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Standard Operating Procedure for data transfer in RESPOND and EuroSIDA.

Version 8.0

Table of Content

Introduction

The Standard Operating Procedure (SOP) for data transfer in RESPOND and EuroSIDA provides guidelines for electronic data submission aiming to standardise and harmonise international cohort 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 1.120 release version of HICDEP is available at the HICDEP website: https://hicdep.org/Wiki/v/12/pt/2. Changes and additions to HICDEP are always part of an ongoing process for projects that extend over time.

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

Data submission

New fields

New instructions in version 8.0 are marked with turquoise.

Data preparation

To facilitate your submission of data, please extract your data into the Microsoft Access template, which is downloadable here. For RESPOND, please use the RESPOND template. For EuroSIDA, please use the EuroSIDA 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 in the requested fields** (i.e., do not apply any time limits to supplied 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 includes the most correct and updated data, and thus overlapping data from previous datasets within a five-year period. Changes to your data within a five-year period will, therefore, overwrite already downloaded data in the database

NB! *Do not remove any data from follow-up dataset between yearly submissions unless otherwise agreed with the coordinating center beforehand. I.e., add newly collected data to the dataset and keep all previously supplied data in the dataset.*

Please name your access file according to the following standards:

REST_Studyname_dataset_centernumber_uploadversion_YYYY_MM_DD

e.g.

REST_RESPOND_DS7_999_V01_2024_07_15

(Study name: RESPOND, EuroSIDA)

Dataset: current version of the dataset [**RESPOND**: DS7, **EuroSIDA:** DS52]

Center number: your individual Center_ID

Upload version: V01 for first upload, V02 for second upload etc

Additional data submission in REDCap for RESPOND and EuroSIDA:

Please complete the following event form in REDCap when relevant:

For Patients who developed one or more of the following clinical events after **January 1st 2017:**

- Bone fracture (FRA)
- 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 (STR)

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 the tables you provide. Please go through a simple checklist (Appendix 2) before your submission.

Additional data submission in REDCap (only valid for EuroSIDA):

- Add cabotegravir forms for individuals initiating treatment with long-acting Cabotegravir and Rilpivirine

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 at the top of the webpage. Please refer to the REST user guide provided along with this SOP.
See more in the REST guide here

Please make sure you have a login for the tool. If you don't have a login, 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 the dataset.

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

Timelines

REST opens for Data submission on **1st September 2024**, and the deadline for data submission is **1st December 2024**.
EuroSIDA follow-up forms in REDCap open for Data submission on **1st October 2024**, and the deadline for data submission is **1st December 2024**.

Addendum

List of changes made between SOP version 7.0 and 8.0:

tblCEP:

- New CEP_SPECs have been added to specify, and replace) CEP_SPEC = GYCA, non-cervical gynaecologic cancers:
  - CEP_SPEC = OVAC for ovarian cancers
  - CEP_SPEC = UTER for cancers of the uterus
  - CEP_SPEC = VAGC for vaginal cancers
  - CEP_SPEC = VULC for vulva cancers
  - CEP_SPEC = GYCU for non-cervical gynaecologic cancers, unknown subtype

- A new CEP_SPECs have been added for CEP_ID= FRA
  - CEP_SPEC = knee for kneecap fractures

- The definition for CEP_ID = FRA, CEP_SPEC = LOAR have been revised to specify that the specification also includes elbow fractures

- CEP_ID = COVAM, for COVID-related admissions, and adjacent CEP_Vs, are no longer collected

tblDIS:

- DIS_SPECs have been added to differentiate Kaposi's sarcomas:
  - DIS_SPEC = KSV for visceral Kaposi's sarcoma
  - DIS_SPEC = KSMC for mucocutaneous Kaposi's sarcomas
  - DIS_SPEC = KSU Kaposi's sarcomas of unknown subtype

- DIS_SPEC has been added to differentiate unknown and other histology of NHG:
  - DIS_SPEC = NHGO for other histology of non-Hodgkin lymphoma

tblLAB_VIRO:

- LAB_ID = COVRNA for SARS-COV-2 testing is no longer collected

tblMED:

