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Standard Operating Procedure for data transfer in RESPOND, EuroSIDA, and CARE.

Valid for enrolment and follow up in EuroSIDA, RESPOND and CARE

Contents

Introduction

The Standard Operating Procedure (SOP) for RESPOND, EuroSIDA and CARE provides a guideline for electronic data submission with aims of standardizing data and improving data quality. The SOP covers the procedure of data submission as well as data schema.

The data collection structure, to the extent possible, conforms to the HICDEP standard (HIV Cohorts Data Exchange protocol). The 1.110 release version of HICDEP is available at the HICDEP website: https://www.hicdep.org/Wiki/v/9/pt/2. Changes and additions are always part of the on-going process for projects that extend over time..

Thank you very much for your contribution to these collaborative projects!

Data submission

Data preparation

To facilitate your submission of data, please extract your data into the Microsoft Access template downloadable on the CHIP.dk website. For RESPOND, please use the RESPOND template. For EuroSIDA, please use the EuroSIDA template. For CARE, please use the CARE template.

The tables section describes the table names, data types and how to code numeric and character values, which generally follow the latest HICDEP format.

Data must be submitted via the RESPOND electronic submission tool (REST). The following applies:

- For both baseline enrolment- and follow-up data please submit all available data.
- Patients who have died or are lost to follow-up should remain in the dataset with all their available data.
- We assume that the latest submitted dataset include the most correct and updated data overlapping data from previous datasets within a five-year period. Changes to the data within this five-year period will therefore overwrite already downloaded data in the database.

Additional data submission:

Please complete the following event forms in REDCap when applicable:

For patients who developed one or more of the following clinical events:

- Bone fracture
- AIDS defining cancer (ADM)
- Non-AIDS defining cancer (NADM)
- End-stage liver disease (ESLD) or liver transplantation
- End-stage renal disease (ESRD) or renal transplantation
- Invasive cardiovascular procedure (ICP)
- Myocardial infarction (MI)
- Stroke

A CoDe form (cause of death) for patients that died

Appendix 1 contains a checklist of tables. For your convenience this may be used to keep an overview of tables you provide. Please go through a simple checklist (Appendix 2) before your submission.

Data upload

Electronic data must be uploaded via the RESPOND electronic submission tool (REST) – go to www.chip.dk. On the CHIP website in the upper right corner, you can log in after which you will have access to REST through the **Tools & Standards** tab in the top of the webpage. Please refer to the REST user guide provided along with this SOP.
Please make sure you have a login for the tool. Otherwise, please contact the coordinating centre.
REST will perform a number of quality checks on the data and submission is only considered successful once the data passes the quality check. If your data does not pass the quality check, please make the adjustments as indicated by REST and re-upload.

Note that it is your responsibility to ensure that the data are in accordance with your regional laws on data protection and that you have adjusted the data for submission accordingly.

Deadline

The deadline for data submission is **1st December 2021**.

Addendum for changes made between SOP version 4.1 and 5:

TblART:

- ART_IDs for two antiretroviral drugs licensed for HIV treatment in the Russian federation without ATC codes have been added: Elsulfavirine (*ESV*) and phosphazide (phosphorylated zidovudine, *pZDV*).
- A new reason for treatment discontinuation (*ART_RS*) have been added to accommodate the use of long-acting injectable antiretroviral drugs: *incorrect route of administration* (92.22)
- A new reason for treatment discontinuation (*ART_RS*) have been added to accommodate the use of long-acting injectable antiretroviral drugs: *unwanted weight changes* (*18*)

TblBAS:

- FAM_Y has been renamed CVD_FAM_Y, and have been moved from Tbl_VIS to Tbl_BAS

Tbl_CEP

- Liver transplantation (LIVT) has been changed from a separate CEP_ID to a CEP_SPEC for ESLD to provide a consistent hierarchy.
- Kidney transplantation (KIDT*)* has been changed from a separate CEP_ID to a CEP_SPEC for ESRD. In addition, peritoneal- and haemodialysis > 3 months (*KDIY*) and unspecified ESRD (UNKP) have been added as CEP_SPECs for ESRD, providing a consistent hierarchy.
- CEP_SPEC= UNKP has been added for CEP_ID = ICP, to accommodate situations where the specific procedure is unknown.
- CEP_SPEC = CAS has been added for CEP_ID=ICP to specify carotid artery stenting
- CEP_SPECs (DIY, IMV, NIVM, ECMO, HFOS) for CEP_ID = COVAM (COVID-related admission) has been removed. Type of admission (should still be entered by use of CEP_V (1=Non-ICU, 2=ICU, 9=Unknown)
- CEP_SPEC (SSAH), have been added for CEP_ID =STR, to accommodate reporting of Subarachnoid haemorrhage

Note:

ESLD*: Please only supply the first end-stage liver event in table CEP. If more than one symptom of end-stage-liver disease is present on the same day, please report these as two lines with the same date. NB! All cases of liver transplantation should be reported, regardless of occurring after the first end-stage liver event.*

Correspondingly, an event form should only be supplied for the first end-stage liver disease event, but for all cases of liver transplantation

ESRD: Please only supply the earliest end-stage renal diseases event in table CEP (i.e., the first time the patient initiated haemo-/peritoneal dialyses >3 months. NB! All cases of renal transplantation should be reported, regardless of occurring after the first end-stage renal disease event

Correspondingly, an event form should only be supplied for the first end-stage disease event, but for all cases of liver transplantation

TblDIS:

- The DIS_OTH column has been removed to minimize the amount of free text
- A DIS_SPEC table has been added to specify DIS_IDs
- The DIS_IDs Cervical cancers (CRVC), Kaposi's sarcoma (KS), and non-Hodgkin's lymphomas (NHGB, NHGI, NHGP, and NHGU) have been changed to a Common DIS_ID = ADM, specified by DIS_SPECS CRVC, KS, NHGB, NHGI, NHGP, and NHGU.
- The DIS_IDs for cytomegalovirus retinitis (CMVR) and other cytomegalovirus infections (CMVO) have been replaced by a common DIS_ID = CMV, specified by DIS_SPECs CMVR and CMVO.
- DIS_SPECs have been added for pulmonary (DIS_ID = MCP) and extrapulmonary tuberculosis (DIS_ID = MCX)

TblLAB

- LAB_IDs for serum phosphate (PHOS), total serum-calcium (CALC), and D-vitamin (DVIT) have been added
- LAB_U = 19 has been added to note laboratory measurements in nano-mol per liter (nmol/L)
- LAB_DR for collecting tuberculosis resistance tests has been removed, as data on tuberculosis resistance will no longer be collected.

TblLAB_VIRO:

- Anti-bodies against SARS-CoV-2 have been renamed from COVAB to COVA, adhering to the HICDEP standard.
- PCR tests for SARS-CoV-2 have been renamed from COVPCR to COVRNA, adhering to the HICDEP standard

TblLTFU:

- A short text preceding the table has been added, specifying that all patients should figure in the table, even if not lost to follow-up (DROP_Y =0)

TblMED

- MED_IDs for SARS-CoV-2 vaccines have been added. Please ensure to use the MED IDs provided on p.32-33 for coding the vaccines.

TblMED_HCV

- MED_ID for the direct-acting antiviral drug, narlaprevir (NPV), licensed for Hepatitis C treatment in the Russian Federation, has been added to the data collection.

