

Standard **O**perating **P**rocedures for the 13th merger

Data Management

Data Collection on Adverse Events of Anti-HIV Drugs

The D:A:D study

D:A:D

Participating cohort studies:

EuroSIDA, (20 European countries); Swiss HIV Cohort Study, (Switzerland);
ICONA, (Italy); ATHENA Cohort, (The Netherlands); BASS Cohort, (Spain);
CPCRA, (USA); Nice Cohort, (France); Aquitaine Cohort, (France);
HivBIVUS, (Sweden); Brussels St. Pierre Cohort, (Belgium);
Australian HIV Observational Database, (Australia);

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1	Introduction to the D:A:D SOP for the 13th Merger	3
2	General D:A:D Background	3
3	Timing of the 13th and Subsequent Mergers	3
4	What is New or Different for this Merger?	3
4.1	BAS: RACE renamed to ETHNIC	3
4.2	LTFU: Death Coding	3
4.3	LAB_N: new unit	4
5	What should be Submitted	4
6	D:A:D Data-sections	4
6.1	Demographic, Clinical, and Background Information [BAS: Table 1]	4
6.2	Overlap: Cross-Cohort Identification (Normalized) [OVR_N: Table 2]	4
6.3	Visit-related Data [VIS: Table 3]	4
6.4	Treat. for/influencing Cardiovascular Risks [CAR: Table 4]	4
6.5	Treat. for/influ. Cardiovasc. Risks (Normalized) [CAR_N: Table 5]	5
6.6	Adverse Events (Normalized) [ADV_N: Table 6]	5
6.7	Blood Pressure (Normalized) [BP_N: Table 7]	5
6.8	Laboratory Data (Normalized) [LAB_N: Table 8]	5
6.9	CD4 measurements (Normalized) [LABCD4_N: Table 9]	5
6.10	RNA measurements (Normalized) [LABRNA_N: Table 10]	5
6.11	Virology/Serology: Hepatitis (Normalized) [VIRSER_N: Table 11]	5
6.12	Use of Anti-retroviral Treatments(Normalized) [ART_N: Table 12]	5
6.13	Other HIV-related Treatments(Normalized) [MED_N: Table 13]	5
6.14	Severe Opportunistic Infections & Malignancies [DIS_N: Table 14]	6
6.15	Lost to follow-up and deaths [LTFU: Table 15]	6
7	D:A:D Data Format	6
7.1	<i>Blank</i> Values	6
7.2	Unknown Values	6
8	Data File Transfers to the D:A:D Co-ordinating Center	6
9	Error and Discrepancy Reporting	7
Appendix		8
1.	BAS: DEMOGRAPHIC, CLINICAL & BACKGROUND INFORMATION	9
2.	OVR_N: CROSS-COHORT IDENTIFICATION (overlap)	11
3.	VIS: VISIT RELATED DATA	11
4.	CAR: TREATMENT FOR OR INFLUENCING CARDIOVASCULAR RISKS	11
5.	CAR_N: TREATMENT FOR OR INFLUENCING CADIOVASCULAR RISKS	12
6.	ADV_N: ADVERSE EVENTS	12
7.	BP_N: BLOOD PRESSURE	14
8.	LAB_N: LABORATORY VALUES	14
9.	LABCD4_N: CD4 MEASUREMENTS	15
10.	LABRNA_N: HIV-RNA MEASUREMENTS	15
11.	VIRSER_N: VIROLOGY/SEROLOGY: HEPATITIS	16
12.	ART_N: ANTI-RETROVIRAL TREATMENTS	17
13.	MED_N: OTHER HIV-RELATED TREATMENTS	20
14.	DIS_N: SEVERE OPPORTUNISTIC INFECTIONS & MALIGNANCIES	22
15.	LTFU: LOST TO FOLLOW-UP AND DEATHS	23

1 Introduction to the D:A:D SOP for the 13th Merger

The D:A:D structure, to the extent possible, conforms to the HICDEP protocol. (See the latest version of HICDEP: HIV Cohorts Data Exchange Protocol at the CHIP website: www.cphiv.dk.) Changes and additions are always part of the on-going process for projects that extend over time, and the D:A:D is no exception.

2 General D:A:D Background

The Data Collection on Adverse events of Anti-HIV Drugs (D:A:D) is a prospective multi-cohort study of HIV-infected persons under active follow up. The primary purpose of the study is to assess the incidence of myocardial infarction among HIV/AIDS patients who are receiving anti-retroviral therapy. This, in turn, will allow us to investigate whether treatment with anti-retroviral drugs is associated with development of cardio-vascular disease, an evaluation of long-term side effects.

The study began in 1999 with eleven cohorts worldwide participating with an initial enrolment of more than 23,000 patients. At the 5th merger, an additional 10,000 patients were included. At the 10th merger an additional 16½ thousand patients were enrolled. The project is scheduled to continue at least until 2013.

The centralized data processing for D:A:D takes place once a year. Each cohort gathers and computerizes its own data; subsequently it is merged in a database in Copenhagen. The core data in the study is information on incident cases of cardiovascular disease, which are reported immediately to the local cohort coordinating office by fax, using event reporting forms (available at www.cphiv.dk).

The data collection also includes information on risk factors for cardiovascular disease, such as previous myocardial infarction or stroke, hereditary tendency, smoking status, diabetes mellitus, dyslipidemia and hypertension. At the 5th merger, data on viral hepatitis testing became part of the collection process and at the 7th glucose measurements were introduced. At the 8th merger we began collecting serum creatinine readings. At the 10th merger we greatly expanded the Adverse Events table to collect new clinical endpoints. At the 12th merger bilirubin measurements have been added to the lab-measurements collected.

