optional) Proper name to identify city
GEOCODE_LAT	numeric	Latitude (e.g. 47.376739 for University Hospital Zurich)
GEOCODE_LON	numeric	Longitude (e.g. 8.549156 for University Hospital Zurich)

RURAL	numeric: • 1 = Urban • 2 = Mostly urban • 3 = Mostly rural • 4 = Rural • 9 = Unknown	Code for the site situation (facility location)
LEVEL	numeric: • 1 = Health centre • 2 = District hospital • 3 = Regional, provincial or university hospital • 9 = Unknown	Code for level of care
ADULTPED	character: "PED","ADULT", or "BOTH"	Population the center serves
OPEN_D	yyyy-mm-dd	(Optional) Date of opening of dataset: earliest date for which data were included from this site
CLOSE_D	yyyy-mm-dd	(Optional) Date of closing of dataset
ADD_CENTER	yyyy-mm-dd	Inclusion date: date that the site was added to the cohort
DROP_CENTER	yyyy-mm-dd	(Optional) Exclusion date: date that the site was dropped from the cohort
SURVEY_INTERNET	numeric: • 1 = sufficient Access to complete online surveys • 2 = degraded Access making online Survey completion difficult • 3 = no internet access • 9 = Unknown	Quality of internet access for completing online Surveys.

SURVEY_PAPER	numeric: • 1 = site has resources to print and transfer Surveys • 2 = site has resources to print, but not Transfer surveys • 3 = site does not have resources to print, but can transfer surveys • 4 = site Needs assistance in both printing and transferring surveys • 8 = not applicable • 9 = Unknown	Resources for printing and transferring paper surveys to a central location for data entry.
LAST_REVIEWED_D	yyyy-mm-dd	Date when Center data in this table was last reviewed and/or updated.
LAST_REVIEWED_D_A	character: see coding of date precision	optional precision annotation for last review date LAST_REVIEW_D

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes

AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

Table: tblCEP - Clinical Events and Procedures

Description: holds type and date of **clinical events and procedures** including serious non-AIDS conditions. Former known as tblAE (adverse event).

Note: Fields marked **bold** form the unique identifier for a record of the table.

EVENT_ID	numeric	Unique Event Identifier (foreign key to the different event tables)
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
CEP_D	yyyy-mm-dd	date of event
CEP_ID	character. see coding table for valid codings.	identifies type of event
CEP_SPEC	character. see coding table for valid codings.	further specification
CEP_V	numeric. See coding table for interpretation.	Depending on CEP_ID and CEP_SPEC: value of given event
SRCDOC_Y	numeric: • 1 = Yes • 0 = No	whether the source documentation is available
SRCDOC_D	yyyy-mm-dd	date for source documentation verification
VERIFY_Y	numeric: • 1 = Yes • 0 = No	Has the monitor verified the source documentation?
VERIFY_D	yyyy-mm-dd	date for monitor verification
APPROV_Y	numeric: • 1 = Yes • 0 = No	final verification/approval

APPROV_D	yyyy-mm-dd	final verification date
APPROV_S	character	signature for final verification

Additional Fields

Field name	Format	Description
CEP_Y	numeric: • 1 = Yes • 0 = No • 9 = Unknown	has the patient had an event?
CEP_NAME	character	full name of the event
CEP_DESCRIP	character	full description of the event
CEP_R_Y	numeric: • 0 = not related • 1 = definitive • 2 = remote/unlikely • 3 = possible • 4 = probable	relation to treatment

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes

AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

CEP_ID - Coding Table

Code	Event
AMI	Acute myocardial infarction
ASCI	Ascites
ASP	Invasive aspergillosis
AVN	Avascular necrosis in the femural head
BACT	Bacteremia
BART	Bartonellosis
CERC	Cervical cerclage
CHAG	Chagas disease (American trypanosomiasis) of the CNS
CLD	Chronic liver disease
DIA	Diabetes mellitus
ENDO	Endocarditis
ESRD	End stage renal disease
FAT	Fatal case with insufficient data
FIBS	Fibroscan stiffness (add elasticity value in CEP_V)
FRA	Bone fracture (irrespective of location)
HEP	Hepatic encephalopathy
HESY	Hepatorenal syndrome
HOSP	Hospitalisation
ICP	Invasive Cardiovascular Procedures
ICU	Admission for the ICU
JAUN	Jaundice
LAC	Lactic acidosis
LEIS	Leishmaniasis, visceral
LIVB	Liver biopsy
LIVD	Liver decompensation
LIVT	Liver transplantation
MENI	Meningitis

MCDI	Microsporidosis diarrhoes (dur. > 1 month)
NADM	Non-AIDS defining malignancies
NOCA	Nocardiosis
OESO	Oesophageal variceal bleeding
OSTI	Ostitis
PAN	Pancreatitis
PCE	Pneumocystis carinii extrapulmonary
PMAR	Penicillium marneffei, disseminated
PERI	Spontaneous bacterial peritonitis
PNEU	Pneumonia
PYEL	Pyelonephritis
REQU	Rhodococcus equi disease
STR	Stroke (infarction or haemorrhagia)
USAB	Ultrasound imaging of the abdomen
CTAB	CT abdomen
ARFI	Acoustic Radiation Force Impulse

Coding Table: Pregnancy-related adverse events

Code	**Event**
ANEM	Anemia (<10g/l)
FEV	Fever (> 38 0C and > 1 day)
URITINF	Urinary tract infection
HEMATOMA	Hematoma
ENDOM	Endometritis
WOUINF	Wound infection
PERIT	Peritonitis
PNEU	Pneumonia
SEPSIS	Sepsis (fever and pos blood culture)
THROMB	Thromboembolism
DIC	Disseminated intravascular coagulation (DIC)
SUBI	Subileus/ ileus

HEMOR	Hemorrhage
PSY	Psychosis
PREECL	Preeclampsia/eclampsia
ANEMBL	Severe anemia requiring blood transfusion

Coding Table: Early childhood-related adverse events

Code	**Event**
DEVD	Developmental delay
SEIZ	Seizures
ONEU	Other neurological symptoms (use with AE_DESCRIP)
OABN	Other abnormal findings (use with AE_DESCRIP)

Case Definitions

CEP_SPEC - Coding Table

Note: The codes for NADM are tentative and subject to change for the next release.

Code (CEP_ID)	Code (CEP_SPEC)	Description
AMI	DAMI	Definitive Myocardial infarction
AMI	PAMI	Possible Myocardial infarction
LIVB	F0	no fibrosis
LIVB	F1	portal fibrosis without septa
LIVB	F2	portal fibrosis with few septa
LIVB	F3	numerous septa without cirrhosis
LIVB	F4	cirrhosis
HEP	I	Hepatic encephalopathy stage I
HEP	II	Hepatic encephalopathy stage II
HEP	III	Hepatic encephalopathy stage III
HEP	IV	Hepatic encephalopathy stage IV
HEP	III+IV	Hepatic encephalopathy stage III or IV
ICP	ANG	Invasive Cardiovascular Procedures: Coronary angioplasty/stenting
ICP	BYP	Invasive Cardiovascular Procedures: Coronary artery by-pass grafting
ICP	END	Invasive Cardiovascular Procedures: Carotic endarterectomy
NADM	ALL	Leukemia: Acute lymphoid
NADM	AML	Leukemia: Acute myeloid
NADM	ANAL	Anal dysplasia, grade 2 or higher
NADM	ANUS	Anal cancer

NADM	BLAD	Bladder cancer
NADM	BRCA	Breast cancer
NADM	BRAIN	Brain cancer
NADM	CERV	Cervical dysplasia/carcinoma in situ, grade 2 or higher
NADM	CLL	Leukemia: Chronic lymphoid
NADM	CML	Leukemia: Chronic myeloid
NADM	COLO	Colon cancer
NADM	COTC	Connective tissue cancer
NADM	HDL	Hodgkin lymphoma
NADM	HENE	Head and neck cancer
NADM	KIDN	Kidney cancer
NADM	LEUK	Leukemia: unspecified
NADM	LIPC	Lip cancer
NADM	LIVR	Liver cancer
NADM	LUNG	Lung cancer
NADM	MALM	Malignant melanoma
NADM	MEAC	Metastasis: of adenocarcinoma
NADM	MEOC	Metastasis: of other cancertype
NADM	MESC	Metastasis: of squamuos cell carcinoma
NADM	META	Metastasis: unspecified
NADM	MULM	Multiple myeloma
NADM	PENC	Penile cancer
NADM	PROS	Prostate cancer
NADM	RECT	Rectum cancer
NADM	STOM	Stomach cancer
NADM	TESE	Testicular seminoma
NADM	UTER	Uterus cancer
STR	SHAE	Stroke: Haemorrhagia
STR	SINF	Stroke: Infarction
STR	SUNK	Stroke: Unknown

FRA	SKUL	Skull
FRA	FABO	Facial bones (including nose)
FRA	COLB	Collar bone
FRA	SHOU	Shoulder
FRA	UPAR	Upper arm
FRA	LOAR	Lower arm (including hands)
FRA	FING	Fingers
FRA	RIB	Rib
FRA	TOSP	Thoracic spine
FRA	CESP	Cervical spine
FRA	LUSP	Lumbar spine
FRA	FEM	Femur
FRA	HIP	Hip
FRA	LOLG	Lower leg (including feet)
FRA	TOE	Toes
FRA	OTH	Other

CEP_V - Coding Table

CEP_ID	CEP_SPEC	Interpretation of CEP_V
FIBS		Fibroscan elasticity given in (KPa)
HOSP		Number of days addmited to the hospital
ICU		Number of days addmited to the ICU
FRA		1 = Traumatic, 2 = Osteoporotic/Fragility, 3 = Pathologic

Table: tblDELIVERY_CHILD - Delivery information related to the child(ren)

Description: holds **delivery** information related to the child

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
MOTHER_ID	Character (or numeric if possible)	Patient ID of pregnant woman (mother of the child)
MEMRUP_D	yyyy-mm-dd	Date of rupture of membranes
CHILD_ID	Character (or numeric if possible)	Patient ID of the child (If child is not enrolled into care at a Center, enter mother's ID with dashed numeric Suffix such as [MOTHER_ID]-1, [MOTHER_ID]-2, etc. here)
CHILD_ENROL	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is child enrolled into care at a center / an IeDEA site?
B_SEQ	numeric	If multiple births, indicate number (1=first born)
DELIV_D	yyyy-mm-dd	Date of delivery
DELIV_D_A	character: see coding of date precision	optional precision annotation for date of delivery DELIV_D
DELIV_T	hh:mm	Time of delivery

DELIV_M	character: • 1=Vaginally, spontaneous • 2=Vaginally, forceps • 3=Vaginally, vacuum • 4=Vaginally, assisted (not further specified) • 5=Vaginally, unknown • 10= Cesarean section, primary/elective (before onset of labour and rupture of membrane) • 11=Cesarean section, Secondary • 12=Cesarean section (not further specified)	Mode of delivery
LABOUR_P	numeric	Duration of labour in hours (from cervical dilatation (>=3 cm) until delivery)
BREECH_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Was the child born from a breech presentation?

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes

AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

Table: tblDELIVERY_MUM - Delivery information related to the mother

Description: holds **delivery** information related to the mother

This table contains information about the delivery specific to the mother. Child-specific information is recorded in tblDELIVERY_CHILD instead.

Please also read the notes on pregnancy tables.

Note: Fields marked **bold** form the unique identifier for a record of the table.

MOTHER_ID	Character (or numeric if possible)	Patient ID of pregnant woman (mother of the child)
PREG_SEQ	numeric	Sequence number of the pregnancy for the specified mother
MEMRUP_D	yyyy-mm-dd	Date of rupture of membranes
MEMRUP_T	hh:mm	Time of rupture of membranes
ROM_DUR	numeric (metric: hours), 999 = unknown	Duration of rupture of membranes
ROM_DUR_A	character: • <= less than value specified • >= greater than value specified • == value specified	Qualifier for Duration of rupture of membranes (relates to value specified for ROM_DUR).
DELIV_LOCATION	numeric: • 1= health facility • 2= home • 3= other • 9= unknown	Location of delivery

PLANNED_HOME	numeric: • 0= No • 1= Yes • 9= Unknown	If Patient delivered at home, was it planned in advance?
DELIV_ASSIST	numeric: • 1= Doctor / Nurse / Midwife • 2= Traditional Birth Attendant • 3= Relative / Friend • 4= No one • 9= unknown	Who assisted with the delivery? (If multiple, select Response with the lowest associated numeric code)
LABOUR	character: • 1=Spontanous • 2=Induced • 3=No labour (elective C-section)	Onset of labor
INTERV	character: • 0=No • 1=Fetal blood sampling FBS • 2=Internal electrodes • 3=1+2 • 90=Other • 91=1+Other • 92=2+Other • 93=1+2+Other	Interventions during delivery
INTERV_O	character	Interventions during delivery - other
TEAR_Y	numeric: • 0=No • 1=Yes • 9=Unknown	Episiotomy/tear
BLDLOSS	numeric (mL)	Estimated blood loss during delivery

CONTREAT	character: • 0=No, treatment has been interrupted • 1=Yes, at the foreseen intervals • 2=Yes, but not at forseen time points • 9=Unknown	Did the patient continue the usual antiretroviral therapy?
DISCHA_D	yyyy-mm-dd	Date of discharge from hospital

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes

AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblDELIVERY_MUM	CrossTable	DMC001	MOTHER_ID doesn't exist in tblPREG		Yes
tblDELIVERY_MUM	CrossTable	DMC002	MOTHER_ID doesn't exist in tblDELIVERY_CHILD with same MEMRUP_D		Yes
tblDELIVERY_MUM	WithinTable	DMW001	PREG_SEQ invalid (PREG_SEQ> 1 and PREG_SEQ=x, but PREG_SEQ=x-1 doesn't exist)		Yes
tblDELIVERY_MUM	WithinTable	DMW002	DISCHA_D < MEMRUP_D		Yes
tblDELIVERY_MUM	WithinTable	DMW004	INTERV=0-3 but INTERV_O non null		Yes
tblDELIVERY_MUM	WithinTable	DMW003	INTERV=90,91, 92 or 93 but INTERV_O null		Yes

Table: tblDIS - CDC-C and WHO Stage Diseases

Description: holds type and date of CDC-C **diseases** and malignancies.

Note: Fields marked **bold** form the unique identifier for a record of the table.

PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
DIS_ID	character. see coding table for valid codings.	Code to identify event
DIS_D	yyyy-mm-dd	Start date of event (Date of disease diagnosis)
DIS_WD	numeric. see coding table for valid codings.	Means/Certainty of diagnosis
DIS_OTH[1]	character	Other location, only to be filled out if DIS_ID code alone is not sufficient

[1] DIS_OTH might be part of the record's unique identification

Additional Fields

Please see tblCEP for specification on optional fields.