TblOVERLAP

- The Table has been removed

TblSAMPLEs

- WB (=whole blood) has been added to specify SAMP_TYPE to accommodate the collections of whole blood samples.

TblVIS_SUBS

- A definition for Units of alcohol has been added for ALCO, basing a standard drink of alcohol as 10g or 12.7 mL of pure alcohol (examples provided in the table).

  If your cohort/site follows another definition for a standard drink of alcohol, please contact the RESPOND, EuroSIDA, or CARE coordination secretariat as appropriate, noting the definition used by your cohort/site.

- The Alcohol Use Disorders Identification Test (AUDIT-C, ALCC) has been added to the data collection and replaces ALCO whenever AUDIT-C scores are available, providing additional granulation of the alcohol use/abuse data collection

- A **SUBS_SPEC** coding table has been added. The table holds variables for specifying ALCC: Alcohol consumption frequency (FRE), Alcohol consumption quantity (QUA), Excessive alcohol consumption frequency (EXE). In addition, a specification for the AUDIT-C sum score has been added (ACSUM) if only the sum score is known.

- A **SUBS_V** Coding table has been added. The table holds values corresponding to ALCC_SPEC (0-4,9)

1. Tables

Please follow the instruction here for table names, field names, field types as well as how to code for values. Please provide all relevant available data.

How to code unknown values:

- For unknown and missing values other than date, please see specification in the corresponding tables.
- If only the day is unknown (yyyy-mm-??), please enter the 15th with the known month and year (yyyy-mm-15). I.e. unknown day in September 2019: 2019-09-15.
- If both day and month are unknown (yyyy-??-??), please enter the 1st July with the known year (yyyy-07-01). I.e. unknown day and month in 2019 : 2019-07-01.
- If a date is completely unknown (????-??-??), please enter 1911-11-11.

How to code non-applicable values:
For non-applicable values please leave the field *empty*. i.e. if a patient does not have weight recorded at the visit, please enter the visit date, but leave the weight field empty

Must Have values:
Yellow highlighted field names indicate core data which must be reported for all participants. Missing data in any of these fields is considered as incomplete data/reporting and is considered insufficient for reimbursement if recurrent.

Bold letter field names indicate **required** values if a record is provided.

Underscored field names indicate **required** values depending on whether specific variables have been provided. I.e. if abacavir is reported in tblART, and treatment has ended, then reasons for discontinuation and stop date also required

All tables should be submitted with **all fields** shown in the SOP. If no data is available, the table should be left empty.

Please note that must have values must be completed, at all times where possible. E.g. if an ART treatment is ongoing, you should NOT write anything in the ART_ED field. This is only a must provide value if the treatment has stopped, and an end date exists.

New fields
New fields from version 4 are marked with purple.

1. tblART

Holds type of antiretroviral drug, start and stop dates and reason for stopping. Please submit all ongoing and completed treatments.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
ART_ID	Character. Please use WHO ATC coding. If not in the WHO ATC coding list. Consult the coding table in the HICDEP Specifically, use: J05AG-ESV: for Elsulfavirine J05AF-pZDV: for phosphazide J05AE01: for Saquinavir (do not differentiate between hard and soft gel capsules by using the codes J05AE01-SQS or J05AE01-SQH) J05AE03: for ritonavir (do not differentiate between high or low dose using the codes J05AE03-L' or J05AE03-H)	ATC Code representing the antiretroviral treatment If an ATC does not exist, please provide the drug name
ART_SD	Date (yyyy-mm-dd)	Date of initiation of treatment
ART_ED	Date (yyyy-mm-dd)	Date of stopping treatment Only if treatment is stopped then you must provide both ART_ED and ART_RS
ART_RS	Character. For valid coding, please consult the HICDEP ART_RS coding table, as well as *4.3 injection site reaction* *4.4 Injection fatigue (not related to safety)* *18: unwanted weight changes* *92.22 Incorrect route administration*	Reason for stopping treatment.
ART_FORM	numeric 1 = Tablet/capsule 7 = Intramuscular 9 = Unknown	Route of administration

1.1. tblBAS

Holds **basic** information such as demographics, basic clinical information and date of AIDS diagnosis

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
BIRTH_D	Date (yyyy-mm-dd)	Birth date
CVD_FAM_Y	0=No 1=Yes 9=Unknown	First degree relative of the patient (father, mother, brother or sister) have experienced a myocardial infarction or a stroke before age 50
FRSVIS_D	Date (yyyy-mm-dd)	First seen at clinic
GENDER	Numeric: 1 = Male 2 = Female 3 = Transgender 5 = Other 9 = Unknown	Gender/sex
HEIGH	Numeric (metric in cm): 999=Unknown	Height of patient at visit/most current
MODE	Numeric. See coding table for valid coding.	Mode of HIV infection
ORIGIN	Characters (numeric codes). See coding table for valid coding. Please use code 001 for unknown values	Country or region of birth
ETHNIC	Numeric. See coding table for valid coding.	Ethnicity of patient
HIV_POS_D	Date (yyyy-mm-dd)	Date of first positive HIV test
HIV_NEG_D	Date (yyyy-mm-dd)	Date of latest negative HIV test
AIDS_Y	Numeric • 1=Yes • 0=No • 9=Unknown	Was the patient diagnosed with AIDS?
AIDS_D	Date (yyyy-mm-dd)	Date of AIDS diagnosis

1.2. **tblCEP**

Holds type and date of adverse clinical events including serious non-AIDS conditions.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
CEP_ID	Character. See CEP_ID coding table below for valid coding	Identify type of events
CEP_D	Date (yyyy-mm-dd)	Date of onset of the event
CEP_SPEC	Character. See CEP_SPEC coding table below for valid coding.	Further specify the event identified by CEP_ID. Only applicable for CEP_ID: ESLD, FRA, ICP, NADM, STR, BMD, LIVB
CEP_V	Numeric. See CEP_V coding table below for interpretation.	Depending on CEP_ID and CEP_SPEC: value of the given event. Only applicable for CEP_ID: AFRI, COVAM, FIBS, FRA, BMD.

CEP_ID Coding table

Code (CEP_ID)	Description (Event)
AMI	Myocardial infarction **please fill out RESPOND Event Form for MI** For specific information on myocardial infarction events, please consult the RESPOND Manual of operations vs. 1.6 (RESPOND MOOP vs. 1.6)
BMD_S	Bone Mass Density of the spine (add value to CEP_V)
BMD_H	Bone Mass Density of the hip (add value to CEP_V)
BMD_F	Bone Mass Density of the femur (add value to CEP_V)
COVAM	Hospital admission due to infection with SARS-CoV-2 (please add value in CEP_V) **please fill out the COVID-19 admission form (link to COVID-19 admission form) if participating in the COVID-19 study**
CTAB	CT of liver/abdomen (screening for hepatocellular carcinoma)