3 Timing of the 13th and Subsequent Mergers

The deadline for data submission for this merger is Friday, June 1st 2012. During the 6 weeks after the submission of data, until around mid-July, we will send out error and discrepancy information in the form of small databases. We will spend the next 1½ months processing your response to these reports and working closely with you to clean the data. The cleaning of the data should be completed around September 1st.

The data transfer date for the 14th merger is planned for Friday, May 31st 2013.

4 What is New or Different for this Merger?

4.1 BAS: RACE renamed to ETHNIC

This change was done to further implement the HICDEP naming convention.

4.2 LTFU: Death Coding

NADM (Non-AIDS Defining Malignancies) has been added to the death-codes list (death_r1=17).

There is currently work underway to match up the CoDe death codings with the DAD death codings making a common coding list. This will be implemented at a future merger.

4.3 LAB_N: new unit

A new unit (11: $\mu\text{kat/L}$) has been added to reflect the unit used in measuring ALT (Alanin-Aminotransferase) and AST (Aspartat aminotransferase).

5 What should be Submitted

For all Cohorts, (I, II, and III), please submit **all** the data you have--**past and present**--for each patient. This also refers to the new clinical endpoints (chronic liver disease, end stage renal disease, and non-AIDS defining malignancies). At the very minimum, **ALL** patients must appear in the BAS (demographic, clinical, and background information) table including those who have died, dropped-out, been lost to follow-up, or not shown up for their 13th merger visit.

6 D:A:D Data-sections

6.1 Demographic, Clinical, and Background Information [BAS: Table 1]

Each patient, whether seen at the 13th merger or not, should appear once in this table.

Please make sure that the enrolment date, ENROL_D, is the date that the patient enrolled in the local cohort. (This has been misinterpreted by some at earlier mergers.) Participation in the D:A:D study begins with the baseline visit date.

Some cohorts are prohibited from reporting certain types of data such as date of birth, origin or race. For BIRTH_D or ORIGIN, please leave these fields *blank*. For RACE, use the code "98".

This is the most complex table of them all. We have included the old coding schemes to make crosschecking easier. The structure of this table is unchanged for this merger. See the Appendix for the details.

6.2 Overlap: Cross-Cohort Identification (Normalized) [OVR_N: Table 2]

The structure of this table is unchanged for this merger.

Patients who are known to be in other cohorts participating in D:A:D should be entered in this table, once for each cohort. This SOP documentation provides for 3 fields for this information. In addition to COHORT, the COH_OTH field contains a 20-character name identifying the other cohort and the PAT_OTH field is for the unique patient identifier used in this cohort.

If none of your patients is a member of another cohort participating in D:A:D, please do not submit this table.

6.3 Visit-related Data [VIS: Table 3]

Please provide visit data for all visits, not just from the last visit. The structure of this table is unchanged for this merger. See the Appendix for details.

6.4 Treat. for/influencing Cardiovascular Risks [CAR: Table 4]

Please submit the data from all visits, not just from the last visit. The structure of this table is unchanged for this merger. See the CAR table in the Appendix.

6.5 Treat. for/influ. Cardiovasc. Risks (Normalized) [CAR_N: Table 5]

The structure of this table is unchanged for this merger. Cohorts that are able to provide start and stop dates for these treatments should submit this table. They should also submit the CAR table. (See above.) For each drug treatment episode, please provide CAR_SD (treatment start date) and CAR_ED (treatment end date). If the treatment is on-going, please leave the CAR_ED field *blank*. The different drug interventions are identified with the ATC code in the CAR_ID field. See the CAR_N table in the Appendix.

6.6 Adverse Events (Normalized) [ADV_N: Table 6]

The structure of this table is unchanged at this merger. See the ADV_N table in the Appendix for details.

6.7 Blood Pressure (Normalized) [BP_N: Table 7]

The structure of this table is unchanged for this merger. See the BP_N table in the Appendix for details.

6.8 Laboratory Data (Normalized) [LAB_N: Table 8]

The structure of this table is unchanged for this merger. Please check the LAB_N table in the Appendix for details.

6.9 CD4 measurements (Normalized) [LABCD4_N: Table 9]

The structure of this table is unchanged for this merger. See the LABCD4_N table in the Appendix for details.

6.10 RNA measurements (Normalized) [LABRNA_N: Table 10]

Measurements under the testing threshold should either be coded as minus the measurement value, or, if no value is available, then as minus 1 (-1). The structure of this table is unchanged for this merger. See the LABRNA_N table in the Appendix.

6.11 Virology/Serology: Hepatitis (Normalized) [VIRSER_N: Table 11]

The structure of this table is unchanged for this merger. See the VIRSER_N table in the Appendix.

6.12 Use of Anti-retroviral Treatments(Normalized) [ART_N: Table 12]

The structure of this table is unchanged for this merger. Either the old or the new code may be used to classify anti-retroviral treatments. Each anti-retroviral treatment is identified by its ATC code, which can be up to 12 characters. If the patient has been given ART, enter the proper ATC code in the ART_ID field followed by ART_SD (start date) and ART_ED (stop date). If the patient is currently undergoing treatment, the stop date should be *blank*. The ART_N table in the Appendix describes the coding of these variables in more detail including the ART_RS (Reason for Stopping treatment) field.

6.13 Other HIV-related Treatments(Normalized) [MED_N: Table 13]

The structure of this table is unchanged for this merger. Each HIV-related treatment is identified by an ATC code that can be up to 12 characters. These codes should be entered in the MED_ID field if the patient has been treated with the corresponding drug, followed by the MED_SD (start date) and MED_ED (end date). If the patient is currently undergoing treatment, please leave the end date *blank*. Please notice that a few of the treatments have the same ATC code and, perhaps what is more important, some of the old codes have been split into two separate ATC codes. The MED_N table in the Appendix describes the coding of these variables in more detail and includes the old code designations.