Field name	Format	Description
DIS_ED	yyyy-mm-dd	End date of Event (If end date is available, disease outcome should be specified)
DIS_ED_A	character: see coding of date precision	optional precision annotation for end of infection date DIS_ED
DIS_SITE	numeric. see coding table for valid codings.	Event site

DIS_OUTCOME	numeric. see coding table for valid codings.	Disease outcome

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblDIS	WithinTable	DW001	Duplicate records for same DIS_ID and same DIS_D		Yes

tblDIS	WithinTable	DW002	Miscoded DIS_WD as codes on table definition		Yes
tblDIS	WithinTable	DW003	Miscoded DIS_ID - as in code list attached to table definition		Yes
tblDIS	WithinTable	DW004	DIS_D missing		Yes
tblDIS	WithinTable	DW005	DIS_ID missing		Yes
tblDIS	WithinTable	DW006	Same event recorded twice - 2 records, same DIS_ID, DIS_D within 6 months		Yes
tblDIS	WithinTable	DW007	DIS_ED present but before DIS_D		Yes
tblDIS	CrossTable	DC001	Patient has no record in BAS		Yes
tblDIS	CrossTable	DC002	AIDS-defining records, yet AIDS=0 in tblBAS		Yes
tblDIS	CrossTable	DC003	First AIDS-defining DIS_D not equal to AIDS_D in tblBAS		Yes

DIS_ID - Coding Table

Code	Severe Opportunistic Infection / Malignancies
ANGC	Angular cheilitis
BCGD	BCG disease - disseminated
BCIR	Recurrent severe persumed bacterial infection (excluding pneumonia)
BCNE	Bacterial pneumonia, recurrent (>2 episodes within 1 year)
BLD	Unexplained anaemia (<8g/dl), and or neutropaenia (<500/mm3 - 2; <1000/mm3 - children), and or thrombocytopaenia (<50000/mm3) > 1 month
CANE	Candidiasis oesophogeal
CANM	Candidiasis (oral) (outside neonatal period)
CANO	Candidiasis (oesophogeal, bronchi, trachea, or lungs)
CANT	Candidiasis (bronchi, trachea, or lungs)
CLD	Chronic HIV-associated lung disease
CMO	HIV-associated cardiomyopathy
CMVO	Cytomegalovirus other Location (site other than liver, Spleen or lymph nodes)
CMVR	Cytomegalovirus (CMV) chorioretinitis (onset at age > 1 month)
COCC	Coccidioidomycosis, disseminated or extrapulmonary
CRCO	Cryptococcosis, extrapulmonary
CRSP	Cryptosporidiosis (duration > 1 month)
CRVC	Cervical cancer (invasive)
DEM	AIDS dementia complex
DIAC	Unexplained chronic diarrhoea (> 1 month for adults; > 14 days for children)
ENC	HIV encephalopathy
DEM	AIDS dementia complex

FBLS	Focal Brain lesion
FEVC	Unexplained persistent fever (> 1 month)
FNIF	Fungal nail infections of fingers
HERP	Herpes simplex virus ulcers (duration > 1 month) or pneumonitis/esophagitis
HERPV	Visceral Herpes simplex infection
HIST	Histoplasmosis, extrapulm.
HZS	Herpes zoster (single dermatome)
ISDI	Isosporiasis diarrhoea (duration > 1 month)
KS	Kaposi Sarcoma
LEIS	Leishmaniasis visceral
LEU	Progressive multifocal leucoencephalopathy
LIP	Symptomatic lymphoid interstitial pneumonitis
LNTB	Lymph node tuberculosis
MC	Mycobact. avium complex (MAC) or Kanasii, extrapulm.
MCDI	Microsporidosis diarrhoea (duration > 1 month)
MCP	Mycobact. tuberculosis pulm.
MCPO	Mycobact. pulm., other
MCX	Mycobact. tuberculosis extrapulm
MCXO	Mycobact. extrapulm., other
NHG	Non-Hodgkin Lymphoma -not specified
MNUM	Unexplained moderate malnutrition or wasting
MNUS	Unexplained severe malnutrition or wasting
MYCD	Any disseminated mycosis
NHG	Non-Hodgkin Lymphoma - not specified
NHGB	Non-Hodgkin Lymphoma – Burkitt (Classical or Atypical)
NHGI	Non-Hodgkin Lymphoma – Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic)
NHGP	Non-Hodgkin Lymphoma - Primary Brain Lymphoma

NHGU	Non-Hodgkin Lymphoma - Unknown/other histology
NPO	HIV-associated nephropathy
NUS	Acute necrotising ulcerative stomatitis, gingivitis or periodontitis
OHLP	Oral hairy leukoplakia
ORUL	Recurrent oral ulcerations
PCP	Pneumocystis carinii pneumonia (PCP)
PGL	Persistent Generalized Lymphadenopathy
PPE	Papular pruritic eruptions
RTIR	Recurrent or chronic respiratory tract infection (RTIs, sinusitis, bronchitis, otitis media, otorrhea, pharyngitis)
SAM	Salmonella bacteriaemia (non-tyhpoid) (recurrent)
SEBD	Seborrheic dermatitis
TOX	Toxoplasmosis, brain
WAST	HIV Wasting Syndrome
WTLM	Moderate unexplained weight loss (<10% of body weight)
WTLS	Severe unexplained weight loss (>10% of body weight)

Coding Table: Mother-to-child and paediatric specific

Stage	Code	CDC disease description
A	CA-LYM	Lymphadenopathy
A	CA-HEY	Hepatomegaly
A	CA-SPL	Splenomegaly
A	CA-DER	Dermatitis
A	CA-PAR	Parotitis
A	CA-URI	Recurrent or persist. UR infection, sinusitis, or otitis media

B	CB-ANE	Anemia
B	CB-BMP	Bacterial meningitis, pneumonia, or sepsis
B	CB-CAN	Candidiasis oropharyngeal for >2 months (age>6)
B	CB-CMY	Cardiomyopathy
B	CB-CMN	CMV onset before 1 month
B	CB-DIA	Diarrhea (recurrent or chronic)
B	CB-FEV	Fever (lasting >1 month)
B	CB-HEP	Hepatitis
B	CB-HSS	Herpes simplex stomatitis (>2 episodes in 1 year)
B	CB-HCV	HSV bronchitis, pneumonitis, esophagitis (<1 month)
B	CB-HZO	Herpes zoster, multidermatomal or relapse
B	CB-LEI	Leiomyosarcoma
B	CB-LYM	Lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia complex
B	CB-NEP	Nephropathy
B	CB-NOC	Nocardiosis
B	CB-TON	Toxoplasmosis (start before 1 month)
B	CB-VAR	Varicella, disseminated
C	CC-EPD	Pneumocystis disease, extrapulmonary
C	CC-TOD	Toxoplasmosis disseminated
C	CC-COM	Cryptococcal meningitis
C	CC-GEN	M. genavense disease
C	CC-LOB	Lymphoma,primary, cerebral
C	CC-ICC	Carcinoma, cervical, invasive
C	CC-ILE	Intracerebral lesions, indeterminated

Case definitions

Code	Severe Opportunistic Infection/Malignancies	Definitive/Autopsy or presumptive?	Definition
DEM	AIDS dementia complex	D	Disabling cognitive and/or motor dysfunction, or milestone loss in a child, and no other causes by CSF exam and brain imaging or by autopsy
DEM	AIDS dementia complex	P	Same as above but no CSF and brain imaging performed
BCNE	Bacterial pneumonia, recurrent (>2 episodes within 1 year)	D	New X-ray evidence not present earlier and culture of pathogen that typically causes pneumonia (other than P .carinii or M. tuberculosis
BCNE	Bacterial pneumonia, recurrent (>2 episodes within 1 year)	P	Acute radiological findings (new X-ray evidence not present earlier) and acute clinical findings
CANO	Candidiasis, oesophageal, bronchi, trachea, or lungs	D/A	Gross inspection by endoscopy/autopsy or by microscopy (histology)
CANO	Candidiasis, oesophageal, bronchi, trachea, or lungs	P	Recent onset retrosternal pain on swallowing and confirmed oral or pharyngeal candidiasis

CRCO	Cryptococcosis, extrapulm.	D/A	Microscopy, culture of, or antigen detection in affected tissue
CRSP	Cryptosporidiosis (duration > 1 month)	D/A	Microscopy. Duration of diarrhoea for more then 1 month
CMVR	Cytomegalovirus (CMV) chorioretinitis	P	Loss of vision and characteristic appearance on serial ophtalmoscopy, progressing over serial months
CMVO	CMV – other location	D/A	Microscopy (histology or cytology)
HERP	Herpes simplex virus ulcers (duration > 1 month) or pneumonitis/esophagitis	D	Microscopy, culture of, or antigen detection in affected tissue
HIST	Histoplasmosis, extrapulm.	D/A	Microscopy, culture of, or antigen detection in affected tissue
WAST	HIV Wasting Syndrome	D	Weight loss (over 10% of baseline) with no other cause, and 30 days or more of either diarrhoea or weakness with fever
ISDI	Isosporiasis diarrhoea (duration > 1 month)	D/A	Microscopy (histology or cytology). Duration of diarrhoea for more than 1 month

LEIS	Leishmaniasis, visceral	D/A	Histology or culture of Leishmania amastigotes in bone marrow or detection of amastigotes in tissue/fluid from affected organ in a patient with symptoms and signs consistent with disseminated Leishmaniasis
MCDI	Microsporidosis diarrhoes (dur. > 1 month)	D/A	Stool microscopy or rectal biopsy in patient with persistent diarrhoea
MC	Mycobact. avium complex (MAC) or Kanasii, extrapulm.	D	Culture
MCP	Mycobact. tuberculosis pulm.	D	Culture
MCX	Mycobact. tuberculosis extrapulm	D	Culture
MCPO	Mycobact. pulm., other	D	Culture (indicate type)
MCPO	Mycobact. pulm., other	P	Acid fast bacteria (species not identified by culture) in sputum
MCXO	Mycobact. extrapulm., other	D	Culture (indicate type)
MCXO	Mycobact. extrapulm., other	P	Acid fast bacteria (species not identified by culture) on microscopy of normally sterile body fluid/tissue
PCP	Pneumocystis carinii pneumonia (PCP)	D	Microscopy (histology or cytology)

PCP	Pneumocystis carinii pneumonia (PCP)	P	Recent onset of dyspnoea on exertion or dry cough, and diffuse bilateral infiltrates on chest X-ray and pO2 <70 mmHg and no evidence of bacterial pneumonia
LEU	Progressive multifocal leucoencephalopathy	D/A	Microscopy (histology or cytology)
LEU	Progressive multifocal leucoencephalopathy	P	Progressive deterioration in neurological function and CT/MR scan evidence
SAM	Salmonella bacteriaemia (non-tyhpoid) (recurrent)	D	Culture
TOX	Toxoplasmosis, brain	D	Microscopy (histology/cytology)
TOX	Toxoplasmosis, brain	P	Recent onset focal neurological abnormalities or reduced level of consciousness, and mass effect lesion on scan, and specific therapy response
FBLS	Focal Brain lesion	?	TODO:: To be updated ASAP
KS	Kaposi Sarcoma	D/A	Histology
KS	Kaposi Sarcoma	P	Characteristic erythematous/violaceous plaque-like lesion on skin or mucous membranes
NHG	Non-Hodgkin Lymphoma -not specified	?	TODO:: To be updated ASAP

NHGB	Non-Hodgkin Lymphoma – Burkitt (Classical or Atypical)	D	Histology
NHGI	Non-Hodgkin Lymphoma – Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic)	D	Histology
NHGU	Non-Hodgkin Lymphoma - Unknown/other histology	?	TODO:: To be updated ASAP
NHGP	Non-Hodgkin Lymphoma - Primary Brain Lymphoma	D	TODO:: To be updated ASAP
NHGP	Non-Hodgkin Lymphoma - Primary Brain Lymphoma	P	Recent onset of focal neurological symptoms and signs or reduced level of consciousness, CT/MR scan evidence of a lesion or lesions having mass effect, no response to toxo therapy, no evidence of lymphoma outside the brain
CRVC	Cervical Cancer	D/A	Histology

DIS_WD - Coding Table

Code	Means of diagnosis
1	Definitive diagnosis
2	Presumptive diagnosis
3	Diagnosis from autopsy
4	Diagnosis from registry

DIS_SITE - Coding Table

Code	Description
1	Abdominal
2	Bone/Joint
3	CNS/Meningeal
4	Genitourinary
5	Laryngeal
6	Lymphatic
7	Meningeal/CNS
8	Miliary
9	Pericardial
10	Pleural
88	Not applicable
95	Not ascertained
99	Unknown

DIS_OUTCOME - Coding Table

Code	Description
0	Not evaluated
1	Cured (lab confirmation)
2	Treatment completed (but cure not confirmed)
3	Treatment failed
4	Died
5	LTFU/Default (from disease Treatment esp. TB, not necessarily from HIV clinic)
9	Unknown

Table: tblLAB - Laboratory values

Description: holds type, date, value and unit of **laboratory tests**.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
LAB_ID	character. see coding table for valid codings.	Code representing the measurement
LAB_D	yyyy-mm-dd	Date of measurement/sample
LAB_D_A	character: see coding of date precision	optional precision annotation for date of measurement/sample
LAB_R	• 1 = Positive (including trace, 1+, 2+, etc.) • 0 = Negative • 9 = Unknown/borderline	Measurement result
LAB_V	numeric: -1 = undetectable or detection limit as negative value	Value of measurement
LAB_U	numeric. see coding table for valid codings.	Unit of measurement

Additional Fields

Other detailed information regarding the patient and the measurement would be relevant, like the proposed fasting information shown below.

Field name	Format	Description
LAB_FA	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Was the blood sample taken while fasting?
LAB_ST	character. see coding table for valid codings.	Code representing the specimen type

Depending on the set of measurements collected and the mandatory fields applicable to these individual measurements, it might be useful to separate the LAB table into several sub tables. This is already shown for the CD4 and RNA measurements: the level of detail needed for CD4 is less than for the LAB variables in general (no unit since it's always the same), while for RNA the data required is more detailed (assay and detection limit).

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes

AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLAB	WithinTable	LW001	Duplicate records		Yes
tblLAB	WithinTable	LW002	Missing LAB_D		Yes
tblLAB	WithinTable	LW003	Missing LAB_V		Yes
tblLAB	WithinTable	LW004	Missing LAB_U		Yes
tblLAB	WithinTable	LW005	Missing LAB_ID		Yes
tblLAB	WithinTable	LW008	Missing LAB_FA		Yes
tblLAB	WithinTable	LW009	Missing LAB_ST		Yes
tblLAB	WithinTable	LW010	LAB_V out of range for unit LAB_U		Yes
tblLAB	CrossTable	LC001	Patient has no record in BAS table		Yes

LAB_ID - Coding Table

Code	Measurement
A1C	Haemoglobin A1C
ACRA	Albumin Creatinin Ratio
ALB	Albumine
AFP	Alfa Fetoprotein
ALP	Alkaline Phosphatase
ALT	Alanin-Aminotransferase
AMY	Amylase
AST	Aspartat aminotransferase
BIL	Total Bilirubin
BUN	Blood Urea Nitrogen
CD3	CD3
CD3P	% CD3 of leukocytes
CD8	CD8
CD8P	% CD8 of leukocytes
CHOL	Total Cholesterol
CL-	Cl-
CRE	Creatinine
DIPB	Dipstick result for blood in Urine
DIPG	Dipstick result for glucose in Urine
DIPK	Dipstick result for ketones in Urine
DIPLE	Dipstick result for leucocyte esterase in Urine
DIPP	Dipstick result for protein in Urine
GGT	Gamma-glutamyltransferase
GLUC	Glucose
HAEM	Haemoglobin
HDL	Serum HDL
HEMA	Hematocrit
IGRA	Interferon-Gamma Release Assay
INR	Quick/INR

LACT	Lactate
LDL	Serum LDL
LEUK	Leukocytes
LYM	Lymphocytes
LYMP	% Lymphocytes of leukocytes
MCV	MCV
NA+	Na+
NEU	Neutrophils
PCRA	Protein Creatinin Ratio
PHA	PH arterial
PHV	PH venous
PP	PP factor (II, VII, X)
PROT	Protein
PSA	Prostate-specific antigen
PTH	Parathyroid Hormone
PTR	Prothrombin rate
TBC	TB culture
TBM	TB smear/microscopy
TBHIST	TB histology
TBGX	TB GeneXpert
TBNAAT	TB NAAT/LPA (non-GeneXpert)
THR	Thrombocytes
TRIG	Serum Triglyceride
URA	Uric acid
UREA	Urea/Blood Urea Nitrogen

LAB_U - Coding Table

It is recommended to use the string codes from the below table since this makes the data human readable.

