

CRF Layout (Pagemap)

Studyname Test-case

Project # 99/000

DataFax # 001

Visit	010	Entry	P	Pre-baseline	(Sub)	Has
Page	Name	Code	Plateno	Visitno	Required	Visitdate
1	Inclusion Criteria	IN-1	010	010	R	Yes
2	Exclusion Criteria	EX-1	020	010	R	No
3	Medical History		050	010	R	No
4	Physical examination		070	010	R	No
5	Medication History	MX-1	100	010	R	No
6	Medication History (continued)		101	010	O	No

Visit	020	Day 1	B	Baseline	(Sub)	Has
Page	Name	Code	Plateno	Visitno	Required	Visitdate
7	Demographic Data	DMG-1	040	020	R	Yes
8	Serology	SER-1	125	020	R	No
9	Biochemistry		131	020	R	No
10	Biochemistry (cont.)		133	020	R	No
11	Urinalysis (Microscopy)	UR-4	160	020	R	No

Visit	030	Day 2	S	Scheduled Follow-up	(Sub)	Has
Page	Name	Code	Plateno	Visitno	Required	Visitdate
12	Vital Signs	VS-1	250	030	R	Yes
13	Drug Administration		170	030	R	No
14	Drug Administration		170	031	R	No
15	Drug Administration		170	032	R	No
16	Adverse Event Check	AE-1	190	030	R	No
17	Concomitant Medication Check	CM-1	220	030	R	No

Visit	040	Day 3	S	Scheduled Follow-up	(Sub)	Has
Page	Name	Code	Plateno	Visitno	Required	Visitdate
18	Vital Signs	VS-1	250	040	R	Yes
19	Drug Administration		170	040	R	No
20	Adverse Event Check	AE-1	190	040	R	No
21	Concomitant Medication Check	CM-1	220	040	R	No

Visit	100	End of Study	T	Termination	(Sub)	Has
Page	Name	Code	Plateno	Visitno	Required	Visitdate
22	End of Study	EOS-1	310	100	R	Yes
23	Investigator's Signature	SIG-1	321	100	R	No

Plate Usage

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Project # 99/000
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Plate	Plate label	Code	Page	(Sub)visit
010	Inclusion Criteria	IN-1	001	010 Entry
020	Exclusion Criteria	EX-1	002	010 Entry
040	Demographic Data	DMG-1	007	020 Day 1
050	Medical History		003	010 Entry
070	Physical examination		004	010 Entry
100	Medication History	MX-1	005	010 Entry
101	Medication History (continued)		006	010 Entry
125	Serology	SER-1	008	020 Day 1
131	Biochemistry		009	020 Day 1
133	Biochemistry (cont.)		010	020 Day 1
160	Urinalysis (Microscopy)	UR-4	011	020 Day 1
170	Drug Administration		013	030 Day 2
			014	031 Day 2
			015	032 Day 2
			019	040 Day 3
190	Adverse Event Check	AE-1	016	030 Day 2
		AE-1	020	040 Day 3
220	Concomitant Medication Check	CM-1	017	030 Day 2
		CM-1	021	040 Day 3
250	Vital Signs	VS-1	012	030 Day 2
		VS-1	018	040 Day 3
310	End of Study	EOS-1	022	100 End of Study
321	Investigator's Signature	SIG-1	023	100 End of Study

DFX Pages

Studyname Test-case

Project # 99/000

DataFax # 001

Plateno	Platename	Pageno	In DFX
010	Inclusion Criteria	001	<input checked="" type="checkbox"/>
020	Exclusion Criteria	002	<input checked="" type="checkbox"/>
050	Medical History	003	<input checked="" type="checkbox"/>
070	Physical examination	004	<input checked="" type="checkbox"/>
100	Medication History	005	<input checked="" type="checkbox"/>
101	Medication History (continued)	006	<input checked="" type="checkbox"/>
040	Demographic Data	007	<input checked="" type="checkbox"/>
125	Serology	008	<input checked="" type="checkbox"/>
131	Biochemistry	009	<input checked="" type="checkbox"/>
133	Biochemistry (cont.)	010	<input checked="" type="checkbox"/>
160	Urinalysis (Microscopy)	011	<input checked="" type="checkbox"/>
250	Vital Signs	012	<input checked="" type="checkbox"/>
170	Drug Administration	013	<input checked="" type="checkbox"/>
170	Drug Administration	014	<input type="checkbox"/>
170	Drug Administration	015	<input type="checkbox"/>
190	Adverse Event Check	016	<input checked="" type="checkbox"/>
220	Concomitant Medication Check	017	<input checked="" type="checkbox"/>
250	Vital Signs	018	<input type="checkbox"/>
170	Drug Administration	019	<input type="checkbox"/>
190	Adverse Event Check	020	<input type="checkbox"/>
220	Concomitant Medication Check	021	<input type="checkbox"/>
310	End of Study	022	<input checked="" type="checkbox"/>
321	Investigator's Signature	023	<input checked="" type="checkbox"/>