- Drugs belonging to the following ATC groups have been added:
  - A02, Drugs against gastric acid-related disease,
  - B01A, Anticoagulants
  - H02AB, Glucocorticoids
  - J04A, Tuberculosis treatment
  - L01, Anti-neoplastic drugs
  - L02, Hormones and hormone antagonists
  - L04A, Immunosuppressants
  - M05B, Anti-osteoporotic drugs
  - N02A, Opioids
  - N03, Anti-epileptic drugs
  - N04, Anti-Parkinson drugs

- N06D, Anti-dementia drugs
- R03, Drugs for obstructive pulmonary disease

- Drugs belonging to the ATC groups C02, Antihypertensives, C03 Diuretics, C04 Peripheral vasodilators, C07, Beta-receptor blocking agents, and C08 Calcium channel antagonists previously defined under the code C-HYP (Other anti-hypertensive agents) have been added as separate groups to be collected.

- It has been clarified that all drugs within the noted ATC groups are collected by individual ATC codes.

- ATC groups have been stratified by must-have ATC codes and ATC codes that can be supplied if collected.

- The following ATC code for opportunistic infection prophylaxis has been added:

  - J01EE01, Sulfamethoxazole + Trimethoprim
  - J01FA09, Clarithromycin
  - J01FA10, Azithromycin
  - J02AC01, Fluconazole
  - J04BA02, Dapsone
  - J05AB01, Aciclovir
  - J05AB11, Valaciclovir
  - P01CX01, Pentamidine
  - P01AX06, Atovaquone

- **COVID vaccines ATC** J07BX03-XXX are no longer collected.

tblMED_HCV

- It has been clarified that all drugs belonging to the ATC group J05AP are collected.

Appendix

- Appendix 4 has been added with a link to a look up tool and full list of ATC codes collected in RESPOND and EuroSIDA

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 the date, please see the specifications 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 of 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 must-have data that must be reported for all patients. Missing data in any of these fields is considered incomplete data/reporting and might be subjected to a deduction in reimbursement.

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 are 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.

1. tblART

Contains 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)
ART_ID	Character. Please use WHO ATC coding. If not in the WHO ATC coding list. Consult the coding table on the HICDEP page 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) J05A: Antiretroviral of unknown type. Use only this code, and do not use unspecific class codes such, e.g., as J05AE for protease inhibitors J05A-PBT: Antiretrovirals given as part of randomized blinded trials. Once the drug is revealed, the actual ATC code of the drug should be supplied instead	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_SD for injectable treatments is the first date the injectable treatment is administered. The dates of all the actual injections should be reported in tblART_LAI
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

Name	Format and definition	Description
		For individuals receiving long-acting injectable ART (cabotegravir or rilpivirine), if the long-acting ART is discontinued or the Patient is lost to follow-up, the stop date should be the date when the next injection should have taken place
ART_RS	Character. For valid coding, please consult the HICDEP ART_RS coding table, as well as 92.22 Incorrect route administration 92.7: Initiation of long-acting antiretroviral therapy 94.3: Inability to come to the clinic and receive the injection 94.4: Long-acting treatment out of stock 94.5. Injection site adverse effect of long-acting injectable treatment 94.6 Personal decision to discontinue long-acting injectable treatment 94.7 Other reason for discontinuing long-acting injectable treatment, not described anywhere else	Reason for stopping treatment.
ART_FORM	numeric 1 = Tablet/capsule 7 = Intramuscular 9 = Unknown	Route of administration

1.1. **tblART_LAI**

Contains data on injection dates for long-acting injectable antiretroviral therapy.

	Format and definition	**Description**
PATIENT	Numeric	Code to identify Patient (10-digit RESPOND ID or 7-digit EuroSIDA ID)
ART_ID	Character. Please use WHO ATC coding. If not in the WHO ATC coding list. Consult the coding table on the HICDEP page Specifically, use: This table is only to be used to report injection dates for long-acting injectable treatments (i.e., injectable formulations of cabotegravir and rilpivirine) ART start date (ART_SD), ART end date (ART_ED), and reasons for treatment discontinuations of LAI should only be entered in tblART ART_SD and ART_ED should not be used for each injection cycle. Bridging therapy with oral cabotegravir and rilpivirine should be entered as separate therapies in tblART, with ART_ED being the last day of oral therapy before the next injection.	ATC Code representing the antiretroviral treatment If an ATC does not exist, please provide the drug name.
ART_DOI	Date (yyyy-mm-dd)	For individuals receiving long-acting injectable ART, the dates of all the actual injections are provided in this column. The injection date should be provided for both Cabotegravir and Rilpivirine, i.e., one line for each ART_ID, even if given on the same date

1.2. **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)
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 men 4 = Transgender women 5 = Other 6 = Transgender unknown 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

1.3. **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)
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: ARFI, COVAM, FIBS, FRA, BMD.