6.14 Severe Opportunistic Infections & Malignancies [DIS_N: Table 14]

The structure of this table is unchanged for this merger. Each infection/malignancy is identified by a two-to-four letter code, which should be entered in the DIS_ID (disease identity) field if the patient has had the corresponding infection/malignancy. In addition, DIS_D (onset date) and DIS_WD (means of diagnosis) of these infections/malignancies should be reported. The DIS_N table in the Appendix describes the coding of these variables in more detail.

6.15 Lost to follow-up and deaths [LTFU: Table 15]

This is a new table added at this merger. It is split off from the BAS table. It will be following the structure and coding of the fields previously submitted in the BAS table.

All of the death and drop-out variables are incorporated in this table. The coding for causes of death is the same as in previous mergers and does **not** conform to the CoDe (Coding causes of Death in HIV) protocol.

A patient is considered a drop-out if he/she has left the cohort, withdrawn consent, or if there is no new information on the patient during the preceding twelve months. Patients without a visit date, death date or drop-out date will be considered lost to follow-up.

7 D:A:D Data Format

Please submit your data using the D:A:D formats described in the tables in the Appendix.

7.1 Blank Values

A “.” represents a missing value in SAS. SAS will automatically convert a *blank* field to the missing value code “.”. Where a variable is not applicable, or not used, (such as the fasting variable for hemoglobin measurements in the LAB_N table), leave the field *blank*. (This also applies to fields where data collection is legally prohibited, such as BIRTH_D for some cohorts.) If data is missing where a response is required or available, the cohort validation programs should detect this and this information will become part of the database for errors and discrepancies.

7.2 Unknown Values

The category “unknown” indicates that the information needed is unknown or purposely left as missing. The codes 9, 99, and 999 are used to designate this category. Please see the tables in the Appendix for the specific coding.

The date 11/11/1911 is to be used, whenever the use of a drug, a treatment episode, etc., is known to have occurred but the date is unknown. Similarly, for other types of variables, there is most often a “yes/no” question, followed by the “date” question (for example: “Has the patient an AIDS diagnosis?” and then: “If yes, date of AIDS diagnosis”). For these types of questions, if the event is known to have occurred but the date is unknown, code the date as: 11/11/1911. Then the D:A:D validation programs will detect a ‘yes AIDS diagnosis’–‘unknown date of diagnosis’. If the only information available regarding a date is the year, then it should be entered as July 1, XXXX (01/07/XXXX). If the month and year are given, the date should be entered with the day being the 15th.

8 Data File Transfers to the D:A:D Co-ordinating Center

Please submit your data using SAS or ACCESS formats. SAS data sets are preferable—and SAS version 8 or 9 is preferable to version 6. ACCESS 2007, ACCESS 2000 and ACCESS 1997 tables

are also acceptable. All datasets will be converted to SAS version 9 here at the coordinating center. Please sort each table by its key field(s). (The key fields are marked with an asterisk (*) in the tables.)

Please submit 14 or 15 raw data sets for this merger. (Submit the OVR_N: Overlap: Cross-Cohort Identification Table only if you have patients participating in other D:A:D cohorts.). The list of tables to submit is on the first page of the Appendix.

An ftp server (IP-adress: 130.226.172.44) has been set-up with a password protected folder for each of the cohorts. Please contact Rikke S. Brandt (rsb@cphiv.dk) for you username and password. Only you and the coordinating center will have access to your folder. The other cohorts will not be able to look at your submitted data.

9 Error and Discrepancy Reporting

Within six weeks of data submission we will e-mail material to the cohort data managers in order for them to check and correct their data and to replace “missing” values.

Please include the VERIFIED=1 variable for already verified outliers so that you will not spend time re-verifying these.

Please note that the discrepancy reports for this merger will include checks across mergers comparing this years submission to the latest mergers, especially on the BAS, CAR, CAR_N and VIS tables. The reason is that missing values in these tables will affect the risk-profile of the patients and have an impact on a lot of analysis that are performed at the mergers. For example the ability to calculate BMI at baseline is made impossible if the weight value at the visit record closest to the baseline date is missing – this has in previous mergers resulted in the coordinating-center looking at previously submitted data to be able to extract this information. This will hopefully be clarified at this merger with the added checks against ‘historic’ data.

The cohort data managers should enter the corrected data into their own database and then send the revised tables to the D:A:D data manager. These revised tables will then be re-checked, and then, if there are no further problems, added to the rest of the cohort’s data.

Appendix

The following 15 tables describe the formats for the 13th merger data submission.

Shading is used to indicate changes and additions for the 13th merger.

Variables marked with an asterisk (*) are the key variables in each table. Taken in combination, this means that these variables must define a unique table entry.

Regarding cardiovascular risks, please submit **both** the CAR and CAR_N tables if possible. The CAR table is a “snapshot” of the cardiovascular interventions the patient is currently undergoing at the time of each visit, VIS_D. The CAR_N table is more comprehensive. It includes the type of intervention treatment, starting (CAR_SD) and stopping (CAR_ED) dates for each episode. For the CAR_N table we are interested in all treatment episodes, not just the current one, and if the treatment is on-going, leave the CAR_ED (CAR end date) blank.