Total number of Unique Pages 17

PAGENO OF TOTAL

S	10	Entry	
S	20	Day 2	
S	30	Day 21	
S	31	Day 22	
S	32	Day 23	
S	40	Day 3	
S	100	Day 14	
010	010	page 1	of 23
020	010	page 2	of 23
050	010	page 3	of 23
070	010	page 4	of 23
100	010	page 5	of 23
101	010	page 6	of 23
040	020	page 7	of 23
125	020	page 8	of 23
131	020	page 9	of 23
133	020	page 10	of 23
160	020	page 11	of 23
250	030	page 12	of 23
170	030	page 13	of 23
170	031	page 14	of 23
170	032	page 15	of 23
190	030	page 16	of 23
220	030	page 17	of 23
250	040	page 18	of 23
170	040	page 19	of 23
190	040	page 20	of 23
220	040	page 21	of 23
310	100	page 22	of 23
321	100	page 23	of 23

10|P|Entry|10|9|-7|0|010 020 050 070 100|101|299
20|B|Day 1|40|9|0|0|040 125 131 133 160||299
30|S|Day 2 #1|250|9|1|0|170 190 220 250||299
31|r|Day 2 #2|||0|0|170||299
32|r|Day 2 #3|||0|0|170||299
40|S|Day 3|250|9|2|0|170 190 220 250||299
100|T|End of Study|310|9|14|0|310 321||299

10		10		1
20		10		2
50		10		3
70		10		4
100		10		5
101		10		6
40		20		7
125		20		8
131		20		9
133		20		10
160		20		11
250		30		12
170		30		13
170		31		14
170		32		15
190		30		16
220		30		17
250		40		18
170		40		19
190		40		20
220		40		21
310		100		22
321		100		23
*		*		999

DataFax Study # <u> 1 </u>	Study Name <u> Test-case </u>
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4. Plate Definitions

PostScript File(s) \$STUDY_DIR/frame/DF_001.dfx.ps

DFsetup - Plate - Import and Edit

Plate #	Label	SEQ # in B'code? (P=Yes)	Do ICR (P=Yes)	Early Term. (P=Yes)	Plate Action (P=Yes)
10	Inclusion Criteria [IN-1]	Y	Y	N	N
20	Exclusion Criteria [EX-1]	Y	Y	N	N
40	Demographic Data [DMG-1]	Y	Y	N	N
50	Medical History	Y	Y	N	N
70	Physical examination	Y	Y	N	N
100	Medication History [MX-1]	Y	Y	N	N
101	Medication History (continued)	Y	Y	N	N
125	Serology [SER-1]	Y	Y	N	N
131	Biochemistry	Y	Y	N	N
133	Biochemistry (cont.)	Y	Y	N	N
160	Urinalysis (Microscopy) [UR-4]	Y	Y	N	N
170	Drug Administration	Y	Y	N	N
190	Adverse Event Check [AE-1]	Y	Y	N	N
192	Adverse Events # [AE-3]	Y	Y	N	N
220	Concomitant Medication Check [CM-1]	Y	Y	N	N
222	Concomitant Medication [CM-3]	Y	Y	N	N
250	Vital Signs [VS-1]	Y	Y	N	N

Defined by <u> Eric </u>	Entered by <u> Eric </u>	Verified by <u> </u>
Date <u> Sep 03, 1999 </u>	Date <u> Sep 03, 1999 </u>	Date <u> Sep 03, 1999 </u>

DataFax Study # <u>116</u>	Study Name <u>Test-case</u>
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8a. Variable Styles

Basic Features

Style Name <u>Date_Req</u>	Style Type
Unique Name _____	<input type="checkbox"/> Number
Generic Name _____	<input checked="" type="checkbox"/> Date
Description _____	<input type="checkbox"/> String
Legal <u>01/01/20~today</u>	<input type="checkbox"/> Choice
Help <u>Legal range is \$(legal)</u>	<input type="checkbox"/> Check
Value is <input type="checkbox"/> Optional <input checked="" type="checkbox"/> Required	<input type="checkbox"/> VAS

