

Oncology

Legacy Data => SDTM

TU Tumor Identification

TR Tumor Results

RS Response



Oncology Disease-specific Therapeutic Area Supplement to the Study Data Tabulation Model Implementation Guide

Prepared by the
**CDISC Submission Data Standards Oncology Sub-
Team**

TU Tumor Identification

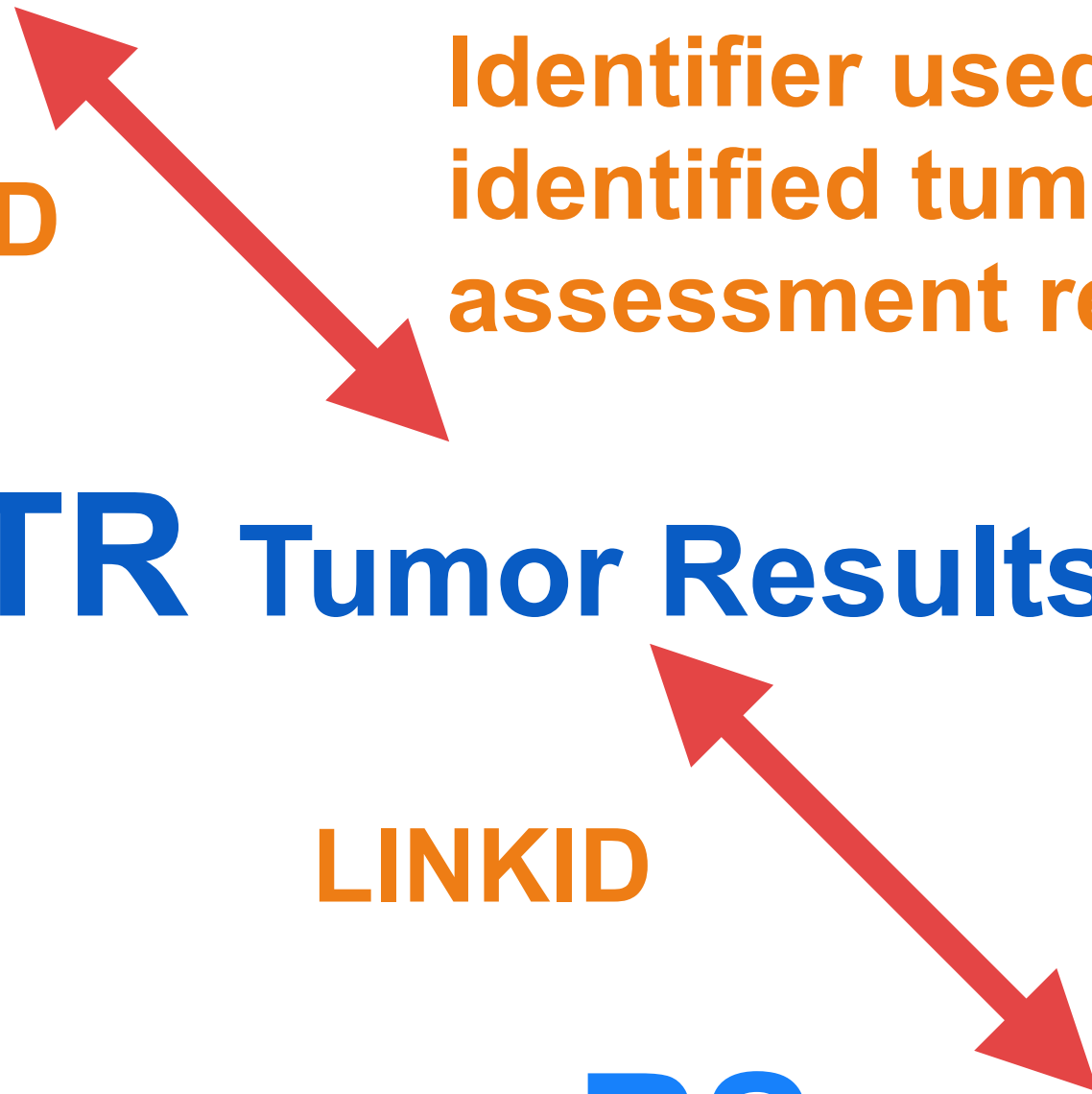
LINKID

Identifier used to link
identified tumors to the
assessment results.

TR Tumor Results

LINKID

RS Response



Conversion

Main Challenges:

1. ONE SAS file converted to THREE Domains
2. Identify LINKID
3. RS Domain: Differentiated in Target Response and Overall Response

TU Tumor Identification

TR Tumor Results

RS Response

Conversion

Visitnumm - Date Challenges:

- 1. All Records in the TYM.xpt file are reported as Unscheduled observations.**
- 2. SDTM request a VISITNUM according to the reported observation date.**

A	B	C	D	E	F	I	J	K	L	T	X	Y	AA
STUDYID	DOMAIN	USUBJID	TUSEQ	TULOC	TUGRPID	TULINKID	TUORRES	TUTESTCD	TUTEST	TUMETHOD	VISITNUM	VISIT	TUDTC
ABC456	TU	10022.1009	1	BONE METS			NON-TARGET	TUMIDENT	Target lesion measurement	Methode 6	17.1	UNSCHEDULED	15.01.2010
ABC456	TU	10022.1009	2	SMALLER LIVER LESION			NON-TARGET	TUMIDENT	Target lesion measurement	Methode 6	17.1	UNSCHEDULED	15.01.2010
ABC456	TU	10022.1009	3	RIGHT LOBE LIVER		3	TARGET	TUMIDENT	Target lesion measurement	Methode 6	17.1	UNSCHEDULED	15.01.2010
ABC456	TU	10022.1009	6	LEFT LOBE LIVER			NEW	TUMIDENT	Target lesion measurement	5	17.1	UNSCHEDULED	27.12.2010
ABC456	TU	10022.1009	4	LIVER METS			NON-TARGET	TUMIDENT	Target lesion measurement	Methode 6	17.1	UNSCHEDULED	27.12.2010

