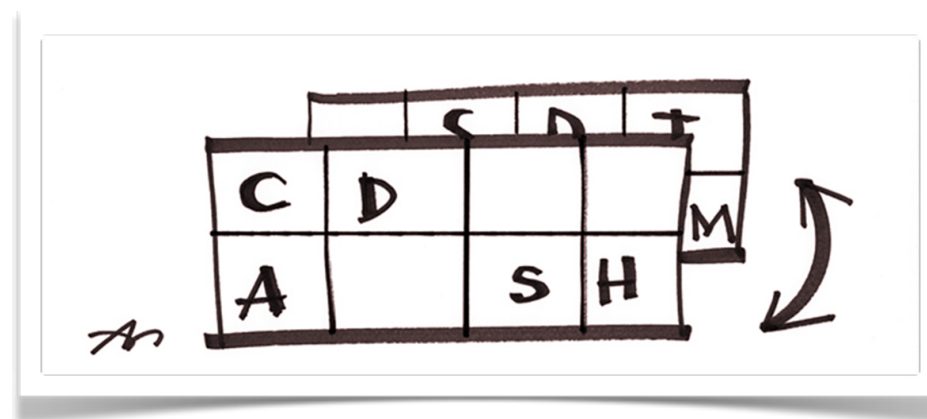
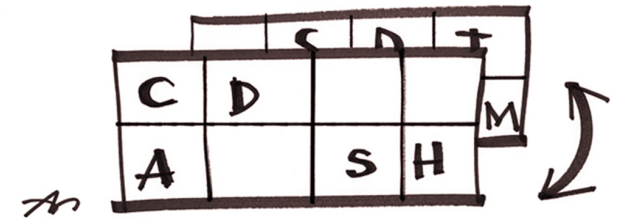


"Overnight" Conversion to SDTM Datasets





Why CDISC / SDTM ?

FDA is strongly encouraging sponsors to submit data in standard form as a key part of its efforts to continue with advancement of review efficiency and quality.*

FDA wants SDTM

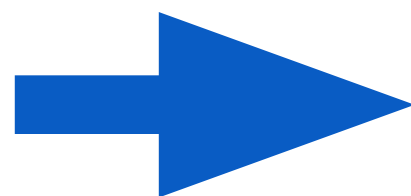
* CDER Common Data Standards Issues Document, May 2011