- | | | |
|-----|------------------|--|
| 1. | BAS: | Demographic, Clinical and Background Information |
| 2. | OVR_N: | Overlap: Cross-Cohort Identification (Normalized) |
| 3. | VIS: | Visit-related Data |
| 4. | CAR: | Treatment for or Influencing Cardiovascular Risks |
| 5. | CAR_N: | Treatment for or Influencing Cardiovascular Risks (Normalized) |
| 6. | ADV_N: | Adverse Events (Normalized) |
| 7. | BP_N: | Blood Pressure (Normalized) |
| 8. | LAB_N: | Laboratory Data (Normalized) |
| 9. | LABCD4_N: | CD4 Measurements (Normalized) |
| 10. | LABRNA_N: | RNA Measurements (Normalized) |
| 11. | VIRSER_N: | Virology/Serology: Hepatitis (Normalized) |
| 12. | ART_N: | Use of Anti-Retroviral Treatments (Normalized) |
| 13. | MED_N: | Other HIV-Related Treatments (Normalized) |
| 14. | DIS_N: | Severe Opportunistic Infections & Malignancies (Normalized) |
| 15. | LTFU: | Lost to Follow-Up and Deaths |

1. BAS: DEMOGRAPHIC, CLINICAL & BACKGROUND INFORMATION									
Explanation of variable	Code to identify patient	Code for clinic/ centre/ hospital where patient is seen.	Gender	Birth date	Patient's height [m]	Region of origin of patient	Region of origin of patient: other	Ethnicity/Race of patient	Date of enrolment in local cohort
Field name	*PATIENT	CENTER	GENDER	BIRTH_D	HEIGH	ORIGIN	ORI_OTH	ETHNIC	ENROL_D
Format of data	Character 20	Character 20	1=Male 2=Female 9=Unknown	Date format	999=Unknown	See below for coding	Character 20	Numeric See below for coding	Date format

Explanation of variable	Mode of infection	Mode of infection: other	Date first seen at clinic	Date of last negative HIV test	Date of seroconversion	Source of the SEROCO_D	Has pt. an AIDS diagnosis	Date of AIDS diagnosis	Has pt. received antiretroviral treatment
Field name	MODE	MOD_OTH	FRSVIS_D	HIVN_D	SEROCO_D	SEROCO_M	AIDS_Y	AIDS_D	RECART_Y
Format of data	Numeric See below for coding	Character 20	Date format	Date format	Date format	Numeric See below for coding	0=No 1=Yes 9=Unknown	Date format	0=No 1=Yes 9=Unknown

Explanation of variable	Date of first positive HIV test	Cohort group identifier
Field name	HIVP_D	ENROL
Format of data	Date format	1=I 2=II 3=III

1a. Code (bas_code_origin)	Region	Old code
10	Africa	2
11	Northern Africa	21
12	Sub-Saharan Africa	22
20	Asia	3
30	Oceania (not Australia)	3
40	Australia & New Zealand	5
50	Americas	6
51	North America	61
52	Central & South America	62
60	Middle East	7
70	Europe	8
71	Western Europe	81
72	Eastern Europe	82
99	Unknown	9

1b. Code (bas_code_race)	Race	Old code
10	White	1
20	Black	2
21	Black African	2
22	Black Caribbean	2
30	Hispanic	3
40	Asian	4
50	American	
60	Indigenous	6
1020	White-Black	7
1040	White-Asian	8
2030	Black-Hispanic	10
3040	Hispanic-Asian	11
102040	White-Black-Asian	
97	other	
98	Prohibited	
99	Unknown	9,12

1c. Code (bas_code_mode)	Mode of infection	Old code
1	homo/bisexual	1
2	injecting drug user	2
3	(1 + 2)	3
4	haemophiliac	4
5	transfusion, non-haemophilia related	5
6	heterosexual contact	6
7	(6 + 2)	7
8	Perinatal	8
90	other, (specify)	10
99	Unknown	99

1d. Code (bas_code_seroco_m)	SEROCO_M: Source of SEROCO_D
1	Midpoint between last neg. and first pos. HIV-1 test
2	Lab evidence of seroconversion
3	Seroconversion illness
4	First pos HIV-1 test
9	Other

2. OVR_N: CROSS-COHORT IDENTIFICATION (overlap)				
Explanation of Variable	Code to identify your D:A:D patient	Name of the cohort	Name of other D:A:D cohort	Unique patient identifier in other D:A:D cohort
Field name	*PATIENT	*COHORT	*COH_OTH	PAT_OTH
Format of data	Character 20	Character 20	Character 20	Character 20

3. VIS: VISIT RELATED DATA										
Explanation of variable	Code to identify patient	Visit date	Patient's weight [kg]	Is the patient currently a smoker	Is pt. experiencing fat loss from extremities, buttocks or face	Is pt. gaining fat in abdomen, neck, breast or other locations	Is pt. experiencing lipodystrophy	Was the patient ever a smoker	First degree relative with AMI before age 50	Age at visit [years]
Field name	*PATIENT	*VIS_D	WEIGH	SMK_Y	LOSS_Y	GAIN_Y	LIP_Y	SMD_Y	FAM_Y	AGE
Format of data	Character 20	Date format	999=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	Numeric

4. CAR: TREATMENT FOR OR INFLUENCING CARDIOVASCULAR RISKS									
Explanation of variable	Patient ID	Visit date	Currently taking anti-platelets	Currently taking ACE inhibitors	Currently taking other anti-hypertensive agents	Currently taking lipid lowering agents	Currently taking oral anti-diabetic agents	Currently taking insulin or insulin derivatives	Currently taking anabolic steroids/appetite stimulants
Field name	*PATIENT	*VIS_D	PLT_Y	ACE_Y	HYP_Y	LOW_Y	ORA_Y	INS_Y	ANA_Y
Format of data	Character [20]	Date format	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown	0=No 1=Yes 9=Unknown

5. CAR_N: TREATMENT FOR OR INFLUENCING CADIOVASCULAR RISKS				
Explanation of Variable	Code to identify patient	Code for drug	Treatment start date	Treatment end date
Field name	*PATIENT	*CAR_ID	*CAR_SD	CAR_ED
Format of data	Character 20	Character 12 ATC-coding See below	Date format	Date format

Please refer to http://www.whocc.no/atc_ddd_index/ for the full ATC codes for drugs in the categories mentioned below the first part of the codes can be found in the old code column– we still collect only the drugs that fall into the categories mentioned.