	A	B	C	D	E	F	N	U	Y	Z	AB
1	STUDYID	DOMAIN	USUBJID	TRSEQ	TRORRES	TRORTRTESTCD	TRLINKID	TRMETHOD	VISITNUM	VISIT	TRDTC
127	ABC456	TR	10022.1009	1	1.3 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	15.01.2010
128	ABC456	TR	10022.1009	19	1.1 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	03.03.2010
129	ABC456	TR	10022.1009	15	1.1 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	14.04.2010
130	ABC456	TR	10022.1009	13	0.6 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	26.05.2010
131	ABC456	TR	10022.1009	11	0.4 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	02.07.2010
132	ABC456	TR	10022.1009	10	0.5 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	19.08.2010
133	ABC456	TR	10022.1009	7	0.4 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	04.10.2010
134	ABC456	TR	10022.1009	16	0.4 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	15.11.2010
135	ABC456	TR	10022.1009	4	0.4 cm	LDIAM	3	Methode 6	17.1	UNSCHEDULED	27.12.2010

STUDYID	DOMAIN	USUBJID	RSSEQ	RSORRES	RSSPID	RSTESTCD	RSTEST	RSLINKID	VISITNUM	VISIT	RSBTC	F
ABC456	RS	10022.1009	15	Complete response		TRGRESP	Target Response	1	888	UNSCHEDULED	19.08.2010	
ABC456	RS	10022.1009	13	Complete response		TRGRESP	Target Response	1	888	UNSCHEDULED	04.10.2010	
ABC456	RS	10022.1009	20	Complete response		TRGRESP	Target Response	1	888	UNSCHEDULED	15.11.2010	
ABC456	RS	10022.1009	10	Stable disease		TRGRESP	Target Response	1	888	UNSCHEDULED	27.12.2010	
ABC456	RS	10022.1009	23	Partial response		TRGRESP	Target Response	2	888	UNSCHEDULED	03.03.2010	
ABC456	RS	10022.1009	21	Partial response		TRGRESP	Target Response	2	888	UNSCHEDULED	14.04.2010	
ABC456	RS	10022.1009	18	Partial response		TRGRESP	Target Response	2	888	UNSCHEDULED	26.05.2010	
ABC456	RS	10022.1009	16	Partial response		TRGRESP	Target Response	2	888	UNSCHEDULED	02.07.2010	
ABC456	RS	10022.1009	14	Partial response		TRGRESP	Target Response	2	888	UNSCHEDULED	19.08.2010	
ABC456	RS	10022.1009	12	Partial response		TRGRESP	Target Response	2	888	UNSCHEDULED	04.10.2010	
ABC456	RS	10022.1009	11	Partial response		TRGRESP	Target Response	2	888	UNSCHEDULED	15.11.2010	
ABC456	RS	10022.1009	9	Partial response		TRGRESP	Target Response	2	888	UNSCHEDULED	27.12.2010	
ABC456	RS	10022.1009	8	Stable disease		OVRLRESP	Overall response		888	UNSCHEDULED	03.03.2010	

TR

RS

REC1N

SIT9C (SIT9C) = 1
DTAREP1C (YNO1C)
Set DTAREP1C = 1 if records are present

Page 58

ID Center No. Subject No. Subject's initials 1. 2. fam. Basis Summary (888)

RECIST solid tumor response assessment - Target lesion measurements
Target lesions must be defined at baseline. Please enter lesions occurring after baseline on the New lesions form.

Lesion No.	Describe location of lesion	Location (enter code No.)	Evaluation method (enter code No.)	Date of baseline evaluation	Baseline evaluation (longest diameter)	Evaluation method (enter code No.)	Date of evaluation 1	Evaluation 1 (longest diameter)
				day month year	cm		day month year	cm
1	LES1N=XXLINKID	LES1TZA						
2	TU	LES1T7C (LESSIT7C)						
3								
4								
5								
6								
7								
8								
9								
10								

CRF1A

Panel: TUM

tum.P002_1 0-1 White copy to MDRC / Lt. blue copy to EDM / Yellow copy to Investigator

REC1N

SIT9C (SIT9C) = 2
DTAREP1C (YNO1C)
Set DTAREP1C = 1 if records are present

Page 66

ID Center No. Subject No. Subject's initials 1. 2. fam. Basis Summary (888)

RECIST solid tumor response assessment - Non-target lesion measurements
Non-target lesions must be defined at baseline. Please enter lesions occurring after baseline on the New lesions form.

Lesion No.	Describe location of lesion	Location (enter code No.)	Evaluation method (enter code No.)	Date of baseline evaluation	Evaluation method (enter code No.)	Date of evaluation 1	Evaluation 1
				day month year		day month year	
1	LES1N	LES1TZA					
2							
3							
4							
5							
6							
7							
8							
9							
10							

CRF1A

Panel: TUM

tum.P003_1 0-1 White copy to MDRC / Lt. blue copy to EDM / Yellow copy to Investigator

TU Tumor Identification

TR Tumor Results

RS Response

RECIST solid tumor response assessment

Overall response category (Evaluation)

Overall lesion response
1=Complete response
2=Partial response
3=Stable disease
4=Progressive disease
77=Unknown

Evaluation no.	Date of response	Overall lesion response
	RES1D (RES10 der)	OVRLS2C (TMTRES5C)
	day month year	1 2 3 4 77
1		
2		
3		
4		

RS Overall Response (without RSLINKID)



CRF

REC1N

Page 58

ID

Center No. _____ Subject No. _____

Subject's initials
 1. 2. fam.