SDTM Manually or

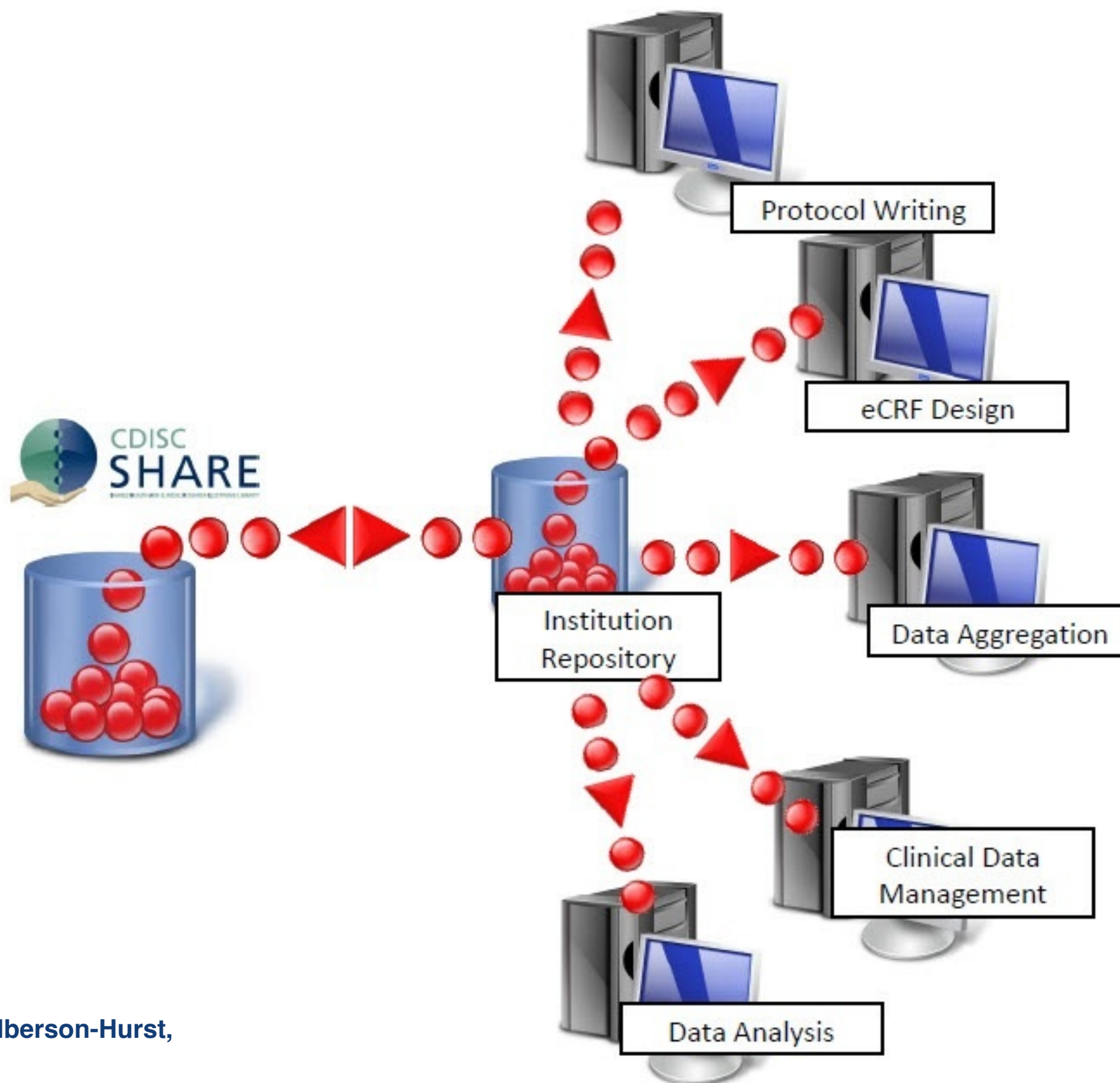
- 1. Your eCRF generates SDTM**
and you get SDTM for "free"
- 2. Conversion from Your Legacy Data**
Automated "Overnight" - cost efficient

