

HICDEP: D:A:D event tables

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About this document

This document specifies the data format used to collect information on the events collected in D:A:D.

A sample database in Microsoft Access 2000 with data entry screens is available online:

<http://www.cphiv.dk/HICDEP/Files/tabid/160/Default.aspx>

tbIAE_EVENT – D:A:D event form**tbIAE_EVENT (DAD Event form)**

<i>Explanation of variable</i>	Unique Event Identifier	Features associated with the event: Symptoms	Features associated with the event: Enzymes (Myocardial infarction and possible coronary death only)	Features associated with the event: ECG (Myocardial infarction and possible coronary death only)	Brief narrative description in English
<i>FIELD NAME</i>	EVENT_ID	SYMPTOMS	ENZYMES	ECG	DESCRIBE
<i>Format of data</i>	Numeric	Character	Character	Character	Character

tblAE_DIA - Diabetes Mellitus**tblAE_DIA (Adverse Event: Diabetes Mellitus)**

<i>Explanation of variable</i>	Unique Event Identifier	Has diabetes been diagnosed by repeated elevated fasting plasma glucose	Measurements date 1	fasting plasma glucose 1	unit (of measure) 1	Measurements date 2	fasting plasma glucose 2
FIELD NAME	EVENT_ID	DIABET_Y	GLUC1_D	GLUC1_V	GLUC1_U	GLUC2_D	GLUC2_V
<i>Format of data</i>	Numeric	Numeric: 1=Yes 0=No	Date: yyyy-mm-dd	Numeric	Character	Date: yyyy-mm-dd	Numeric

tblAE_DIA (continued)

<i>Explanation of variable</i>	unit (of measure) 2	If no measurement of fasting glucose, then how was diabetes diagnosed	Patient received medical treatment other than ART	Specify drug by generic name	Medical history of pancreatitis	All available information regarding the event has been collected
FIELD NAME	GLUC2_U	DIAHOW_S	MEDIC_Y	MEDIC_S	PANCRE_Y	AEINFO_Y
<i>Format of data</i>	Character	Character	Numeric: 1=Yes 0=No	Character	Numeric: 1=Yes 0=No 9=Unknown	Numeric: 1=Yes 2=No

tblAE_ICP - Invasive cardiovascular procedures**tblAE_ICP (Adverse Event: Cases of invasive cardiovascular procedures)**

<i>Explanation of variable</i>	Unique Event Identifier	Which invasive cardiovascular procedure: Coronary artery by-pass grafting	Which invasive cardiovascular procedure: Coronary angioplasty / stenting	Which invasive cardiovascular procedure: Carotid endarterectomy	Was the procedure conducted in relation to a myocardial infarction
FIELD NAME	EVENT_ID	BYP_Y	ANG_Y	END_Y	MIREL_Y
<i>Format of data</i>	Numeric	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 0=No 1=Yes – acute intervention during MI 2=Yes – the procedure was complicated by an MI 3=Yes – after MI

tblAE_ICP (continued)

<i>Explanation of variable</i>	Was the procedure complicated by stroke	Copies of original hosp. record collected	If “yes” to records collected then specify which, if “no, cannot be obtained” then state reason	All available information regarding the event has been collected
FIELD NAME	STRREL_Y	RECCOL_Y	RECCOL_S	AEINFO_Y
<i>Format of data</i>	Numeric: 0=No 1=Yes	Numeric: 1=yes 0=no, will follow later 0=No, cannot be obtained	Character	Numeric: 1=Yes 2=No

tblAE_MI – Myocardial infarction**tblAE_MI (Adverse Event: Cases of MI)**

<i>Explanation of variable</i>	Unique Event Identifier	Number of available ECG's, copies of which are included. Total (aim 3-6)	Number of available ECG's, copies of which are included. Prior to MI (aim 1-2)	Number of available ECG's, copies of which are included. From time of MI (aim 1-2)	Number of available ECG's, copies of which are included. After MI (aim 1-2)	Are all ECG's marked with: pt ID-code	Are all ECG's marked with: date & time	Are all ECG's marked with: ecg-velocity
FIELD NAME	EVENT_ID	ECGTOT_V	ECGPRI_V	ECGFRM_V	ECGAFT_V	ECGPID_Y	ECG_D_Y	ECGVEL_Y
<i>Format of data</i>	Numeric	Numeric	Numeric	Numeric	Numeric	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No

tblAE_MI (continued)