DIA	Diabees mellitus
ESLD	End stage liver disease Please provide CEP_SPECs as indicated in the CEP_SPEC coding table below. Applies if any of the following symptoms of decompensated liver disease have been present: • Ascites • Hepatic encephalopathy grade III og IV • Hepatorenal syndrome • Oesophageal or gastric variceal bleeding • Liver transplantation **Please fill out a RESPOND event Form for ESLD** Only fill out a form for the earliest occurring symptom(s), and only one form, if more symptoms were present on the same data. For specific information on End-stage liver disease events, please consults the RESPOND MOOP vs. 1.6
ESRD	End Stage Renal Disease Please provide CEP_SPECs as indicated in the CEP_SPEC coding below Applies if any of the following have occurred • Peritoneal or haemodialysis for a duration of more than 3 consecutive months (for chronic renal disease) • Kidney transplant (for chronic renal disease) **Please fill out RESPOND Event Form for ESRD** For specific information on End-stage renal disease events, please consults the RESPOND MOOP vs. 1.6
FIBS	Fibroscan stiffness (please add elasticity value in CEP_V)
ARFI	Acoustic Radiation Force Impulse (please add value in CEP_V)
FRA	Bone fracture (add value to CEP_V) Please provide CEP_SPECs as indicated in the CEP_SPEC coding below **Please fill out a RESPOND Event Form for FRA** For specific information on fractures events, please consults the RESPOND MOOP vs. 1.6

ICP	Invasive Cardiovascular Procedures Please provide CEP_SPECs as indicated in the CEP_SPEC coding table below Applies if any of the following procedures have been conducted: • Coronary angioplasty/stenting • Coronary by-pass surgery • Carotid endarterectomy/stenting • Carotid artery stenting **Please fill out a RESPOND Event Form for ICP** For specific information on invasive cardiovascular procedure events, please consults the RESPOND MOOP vs. 1.6
LIVB	Liver biopsy (add value to CEP_SPEC)
NADM *Note that Anal dysplasia should not be reported*	Non-AIDS defining malignancies Please provide CEP_SPECs as indicated in the CEP_SPEC coding table below **Please fill out a RESPOND Event Form for NADM** For specific information on NADM events, please consult the RESPOND MOOP vs. 1.6
STR	Stroke Please provide CEP_SPECs as indicated in the CEP_SPEC coding table below **Please fill out a RESPOND Event Form for STR** For specific information on STR events, please consult the RESPOND MOOP vs. 1.6
SYPH	Syphilis (treatment for syphilis within the last 12 months)
USAB	Ultrasound imaging of the abdomen (screening for hepatocellular carcinoma)

CEP_SPEC Coding table

Code (CEP_ID)	Code (CEP_SPEC)	Description
BMD_S BMD_H BMD_F	BMDT	BMDT=Bone mass density T –score (add score (standard deviation) to CEP_V)
BMD_S BMD_H BMD_F	BMDZ	BMDZ=Bone mass density Z-score (add score (standard deviation) to CEP_V)
BMD_S BMD_H BMD_F	BMDA	BMDA_Bone mass density area (add score to CEP_V)
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	
ESLD	ASCI	Ascites	Please provide only the first occurrence of ESLD If more symptoms of ESLD were present at the same date, please provide a row for each symptom, with identical dates Please always report the occurrence of Liver transplantation, even if ESLD have been reported previously
ESLD	HEP	Hepatic encephalopathy grade III or IV	
ESLD	HESY	Hepatorenal syndrome	
ESLD	OESO	Oesophageal variceal bleeding	
ESLD	LIVT	Liver transplantation	
ESLD	UNKP	Unspecified ESLD	
ESRD	KDIY	peritoneal or haemodialysis for a duration of more than 3 consecutive months (for chronic renal disease)	Please provide only the first occurrence of peritoneal or haemodialysis for a duration of more than 3 consecutive months Please always report the occurrence of kidney transplantation, even if ESRD have been reported previously
ESRD	KIDT	Kidney transplant (for chronic renal disease)	
ESRD	UNKP	Unspecified ESRD	
FRA	COLB	Collar bone	
FRA	CESP	Cervical spine	
FRA	FABO	Facial bones (including nose)	
FRA	FEM	Femur	
FRA	FING	Fingers	
FRA	SHOU	Shoulder	
FRA	HIP	Hip	
FRA	LOAR	Lower arm (including hands)	
FRA	LOLG	Lower leg (including feet)	
FRA	LUSP	Lumbar spine	
FRA	OTH	Other	
FRA	PEL	Pelvic	

FRA	RIB	Rib
FRA	SKUL	Skull
FRA	TOE	Toes
FRA	TOSP	Thoracic spine
FRA	UPAR	Upper arm
FRA	UNKP	Unknown location
ICP	ANG	Coronary angioplasty/stenting
ICP	BYP	Coronary by-pass surgery
ICP	END	Carotid endarterectomy
ICP	CAS	Carotid artery stenting
ICP	UNKP	Invasive cardiovascular procedure, specific procedure unknown
NADM	ALL	Acute lymphoid
NADM	AML	Acute myeloid
NADM	ANUS	Anal cancer
NADM	BLAD	Bladder cancer
NADM	BONE	Bone cancer
NADM	BRAIN	Brain cancer
NADM	BRCA	Breast cancer
NADM	COLO	Colon cancer
NADM	COTC	Connective tissue cancer
NADM	CLL	Chronic lymphoid
NADM	CML	Chronic myeloid
NADM	ESOP	Esophagus cancer
NADM	HDL	Hodgkin lymphoma
NADM	HENE	Head and neck cancer, unknown subtype

NADM	HENEHPC	Hypopharyngeal cancer
NADM	HENELXC	Laryngeal cancer
NADM	HENECOC	Oral cavity cancer
NADM	HENEOPC	Oropharyngeal cancer
NADM	HENERPC	Rhinopharyngeal cancer
NADM	HENESGC	Saliva gland cancer
NADM	HENESNC	Sino/nasal cavity cancer
NADM	HENETYC	Thyroid cancer
NADM	GALL	Gallbladder cancer
NADM	GYCA	Gynaecological cancer (other than cervical cancer)
NADM	KIDN	Kidney cancer
NADM	LIPC	Lip cancer
NADM	LIVR	Liver cancer
NADM	LUNG	Lung cancer
NADM	MALM	Malignant melanoma
NADM	MEAC	Metastasis of adenocarcinoma
NADM	MESC	Metastasis of squamous cell carcinoma
NADM	META	Metastasis: unspecified
NADM	MEOC	Metastasis of other cancer type
NADM	MULM	Multiple myeloma
NADM	PANC	Pancreas cancer
NADM	PENC	Penile cancer
NADM	PROS	Prostate cancer
NADM	RECT	Rectum cancer
NADM	STOM	Stomach cancer

NADM	TESE	Testicular seminoma
NADM	OTH	Other malignancy type
NADM	UNKP	Unknown malignancy type
STR	SHAE	Haemorrhagic
STR	SINF	Infarction
STR	SSAH	Subarachnoid haemorrhage
STR	SUNK	Unknown

CEP_V Coding table

CEP_ID	**CEP_SPEC**	**Interpretation of CEP_V**
ARFI		m/s
COVAM		1 = Hospital admission in non-ICU ward 2 = Hospital admission in ICU ward 9 = unknown
FIBS		kPa
FRA		1 = Traumatic 2 = Osteoporotic/Fragility 3 = Pathologic 9 = Unknown
BMD_S BMD_H BMD_F	BMDT BMDZ	Standard deviation (SD), max:+10, min: -10
BMD_S BMD_H BMD_F	BMDA	Min: 0, max: 50, unit: g/cm2 (2 decimals)

1.3. tblDIS

Holds type and date of CDC-C diseases and malignancies (AIDS defining).