Clivax is designed for both

Infrastructure



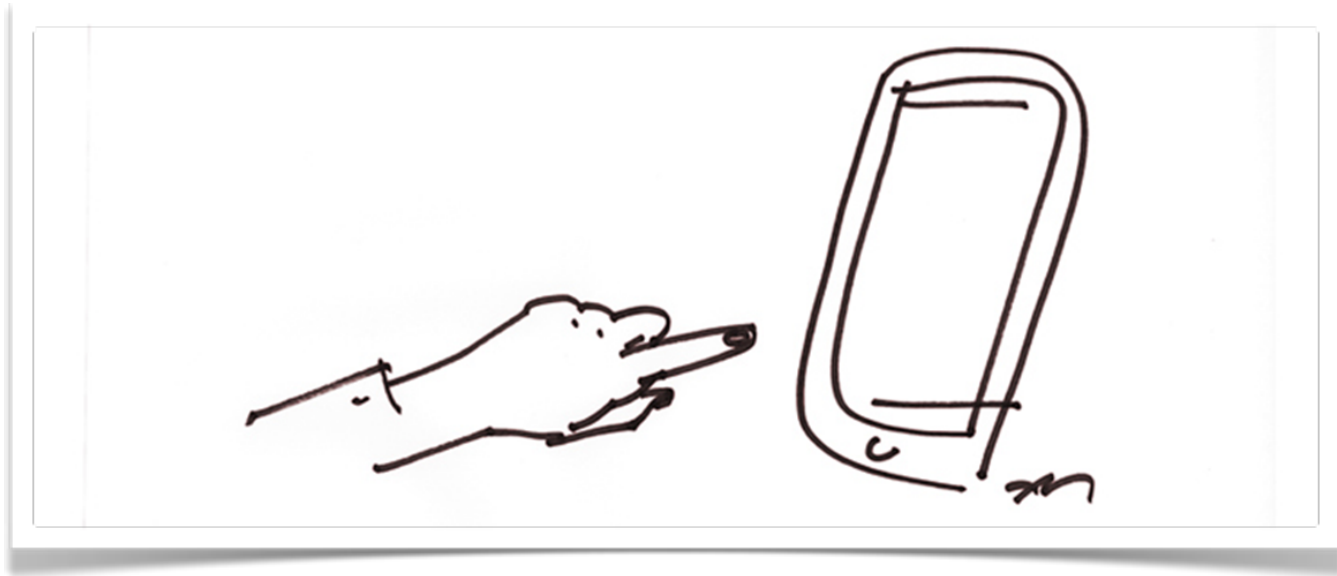
Simplicity



Source: Dave Iberson-Hurst,
CDISC

FDA

Simplicity



Without IT Specialists
100% Browser Based

Clivax ▶

- 5 Applications

- 1 Appl.

- Setup
16 Weeks

- 1 Day

- SDTM
Mapping

- "Free"
Not necessary

- Legacy
Converting
1.5 Man year

- 7 Days

Conversion Project

Legacy Data

**Rawmaterials with 500.000
data points.**

Source Oracle System.

Format SAS.

SDTM

**Final SDTM Datasets 177.000
data points.**

18 Domains.

7 Supp Domains.

Cooperation

CRO: **Independent Clinical Research Consulting**
ICRC-Weyer GmbH, Berlin
Specialist in CDISC / SDTM

Software: **mathiesen & mathiesen AG, Basel**
Developer of CLIVAX

Legacy Data / SAS

c:\dok\clivax\projekte\de_icrc-weyer_berlin\studie_03\testdata\ae.sas7bdat

Library AE

Freeze Hide Show... Format Filter... Font... Find

Table View

	STUDY	DCMNAME	DCMSUBNM	SUBSETSN	DOCNUM	INVSITE	INV	PT	ACCESSTS	
1	ABC1234	ADVERSE EV. 01	AE_01	1	S69441101	013	026	5	30MAR2011:12...	
2	ABC1234	ADVERSE EV. 01	AE_01	1	S69441401	013	026	5	30MAR2011:12...	
3	ABC1234	ADVERSE EV. 01	AE_01	1	S69441601	013	026	5	30MAR2011:12...	
4	ABC1234	ADVERSE EV. 01	AE_01	1	S69441901	013	026	3	18MAR2011:13...	

<AE>

```

<STUDY>ABC1234</STUDY>
<DCMNAME>ADVERSE EV. 01</DCMNAME>
<DCMSUBNM>AE_01</DCMSUBNM>
<SUBSETSN>1</SUBSETSN>
<DOCNUM>S69441101</DOCNUM>
<INVSITE>013</INVSITE>
<INV>026</INV>
<PT>5</PT>
<ACCESSTS>2011-03-30T12:21:46</ACCESSTS>

```

SDTM Data / XML

```
- <EG>
  <STUDYID>PHUSE01</STUDYID>
  <DOMAIN>EG</DOMAIN>
  <USUBJID>PHUSE01.001</USUBJID>
  <EGSEQ>2</EGSEQ>
  <EGTESTCD>INTP</EGTESTCD>
  <EGTEST/>
  <EGCAT/>
  <EGPOS/>
  <EGORRES>ABNORMAL, NOT CLINICALLY SIGNIFICANT</EGORRES>
  <EGORRESU/>
  <EGSTRESC>ABNORMAL, NOT CLINICALLY SIGNIFICANT</EGSTRESC>
  <EGSTRESN>ABNORMAL, NOT CLINICALLY SIGNIFICANT</EGSTRESN>
  <EGSTRESU/>
  <EGSTAT/>
  <EGREASND/>
  <EGMETHOD/>
  <EGBLFL/>
  <EGDRVFL/>
  <EGEVAL/>
  <VISITNUM>0</VISITNUM>
  <VISIT>SCREENING</VISIT>
  <EGDTC>2010-11-30T09:10</EGDTC>
  <EGTPT/>
  <EGTPTNUM>0</EGTPTNUM>
</EG>
```