CEP_ID Coding table

Code (CEP_ID)	Description (Event)
AMI	Myocardial infarction **Please fill out a RESPOND Event Form for MI** For specific information on myocardial infarction events, please consult the RESPOND Manual of Operations vs. 1.8 (RESPOND MOOP v1.7)
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)
CTAB	CT of liver/abdomen (screening for hepatocellular carcinoma)
DIA	Diabetes mellitus

ESLD Only provided the earliest ESLD event. If more symptoms of ESLD are present at the same (earliest) date, please provide a row for each symptom, with identical dates. **Note** that all cases of liver transplants should be supplied	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 or 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 consult the RESPOND MOOP v1.7
ESRD Only provided the earliest occurring dialysis event. **Note** that all cases of renal transplants should be supplied	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 a RESPOND Event Form for ESRD** For specific information on end-stage renal disease events, please consult the RESPOND MOOP v1.7
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 fracture events, please consult the RESPOND MOOP v1.7
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 consult the RESPOND MOOP v1.7
LIVB	Liver biopsy (add value to CEP_SPEC)
NADM *Only the first occurrence of a specific cancer should be reported. (I.e., relapses and metastases from known primary cancers should not be reported)* ***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 v1.7
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 v1.7
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 fracture	
FRA	CESP	Cervical spine fracture	
FRA	FABO	Facial bones (including nose) fracture	

FRA	FEM	Femur fracture
FRA	FING	Fingers fracture
FRA	HIP	Hip fracture
FRA	KNEE	Kneecap fracture
FRA	LOAR	Lower arm fracture (including hands and elbow)
FRA	LOLG	Lower leg fracture (including feet)
FRA	LUSP	Lumbar spine fracture
FRA	OTH	Other fracture
FRA	PEL	Pelvic fracture
FRA	RIB	Rib fracture
FRA	SHOU	Shoulder fracture
FRA	SKUL	Skull fracture
FRA	TOE	Toes fracture
FRA	TOSP	Thoracic spine fracture
FRA	UPAR	Upper arm fracture
FRA	UNKP	Fracture, location unknown
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 leukaemia
NADM	AML	Acute myeloid leukaemia
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	GYCU	Gynaecological cancer, unknown subtype (other than cervical cancer)
NADM	KIDN	Kidney cancer
NADM	LEUK	leukaemia, unspecified
NADM	LIPC	Lip cancer
NADM	LIVR	Liver cancer
NADM	LUNG	Lung cancer

NADM	MALM	Malignant melanoma	
NADM	MEAC	Metastasis of adenocarcinoma	While relapses and metastases from the same primary cancer are not collected, there can be cases where metastases are the first appearance of a cancer, and the primary location is unknown. In these cases, please report the respective metastasis CEP_SPEC.
NADM	MESC	Metastasis of squamous cell carcinoma	
NADM	META	Metastasis: unspecified	
NADM	MEOC	Metastasis of other cancer type	
NADM	MULM	Multiple myeloma	
NADM	OVAC	Ovarian cancer	
NADM	OTH	Other malignancy type	
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	UNKP	Unknown malignancy type	
NADM	UTER	Uterus cancer	
NADM	VAGC	Vaginal cancer	
NADM	VULC	Vulva cancer	
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
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)

1.4. **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)
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 *Only the first occurrence of a specific cancer such be reported. (I.e. relapses and metastases from known primary cancers should not be reported)*	AIDS-defining malignancy Please provide DIS_SPECs as indicated in the DIS_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 – Other histology – Unknown histology **Please fill out a RESPOND Event Form for ADM** For specific information on ADM events, please consult the RESPOND MOOP v1.7
DEM	AIDS dementia complex
BCNE	Bacterial pneumonia, recurrent (≥ 2 episodes within 1 year)
CAND	Candidiasis infections (not including isolated oral candidiasis) Please provide DIS_SPECs as indicated in the DIS_SPEC coding table below Applies if any of the following events have occurred: • Candidiasis of the oesophagus • Candidiasis of bronchi, trachea, or lungs