Unit Code	Unit String
1	mmol/L
2	g/L
3	g/dL
4	mg/dL
5	IU/L (u/L)
6	µmol/L
7	INR
8	1E+9/L
9	1E+6/L
10	cells/µL
11	µkat/L
12	%
13	µg/L = ng/mL
14	mg/24h
15	mg/mmol
16	fl (Femtoliter)
17	µg/mL = mg/L
99	no units (e.g. for Dipstick results)

LAB_ST - Coding Table

Code	Specimen Type
WB	Whole blood
P	Plasma
S	Serum
U24	24h Urine
U	Urine
CSF	Cerebrospinal fluid
SP	Sputum
SA	Saliva
UNK	Unknown
OTH	Other

Table: tblLAB_BP - Laboratory values - Blood pressure

Description: holds date, diastolic and systolic values and unit of **blood pressure** measurements.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
BP_D	yyyy-mm-dd	Date of Measurement/Sample
BP_D_A	character: see coding of date precision	Precision annotation variable for measurement date
BP_SYS	numeric	Systolic Blood Pressure
BP_DIA	numeric	Diastolic Blood Pressure
BP_U	numeric. see coding table for valid codings.	Unit of measurement

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes

AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

BP_U - Coding Table

Code	Unit for blood pressure
1	mmHg
2	cmHg
3	Kpa

Table: tblLAB_CD4 - Laboratory values

Description: holds date and value of **CD4 measurements**.

Note: If needed, a CD8 table (tblLAB_CD8) could be formed from the same structure.

Note: Fields marked **bold** form the unique identifier for a record of the table.

PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
CD4_D	yyyy-mm-dd	Date of measurement
CD4_V	numeric (per microliter): -1 = undetectable or detection limit as negative value	Value of CD4 measurement

Additional Fields

CD4_V is assumed to contain absolute CD4 cell counts per mL as standard. In case CD4 % (with respect to CD45+ lymphocytes as denominator) should be collected as well, please append the following field to the table:

Field name	**Format**	**Description**
CD4_U	numeric with codes (or full string): • 1 = cells/µl • 2 = %	Unit of measurement
CD4_D_A	character: see coding of date precision	precision of measurement date

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?

AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLAB_CD4	WithinTable	CW001	CD4 value out of range		Yes
tblLAB_CD4	WithinTable	CW002	Duplicate records for same date		Yes
tblLAB_CD4	WithinTable	CW003	Missing CD4_D		Yes
tblLAB_CD4	WithinTable	CW004	Missing CD4_V		Yes
tblLAB_CD4	WithinTable	CW005	Missing CD4_U		Yes
tblLAB_CD4	WithinTable	CW006	Miscoded CD4_U as coding list on table definition		Yes

tblLAB_CD4	WithinTable	CW007	CD4_U=2 (percentage) and CD4_V>100		Yes
tblLAB_CD4	WithinTable	CW008	CD4_U=(1 or 3) and CD4_V>3000		Yes
tblLAB_CD4	WithinTable	CW009	CD4 counts spike up or down suddenly (large change in less than a year)		Yes
tblLAB_CD4	CrossTable	CC001	Patient has no record in BAS		Yes

Table: tblLAB_HCV - Information on **H**epatitis **C** **V**irus genotype and subtype

Description: holds information on HCV genotype and subtype

Core Fields

Field name	Format	Description
PATIENT	Numeric	Code to identify patient (Cohort Patient ID)
SAMPLE_D	Date (yyyy-mm-dd)	Date of the actual sample taken (NOT the test date)
GENOTYPE	numeric: • 1 • 2 • 3 • 4 • 5 • 6	HCV-genotype Please supply a row for each combination of Genotype and Subtype, e.g.: 9999999 01-01-1901 1 a 9999999 01-01-1901 1 b (the genotype and subtype should be submitted in separate columns)
SUBTYPE	Character: • a • b • c • d • e • f • g • h • i • j	HCV-subtype If unknown leave blank

Additional Fields

Field name	Format	Description
VIROTYPE	numeric: • 2 = HCV	Type of Virus

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

Table: tblLAB_RES - Resistance testing

Description: holds **background information** on the resistance test, **laboratory**, library, kit, software and type of test

Note: This table is tightly linked to tblLAB_RES_LVL_1, tblLAB_RES_LVL_2 and tblLAB_RES_LVL_3.

Resistance should be reported at lowest level of interpretation possible – so if the nucleotide sequence is available this should be reported rather than the list of mutations or resistance scores. However, the resistance test results should be captured if they have been part of the physician's treatment decisions for the patient.

Non-amplifiable resistance tests should not be reported.

These four tables are designed to capture several possible formats the clinics and cohorts might have recorded resistance test data in. Once this data is gathered it should like all other tables be quality assessed.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
TEST_ID	character (or numeric if possible)	An arbitrary value identifying a resistance test result
SAMPLE_D	yyyy-mm-dd	Date of the actual sample taken (NOT the test date)
SAMPLE_D_A	character: see coding of date precision	optional precision annotation for date of sample
SEQ_DT	yyyy-mm-dd hh:mm	Date and time when the sequencing was performed
SEQ_DT_A	character: see coding of date precision	optional precision annotation for date of sequencing
LAB	character	Name of laboratory where the test was performed

LIBRARY	character	Library/algorithm used to identify resistance mutations
REFSEQ	character	Name/identifier of reference strain used to find mutations
KIT	character	Vendor and version/name of the kit used for the test
SOFTWARE	character	Software and version used to determine resistance
TESTTYPE	numeric: • 1 = Genotype (e.g., GeneXpert, NAAT/LPA • 2 = Phenotype (e.g., culture) • 9 = Other	Type of test
TESTTYPE_M	character: • SSQ = Sanger sequencing based • NSQ = Next generation sequencing • other, Other	Type of method used
PATHOGENTYPE	character: MeSH terminology https://meshb.nlm.nih.gov/search	Type of pathogen
VIRUSTYPE	numeric: • 1 = HIV • 2 = HCV	Type of Virus
SUBTYPE	character	Subtype of HIV- or HCV-RNA

Additional Fields

As shown with the core fields, the *TEST_ID* is the link between the 3 levels of data and the test background information table.

Some prior assessment of the assigned test identifiers has to be done in order to avoid duplicates.

In a running database the duplicate issues are easily resolved by adding a unique auto-generated key as the identifier between 3 levels of data and the test background information table.

Along with the *TEST_ID* it might be necessary to store the ID assigned to the sample at both the testing laboratory but also the centres laboratory in order to track the sample.

Field name	**Format**	**Description**
SAMP_LAB	character (or numeric if possible)	The assigned sample ID at the lab where the resistance test is preformed.
SAMP_INT	character (or numeric if possible)	The assigned sample ID from the centre.

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes

AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLAB_RES	WithinTable	LRW001	Duplicate records for same patient on same date		Yes
tblLAB_RES	WithinTable	LRW002	Missing PATIENT		Yes
tblLAB_RES	WithinTable	LRW003	Missing TEST_ID		Yes
tblLAB_RES	WithinTable	LRW004	Missing SAMPLE_D		Yes
tblLAB_RES	WithinTable	LRW005	Missing SEQ_DT		Yes
tblLAB_RES	WithinTable	LRW006	Missing LAB		Yes
tblLAB_RES	WithinTable	LRW007	Missing LIBRARY		Yes
tblLAB_RES	WithinTable	LRW008	Missing REFSEQ		Yes
tblLAB_RES	WithinTable	LRW009	Missing KIT		Yes
tblLAB_RES	WithinTable	LRW010	Missing SOFTWARE		Yes
tblLAB_RES	WithinTable	LRW011	Missing TESTTYPE		Yes
tblLAB_RES	WithinTable	LRW012	Missing SUBTYPE		Yes
tblLAB_RES	WithinTable	LRW013	SEQ_DT has no time part		Yes
tblLAB_RES	WithinTable	LRW014	Missing VIRUSTYPE		Yes

tblLAB_RES	CrossTable	LRC001	PATIENT has no record in tblBAS		Yes
tblLAB_RES	CrossTable	LRC002	This TEST_ID has both LVL_1 and LVL_2 records		Yes

Table: tblLAB_RES_LVL_1 - Nucleotide sequences (PRO, RT, GP41, GP120)

Description: holds nucleoside sequence for the PRO and RT sequences

Note: This table is tightly linked to tblLAB_RES.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
TEST_ID	character (or numeric if possible)	Identifier linking this record to tblLAB_RES
SEQTYPE	character: • PRO = PRO sequence • RT = RT sequence • GP41 = GP41 sequence • GP120 = GP120 sequence	Type of nucleotide sequence if available
SEQ_START	numeric	Start position for the sequence
SEQ_STOP	numeric	Stop position for the sequence
SEQ_NUC	character	Nucleotide sequence if available

Additional Fields

In cases where the amino acid sequence is collected rather than the nucleotide sequence, the field SEQ_NUC might be replaced with SEQ_AA, which is the nucleotide sequence, expressed in an amino acid sequence:

Field name	Format	Description
SEQ_AA	character	Amino acid sequence if available (empty if test was phenotype)

However using the amino acid sequence does not give the same detail of data as the nucleoside sequence: wobbles in the nucleoside sequence can either complicate the reading and alignment of the amino acid sequence or the wobbles can be lost and silent mutations are lost.

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLAB_RES_LVL_1	WithinTable	L1W001	Duplicate records per TEST_ID and SEQTYPE		Yes
tblLAB_RES_LVL_1	WithinTable	L1W002	SEQ_START > SEQ_STOP		Yes

tblLAB_RES_LVL_1	WithinTable	L1W003	SEQ_NUC contains invalid IUPAC character		Yes
tblLAB_RES_LVL_1	WithinTable	L1W004	Missing TEST_ID		Yes
tblLAB_RES_LVL_1	WithinTable	L1W005	Missing SEQ_START		Yes
tblLAB_RES_LVL_1	WithinTable	L1W006	Missing SEQ_STOP		Yes
tblLAB_RES_LVL_1	WithinTable	L1W007	Missing SEQ_NUC		Yes
tblLAB_RES_LVL_1	CrossTable	L1C001	TEST_ID not in tblLAB_RES.TEST_ID		Yes

Table: tblLAB_RES_LVL_2 - Mutations

Description: holds mutations and positions of these.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
TEST_ID	character (or numeric if possible)	Identifier linking this record to tblLAB_RES
GENE	character: • PRO = PRO sequence • RT = RT sequence • GP41 = GP41 sequence • GP120 = GP120 sequence	Type of sequence/gene (PRO, RT, GP41, GP120)
AA_POS	numeric	Position of the mutation in the sequence
AA_POS_SUB	character: • a = first • b = second • etc.	Subposition used to code insertions
AA_FOUND_1	character. empty = Amino acid has been deleted.	Mutation (Amino acid) found in the sequence
AA_FOUND_2	character. empty = Amino acid has been deleted.	Mutation (Amino acid) found in the sequence (if more than 1)
AA_FOUND_3	character. empty = Amino acid has been deleted.	Mutation (Amino acid) found in the sequence (if more than 2)
AA_FOUND_4	character. empty = Amino acid has been deleted.	Mutation (Amino acid) found in the sequence (if more than 3)

AA_FOUND_# could be extended if mixtures with more than 4 amino acids are found.

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLAB_RES_LVL_2	WithinTable	L2W001	AA_FOUND_x but nothing in AA_FOUND(x-1)		Yes

tblLAB_RES_LVL_2	WithinTable	L2W002	Duplicate records per TEST_ID, GENE, AA_POS and AA_POS_SUB		Yes
tblLAB_RES_LVL_2	WithinTable	L2W003	Missing TEST_ID		Yes
tblLAB_RES_LVL_2	WithinTable	L2W004	Missing GENE		Yes
tblLAB_RES_LVL_2	WithinTable	L2W005	Missing AA_POS		Yes
tblLAB_RES_LVL_2	WithinTable	L2W006	Missing AA_POS_SUB		Yes
tblLAB_RES_LVL_2	WithinTable	L2W007	Missing AA_FOUND_1		Yes
tblLAB_RES_LVL_2	CrossTable	L2C001	TEST_ID not in tblLAB_RES.TEST_ID		Yes

Table: tblLAB_RES_LVL_3 - Resistance test result

Description: holds resistance result in relation to antiretroviral drug.

Note: This table is tightly linked to tblLAB_RES.

Note: Fields marked **bold** form the unique identifier for a record of the table.

TEST_ID	character (or numeric if possible)	Identifier linking this record to tblLAB_RES
ATC_CODE	character	ATC code of the medication
RES_SCOR	character	Score of resistance or recommendation given from the test

Additional Fields

For phenotype test results it will be necessary to extend the table with a field to store the cut-off value:

Field name	**Format**	**Description**
RES_CUT	character	Cut-off value for phenotype test result
RES_SCOR_ID	character: • a = first • b = second • etc. character: • S = sensitive • L = low level • I = intermediate • H = high level	Coded score of the resistance or recommendation given from the test

However using the amino acid sequence does not give the same detail of data as the nucleoside sequence: wobbles in the nucleoside sequence can either complicate the reading and alignment of the amino acid sequence or the wobbles can be lost and silent mutations are lost.

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLAB_RES_LVL_3	WithinTable	L3W001	Duplicate records for same TEST_ID and ATC_CODE		Yes

tblLAB_RES_LVL_3	WithinTable	L3W002	Missing TEST_ID		Yes
tblLAB_RES_LVL_3	WithinTable	L3W003	Missing ATC_CODE		Yes
tblLAB_RES_LVL_3	WithinTable	L3W004	Missing RES_SCOR		Yes
tblLAB_RES_LVL_3	CrossTable	L3C001	TEST_ID not in tblLAB_RES.TEST_ID		Yes

Table: tblLAB_RNA - Laboratory values

Description: holds date, value, detection limit and type of **viral assay**.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
RNA_D	yyyy-mm-dd	Date of Measurement/Sample
RNA_D_A	character: see coding of date precision	Precision annotation variable for date of measurement
RNA_V	numeric: -1 = undetectable or detection limit as negative value	HIV-RNA measurement value
RNA_L	numeric	Lower Limit of HIV-RNA Assay
RNA_T	numeric. see coding table for valid codings.	IF AVAILABLE, What type of VIRAL ASSAY was used for this measurement?

Additional Fields

Field name	Format	Description
RNA_UL	numeric	IF AVAILABLE, Upper Limit of assay

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?

AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLAB_RNA	WithinTable	RW001	Duplicate records for same RNA_D		Yes
tblLAB_RNA	WithinTable	RW002	RNA_V < 0 and RNA_L missing		Yes
tblLAB_RNA	WithinTable	RW003	RNA_V > 10 000 and (RNA_V modulo 1000) = 1 and RNA_UL missing		Yes

tblLAB_RNA	WithinTable	RW004	Missing RNA_D		Yes
tblLAB_RNA	WithinTable	RW005	Missing RNA_V		Yes
tblLAB_RNA	WithinTable	RW006	RNA_V > 10 million		Yes
tblLAB_RNA	WithinTable	RW007	RNA_V < RNA_L and RNA_V >= 0		Yes
tblLAB_RNA	WithinTable	RW008	RNA_V > RNA_UL		Yes
tblLAB_RNA	CrossTable	RC001	Patient has no record in BAS		Yes

RNA_T - Coding Table

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
42	Abbott RealTime HIV-1 m2000
50	Monitor 1.0
51	Monitor 1.0 ultra-sensitive
55	Monitor 1.5
56	Monitor 1.5 ultra-sensitive
59	Monitor unspecified
65	Cobas 1.5
66	Cobas 1.5 ultra-sensitive
90	Other
99	Unknown

Table: tblLAB_VIRO - Laboratory values - viro-/serology

Description: holds test results for **viro-/serological tests** (hepatitis etc.)