<i>Explanation of variable</i>	Serological markers CK	Serological markers CK unit	Serological markers CK-MB	Serological markers CK_MB unit	Serological markers Troponin T	Serological markers Troponin T unit	Serological markers Troponin I	Serological markers Troponin I unit
FIELD NAME	CK1_V	CK1_U	CKMB1_V	CKMB1_U	TROPT1_V	TROPT1_U	TROPI1_V	TROPI1_U
<i>Format of data</i>	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character

tblAE_MI (continued)

<i>Explanation of variable</i>	Serological markers LDH-1	Serological markers LDH-1 unit	Serological markers LDH-2	Serological markers LDH-2 unit	Serological markers Other serology marker – which	Serological markers Other serology marker – value	Serological markers Other serology marker – unit	Serological markers Time from MI / hours
<i>FIELD NAME</i>	LDH1_1_V	LDH1_1_U	LDH2_1_V	LDH2_1_U	OTHSM1_S	OTHSM1_V	OTHSM1_U	HOUR1_V
<i>Format of data</i>	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)

tblAE_MI (continued)

<i>Explanation of variable</i>	Serological markers CK	Serological markers CK unit	Serological markers CK-MB	Serological markers CK_MB unit	Serological markers Troponin T	Serological markers Troponin T unit	Serological markers Troponin I	Serological markers Troponin I unit
<i>FIELD NAME</i>	CK2_V	CK2_U	CKMB2_V	CKMB2_U	TROPT2_V	TROPT2_U	TROPI2_V	TROPI2_U
<i>Format of data</i>	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character

tblAE_MI (continued)

<i>Explanation of variable</i>	Serological markers LDH-1	Serological markers LDH-1 unit	Serological markers LDH-2	Serological markers LDH-2 unit	Serological markers Other serology marker – which	Serological markers Other serology marker – value	Serological markers Other serology marker – unit	Serological markers Time from MI / hours
<i>FIELD NAME</i>	LDH1_2_V	LDH1_2_U	LDH2_2_V	LDH2_2_U	OTHSM2_S	OTHSM2_V	OTHSM2_U	HOUR2_V
<i>Format of data</i>	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)

tblAE_MI (continued)

<i>Explanation of variable</i>	Serological markers CK	Serological markers CK unit	Serological markers CK-MB	Serological markers CK_MB unit	Serological markers Troponin T	Serological markers Troponin T unit	Serological markers Troponin I	Serological markers Troponin I unit
<i>FIELD NAME</i>	CK3_V	CK3_U	CKMB3_V	CKMB3_U	TROPT3_V	TROPT3_U	TROPI3_V	TROPI3_U
<i>Format of data</i>	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character

tblAE_MI (continued)

<i>Explanation of variable</i>	Serological markers LDH-1	Serological markers LDH-1 unit	Serological markers LDH-2	Serological markers LDH-2 unit	Serological markers Other serology marker – which	Serological markers Other serology marker – value	Serological markers Other serology marker – unit	Serological markers Time from MI / hours
<i>FIELD NAME</i>	LDH1_3_V	LDH1_3_U	LDH2_3_V	LDH2_3_U	OTHSM3_S	OTHSM3_V	OTHSM3_U	HOUR3_V
<i>Format of data</i>	Character (or numeric if possible)	Character	Character (or numeric if possible)	Character	Character	Character (or numeric if possible)	Character	Character (or numeric if possible)

tblAE_MI (continued)