COCC	Coccidioidomycosis, disseminated or extrapulmonary
CRCO	Cryptococcosis, extrapulm.
CRSP	Cryptosporidiosis, chronic intestinal (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 bronchitis/pneumonia/oesophagitis
HIST	Histoplasmosis (disseminated or extrapulm.)
WAST	HIV wasting syndrome
ISDI	Isosporiasis diarrhoea (duration > 1 month)
LEU	Progressive multifocal leukoencephalopathy (PML)
MC	Mycobacterium avium complex (MAC/Kansasii; disseminated or extrapulmonary)
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, disseminated or extrapulmonary Please provide DIS_SPECs as indicated in the DIS_SPEC coding table below
MCXO	Mycobacterium, other type, disseminated or extrapulmonary
PCP	Pneumocystis jirovecii pneumonia (previously *carinii*)
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 v1.7
ADM	KSMC	Kaposi's sarcoma muco-cutaneous subtype **Please fill out RESPOND Event Form for ADM.**

		For specific information on ADM events, please consult the RESPOND MOOP v1.7
ADM	KSV	Kaposi's sarcoma visceral subtype **Please fill out a RESPOND Event Form for ADM**. For specific information on ADM events, please consult the RESPOND MOOP v1.7
ADM	KSU	Kaposi's sarcoma unknown type **Please fill out a RESPOND Event Form for ADM**. For specific information on ADM events, please consult the RESPOND MOOP v1.7
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 v1.7
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 v1.7
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 v1.7
ADM	NHGO	Non-Hodgkin Lymphoma – Other histology **Please fill out a RESPOND Event Form for ADM**. For specific information on ADM events, please consult the RESPOND MOOP v1.7
ADM	NHGU	Non-Hodgkin Lymphoma – Unknown histology **Please fill out a RESPOND Event Form for ADM**. For specific information on ADM events, please consult the RESPOND MOOP v1.7
CAND	CANO	Oesophageal candidiasis (not including isolated oral candidiasis)
CAND	CANT	Candidiasis of the bronchi, trachea, or lungs
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	Extrapulmonary Mycobacterium tuberculosis, specific location unknown

1.5. **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)
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. For DIPP and HLAB5701 please leave this field empty and fill out LAB_R
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 *Performance based reimbursement (only relevant for RESPOND) is based on data completeness for GLUC OR HbA1C*	GLUC	mmol/L	1
		mg/dL	4
Haemoglobin	HAEM	mmol/L	1
		g/L	2
Haemoglobin A1c	HbA1C	%	12

Performance based reimbursement (only relevant for RESPOND) is based on data completeness for GLUC OR HbA1c		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) *Should be used to indicate that proteinuria has been detected. The actual value of the proteinuria should not be noted. (i.e. only LAB_R should be reported, and LAB_V should be left empty, and the lab_U = 99)*	DIPP		99
Thrombocytes (Platelets)	THR	10^9/L	8
Triglycerides	TRIG	mmol/L	1
		mg/dL	4

1.6. **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)
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

1.7. **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)
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

1.8. **tblLAB_HCV_RES**

Holds information on HCV genotype and subtype.

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)

Name	Format and definition	Description
PATIENT	Numeric	Code to identify Patient (10-digit RESPOND ID or 7-digit EuroSIDA 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
SUBTYPE	Character: a b c d e f g h i j	HCV-subtype If unknown leave blank

1.9. **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)
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

1.10. **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)
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 – value must be >0

1.11. **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)
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