5a. Code for drug (car_id)	Description	Old code (prior to merger 12)
	Anti-platelets (PLT)	B01AC
	ACE inhibitors (ACE)	C09
	Other anti-hypertensive agents (HYP) [C02, C03, C04, C07,C08]	C-HYP
	Lipid lowering agents (LOW)	C10
	Anti-diabetic agents (ORA)	A10B
	Insulin/ insulin derivatives (INS)	A10A
	Anabolic steroids/ appetite stimulants (ANA)	A14A

6. ADV_N: ADVERSE EVENTS						
		Do not code!				
Explanation of Variable	Code to identify patient	Unique event identifier	Event type	Specify event type for NADM	Text field for other (unspecified) NADM	Date of event
Field name	*PATIENT	EVENT_ID	*AE_ID	*AE_SPEC	*OTH_SPEC	*AE_D
Format of data	Character 20	Numeric	Character 4 See below	Character 4 See below	Character 50	Date format

Explanation of variable	Location of Cancer (for NADM). example: lung	ICD10 code (for NADM)
Field name	LOCATION	ICD10
Format of data	Character 50	Up to 8 characters

NB: Either the LOCATION or the ICD10 code should be provided where available, not both

6a. Coding for Adverse Event types		
AE_ID	AE_SPEC	Adverse Event
AMI		Acute myocardial infarction
STR		Stroke (infarction or haemorrhagis)
DIA		Diabetes mellitus
ICP	BYP	Coronary artery by-pass grafting
ICP	END	Carotic endarterectomy
ICP	ANG	Coronary angioplasty/stenting
CLD		Chronic liver disease
ESRD		End stage renal disease
NADM	ALL	Leukemia: Acute lymphoid
NADM	AML	Leukemia: Acute myeloid
NADM	ANUS	Anus cancer
NADM	BLAD	Bladder cancer
NADM	BONE	Bone cancer
NADM	BRAC	Brain cancer
NADM	BRCA	Breast cancer
NADM	CLL	Leukemia: Chronic lymphoid
NADM	CML	Leukemia: Chronic myeloid
NADM	COLO	Colon cancer
NADM	COTC	Connective tissue cancer
NADM	ESOP	Esophagus cancer
NADM	GALL	Gallbladder cancer
NADM	GYCA	Gynecologic cancer
NADM	HENE	Head and neck (incl. face) cancers
NADM	HDL	Hodgkin lymphoma
NADM	KIDN	Kidney cancer
NADM	LEUK	Leukemia: unspecified
NADM	LIPC	Lip cancer
NADM	LIVR	Liver cancer
NADM	LUNG	Lung cancer
NADM	MALM	Malignant melanoma
NADM	MEAC	Metastasis: of adenocarcinoma
NADM	MEOC	Metastasis: of other cancertype
NADM	MESC	Metastasis: of squamuos cell carcinoma
NADM	META	Metastasis: unspecified
NADM	MULM	Multiple myeloma
NADM	PANC	Pancreas cancer
NADM	PENC	Penile cancer
NADM	PROS	Prostate cancer
NADM	RECT	Rectum cancer
NADM	STOM	Stomach cancer
NADM	TESE	Testicular seminoma
NADM	UTER	Uterus cancer
NADM	OTH	Non-Aids Defining Malignancy: Other

7. BP_N: BLOOD PRESSURE				
Explanation of variable	Code to identify patient	Date of Measurement	Systolic blood pressure [mmHg]	Diastolic blood pressure [mmHg]
Field name	*PATIENT	*BP_D	BP_SYS	BP_DIA
Format of data	Character 20	Date format	Numeric	Numeric

8. LAB_N: LABORATORY VALUES							
Explanation of variable	Code to identify patient	Type of measurement	Specimen type (Glucose only)	Date of measurement	Measurement value	Unit of measurement	Measurement done while fasting
Field name	*PATIENT	*LAB_ID	*LAB_ST	*LAB_D	LAB_V	LAB_U	LAB_FA
Format of data	Character 20	Character 4 See coding below	Character 2 WB=Whole Blood P=Plasma S=Serum	Date format	Numeric (-1 = undetect. If detectable but under the threshold, then:-<value>)	Character 10 (or numeric) See coding below	Numeric 0=No 1=Yes 9=Unknown blank for haemoglobin

8a. Code (lab_code)	Type of measurement
CHOL	Total cholesterol
HDL	Serum HDL
TRIG	Serum triglyceride
HAEM	Haemoglobin
GLUC	Glucose
CRE	Serum Creatinine
BIL	Total Bilirubin
ALB	Albumine
ALT	Alanin-Aminotransferase
AST	Aspartat aminotransferase
PLT	Platelet count

8b. Measurement unit code (lab_code_units)	Definition
1: mmol/L	mmol/L
2: gm/L	gm/L
3: gm/dL	gm/dL
4: mg/dL	mg/dL
5: IU/L	Units/L
6: micromol/L	μ/L
8: 1E+9/L	1E+9/L
11: μkat/L	μkat/L

9. LABCD4_N: CD4 MEASUREMENTS			
Explanation of variable	Code to identify patient	Date of measurement	Measurement [counts/micro liter]
Field name	*PATIENT	*CD4_D	CD4_V
Format of data	Character 20	Date format	Numeric (-1 = undetectable; if detectable but under the threshold, then: -<value>)

10. LABRNA_N: HIV-RNA MEASUREMENTS					
Explanation of variable	Code to identify patient	Date of measurement	HIV-RNA measurement [copies/ml]	Lower limit of HIV-RNA assay [copies/ml]	Type of viral assay used for measurement
Field name	*PATIENT	*RNA_D	RNA_V	RNA_L	RNA_T
Format of data	Character 20	Date format	(-1 = undetectable; if detectable but under the threshold, then: -<value>)	999= unknown	Numeric See coding below

