Standard Operating Procedures

for the 10th merger

Data Management

Data Collection on Adverse Events of Anti-HIV Drugs

The D:A:D study

D:A:D

Version 2.0 **Authors: Rikke Salbøl Brandt (Data Manager) rsb@cphiv.dk**
Allen Sawitz asa@cphiv.dk

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);

Copenhagen HIV Programme (CHIP)
University of Copenhagen, Faculty of Health Science
The Panum Institute/Building 21.1
Blegdamsvej 3b
2200 Copenhagen N, Denmark

CHIP COPENHAGEN HIV PROGRAMME

Phone: +45 35 45 57 57
Fax: +45 35 45 57 58

1 Introduction to the D:A:D SOP for the 10th Merger: version 2.0

This document updates the document: D:A:D SOP for the 10th merger: version 1.0 which was sent to you at the beginning of March, 2009. We encourage you to use this document in preparation for the 10th merger. However, because many of you are already working on your 10th merger data submission, we will also accept data based on version 1.0 of this document. 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 this merger, the 10th, we expect to enrol an additional 17,500 patients. The project is scheduled to continue at least until 2012.

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 this merger we have greatly expanded the Adverse Events table so that we are now able to collect new clinical endpoints.

3 Timing of the 10th and Subsequent Mergers

The deadline for data submission for this merger is Friday, May 29th 2009 . 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 11th merger is planned for Tuesday, June 1st 2010.

4 What is New or Different for this Merger?

4.1 Version 2.0 compared with version 1.0

Version 2.0 of this document includes two new variables: SEROCO_M in the BAS table and COHORT in the OVR_N table. We have also changed the sequence of variables in the BAS table and in the VIS table and extended the list of categories for many variables. We have removed a category, changed another, and corrected a third. All of these changes have been made in order to bring the D:A:D study more in line with the HICDEP documentation.

4.2 Cohort III

At this merger we are enlarging the D:A:D population with about 17,500 new patients; we are calling this group Cohort III. This will bring the total number of D:A:D patients to about 50,000. Each cohort has received an e-mail with the number of patients expected from the cohort and the date to begin enrolment (usually just after the closing date for Cohort II patients). Cohort III should include all new HIV-1 patients added to and successively enrolled into the local cohort on or after the beginning enrolment date.

4.3 Adverse Events Table: Revised and Extended

This table has been greatly revised and extended at this merger. Most of the variable names have been changed and new ones have been added. Three new clinical events are now included in the collection process (chronic liver disease, end stage renal disease, and non-AIDS defining malignancies. In version 2.0 we have removed one category from the list of non-AIDS defining malignancies. Please see section 5 and 6.6 for details.

4.4 Virology/Serology

Two new measurement units have been added. See the VIRSER_N table in the Appendix.

4.5 Use of Anti-retroviral Treatments

Two old treatments are now registered under new ATC codes and a new treatment has been added. Version 2.0 additionally includes 26 new treatment codes, some of which refer to already existing treatments. Either the old or the new code may be used to classify such treatments. See section 6.12 and the ART_N table in the Appendix.

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 10th merger visit.

6 D:A:D Data-sections

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

The structure of this table has been changed for the version 2.0 documentation of this merger. Each patient, whether seen at the 10th merger or not, should appear once in this table.

Cohort III patients should be tagged by setting the group identifier variable ENROL to "3".

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.

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.

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".

Version 2.0 provides for the new variable SEROCO_M, which defines the source of the date of seroconversion, SEROCO_D. The sequence of the variables in this table has also changed. There are 3 new racial categories (RACE) and 2 new dropping out categories (DROP_RS).

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

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

The structure of this table has been changed in the version 2.0 documentation of this merger. We have added the text field COHORT to this table where you can enter the name of your cohort. Patients who are known to be in other cohorts participating in D:A:D should be entered in this table, once for each cohort. The version 2.0 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 has changed in the version 2.0 documentation for this merger. Although the variables are the same, they are listed in a different sequence. 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 seven different drug interventions are identified with an up to12-character 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 has been revised and expanded at this merger. In addition to the adverse events we already collect, (MI, stroke, diabetes, bypass, endarterectomy, and angioplasty), we have added three new clinical events: chronic liver disease (CLD), end stage renal disease (ESRD), and non-AIDS defining malignancies (NADM). With regard to NADM we have included the 4 character specification field AE_SPEC and a 50 character OTH_SPEC field for unspecified non-AIDS defining malignancies. Please note that the event type field is now called AE_ID and has a length of 4 characters. EVENT_ID is now a numeric field, which is reserved for future use. Please leave this field blank at this merger. Please provide us with AE_D (adverse event date).