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
VS_ID	character. see coding table	Viral test
VS_D	yyyy-mm-dd	Measurement date
VS_D_A	character: see coding of date precision	optional precision annotation for date of measurement
VS_R	numeric: • 1 = Positive • 0 = Negative • 9 = Unknown/borderline	Measurement result
VS_V	numeric	Measurement value (HCV-RNA & HBV-DNA only) (copies/ml)
VS_U	character. see coding table for valid codings.	Measurement unit

Additional Fields

Field name	Format	Description
VS_LL	numeric	IF AVAILABLE, Lower limit of assay

VS_UL	numeric	IF AVAILABLE, Upper limit of assay
VS_T	character. see coding table for valid codings.	IF AVAILABLE, type of ASSAY used for this measurement
VS_ST	character	Specimen type

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLAB_VIRO	CrossTable	LVC001	Patient doesn't have a record in BAS		Yes

tblLAB_VIRO	WithinTable	LVW002	Missing patient		Yes
tblLAB_VIRO	WithinTable	LVW003	Missing VS_ID		Yes
tblLAB_VIRO	WithinTable	LVW004	Missing VS_D		Yes
tblLAB_VIRO	WithinTable	LVW005	Missing VS_R		Yes
tblLAB_VIRO	WithinTable	LVW006	Missing VS_V		Yes
tblLAB_VIRO	WithinTable	LVW007	Missing VS_U		Yes
tblLAB_VIRO	WithinTable	LVW008	More or less than exactly 1 positive HIV test per patient		Yes
tblLAB_VIRO	WithinTable	LVW009	More than 1 negative HIV test for a patient		Yes
tblLAB_VIRO	WithinTable	LVW010	Date of negative test after date of positive test		Yes
tblLAB_VIRO	WithinTable	LVW011	Duplicate records		Yes

VS_ID - Coding Table

Code	Viral Test
BVA	Bacterial vaginosis unspecified method
BVAC	Bacterial vaginosis - clinical
BVAG	Bacterial vaginosis - gram stain
CHLA	Chlamydia
CMVA	CMV antibodies
CRYP	Cryptococcal test - other/type unknown
CRAG	Cryptococcal Antigen test (CrAg)
GONO	Gonorrhoea
HBV	Marker for hepatitis B infection (=HBVAC) - test unknown
HBVAC	HBV antibody (core)
HBVACIGM	HBV antibody (core IgM)
HBVACIGG	HBG antibody (core IgG)
HBVAE	HBV antibody (envelope)
HBVAS	HBV antibody (surface)
HBVD	HBV-dna
HBVGE	HBV antigen (envelope)
HBVGS	HBV antigen (surface)
HCV	Marker for hepatitis C infection - test unknown
HCVA	HCV antibody
HCVG	HCV antigen
HCVBD	HCV b-dna
HCVR	HCV-rna
HDVA	Hepatitis delta antibody
HIV-1R	HIV-1 rapid test
HIV-1S	HIV-1 serology test (ELISA, Western Blot)
HIV-1DNA	HIV-1 DNA PCR test (qualitative)
HIV-2R	HIV-2 rapid test
HIV-2S	HIV-2 serology test (ELISA, Western Blot)

HIV-2DNA	HIV-2 DNA PCR test (qualitative)
HPV	Human Papillomavirus
MYCO	Mycoplasma
P24AG	P24 Ag
RUB	Rubella
STR	Streptococcus, group B
SYPHDV	Syphilis Direct Visualization (Darkfield microscopy)
SYPHSC	Syphilis Screening (RPR, VDRL)
SYPHCON	Syphilis Confirmatory (FTA-Abs, MHA-TB, TPPA, EIA)
TOXA	Toxo antibodies
UREP	Ureaplasma

VS_U - Coding Table

Code	Test measurement unit
1	copies/mL
2	IU/mL
3	Geq (millions of genome equivalent)

VS_T - Coding Table

Code	Viral test used
1	Roche qualitative (Amplicor) [HCV and 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	Abbott Real Time [HCV and HBV]
7	Siemens VERSANT [HCV and HBV] DNA (bNA)
8	Quiagen artus [HCV and HBV] PCR kit
9	Other
10	Rapid diagnostic test -3rd generation [HIV]
11	Rapid diagnostic test -4th generation [HIV]
12	Self-test-oral [HIV]
13	Self-test-blood-based [HIV]
14	Immunoassay (EIA, CLIA, ECL) - 3rd generation [HIV]
15	Immunoassay (EIA,CLIA, ECL) plus p24 - 4th generation [HIV]
16	WB: Western blot/immunoblot [HIV]
17	NAT (Nucleic Acid Test) [HIV]

Table: tblLTFU - Death and drop-out

Description: holds data on **death and drop-out**

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
DROP_Y	numeric: • 0 = No • 1 = Yes	Has the patient dropped out?
DROP_D	yyyy-mm-dd	If patient has dropped out, date of last visit
DROP_D_A	character: see coding of date precision	optional precision annotation for date of last visit
DROP_RS	numeric. see coding table for valid codings.	Reason for drop
DEATH_Y	numeric: • 0 = No • 1 = Yes	Has the patient died?
DEATH_D	yyyy-mm-dd	Date of Death
DEATH_D_A	character: see coding of date precision	optional precision annotation for date of death
SUD_DEATH_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Sudden Death?

EXP_DEATH_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Expected Death?
AUTOP_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Was an autopsy Performed?
DEATH_R1	character. see coding table for valid codings.	Cause of death
DEATH_RC1	character with codes: • I = Immediate cause • U = Underlying cause/condition • C = Contributing cause • N = Not available	Coding of causal relation of the code given in DEATH_R1 to the death
DEATH_R2	character. see coding table for valid codings.	Cause of death
DEATH_RC2	character with codes: • I = Immediate cause • U = Underlying cause/condition • C = Contributing cause • N = Not available	Coding of causal relation of the code given in DEATH_R2 to the death
DEATH_R3	character. see coding table for valid codings.	Cause of death
DEATH_RC3	character with codes: • I = Immediate cause • U = Underlying cause/condition • C = Contributing cause • N = Not available	Coding of causal relation of the code given in DEATH_R3 to the death

DEATH_SOURCE	character	Source of information for coding of death (e.g. CoDe within own cohort, CoDe from D:A:D, CoDe from ART-CC, etc.)
MOTHERDEATH_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Hast the patient's biological mother died?
MOTHERDEATH_D	yyyy-mm-dd	Date of death of the patient's biological mother
MOTHERDEATH_D_A	character: see coding of date precision	optional precision annotation for date of death of patient's mother
FATHERDEATH_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Hast the patient's biological father died?
FATHERDEATH_D	yyyy-mm-dd	Date of death of the patient's biological father
FATHERDEATH_D_A	character: see coding of date precision	optional precision annotation for date of death of patient's father

List of *DEATH_R#* and *DEATH_RC#* should be continued for as many reasons that are recorded.

The *DEATH_RC#* fields should enable cohorts to transfer data in accordance with the Coding of Death project (CoDe). You are welcome to contact the CoDe group for electronic sample forms for detailed collection of data used for the CoDe review process.

CoDe defines 1 immediate, 2 contributing and 1 underlying cause of death.

Additional Fields

Field name	**Format**	**Description**
ICD10_1	character	Cause of death as ICD-10 if available

ICD10_2	character	Cause of death as ICD-10 if available
ICD10_31	character	Cause of death as ICD-10 if available
ICD9_1?	character	Cause of death as ICD-9 if available
ICD9_2	character	Cause of death as ICD-9 if available
ICD9_31	character	Cause of death as ICD-9 if available
DEATH_OT	character	Reason for death – other - description
L_ALIVE_D	yyyy-mm-dd	Last date known to be alive
L_ALIVE_D_A	character: see coding of date precision	optional precision annotation for last date of Information / lknown to be alive

1: List of *ICD10_#* and *ICD9_#*inplace of or together with *DEATH_R#* and together *DEATH_RC#* and should be continued for as many reasons that are recorded.
CoDe defines 1 immediate, 2 contributing and 1 underlying cause of death.

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes

AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblLTFU	WithinTable	LFW001	DROP_Y and DEATH_Y both non-null		Yes
tblLTFU	WithinTable	LFW002	DEATH_Y and DROP_RS both non-null		Yes
tblLTFU	WithinTable	LFW003	Any of DEATH_Rx or DEATH_RCx non-null but DEATH_Y=0		Yes
tblLTFU	WithinTable	LFW004	R2/RC2 non-null but R1/RC1 null		Yes
tblLTFU	WithinTable	LFW005	R3/RC3 non-null but R2/RC2 null		Yes
tblLTFU	WithinTable	LFW006	Duplicate patients		Yes
tblLTFU	WithinTable	LFW007	Missing DROP_Y		Yes

tblLTFU	WithinTable	LFW008	Missing DROP_D if DROP_Y=1		Yes
tblLTFU	WithinTable	LFW009	Missing DROP_RS if DROP_Y=1		Yes
tblLTFU	WithinTable	LFW010	Missing DEATH_Y		Yes
tblLTFU	WithinTable	LFW011	Missing DEATH_D if DEATH_Y=1		Yes
tblLTFU	WithinTable	LFW012	DEATH_D non null but DEATH_Y=0		Yes
tblLTFU	CrossTable	LFC001	Patient not found in tblBAS		Yes
tblLTFU	CrossTable	LFC002	patient in tblBAS hasn't got a record in tblLTFU		Yes
tblLTFU	CrossTable	LFC003	tblBAS has AIDS=0 but DEATHRx =8.1		Yes

DROP_RS - Coding Table

Note: If consent is withdrawn, all patient data except for the patient id and reason for drop out may have to be deleted.

Code	Reason for Drop Out
0	Patient was not infected (mainly for children)
1	Patient lost to follow-up / not known to be dead
2	Patient has not had visit within required amount of time
2.1	Patient did not respond to several invitations
3	Patient moved away
3.1	Patient moved to another country
4	Patient moved and is followed by another centre
4.1	Paediatric patient transferred to adult care
5	Patients decision
5.1	Patients caretaker wanted to discontinue (for children)
6	Consent withdrawn
7	Incarceration/jail
8	Institutionalisation (drug treatment, psychological …etc.)
9	Other

DEATH_R1 - Coding Table

The following table represents the Coding of Death (CoDe) standard. The newest version is available in the Review Form 2.2.

Use the most specific coding available whenever possible.

Code	Cause of Death
01	AIDS (ongoing active disease)
01.1	Infection
01.2	Malignancy
02	Infection (other than 01.1)
02.1	Bacterial
02.1.1	Bacterial with sepsis
02.2	Others
02.2.1	Others with sepsis
02.3	Unknown aetiology
02.3.1	Unknown with sepsis
03	Chronic viral hepatitis (progression of/complication to)
03.1	HCV
03.1.1	HCV with cirrhosis
03.1.2	HCV with liver failure
03.1.3	HCV with liver cancer
03.2	HBV
03.2.1	HBV with cirrhosis
03.2.2	HBV with liver failure
03.2.3	HBV with liver cancer
04	Malignancy (other than 01.2 and 03, 03.1, 03.2)
04.03	ANUS - Anal cancer
04.04	BLAD - Bladder cancer
04.05	BONE - Bone cancer
04.06	BRAC - Brain cancer
04.07	BRCA - Breast cancer

04.10.1	ALL - Leukaemia: Acute lymphoid
04.10.2	AML - Leukaemia: Acute myeloid
04.10.3	CLL - Leukaemia: Chronic lymphoid
04.10.4	CML - Leukaemia: Chronic myeloid
04.10.9	LEUK - Leukaemia: unspecified
04.18	COLO - Colon cancer
04.11	COTC - Connective tissue cancer
04.12	ESOP - Esophagus cancer
04.13	GALL - Gallbladder cancer
04.14	GYCA - Gynaecologic cancer
04.15	HDL - Hodgkin lymphoma
04.16	HENE - Head and neck (incl. face) cancers
04.17	KIDN - Kidney cancer
04.19	LIPC - Lip cancer
04.20	LIVR - Liver cancer
04.21	LUNG - Lung cancer
04.22	MALM - Malignant melanoma
04.27	MULM - Multiple myeloma
04.29	PANC - Pancreas cancer
04.31	PENC - Penile cancer
04.32	PROS - Prostate cancer
04.33	RECT - Rectum cancer
04.34	STOM - Stomach cancer
04.35	TESE - Testicular seminoma
04.36	UTER - Uterus cancer
04.40.1	MEAC - Metastasis: of adenocarcinoma
04.40.2	MEOC - Metastasis: of other cancer type
04.40.3	MESC - Metastasis: of squamuos cell carcinoma
04.40.9	META - Metastasis: unspecified
04.90	OTH - Other Malignancy Type
04.99	UNKP - Unknown Malignancy Type

05	Diabetes Mellitus (complication to)
06	Pancreatitis
07	Lactic acidosis
08	MI or other ischemic heart disease
08.1	AMI
08.1.1	Definitive AMI (Dundee 1)
08.1.2	Possible AMI (Dundee 2/9)
08.2	Other ischemic heart disease
09	Stroke
10	Gastro-intestinal haemorrhage (if chosen, specify underlying cause)
11	Primary pulmonary hypertension
12	Lung embolus
13	Chronic obstructive lung disease
14	Liver failure (other than 03, 03.1, 03.2)
15	Renal failure
16	Accident or other violent death (not suicide)
17	Suicide
18	Euthenasia
19	Substrance abuse (active)
19.1	Chronic Alcohol abuse
19.2	Chronic intravenous drug-use
19.3	Acute intoxication
20	Haematological disease (other causes)
21	Endocrine disease (other causes)
22	Psychiatric disease (other causes)
22.1	Mental and behavioural disorders due to use of psychoactive substances (other than alcohol and intravenous opioids)
22.2	Schizophrenia, schizotypal and delusional Disorders

22.3	Mood /Affective disorders (Major depressive disorder, Bipolar disorder and other mood disorders)
22.4	Neurotic, stress-related and somatoform disorders (including anxiety disorders, phobias, OCD, stress reaction, dissociative disorders, somatoform disorders)
22.5	Behavioral syndromes associated with physiological disturbances and physical factors (including eating disorders, sleep disorders, sexual disorders)
22.90	Other psychiatric disorders
23	CNS disease (other causes)
23.1	Movement disorders (Parkinson’s disease; dystonias and Parkinson-like syndromes)
23.2	Degenerative disorders of the central nervous system (Alzheimer's disease; Creutzfeldt–Jakob disease and other degenerative diseases of nervous system)
23.3	Demyelinating diseases of the central nervous system (Multiple sclerosis, other demyelinating diseases)
23.4	Epilepsy (including localised and generalized epilepsy and epileptic syndromes)
23.5	Polyneuropathies (Guillain–Barré syndrome and other polyneuropathies/disorders of the peripheral nervous system)
23.6	Diseases of myoneural junction and muscle (Miastenia gravis and other myoneural disorders)
23.90	Other disorders of the nervous system
24	Heart or vascular (other causes)
25	Respiratory disease (other causes)
26	Digestive system disease (other causes)
27	Skin and motor system disease (other causes)
28	Urogential disease (other causes)