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
DIS_ID	Character. See DIS_ID coding table below for valid coding	Identify type of AIDS event
DIS_D	Date (yyyy-mm-dd)	Date of onset of the event
DIS_SPEC	Character. See DIS_SPEC coding table below for valid coding.	Specifies the event identified by DIS_ID. Only applicable for DIS_IDs: ADM, MCP, MCX, and CVM

DIS_ID Coding table

Code (DIS_ID)	Description (Event)
ADM	AIDS defining malignancy Please provide CEP_SPECs as indicated in the CEP_SPEC coding table below Applies if any of the following events have occurred: • Cervical cancer • Kaposi's sarcoma • Non-Hodgkin Lymphoma – Burkitt (Classical and Atypical) – Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic) – Primary Brain Lymphoma – Unknown/other histology **Please fill out a RESPOND Event Form for ADM** For specific information on ADM events, please consults the RESPOND MOOP vs. 1.6
DEM	AIDS dementia complex
BCNE	Bacterial pneumonia, recurrent (≥ 2 episodes within 1 year)
CANO	Oesophageal candidiasis
COCC	Coccidioidomycosis, disseminated or extrapulmonary
CRCO	Cryptococcosis, extrapulm.
CRSP	Cryptosporidiosis (duration > 1 month)
CMV	Cytomegalovirus Please provide DIS_SPECs as indicated in the DIS_SPEC coding table below

FBLS	Focal brain lesion
HERP	Herpes simplex ulcers (duration > 1 month) or pneumonia/oesophagitis
HIST	Histoplasmosis (extrapulm.)
WAST	HIV wasting syndrome
ISDI	Isosporiasis diarrhoea (duration > 1 month
LEU	Progressive multifocal leukoencephalopathy (PML)
MC	Mycobacterium MAC/Kansasii (extrapulmonary only.)
MCP	Mycobacterium tuberculosis, pulmonary Please provide DIS_SPECs as indicated in the DIS_SPEC coding table below
MCPO	Mycobacterium, other type, pulmonary
MCX	Mycobacterium tuberculosis, extrapulmonary Please provide DIS_SPECs as indicated in the DIS_SPEC coding table below
MCXO	Mycobacterium, other type, extrapulmonary
PCP	Pneumocystis jiroveci pneumonia
SAM	Salmonella bacteriaemia (non-typhoid) (recurrent)
TOX	Toxoplasmosis, brain

DIS_SPEC Coding table

Code (DIS_ID)	Code (DIS_SPEC)	Description
ADM	CRVC	Cervical cancer **Please fill out a RESPOND Event Form for ADM.** For specific information on ADM events, please consult the RESPOND MOOP vs. 1.6
ADM	KS	Kaposi's sarcoma **Please fill out RESPOND Event Form for ADM.** For specific information on ADM events, please consult the RESPOND MOOP vs. 1.6
ADM	NHGB	Non-Hodgkin Lymphoma – Burkitt (Classical and Atypical) **Please fill out a RESPOND Event Form for ADM.** For specific information on ADM events, please consult the RESPOND MOOP vs. 1.6

ADM	NHGI	Non-Hodgkin Lymphoma – Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic) **Please fill out a RESPOND Event Form for ADM.** For specific information on ADM events, please consult the RESPOND MOOP vs. 1.6
ADM	NHGP	Non-Hodgkin Lymphoma – Primary Brain Lymphoma **Please fill out a RESPOND Event Form for ADM.** For specific information on ADM events, please consult the RESPOND MOOP vs. 1.6
ADM	NHGU	Non-Hodgkin Lymphoma – Unknown/other histology **Please fill out a RESPOND Event Form for ADM.** For specific information on ADM events, please consult the RESPOND MOOP vs. 1.6
CMV	CMVO	Cytomegalovirus (pneumonia, oesophagitis, colitis, adrenalitis, other organs [excluding spleen, Hepatitis or lymphadenitis])
CMV	CMVR	Cytomegalovirus retinitis
MCP	LARY	mycobacterium tuberculosis in the larynx
MCP	MILI	Miliary (pulmonary infection with a radiographic appearance of millet seeds scattered throughout the lung)
MCP	PULM	Mycobacterium tuberculosis in lung tissue
MCP	TRTR	Mycobacterium tuberculosis in the tracheobronchial tree
MCP	UNKP	Pulmonary mycobacterium tuberculosis, specific location unknown
MCX	BLBM	Detection of mycobacterium tuberculosis in blood and/or bone marrow cultures
MCX	BOJO	Mycobacterium tuberculosis in bones (other than spine) or joints
MCX	COMI	Mycobacterium tuberculosis in the CNS other than meningitis
MCX	GENU	Mycobacterium tuberculosis in the genito-urinary tract
MCX	LYEX	Mycobacterium tuberculosis in extrathoracic Lymph nodes
MCX	LYIT	Mycobacterium tuberculosis in intrathoracic Lymph nodes (without lung involvement
MCX	MENG	Meningitis caused by Mycobacterium tuberculosis
MCX	OTH	Mycobacterium tuberculosis detected in location not specifiable elsewhere
MCX	PECA	Mycobacterium tuberculosis in the pericardium
MCX	PETO	Mycobacterium tuberculosis in the peritoneum or digestive tract

MCX	PLRA	Mycobacterium tuberculosis in the Pleura (isolated without lung involvement)
MCX	SKIN	Mycobacterium tuberculosis in the skin
MCX	SPNE	Mycobacterium tuberculosis in the spine
MCX	UNKP	Extra pulmonary Mycobacterium tuberculosis, specific location unknown

1.4. **tblLAB**

Holds type, date, value and unit of laboratory tests.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
LAB_ID	Character. See LAB_ID coding table below for valid coding.	Code representing the measurement.
LAB_D	Date (yyyy-mm-dd)	Date of measurement/sample
LAB_U	Numeric. See coding table for valid coding below.	Unit of measurement
LAB_V	Numeric -1 = undetectable/below level of detection	Value of measurement
LAB_FA	Numeric • 1=Yes • 0=No • 9=Unknown	Fasting
LAB_ST	Character: WB = Whole blood P = Plasma S = Serum U = Urine	Specimen type
LAB_R	numeric: • 1 = Positive (including trace, 1+, 2+, etc.) • 0 = Negative • 9 = Unknown/borderline	Measurement result (only applies to DIPP and HLAB5701)

LAB_ID and LAB_U Coding tables

Description	LAB_ID	Permissible units	LAB_U
Alanine aminotransferase	ALT	IU/L (U/L)	5
Aspartate aminotransferase	AST	IU/L (U/L)	5
Albumin	ALB	g/dL	3
		µmol/L	6
Bilirubin (total)	BIL	mg/dL	4
		µmol/L	6
Calcium (Total)	CALC	mmol/L	1
		mg/dL	4
Cholesterol (total)	CHOL	mmol/L	1
		mg/dL	4
CD8 T-cell count	CD8	cells/µl	10
Creatinine	CRE	µmol/L	6
		mg/dL	4
D-vitamin	DVIT	nmol/L	19
		ng/mL	13
Glucose	GLUC	mmol/L	1
		mg/dL	4
Haemoglobin	HAEM	mmol/L	1
		g/L	2
Haemoglobin A1c	HbA1C	%	12
		mmol/mol	18
High density lipoprotein	HDL	mmol/L	1
		mg/dL	4