Specific Features

Number	Display (digits) _____	Store (digits) _____	Format _____
Remark	<i>Display and Store include special Format characters, like '/' or '.'</i>		
Date	Display (digits) <u>8</u>	Store (digits) <u>8</u>	Format <u>dd/mm/yy</u>
	Range for 2 digit years is: <u>1920</u> - <u>2019</u>		
	Set partial dates: <input type="checkbox"/> never <input type="checkbox"/> to first of month/year		
	<input checked="" type="checkbox"/> to middle of month/year <input type="checkbox"/> to last of month/year		
String	Display (chars) _____	Store (chars) _____	Format _____
	Mapping <input type="checkbox"/> None <input type="checkbox"/> lower to UPPER <input type="checkbox"/> UPPER to lower		
	Treat As <input type="checkbox"/> Unscannable text <input type="checkbox"/> Pre-printed numerals		
Choice	None		
Check	None		
VAS	Precision _____	Minimum _____	Maximum _____

(see over)

Visit Map Test (ID=1)

Studyname Test-case

Project # 99/000

DataFax # 001

Visit 010 Entry P Pre-baseline

Page #	R/O	Plate #	Name	(Sub)Visit #	Type	Action
1	R	010	Inclusion Criteria	010	P	Do not fax this page: Entire Visit is set to Missing
2	R	020	Exclusion Criteria	010	P	Do not fax this page: Entire Visit is set to Missing
3	R	050	Medical History	010	P	Do not fax this page: Entire Visit is set to Missing
4	R	070	Physical examination	010	P	Do not fax this page: Entire Visit is set to Missing
5	R	100	Medication History	010	P	Do not fax this page: Entire Visit is set to Missing
6	O	101	Medication History (continued)	010	P	Do not fax this page: Entire Visit is set to Missing

Visit 020 Day 1 B Baseline

Page #	R/O	Plate #	Name	(Sub)Visit #	Type	Action
7	R	040	Demographic Data	020	B	Fax this page; Add QC note to ID field; Set Visitdate to 18/08/99
8	R	125	Serology	020	B	Fax this page; Add QC note to ID field
9	R	131	Biochemistry	020	B	Fax this page; Add QC note to ID field
10	R	133	Biochemistry (cont.)	020	B	Do not fax this page: Page is set to Missing
11	R	160	Urinalysis (Microscopy)	020	B	Do not fax this page: Page is set to Missing

Visit 030 Day 2 S Scheduled Follow-up

Page #	R/O	Plate #	Name	(Sub)Visit #	Type	Action
12	R	250	Vital Signs	030	S	Do not fax this page: Entire Visit is set to Missing
13	R	170	Drug Administration	030	S	Do not fax this page: Entire Visit is set to Missing
14	R	170	Drug Administration	031	r	Fax this page
15	R	170	Drug Administration	032	r	Fax this page
16	R	190	Adverse Event Check	030	S	Do not fax this page: Entire Visit is set to Missing
17	R	220	Concomitant Medication Chec	030	S	Do not fax this page: Entire Visit is set to Missing

Visit 040 Day 3 S Scheduled Follow-up

Page #	R/O	Plate #	Name	(Sub)Visit #	Type	Action
18	R	250	Vital Signs	040	S	Fax this page; Add QC note to ID field; Set Visitdate to 20/08/99
19	R	170	Drug Administration	040	S	Fax this page; Add QC note to ID field
20	R	190	Adverse Event Check	040	S	Do not fax this page: Page is set to Missing
21	R	220	Concomitant Medication Chec	040	S	Do not fax this page: Page is set to Missing

DataFax Study # <u>001</u>	Study Name <u>Test-case</u>
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25b. Visit Map Test Case Specifications

Test Case ID #: 0001 Initials: _____

Visit/ Seq #	Visit Type	Visit Date	Visit Date Location (plate.field)	Required Plates		Cond Plts	Opt. Plts	Ms'd Visit Plt	Early Term Plt
				Entered	Not Entered				
<u>020</u>	<u>B</u>	<u>18/08/99</u>	<u>40.9</u>	<u>40 125 131</u>	<u>133 160</u>	-		-	-
<u>031</u>	<u>r</u>			<u>170</u>		-		-	-
<u>032</u>	<u>r</u>			<u>170</u>		-		-	-
<u>040</u>	<u>S</u>	<u>20/08/99</u>	<u>250.9</u>	<u>170 250</u>	<u>190 220</u>	-		-	-
<u>100</u>	<u>T</u>	<u>01/09/99</u>	<u>310.9</u>	<u>310</u>	<u>321</u>	-		-	-