<i>Explanation of variable</i>	Duration of symptoms (>20 min)	Quality of symptoms, summary	Quality of symptoms	All available information regarding the event has been collected
<i>FIELD NAME</i>	SYMPD_S	SYMPQ_S	SYMPQUAL	AEINFO_Y
<i>Format of data</i>	Character	Character	Numeric: 1=Typical 2=Atypical 3=Description incomplete 0=No information available	Numeric: 1=Yes 2=No

tblAE_STR - Stroke**tblAE_STR (Adverse Event: Cases of Stroke)**

<i>Explanation of variable</i>	Unique Event Identifier	Stroke identified as	clinical presentation	clinical presentation, findings	Focal/Global	Duration of symptoms (>24 hours?)
<i>FIELD NAME</i>	EVENT_ID	STRIDENT	CLINP_Y	CLINP_S	STRTYPE	SYMPD_S
<i>Format of data</i>	Numeric	Numeric: 1=Haemorrhage 2=Infarction 3=Subarachnoideal haemorrhage 9=Unknown	Numeric: 1=Yes 2=No	Character	Numeric: 1=Focal 2=Global	Character

tblAE_STR (continued)

<i>Explanation of variable</i>	CT-scanning of cerebrum	CT-scanning of cerebrum, findings	MR-scanning of cerebrum	MR-scanning of cerebrum, findings	Examination of cerebrospinal fluid conducted	Examination of cerebrospinal fluid conducted, findings
<i>FIELD NAME</i>	CTSCAN_Y	CTSCAN_S	MRSCAN_Y	MRSCAN_S	EXCBFL_Y	EXCBFL_S
<i>Format of data</i>	Numeric: 1=Yes 2=No	Character	Numeric: 1=Yes 2=No	Character	Numeric: 1=Yes 2=No	Character

tblAE_STR (continued)

<i>Explanation of variable</i>	evidence if space-occupying lesions	evidence of CNS-infection	any medical condition, which could possibly have precipitated the stroke	any medical condition, which could possibly have precipitated the stroke, indicate which	Previous history of neurological disorder (HIV-related or other)	Previous history of neurological disorder (HIV-related or other), brief description	All available information regarding the event has been collected
<i>FIELD NAME</i>	EVISOL_Y	EVICNS_Y	MEDCON_Y	MEDCON_S	NEUDIS_Y	NEUDIS_S	AEINFO_Y
<i>Format of data</i>	Numeric: 1=Yes 0=No 9=Unknown	Numeric: 1=Yes 0=No 9=Unknown	Numeric: 1=Yes 2=No 9=Unknown	Character	Numeric: 1=Yes 0=No 9=Unknown	Character	Numeric: 1=Yes 2=No

tbIAE_CLD - Chronic Liver Disease**tbIAE_CLD (Adverse Event: Chronic Liver Disease)**

<i>Explanation of variable</i>	Unique Event Identifier	Definition of endpoint: bleeding from gastric or esophageal varices	Definition of endpoint: hepatic encephalopathy stage III or IV	Definition of endpoint: hepatorenal syndrome (acute renal failure with existing chronic liver disease)	Definition of endpoint: the patient has undergone liver transplantation	Specific diagnosis of patients liver disease
FIELD NAME	EVENT_ID	BLEED_Y	HEPENC_Y	HEPSYN_Y	TRANSP_Y	DIAG_S
<i>Format of data</i>	Numeric	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Character

tbIAE_CLD (continued)

<i>Explanation of variable</i>	ICD-10 code for diagnosed liver disease	ICD-9 code for diagnosed liver disease	Chronic HCV	Chronic HBV	Current or past alcohol abuse
FIELD NAME	ICD10	ICD9	HCV_Y	HBV_Y	ALCOH_Y
<i>Format of data</i>	Character	Character	Numeric: 1=Yes 0=No 9=Unknown	Numeric: 1=Yes 0=No 9=Unknown	Numeric: 1=Yes 0=No 9=Unknown

tbIAE_CLD (continued)