10a. Code (lab_rna_code_assay)	Viral assay used
5	Roche Taqman
10	Roche 1.0
15	Roche 1.5 ultra-sensitive
19	Any Roche (unspecified)
20	NASBA
21	NASBA ultra-sensitive
29	Any NASBA (unspecified)
31	Chiron b-DNA 1.0
32	Chiron b-DNA 2.0
33	Chiron b-DNA 3.0
39	Any Chiron (unspecified)
40	Abbott ultra-sensitive
41	Abbott LCx
42	Abbott Real time HIV M200
50	Monitor 1.0
51	Monitor 1.0 ultra-sensitive
55	Monitor 1.5
56	Monitor 1.5 ultra-sensitive
59	Monitor unspecified
65	Cobas 1.5
66	Cobas 1.5 ultra-sensitive
90	Other
99	Unknown

11. VIRSER_N: VIROLOGY/SEROLOGY: HEPATITIS					
Explanation of variable	Code to identify patient	Viral test	Measurement date	Measurement result	Measurement value
Field name	*PATIENT	*VS_ID	*VS_D	VS_R	VS_V
Format of data	Character 20	Character 5 See coding below	Date format	0= negative 1= positive 9= borderline	HCVR & HBVD only (-1 = undetectable; if detectable but under the threshold, then: -<value>)

Explanation of variable	Measurement unit	Lower limit of test	Upper limit of test	Type of viral test
Field name	VS_U	VS_LL	VS_UL	VS_T
Format of data	See coding below	999= unknown	999= unknown	Numeric See coding below

11a. Code (virser_code)	Viral test
HCV	Marker for hepatitis C infection - test unknown
HCVA	HCV antibody
HCVG	HCV antigen
HCVR	HCV-rna
HBV	Marker for hepatitis B infection (=HBVAC) - test unknown
HBVAS	HBV antibody (surface)
HBVAE	HBV antibody (envelope)
HBVAC	HBV antibody (core)
HBVGS	HBV antigen (surface)
HBVGE	HBV antigen (envelope)
HBVD	HBV-dna

11b. Code (virser_code_units)	Test measurement unit
1	Copies/ml
2	UI/ml (International units/ml)
3	Geq (millions of genome equivalent)
4	pg/ml (picograms/ml)
9	Other

11c. Code (virser_code_test)	Viral test used
1	Roche qualitative (Amplicor) [HCV and HBV]
2	Roche quantitative test for HBV (Cobas Amplicor HBV monitor)
3	Bayer Bdna quantitative [HCV]
4	Bayer Bdna quantitative [HBV]
5	Roche Taqman
9	Other

12. ART_N: ANTI-RETROVIRAL TREATMENTS					
Explanation of variable	Code to identify patient	ATC code representing the antiretroviral treatment	Treatment start date	Treatment end date	Reason for stopping treatment
Field name	*PATIENT	*ART_ID	*ART_SD	ART_ED	ART_RS
Format of data	Character 20	Character 12	Date format	Date format	Numeric See coding below

If a new drug is used that does not appear in the lists in this SOP, then please refer to http://www.whooc.no/atc_ddd_index/ for an updated list.

12a. Extended ATC codes (art_code_drug)	Anti-Retroviral Drugs	Old codes
J05A	ART unspecified	
J05A-PBT	Participant in Blinded Trial	PBT
J05AE	PI unspecified	
J05AE01	Saquinavir (gel, not specified)	SQV
J05AE01-SQH	Saquinavir hard gel (INVIRASE)	SQH
J05AE01-SQS	Saquinavir soft gel (FORTOVASE)	SQS
J05AE02	Indinavir (CRIXIVAN)	IDV
J05AE03	Ritonavir (NORVIR)	RTV
J05AE03-H	Ritonavir high dose (NORVIR)	
J05AE03-L	Ritonavir low dose (NORVIR)	
J05AE04	Nelfinavir (VIRACEPT)	NFV
J05AE05	Amprenavir (141W94) (AGENERASE)	APV
J05AE06	Lopinavir/Ritonavir (ABT-378/r, Kaletra)	ABT
J05AE07	Fosamprenavir (trial drug)	FSP, J05AE-FSP
J05AE08	Atazanavir (ZRIVADA)	BMS, J05AE-ATV
J05AE09	Tipranavir (trial drug)	TPR, J05AE-TPR
J05AE10	Darunavir (TMC114) (PREZISTATM)	J05AE-TMC
J05AE-MOZ	Mozenavir (DMP-450)	
J05AF	NRTI unspecified	
J05AF01	Zidovudine (AZT, RETROVIR)	AZT
J05AF02	Didanosine (ddI) (VIDEX)	DDI
J05AF03	Zalcitabine (ddC) (HIVID)	DDC
J05AF04	Stavudine (d4T) (ZERIT)	D4T
J05AF05	Lamivudine (3TC, EPIVIR)	TTC
J05AF06	Abacavir (1592U89) (ZIAGEN)	ABC
J05AF07	Tenofovir (VIREAD)	TEN
J05AF08	Adefovir (PREVEON)	ADE
J05AF09	Emtricitabine (trial drug)	FTC
J05AF-ALO	Alovudine	
J05AF-AMD	Amdoxovir (DADP)	
J05AF30-COM	Zidovudine/Lamivudine - COMBIVIR (AZT/3TC, RETROVIR/EPIVIR)	COM
J05AF-FOZ	Fozivudine tidoxi	
J05AF30-KIV	Kivexa (3TC + ABC)	J05AF30-KVX
J05AF-LDN	Lodenoisine (trialdrug)	
J05AF-RVT	Reverset	
J05AF30-TRU	Truvada	
J05AF30-TZV	Trizivir	TZV

J05AG	NNRTI unspecified	
J05AG01	Nevirapine (VIRAMUN)	NVP
J05AG02	Delavirdine (U-90152) (RESCRIPTOR)	DVL
J05AG03	Efavirenz (DMP-266) (STOCRIN, SUSTIVA)	EFV
J05AG04	Etravirine (TMC125)	J05AG-TMC
J05AG-CPV	Capravirine	
J05AG-DPC083	DPC083 (trial drug)	DPC
J05AG-DPC961	DPC 961	
J05AG-EMV	Emivirine (MKC442)	
J05AG-ETV	Etravirine (TMC 125)	
J05AG-LOV	Loviride	LOV
J05AG-RPV	Rilpivirine (TMC-278)	
J05AR01	Combivir (Zidovudine/Lamivudine)	
J05AR02	Kivexa (Lamivudine/Abacavir)	
J05AR03	Truvada (Tenofovir/Emtricitabine)	
J05AR04	Trizivir (Zidovudine/Lamivudine/Abacavir)	
J05AR05	Douvir-N (Zidovudine/Lamivudine/Nevirapine)	
J05AR06	Atripla (Emtricitabine/Tenofovir/Efavirenz)	
J05AX07	Enfuvirtide (FUZEON, T-20/Ro 29-9800)	T20, ENF
J05AX08	Raltegravir (MK-0518)	
J05AX09	Maraviroc (UK427857)	J05AX-MVC
J05AX-EVG	Elvitegravir (Gilead)	
J05AX-VIC	Vicriviroc	
L01XX05	Hydroxyurea/Hydroxycarbamid (LITALIR)	HYD
P02CB	Atervidine	ATV

12b. Code (art_code rs)	Coding for Reason of Stopping Treatment	Old code
1	Treatment failure (i.e. virological, immunological, and /or clinical failure)	
1.1	Virological failure	
1.2	Partial virological failure	
1.3	Immunological failure – CD4 drop	
1.4	Clinical progression	
2	Abnormal fat redistribution	
3	Concern of cardiovascular disease	
3.1	Dyslipidaemia	
3.2	Cardiovascular disease	
4	Hypersensitivity reaction	
5	Toxicity, predominantly from abdomen/G-I tract	
5.1	Toxicity – GI tract	
5.2	Toxicity – Liver	
5.3	Toxicity – Pancreas	
6	Toxicity, predominantly from nervous system	
7	Toxicity, predominantly from kidneys	
8	Toxicity, predominantly from endocrine system	
8.1	Diabetes	
9	Haematological toxicity (anemia ...etc.)	
10	Hyperlactataemie/lactic acidosis	
70	Pregnancy – toxicity concerns	96 (Pregnancy)
75	Pregnancy – prevention of mother to child transmission	96 (Pregnancy)
76	Post-partum prophylaxis	
77	Dose change for height/ weight	
88	Death	
90	Side effects – any of the above but unspecified	
90.1	Co morbidity	
91	Toxicity, not mentioned above	
91	Toxicity, any	
92	Availability of more effective treatment (not specifically failure or side effect related)	
92.1	Simplified treatment available	
92.2	Treatment to complex	
92.3	Drug interaction	
93	Structured Treatment Interruption (STI)	
93.1	Structured Treatment Interruption (STI) – at high CD4	
94	Patient's wish/ decision, not specified above	
94.1	Non-compliance	
95	Physician's decision, not specified above	
96	Pregnancy	
97	Study treatment	
98	Other causes, not specified above	
99	Unknown	

13. MED_N: OTHER HIV-RELATED TREATMENTS				
Explanation of variable	Code to identify patient	ATC treatment code	Treatment start date	Treatment end date
Field name	*PATIENT	*MED_ID	*MED_SD	MED_ED
Format of data	Character 20	Character 12 See coding below	Date format	Date format

If a new drug is used that does not appear in the lists in this SOP, then please refer to http://www.whooc.no/atc_ddd_index/ for an updated list.

13a. Extended ATC codes (med code)	Other HIV-related drugs	Old codes
J01EA01	Trimethoprim	TRI
J01EC02	Sulfadiazine	SUL
J01EE	Cotrimoxazole (BACTRIM, EUSAPRIM, NOFIL)	COT
J01FA09	Clarithromycine (KLACID)	CLA
J01FA10	Azithomycine (ZITHROMAX)	AZM
J01FF01	Clindamycine	CLI
J01GB06	Amikacine (AMIKINE)	AMI
J01MA02	Ciprofloxacin (CIPROXINE, CILOXAN)	CIP
J01MA12	Levofloxacin (TAVANIC)	
J01RA02	Cosoltrime (MADERAN)	CST
J02AA01	Amphotericin B (FUNGIZON)	AMP
J02AB	Imidazoles (DAKTARIN, NIZORAL, PEVARYL ...)	IMI
J02AB02	Ketoconazole	KET
J02AC01	Fluconazole (DIFLUCAN)	FLU
J02AC02	Itraconazole (SPORANOX)	ITR
J02AC03	Voriconazole	
J04AB02	Rifampin (RIMATICIN)	RFA
J04AB04	Rifabutin (MYCOBUTIN)	RIF
J04AC01	Isoniazide (RIMIFON)	ISO
J04AK01	Pyrazinamide (PYRAZINAMID)	PRA
J04AK02	Ethambutol (EMB, MYAMBUTOL)	ETH
J04AM02	RIFATER	RFT
J04BA01	Clofazimine (LAMPREN)	
J04BA02	Dapsone	DAP
J05AB01	Aciclovir (ZIVORAX)	ACY
J05AB04	Ribavirin	RIB
J05AB06	Ganciclovir (CYMEVENE)	GAN
J05AB09	Famciclovir	FAM
J05AB11	Valaciclovir (VALTEX)	ACY
J05AB12	Cidofovir (VISTIDE)	CID
J05AD01	Foscarnet (FOSCAVIR)	FOS
J05AF10	Entecavir	
J05AF11	Telbivudine	
L01AA01	Cyclophosphamide (ENDOXAN)	CYC
L01AD02	CCNU (LOMUSTINE)	CCN
L01AX04	Dacabazine (DTIC - Dome)	DAC
L01BA01	Methotrexate	MET
L01CA01	Vinblastin (VELBE)	VIN
L01CA02	Oncovin (VINCRISTINE)	ONC