Domain EG
and
SuppDomain
SUPPEG

```
- <SUPPEG>
  <STUDYID>PHUSE01</STUDYID>
  <RDOMAIN>EG</RDOMAIN>
  <USUBJID>PHUSE01.001</USUBJID>
  <IDVAR>EGSEQ</IDVAR>
  <IDVARVAL>2</IDVARVAL>
  <QNAM>INTP</QNAM>
  <QLABEL>Clinical Significant</QLABEL>
  <QVAL>N</QVAL>
  <QORIG>CRF</QORIG>
  <QEVAL>INVESTIGATOR</QEVAL>
</SUPPEG>
```

SDTM

Domain and Suppdomain

10010_7z_2011-10-02T15_21_57.7z
SUPPXA_XML_2011-10-02T15_21_57.xml
SV_XML_2011-10-02T15_21_57.xml
XA_XML_2011-10-02T15_21_57.xml
SUPPVS_XML_2011-10-02T15_21_57.xml
VS_XML_2011-10-02T15_21_57.xml
SU_XML_2011-10-02T15_21_57.xml
SC_XML_2011-10-02T15_21_57.xml
PE_XML_2011-10-02T15_21_57.xml
SUPPPE_XML_2011-10-02T15_21_57.xml
SUPPML_XML_2011-10-02T15_21_57.xml
ML_XML_2011-10-02T15_21_57.xml
MH_XML_2011-10-02T15_21_57.xml
SUPPMH_XML_2011-10-02T15_21_57.xml
EX_XML_2011-10-02T15_21_57.xml
SUPPEG_XML_2011-10-02T15_21_57.xml
EG_XML_2011-10-02T15_21_57.xml
DS_XML_2011-10-02T15_21_57.xml
SUPPDS_XML_2011-10-02T15_21_57.xml
CM_XML_2011-10-02T15_21_57.xml
CO_XML_2011-10-02T15_21_57.xml
AE_XML_2011-10-02T15_21_57.xml

Legacy Data

5 Conversion Steps (Without Programming)

Study Structure Analysis

1. Define Study
2. Import Raw Data
3. Assign Issues
4. Integrate Assigned Data in System
5. Use Share, Domain

Export SDTM



```
<AE>
<STUDY>123456</STUDY>
<DCMNAME>ADVERSE EV. 01</DCMNAME>
<DCMSUBNM>AE_01</DCMSUBNM>
<SUBSETSN>1</SUBSETSN>
<DOCNUM>S69441101</DOCNUM>
<INVSITE>013</INVSITE>
<INV>026</INV>
<PT>5</PT>
<ACCESSTS>2011-03-30T12:21:46</ACCESSTS>
<LOGINTS>2011-03-16T08:15:12</LOGINTS>
<LSTCHGTS>2011-03-30T12:21:46</LSTCHGTS>
<LOCKFLAG>N</LOCKFLAG>
<CPEVENT>ALL VISITS</CPEVENT>
<DCMDATE />
<DCMTIME />
<REPEATSN>1</REPEATSN>
<ACTEVENT>999</ACTEVENT>
<SUBEVENT_NUMBER>0</SUBEVENT_NUMBER>
<VISIT_NUMBER>999</VISIT_NUMBER>
<QUALIFYING_VALUE>1</QUALIFYING_VALUE>
<QUALIFYING_QUESTION>256501</QUALIFYING_QUESTION>
<LAB />
<LABRANGE_SUBSET_NUMBER>0</LABRANGE_SUBSET_NUMBER>
<LAB_ASSIGNMENT_TYPE_CODE />
<LAB_ID>0</LAB_ID>
<AESPID>1</AESPID>
<AETERM>HEADACHE</AETERM>
<AEDECOD>HEADACHE</AEDECOD>
<AEBODSYS>Nervous system disorders</AEBODSYS>
<AESTDC>20101214</AESTDC>
<AESTTC>0840</AESTTC>
<AESER>N</AESER>
<OTACN1>TREATMENT WITH DRUGS</OTACN1>
<OTACN2 />
<OTACN3 />
<OTACN4>N</OTACN4>
```

[illegible]