QC Notes: On page(s): 7 8 9 19 18 22

Expected Overdue Visits: 10 30

Defined by <u>Eric</u>	Entered by <u>Eric</u>	Verified by _____
Date <u>Sep 03, 1999</u>	Date <u>Sep 03, 1999</u>	Date <u>Sep 03, 1999</u>

DataFax Schema: Variable Details

Studyname Testcase
Project # 1999-015
DataFax # 129

Plate 013 Inclusion Criteria

Variable #	Unique Name	Type	Stylename	Req	Formatting		Date Settings			Legal range	Help	EDIT Checks		Field		Skips # if Field =
					Display	Store	Impute	Pivot Yr	Plate Enter			Plate Exit	Enter	Exit		
7	SUBID_013	Integer	Patid_Req	<input checked="" type="checkbox"/>	2	2				01~24	Legal range is 01~24					
8	INIT_013	String	Patinit_Req	<input checked="" type="checkbox"/>	3	3										
9	IN1_YN_013	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				1	LEGAL IS 1					
10	IN2_YN_013	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				1	LEGAL IS 1					
11	IN3_YN_013	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				1	LEGAL IS 1					
12	IN4_YN_013	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				1	LEGAL IS 1					
13	IN5_YN_013	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				1	LEGAL IS 1					
14	INFC_DT_013	Date	Date_Inf_Cons	<input checked="" type="checkbox"/>	8	8	dd/mm/yy	0	1920	01/01/98~today	Legal range is 01/01/98~toda					
15	ICOM_013	String	Icom	<input type="checkbox"/>	60	200										

Plate 023 Exclusion Criteria

Variable #	Unique Name	Type	Stylename	Req	Formatting		Date Settings			Legal range	Help	EDIT Checks		Field		Skips # if Field =
					Display	Store	Impute	Pivot Yr	Plate Enter			Plate Exit	Enter	Exit		
7	SUBID_023	Integer	Patid_Req	<input checked="" type="checkbox"/>	2	2				01~24	Legal range is 01~24					
8	INIT_023	String	Patinit_Req	<input checked="" type="checkbox"/>	3	3										
9	EX1_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
10	EX2_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
11	EX3_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
12	EX4_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
13	EX5_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
14	EX6_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
15	EX7_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
16	EX8_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
17	EX9_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
18	EX10_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
19	EX11_YN_023	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1				2	Legal is 2					
20	ICOM_023	String	Icom	<input type="checkbox"/>	60	200										

Plate 024 Exclusion Criteria (continued)

Variable #	Unique Name	Type	Stylename	Req	Formatting		Date Settings		Legal range	Help	EDIT Checks		Field Enter	Field Exit	Skips # if Field =
					Display	Store	Impute	Pivot Yr			Plate Enter	Plate Exit			
7	SUBID_024	Integer	Patid_Req	<input checked="" type="checkbox"/>	2	2			01~24	Legal range is 01~24					
8	INIT_024	String	Patinit_Req	<input checked="" type="checkbox"/>	3	3									
9	EX12_YN_024	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1			2	Legal is 2					
10	EX13_YN_024	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1			2	Legal is 2					
11	EX14_YN_024	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1			2	Legal is 2					
12	EX15_YN_024	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1			2	Legal is 2					
13	EX16_YN_024	Choice	YesNo_Req	<input checked="" type="checkbox"/>	1	1			2	Legal is 2					
14	EX_CO_024	String	Comment_60/2	<input type="checkbox"/>	60	200									
15	ICOM_024	String	Icom	<input type="checkbox"/>	60	200									

Plate 030 Statement Medical Doctor / Testing adhesives

Variable #	Unique Name	Type	Stylename	Req	Formatting		Date Settings		Legal range	Help	EDIT Checks		Field Enter	Field Exit	Skips # if Field =
					Display	Store	Impute	Pivot Yr			Plate Enter	Plate Exit			
7	SUBID_030	Integer	Patid_Req	<input checked="" type="checkbox"/>	2	2			01~24	Legal range is 01~24					
8	INIT_030	String	Patinit_Req	<input checked="" type="checkbox"/>	3	3									
9	ELIG_030	Choice	SimpleChoice	<input checked="" type="checkbox"/>	1	1			0,1,2						
10	MDNAME_030	String	SimpleString	<input checked="" type="checkbox"/>	25	50									
11	MDSIG_YN_03	Check	SimpleCheck	<input checked="" type="checkbox"/>	1	1									
12	MDS_DT_030	Date	Date_Req	<input checked="" type="checkbox"/>	8	8	dd/mm/yy	2	1920	01/01/20~today	Legal range is 01/01/20~toda				
13	TAPE_030	Choice	SimpleChoice	<input checked="" type="checkbox"/>	1	1			0,1,2,3						
14	ICOM_030	String	Icom	<input type="checkbox"/>	60	200									