Regarding version 2.0 of the documentation please note that we have removed one of the non-AIDS defining malignancy categories: Cervical dysplasia/carcinoma in situ (CERV). This malignancy already appears in the INF_N table; therefore it is deleted here. 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 for this table has changed in the version 2.0 documentation of this merger. The specimen type LAB_ST has a new character length of 2 and "whole blood" is coded WB rather than just B. 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. In version 2.0 of the documentation, 5 new assay types have been added. 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; however, two new measurement units have been added. 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, although two old treatments have new ATC codes, and a new treatment has been added. Version 2.0 of this documentation includes 26 new treatment codes, some of which refer to already existing treatments. Either the old or the new code may be used to classify such 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. In version 2.0 of this documentation 17 new reasons for stopping treatment have been added.

6.13 Other HIV-related Treatments(Normalized) [OTH_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. In the version 2.0 documentation we have added 3 treatments and changed Folinate of calcium (LEUCOVORINE) which was incorrectly coded as V03AF02 to V03AF03. The OTH_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 [INF_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 INF_N table in the Appendix describes the coding of these variables in more detail.

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 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 13 or 14 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.

For security purposes please send your data material with password protection and send us the password in a separate e-mail. WinZip, which we recommend for data compression, has an easy-to-use password facility.

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.

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 14 tables describe the formats for the 10th merger data submission.

Shading is used to indicate changes and additions for the 10th 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.	**OTH_N**:	Other HIV-Related Treatments (Normalized)
14.	**INF_N:**	Severe Opportunistic Infections & Malignancies (Normalized)

1. DEMOGRAPHIC, CLINICAL & BACKGROUND INFORMATION (bas)

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	Race of patient	Date of enrolment in local cohort
Field name	***PATIENT**	**CENTER**	**GENDER**	**BIRTH_D**	**HEIGH**	**ORIGIN**	**ORI_OTH**	**RACE**	**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	Has patient dropped out	If dropped out, last contact date	Reason for dropping out
Field name	**HIVP_D**	**ENROL**	**DROP_Y**	**DROP_D**	**DROP_RS**
Format of data	Date format	1=I 2=II 3=III	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

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

1e. Code (bas_code_drop)	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

1f. 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
12 = Other
99 = Unknown, Fatal case with no information

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. VISIT RELATED DATA (vis)

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=Un-known	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 See below	Date format	Date format

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

6. ADV_N: Adverse Events (adv)

		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	

6a. Coding for Adverse Event types		
AE_ID	**AE_SPEC**	**Adverse Event**
AMI		Acute myocardial infarction
STR		Stroke (infarction or haemorrhagis)
DIA		Diabetes mellitus
BYP		Coronary artery by-pass grafting
END		Carotic endarterectomy
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	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	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 (bp)

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 (lab)

Explanation of variable	Code to identify patient	Type of measurement	Specimen type (Glucose only)	Date of measure-ment	Measurement value	Unit of measure-ment	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 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

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

9. LABCD4_N: (lab_cd4)			
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. LAB-HIVRNA_N (lab_rna)					
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
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 (art)

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

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
J05AF10	Entecavir	
J05AF11	Telbivudine	
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	Lodenosine (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/Emtricabine)	
J05AR04	Trizivir (Zidovudine/Lamivudine/Abacavir)	
J05AR05	Douvir-N (Zidovudine/Lamivudine/Nevirapine)	
J05AR06	Atripla (Emtricitabine/Tenofovir/Efavirenz)	
J05AX07	Enfurvirtide (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. OTH_N: OTHER HIV-RELATED TREATMENTS (med)				
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

13a. Extended ATC codes (med_code)	Other HIV-related drugs	Old codes
J01EA01	Trimethoprim	TRI
J01EC02	Sulfadiazine	SUL
J01EE	Cotrimoxazole (BACTRIM, EUSAPRIM, NOPIL)	COT
J01FA09	Clarithromycine (KLACID	CLA
J01FA10	Azithomycine (ZITHROMAX	AZM
J01FF01	Clindamycine	CLI
J01GB06	Amikacine (AMIKINE)	AMI
J01MA02	Ciprofloxacine (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	Aciclolvir (ZIVORAX)	ACY
J05AB04	Ribavirin	RIB
J05AB06	Ganciclovir (CYMEVENE)	GAN
J05AB09	Famciclovir	FAM
J05AB11	Valaciclovir (VALTEX)	ACY
J05AB12	Cidofovir (VISTIDE)	CID
J05AD01	Foscarnet (FOSCAVIR)	FOS
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	Folinate of calcium (LEUCOVORINE)	FOL, V03AF02

14. INF_N: SEVERE OPPORTUNISTIC INFECTIONS & MALIGNANCIES (dis)				
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, oesophogeal
CRCO	Cryptococcosis, estrapulm.
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	Microsporidosis diarrhoes (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 bacteriaemia (non-tyhpoid) (> 2 episodes/recurrent)
TOX	Toxoplasmosis, brain
FBLS	Focal Brain lesion
	Malignancies
KS	Kaposi Sarcoma
HG	Hodgkins Lymphoma
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_code_diag)	Means of diagnosis
1	Definitive diagnosis
2	Presumptive diagnosis
3	Diagnosis from autopsy
4	Diagnosis from registry