Study Structure Analysis II

1	Domain	Variable Name	Variable Label	Role	Source	Origin
244	EG	STUDYID	Study Identifier	Identifier		Assigned
245	EG	DOMAIN	Domain Abbreviation	Identifier		Assigned
246	EG	USUBJID	Unique Subject Identifier	Identifier	PHUSE01 concatenated with PT	Assigned
247	EG	EGSEQ	Sequence Number	Identifier		Derived
248	EG	EGGRPID	Group ID	Identifier		Not submitted
249	EG	EGREFID	ECG Reference ID	Identifier		Not submitted
250	EG	EGSPID	Sponsor-Defined Identifier	Identifier		Not submitted
251	EG	EGTESTCD	ECG Test or Examination Short Name	Topic	HR, PR, QRSDUR, QT, QTcB, QTcF; INTP	Assigned
252	EG	EGTEST	ECG Test or Examination Name	Synonym Qualifier	if EGORRES=HR then EGTEST= Heart Rate; if EGORRES=PR then EGTEST= PR interval; if EGORRES=QRSDUR then EGTEST= QRS interval; if EGORRES=QT then EGTEST= QT interval; if EGORRES=QTcB then EGTEST= QTcB interval; if EGORRES=QTcF then EGTEST= QTcF interval; if EGTESTCD = INTP THEN Interpretation	Assigned
253	EG	EGCAT	Category for ECG	Grouping Qualifier	IF EGTEST='FINDING' THEN EGCAT='FINDING'; IF EGTEST='PR interval', 'QRS interval', 'QT interval', 'QTcB interval' or 'QTcF interval' THEN EGCAT='INTERVAL'; IF EGTEST='HEART RATE' THEN EGCAT='MEASUREMENT'; IF EGTEST='INTERPRETATION' THEN EGCAT=' '	Assigned
254	EG	EGSCAT	Subcategory for ECG	Grouping Qualifier		Not submitted
255	EG	EGPOS	ECG Position of Subject	Record Qualifier		Protocol
256	EG	EGORRES	Result or Finding in Original Units	Result Qualifier		CRF page 13, 41, 44, 47, 82, 85, 88, 123, 126, 129, 150, 158
	EG	EGORRESU	Original Units	Variable Qualifier	EGTESTCD = INTP THEN EG.INTP Controlled Terminology: BEATS/MIN for EGORRES=HR and msec for EGORRES=PR	Assigned

**Working Documents
XLS**

**Domains
and
SuppDomains**

**ECG
Electrocardiography**

	A	B	C	D	E	F	G	H	I	J	K
1	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL	CompMethod
2	"PHUSE01"	"EG"	"PHUSE01" concatenated with subject number	"EGSEQ"	EG.EGSEQ	EGCLSIG	Clinical Significant	if EG.INTP = ABNORMAL, NOT CLINICALLY SIGNIFICANT then QVAL = N; IF EG.INTP = ABNORMAL, CLINICALLY SIGNIFICANT then QVAL = Y	"CRF"	EG.EGEVAL	Only if EG.INTP = ABNORMAL, NOT CLINICALLY SIGNIFICANT OR ABNORMAL, CLINICALLY SIGNIFICANT

Legacy Data

5 Conversion Steps (Without Programming)

Study Structure Analysis

1. Define Study

2. Import Raw Data

3. Assign Issues

4. Integrate Assigned Data in System

5. Use Share, Domain

Export SDTM



1.1 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 II SysAdmin.