29	Obstetric complications
30	Congenital disorders
31	Symptoms caused by mitochondrial toxicity (other than 06, 07)
32	Bleeding (haemophilia)
33	Sudden infant death
33.1	Child abuse
90	Other causes
91	Unclassifiable causes
92	Unknown
92.1	Unknown, Competing risks

The following additional codes are used in the TB-HIV study, but not yet officially included in CoDe

Code	**Cause of Death**
01.1.1	Tuberculosis
01.1.1.1	Pulmonary tuberculosis
01.1.1.2	Extrapulmonary TB
01.1.1.2.01	Pleura (isolated, without lungs involvement
01.1.1.2.02	Lymphatic intrathoracic (isolated, without lungs involvement)
01.1.1.2.03	Lymphatic extrathoracic
01.1.1.2.04	Pericardia
01.1.1.2.05	Spine
01.1.1.2.06	Bone/joints other than spine
01.1.1.2.07	Meningitis
01.1.1.2.08	CNS other than meningitis
01.1.1.2.09	Genito-urinary tract
01.1.1.2.10	Peritoneal/digestive
01.1.1.2.11	TB with poly-organ failure/ TB sepsis
01.1.1.3	Disseminated tuberculosis
01.1.1.3.01	Lungs

01.1.1.3.02	Miliary
01.1.1.3.03	Pleura
01.1.1.3.04	Lymphatic intrathoracic
01.1.1.3.05	Lymphatic extrathoracic
01.1.1.3.06	Pericardia
01.1.1.3.07	Spine
01.1.1.3.08	Bone/joints other than spine
01.1.1.3.09	Meningitis
01.1.1.3.10	CNS other than meningitis
01.1.1.3.11	Genito-urinary tract
01.1.1.3.12	Peritoneal/digestive
01.1.1.3.13	TB with poly-organ failure/ TB sepsis
01.1.2	other AIDS-defining infection
01.1.2.1	with lungs involvement
01.1.2.2	with CNS involvement
01.2.1	AIDS Malignancy localised to lungs
01.3	IRIS after cART initiation (can only be used as contributing cause of death)
02.1.2	Bacterial pneumonia 02.1.3 Bacterial meningitis
02.2.2	other pneumonia 02.2.3 other with CNS involvement
19.3.1	Toxicity to anti-TB drugs

DEATH_R2 - Coding Table

The following table represents the Coding of Death (CoDe) standard. The newest version is available in the Review Form 2.2.

Use the most specific coding available whenever possible.

Code	Cause of Death
01	AIDS (ongoing active disease)
01.1	Infection
01.2	Malignancy
02	Infection (other than 01.1)
02.1	Bacterial
02.1.1	Bacterial with sepsis
02.2	Others
02.2.1	Others with sepsis
02.3	Unknown aetiology
02.3.1	Unknown with sepsis
03	Chronic viral hepatitis (progression of/complication to)
03.1	HCV
03.1.1	HCV with cirrhosis
03.1.2	HCV with liver failure
03.1.3	HCV with liver cancer
03.2	HBV
03.2.1	HBV with cirrhosis
03.2.2	HBV with liver failure
03.2.3	HBV with liver cancer
04	Malignancy (other than 01.2 and 03, 03.1, 03.2)
04.03	ANUS - Anal cancer
04.04	BLAD - Bladder cancer
04.05	BONE - Bone cancer
04.06	BRAC - Brain cancer
04.07	BRCA - Breast cancer

04.10.1	ALL - Leukaemia: Acute lymphoid
04.10.2	AML - Leukaemia: Acute myeloid
04.10.3	CLL - Leukaemia: Chronic lymphoid
04.10.4	CML - Leukaemia: Chronic myeloid
04.10.9	LEUK - Leukaemia: unspecified
04.18	COLO - Colon cancer
04.11	COTC - Connective tissue cancer
04.12	ESOP - Esophagus cancer
04.13	GALL - Gallbladder cancer
04.14	GYCA - Gynaecologic cancer
04.15	HDL - Hodgkin lymphoma
04.16	HENE - Head and neck (incl. face) cancers
04.17	KIDN - Kidney cancer
04.19	LIPC - Lip cancer
04.20	LIVR - Liver cancer
04.21	LUNG - Lung cancer
04.22	MALM - Malignant melanoma
04.27	MULM - Multiple myeloma
04.29	PANC - Pancreas cancer
04.31	PENC - Penile cancer
04.32	PROS - Prostate cancer
04.33	RECT - Rectum cancer
04.34	STOM - Stomach cancer
04.35	TESE - Testicular seminoma
04.36	UTER - Uterus cancer
04.40.1	MEAC - Metastasis: of adenocarcinoma
04.40.2	MEOC - Metastasis: of other cancer type
04.40.3	MESC - Metastasis: of squamuos cell carcinoma
04.40.9	META - Metastasis: unspecified
04.90	OTH - Other Malignancy Type
04.99	UNKP - Unknown Malignancy Type

05	Diabetes Mellitus (complication to)
06	Pancreatitis
07	Lactic acidosis
08	MI or other ischemic heart disease
08.1	AMI
08.1.1	Definitive AMI (Dundee 1)
08.1.2	Possible AMI (Dundee 2/9)
08.2	Other ischemic heart disease
09	Stroke
10	Gastro-intestinal haemorrhage (if chosen, specify underlying cause)
11	Primary pulmonary hypertension
12	Lung embolus
13	Chronic obstructive lung disease
14	Liver failure (other than 03, 03.1, 03.2)
15	Renal failure
16	Accident or other violent death (not suicide)
17	Suicide
18	Euthenasia
19	Substrance abuse (active)
19.1	Chronic Alcohol abuse
19.2	Chronic intravenous drug-use
19.3	Acute intoxication
20	Haematological disease (other causes)
21	Endocrine disease (other causes)
22	Psychiatric disease (other causes)
22.1	Mental and behavioural disorders due to use of psychoactive substances (other than alcohol and intravenous opioids)
22.2	Schizophrenia, schizotypal and delusional Disorders

22.3	Mood /Affective disorders (Major depressive disorder, Bipolar disorder and other mood disorders)
22.4	Neurotic, stress-related and somatoform disorders (including anxiety disorders, phobias, OCD, stress reaction, dissociative disorders, somatoform disorders)
22.5	Behavioral syndromes associated with physiological disturbances and physical factors (including eating disorders, sleep disorders, sexual disorders)
22.90	Other psychiatric disorders
23	CNS disease (other causes)
23.1	Movement disorders (Parkinson’s disease; dystonias and Parkinson-like syndromes)
23.2	Degenerative disorders of the central nervous system (Alzheimer's disease; Creutzfeldt–Jakob disease and other degenerative diseases of nervous system)
23.3	Demyelinating diseases of the central nervous system (Multiple sclerosis, other demyelinating diseases)
23.4	Epilepsy (including localised and generalized epilepsy and epileptic syndromes)
23.5	Polyneuropathies (Guillain–Barré syndrome and other polyneuropathies/disorders of the peripheral nervous system)
23.6	Diseases of myoneural junction and muscle (Miastenia gravis and other myoneural disorders)
23.90	Other disorders of the nervous system
24	Heart or vascular (other causes)
25	Respiratory disease (other causes)
26	Digestive system disease (other causes)
27	Skin and motor system disease (other causes)
28	Urogential disease (other causes)

29	Obstetric complications
30	Congenital disorders
31	Symptoms caused by mitochondrial toxicity (other than 06, 07)
32	Bleeding (haemophilia)
33	Sudden infant death
33.1	Child abuse
90	Other causes
91	Unclassifiable causes
92	Unknown
92.1	Unknown, Competing risks

The following additional codes are used in the TB-HIV study, but not yet officially included in CoDe

Code	**Cause of Death**
01.1.1	Tuberculosis
01.1.1.1	Pulmonary tuberculosis
01.1.1.2	Extrapulmonary TB
01.1.1.2.01	Pleura (isolated, without lungs involvement
01.1.1.2.02	Lymphatic intrathoracic (isolated, without lungs involvement)
01.1.1.2.03	Lymphatic extrathoracic
01.1.1.2.04	Pericardia
01.1.1.2.05	Spine
01.1.1.2.06	Bone/joints other than spine
01.1.1.2.07	Meningitis
01.1.1.2.08	CNS other than meningitis
01.1.1.2.09	Genito-urinary tract
01.1.1.2.10	Peritoneal/digestive
01.1.1.2.11	TB with poly-organ failure/ TB sepsis
01.1.1.3	Disseminated tuberculosis
01.1.1.3.01	Lungs

01.1.1.3.02	Miliary
01.1.1.3.03	Pleura
01.1.1.3.04	Lymphatic intrathoracic
01.1.1.3.05	Lymphatic extrathoracic
01.1.1.3.06	Pericardia
01.1.1.3.07	Spine
01.1.1.3.08	Bone/joints other than spine
01.1.1.3.09	Meningitis
01.1.1.3.10	CNS other than meningitis
01.1.1.3.11	Genito-urinary tract
01.1.1.3.12	Peritoneal/digestive
01.1.1.3.13	TB with poly-organ failure/ TB sepsis
01.1.2	other AIDS-defining infection
01.1.2.1	with lungs involvement
01.1.2.2	with CNS involvement
01.2.1	AIDS Malignancy localised to lungs
01.3	IRIS after cART initiation (can only be used as contributing cause of death)
02.1.2	Bacterial pneumonia 02.1.3 Bacterial meningitis
02.2.2	other pneumonia 02.2.3 other with CNS involvement
19.3.1	Toxicity to anti-TB drugs

DEATH_R3 - Coding Table

The following table represents the Coding of Death (CoDe) standard. The newest version is available in the Review Form 2.2.

Use the most specific coding available whenever possible.

Code	Cause of Death
01	AIDS (ongoing active disease)
01.1	Infection
01.2	Malignancy
02	Infection (other than 01.1)
02.1	Bacterial
02.1.1	Bacterial with sepsis
02.2	Others
02.2.1	Others with sepsis
02.3	Unknown aetiology
02.3.1	Unknown with sepsis
03	Chronic viral hepatitis (progression of/complication to)
03.1	HCV
03.1.1	HCV with cirrhosis
03.1.2	HCV with liver failure
03.1.3	HCV with liver cancer
03.2	HBV
03.2.1	HBV with cirrhosis
03.2.2	HBV with liver failure
03.2.3	HBV with liver cancer
04	Malignancy (other than 01.2 and 03, 03.1, 03.2)
04.03	ANUS - Anal cancer
04.04	BLAD - Bladder cancer
04.05	BONE - Bone cancer
04.06	BRAC - Brain cancer
04.07	BRCA - Breast cancer

04.10.1	ALL - Leukaemia: Acute lymphoid
04.10.2	AML - Leukaemia: Acute myeloid
04.10.3	CLL - Leukaemia: Chronic lymphoid
04.10.4	CML - Leukaemia: Chronic myeloid
04.10.9	LEUK - Leukaemia: unspecified
04.18	COLO - Colon cancer
04.11	COTC - Connective tissue cancer
04.12	ESOP - Esophagus cancer
04.13	GALL - Gallbladder cancer
04.14	GYCA - Gynaecologic cancer
04.15	HDL - Hodgkin lymphoma
04.16	HENE - Head and neck (incl. face) cancers
04.17	KIDN - Kidney cancer
04.19	LIPC - Lip cancer
04.20	LIVR - Liver cancer
04.21	LUNG - Lung cancer
04.22	MALM - Malignant melanoma
04.27	MULM - Multiple myeloma
04.29	PANC - Pancreas cancer
04.31	PENC - Penile cancer
04.32	PROS - Prostate cancer
04.33	RECT - Rectum cancer
04.34	STOM - Stomach cancer
04.35	TESE - Testicular seminoma
04.36	UTER - Uterus cancer
04.40.1	MEAC - Metastasis: of adenocarcinoma
04.40.2	MEOC - Metastasis: of other cancer type
04.40.3	MESC - Metastasis: of squamuos cell carcinoma
04.40.9	META - Metastasis: unspecified
04.90	OTH - Other Malignancy Type
04.99	UNKP - Unknown Malignancy Type

05	Diabetes Mellitus (complication to)
06	Pancreatitis
07	Lactic acidosis
08	MI or other ischemic heart disease
08.1	AMI
08.1.1	Definitive AMI (Dundee 1)
08.1.2	Possible AMI (Dundee 2/9)
08.2	Other ischemic heart disease
09	Stroke
10	Gastro-intestinal haemorrhage (if chosen, specify underlying cause)
11	Primary pulmonary hypertension
12	Lung embolus
13	Chronic obstructive lung disease
14	Liver failure (other than 03, 03.1, 03.2)
15	Renal failure
16	Accident or other violent death (not suicide)
17	Suicide
18	Euthenasia
19	Substrance abuse (active)
19.1	Chronic Alcohol abuse
19.2	Chronic intravenous drug-use
19.3	Acute intoxication
20	Haematological disease (other causes)
21	Endocrine disease (other causes)
22	Psychiatric disease (other causes)
22.1	Mental and behavioural disorders due to use of psychoactive substances (other than alcohol and intravenous opioids)
22.2	Schizophrenia, schizotypal and delusional Disorders

22.3	Mood /Affective disorders (Major depressive disorder, Bipolar disorder and other mood disorders)
22.4	Neurotic, stress-related and somatoform disorders (including anxiety disorders, phobias, OCD, stress reaction, dissociative disorders, somatoform disorders)
22.5	Behavioral syndromes associated with physiological disturbances and physical factors (including eating disorders, sleep disorders, sexual disorders)
22.90	Other psychiatric disorders
23	CNS disease (other causes)
23.1	Movement disorders (Parkinson’s disease; dystonias and Parkinson-like syndromes)
23.2	Degenerative disorders of the central nervous system (Alzheimer's disease; Creutzfeldt–Jakob disease and other degenerative diseases of nervous system)
23.3	Demyelinating diseases of the central nervous system (Multiple sclerosis, other demyelinating diseases)
23.4	Epilepsy (including localised and generalized epilepsy and epileptic syndromes)
23.5	Polyneuropathies (Guillain–Barré syndrome and other polyneuropathies/disorders of the peripheral nervous system)
23.6	Diseases of myoneural junction and muscle (Miastenia gravis and other myoneural disorders)
23.90	Other disorders of the nervous system
24	Heart or vascular (other causes)
25	Respiratory disease (other causes)
26	Digestive system disease (other causes)
27	Skin and motor system disease (other causes)
28	Urogential disease (other causes)

29	Obstetric complications
30	Congenital disorders
31	Symptoms caused by mitochondrial toxicity (other than 06, 07)
32	Bleeding (haemophilia)
33	Sudden infant death
33.1	Child abuse
90	Other causes
91	Unclassifiable causes
92	Unknown
92.1	Unknown, Competing risks

The following additional codes are used in the TB-HIV study, but not yet officially included in CoDe

Code	**Cause of Death**
01.1.1	Tuberculosis
01.1.1.1	Pulmonary tuberculosis
01.1.1.2	Extrapulmonary TB
01.1.1.2.01	Pleura (isolated, without lungs involvement
01.1.1.2.02	Lymphatic intrathoracic (isolated, without lungs involvement)
01.1.1.2.03	Lymphatic extrathoracic
01.1.1.2.04	Pericardia
01.1.1.2.05	Spine
01.1.1.2.06	Bone/joints other than spine
01.1.1.2.07	Meningitis
01.1.1.2.08	CNS other than meningitis
01.1.1.2.09	Genito-urinary tract
01.1.1.2.10	Peritoneal/digestive
01.1.1.2.11	TB with poly-organ failure/ TB sepsis
01.1.1.3	Disseminated tuberculosis
01.1.1.3.01	Lungs

01.1.1.3.02	Miliary
01.1.1.3.03	Pleura
01.1.1.3.04	Lymphatic intrathoracic
01.1.1.3.05	Lymphatic extrathoracic
01.1.1.3.06	Pericardia
01.1.1.3.07	Spine
01.1.1.3.08	Bone/joints other than spine
01.1.1.3.09	Meningitis
01.1.1.3.10	CNS other than meningitis
01.1.1.3.11	Genito-urinary tract
01.1.1.3.12	Peritoneal/digestive
01.1.1.3.13	TB with poly-organ failure/ TB sepsis
01.1.2	other AIDS-defining infection
01.1.2.1	with lungs involvement
01.1.2.2	with CNS involvement
01.2.1	AIDS Malignancy localised to lungs
01.3	IRIS after cART initiation (can only be used as contributing cause of death)
02.1.2	Bacterial pneumonia 02.1.3 Bacterial meningitis
02.2.2	other pneumonia 02.2.3 other with CNS involvement
19.3.1	Toxicity to anti-TB drugs

Table: tblMED - Other medication

Description: holds type, start and stop dates for **other medication/treatments**.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
MED_ID	character. see coding table for valid codings.	Code representing the treatment
MED_SD	yyyy-mm-dd	Date of Initiation of Treatment
MED_SD_A	character: see coding of date precision	Precision annotation variable for date of initiation of drug
MED_ED	yyyy-mm-dd	Date of stopping treatment
MED_ED_A	character: see coding of date precision	Precision annotation variable for date of stopping drug
MED_RS	character. see coding table for valid codings (identical to stopping reasons for ART)	reason for stopping treatment

Additional Fields

Field name	Format	Description
MED_RS2	character. see coding table for valid codings (identical to stopping reasons for ART)	Additional reason for stopping treatment
MED_RS3	character. see coding table for valid codings (identical to stopping reasons for ART)	Additional reason for stopping treatment

MED_RS4	character. see coding table for valid codings (identical to stopping reasons for ART)	Additional reason for stopping treatment
MED_DO	numeric	Dosage (mg or mL) per intake unless MED_FR=-1 (optional)
MED_FR	numeric: • -1 = Frequency not known. MED_DO contains dosage per day • 0.33 = 1 dose every third day • 0.5 = 1 dose every second day • 1 = 1 daily dose/qd • 2 = 2 daily doses/bid • 3 = 3 daily doses/tid • 4... = code gives number of daily doses	Frequency
DOT_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown / Not performed	Directly observed Treatment (optional)
MEDSTART_RS	numeric: • 1 = Treatment (incl. for presumptive dx) • 2 = Prophylaxis (Primary or secondary) • 9 = Unknown	Reason for starting medication (optional)

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes

AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblMED	WithinTable	MW001	Duplicate records		Yes
tblMED	WithinTable	MW002	MED_ONG=0 and MED_ED null	EPPICC	No
tblMED	WithinTable	MW003	MED_ONG=1 and MED_ED non-null	EPPICC	No
tblMED	WithinTable	MW004	Missing MED_ID		Yes
tblMED	WithinTable	MW005	Missing MED_SD		Yes
tblMED	WithinTable	MW006	Misisng MED_ED		Yes
tblMED	WithinTable	MW007	Overlapping periods of same drug		Yes

tblMED	WithinTable	MW008	MED_ED < MED_SD		Yes
tblMED	WithinTable	MW009	MED_RS not null, but end date NULL		Yes
tblMED	CrossTable	MC001	Patient has no records in tblBAS		Yes

MED_ID - Coding Table

See also the notes on the extended ATC-Codes and the ATC Index.

Similar to the drugs listed below you can report any other non-ART medication with it's ATC-Code.

Codes (Extended ATC-Codes)	Other medication
A10A	Insulin or derivatives hereof
A10B	Oral antidiabetic agents
A11CC	vitamin D
A14A	Anabolic steroids/appetite stimulants
B01AC	Anti-platelets
C-HYP	Other anti-hypertensive agents [C02, C03, C04, C07, C08]
C09	ACE inhibitors
C10	Lipid lowering agents
G02CA	Tocolysis
H02	Corticosteroids
J01	Antibiotics
J01AA08	Minocycline (MINOCIN)
J01EA01	Trimethoprim (MONOTRIM, NOPIL)
J01EC02	Sulfadiazine
J01EE	Cotrimoxazole - Comb. of sulfonamides and trimethoprim (BACTRIM, EUSAPRIM, NOPIL)
J01EE01	Sulfamethoxazole and trimethoprim (Bactrim)
J01EE03	Sulfametrole and trimethoprim - Cosoltrime (MADERAN)
J01FA09	Clarithromycine (KLACID)
J01FA10	Azithomycine (ZITHROMAX)
J01FF01	Clindamycine (DALACIN)
J01GA01	streptomycin
J01GB06	Amikacine (AMIKINE)
J01MA02	Ciprofloxacine (CIPROXINE, CILOXAN)
J01MA12	Levofloxacin (TAVANIC)

J01MA14	Moxifloxacin
J01RA02	Cosoltrime (MADERAN)
J02AA01	Amphotericin B (FUNGIZON)
J02AB	Imidazoles (DAKTARIN, NIZORAL, PEVARYL …)
J02AB02	Ketoconazole
J02AC01	Fluconazole (DIFLUCAN)
J02AC02	Itraconazole (SPORANOX)
J02AC03	Voriconazole
J02AC04	Posaconazole
J02AC05	Isavuconazole
J02AX01	Flucytosine
J02AX04	caspofungin
J04AB02	Rifampin (RIMATICIN)
J04AB04	Rifabutin (MYCOBUTIN)
J04AB05	Rifapentine (Priftin)
J04AC01	Isoniazide (RIMIFON)
J04AK01	Pyrazinamide (PYRAZINAMID)
J04AK02	Ethambutol (EMB, MYAMBUTOL)
J04AM05	RIFATER
J04BA01	Clofazimine (LAMPREN)
J04BA02	Dapsone
J05AB01	Aciclovir (ZIVORAX)
J05AB04	Ribavirin
J05AB06	Ganciclovir (CYMEVENE)
J05AB09	Famciclovir
J05AB11	Valaciclovir (VALTEX)
J05AB12	Cidofovir (VISTIDE)
J05AB15	Valganciclovir
J05AD01	Foscarnet (FOSCAVIR)
J05AE11	Telaprevir (INCIVEK, INCIVO)

J05AE12	Boceprevir (VICTRELIS)
J05AE13	Faldaprevir
J05AE14	Simeprevir
J05AE15	Asunaprevir
J05AF08	Adefovir (PREVEON)
J05AF10	Entecavir
J05AF11	Telbivudine
J05AF12	Clevudine
J05AR-DAAS	Daclatasvir/Asunaprevir
J05AX GRAZ-ELB	Grazoprevir/Elbasvir
J05AX14	Daclatasvir
J05AX15	Sofosbuvir
J05AX16	Dasabuvir
J05AX65	Ledipasvir/Sofosbuvir
J05AX67	Ombitasvir, paritaprevir(ABT-450) and ritonavir
J07BM0	HPV Vaccine
J07BM01	HPV Vaccine (types 6, 11, 16, 18)
J07BM02	HPV Vaccine (types 16, 18)
J07BM03	HPV Vaccine (types 6, 11, 16, 18, 31, 33, 45, 52, 58)
L01AA01	Cyclophosphamide (ENDOXAN)
L01AD02	CCNU (LOMUSTINE)
L01AX04	Dacabazine (DTIC - Dome)
L01BA01	Methotrexate
L01CA01	Vinblastin (VELBE)
L01CA02	Oncovin (VINCRISTINE)
L01CB01	Etoposide (VEPESIDE, EXITOP 100)
L01DB01	Doxorubicine, Adriamycine (DOXIL, CAELYX, ADRIBLASTIN)
L01DC01	Bleomycine
L01XB01	Procarbazine (NATULAN)
L03AA02	G-CSF/Filgastrim (NEUPOGEN)

L03AB	Interferons
L03AB-AL2	Peginterferon alfa-2a/alfa-2b (PEGINTRON, PEGASYS)
L03AB10	Peginterferon alfa-2b (PEGINTRON)
L03AB11	Peginterferon alfa-2a (PEGASYS)
L03AC-IL2	Interleukin 2 (PROLEUKIN)
M05BA	bisphosphonate
N03A	Antiepileptics
N05A	Antipsychotics
N05CD	Benzodiazepine derivatives
N05CF	Benzodiazepine related drugs
N06A	Antidepressant
N07BC	Other drugs used in opioid dependence
N07BC01	Buprenorphine
N07BC02	Methadone
N07BC03	Levacetylmethadol
N07BC04	Lofexidine
N07BC51	Buprenorphine, combinations
P01AX06	Atovaquone (WELLVONE, MEPRONE)
P01BA03	Primaquine
P01BD01	Pyrimethamine (DARAPRIM)
P01BD51	Pyrimethamine/Sulfadoxine (FANSIDAR)
P01CX01	Pentamidine aerosol (PENTACARNET)
V03AB15	Naloxone
V03AF03	Folinate of calcium (LEUCOVORINE)

MED_RS - Coding Table

Most reasons mentioned below could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This list is identical to the stopping reasons for ART (ART_RS)

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity
15	Social contra-indication

16	Contra-indication unspecified
16.8	Contra-indication expired
16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (e.g. DAA's for HCV, antibiotics
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance
94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

MED_RS2 - Coding Table

Most reasons mentioned below could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This list is identical to the stopping reasons for ART (ART_RS)

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity

15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired
16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance
94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

MED_RS3 - Coding Table

Most reasons mentioned below could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This list is identical to the stopping reasons for ART (ART_RS)

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity

15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired
16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance
94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

MED_RS4 - Coding Table

Most reasons mentioned below could be coded in ICD-10 codes, it is still certain that many reasons will never be defined in terms of ICD-10 (STI, physicians and patients decision), so to avoid a mixture of two different coding systems it is advised to go with the above list and build upon that for now. This list is identical to the stopping reasons for ART (ART_RS)

Code	Reason for Stopping Treatment
1	Treatment failure (i.e. virological, immunological, and/or clinical failure
1.1	Virological failure
1.2	Partial virological failure
1.3	Immunological failure - CD4 drop
1.4	Clinical progression
1.5	Resistance (based on test result)
2	Abnormal fat redistribution
3	Concern of cardiovascular disease
3.1	Dyslipidaemia
3.2	Cardiovascular disease
4	Hypersensitivity reaction (skin eruption etc.)
5	Toxicity, predominantly from abdomen/G-I 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
6.2	Toxicity - neuropsychiatric
6.3	Toxicity - headache
7	Toxicity, predominantly from kidneys
8	Toxicity, predominantly from endocrine system
8.1	Diabetes
9	Haematological toxicity (anemia etc.)
10	Hyperlactataemie/lactic acidosis
11	Bone toxicity

15	Social contra-indication
16	Contra-indication unspecified
16.8	Contra-indication expired
16.9	Contra-indication – other
17	MTCT regimen completed
70	Pregnancy - toxicity concerns (during pregnancy)
75	Pregnancy - switch to a more appropriate regimen for PMTCT
88	Death
90	Side effects - any of the above but unspecified
90.1	Comorbidity
91	Toxicity, not mentioned above
91.1	Toxicity, unspecified
92	Availability of more effective treatment (not specifically failure or side effect related)
92.1	Simplified treatment available
92.2	Treatment too complex
92.3	Drug interaction
92.31	Drug interaction - commencing TB/BCG treatment
92.32	Drug interaction - ended TB/BCG treatment
92.33	Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available)
92.4	Protocol change
92.5	Regular treatment termination (used in tblMED e.g. for DAA's against HCV, antibiotics)
92.6	End of empiric treatment
92.9	Change in treatment not due to side-effects, failure, poor adherence or contra-indication
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-compliance
94.2	Defaulter
95	Physician's decision, not specified above
96	Pregnancy (see also more specific codes 70 and 75
96.1	Pregnancy intended
96.2	Pregnancy ended
97	Study treatment
97.1	Study treatment commenced
97.2	Study treatment completed
97.6	Drug not available
98	Other causes, not specified above
99	Unknown

Table: tblNEWBORN - Newborn

Description: holds information related to **newborns**

Please also read the notes on pregnancy tables

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
CHILD_ID	Character (or numeric if possible)	Patient ID of the child (If child is not enrolled into care, enter mother's ID with dashed numeric Suffix such as [MOTHER_ID]-1, [MOTHER_ID]-2, etc. here)
ENTRY_PMTCT_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Did the child enter your program through a PMTCT program/Trial? Note: Children can be considered to have entered through a PMTCT program if their mother received PMTCT drugs (either in a dedicated PMTCT program or an integrated program) and the infant was diagnosed in PMTCT follow-up and enrolled at
BREASTFD_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Was the child ever breastfed?
BREASTFD_DUR	numeric: number of weeks	For how many weeks was the child breastfed?

BRFEED_SD	yyyy-mm-dd	Breastfeeding, start date.
BRFEED_ED	yyyy-mm-dd	Breastfeeding, end date.
FAT_ETH	See coding table.	Ethnicity of father
APGAR_1	numeric	1st APGAR score
APGARM_1	numeric	minute at which the 1st APGAR test was performed
APGAR_2	numeric	2nd APGAR score
APGARM_2	numeric	minute at which the 2nd APGAR test was performed
APGAR_3	numeric	3rd APGAR score
APGARM_3	numeric	minute at which the 3rd APGAR test was performed
ICU_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Referral to intensive/intermediate care unit?
ICU_S	character	if yes, specify reason
ICU_D	yyyy-mm-dd	Date of entry to intensive/intermediate care unit
ABNORM_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	did any abnormalities occur? (if yes, recorded in tblNEWBORN_ABNORM)

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes

AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblNEWBORN	CrossTable	NC001	CHILD_ID doesn't exist in tblDELIVERY_CHILD		Yes
tblNEWBORN	CrossTable	NC002	ABNORM_Y = 1, yet no records in tblNEWBORN_ABNORM		Yes
tblNEWBORN	CrossTable	NC003	ABNORM_Y = 0 or 9, yet records in tblNEWBORN_ABNORM		Yes
tblNEWBORN	WithinTable	NW001	BRFEED_SD> BRFEED_ED		Yes

tblNEWBORN	WithinTable	NW002	APGARM_x's out of order (e.g APGARM_3 < APGARM_2)		Yes
tblNEWBORN	WithinTable	NW003	ICU_Y=1, but ICU_S or ICS_D null		Yes
tblNEWBORN	WithinTable	NW004	ICU_Y=0 or 9, but ICU_S or ICU_D non null		Yes

FAT_ETH - Coding Table

Codes are hierarchically structured, therefore please indicate most detailed code as possible.

Code	Ethnicity of patient
10	White/Caucasian
20	Black
21	> Sub-Saharan African
22	> Caribbean
23	> African-American
24	> Other Black
30	Hispanic/Latino/Latin American
40	Asian
41	> Chinese
42	> Southeas Asia (e.g. Thai, Vietnamese, Philippino)
43	> Indian Subcontinent (Indian, Pakistani, Bangladeshi)
44	> Japanese
45	> Other asian
50	Indigenous people from Americas or Alaska Native
60	Indigenous people from other continents/locations
70	Other ethnic groups
71	> Maghrebian
72	> Middle East/Arabic
73	> Turkish
74	> Roma people/Gypsy (whichever is term is acceptable)
xxyy(zz)	Mixed race/ethnicity. Combine 2-digits numbers from above (e.g. 1020 for white+black)
98	Prohibited (there are countries with legal restrictions to collect information on ethnicity)
99	Unknown

Limitations

The definition of ethnicity is complex and there is no ideal definition for all countries and for all times. Likewise is the definition of race and though conceptually different from ethnicity, they are often used interchangeably. As described by many authors, ethnicity is a fluid and imprecise concept heavily influenced by societal views. If definition of ethnicity is complex, inevitably its categorization will be complex too. The definition and categorization used in HICDEP acknowledges these limitations and aims by no means to solve the intense international debate of this issue but to provide a homogeneous and practical approach for HIV research. We have partially used existing administrative classifications as they provide the advantage to have, in some instances, census population denominators but are invariably too detailed for practical use in the context of HICDEP.

We suggest users to ask themselves "why is this variable necessary to answer my research question?" to avoid some of the common mistakes highlighted in the publications below which have attributed to exclusively biological and/or genetic traits differences heavily influenced by the profound social, cultural and political differences inherent to those categories. We aim to provide a standardized definition that, in addition to the information on country or region of birth already collected within HICDEP, can be used by cohort studies of HIV infected people from different countries. Therefore, in order to encompass these different scenarios, some terms may have little meaning for some settings. Finally, this classification allows for multiple options and whenever possible, should be based on the patients' self-identification.

1. Ahdieh L, Hahn RA. Use of the terms 'race', 'ethnicity', and 'national origins': a review of articles in the American Journal of Public Health, 1980–1989. Ethnicity and Health 1996; 1:95–8

2. Bhopal R. Glossary of terms relating to ethnicity and race: for reflection and debate. J. Epidemiol. Community Health 2004; 58:441–445
3. Cooper RS, Kaufman JS, Ward R. Race and Genomics. N Engl J Med 2003; 348; 12: 1166-1170
4. European Centre for Disease Prevention and Control. Improving HIV data comparability in migrant populations and ethnic minorities in EU/EEA/EFTA countries: findings from a literature review and expert panel. Stockholm: ECDC; 2011.www.ecdc.europa.eu

Table: tblNEWBORN_ABNORM - Abnormalities

Description: holds information related to **abnormalities** of newborns

Abnormalities in newborns are recorded here, one abnormality per row. The absence of a record is to be interpreted as "unknown whether the abnormality existed" since most cohorts only record positive events.
Please also read the notes on pregnancy tables.

Note: Fields marked **bold** form the unique identifier for a record of the table. For multiple abnormalities, please specify one record per abnormality.

CHILD_ID	Character (or numeric if possible)	Patient ID of the child
ABNORM_T_S	character: • O = Old Hicdep-style coding • N = New IeDEA-style coding	abnormality type coding system
ABNORM_T	New IeDEA-style coding, see coding table Old Hicdep-style coding, character: • 1 = Birth defect(s) (detectable in physical examination including skin abnormalities) • 2 = Congenital infection(s) • 3 = Drug withdrawal syndrome • 4.1 = Neurological disorder(s): abnormal reflexes • 4.2 = Neurological disorder(s): abnormal motility • 4.3 = Neurological disorder(s): abnormal tonus • 90 = Other health problems	type of abnormality

ABNORM_S	character	further specification of the abnormality

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblNEWBORN_ABNORM	CrossTable	NAC001	CHILD_ID doesn't exist in NEWBORN		Yes
tblNEWBORN_ABNORM	WithinTable	NAW001	ABNORM_T=90 but ABNORM_S null		Yes

ABNORM_T - Coding Table

Code	Newborn / Congenital abnormality
1.1	Hydrocephalus
1.2	Microcephaly
1.3	Neural tube defects
1.4	Central Nervous System (CNS) - Other
2.1	Cleft lip and palate
2.2	Eye, Ear, Face and Neck - Other
3.1	Acyanotic defects (e.g., ASD, VSD, AV canal, PDA)
3.2	Cyanotic defects (e.g. Tetralogy of Fallot, transposition, pulmonary atresia, truncus, Ebstein's)
3.3	Heart - Other
4.1	Gastroschisis
4.2	Intestinal atresia
4.3	Tracheo-esophageal Fistula
4.4	Omphalocele
4.5	Anorectal malformation
4.6	Gastro-intestinal system - Other
5.1	Ambiguous genitalia
5.2	Ambiguous genitalia
5.3	Genitals - Other
6.1	Posterior urethral valves
6.2	Renal and urinary system - Other
7.1	Talipes equinovarus (club foot)
7.2	Limb defects – Other
8.1	Down syndrome
8.2	Chromosomal anomaly – Other
9.1	Other Organ System(s) Abnormality

Table: tblOVERLAP - Cross-cohort identification

Description: holds information on the patient's **participation in other cohorts**

Note: Fields marked **bold** form the unique identifier for a record of the table.

PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
COHORT	character	Code/name of the cohort
PAT_OTH	character	Unique patient identifier in other cohorts
COH_OTH	character	Name of the cohort

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes

AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblOVERLAP	WithinTable	OW001	Invalid other cohort		Yes
tblOVERLAP	CrossTable	OC001	PATIENT not found in tblBAS for that cohort		Yes
tblOVERLAP	CrossTable	OC002	PAT_OTH not found in tblBAS for that overlapping cohort		Yes

Table: tblPREG - Pregnancy

Description: holds general **pregnancy**-related information

Note: Fields marked **bold** form the unique identifier for a record of the table.

MOTHER_ID	Character (or numeric if possible)	Patient ID of mother of the child
PREG_SEQ	numeric	Sequence number of the pregnancy for the specified mother
MENS_D	yyyy-mm-dd	Date of last menstrual period (If date not known exactly please give approximated date)
MENS_D_A	character: see coding of date precision	Precision annotation variable for date of last menstrual period
EST_CONCEPT_D	yyyy-mm-dd	Estimated date of conception. Derive in accordance with local norms based on ultrasound, date of last menstrual period (plus 2 weeks), fundal height, newborn exam/signs/symptoms, etc.
EST_CONCEPT_D_A	character: see coding of date precision	Precision annotation variable for estimated date of conception

CONCEPT	character: • 1=Natural • 2=Infertility treatment unspecified • 2.1=IVF (In Vitro Fertilisation) • 2.2=ICSI (IntraCytoplasmic Sperm Injection) • 2.3=Ovulation induction • 3=Artificial insemination • 4=Self insemination • 9=Unknown	Conception
ANC_D	yyyy-mm-dd	Date of first antenatal care contact
ANC_D_A	character: see coding of date precision	Precision annotation variable for date of first antenatal care contact
PREG_TEST_D	yyyy-mm-dd	Date of first positive pregnancy test
PREG_TEST_D_A	character: see coding of date precision	Precision annotation variable for date of first pregnancy test
NUM_FETUS	numeric	Number of fetuses
INPREG_Y	character: • 1=Yes • 2=No: ectopic • 3=No: missed abortion • 4=No: death in utero (IUFT)	At first gynaecological visit: intact intrauterine pregnancy?
INHIST_Y	numeric: • 0=No • 1=Yes • 9=Unknown	If no in INPREG_Y was a histological investigation of reason made.
INHIST_S	character	If yes, please specify reason

INV_PROC	• 0=No • 1=Yes, chorionic villus sampling (CVS) • 2=Cordocentesis • 3=Amniocentesis • 9=Unknown	Invasive procedure
KARYO_T	• 0=Not done • 1=Normal • 2=Abnormal • 9=Unknown	Karyotype
KARYO_A	character	If abnormal, please specify
CHORIO	character: • 1=Monochorionic • 2=Dichorionic • 3=Trichorionic • etc. • 9=Unknown	For multiple pregnancies
ULTR_1	character: • 0=No • 1=Yes, normal • 2=Yes, abnormal • 9=Unknown	Ultrasound 1. Trimester (if > 1 ultrasound during trimester, code as 2 if any are abnormal)
ULTR_A_1	character	If abnormal, please specify
ULTR_2	character: • 0=No • 1=Yes, normal • 2=Yes, abnormal • 9=Unknown	Ultrasound 2. trimester (if > 1 ultrasound during trimester, code as 2 if any are abnormal)
ULTR_A_2	character	If abnormal, please specify

ULTR_3	character: • 0=No • 1=Yes, normal • 2=Yes, abnormal • 9=Unknown	Ultrasound 3. Trimester (if > 1 ultrasound during trimester, code as 2 if any are abnormal)
ULTR_A_3	character	If abnormal, please specify
PROB_Y	numeric: • 1 = Yes • 0 = No • 9 = Unknown	did any obstetrical problems occur? (if yes, recorded in tblPREG_OBS)

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes

AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblPREG	WithinTable	PW001	ANC_D <mens_d< td=""></mens_ d<>		Yes
tblPREG	WithinTable	PW002	INPREG_Y=2, 3,4 but INHIST_Y null		Yes
tblPREG	WithinTable	PW003	INPREG_Y=1 but INHIST_Y non null		Yes
tblPREG	WithinTable	PW004	INHIST_Y=1 but INHIST_S null		Yes
tblPREG	WithinTable	PW004	INHIST_Y=0 or 9 but INHIST_S non null		Yes
tblPREG	WithinTable	PW005	KARYO_T=2 but KARYO_A null		Yes
tblPREG	WithinTable	PW006	KARYO_T<>2 but KARYO_A non null		Yes
tblPREG	WithinTable	PW007	ULTRA_x =2, but ULTR_A_x null		Yes
tblPREG	WithinTable	PW008	ULTRA_x <>2, but ULTR_A_x non null		Yes
tblPREG	CrossTable	PC001	PROB_Y = 1 but no records in tblPREG_OBS		Yes

tblPREG	CrossTable	PC002	PROB_Y = 0 or 9 but records in tblPREG_OBS		Yes

Table: tblPREG_OBS - Obstetrical problems during pregnancy

Description: holds information on **obstetrical problems during pregnancy**

This table describes problems **during a pregnancy**. Abnormalities in newborns are recorded in tblNEWBORN_ABNORM instead.
Please also read the notes on pregnancy tables.

Note: Fields marked **bold** form the unique identifier for a record of the table.

MOTHER_ID	Character (or numeric if possible)	patient id of mother
PREG_SEQ	numeric	Sequence number of the pregnancy for the specified mother
PROB_T	character: • 1 = Preterm contractions • 2 = Shortened cervix • 3 = Preterm rupture of membranes • 4 = Antepartum bleeding • 5 = Intrauterine growth retardation (IUGR) • 6 = Preeclampsia/HELLP • 7 = Hypertension • 8 = Gestational diabetes (unspecified type) • 8.1 = Gestational diabetes (Diet) • 8.2 = Gestational diabetes (Insulin) • 9 = Placental abruption • 10 = Placenta praevia • 99 = Other, specify in PROB_S	type of obstetrical problem

PROB_S	character.	description of other (99) obstetrical problem
CERVIX_S	numeric (mm)	In case of shortened cervix, the length of the cervix in millimeters.

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblPREG_OBS	CrossTable	POC001	MOTHER_ID+ PREG_SEQ doesn't exist in tblPREG		Yes

tblPREG_OBS	WithinTable	POW001	PROB_T=99 but PROB_S null		Yes
tblPREG_OBS	WithinTable	POW002	PROB_T<>99 but PROB_S non null		Yes
tblPREG_OBS	WithinTable	POW003	PROB_T=2 but CERVIX_S null		Yes
tblPREG_OBS	WithinTable	POW003	PROB_T<>2 but CERVIX_S non null		Yes

Table: tblPREG_OUT - Pregnancy outcome

Description: describes the **pregnancy outcome**

Please also read the notes on pregnancy tables.

Note: Fields marked **bold** form the unique identifier for a record of the table.

MOTHER_ID	Character (or numeric if possible)	Patient ID of mother of the child
PREG_SEQ	numeric	Sequence number of the pregnancy for the specified mother
CHILD_ID	Character (or numeric if possible)	Patient ID of the child (if child is not enrolled into care, enter mother's ID with dashed numeric Suffix such as [MOTHER_ID]-1, [MOTHER_ID]-2, etc. here)
OUTCOM	character: • 1=Born alive, HIV negative • 2=Born alive, HIV positive • 3=Born alive, unknown HIV Status • 4=Born alive • 10=Stillborn • 11=Spontaneous miscarriage • 20=Termination: surgical • 21=Termination: medication • 22=Termination: method unknown	Pregnancy outcome

OUTCOM_R	Numeric: • 1=Fetus with malformation • 2=Dead fetus • 3=Unwanted pregnancy • 8=Other • 9=Unknown	Reason for termination
OUTCOM_D	yyyy-mm-dd	Date of birth or termination of pregnancy
OUTCOM_D_A	character: see coding of date precision	Precision annotation variable for date of birth or termination of pregnancy
B_GAGEW	numeric	Gestational age in complete weeks at birth or termination
B_GAGED	numeric	Gestational age in days in addition to weeks at birth or termination
CHILD_HIV	numeric: • 1 = HIV exposed, Status indeterminate • 2 = HIV infected • 3 = HIV uninfected	HIV Status for a child not enrolled into HIV care
CHILD_HIV_D	yyyy-mm-dd	Date associated with ascertainment of HIV status for child not enrolled into HIV care
CHILD_HIV_D_A	character: see coding of date precision	Precision annotation variable for date associated with ascertainment of HIV status for child

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?

AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblPREG_OUT	CrossTable	PTC001	MOTHER_ID+ PREG_SEQ doesn't exist in tblPREG		Yes
tblPREG_OUT	CrossTable	PTC002	OUTCOM=1,2 or 3 and CHILD_ID doesn't exisit in tblNEWBORN or tblDELIVERYCHILD		Yes

tblPREG_OUT	CrossTable	PTC003	OUTCOM=10, 11,20 or 21 and CHILD_ID exists in tblNEWBORN or tblDELIVERYCHILD		Yes
tblPREG_OUT	WithinTable	PTW001	OUTCOME=20 or 21 and OUTCOM_R null		Yes
tblPREG_OUT	WithinTable	PTW002	OUTCOME not 20 or 21 and OUTCOM_R non null		Yes

Table: tblPROGRAM - Program informtion

Description: holds information on the **program with which the center is associated**

Note: Fields marked **bold** form the unique identifier for a record of the table.

PROGRAM	character	Program name
REGION	character: • AP = Asia-Pacific • CA = Central Africa • CN = Caribbean, Central and South America • EA = East Africa • EU = Europe • NA = North America • SA = Southern Africa • WA = West Africa	Region of operation

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes

AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

Table: tblREFILL - Prescription refill data

Description: holds information on **prescription refills**

Note: Fields marked **bold** form the unique identifier for a record of the table.

PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
REFILL_D	yyyy-mm-dd	Date of the prescription refill
DRUG_ID	character. see coding table for valid codings.	Drug which was prescribed
SUPPLY	numeric	How many days supply of the drug was supplied

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes

AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblREFILL	CrossTable	PRC001	Patient doesn't have a record in BAS		Yes
tblREFILL	WithinTable	PRW002	Missing PATIENT		Yes
tblREFILL	WithinTable	PRW003	Missing REFILL_D		Yes
tblREFILL	WithinTable	PRW004	Missing DRUG_ID		Yes
tblREFILL	WithinTable	PRW005	Missing SUPPLY		Yes
tblREFILL	WithinTable	PRW006	SUPPLY < 1		Yes

DRUG_ID - Coding Table

ATC-Code of drug. See the MED_ID (tblMED) coding table and ART_ID (tblART) coding table, and the ART_ID (tblART) notes on extended ATC-Codes.

Table: tblSAMPLES - Blood Samples

Description: holds information on the storage of blood, urine and other **biological samples**

Note: Fields marked **bold** form the unique identifier for a record of the table.

PATIENT	character (or numeric if possible)	patient cohort identifier
SAMP_LAB_D	yyyy-mm-dd	date when the sample was taken
SAMP_TYPE	character: • BS = blood serum • BP = blood plasma • C = viable cells • D = cell pellet (DNA) • S = semen • OTH:x = other sample type x (none of the above)	type of the sample
SAMP_ID	character	identification symbol allowing the localization of the sample in the laboratory
SAMP_LAB	character	laboratory where the samples are stored
SAMP_FREEZE_D	yyyy-mm-dd	date when the sample was frozen
SAMP_FREEZE_T	hh:mm	time when the sample was frozen
SAMP_ALIQ_NO	numeric	number of aliquots available

SAMP_ALIQ_SIZE	numeric	size of the aliquot: • in ml for serum, plasma and cell pellet aliquots • in millions of cells for viable cell aliquots
SAMP_ALIQ_U	character: • 0 = millions of cells • 1 = ml	unit of measurement for the SAMP_ALIQ_SIZE value

Additional Fields

Field name	Format	Description
SAMP_LAB_T	hh:mm	time when the sample was taken
SAMP_TEMP	numeric	temperature of the storage unit containing the samples (in °C)
SAMP_DEFROST	numeric: • 1 = Yes • 0 = No • 9 = Unknown	have the samples already been defrosted?

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes

AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

Table: tblVIS - Basic follow-up/visit related data

Description: holds **visit related information** such as weight, wasting, smoking, occupational status etc.

Core Fields

Note: Fields marked **bold** form the unique identifier for a record of the table.

Field name	Format	Description
PATIENT	character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
VIS_D	yyyy-mm-dd	Date of patient visit
VIS_D_A	character: see coding of date precision	Precision annotation variable for date of visit
CENTER	character	Center the patient visits. Links to tblCENTER.
WEIGH	numeric (metric: kg): 999 = Unknown	Weight of patient at visit
GAIN_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is the patient gaining fat in the abdomen, neck, breast or other defined locations?
LOSS_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is the patient experiencing loss of fat from extremities, buttocks or face?

Depending on the collaboration this data might be collected in intervals of a year, e.g. from July last to July this year. In that case all visit dates or a fixed number of visit dates for that period should be gathered, if the patient did not have a visit in the defined period, a record with the PATIENT id and empty fields for VIS_D etc. should be included.

Additional Fields

Field name	Format	Description
CDC_STAGE	character. see coding table for valid codings.	Clinical CDC stage at time of visit?
WHO_STAGE	numeric. • 1 = WHO Stage I • 2 = WHO Stage II • 3 = WHO Stage III • 4 = WHO Stage IV • 9 = Unknown	Clinical WHO stage at time of visit?
FAM_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Family history of CVD: Have any first degree relatives experienced myocardial infarction or stroke before the age of 50 years?

The following optional fields are meant to be used to **document the transition process from adolescent to adult**.

CLINIC_TYPE	numeric • 1 = paediatric • 2 = adolescent within paediatric care • 3 = adolescent within adult care • 4 = adolescent stand alone • 5 = adult • 9 = missing	Type of clinic/service the patient is currently attending

SPEC_TYPE	numeric • 1 = Physician providing paediatric care • 2 = Physician providing adolescent care • 3 = Physician providing adult care • 4 = Physician providing paediatric and adult care • 5 = other healthcare provider (e.g. nurse) • 9 = missing	Type of specialist providing care. Combinations if multiple specialists are involved (e.g. 23, 45).
TRANS_STAGE	numeric • 0 = transition not started • 1 = transition in progress • 2 = transition completed • 9 = not applicable/missing	Stage of transition from pediatric to adult care at current visit. Transition has not yet started when the patient only sees paediatricians. Transition is complete when the patient only sees adult physicians.

The following fields are meant to be used **for adolescents and adults**.

EMPLOY	numeric. see coding table for valid codings.	What is the patient's current situation regarding labour?
CONTRACT	numeric. see coding table for valid codings.	If the patient is an employee, what is the type of the patient's employment contract?
SMOKING_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is the patient currently a smoker?
PREG_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is the patient currently pregnant? If possible, provide additional details in tblPREG

GENDER_IDENT	numeric: • 1 = Male • 2 = Female • 3 = Transgender male • 4 = Transgender female • 5 = Other • 6 = Non-binary • 9 = Unknown	Current gender with which the patient identifies
SCHOOL	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is the patient currently attending school or on break for customary school holidays?
SCHOOL_LVL	numeric: see coding table	Current level of education (ISCED97 refers to the 1997 International Standard Classification of Education)

The following fields are meant to be used **for HIV-infected children and adolescents only**.

STATUS_KNOWN	numeric: • 0 = No • 1 = Yes • 2 = Disclosure ongoing • 9 = Unknown	Does the patient know his/her HIV status?

The following fields are meant to be used **for children and infants**.

HEIGH	numeric (metric in m). 999 = Unknown	Height/length of patient at visit in meters (m)
LIVEWITH	numeric: • 1 = Mother • 2 = Father • 12 = Mother and Father • 3 = Foster family • 4 = Institution • 9 = Other	Child lives with/in

HEALTHY_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is child healthy?
FEEDOTH_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Is the Patient currently receiving Foods or liquids other than breast milk?
CAREGIVER	numeric: • 1 = Mother • 2 = Father • 3 = Sibling • 4 = Grandparent • 5 = Aunt or Uncle • 6 = Self • 7 = Other family member • 8 = Other non-family member • 9 = Unknown • 10 = Other non-coded	Who is the patient's primary caregiver?
BROUGHT_PATIENT	numeric: • 1 = Mother • 2 = Father • 3 = Sibling • 4 = Grandparent • 5 = Aunt or Uncle • 6 = Self • 7 = Other family member • 8 = Other non-family member • 9 = Unknown • 10 = Other non-coded	Who brought the Patient to this clinic visit?

HIV_STATUS	numeric: • 1 = HIV exposed, status indeterminate • 2 = HIV infected • 3 = HIV uninfected	Current HIV status

The following fields are meant to be used **for infants**:

HEIGH_P	numeric	Height/length of patient at visit in percentiles
WEIGH_P	numeric	Weight of patient at visit in percentiles
HEADC	numeric	Head circumference measured in millimeters (mm)
HEADC_P	numeric	Head circumference in percentiles
BREASTF_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Currently Breastfeeding?

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes

AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes
AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes
tblVIS	WithinTable	VW001	Duplicate records, same VIS_D		Yes
tblVIS	WithinTable	VW002	Height decreasing over time		Yes
tblVIS	WithinTable	VW003	Height out of acceptable range		Yes
tblVIS	WithinTable	VW004	Weight out of acceptable range		Yes
tblVIS	CrossTable	VC001	patient has no record in BAS table		Yes
tblVIS	CrossTable	VC002	No weights within 3 mths of starting FPV/DRV	EPPICC	Yes

CDC_STAGE - Coding Table

Code	Description
N	N
A	A
A1	A1
A2	A2
A3	A3
B	B
B1	B1
B2	B2
B3	B3
C	C
C1	C1
C2	C2
C3	C3
9	Unknown

EMPLOY - Coding Table

Code	Description
1	Employed as an employee
2	Self-employed / Family worker
3	Apprentice / trainee
4	Unemployed and actively seeking work
5	Student
6	Retired / Pre-retired
7	Engaged in family duties
8	Unable to work due to ill health
9	Other situation
99	Unknown

CONTRACT - Coding Table

Code	Description
1	Indefinite duration
2	Fixed-term
3	Other
9	Unknown

SCHOOL_LVL - Coding Table

Code	Description
0	None
1	primary education (ISCED97-1)
2	lower secondary (ISCED97-2) OR end of basic education
3	upper secondary or post-secondary non-tertiary (ISCED97 3 and 4)
4	university or post-graduate (ISCED97 5A and 5B)
8	other, only if none of the codes 0 to 4 applies
9	unknown

Table: tblVIS_SUBS - Patients use of substances like alcohol, cigarettes and drugs

Description: holds information on patients **use of substances like alcohol, cigarettes and drugs**

Core Fields

Field name	Format	Description
PATIENT	Numeric	Code to identify patient (Cohort Patient ID)
SUBS_D	Date (yyyy-mm-dd)	Date of assessment
SUBS_ID	Character: • ALCO = Alcohol • IDU = Intravenous Drugs • NDU = Non-injecting Drugs • SMK = Smoking • SMKD = Ever smoked	Type of substance In case of abuse, it should be defined what is considered as abuse, Eg. : Alcohol: For men: An intake of >25 alcohol containing units a week. For women: An intake of > 20 alcohol containing units a week.
SUBS_Y	numeric: • 0 = No • 1 = Yes • 9 = Unknown	Patient's substance use at assessment date

Additional Fields

Field name	Format	Description
SUBS_FR	Numeric	Frequency For ALCO: Number of alcohol containing units per day For SMK: Number of years smoking/not smoking (depending on SUBS_Y)

QA Checks:

Table	Crosstable	Error Code	Description	Study specific	HICDEP?
AllTables	CrossTable	ATC001	any date in database after DEATH_D in tblLTFU		Yes
AllTables	CrossTable	ATC002	any date in database after DROP_D in tblLTFU		Yes
AllTables	CrossTable	ATC003	any date in database before BIRTH_D in tblBAS		Yes
AllTables	CrossTable	ATC004	any date in database in the future		Yes
AllTables	CrossTable	ATC005	patients submitted previously who have been missed out		Yes

AllTables	CrossTable	ATC006	Any fields not coded as coding lists on table definition		Yes

Considerations For Using The Format To Create A Database

Administrative fields

Sometimes it might be needed to have a fixed value that shows from which visit or merger a value originates, this does not only apply to the *VIS* table but could be applied to all tables. This however does depend on the nature of the database and needs for data management, the field below should be considered an administrative support field for data management.

VISIT
Visit number
Numeric: 0 = Baseline Visit 1 = First follow up visit 2 = Second follow up visit etc.

Often the above field is used for clinical trials databases where there is a need to associate the data directly with a given week's follow-up. Codes could then be the week number e.g. 4, 12, 24 etc or –1 for screening/randomisation and 0 for baseline visits.

In some cases it might be useful to have a separate field that defines the correct order of the periods. This becomes important where several dates are incomplete (unknown days, unknown months and possibly unknown years). The ordering by date would then not be correct.

One solution to this is use a *PERI_ID* field that numbers the periods from the 1st until Nth usage:

PERI_ID
Period of usage (1st, 2nd, 3rd etc.)
Numeric

However this is an optional field that for most cohorts may not be needed. It also requires additional maintenance to keep it updated.

For databases that work with double data entry, such as most clinical databases, it becomes necessary to make each data entry unique and backwards traceable. For this to work a field like the above would have to be part of the primary key of each table that requires double data entry.

ENTRY_ID
Number of data entry

Numeric: 1 = first data entry 2 = second data entry 3 = comparison of 1st and 2nd data entry 4 = final approved record including corrections

With respect to performance, it might also be a good design to have 3 copies of each table, one to hold the data while being entered and compared, one for the two data entries to be archived into once a final record has been approved and a table holding the final and approved values. This way it is avoided that queries will have to work on checking for ENTRY_ID = 4 and to select amongst a table holding 3 times the almost same data.

As part of an audit trail in a database a time stamp field could be added for each record to fix the exact time when the record last was inserted or updated. Along with the time stamp name of the user who entered or altered data can be recorded.

T_STAMP	**USER_LOG**
Date and time of data entry	Username of user that last inserted or updated data
yyyy-mm-dd hh:mm:ss	character

Often it's necessary to keep a log of user action in a separate table. The above suggestion will only be valid for inserts and updates, and only be valid for the most recent action performed.

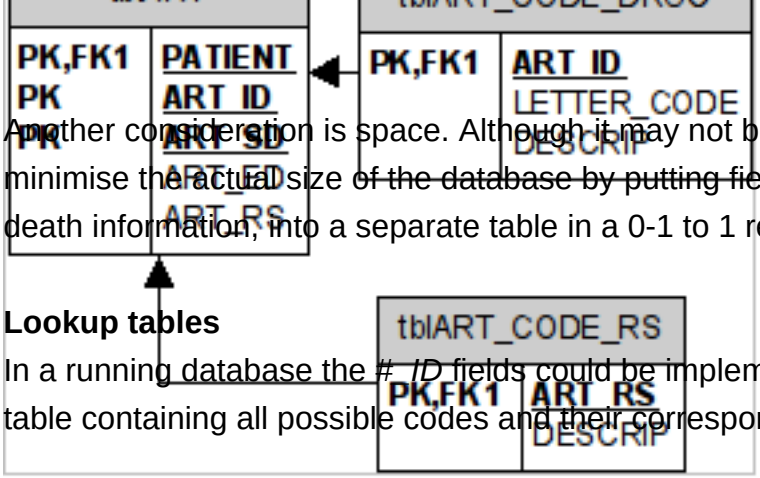
To record a complete audit trail a logging facility must be implemented. In most database management systems this is done using triggers on the tables. For any insert, update or delete actions performed on the data, the user, time stamp, old value and new value are recorded in the logging table.

The *T_STAMP* field could also include information about which time zone is relevant for data entry. Depending on database requirements this might in fact be mandatory if the FDA's 21 CRF part 11 on electronic records and signatures applies.

Further normalisation

Depending on performance considerations it might be worth looking at how data are queried for data entry and data analysis. A smaller tblBAS table might increase performance: Since processing a smaller table is always faster than processing a larger table, one could put drop-out, death, birthday, date of aids diagnosis, etc. into separate tables and keep the core patient list in a separate master table

But if the database is used e.g. for BMI calculations directly on the running database, performance might be enhanced by keeping the patient list and the height together in the same table so that a query involves 2 tables (*tblBAS* and *tblVIS*) rather than perhaps 3 or more.



Another consideration is space. Although it may not be much of an issue, it will be possible to minimise the actual size of the database by putting fields that may be empty for most patients, like death information, into a separate table in a 0-1 to 1 relation to the master table.

Lookup tables

In a running database the *#_ID* fields could be implemented as a foreign key to a linked lookup table containing all possible codes and their corresponding definitions in a text string.

This setup not only enables integrity of the data, but also defines the domain1 for the *#_ID* values and enables data to both become human readable and easily recoded2.

An important note on lookup tables is that the performance on a large database can be slowed significantly by using character based keys to link lookup tables with the primary table as it is presented in this document. A work around is to use numeric value for the codes.

1: Domain is a term in the definition of the relational database model that defines a set of allowed values for a given set of fields (attributes), the mixing of different domains is not allowed in order to preserve the integrity of a relational and normalised model.

2: Easily recoded permanently if the relation is specified as cascade on update or recoded dynamic by selecting a different column from the lookup table when querying the data through SQL

Performance

As already outlined in the above section, there are also performance issues that may have to be considered.

When using the suggested data types presented in this document for a database implementation, it may be worth looking at the actual data at hand when defining the final data types. The aim of this document is to present a format that will work between cohorts with rather different setups.

If it is at all possible in many cases there may be a large performance gain by using numeric instead of character fields. Character fields have been suggested here for, amongst others, the *PATIENT* field. If the *PATIENT* id is purely numeric it's worth using a numeric data type since it always faster for querying than a character field.

Whenever the field has to be character, make sure that only the needed amount of space is assigned for the field length; there is no need to assign 50 characters of memory if the field in fact only stores a 3-letter code.