Plate 046 Demographic Data / Smoking and Alcohol Habbits

Variable #	Unique Name	Type	Stylename	Req	Formatting		Date Settings		Legal range	Help	EDIT Checks		Field Enter	Field Exit	Skips # if Field =
					Display	Store	Impute	Pivot Yr			Plate Enter	Plate Exit			
7	SUBID_046	Integer	Patid_Req	<input checked="" type="checkbox"/>	2	2			01~24	Legal range is 01~24					
8	INIT_046	String	Patinit_Req	<input checked="" type="checkbox"/>	3	3									
9	VIS_DT_046	Date	VisitDate	<input checked="" type="checkbox"/>	8	8	dd/mm/yy	0	1920	15/07/99~today	Legal range is 15/07/99~toda				
10	BIRTH_DT_046	Date	BirthDate	<input checked="" type="checkbox"/>	8	8	dd/mm/yy	0	1920						
11	SEX_046	Choice	Sex	<input checked="" type="checkbox"/>	1	1									
12	CONTRAC_046	String	Comment_33/1	<input type="checkbox"/>	33	100									

DataFax #122

Plate #050
PLT

Visit #000
VISIT

Study no 99-ETA-01

Screening visit
(Day -21 to -1)

Subject no

Subject initials

Medical History (except prostate cancer)

Document all past and present conditions/surgical procedures

	Medical history	
	yes	no
	If yes, comment and give dates if possible	
Dermatological system	<input type="text" value="MHXSK_YN"/>	<input type="text" value="MHXSK_CO"/>
Ears, Nose, Throat	<input type="text" value="MHXEN_YN"/>	<input type="text" value="MHXEN_CO"/>
Eyes	<input type="text" value="MHXOP_YN"/>	<input type="text" value="MHXOP_CO"/>
Cardiovascular system	<input type="text" value="MHXCV_YN"/>	<input type="text" value="MHXCV_CO"/>
Respiratory system	<input type="text" value="MHXRS_YN"/>	<input type="text" value="MHXRS_CO"/>
Gastro-intestinal system	<input type="text" value="MHXGI_YN"/>	<input type="text" value="MHXGI_CO"/>
Hepatic system	<input type="text" value="MHXHP_YN"/>	<input type="text" value="MHXHP_CO"/>
Urinary/renal system	<input type="text" value="MHXUR_YN"/>	<input type="text" value="MHXUR_CO"/>
Reproductive system	<input type="text" value="MHXRP_YN"/>	<input type="text" value="MHXRP_CO"/>
Musculoskeletal system	<input type="text" value="MHXMS_YN"/>	<input type="text" value="MHXMS_CO"/>
Neurological system	<input type="text" value="MHXNE_YN"/>	<input type="text" value="MHXNE_CO"/>
Psychiatric function	<input type="text" value="MHXPS_YN"/>	<input type="text" value="MHXPS_CO"/>
Endocrine system/ metabolism	<input type="text" value="MHXEC_YN"/>	<input type="text" value="MHXEC_CO"/>
Immunological system (incl. allergies)	<input type="text" value="MHXIM_YN"/>	<input type="text" value="MHXIM_CO"/>
Haematological/ lymphatic system	<input type="text" value="MHXHM_YN"/>	<input type="text" value="MHXHM_CO"/>
Other relevant history (e.g. family history, occupational)	<input type="text" value="MHXOT_YN"/>	<input type="text" value="MHXOT_CO"/>