1.12. **tblLTFU**

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

1.13. **tblMED**

Holds type, start and stop dates for medications. 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)
MED_ID	Character. Please use WHO ATC coding for drugs belonging to the ATC group(s) below (all drugs in the group should be supplied) Please also see RESPOND tblMED Lookup Tool or Appendix 4 Where all individual ATC codes collected in RESPOND and EuroSIDA are noted, and where the individual ATC codes can be searched Must have ATC codes: • A10: Antidiabetic medication • B01: Antithrombotic agents • C02: Antihypertensive medication • C03: Diuretics • C04: Peripheral vasodilators • C07: Beta-receptor blocking agents • C08: Calcium channel antagonists • C09: RAAS inhibitors • C10: Lipid-lowering treatment • H02AB: Glucocorticoids • M05B: Anti-osteoporotic medication Only if antihypertensive medication is not collected individually can C-HYP be used for other anti-hypertensive agents [C02, C03, C04, C07, C08] and C09 for RAAS inhibitors. ! NB: Injectable antidiabetic medication should also be reported if given with weight loss as an indication ATC codes to be supplied if collected: • A02: Drugs against gastric acid-related disease • J04A: Tuberculosis medication • L01: Anti-neoplastic drugs • L02: Hormones and hormone antagonists • L04A: Immunosuppressants • N02A: Opioids • N03: Anti-epileptic medication • N04: Anti-Parkinson medication • N06D: Anti-dementia medication	Code representing the treatment.

Name	Format and definition	Description
	• N07BC: Opioid substitution treatment • R03: Drugs for obstructive pulmonary disease • Opportunistic infection prophylaxis (individual ATC collected in MED_ID Coding table below) • Antibacterials used for tuberculosis treatment (individual ATC collected in MED_ID Coding table below)	
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	Class
J01EE01	Sulfamethoxazole + Trimethoprim	Opportunistic infection prophlaxis
J01MA14	Moxifloxacin	Antibacterials used in tuberculosis treatment
J01MA12	Levofloxacin	Antibacterials used in tuberculosis treatment
J01MA01	Ofloxacin	Antibacterials used in tuberculosis treatment
J01MA02	Ciprofloxacin	Antibacterials used in tuberculosis treatment
J01GB06	Amikacin	Antibacterials used in tuberculosis treatment
J01GB04	Kanamycin	Antibacterials used in tuberculosis treatment
J01GA01	Streptomycin	Antibacterials used in tuberculosis treatment
J04BA01	Clofazimine	Antibacterials used in tuberculosis treatment
J01XX08	Linezolid	Antibacterials used in tuberculosis treatment
J01DH02	Meropenem	Antibacterials used in tuberculosis treatment
J01CR02	Amoxicillin/clavulanic acid	Antibacterials used in tuberculosis treatment
J01DH51	Imipenem	Antibacterials used in tuberculosis treatment
J01FA09	Clarithromycin	Opportunistic infection prophlaxis
J01FA10	Azithromycin	Opportunistic infection prophlaxis
J02AC01	Fluconazole	Opportunistic infection prophlaxis
J04BA02	Dapsone	Opportunistic infection prophlaxis

J05AB01	Aciclovir	Opportunistic infection prophlaxis
J05AB11	Valaciclovir	Opportunistic infection prophlaxis
P01CX01	Pentamidine	Opportunistic infection prophlaxis
P01AX06	Atovaquone	Opportunistic infection prophlaxis

1.14. **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)
MED_ID	Character. Please use WHO ATC coding for drugs belonging to the ATC group(s) Please also see RESPOND tblMED Lookup Tool or Appendix 4 Where all individual ATC codes collected are noted, and where individual ATC codes can be searched Only if not in the ATC coding list, consult the MED_ID coding table below.	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
J05AP-NPV	Narlaprevir
HCV_PBT	Patient in blinded trial
HCVES_OTH	Other drug

1.15. **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)
PREG_TEST_D	Date (yyyy-mm-dd)	Date of first positive pregnancy test

1.16. **TblSAMPLES**

This table contains information about stored plasma samples. If the Patient 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)
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

1.18. **TblVIS**

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)
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 no weight was done on the given data, please leave the field empty on the given visit date	Weight of Patient at visit

1.19. **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)
SUBS_D	Date (yyyy-mm-dd)	Date of assessment. *Please report SUBS_D at each visit when information on substance use has been collected*
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. *Please report SUBS_Y at each visit when information on substance use has been collected*
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 are 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	
tblART_LAI	
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 PATIENT IDs consist of exactly 10 numbers.

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. 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 if you have any questions regarding this SOP.

Appendix 3. Overview of variable history from 2020

Variable	description	Active / inactive	Add in calendar year	Removed in Calendar year	Replaced	
					replaces	Calendar year
tblART						
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			
J05A	Unknown antiretroviral drug	Active	2022			
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			
92.7	*Initiation of long-acting antiretroviral therapy*	Active	2022			
94.3	*Inability to come to the clinic and receive the injection*	Active	2022			
94.4:	Long-acting treatment out of stock					
94.5	*Injection site adverse effect of long-acting injectable treatment*	Active	2023			
94.6	*Personal decision to discontinue long-acting injectable treatment*	Active	2023			
94.7	*Other reason for discontinuing long-acting injectable treatment, not described anywhere else*	Active	2023			
tblART_LAI						
TblART_LAI was added in 2023 (RESPOND DS 6 EuroSIDA dataset 51)						
ART_DOI	Injection date	Active	2023			
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
Gender	3= Transgender man 4= Transgender woman 6= Transgender unknown	Active	2023		3 = Transgender	2023
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			
HIP	Hip	Active	2020			
KNEE	Kneecap	Active	2024			
LOAR	Lower arm (including hands and elbow [specified in 2024])	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			
SHOU	Shoulder	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			
GYCU	Gynaecological cancer (other than cervical cancer) *unknown subtype*	Active	2024		GYCA	2024
KIDN	Kidney cancer	Active	2020			
LEUK	leukaemia, unspecified	Active	2022			
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			

OVAL	Ovarian cancer	Active	2024		GYCA	2024
UNKP	Unknown malignancy type	Active	2020			
UTER	Uterine Cancers	Active	2024		GYCA	2024
VAGC	Vaginal cancers	Active	2024		GYCA	2024
VULC	Vulva cancers	Active	2024		GYCA	2024
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	Inactive	2020	2024		
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	Inactive	2021	2024	COVAB	2021
COVAB	SARS-CoV-2 Anti-body test	Inactive	2020	2023	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
KSV	ADM specification: visceral Kaposi's sarcomas	Active	2024		DIS_SPEC: KS	2024
KSMC	ADM specification: mucocutaneous Kaposi's sarcomas	Active	2024		DIS_SPEC: KS	2024
KSU	ADM specification: Kaposi's sarcomas of unknown subtype	Active	2024		DIS_SPEC: KS	2024
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 histology	Active	2021		DIS_ID: NHGU	2021
NHGO	ADM specification: Other histology	Active	2024		DIS_ID: NHGO	2024
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	Active	2021			

		peritoneum or digestive tract					
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 **s**pine	Active	2021			
UNKP		MCX specification: mycobacterium tuberculosis unknown location	Active	2021			
CAND		DIS_ID for candidiasis	Active	2023			
CANO		Candidiasis specification: Oesophageal candidiasis (not including isolated oral candidiasis)	Active	2023			
CANT		Candidiasis specification: Candidiasis of the bronchi, trachea, or lungs	Active	2023			
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	Inactive	2021	2024	COVPCR	2021
COVAB		SARS-CoV-2 Antibody test	Inactive	2020	2021		
COVA		SARS-CoV-2 Antibody test	Inactive	2021		COVAB	2021
tblMED							
ATC groups where individual drugs within the groups are supplied	**A02**	Drugs against gastric acid	Active	2024			
	A10	Antidiabetic medication	Active	2024			
	B01	Antithrombotic agents	Active	2024			
	C02	Antihypertensive medication	Active	2024			
	C03	Diuretics	Active	2024			
	C04	Peripheral vasodilators	Active	2024			
	C07	Beta-receptor blocking agents	Active	2024			
	C08	Calcium channel antagonists	Active	2024			
	C09	RAAS inhibitors	Active	2024			
	C10	Lipid-lowering treatment	Active	2024			
	H02AB	Glucocorticoids	Active	2024			
	J04A	Tuberculosis medication	Active	2024			
	L01	Anti-neoplastic drugs	Active	2024			
	L02	Hormones and hormone antagonists	Active	2024			
	L04A	Immunosuppressants	Active	2024			
	M05B	Anti-osteoporotic medication	Active	2024			
	N02A	Opioids	Active	2024			
	N03	Anti-epileptic medication	Active	2024			
	N04	Anti-Parkinson medication	Active	2024			
	N06D	Anti-dementia medication	Active	2024			
	N07BC	Opioid substitution treatment	Active	2024			