Basis Summary

(888)

```
SIT9C (SIT9C) = 1
DTAREP1C (YNO1C)
*Set DTAREP1C = 1 if records are present
```

RECIST solid tumor response assessment - Target lesion measurements

Target lesions must be defined at baseline. Please enter lesions occurring after baseline on the New lesions form.

Lesion No.	Describe location of lesion	Location (enter code No.)	Evaluation method (enter code No.)	Date of baseline evaluation	Baseline evaluation (longest diameter)	Evaluation method (enter code No.)	Date of evaluation 1	Evaluation 1 (longest diameter)
				day month year	cm		day month year	cm
LES1N	LESSIT2							

	TU	TR
2	LESSIT7C (LESSIT7C)	ASM1D (ASM10 der) MET7C (MET7C)
3		
4		
5		

Panel: IUM

RECIN

Set DTAREP1C = 1 if records are present

DTAREP1C (YNO1C)

SIT9C (SIT9C) = 2

ID

Center No.

Subject No.

Subject's initials

1. 2. fam.

Basis
Summary

(888)

RECIST solid tumor response assessment - Non-target lesion measurements

Non-target lesions must be defined at baseline. Please enter lesions occurring after baseline on the New lesions form.

Status of lesions

1=Absent/Normalized

66=Not done

2=Present

77=Unknown

3=Worsening

Lesion No.	Describe location of lesion	Location (enter code No.)	Evaluation method (enter code No.)	Date of baseline evaluation	Evaluation method (enter code No.)	Date of evaluation 1	Evaluation 1
				day month year		day month year	Status of lesions
1							1 2 3 66 77
2							1 2 3 66 77
3							1 2 3 66 77
4							1 2 3 66 77
5							1 2 3 66 77
6							1 2 3 66 77
7							1 2 3 66 77
8							1 2 3 66 77

RS

Target
Response
(with RSLINKID)

Panel: TUM

RECIST solid tumor response assessment

Overall response category (Evaluation)

Overall lesion response
1=Complete response
2=Partial response
3=Stable disease
4=Progressive disease
77=Unknown

Evaluation
no.

EVL1N

Date of
response

RES1D (RES1O der)

Overall lesion
response

OVRLES2C (TMTRES5C)

RS
**Overall
Response
(without
RSLINKID)**

1

day month year

1 2 3 4 77
☐ ☐ ☐ ☐ ☐

2

day month year

1 2 3 4 77
☐ ☐ ☐ ☐ ☐

3

day month year

1 2 3 4 77
☐ ☐ ☐ ☐ ☐

4

day month year

1 2 3 4 77
☐ ☐ ☐ ☐ ☐

SAS File

TUM.xpt

STYSID1A	TIMPNT1N	VIS1N	VISNAM1A	ASM1D	ASM1O	DTAREP1C	EVL1N	LES1N	LESSIT2A	LESSIT7C	LESSTA5C	LONDMT2N	MET7C	OVRLES2C	REC1N	RES1D	RES1O	SIT9C
ABC123_8888	80	888	Summary	27DEC2010	12/27/2010		1	8	3	DOME OF LIVER			0	6		2		
ABC123_8888	80	888	Summary	15. Jan 10	1/15/2010		1	0	3	RIGHT LOBE LIVER			1.3	6		3		
ABC123_8888	80	888	Summary	03MAR2010	03.03.2010		1	1	3	RIGHT LOBE LIVER			1.1	6		3		
ABC123_8888	80	888	Summary	14. Apr 10	4/14/2010		1	2	3	RIGHT LOBE LIVER			1.1	6		3		
ABC123_8888	80	888	Summary	26MAY2010	5/26/2010		1	3	3	RIGHT LOBE LIVER			0.6	6		3		
ABC123_8888	80	888	Summary	02. Jul 10	07.02.2010		1	4	3	RIGHT LOBE LIVER			0.4	6		3		
ABC123_8888	80	888	Summary	19. Aug 10	8/19/2010		1	5	3	RIGHT LOBE LIVER			0.5	6		3		
ABC123_8888	80	888	Summary	04OCT2010	10.04.2010		1	6	3	RIGHT LOBE LIVER			0.4	6		3		
ABC123_8888	80	888	Summary	15. Nov 10	11/15/2010		1	7	3	RIGHT LOBE LIVER			0.4	6		3		
ABC123_8888	80	888	Summary	27DEC2010	12/27/2010		1	8	3	RIGHT LOBE LIVER			0.4	6		3		
ABC123_8888	80	888	Summary					1								3	03MAR2010	03.03.2010
ABC123_8888	80	888	Summary					2								3	14. Apr 10	4/14/2010
ABC123_8888	80	888	Summary					3								2	26MAY2010	5/26/2010
ABC123_8888	80	888	Summary					4								2	02. Jul 10	07.02.2010
ABC123_8888	80	888	Summary					5								2	19. Aug 10	8/19/2010
ABC123_8888	80	888	Summary					6								2	04OCT2010	10.04.2010
ABC123_8888	80	888	Summary					7								2	15. Nov 10	11/15/2010
ABC123_8888	80	888	Summary	27DEC2010	12/27/2010		1	8		LEFT LOBE LIVER				5		1		
ABC123_8888	80	888	Summary					8									27DEC2010	12/27/2010