HLA B*5701	HLAB5701		99
International normalized ratio	INR		7
Low density lipoprotein	LDL	mmol/L	1
		mg/dL	4
Phosphate	PHOS	mmol/L	1
		mg/dL	4
Proteinuria (dipstick result for protein in urine)	DIPP		99
Thrombocytes (Platelets)	THR	10^9/L	8
Triglycerides	TRIG	mmol/L	1
		mg/dL	4

1.5. **tblLAB_BP**

Holds date, diastolic and systolic values and unit of blood pressure measurements.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
BP_D	Date (yyyy-mm-dd)	Date of measurement/sample
BP_SYS	Numeric	Systolic blood pressure
BP_DIA	Numeric	Diastolic blood pressure
BP_U	Numeric. See coding table for valid coding.	Unit of measurement

1.6. **tblLAB_CD4**

Holds date and laboratory values of CD4 measurements.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
CD4_D	Date (yyyy-mm-dd)	Date of measurement
CD4_V	Numeric (per microliter):	Value of CD4 measurement
CD4_U	Numeric: 1 = cells/µl	Unit of measurement

1.7. **tblLAB_HCV_RES**

Holds information on HCV genotype and subtype.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE 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 2015-01-01 1 a 9999999 2015-01-01 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

1.8. **tblLAB_RES**

Holds background information on HIV resistance tests.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
TEST_ID	Character	An arbitrary value uniquely identifying a resistance test result
SAMPLE_D	yyyy-mm-dd	Date of the actual sample taken (NOT the test date)
SEQ_DT	yyyy-mm-dd	Date and time when the sequencing was performed

1.9. **tblLAB_RNA**

Holds date, value and detection limit of HIV-RNA

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
RNA_D	Date (yyyy-mm-dd)	Date of measurement/sample
RNA_V	Numeric -1 = undetectable/below level of detection	HIV-RNA measurement value with unit **copies/ml**
RNA_L	Numeric	Lower limit of detection of HIV-RNA assay

1.10. tblLAB_VIRO

Holds test results for viro-/serological tests of hepatitis B and hepatitis C. For every entry, a value must be entered in either VS_R OR VS_V

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
VS_ID	Character: See VS_ID coding table below.	Type of viral test
VS_D	Date (yyyy-mm-dd)	Date of measurement
VS_R	Numeric: 0= negative 1= positive 9= unknown/borderline	Measurement result
VS_TT	Character 1 = Quantitative 2 = Qualitative	Type of test (only relevant for HCV-RNA and HBV-DNA)
VS_V	Numeric -1 = undetectable/below level of detection	Measurement value (HCV-RNA & HBV-DNA only); quantitative test
VS_U	Numeric: 1=copies/mL 2=IU/mL 3=Geq (millions of genome equivalents)	Measurement unit
VS_LL	Numeric	Lower limit of detection

VS_ID coding table

VS_ID	Description
HBVGS	HBV surface antigen (HBsAg)
HCVA	HCV antibody (anti-HCV IgG)
HCVG	HCV antigen
HCVR	HCV-RNA
HBVD	HBV-DNA
COVRNA	SARS-CoV-2 PCR
COVA	SARS-CoV-2 Antibody test

1.11. tblLTFU

All submitted participants should figure in the table. Participants who are NOT lost to follow and who have NOT died, should be noted as DROP_Y=0

Holds data on death and lost to follow up

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
DROP_Y	Numeric: 0 = No 1 = Yes	Has the patient dropped out? Please complete for all patients
DROP_D	Date (yyyy-mm-dd)	If yes, date of last visit
DROP_RS	Character. See coding table for valid coding.	If the patient has not been seen within the last 12 months, please indicate reason of dropout
DEATH_Y	Numeric: 0 = No 1 = Yes	Has the patient died? If yes, please fill in the CoDe form in Redcap
DEATH_D	Date (yyyy-mm-dd)	Date of death

1.12. tblMED

Holds type, start and stop dates for medications for cardiovascular diseases, treatment of tuberculosis and opioid substitution therapy. Please submit all ongoing and completed treatments.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
MED_ID	Character. Please use WHO ATC coding. If not in the WHO ATC coding list, consult the MED_ID coding table below or HICDEP coding table for valid coding. For SARS-CoV-2 vaccination, please use the codes provided in the MED_ID coding table below and do NOT only provide the ATC code J07BX03	Code representing the treatment.
MED_SD	Date (yyyy-mm-dd)	Date of initiation of treatment
MED_ED	Date (yyyy-mm-dd)	Date of stopping treatment. Only if treatments are stopped must MED_ED be provided

MED_ID Coding table.

MED_ID	Description
A10A	Insulin or derivatives hereof
A10B	Oral antidiabetic agents
B01AC	Anti-platelets
C-HYP	Other anti-hypertensive agents [C02, C03, C04, C07, C08]
C09	ACE inhibitors
C10	Lipid lowering agents (unspecified)
C10AA	Lipid lowering agents, statins
C10AB	Lipid lowering agents, fibrates
N07BC	Drugs used for opioid substitution therapy
J04AC01	Isoniazid
J04AK02	ethambutol

J04AK01	pyrazinamide
J04AB02	rifampicin
J04AB04	Rifabutin
J01MA14	moxifloxacin
J01MA12	levofloxacin
J01MA01	ofloxacin
J01MA02	ciprofloxacin
J01GB06	amikacin
J01GB04	kanamycin
J04AB30	capreomycin
J01GA01	streptomycin
J04AB01	cycloserine
J04AK03	terizidone
J04AD03	ethionamide
J04AD01	prothionamide
J04AA01	P-aminosalicylic acid (PAS)
J04AK07	thioacetazone
J04AK08	pretomanid
J04BA01	clofazimine
J01XX08	linezolid
J01DH02	meropenem
J01DH51	imipenem
J01CR02	amoxicillin/clavulanic acid
J04AK06	delamanid
J04AK05	bedaquiline
J07BX03-AZT	Vaxzevria (AstraZeneca COVID-19 vaccine)
J07BX03-AZG	Generic version of Vaxzevria (Generic AstraZeneca COVID-19 vaccine, including Covishield)
J07BX03-BBI	BBIBP-CorV (Sinopharm, Chinese produced COVID-19 vaccine)
J07BX03-CSB	CanSinoBio (CanSino Biologics, Chinese produced COVID-19 vaccine)
J07BX03-EPI	EpiVacCorona (Russian federal COVID-19 vaccine)
J07BX03-JAJ	Johnson & Johnson vaccine (Janssen COVID-19 vaccine)