<i>Explanation of variable</i>	Has Liver biopsy been performed	Has fibroscan of the liver been performed	Date of most recent biopsy/fibroscan	Metavir stage of fibrosis (F0-F4)	Report summary of biopsy or fibroscan
FIELD NAME	BIOPSY_Y	FIBSC_Y	BIOFIB_D	METAV_V	BIOFIB_S
<i>Format of data</i>	Numeric: 1=Yes 0=No 9=Unknown	Numeric: 1=Yes 0=No 9=Unknown	Date: yyyy-mm-dd	Numeric: 0-4	Character

tblAE_ESRD - End Stage Renal Disease**tblAE_ESRD (Adverse Event: End Stage Renal Disease)**

<i>Explanation of variable</i>	Unique Event Identifier	Definition of endpoint: haemodialysis	Definition of endpoint: peritoneal dialysis	Definition of endpoint: the patient has undergone kidney transplantation	Renal disease category: HIV associated nephropathy	Renal disease category: glomerulonephritis
FIELD NAME	EVENT_ID	HAEDIA_Y	PERDIA_Y	TRANSP_Y	HIVNEP_Y	GLONEP_Y
<i>Format of data</i>	Numeric	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No

tblAE_ESRD (continued)

<i>Explanation of variable</i>	Renal disease category: interstitial nephritis	Renal disease category: polycystic kidney disease	Renal disease category: hereditary / congenital	Renal disease category: vascular	Renal disease category: diabetic nephropathy	Renal disease category: systemic disease
FIELD NAME	INTNEP_Y	POLYC_Y	CONGEN_Y	VASCUL_Y	DIANEP_Y	SYSTEM_Y
<i>Format of data</i>	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No

tblAE_ESRD (continued)

<i>Explanation of variable</i>	Renal disease category: other	Renal disease category: unknown	Diagnosis of the patients' kidney disease	ICD-10 code for diagnosed kidney disease	ICD-9 code for diagnosed kidney disease	Has kidney biopsy been performed	Report summary of kidney biopsy
FIELD NAME	OTHER_Y	UNKNOW_Y	DIAG_S	ICD10	ICD9	BIOPSY_Y	BIOPSY_S
<i>Format of data</i>	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Character	Character	Character	Numeric: 1=Yes 0=No 9=Unknown	Character

tbIAE_NADM - Non-Aids-Defining Malignancies**tbIAE_NADM (Adverse Event: Non-Aids-Defining Malignancies (cancer))**

<i>Explanation of variable</i>	Unique Event Identifier	Type of patients' cancer disease	Primary location of cancer (if known)	Primary location of cancer unknown	ICD-10 code for cancer disease	ICD-9 code cancer disease	Stage (spread) at diagnosis
FIELD NAME	EVENT_ID	CANTYP_T	CANLOC_T	CANLOC_Y	ICD10	ICD9	SPREAD_V
<i>Format of data</i>	Numeric	Character	Character	Numeric: 1=Unknown	Character	Character	Numeric: 1=Localized 2=Disseminated 9=Unknown

tbIAE_NADM (continued)

<i>Explanation of variable</i>	Is the pathology report (or summary) available	Summary of pathology report	Diagnosis based on: Radiology	Diagnosis based on: Biochemical assay	Diagnosis based on: Visual inspection	Diagnosis based on: other	Specify what diagnosis is based on
FIELD NAME	PATREP_Y	PATREP_S	DIARAD_Y	DIABIO_Y	DIAVIS_Y	DIAOTH_Y	DIA_S
<i>Format of data</i>	Numeric: 1=Yes, full report 2=Summary of report 0=No 9=Unknown	Character	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Numeric: 1=Yes 2=No	Character