L01CB01	Etoposide (VEPESIDE, EXITOP 100)	ETO
L01DB01	Doxil (CAELYX) Doxorubicine, Adriamycine (ADRIBLASTIN)	DOX, DXL
L01DC01	Bleomycine	BLE
L01XB01	Procarbazine (NATULAN)	PRO
L03AA02	2 G-CSF	CSF
L03AB	Interferon	ITF
L03AC-IL2	Interleukin 2	INT
P01AX06	Atovaquone (WELLVONE, MEPRONE)	ATO
P01BD01	Pyrimethamine (DARAPRIM)	PYR
P01BD51	Pyrimethamine/Sulfadoxine (FANSIDAR)	FAN
P01BD-SUX	Sulfadoxine	SUX
P01CX01	Pentamidine aerosol (PENTACARNET)	PEN
V03AF03	Folate of calcium (LEUCOVORINE)	FOL, V03AF02

14. DIS_N: SEVERE OPPORTUNISTIC INFECTIONS & MALIGNANCIES				
Explanation of variable	Code to identify patient	Event identification	Event date	Means of diagnosis
Field name	*PATIENT	*DIS_ID	*DIS_D	DIS_WD
Format of data	Character 20	Character 4 See coding below	Date format	Numeric See coding below

14a. Code (dis_code)	Severe Opportunistic Infections
DEM	AIDS dementia complex
BCNE	Bacterial pneumonia, recurrent (>2 episodes within 1 year)
CANO	Candidiasis, oesophageal
CRCO	Cryptococcosis, extrapulm.
CRSP	Cryptosporidiosis (duration > 1 month)
CMVR	Cytomegalovirus (CMV) chorioretinitis
CMVO	CMV – other location
HERP	Herpes simplex virus ulcers (duration > 1 month) or pneumonitis/esophagitis
HIST	Histoplasmosis, extrapulm.
WAST	HIV Wasting Syndrome
ISDI	Isosporiasis diarrhoea (duration > 1 month)
LEIS	Leishmaniasis, visceral
MCDI	Microsporidiosis diarrhoea (dur. > 1 month)
MC	Mycobact. avium complex (MAC) or Kanasii, extarpulm.
MCP	Mycobact. tuberculosis pulm.
MCX	Mycobact. tuberculosis extrapulm
MCPO	Mycobact. pulm. , other
MCXO	Mycobact. extrapulm. , other
PCP	Pneumocystis carinii pneumonia (PCP)
LEU	Progressive multifocal leucoencephalopathy
SAM	Salmonella bacteraemia (non-typhoid) (> 2 episodes/recurrent)
TOX	Toxoplasmosis, brain
FBL	Focal Brain lesion
	Malignancies
KS	Kaposi Sarcoma
NHG	Non-Hodgkin Lymphoma -not specified
NHGB	Non-Hodgkin Lymphoma -Burkitt
NHGI	Non-Hodgkin Lymphoma -Immunoblastic
NHGU	Non-Hodgkin Lymphoma -Unknown/other histology
NHGP	Non-Hodgkin Lymphoma -Primary Brain Lymphoma
CRVC	Cervical Cancer
CRVD	Cervical Dysplasia/ carcinoma in situ

14b. Code (dis_wd)	Means of diagnosis
1	Definitive diagnosis
2	Presumptive diagnosis
3	Diagnosis from autopsy
4	Diagnosis from registry

15. LTFU: LOST TO FOLLOW-UP AND DEATHS				
Explanation of variable	Code to identify patient	Has patient dropped out	If dropped out, last contact date	Reason for dropping out
Field name	*PATIENT	DROP_Y	DROP_D	DROP_RS
Format of data	Character 20	0=No 1=Yes	Date format	Numeric See below for coding

Explanation of variable	Has patient died	Death date	Primary underlying cause of death	Was an autopsy performed
Field name	DEATH_Y	DEATH_D	DEATH_R1	AUTOP_Y
Format of data	0=No 1=Yes	Date format	Numeric See below for coding	0=No,1=Yes 9=Unknown

15a. Code (DROP_RS)	Reason for dropping out	Old code
1	Patient lost to follow-up / Not known to be dead	1
2	Patient has not had visit within required amount of time	2
2.1	Patient did not respond to several invitations	
3	Patient moved away	3
3.1	Patient moved to another country	
4	Patient moved and is followed by another centre	4
5	Patient's decision	5
6	Consent withdrawn	
7	Incarceration/jail	6
8	Institutionalisation (drug treatment, psychological ...etc.)	7
9	Other	8

15b. Code (DEATH_R1)	Primary underlying cause of death
1	Acute Myocardial Infarction or Stroke (Event Form required)
2	Other cardiovascular diseases (complete Event Form if necessary)
3	Symptoms caused by mitochondrial toxicity (lactic acidosis, liver failure, etc.)
4	Complications due to diabetes mellitus (complete Event Form if necessary)
5	Pancreatitis
6	Complications due to hepatitis
7	HIV-related
8	Suicide
10	Drug Overdose
17	Non-AIDS Defining Malignancy (Event Form required)
12	Other
99	Unknown, Fatal case with no information