J07BX03-MOD	Spikevax (Moderna COVID-19 vaccine)
J07BX03-OTH	Other COVID-19 vaccine, unspecified
J07BX03-OTH-DNA	Other COVID-19 vaccine, DNA
J07BX03-OTH-RNA	Other COVID-19 vaccine, mRNA
J07BX03-OTH-VIR	Other COVID-19 vaccine, Whole-viral
J07BX03-OTH-VEC	Other COVID-19 vaccine, viral vector
J07BX03-SPU	Sputnik V (Russian federal COVID-19 vaccine)
J07BX03-PHB	Comirnaty (Pfizer/Biontech COVID-19 vaccine)
J07BX03-SIN	Sinovac (Sinovac Biotech, Chinese produced COVID-19 vaccine)
J07BX03-UKN	COVID-19 vaccine of unknown type
J07BX03-VIV	CoviVac (Russian federal COVID-19 vaccine)

1.13. tblMED_HCV

Note: Please provide information about **hepatitis C treatment only**. Please submit all ongoing and completed treatments.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
MED_ID	Character. Please use WHO ATC coding. If not in the WHO ATC coding list, consult the MED_ID coding table below or HICDEP coding table for valid coding.	Code representing the treatment against hepatitis C.
MED_SD	Date (yyyy-mm-dd)	Date of initiation of treatment
MED_ED	Date (yyyy-mm-dd)	Date of stopping treatment. Only if treatment is stopped then you must provide MED_ED
MED_DISC_Y	Numeric: 0 = No 1 = Yes 9 = Unknown	Was treatment interrupted before schedule?
MED_RS	Character. See coding table for valid coding.	If yes, reason for discontinuation

MED_ID coding table

MED_ID	Description
J05AP55	Sofosbuvir/Velpatasvir (Epclusa)
J05AP54	Grazoprevir/elbasvir (Zepatier)
J05AP52	Dasabuvir, ombitasvir, paritaprevir and ritonavir
J05AP57	Glecaprevir/pibrentasvir (Maviret)
J05AP56	Sofosbuvir/velpatasvir/voxilaprevir (Vosevi)
J05AP-NPV	Narlaprevir
HCV_PBT	Participant in blinded trial
HCVES_OTH	Other drug

1.14. tblPREG

Holds information about pregnancies started or completed since 1st of January 2016

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient ID of mother of the child (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
PREG_TEST_D	Date (yyyy-mm-dd)	Date of first positive pregnancy test

1.15. tblSAMPLES

This table contains information about stored plasma samples. If the participant has had a plasma or whole blood sample stored within the last 12 months, please provide information.

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
SAMP_LAB_D	Date (yyyy-mm-dd)	Date when the sample was taken
SAMP_ID	Character	Code to identify sample
SAMP_TYPE	Character: • BP = blood plasma • WB = Whole blood	Type of sample

1.17. tblVIS - data

Holds information about basic follow-up/visits and **weight**. **All visit dates should be filled out, regardless of a weight being available for the specific visit or not.**

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
CENTER	Character	EuroSIDA only: Code for Clinic/Center/Hospital where the patient currently belongs to (3-digit centre ID)
VIS_D	Date (yyyy-mm-dd)	Date of visit
WEIGH	Numeric (metric: kg): If weigh no weigh was done on the given data, please leave the field empty unknown on the given visit d	Weight of patient at visit

1.18. **tblVIS_SUBS**

Holds information on tobacco, alcohol and substance abuse

Name	Format and definition	Description
PATIENT	Numeric	Code to identify patient (10-digit RESPOND ID or 7-digit EuroSIDA ID or 10-digit CARE ID)
SUBS_D	Date (yyyy-mm-dd)	Date of assessment
SUBS_ID Type of substance	ALCO *Only fill out, if AUDIT C is not used to assess alcohol consumption*	Alcohol abuse defined as follows: men: An intake of >25 standard drinks of alcohol a week. women: An intake of >20 standard drinks of alcohol a week. **One standard drink of alcohol = 10 g or 12.7 mL of pure alcohol.** e.g., • 1 standard drink of alcohol = 250 ml of Beer (~5 % vol) • 1 standard drink of alcohol = 100 ml of wine (~13 % vol) • 1 standard drink of alcohol = 30 ml of Spirit (~40 % vol)
	ALCC	Alcohol consumption assessed by the AUDIT C score (add SUBS_SPEC and SUB_V) Please report SUBS_V for ALCC FRE, QUA and EXE if each of the three scores is collected separately. If only a sum score is collected, please enter a sum in the ACSUM. You should *not* report both ACSUM and FRE/QUA/EXE per one assessment.
	IDU	Intravenous Drugs (add value to SUBS_Y)
	NDU	Non-injecting Drugs (add value to SUBS_Y)
	SMK	Smoking (add value to SUBS_Y)
	SMKD	Ever smoked (add value to SUBS_Y)
SUBS_Y	Numeric: 0=No 1=Yes 9=Unknown	Patient's substance use at assessment date
SUBS_SPEC	See SUB_SPEC coding table below for valid coding	Further specify ALCC by: FRE, QUA, EXE and ACSUM

Name	Format and definition	Description
SUBS_V	Numeric. See SUBS_V coding table below for interpretation.	value given for SUBS_SPEC: FRE, QUA, EXE and ACSUM

VIS_SUBS_SPEC Coding table

Code (SUBS_ID)	Code (SUBS_SPEC)	Description
ALCC	FRE	Alcohol consumption frequency (add value to SUBS_V) How often did the patient have a standard drink of alcohol in the past year?
ALCC	QUA	Alcohol consumption quantity (add value to SUBS_V) How many standard drinks of alcohol did the patient have on a typical day when drinking in the past year?
ALCC	EXE	Excessive alcohol consumption frequency (add value to SUBS_V) How often did the patient have six or more standard drinks of alcohol on one occasion in the past year?
ALCC	ACSUM Only provide the sum score, if the respective parts of the AUDIT C score is not available	Sum score for the AUDIT C.

VIS_SUBS_V Coding table

SUBS_ID	SUBS_SPEC	Interpretation of SUBS_V
ALCC	FRE	0 = never 1 = monthly or less 2 = 2-4 times a month 3 = 2-3 times per week 4 = ≥4 times per week
ALCC	QUA	0 = 0-2 drinks 1 = 3-4 drinks 2 = 5-6 drinks

		3 = 7-9 drinks 4 = ≥10 drinks
ALCC	EXE	0 = never 1 = less than monthly 2 = monthly 3 = weekly 4 = daily or almost daily
ALCC	ACSUM	Sum of the AUDIC-C score (0-12)

Appendix 1. Table checklist

Table	Mark with x if the table is provided, otherwise leave it empty
tblART	
tblBAS	
tblCEP	
tblDIS	
tblLAB	
tblLAB_BP	
tblLAB_CD4	
tblLAB_HCV_RES	
tblLAB_RES	
tblLAB_RNA	
tblLAB_VIRO	
tblLTFU	
tblMED	
tblMED_HCV	
tblPREG	
tblSAMPLES	
tblVIS	
tblVIS_SUBS	

Appendix 2. Checkpoint before data submission

Please check the following before submitting data:

1. Check if the patient ID in the field PATIENT is correct:

A correct example (RESPOND): 1119991001 so that the first 3 digits reflect the current cohort number.
A wrong example (RESPOND): 111-9991001, '-' should be removed since PATIENT ID contains only numbers.

A correct example (EuroSIDA): 9991001 so that the first 3 digits reflect the current center number.
A wrong example (EuroSIDA): 999**-**1001, '-' should be removed since PATIENT ID contains only numbers.

Note that EuroSIDA PATIENT IDs consist of exactly 7 numbers whereas RESPOND and CARE PATIENT IDs consist of exactly 10 numbers.

A correct example (CARE): 1300000001 so that the first 3 digits reflect the country.
A wrong example (CARE): 130**-**0000001, '-' should be removed since PATIENT ID contains only digits.

2. Submitted variables correspond to those listed in the coding tables

3. Verify that all data is in **one** Access file for RESPOND and/or **one** Access file for EuroSIDA and/or one Access file for CARE. If not, please separate the data into one file for each study.

Please note that submission might fail if the data schema, data types and/or variables don't follow the definitions in this document.

Please contact respond.rigshospitalet@regionh.dk or eurosida.rigshospitalet@regionh.dk or care.rigshospitalet@regionh.dk if you have any questions regarding this SOP.

Appendix 3. Overview of variable history from 2020

Variable	describtion	Active / inactive	Add in calendar year	Removed in Calendar year	Replaced	
					replaces	Calendar year
Tbl_ART						
ART_FORM	Route of ART administration 1 = Tablet/capsule 7 = Intramuscular 9 = Unknown	Active	2020			
J05AG-ESV	(ART ID =) Elsulfavirine	Active	2021			
J05AF-pZDV	(ART ID =) Phosphazide	Active	2021			
4.3	*ART_RS:* *injection site reaction*	Active	2020			
4.4	*ART_RS:* *Injection fatigue (not related (to safety)*	Active	2020			
3.3	ART_RS 3.3 = Concern about weight gain	Inactive	2021			
18	*ART_RS:* *unwanted weight changes*	Active	2021		ART_RS 3.3 = Concern about weight gain	2021
92.22	*ART_RS:* *Incorrect route administration*	Active	2021			
TblBAS						
HIV_NEG_D	Date of negative HIV test	Active	2020			
CVD_FAM_Y	first degree relative of the patient have experienced a myocardial infarction or a stroke before age 50	Active	2021		FAM_Y	2021
TblCEP						
ESLD	CEP_ID for End-stage liver disease	Active	2020		CEP_ID= ASCI, OESO, HESY and HEP	2020
ASCI	ESLD specification: ascites	Active	2020		CEP_ID= ASCI	2020
OESO	ESLD specification: esophageal varices	Active	2020		CEP_ID= OESO	2020
HESY	ESLD specification: hepato-renal syndrome	Active	2020		CEP_ID= HESY	2020
HEP	ESLD specification : hepatic encephalitis grade III-IV	Active	2020		CEP_ID= HEP	2020
LIVT	ESLD specification: Liver transplantation	Active	2021		CEP_ID= HEP	2021

ANG	CEP_ID= ICP, CEP_SPEC = coronary angioplasty/stenting	Active	2020			
BYP	CEP_ID= ICP, CEP_SPEC = coronary bypass surgery	Active	2020			
END	CEP_ID= ICP, CEP_SPEC = carotid endarterectomy	Active	2020			
CAS	CEP_ID= ICP, CEP_SPEC = carotid artery stenting	Active	2021			
COLB	Collar bone	Active	2020			
CESP	Cervical spine	Active	2020			
FABO	Facial bones (including nose)	Active	2020			
FEM	Femur	Active	2020			
FING	Fingers	Active	2020			
SHOU	Shoulder	Active	2020			
HIP	Hip	Active	2020			
LOAR	Lower arm (including hands)	Active	2020			
LOLG	Lower leg (including feet)	Active	2020			
LUSP	Lumbar spine	Active	2020			
OTH	Other	Active	2020			
PEL	Pelvic	Active	2020			
RIB	Rib	Active	2020			
SKUL	Skull	Active	2020			
TOE	Toes	Active	2020			
TOSP	Thoracic spine	Active	2020			
UFRA	Unknown location of fracture	inactive	2020	2021		
UPAR	Upper arm	Active	2020			
UNKP	Unknown location	Active	2021		UFRA	2021
ANG	CEP_ID= ICP, CEP_SPEC = coronary angioplasty/stenting	Active	2020			
BYP	CEP_ID= ICP, CEP_SPEC = coronary bypass surgery	Active	2020			
END	CEP_ID= ICP, CEP_SPEC = carotid endarterectomy	Active	2020			
ALL	Acute lymphoid	Active	2020			
AML	Acute myeloid	Active	2020			
ANUS	Anal cancer	Active	2020			
BLAD	Bladder cancer	Active	2020			
BONE	Bone cancer	Active	2020			
BRAIN	Brain cancer	Active	2020			
BRCA	Breast cancer	Active	2020			
COLO	Colon cancer	Active	2020			
COTC	Connective tissue cancer	Active	2020			
CLL	Chronic lymphoid	Active	2020			
CML	Chronic myeloid	Active	2020			
ESOP	Esophagus cancer	Active	2020			
HDL	Hodgkin lymphoma	Active	2020			
HENE	Head and neck cancer, unknown subtype	Active	2020			
HENEHPC	Hypopharyngeal cancer	Active	2020			

HENELXC	Laryngeal cancer	Active	2020			
HENECOC	Oral cavity cancer	Active	2020			
HENEOPC	Oropharyngeal cancer	Active	2020			
HENERPC	Rhinopharyngeal cancer	Active	2020			
HENESGC	Saliva gland cancer	Active	2020			
HENESNC	Sino/nasal cavity cancer	Active	2020			
HENETYC	Thyroid cancer	Active	2020			
GALL	Gallbladder cancer	Active	2020			
GYCA	Gynaecological cancer (other than cervical cancer)	Active	2020			
KIDN	Kidney cancer	Active	2020			
LIPC	Lip cancer	Active	2020			
LIVR	Liver cancer	Active	2020			
LUNG	Lung cancer	Active	2020			
MALM	Malignant melanoma	Active	2020			
MEAC	Metastasis of adenocarcinoma	Active	2020			
MESC	Metastasis of squamous cell carcinoma	Active	2020			
META	Metastasis: unspecified	Active	2020			
MEOC	Metastasis of other cancertype	Active	2020			
MULM	Multiple myeloma	Active	2020			
PANC	Pancreas cancer	Active	2020			
PENC	Penile cancer	Active	2020			
PROS	Prostate cancer	Active	2020			
RECT	Rectum cancer	Active	2020			
STOM	Stomach cancer	Active	2020			
TESE	Testicular seminoma	Active	2020			
OTH	Other malignancy type	Active	2020			
UNKP	Unknown malignancy type	Active	2020			
SSAH	Subarachnoid haemorrhage	Active	2021			
KDIY	peritoneal or haemo-dialysis for a duration of more than 3 consecutive months (for chronic renal disease	Active	2021			
KIDT	Kidney transplant	Active	2021			
COVAM	Hospital admission due to infection with SARS-CoV-2	Active	2020			
DIA	Specification for COVAM: Dialysis	Inactive	2020	2021		
IMV	Specification for COVAM: Invasive mechanical ventilation	Inactive	2020	2021		
NIMV	Specification for COVAM: Non-invasive mechanical ventilation	Inactive	2020	2021		
ECMO	Specification for COVAM: ECMO	Inactive	2020	2021		

HFOS	Specification for COVAM: High-flow oxygen supply	Inactive	2020	2021		
TblDIS						
COVA	SARS-CoV-2 Anti-body test	Active	2021		COVAB	2021
COVAB	SARS-CoV-2 Anti-body test	Inactive	2020		COVA	
ADM	DIS_ID for AIDS defining malignancies	Active	2021		DIS_ID: CRVC, KS, NHGB, NHGI, NHGP, NHGU	2021
CRVC	ADM specification: Cervical cancer	Active	2021		DIS_ID: CRVC	2021
KS	ADM specification: Kaposi's sarcoma	Active	2021		DIS_ID: KS	2021
NHGB	ADM specification: Non-Hodgkin Lymphoma – Burkitt (Classical and Atypical)	Active	2021		DIS_ID: NHGB	2021
NHGI	ADM specification: Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic)	Active	2021		DIS_ID: NHGI	2021
NHGP	ADM specification: Primary Brain Lymphoma	Active	2021		DIS_ID: NHGP	2021
NHGU	ADM specification: Unknown/other histology	Active	2021		DIS_ID: NHGU	2021
CMV	DIS_ID for cytomegalovirus infection	Active	2021		DIS_IDs: CMVR, CMVO	2021
CMVR	CMV specification: retinitis caused by cytomegalovirus	Active	2021			
CMVO	CMV specification: Other cytomegalovirus	Active	2021			
LARY	MCP specification: tuberculosis in the larynx	Active	2021			
MILI	MCP specification: Miliary tuberculosis	Active	2021			
PULM	MCP specification: tuberculosis in lung tissue	Active	2021			
TRTR	MCP specification: tuberculosis in the tracheobronchial tree	Active	2021			
UNKP	MCP specification: Pulmonary tuberculosis, specific location unknown	Active	2021			

BLBM	MCX specification: tuberculosis in blood and/or bone marrow	Active	2021			
BOJO	MCX specification: tuberculosis in Bones (other than spine) or joints	Active	2021			
COMI	MCX specification: tuberculosis in the CNS other than meningitis	Active	2021			
GENU	MCX specification: tuberculosis in the genito-urinary tract	Active	2021			
LYEX	MCX specification: tuberculosis in extrathoracic Lymph nodes	Active	2021			
LYIT	MCX specification: tuberculosis in intrathoracic Lymph nodes (without lung involvement	Active	2021			
MENG	MCX specification; tuberculosis meningitis	Active	2021			
OTH	MCX specification: Extra pulmonary tuberculosis detected in location not specifiable elsewhere	Active	2021			
PECA	MCX specification: tuberculosis in the pericardium	Active	2021			
PETO	MCX specification: tuberculosis in the peritoneum or digestive tract	Active	2021			
PLRA	MCX specification: tuberculosis in the Pleura (isolated without lung involvement)	Active	2021			
SKIN	MCX specification: tuberculosis in the skin	Active	2021			
SPNE	MCX specification: tuberculosis in the spine	Active	2021			
UNKP	MCX specification: mycobacterium tuberculosis unknown location	Active	2021			
TblLAB						
PHOS	LAB ID for serum phosphate	Active	2021			
CALC	LAB ID for total serum calcium	Active	2021			
DVIT	LAB ID for D-vitamin	Active	2021			
LAB_DR	TB resistance	Inactive		2021		
HCVG	HCV-antigen test	Active	2020			
COVPCR	SARS-CoV-2 PCR tests	inactive	2020	2012		
COVRNA	SARS-CoV-2 PCR tests	Active	2021		COVPCR	2021

COVAB	SARS-CoV-2 Antibody test	Inactive	2020			
COVA	SARS-CoV-2 Antibody test	Active	2021		COVAB	2021
TbIMED						
J07BX03-AZT	Vaxzevria (AstraZeneca COVID-19 vaccine)	Active	2021			
J07BX03-AZG	J07BX03-AZG (Generic AstraZeneca COVID-19 vaccine, including Covishield)	Active	2021			
J07BX03-BBI	BBIBP-CorV (Sinopharm, Chinese produced COVID-19 vaccine)	Active	2021			
J07BX03-CSB	CanSinoBio (CanSino Biologics, Chinese produced COVID-19 vaccine)	Active	2021			
J07BX03-EPI	EpiVacCorona (Russian federal COVID-19 vaccine)	Active	2021			
J07BX03-JAJ	Johnson & Johnson vaccine (Janssen COVID-19 Vaccine)	Active	2021			
J07BX03-MOD	Spikevax (Moderna COVID-19 Vaccine	Active	2021			
J07BX03-OTH	Other COVID-19 vaccine, unspecified	Active	2021			
J07BX03-OTH-DNA	Other COVID-19 vaccine, DNA	Active	2021			
J07BX03-OTH-RNA	Other COVID-19 vaccine, mRNA	Active	2021			
J07BX03-OTH-VIR	Other COVID-19 vaccine, Whole-viral	Active	2021			
J07BX03-OTH-VEC	Other COVID-19 vaccine, viral vector	Active	2021			
J07BX03-SPU	Sputnik V (Russian federal COVID-19 vaccine)	Active	2021			
J07BX03-PHB	Comirnaty (Pfizer/Biontech COVID-19 vaccine)	Active	2021			
J07BX03-SIN	Sinovac (Sinovac Biotech, Chinese produced COVID-19 vaccine)	Active	2021			
J07BX03-UKN	COVID-19 vaccine of unknown type	Active	2021			
J07BX03-VIV	CoviVac (Russian federal COVID-19 vaccine)	Active	2021			
J07BX03-AZT	Vaxzevria (AstraZeneca COVID-19 vaccine)	Active	2021			
J07BX03-BBI	BBIBP-CorV (Sinopharm, Chinese produced COVID-19 vaccine)	Active	2021			
J07BX03-CSB	CanSinoBio (CanSino Biologics, Chinese	Active	2021			

	produced COVID-19 vaccine)					
J07BX03-EPI	EpiVacCorona (Russian federal COVID-19 vaccine)	Active	2021			
J07BX03-JAJ	Johnson & Johnson vaccine (Janssen COVID-19 Vaccine)	Active	2021			
J07BX03-MOD	Spikevax (Moderna COVID-19 Vaccine	Active	2021			
J07BX03-OTH	Other COVID-19 vaccine, unspecified	Active	2021			
J07BX03-OTH-DNA	Other COVID-19 vaccine, DNA	Active	2021			
TblMED_HCV						
NPV	narlaprevir	Active	2021			
TblOVERLAP (table added for 2020 submission)						
COHORT	identify the study the participant is participating in	Inactive	2020			
TblSAMPLES						
WB	Whole blood samples	Active	2021			
TblVIS						
FAM_Y	first degree relative of the patient have experienced a myocardial infarction or a stroke before age 50	Inactive	2021			
TblVIS_SUBS						
ALCC	The Alcohol Use Disorders Identification Test (AUDIT-C).	Active	2021		Replaces ALCO, when ALCC is collected	
FRE	Alcohol consumption frequency (SUBS_V 0-4, 9)	Active	2021		See ALCC	
QUA	Alcohol consumption quantity (SUBS_V 0-4, 9)	Active	2021		See ALCC	
EXE	Excessive alcohol consumption frequency (SUBS_V 0-4, 9)	Active	2021		See ALCC	
ACSUM	AUDIT C sum score	Active	2021		See ALCC	