J01EE01	Sulfamethoxazole + Trimethoprim	Active	2024			
J01FA09	Clarithromycin	Active	2024			
J01FA10	Azithromycin	Active	2024			
J02AC01	Fluconazole	Active	2024			
J04BA02	Dapsone	Active	2024			
J05AB01	Aciclovir	Active	2024			
J05AB11	Valaciclovir	Active	2024			
P01CX01	Pentamidine	Active	2024			
P01AX06	Atovaquone	Active	2024			
J07BX03-AZT	Vaxzevria (AstraZeneca COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-AZG	J07BX03-AZG (Generic AstraZeneca COVID-19 vaccine, including Covishield)	Inactive	2021	2024		
J07BX03-BBI	BBIBP-CorV (Sinopharm, Chinese produced COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-CSB	CanSinoBio (CanSino Biologics, Chinese produced COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-EPI	EpiVacCorona (Russian federal COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-JAJ	Johnson & Johnson vaccine (Janssen COVID-19 Vaccine)	Inactive	2021	2024		
J07BX03-MOD	Spikevax (Moderna COVID-19 Vaccine	Inactive	2021	2024		
J07BX03-OTH	Other COVID-19 vaccine, unspecified	Inactive	2021	2024		
J07BX03-OTH-DNA	Other COVID-19 vaccine, DNA	Inactive	2021	2024		
J07BX03-OTH-RNA	Other COVID-19 vaccine, mRNA	Inactive	2021	2024		
J07BX03-OTH-VIR	Other COVID-19 vaccine, Whole-viral	Inactive	2021	2024		
J07BX03-OTH-VEC	Other COVID-19 vaccine, viral vector	Inactive	2021	2024		
J07BX03-SPU	Sputnik V (Russian federal COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-PHB	Comirnaty (Pfizer/Biontech COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-SIN	Sinovac (Sinovac Biotech, Chinese produced COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-UKN	COVID-19 vaccine of unknown type	Inactive	2021	2024		
J07BX03-VIV	CoviVac (Russian federal COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-AZT	Vaxzevria (AstraZeneca COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-BBI	BBIBP-CorV (Sinopharm, Chinese produced COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-CSB	CanSinoBio (CanSino Biologics, Chinese produced COVID-19 vaccine)	Inactive	2021	2024		

J07BX03-EPI	EpiVacCorona (Russian federal COVID-19 vaccine)	Inactive	2021	2024		
J07BX03-JAJ	Johnson & Johnson vaccine (Janssen COVID-19 Vaccine)	Inactive	2021	2024		
J07BX03-MOD	Spikevax (Moderna COVID-19 Vaccine	Inactive	2021	2024		
J07BX03-OTH	Other COVID-19 vaccine, unspecified	Inactive	2021	2024		
J07BX03-OTH-DNA	Other COVID-19 vaccine, DNA	Inactive	2021	2024		
J07BX03-NUX	Nuvaxovid (Novavax vaccine)	Inactive	2023	2024		
J07BX03-VAL	Valneva (Valneva Austria vaccine)	Inactive	2023	2024		
J07BX03-VIP	VidPrevtyn (Sanofi Pasteur vaccine)	Inactive	2023	2024		
A10BINJ	Non-insulin injectable antidiabetic agents	Active	2023			
tblMED_HCV						
NPV	narlaprevir	Active	2021		J05AP-NPV	2023
J05AP51	Sofosbuvir/ledipasvir (Harvoni)	Active	2023		As part of J05AP ATC codes	
J05AX15	Sofosbuvir (Sovaldi)	Active	2023		J05AP08 (as part of J05AP ATC codes)	2024
J05AP	Overall ATC group for DAAs	Active	2024		Notion of individual J05AP ATC codes	
tblOVERLAP (table added for 2020 submission)						
COHORT	identify the study the Patient 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	

Appendix 4. Look-up tool for MED_ID codes collected in RESPOND and EuroSIDA

For a detailed overview of MED_IDs collected in RESPOND and EuroSIDA for tblMED and tblMED_HCV, refer to 'RESPOND tblMED Lookup Tool' on the website: https://chip.dk/Research/Studies/RESPOND/Study-documents