TU Tumor Identification

TR Tumor Results

RS Response

SDTM Files

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SDTM Examples

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SDTM Examples

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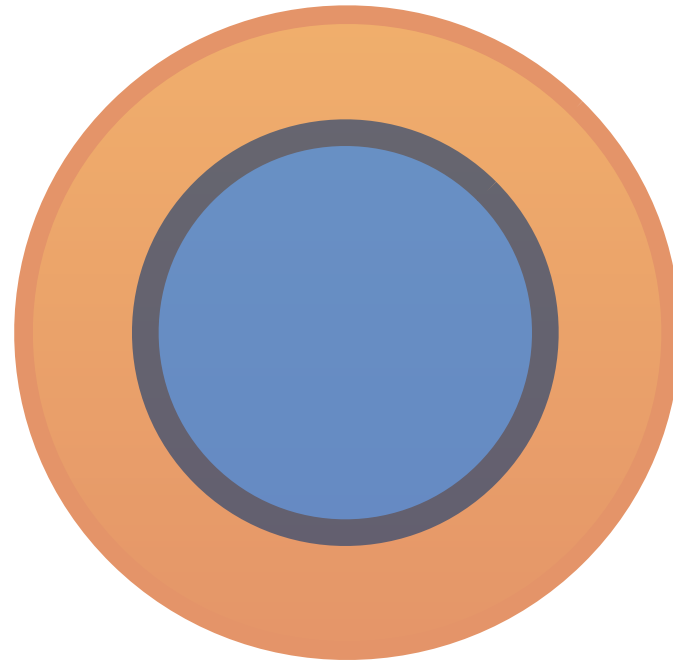
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```

Raw Data



Two times



washed



SDTM

Conversion

Upload and Two Times Washed

Import

Project:

1002 Oncology Novartis

Study:

10022 ABC456

+ Upl. Legacy

Import:

+ L. Import I

+ Prepare for a new Import

Assignment:

+ Domain Sdtm

+ Visit Sdtm

+ CrfP Sdtm

+ Prch Sdtm

+ Date/Time

+ 93imda

Import:

+ L. Import II

+ Prepare for a new Import

Import

Import Legacy

Import Legacy

vax44\Upload\2012-02-23T23_28_27_1002\Original\SAS.zip

Durchsuchen...

+ Upload File

Define Study

User Corner
Logged in as **CLIVAXSYS**
You have no new messages.
[Logout]

Contact | Sitemap | AGB

User Messages

Study Management

Data Management

DashBoard Reports

Metadata I Projekt/Study

MetaData I SysAdmin.

Project/Study/Visit/CRF Part

- > 1001 Phase
- 1002 Oncology
 - > 10020 DEF456
 - > 10021 ABC123
 - 10022 ABC456
 - > 1 Screening / Baseline
 - > 2 Cycle 1 Day 1
 - > 3 Cycle 1 Day 8
 - > 4 Cycle 1 Day 15
 - > 5 Cycle 2 Day 1
 - > 6 Cycle 2 Day 8
 - > 7 Cycle 2 Day 15
 - > 8 Cycle 3 Day 1
 - > 9 Cycle 3 Day 8
 - > 10 Cycle 3 Day 15
 - > 11 Cycle 4 Day 1
 - > 12 Cycle 4 Day 8
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 - > 17 Cycle 6 Day 1
 - > 18 Cycle 6 Day 8
 - > 19 Cycle 6 Day 15
 - > 20 Cycle 7 Day 1
 - > 21 Cycle 7 Day 8
 - > 22 Cycle 7 Day 15
 - > 23 Cycle 8 Day 1
 - > 24 Cycle 8 Day 8
 - > 25 Cycle 8 Day 15
 - > 26 Cycle 9 Day 1
 - > 27 Cycle 9 Day 8
 - > 28 Cycle 9 Day 15

Study Question Preparations

Study

Tools

Study

10022

ABC456

Active

SDTM Name

ABC123

Right Type

normal - Acces

Z Type

<Undefiniert>

Start Date

+

Stop Date

+

Language

Comments

Skip Tag

Tags

Para Tag

Supp Tags 1/2

Supp Tags 3/4/5

StudyID

<STY1A>

Domain

Tags

Subject

Tags / Ini

<SID1A>

<SBJINI1A>

Visit Tags

<VIS1N>

VisitDate

Tag

<VIS1D>

DDMMYYYYYY

Page Tag

<PAG1A>

Copy Domain: TU - TR - RS from SHARE

User Corner
Logged in as **CLIVAXSYS**
You have no new messages.
[Logout]

clivax [Contact](#) [Sitemap](#) [AGB](#)

User Messages **Study Management** **Data Management** **DashBoard Reports** **Metadata I Projekt/Study** **MetaData II SysAdmin.**

CLIVAX/SDTM Param.for eCRF

CLIVAX Paramter for eCRF

- > 1001 Phuse
- > 1002 Oncology
- > 10020 DEF456
- > 10021 ABC123
- > 10022 ABC456
- > 01 Common Identifier
- > 02 Common Timing Var
- > AE Adverse Event
- > CM Concomitant Medic
- > CO Comments
- > DA Drug Accountabili
- > DM Demographics
- > DS Disposition
- > EG ECG Test Results
- > EX Exposure
- > LB Laboratory Test R
- > MH Medical History
- > QS Questionnaires
- > RS Response
- > SC Subject Character
- > SV Subject Visits
- > TR Tumor Results
- > TU Tumor Identificat
- > TV Trial Visits
- > VS Vital Signs
- > XD Dermatology
- > YY Test YY

Project: 1002 Oncology

Study: 10022 ABC456

Domain:

Category:

Sub Category:

Variable [XXTESTCD] [QNAM]

SDTM [XXOCCUR] [XXORRES] [XXSTRESC] [QVAL]

Question Title:

Instructions:

+ Tead + Search Parameter + Tran. Choice + Imp. Items

+ Message Amin. + Edit Domain + New Domain + SDTM

+ Edit Variable + New Variable

+ Bind Supp

CLIVAX/SDTM Param.for eCRF **Import Items**

Select Items to be Imported into: Project 1002 Oncology / Study 10022 ABC456 / Domain / Variable...

Origin: Copy From CDASH Standard + Complete CDASH + SDTM-Part

Domain: RS Response (24) + Complete Domain + SDTM-Part

Parameter: + Selected Parameter +

- > 03 Screen Failure
- > AE Adverse Event (20)
- > CM Concomitant Medicatio (26)
- > CO Comments (11)
- > DA Drug Accountability (16)
- > DM Demographics (16)
- > DS Disposition (9)
- > DV Protocol Deviations
- > EG ECG Test Results (28)
- > EX Exposure (10)
- > FD (13)
- > IE Inclusion and Exclusi (12)
- > LB Laboratory Test Resul (23)
- > MH Medical History (12)
- > ML ML Test
- > PC Pharmacokinetics Conc (23)
- > PD PD Test
- > PE Physical Examination (12)
- > PP Pharmacokinetics Para (15)
- > QS Questionnaires (3)
- > QSC Questionnaires Corn
- > RS Response (24)
- > RSCAT (B)
- > RSDTC (B)

Confirm SDTM Domain Structure

User Corner
Logged in as **CLIVAXSYS**
You have no new messages.
[Logout]

clivax

User Messages Study Management Data Management Data Request

CLIVAX/SDTM Param.for eCRF Sdtm

Project 1002 Oncology / Study 10022 ABC456 / Domain R

Drop Variable:
STUDYID (S)

SDTM Tags:
< STUDYID > VALUE </ STUDYID >
Delete SDTM Tag

Drop Variable:

SDTM Tags:
< DOMAIN > VALUE </ DOMAIN >
Delete SDTM Tag

Drag from list below

- 01 Common Identifier
 - ARMCD (S)
 - DOMAIN (S)
 - IDVAR (S)
 - IDVARVAL (S)
 - INVID (S)
 - RDOMAIN (S)
 - SITEID (S)
 - SPONSOR (S)
 - STUDYID (S)**
 - SUBJID (S)
 - USUBJID (S)
- 02 Common Timing Var
- AE Adverse Event (18)
- CM Concomitant Medic (18)
- CO Comments (11)
- DA Drug Accountability (16)
- DM Demographics (11)
- DS Disposition (9)
- EG ECG Test Results (24)
- EX Exposure
- LB Laboratory Test R (23)
- MH Medical History (11)
- OS Questionnaires (13)
- RS Response (24)
 - ASM1D (P)
 - EVL1N (P)
 - LESSTA5C (P)
 - OVRLS2C (P)
 - RES1D (P)
 - RSACPTFL (S)
 - RSCAT (S)
 - RSDTAREP1C (P)
 - RSDTC (S)
 - RSDY (S)
 - RSDY (S)

```

- <RS>
  <STUDYID>ABC456</STUDYID>
  <DOMAIN>RS</DOMAIN>
  <USUBJID>10022.1001</USUBJID>
  <RSSEQ>1</RSSEQ>
  <RSORRES>Stable disease</RSORRES>
  <RSGRPID/>
  <RSREFID/>
  <RSSPID/>
  <RSTESTCD>OVRLRESP</RSTESTCD>
  <RSTEST>Overall response</RSTEST>
  <RSCAT/>
  <RSSCAT/>
  <RSSTRESC/>
  <RSSTAT/>
  <RSREASND/>
  <RSNAM/>
  <RSEVAL/>
  <RSEVALID/>
  <RSACPTFL/>
  <RSLINKID/>
  <VISITNUM>888</VISITNUM>
  <VISIT>UNSCHEDULED</VISIT>
  <RSDTC>2010-10-25</RSDTC>
  <RSDY/>
</RS>

```

Confirm Parameter Entrance for Conversion

The screenshot displays the Clivax web application interface. On the left, a 'User Corner' shows the user is logged in as 'CLIVAXSYS' with no new messages. Below this is a tree view of 'CLIVAX Paramter for eCRF' categories, with 'STUDYID' selected and circled in red. The main area shows the 'Edit ParameterType' form for 'STUDYID', which is also circled in red. The form includes sections for 'Specifications' and 'Formula'. The 'Variable' field is 'STUDYID', 'Parameter Type' is 'ASCII', and 'Choice Type' is '0'. The 'Formula' field contains 'cd11stud.title_01', which is circled in red. The top navigation bar includes 'User Messages', 'Study Management', 'Data Management', and 'DashBo Reports'.

User Corner
Logged in as **CLIVAXSYS**
You have no new messages.
[Logout]

CLIVAX Paramter for eCRF

- > ■ 1001 Phuse
- ▼ ■ 1002 Oncology
 - > ■ 10020 DEF456
 - > ■ 10021 ABC123
 - ▼ ■ 10022 ABC456
 - ▼ ■ 01 Common Identifier
 - > ■ ARMCD (S)
 - > ■ DOMAIN (S)
 - > ■ IDVAR (S)
 - > ■ IDVARVAL (S)
 - > ■ INVID (S)
 - > ■ RDOMAIN (S)
 - > ■ SITEID (S)
 - > ■ SPONSOR (S)
 - ▼ ■ **STUDYID** (S)
 - > ■ Category
 - > ■ Sub Category

CLIVAX/SDTM Param.for eCRF **Edit ParameterType**

Variable **STUDYID** Question Title

Specifications

Parameter Type ASCII

Choice Type 0

Formula

cd11stud.title_01

SDTM Generate

User Corner
Logged in as **CLIVAXSYS**
You have no new messages.
[Logout]

- Project/Patient
- > 1001 Phuse
- > 1002 Oncology
 - > 10020 DEF456
 - > 10021 ABC123
 - > **10022 ABC456**
 - > 10023 NOVARTIS_IMPORT

Contact | Sitemap | AGB

User Messages	Study Management	Data Management	DashBoard Reports	Metadata I Projekt/Study	MetaData II SysAdmin.
Data Capture		RANDOMIZATION Data Capture Managm. Merge Recipients Time Mgmt. SD/SN Reports Exports			
Project:	1002 Oncology				+ Output
Study:	10022 ABC456				+ Output
Center:					+ Output

User Corner
Logged in as **CLIVAXSYS**
You have no new messages.
[Logout]

- > Reports
- > SignalFrame
- > SDTM
 - 01 Common Identifier Variabl
 - 02 Common Timing Variables
 - AE Adverse Event
 - CM Concomitant Medications
 - CO Comments
 - DA Drug Accountability
 - DM Demographics
 - DS Disposition
 - EG ECG Test Results
 - EX Exposure
 - LB Laboratory Test Results
 - MH Medical History
 - OS Questionnaires
 - RS Response**
 - SC Subject Characteristics
 - SV Subject Visits
 - TR Tumor Results
 - TU Tumor Identification
 - TV Trial Visits
 - VS Vital Signs

Contact | Sitemap | AGB

User Messages	Study Management	Data Management	DashBoard Reports	Metadata I Projekt/Study	MetaData II SysAdmin.
Data Capture		Output			
Project:	1002 Oncology				
Study:	10022 ABC456				
Center:	0				
Patient:	0				
SDTM-All Domains:	RS Response		+ Generate SDTM-All		+ Downl. 7z SDTM-All
SDTM One Domain:			+ Generate SDTM-One	+ Downl. XML SDTM	+ Downl. XML SDTM_SUPP
SDTM One Domain:			+ Generate XML Direkt		+ Downl. 7z SDTM-One
Define.xml:			+ Generate Define XML		

SDTM on your Drive

1. SDTM in SAS Export Format

2. Define.xml

3. Open CDISC Validation

4. Report.xls file

5. Plus SDTM in XML and CSV

Name ^	Änderungsdatum	Typ	Größe
ae.xpt	19.03.2012 03:43	SAS Xport Transpor...	90 KB
cm.xpt	19.03.2012 03:43	SAS Xport Transpor...	91 KB
da.xpt	19.03.2012 03:43	SAS Xport Transpor...	61 KB
dm.xpt	19.03.2012 03:43	SAS Xport Transpor...	3 KB
eg.xpt	19.03.2012 03:43	SAS Xport Transpor...	47 KB
mh.xpt	19.03.2012 03:43	SAS Xport Transpor...	15 KB
rs.xpt	19.03.2012 03:43	SAS Xport Transpor...	17 KB
sv.xpt	19.03.2012 03:43	SAS Xport Transpor...	54 KB
tr.xpt	19.03.2012 03:43	SAS Xport Transpor...	18 KB
tu.xpt	19.03.2012 03:43	SAS Xport Transpor...	11 KB
tv.xpt	19.03.2012 03:43	SAS Xport Transpor...	4 KB
vs.xpt	19.03.2012 03:43	SAS Xport Transpor...	12 KB

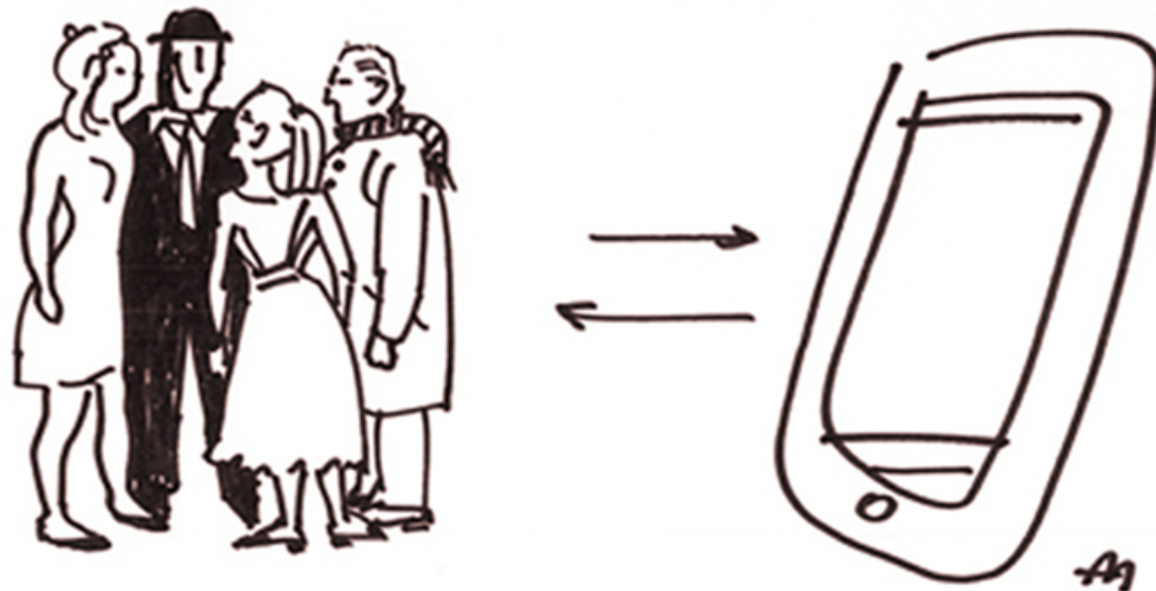
CSV	19.03.2012 03:43	Dateiordner
OpenCdiscValidation	19.03.2012 03:20	Dateiordner
XML	19.03.2012 03:20	Dateiordner
XPT	19.03.2012 03:43	Dateiordner

2012-03-19T03_20_01_0			
CSV			
OpenCdiscValidation			
XML			
XPT			
Query definitions			

Name ^	Änderungsdatum	Typ	Größe
Report.xls	19.03.2012 03:43	Microsoft Excel 97-...	

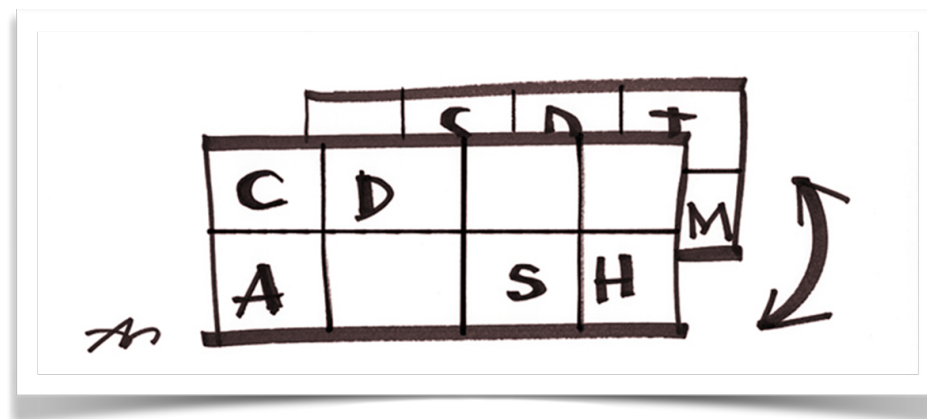
FDA wants SDTM*

Clivax delivers SDTM



* CDER Common Data Standards Issues Document, May 2011

"Overnight" Conversion to SDTM Datasets



Schedule FDA Submission Standardization

- 1. Guidance (Draft) - 2012**
- 2. Comment Period**
- 3. Guidance Final**
- 4. Grace Period A: New Studies = 24 Months**
- 5. Grace Period B: All Studies = 36 Months**

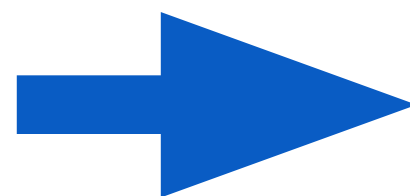
Guidance for Industry

**Providing Regulatory Submissions in Electronic Format -Standardized Study Data
Draft Febr. 2012**

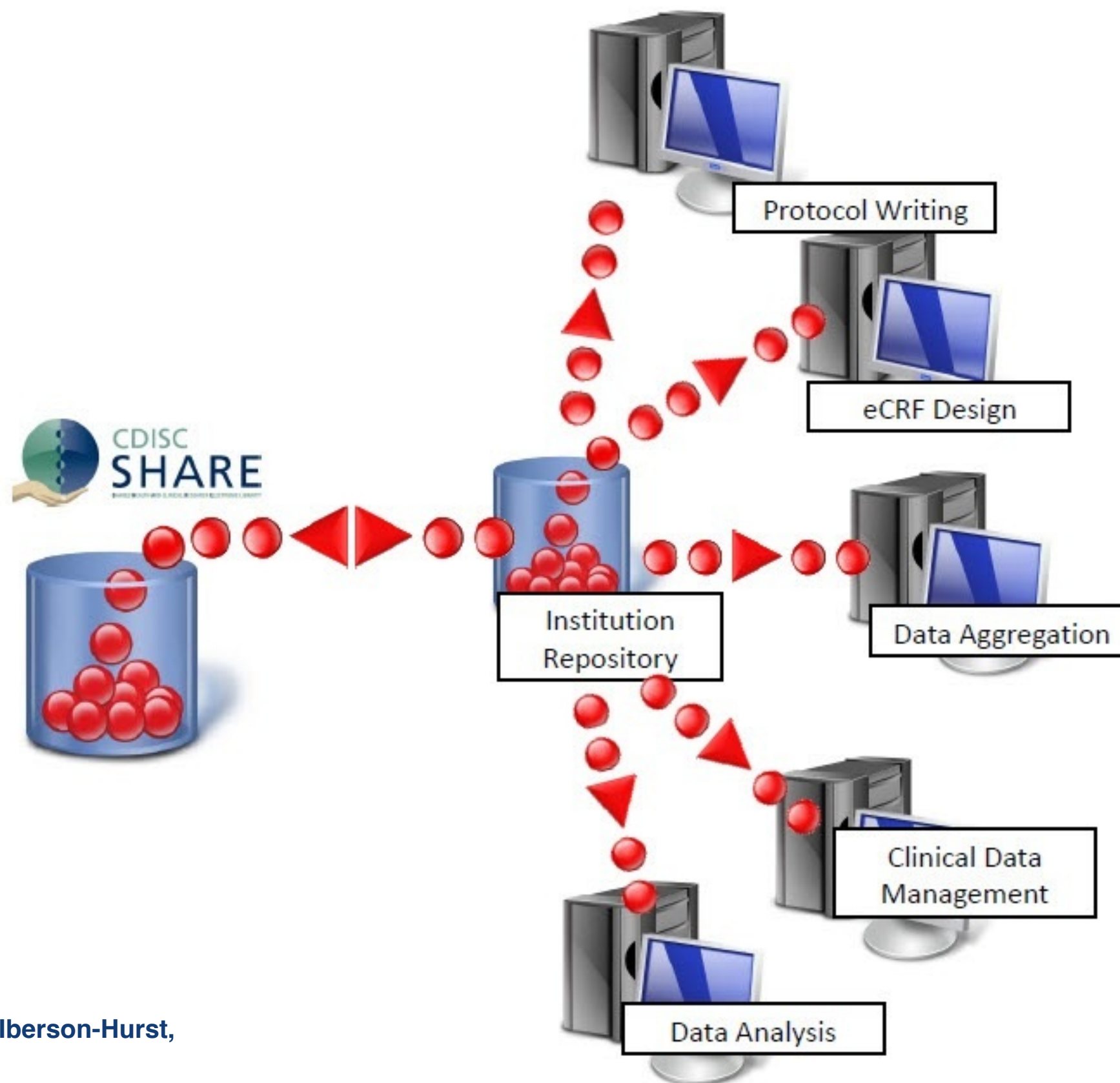
Info Source

Study Data Standards for Submission to CDER

Infrastructure



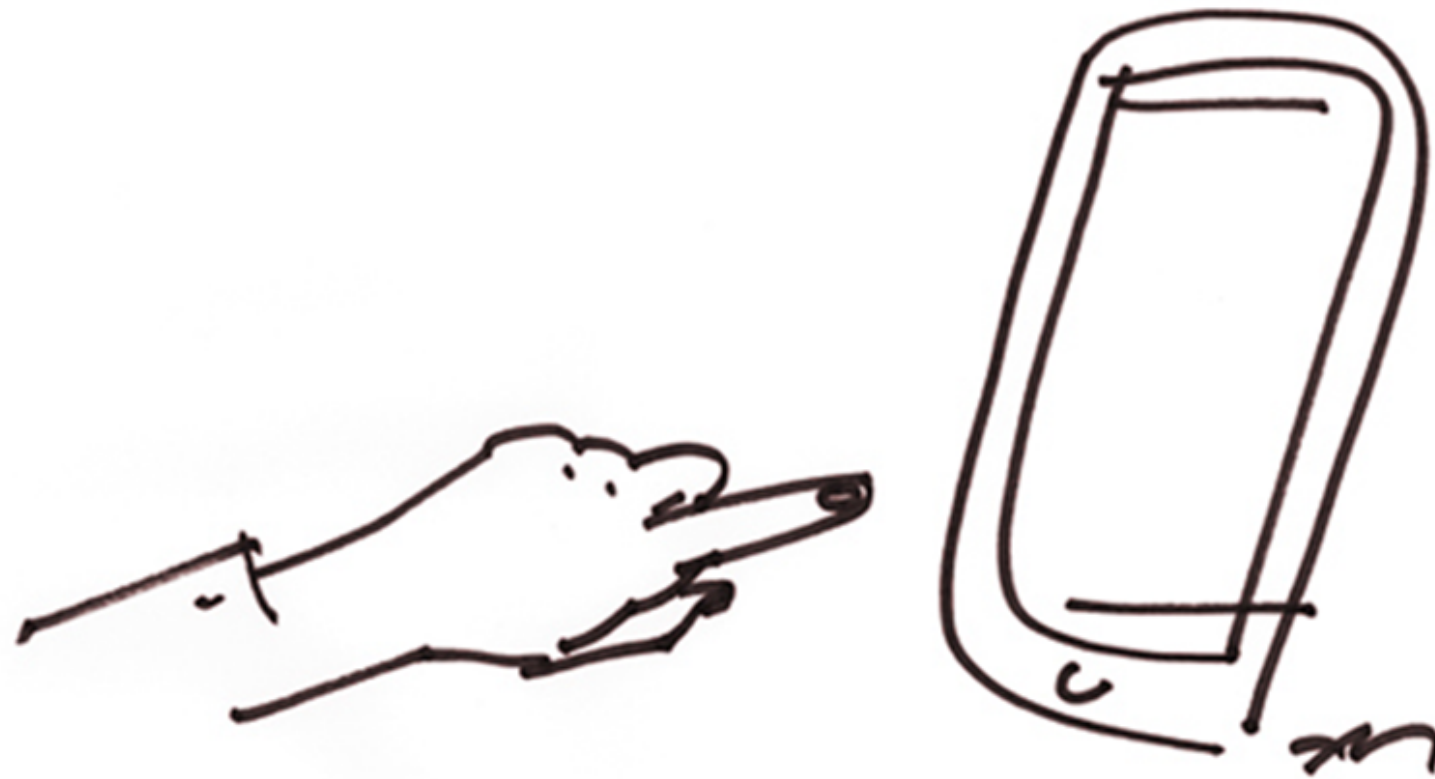
Simplicity



Source: Dave Iberson-Hurst,
CDISC

FDA

Simplicity



End to End

Clivax

- 5 Applications
- 1 Appl

- **Setup**
16 Weeks

- **SDTM**
Mapping

- 1 Day

- **"Free"**
Not necessary

- **Legacy
Converting**
1.5 Man year

- 7 Days

Questions and Contact

mathiesen & mathiesen
AG für informatik

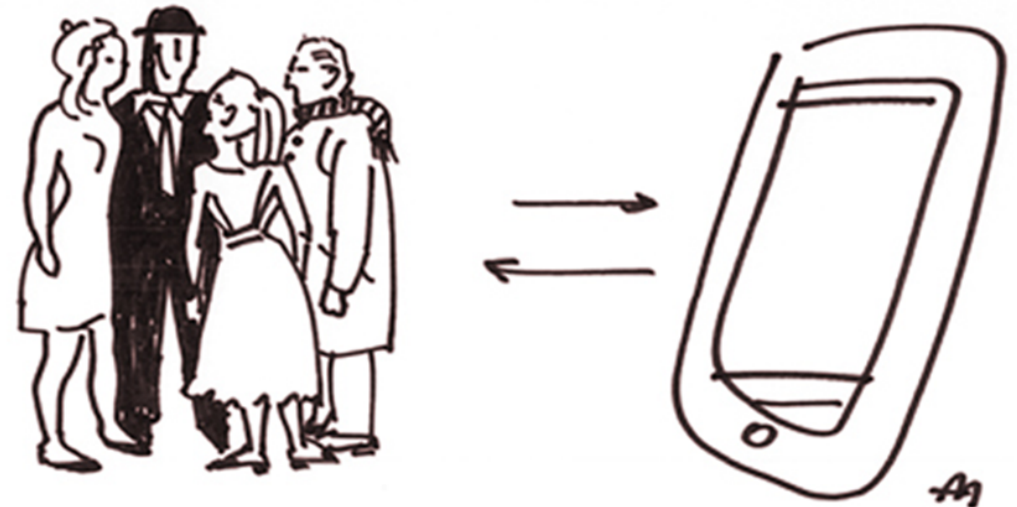
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**swiss made
software**