Translation -/comment field for monitor

Tick if faxed

Initials _____ Date -- / -- / --

```
#####
# Program          : s_trm
# Created by       : Thorin B.V.
# Creation date    : 07-02-2000
# Last Modification date : -
# Description      : DFsas script for exporting the Termination
#                  : in study Testcase
# Required files   : plt313.dat plt320.dat plt321.dat
# Produced output files : trm.sas, trm.d01 trm.d02 trm.d03
#####
# GLOBAL SPECIFICATIONS
```

```
DFNUM 007
SASDIR ../../crfdata/rawdata
SASJOB trm
IDNAME SUBID
F Testcase STUDYID "STUDY IDENTIFICATION"
IMPUTE no
VLABEL yes
BLANK date .
BLANK int .
RECODE choice 0 .
RECODE date * .
MISSING all asis
MERGE no
```

```
# DATA RETRIEVALS
RECORD 313
```

```
5     PLT          "PLATE NUMBER"
6     VISIT        "VISIT NUMBER"
2     VALID313     "VALIDATION LEVEL 313"
10    STOP_YN      "TRM; PREMATURELY DISCONTINUED"
11    RSAE_TF      "TRM; REASON; ADVERSE EVENTS"
12    RSWC_TF      "TRM; REASON; WITHDRAWAL CONSENT"
13    RSFRF_TF     "TRM; REASON; LOST TO FOLLOW UP"
14    RSPV_TF      "TRM; REASON; PROTOCOL VIOLATION"
15    RSRSP_TF     "TRM; REASON; INSUFF. THER. RESPONSE"
16    RSDTH_TF     "TRM; REASON; SUBJECT DIED"
17    RSOTH_TF     "TRM; REASON; OTHER"
18    RSOTH_CO     "TRM; REASON; OTHER; COMMENT"
19    RSPRIM       "TRM; REASON; PRIMARY"
```

```
RECORD 320
```

```
5     PLT          "PLATE NUMBER"
6     VISIT        "VISIT NUMBER"
2     VALID320     "VALIDATION LEVEL 320"
9:s   DTH_DT       "DATE OF DEATH"
9:c   iDTH_DT      "DATE OF DEATH; imputed"
10    CAUSEDTH     "CAUSE OF DEATH"
11    AUTOP_YN     "AUTOPSY PERFORMED"
12:s  AUTOP_DT     "DATE OF AUTOPSY"
12:c  iAUTO_DT     "DATE OF AUTOPSY; imputed"
13    AUTOP_CO     "AUTOPSY FINDINGS"
14    DTHREL       "DEATH; RELATION TO STUDY MED."
15    DTH_CO       "DEATH; COMMENTS"
```

```
RECORD 321
```

```
5     PLT          "PLATE NUMBER"
6     VISIT        "VISIT NUMBER"
2     VALID321     "VALIDATION LEVEL 321"
9     INVNAME      "NAME INVESTIGATOR"
10    INVSG_TF     "INVESTIGATOR SIGNATURE PRESENT"
11:s  INVSG_DT     "DATE INVESTIGATOR SIGNATURE"
```

DataFax #207

Plate #130

Visit #010
10

Subject no 999

Subject initials XXX



Biochemistry

Sample taken 27/11/93 13:14
dd mm yy hh mm

24 hour clock

	Result	Recommended units	In case of other units, specify	Within normal range		If no, is this clinically relevant?	
				yes	no	yes	no
Sodium	0001.01	mmol/L	UN1	A		H	
Potassium	0001.02	mmol/L	UN2	B		J	
Urea	0001.03	mmol/L	UN3	C		K	
Creatinine	0001.04	μmol/L	UN4	D		L	
Glucose	0001.05	mmol/L	UN5	E		M	
ASAT (SGOT)	0001.06	U/L	UN6	F		N	
ALAT (SGPT)	0001.07	U/L	UN7	G		P	

If 'yes', please comment. <Complete AE form in case of clinically relevant abnormalities developing or worsening during the study>

Comments (specify parameter first, then provide comment)

BCH

ICOM Initials _____ Date -- / -- / --

DataFax #207

Plate #070

Visit #100
100

Subject no 999

Subject initials XXX

Physical Examination

Date physical examination 27/11/93
dd mm yy

normal abnormal Comment if abnormal

General appearance	A	GEN
Skin (incl. hair, nails)	B	SK
Ears, Nose, Throat	C	ENT
Eyes	D	OP
Cardiovascular system (incl. peripheral vascular pulsations)	E	CV
Breasts (optional)	F	BR
Chest/Lungs	G	CL
Abdomen	H	AB
Genitalia (optional)	J	GE
Musculoskeletal	K	MS
Neurological status (incl. reflexes)	L	NE
Psychiatric status	M	PS
Lymph nodes	N	LN
Rectal (optional)	P	RE
Other, specify OTSP	Q	OT

ICOM

Initials _____ Date -- / -- / --