Project/Study/Visit/CRF Part

1001 PHUSE

10010 PHUSE01

1 SCREENING

> 10 PER. 1 - DAY 0

> 20 PER. 1 - DAY 1

> 30 PER. 1 - DAY 2

> 40 PER. 1 - DAY 3

> 50 PER. 1 - DAY 4

> 60 PER. 1 - DAY 5

> 70 PER. 1 - DAY 6

> 80 PER. 1 - DAY 7

> 90 PER. 1 - DAY 8

> 100 PER. 1 - DAY 11

> 110 PER. 1 - DAY 15

> 120 PER. 1 - DAY 18

> 130 PER. 2 - DAY 0

> 140 PER. 2 - DAY 1

> 150 PER. 2 - DAY 2

> 160 PER. 2 - DAY 3

> 170 PER. 2 - DAY 4

> 180 PER. 2 - DAY 5

> 190 PER. 2 - DAY 6

> 200 PER. 2 - DAY 7

> 210 PER. 2 - DAY 8

> 220 PER. 2 - DAY 11

> 230 PER. 2 - DAY 15

> 240 PER. 2 - DAY 18

Study Question Preparations

Study

Tools

Study

10010

PHUSE01

Active

SDTM Name

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

Skip Tags

<QUALIFYING_QUESTION>
<LABRANGE_SUBSET_NUMBER>
<LAB_ASSIGNMENT_TYPE_CODE />
<LAB_ID>
<EXO2EX:EXTRT>
<EXO3EX:EXTRT>

1.2 Study Assign to CDISC

Project/Study/Visit/CRF Part

- 1001 PHUSE
- 10010 PHUSE01**
 - 1 SCREENING
 - 10 PER. 1 - DAY 0
 - 20 PER. 1 - DAY 1
 - 30 PER. 1 - DAY 2
 - 40 PER. 1 - DAY 3
 - 50 PER. 1 - DAY 4
 - 60 PER. 1 - DAY 5
 - 70 PER. 1 - DAY 6
 - 80 PER. 1 - DAY 7
 - 90 PER. 1 - DAY 8
 - 100 PER. 1 - DAY 11
 - 110 PER. 1 - DAY 15
 - 120 PER. 1 - DAY 18
 - 130 PER. 2 - DAY 0
 - 140 PER. 2 - DAY 1
 - 150 PER. 2 - DAY 2
 - 160 PER. 2 - DAY 3
 - 170 PER. 2 - DAY 4
 - 180 PER. 2 - DAY 5
 - 190 PER. 2 - DAY 6
 - 200 PER. 2 - DAY 7
 - 210 PER. 2 - DAY 8
 - 220 PER. 2 - DAY 11
 - 230 PER. 2 - DAY 15
 - 240 PER. 2 - DAY 18
 - 250 PER. 3 - DAY 0
 - 260 PER. 3 - DAY 1
 - 270 PER. 3 - DAY 2
 - 280 PER. 3 - DAY 3
 - 290 PER. 3 - DAY 4

Study Question Preparations **Study** **Tools**

Study

SDTM Name

Right Type

Z Type

Start Date

Stop Date

StudyID Tags

Domain Tags

Subject Tags

Visit Tags

Page Tags

1.3 CDISC / SHARE Activate

User Corner
Logged in as **CLIVAXSYS**
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[Logout]

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

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

CLIVAX Paramter for eCRF
v 1001 PHUSE

- v 10010 PHUSE01
 - > 01 Common Identifier
 - > 02 Common Timing Var
 - > AE Adverse Event
 - > CM Concomitant Medic
 - > CO Comments
 - > DM Demographics
 - > DS Disposition
 - > EG ECG Test Results
 - > EX Exposure
 - > LB Laboratory Test R
 - > MH Medical History
 - > ML ML Test
 - > PE Physical Examinat
 - > QS Questionnaires
 - > SC Subject Character
 - > SU Substance Use
 - > SUPP Supplement Gene
 - > SV Subject Visits
 - > VS Vital Signs
 - > XA XA Test

CLIVAX/SDTM Param.for eCRF

Project:	1001 PHUSE	+ Tead		
Study:	10010 PHUSE01	+ Message Amin.	+ Tran. Choice	+ Imp. Items
Domain:		+ Edit Domain	+ New Domain	+ SDTM
Category:				
Sub Category:				
Variable [XXTESTCD] [QNAM]		+ Edit Variable	+ New Variable	
SDTM [XXOCCUR] [XXORRES] [XXSTRESC] [QVAL]		+ Bind Supp		

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

Select Items to be Imported into: Project 1001 PHUSE / Study 10010 PHUSE01 / Domain / Variable...

Parameter + SDTM only SDTM

Origin:	Copy From CDASH Standard	+ Complete CDASH	+ only CDASH-SDTM
Domain:	CM Concomitant Medicatio (26)	+ Complete Domain	+ only SDTM-Domain
Parameter:		+ Selected Parameter	

> Copy From Existing Projects
 v Copy From CDASH Standard
 > 01 Common Identifier Var (1)
 > 02 Common Timing Variabl
 > 03 Screen Failure
 AE Adverse Event (20)
 v CM Concomitant Medicatio (26)
 CMCAT (P)
 CMCLAS (B)
 CMCLASCD (B)
 CMDECOD (B)
 CMDOSE (P)
 CMDOSFRM (B)
 CMDOSFRQ (P)
 CMDOSTOT (P)
 CMDOSTXT (P)
 CMDOSU (P)
 CMENDAT (P)

Legacy Data

5 Conversion Steps (Without Programming)

Study Structure Analysis

1. Define Study

2. Import Raw Data

3. Assign Issues

4. Integrate Assigned Data in System

5. Use Share, Domain

Export SDTM



2. Upload / Import Raw Data

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

CLIVAX Paramter for eCRF
v ■ 1001 PHUSE
■ 10010 PHUSE01

clivax

Contact | Sitemap | AGB

User Messages

Study Management

Data Management

DashBoard Reports

Metadata I Projekt/Study

MetaData II SysAdmin.

Import

Project: 1001 PHUSE

Study: 10010 PHUSE01

Import:

+ Upl. Legacy

+ L. Import I

User Corner
ed in as **CLIVAXSYS**
have no new messages.
out]

clivax

Contact | Sitemap | AGB

User Messages

Study Management

Data Management

DashBoard Reports

Metadata I Projekt/Study

MetaData I SysAdmin.

Import

Import Legacy

Import Legacy

C:\Db_VDF\Vdf16\clivax\DataClivax40\Upload\Phuse01.xml

Durchsuchen...

+ Upload F

Legacy Data

5 Conversion Steps (Without Programming)

Study Structure Analysis

1. Define Study

2. Import Raw Data

3. Assign Issues

4. Integrate Assigned Data in System

5. Use Share, Domain

Export SDTM



User Corner

Logged in as **CLIVAXSYS**

You have no new messages.

[Logout]

CLIVAX Paramter for eCRF

- v ■ 1001 PHUSE
- 10010 PHUSE01

clivax
Contact | Sitemap | AGB

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

Import

Project:	1001 PHUSE				
Study:	10010 PHUSE01	+ Upl. Legacy			
Import:			+ L. Import I		
Assignment:	+ Domain Sdtm	+ Visit Sdtm	+ CrfP Sdtm	+ Prch Sdtm	+ Date/Time
	+ 93imda				
Import:			+ L. Import II		

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.

Import

Domain SDTM

Project: 1001 / Study: 10010

Drop Space	SHARE Domain	SHARE Domain Title
Drop here	01	Common Identifier Variables
Drop here	02	Common Timing Variables
Drop here	03	Screen Failure
Drop here	AE	Adverse Event
CM_01 Drop here	CM	Concomitant Medications
CO_01 Drop here	CO	Comments
CM_02 Drop here	CO	Comments

3.2 Assign Visits

User Corner
Logged in as **CLIVAXSYS2**
You have no new messages.
[Logout]

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

[User Messages](#)
[Study Management](#)
[Data Management](#)
[DashBoard Reports](#)
[Metadata I Projekt/Study](#)
[MetaData II SysAdmin.](#)

[Import](#)
[Visit Sdtm](#)

Project: 1001 / Study: 10010

Drop Space	SHARE Visit Number	SHARE Description
☒ 0	1	Screening
Drop here	1	Screening
Drop here 1	10	PER. 1 - DAY 0
Drop here	20	PER. 1 - DAY 1
Drop here	30	PER. 1 - DAY 2
Drop here	40	PER. 1 - DAY 3
☒ 5	50	PER. 1 - DAY 4
Drop here	50	PER. 1 - DAY 4

Drag Imported Visits
by VISIT NUMBER

- 1
- 2
- 3
- 4
- 9



Drop here

Legacy Data

5 Conversion Steps (Without Programming)

Study Structure Analysis

1. Define Study
2. Import Raw Data
3. Assign Issues
4. