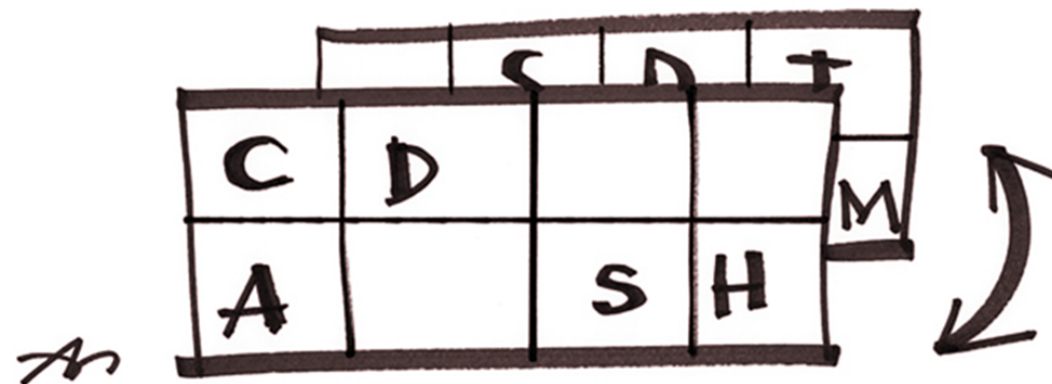


Oncology

Legacy Data => SDTM



List of Content

- 1. Therapeutic Area ONCOLOGY = CDISC-Tumor Domains**
- 2. Main Challenges / Oncology Challenges.**
- 3. Metadata Repository Drives the Process.**
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- 6. Conversion Step by Step.**
- 7. Benefits from Metadata Driven Software.**
- 8. Questions.**

1. CDISC-Tumor Domains



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

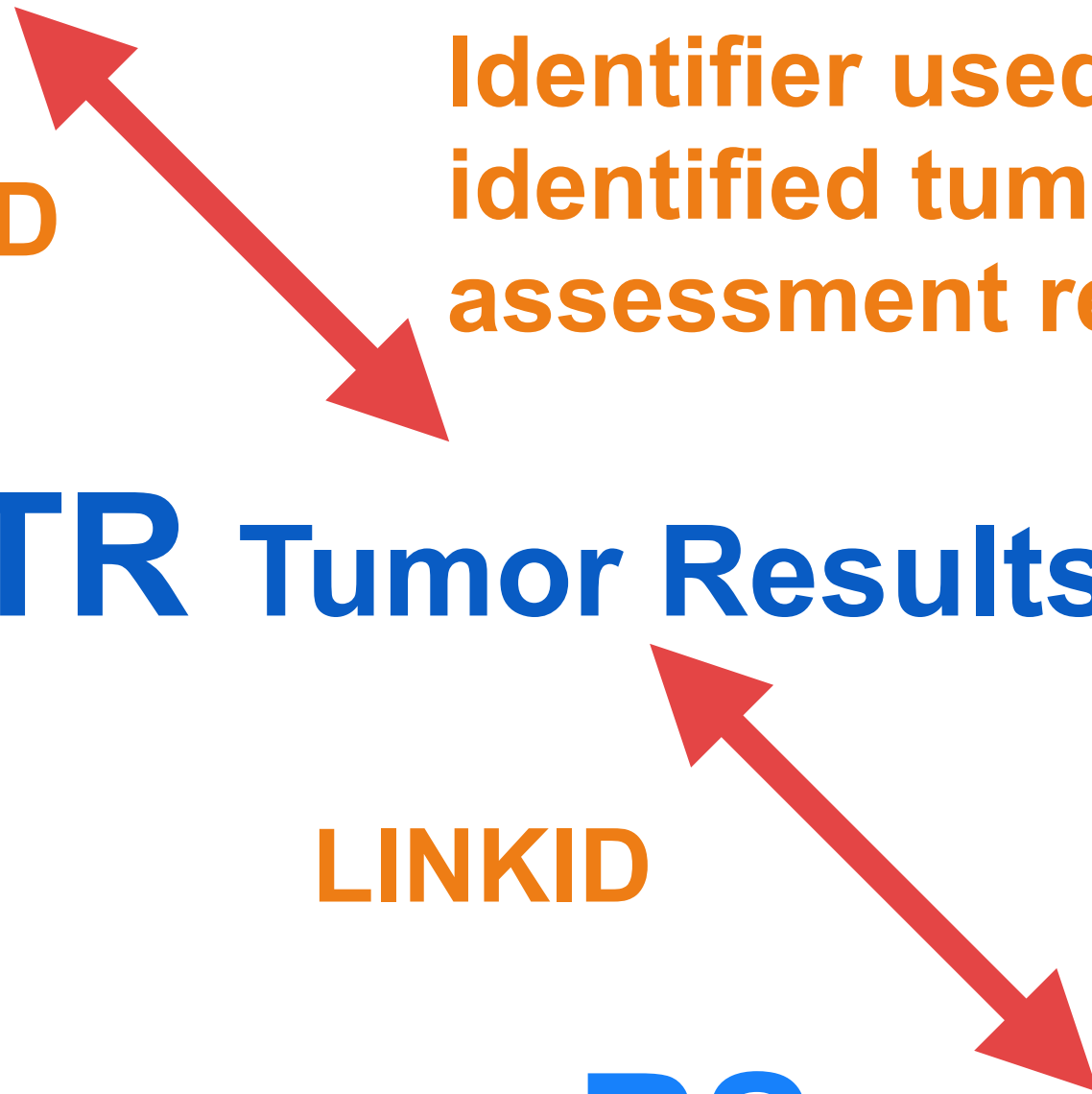
LINKID

Identifier used to link identified tumors to the assessment results.

TR Tumor Results

LINKID

RS Response



List of Content

1. Therapeutic Area ONCOLOGY = CDISC-Tumor Domains
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Main / Oncology Challenges

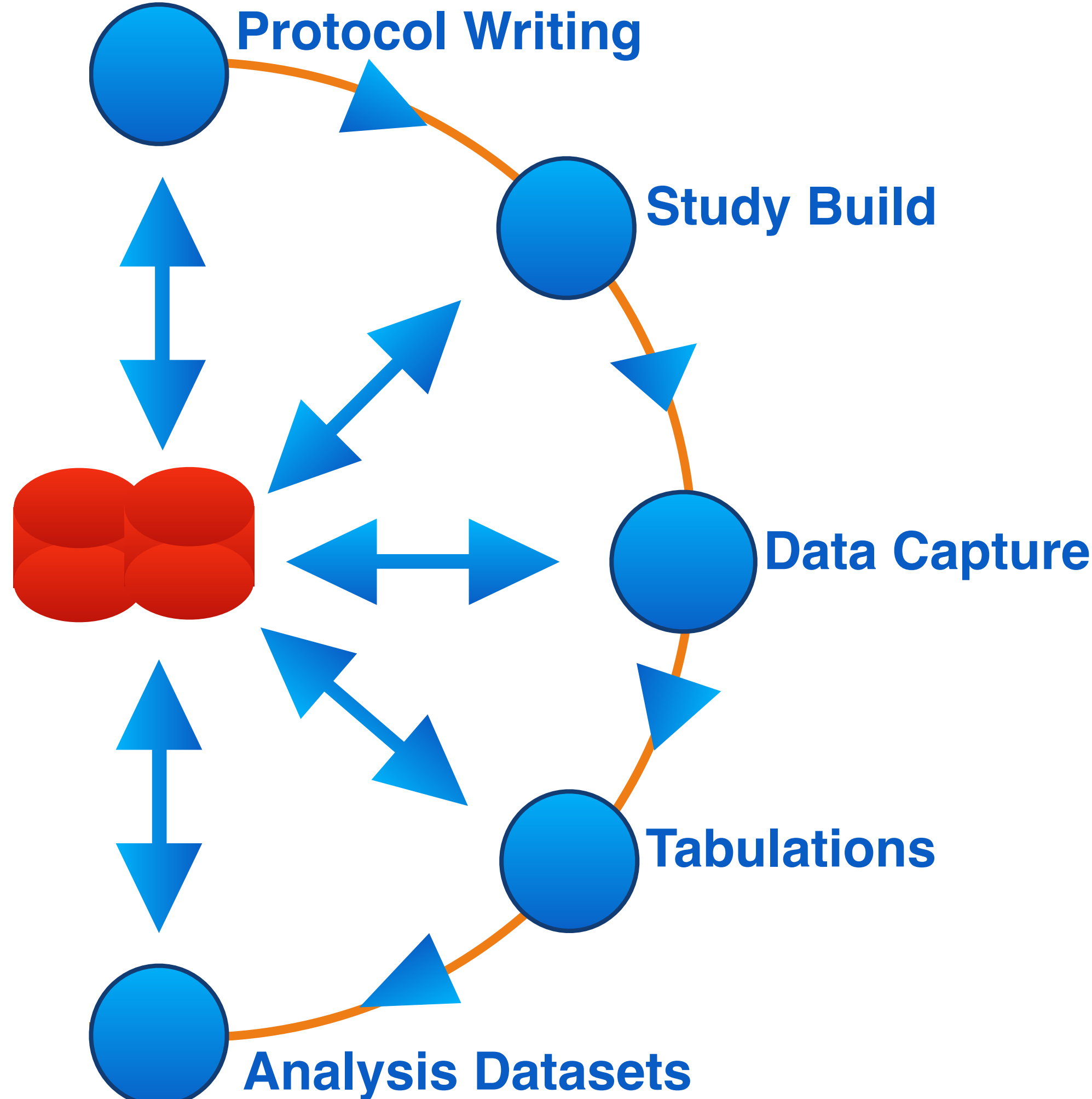
- 1. ONE SAS file converted to THREE Domains**
- 2. Identify LINKID**
- 3. Response Domain (RS):**
Differentiated in Target Response and Overall Response
- 4. Dates and Visits:**
All unscheduled visits has to be in Visit number order
- 5. Date/Time Format:**
Legacy date format -> ISO Standard.
Any time informations to be combined into ISO date standard.

List of Content

1. Therapeutic Area ONCOLOGY = CDISC-Tumor Domains
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Clinical Trials:

Meta Data Repository

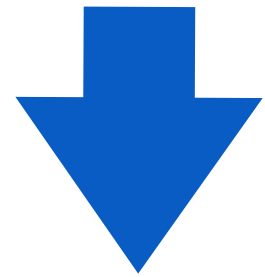


Source: Dave Iberson-Hurst,

CDISC

Metadata driven

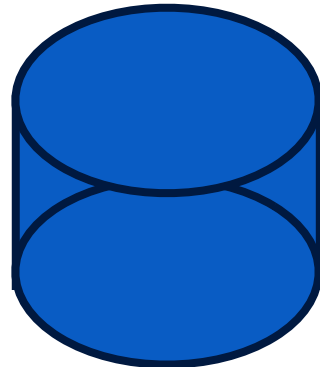
Legacy



Metadata

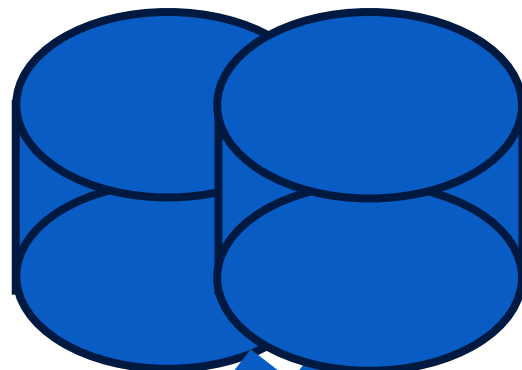


**Standards Library
(SHARE)**



**SDTM
CDASH**

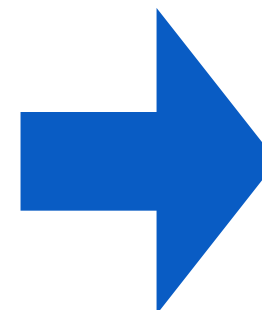
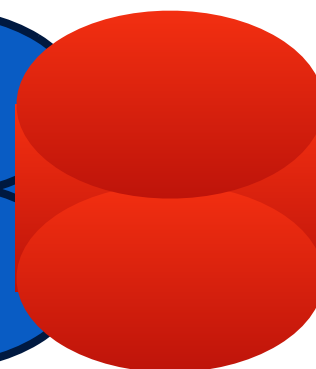
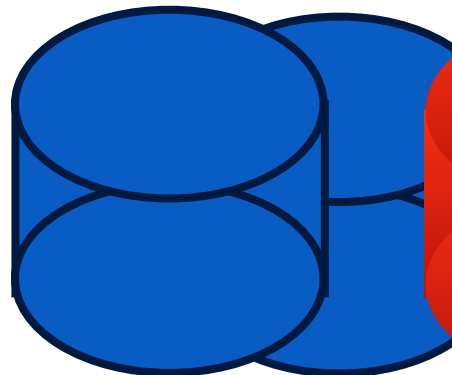
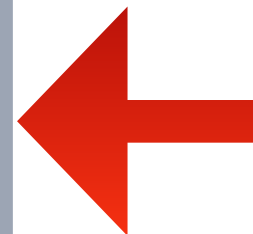
**Study Metadata
Repository**



**Import
I**



**Import
II**



**SDTM
Define.XML
Result.XLS**

List of Content

1. Therapeutic Area ONCOLOGY = CDISC-Tumor Domains
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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

CRF

TYM Part

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 (LESS1T7C)						
3								
4								
5								
6								
7								
8								
9								
10								

CRF1A

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 65

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

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)

REC1N

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

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	LESSIT2A							
2								
3								
4								
5								

LES1N=XXLINKID

TU

LESSIT7C (LESSIT7C)

MET7C (MET7C)

ASM1D (ASM1D der)

EVL1N

LONDMT2N

TR

Panel: LUM

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	
1							
2							
3							
4							
5							
6							
7							
8							

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 (RES10 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
☐ ☐ ☐ ☐ ☐

SDTM Files

TU

<STUDYID>¶
 <DOMAIN>¶
 <USUBJD>¶
 <TUSEQ>¶
 <TUORRES>¶
 <TUGRPID>¶
 <TUREFID>¶
 <TUSPID>¶
 <TULINKID>¶
 <TUTESTCD>¶
 <TUTEST>¶
 <TUCAT>¶
 <TUSCAT>¶
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 <TUNAM>¶
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 <TULAT>¶
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 <TUEVALID>¶
 >TUACPTFL>¶
 <VISITNUM>¶
 <VISIT>¶
 <VISITDY>¶
 <TUDTC>¶
 <TUDY>¶

TR

<STUDYID>¶
 <DOMAIN>¶
 <USUBJD>¶
 <TRSEQ>¶
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 <TRTESTCD>¶
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 <TRSTRESN>¶
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 <TRGRPID>¶
 <TRREFID>¶
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 <VISIT>¶
 <VISITDY>¶

RS

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 <RSACPTFL>¶
 <RSLINKID>¶
 <VISITNUM>¶
 <VISIT>¶
 <RSDTC>¶
 <RSDY>¶

SDTM Result

TU Tumor Identification

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

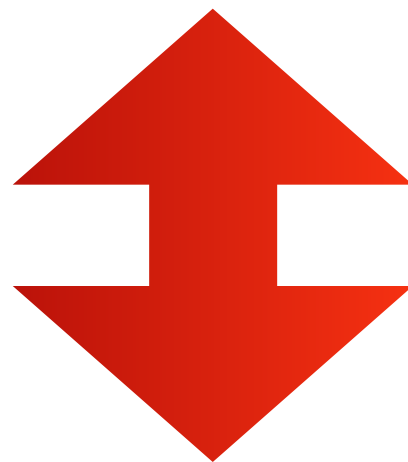
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- 8. Questions.**

5. Challenges in Detail

5.1 THREE Domains

TYM



TU Tumor Identification

TR Tumor Results

RS Response

5.2 TULINKID; TRLINKID; RSLINKID

(Lesion No LES1N = LINKID)

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		LESSIT2A	EVL1N				LONDMT2N	
2		LESSIT7C	ASM1D (A)					
3			MET7C					

5. Challenges in Detail

5.3 Response Domain (RS):

5.3.1 Target Response with "LINKID"

5.3.2 Overall Response without "LINKID"

5. Challenges in Detail

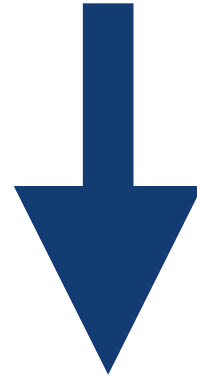
5.4 Dates and Visits:

- **All Records in the TYM.xpt file are reported as Unscheduled observations.**
- **SDTM request a VISITNUM according to the reported observation date.**
- **Date/Time according to the ISO standard.**

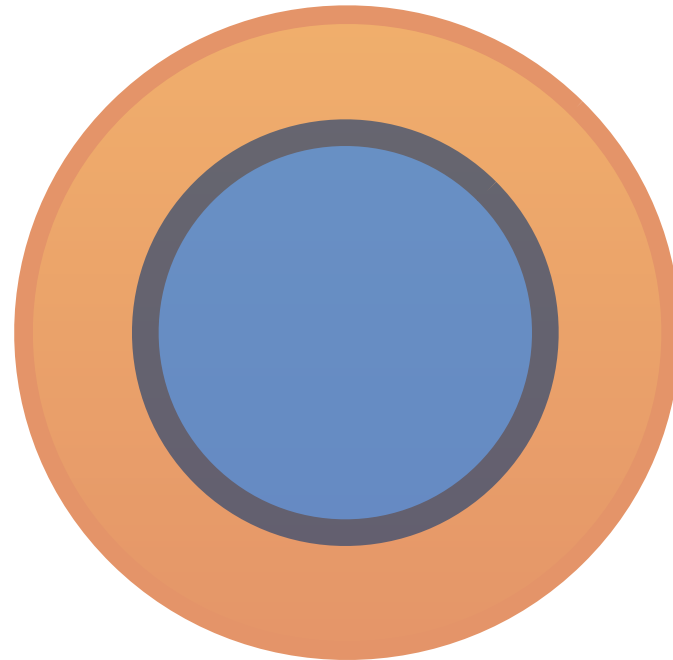
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8. Questions.

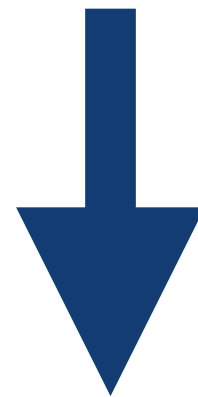
Raw Data



Two times



washed



SDTM

6. Conversion Step by Step

Upload and Two Times Washed

Import

Project: 1002 Oncology Novartis

Study: 10022 ABC456

Import: + Upl. Legacy

+ 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 Legacy

Import Legacy vax44\Upload\2012-02-23T23_28_27_1002\Original\SAS.zip Durchsuchen... + Upload File

Click for upload

1.

Upload

2.

Import I

6. Conversion Step by Step

Define Study and Visit's (Harmonise with Legacy Data)

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 II 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
 - > 13 Cycle 4 Day 15
 - > 14 Cycle 5 Day 1
 - > 15 Cycle 5 Day 8
 - > 16 Cycle 5 Day 15
 - > 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
Tags
<STY1A>

Domain
Tags

Subject
Tags / Ini
Tag
<SID1A>
<SBJINI1A>

Visit Tags
<VIS1N>

VisitDate
Tag
<VIS1D>
DDMMYYYYY

Page Tag
<PAGE1A>

Fill-in and save with F2

6. Conversion Step by Step

Prepare Visit's

Visit Number; Ready for calculation Visit Number X.1 etc

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.

Study Question Preparations | **Visit** | Tools

Project/Study/Visit/CRF Part
> 1001 Phuse
v 1002 Oncology
 > 10020 DEF456
 > 10021 ABC123
 v 10022 ABC456
 > 1 Screening / Baseline
 > 2 Cycle 1 Day 1
 > **3 Cycle 1 Day 8**
 > **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

Visit: 
Visit_OID:
Status I/II:
Interval:
Days in Advance:
Days Delay:
Report Part:

Translation

Fill-in and save with F2

6. Conversion

Date Conversion to SDTM Standard

Legacy Data TYM use two parameters for Date informations

Legacy Data has no time informations

Status	Tag Date	Example	Tag Time	Example	SDTM	DDMMYYYY
activ	AEVSTT1D		117		AEDTC	DDMMYYYY
A	ASM1D	2010-03-23	120		RSDTC	DDMMYYYY
A	CMDSTT1D		118		CMDTC	DDMMYYYY
A	DADTC		122		DADTC	DDMMYYYY
A	DGNSRG1D		119		MHDTC	DDMMYYYY
A	DOB1D		101		DOB1D	DDMMYYYY
A	DTH1D		124		CMDTC	DDMMYYYY
A	ECG1D		126		EGDTC	DDMMYYYY
A	LSTSTR1D		123		DSDTC	DDMMYYYY
A	RES1D		121		RSDTC	DDMMYYYY
A	RSDTC		114		RSDTC	DDMMYYYY
A	SMDSTT1D		125		DATDC	DDMMYYYY
A	TRDTC		116		TRDTC	DDMMYYYY
A	TUDTC		115		TUDTC	DDMMYYYY
A	VIS1D		127		SV DTC	DDMMYYYY
A	VSN1D		102		VSDTC	DDMMYYYY
A						

RSDTC Is the generated Date/Time in SDTM format

RSDTC is the Date Parameter for all three Domains

6. Conversion Step by Step

Metadata Ready

A. CDISC Data - **Ready for Use** - SHARE imported
CDASH, SDTM

B. Use in Current Oncology Project
Copy from A) CDISC Data
Copy from B) Previous Project

Drag and Drop

The screenshot displays the Clivax web application interface. On the left, a 'User Corner' sidebar shows the user is logged in as 'CLIVAXSYS' with no new messages. Below this is a tree view of 'CLIVAX Paramter for eCRF' with items like '1001 Phuse', '1002 Oncology', '10020 DEF456', '10021 ABC123', and '10022 ABC456'. The '1002 Oncology' and '10022 ABC456' items are circled in red. The main content area has a top navigation bar with 'clivax' logo and links for 'Contact', 'Sitemap', and 'AGB'. Below this is a secondary navigation bar with tabs: 'User Messages', 'Study Management', 'Data Management', 'DashBoard Reports', 'Metadata I Projekt/Study' (which is active), and 'MetaData II SysAdmin.'. The active tab shows a section titled 'CLIVAX/SDTM Param.for eCRF' containing a table with project details: 'Project: 1002 Oncology', 'Study: 10022 ABC456', and 'Domain:'. To the right of the table are several action buttons: '+ Tead', '+ Search Parameter', '+ Message Amin.', '+ Edit Domain', '+ Tran. Choice', '+ New Domain', and '+ Imp. Items'. The '+ Imp. Items' button is circled in red.

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

Project:	1002 Oncology	+ Tead	+ Search Parameter
Study:	10022 ABC456	+ Message Amin.	+ Tran. Choice
Domain:		+ Edit Domain	+ New Domain

+ Imp. Items

6. Conversion

Copy Metadata from SHARE Repository

Copy Domain:
TU - TR - RS
from SHARE



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 II SysAdmin.

CLIVAX Paramter for eCRF

- > 1001 Phase
- > 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 Accountability
- > DM Demographics
- > DS Disposition
- > EG ECG Test Results
- > EX Exposure
- > LB Laboratory Test R
- > MH Medical History
- > OS 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

CLIVAX/SDTM Param.for eCRF

Project:	1002 Oncology	+ Tead	+ Search Parameter	+ Imp. Items
Study:	10022 ABC456	+ Message Amin.	+ Tran. Choice	
Domain:		+ Edit Domain	+ New Domain	+ SDTM
Category:				
Sub Category:				
Variable [XXTESTCD] [QNAM]		+ Edit Variable	+ New Variable	
SDTM [XXOCCUR] [XXORRES] [XXSTRESC] [QVAL]		+ Bind Supp		
Question Title:				
Instructions:				

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	

Click for METADATA Repository copy

- > 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)

6. Conversion

Confirm SDTM Domain Structure

Drag and Drop

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

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

Drop for SDTM Structure

```

- <RS>
<STUDYID>ABC456</STUDYID>
<DOMAIN>RS</DOMAIN>
<USUBJID>10022.1001</USUBJID>
<RSSEQ>1</RSSEQ>
<RSORRES>Stable disease</RSORRES>
<RSGRPID>
<RSREFID>
<RSSPID>
<RSTESTCD>OVLRESP</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>

```

6. Conversion

Confirm Parameter Entrance for Conversion

The screenshot displays the Clivax web application interface. On the left, a 'User Corner' sidebar shows the user is logged in as 'CLIVAXSYS' with no new messages and a [Logout] link. Below this is a tree view of 'CLIVAX Paramter for eCRF' categories, including '1001 Phuse', '1002 Oncology', and '10022 ABC456'. The 'STUDYID' parameter is highlighted in the tree. The main content area has a top navigation bar with 'User Messages', 'Study Management', 'Data Management', and 'DashBo Reports'. Below this is a sub-header 'CLIVAX/SDTM Param.for eCRF' and a tab 'Edit ParameterType'. The form contains the following fields:

- Variable:** A text box containing 'STUDYID'.
- Question Title:** A text box that is currently empty.
- Specifications:**
 - Parameter Type:** A dropdown menu set to 'ASCII'.
 - Choice Type:** A text box containing '0'.
- Formula:** A text box containing 'cd11stud.title_01'.

Red circles highlight the 'STUDYID' variable, the 'STUDYID' parameter in the tree, and the 'cd11stud.title_01' formula. A red arrow points from the formula field to a red-bordered box containing the text 'Fill-in and save with F2'.

6. Conversion Generate SDTM

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

Project/Patient
 > 1001 Phuse
 v 1002 Oncology
 > 10020 DEF456
 > 10021 ABC123
 v **10022 ABC456**
 > 1 NOVARTIS_IMPORT

clivax | Contact | Sitemap | AGB

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

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

> Reports
 > SignalFrame
 v **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

clivax | Contact | Sit

User Messages	Study Management	Data Management	DashBoard Reports	Metadata I Projekt/Stu
		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
SDTM One Domain:			+ Generate XML Direkt	+ Downl. XML SDTM_SUPP
Define.xml:			+ Generate Define XML	+ Downl. 7z SDTM-One

Click for SDTM generate

6. Conversion

SDTM on your Drive

- **SDTM in SAS Export Format;**
The three Oncology domains among the total domains from the converted study.
- **Define.xml**
- **Open CDISC Validation**
- **Report.xls file**

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-...	

6. Conversion SDTM Examples

TU

```
-<TU>
  <STUDYID>ABC456</STUDYID>
  <DOMAIN>TU</DOMAIN>
  <USUBJID>10022.1084</USUBJID>
  <TUSEQ>1</TUSEQ>
  <TULOC>BONE METS</TULOC>
  <TUGRPID/>
  <TUREFID/>
  <TUSPID/>
  <TULINKID>2</TULINKID>
  <TUORRES>NON-TARGET</TUORRES>
  <TUTESTCD>TUMIDENT</TUTESTCD>
  <TUTEST>Target lesion measurements</TUTEST>
  <TUCAT/>
  <TUSCAT/>
  <TUSTRESC/>
  <TUNAM/>
  <TULAT/>
  <TUDIR/>
  <TUDSTRBN/>
  <TUMETHOD>Methode 6</TUMETHOD>
  <TUEVAL/>
  <TUEVALID/>
  <TUACPTFL/>
  <VISITNUM>1.1</VISITNUM>
  <VISIT>UNSCHEDULED</VISIT>
  <VISITDY>0</VISITDY>
  <TUDTC>2010-01-15</TUDTC>
  <TUDY>8</TUDY>
</TU>
```

TR

```
-<TR>
  <STUDYID>ABC456</STUDYID>
  <DOMAIN>TR</DOMAIN>
  <USUBJID>10022.1084</USUBJID>
  <TRSEQ>1</TRSEQ>
  <TRORRES>1.3</TRORRES>
  <TRORRESU>cm</TRORRESU>
  <TRTESTCD>LDIAM</TRTESTCD>
  <TRSTRESC>1.3</TRSTRESC>
  <TRSTRESN>1.3</TRSTRESN>
  <TRSTRESU>cm</TRSTRESU>
  <TRGRPID/>
  <TRREFID/>
  <TRSPID/>
  <TRLINKID>3</TRLINKID>
  <TRTEST/>
  <TRCAT/>
  <TRSCAT/>
  <TRSTAT/>
  <TRREASND/>
  <TRNAM/>
  <TRMETHOD>Methode 6</TRMETHOD>
  <TREVAL/>
  <TREVALID/>
  <TRACPTFL/>
  <VISITNUM>1.1</VISITNUM>
  <VISIT>UNSCHEDULED</VISIT>
  <VISITDY>0</VISITDY>
  <TRDTC>2010-01-15</TRDTC>
  <TRDY>8</TRDY>
</TR>
```

6. Conversion SDTM Examples

RS

```
-<RS>
  <STUDYID>ABC456</STUDYID>
  <DOMAIN>RS</DOMAIN>
  <USUBJID>10022.1084</USUBJID>
  <RSSEQ>8</RSSEQ>
  <RSORRES>Partial response</RSORRES>
  <RSGRPID/>
  <RSREFID/>
  <RSSPID/>
  <RSTESTCD>TRGRESP</RSTESTCD>
  <RSTEST>Target Response</RSTEST>
  <RSCAT/>
  <RSSCAT/>
  <RSSTRESC/>
  <RSSTAT/>
  <RSREASND/>
  <RSNAM/>
  <RSEVAL/>
  <RSEVALID/>
  <RSACPTFL/>
  <RSLINKID>2</RSLINKID>
  <VISITNUM>49.1</VISITNUM>
  <VISIT>UNSCHEDULED</VISIT>
  <RSDTC>2010-12-27</RSDTC>
  <RSDY>354</RSDY>
</RS>
```

```
-<RS>
  <STUDYID>ABC456</STUDYID>
  <DOMAIN>RS</DOMAIN>
  <USUBJID>10022.1084</USUBJID>
  <RSSEQ>1</RSSEQ>
  <RSORRES>Progressive disease</RSORRES>
  <RSGRPID/>
  <RSREFID/>
  <RSSPID/>
  <RSTESTCD>OVRI RESP</RSTESTCD>
  <RSTEST>Overall response</RSTEST>
  <RSCAT/>
  <RSSCAT/>
  <RSSTRESC/>
  <RSSTAT/>
  <RSREASND/>
  <RSNAM/>
  <RSEVAL/>
  <RSEVALID/>
  <RSACPTFL/>
  <RSLINKID/>
  <VISITNUM>49.1</VISITNUM>
  <VISIT>UNSCHEDULED</VISIT>
  <RSDTC>2010-12-27</RSDTC>
  <RSDY>354</RSDY>
</RS>
```

6. Conversion

Define.XML

```
<?xml version="1.0" encoding="UTF-8" ?>
- <ODM xmlns="http://www.cdisc.org/ns/odm/v1.2" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:xlink="http://www.w3.org/1999/xlink" xmlns:def="http://www.cdisc.org/ns/def/v1.0"
  xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.2 http://www.cdisc.org/schema/def/v1.0/define1-0-0.xsd"
  FileOID="Value" ODMVersion="1.2" FileType="Snapshot" CreationDateTime="Value">
- <Study xmlns="" OID="ABC456">
  - <GlobalVariables>
    <StudyName>ABC456</StudyName>
    <StudyDescription>ABC456</StudyDescription>
    <ProtocolName>ABC456</ProtocolName>
  </GlobalVariables>
- <MetaDataVersion>
  - <def:ValueListDef OID="ValueList.EG.EGTESTCD">
    <ItemRef ItemOID="EG.EGTESTCD.ECGABN1A" OrderNumber="1" Mandatory="No" />
    <ItemRef ItemOID="EG.EGTESTCD.HRTRAT1N" OrderNumber="2" Mandatory="No" />
    <ItemRef ItemOID="EG.EGTESTCD.PRI1N" OrderNumber="3" Mandatory="No" />
    <ItemRef ItemOID="EG.EGTESTCD.QRSDUR1N" OrderNumber="4" Mandatory="No" />
    <ItemRef ItemOID="EG.EGTESTCD.QTIUNC1N" OrderNumber="5" Mandatory="No" />
  </def:ValueListDef>
  - <def:ValueListDef OID="ValueList.VS.VSTESTCD">
    <ItemRef ItemOID="VS.VSTESTCD.BSA1N" OrderNumber="6" Mandatory="No" />
    <ItemRef ItemOID="VS.VSTESTCD.WGT1N" OrderNumber="7" Mandatory="No" />
  </def:ValueListDef>
  - <def:ValueListDef OID="ValueList.EG.EGCAT">
    <ItemRef ItemOID="EG.EGCAT.FINDING" OrderNumber="1" Mandatory="No" />
  </def:ValueListDef>
  - <def:ValueListDef OID="ValueList.MH.MHCAT">
    <ItemRef ItemOID="MH.MHCAT.cd14pati.value01" OrderNumber="2" Mandatory="No" />
  </def:ValueListDef>
  - <def:ValueListDef OID="ValueList.RS.RSCAT">
```

6. Conversion

Result.xls

OpenCDISC Validator Report							
Configuration: C:\db_vdf\Vdf16\Clivax44\Programs\opencdisc-validator\config\config-sdtm-3.1.2.xml							
Define.xml: Not provided							
Generated: 2012-03-19T03:43:38							
Processed Sources							
Name	Label	Class	Source	Records	Errors	Warnings	Infos
AE	Adverse Events	Events	ae.xpt	272	67	299	1
CM	Concomitant Medications	Interventions	cm.xpt	386	426	92	0
DA	Drug Accountability	Findings	da.xpt	523	0	2175	0
DM	Demographics	Special Purpose	dm.xpt	11	6	12	1
EG	ECG Test Results	Findings	eg.xpt	170	27	499	1
MH	Medical History	Events	mh.xpt	93	75	48	0
RS	RS	Findings	rs.xpt	115	115	115	0
SV	Subject Visits	Study Design	sv.xpt	638	58	698	0
TR	TR	Findings	tr.xpt	141	141	282	0
TU	TU	Findings	tu.xpt	43	43	129	0
TV	Trial Visits	Trial Design	tv.xpt	59	59	13	0
VS	Vital Signs	Findings	vs.xpt	97	0	133	1
Total				2548	1017	4495	4
Unprocessed Sources							
Name	Label	Class	Reason		Errors	Warnings	Infos
Total					0	0	0
Grand Total				2548	1017	4495	4

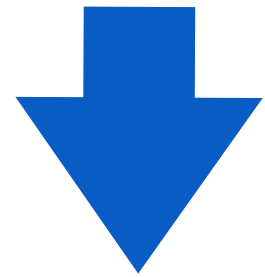
List of Content

- 1. Therapeutic Area ONCOLOGY = CDISC-Tumor Domains**
- 2. Main Challenges / Oncology Challenges.**
- 3. Metadata Repository Drives the Process.**
- 4. Legacy Data Structure <-> SDTM Structure.**
- 5. Challenges in Detail.**
- 6. Conversion Step by Step.**
- 7. Benefits from Metadata Driven Software.**
- 8. Questions.**

CDISC

Metadata driven

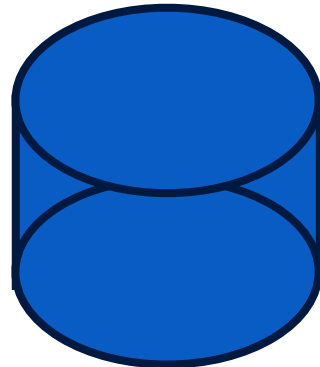
Legacy



Metadata

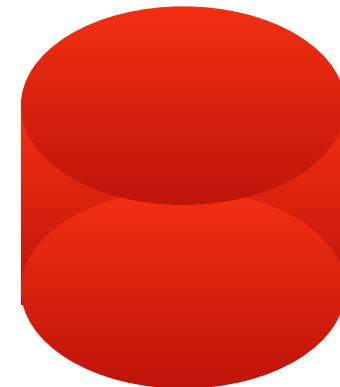
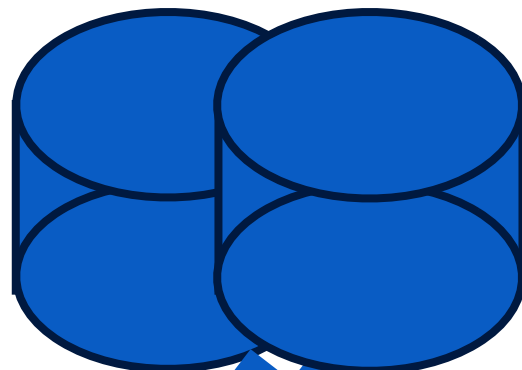


**Standards Library
(SHARE)**

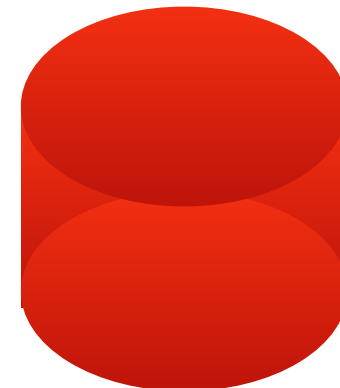


**SDTM
CDASH**

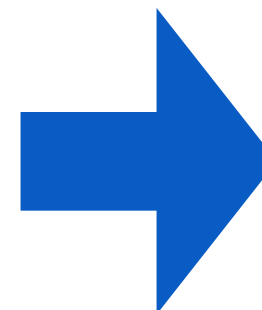
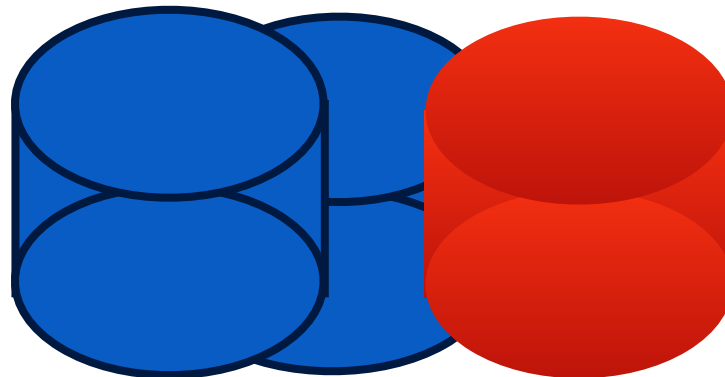
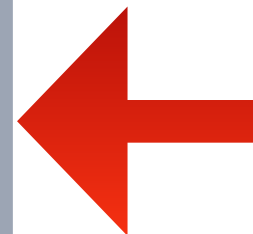
**Study Metadata
Repository**



**Import
I**



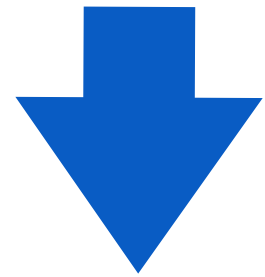
**Import
II**



**SDTM
Define.XML
Result.XLS**

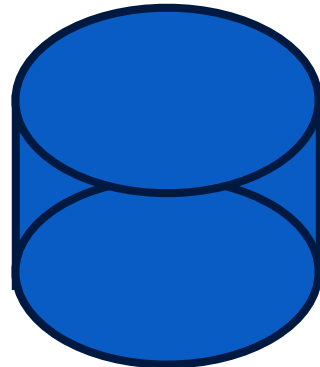
CDISC

Metadata driven



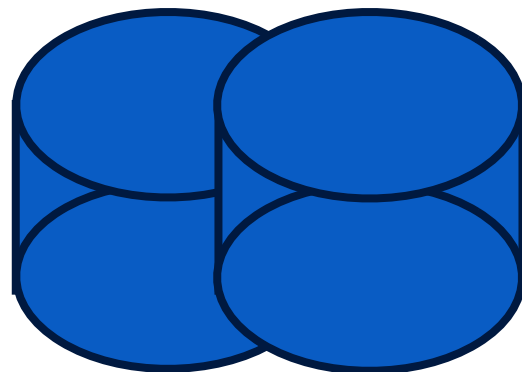
Metadata

**Standards Library
(SHARE)**



**SDTM
CDASH**

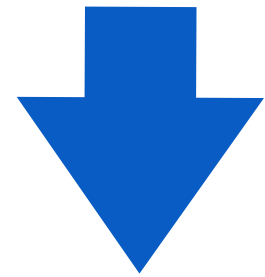
**Study Metadata
Repository**



**SDTM
Define.XML
Result.XLS**

CDISC

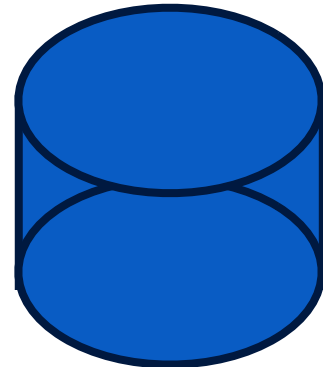
Metadata driven



Metadata

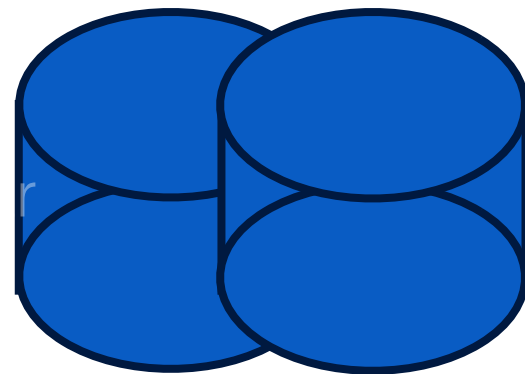
**Study Build
/ SDTM**

**Standards Library
(SHARE)**

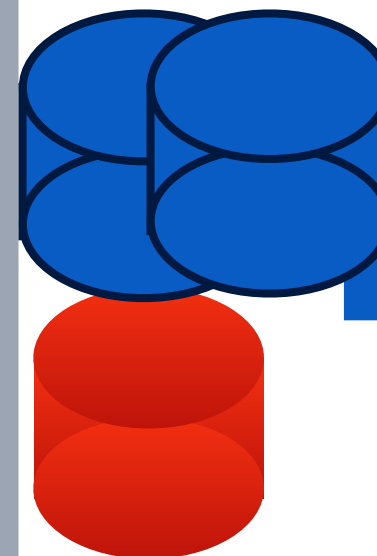
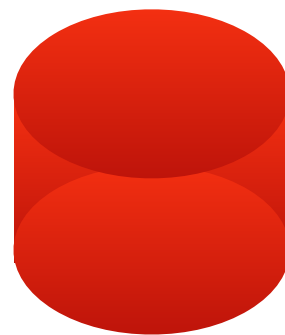
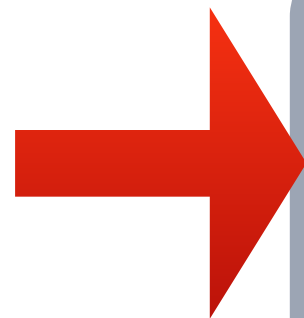


**SDTM
CDASH**

**Study Metadata
Repository**



**eCRF
Blank.CRF**



**SDTM
Define.XML
Result.XLS**

7. New Study with eCRF Step by Step

Define Study and Visit's

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
 - > 13 Cycle 4 Day 15
 - > 14 Cycle 5 Day 1
 - > 15 Cycle 5 Day 8
 - > 16 Cycle 5 Day 15
 - > 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
Tags
<STY1A>

Domain
Tags

Subject
Tags / Ini
Tag
<SID1A>
<SBJINI1A>

Visit Tags
<VIS1N>

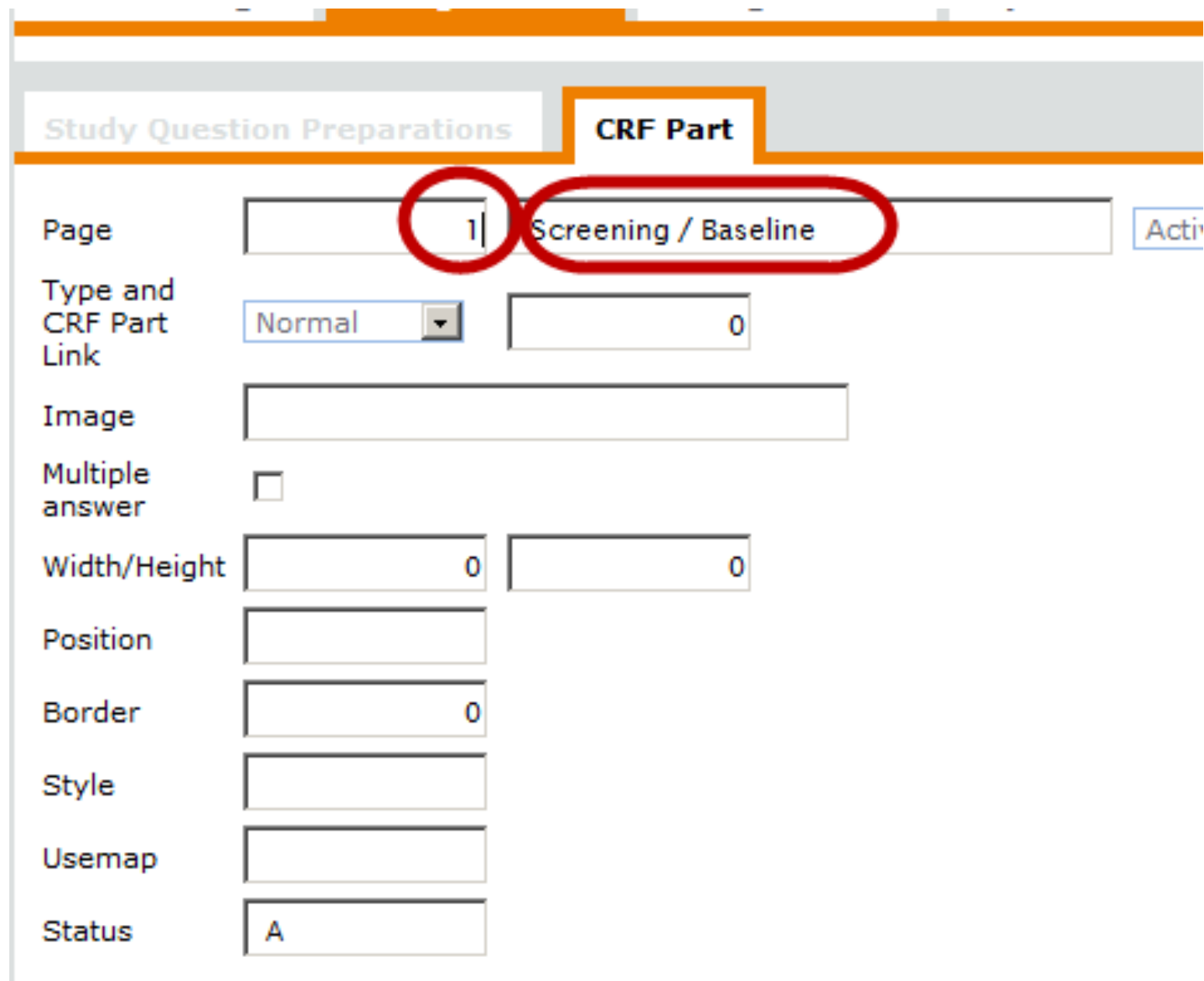
VisitDate
Tag
<VIS1D>
DDMMYYYYY

Page Tag
<PAGE1A>

Fill-in and save with F2

7. New Study with eCRF Step by Step

eCRF "Pages"



The screenshot shows the 'eCRF "Pages"' configuration interface. The 'CRF Part' tab is selected. The 'Page' field is set to '1' and the 'Screening / Baseline' dropdown is highlighted with a red circle. Other fields include 'Type and CRF Part Link' (Normal), 'Image' (empty), 'Multiple answer' (unchecked), 'Width/Height' (0, 0), 'Position' (empty), 'Border' (0), 'Style' (empty), 'Usemap' (empty), and 'Status' (A).

Field	Value
Page	1
Screening / Baseline	Screening / Baseline
Type and CRF Part Link	Normal
Image	
Multiple answer	☐
Width/Height	0 0
Position	
Border	0
Style	
Usemap	
Status	A

7. New Study with eCRF

Step by Step

Create eCRF by "Drag and Drop"

The screenshot displays the 'Study Question Preparations' interface. On the left, a sidebar lists study variables, with 'WGT1N' circled in red. A large red arrow points from this variable to the 'Drop Question' form in the main area. The form contains the following fields:

- Drop Question:** (Text input field)
- Parameter Name:** WGT1N (Circled in red)
- Question Title (Edit):** Vital Signs (Circled in red)
- Question Instru. (Edit):** (Text input field)
- Question Prompt (Edit):** Weight (Kg) (Circled in red)
- Delete This Question:** (Button)
- Drop Sub-Question:** (Text input field)

The top navigation bar includes 'User Messages', 'Study Management', 'Data Management', and 'DashBoard Reports'. The left sidebar also includes a 'Drop for eCRF Structure' label with a red arrow pointing to the 'Drop Question' form.

7. New Study with eCRF Step by Step

eCRF and BlankCRF

Project 1002 Oncology Novartis / Study 10023 ABC789 / Center -1 / Patient -1005 / Visit 1 11.03.2012 /
Screening / Baseline

Vital Signs

Weight (Kg)

90

OK



Print page 

7. New Study with eCRF Step by Step

eCRF and BlankCRF

SGS

Page 2 von 3

Basel, 29.05.2012

Screening/Baseline

DM = Demographics

Date of birth:

Answer

30.04.2012

BRTHDTC when DMTESTCD = DOB1D

Sex:

Answer

☐

Male

☐

Female

SEX when DMTESTCD = SEX1C

7. New Study with eCRF

Step by Step

SDTM Generate

- > ■ Reports
- > ■ SignalFrame
- ▼ ■ SDTM
 - 01 Common Identifier Variables
 - 02 Common Timing Variables
 - AE Adverse Event
 - CM Concomitant Medications
 - CO Comments
 - DA Drug Accountability
 - DM Demographics
 - DS Disposition
 - EX Exposure
 - LB Laboratory Test Results
 - MH Medical History
 - QS Questionnaires
 - SC Subject Characteristics
 - SV Subject Visits
 - TU Tumor Identification
 - TV Trial Visits
 - **VS Vital Signs**
 - XD Dermatology
 - YY yy test
 - ZI Antineoplastic Therapies
- > ■ DynamicAI
- > ■ Message

Data Capture		Output	
Project:	1002 Oncology Novartis		
Study:	10023 ABC789		
Center:	0		
Patient:	0		
SDTM-All Domains:	VS Vital Signs	+ Generate SDTM-All	+ Downl. 7z SDTM-All
SDTM One Domain:		+ Generate SDTM-One	+ Downl. XML SDTM
SDTM One Domain:		+ Generate XML Direkt	+ Downl. XML SDTM_SUPP
Define.xml:		+ Generate Define XML	+ Downl. 7z SDTM-One

Click for SDTM generate

7. New Study with eCRF SDTM on your Drive

- **SDTM in SAS Export Format;**
The three Oncology domains among the total domains from the converted study.
- **Define.xml**
- **Open CDISC Validation**
- **Report.xls file**
- **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	Name ^	Änderungsdatum	Typ	Größe
CSV				
OpenCdiscValidation	Report.xls	19.03.2012 03:43	Microsoft Excel 97-...	
XML				
XPT				
Query definitions				

Your Benefits from Metadata Driven Software

- **Flexible Capable System.**
- **Covering from "Protocol to Submission".**
- **SDTM Submission included at minimum Cost.**
- **SDTM by hitting the "Button".**
- **Saving Resources.**
- **No EDP Personnel required.**
- **Conversion within 7 days.**
- **Setup within 4 hours.**

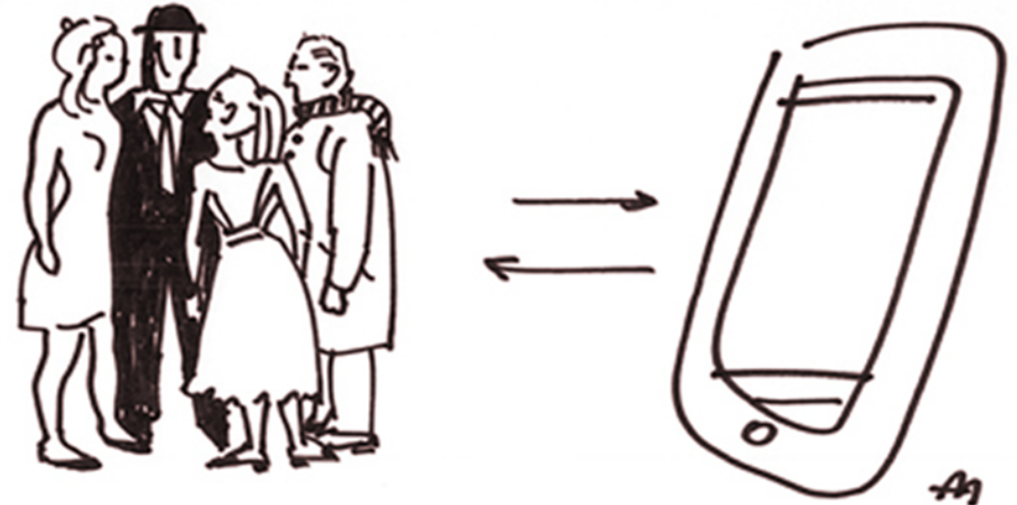
Questions and Contact

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**swiss made
software**

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Clivax delivers SDTM

SDTM per DataPoints

Datapoints		Study 50'000	Study 100'000	Study 500'000	Study 1'000'000	Study 2,000'000	Study 4'000'000
Basis		€ 15'000	€ 15'000	€ 15'000	€ 15'000	€ 15'000	€ 15'000
€ 0.10	0 - 50'000	€ 5'000	€ 5'000	€ 5'000	€ 5'000	€ 5'000	€ 5'000
€ 0.05	-100'000		€ 2'500	€ 2'500	€ 2'500	€ 2'500	€ 2'500
€ 0.025	-500'000			€ 10'000	€ 10'000	€ 10'000	€ 10'000
€ 0.020	-1'000'000				€ 10'000	€ 10'000	€ 10'000
€ 0.015	-2'000'000					€ 15'000	€ 15'000
€ 0.010	-4'000'000						€ 20'000
Total		€ 20'000	€ 22'500	€ 32'500	€ 42'500	€ 57'500	€ 77'500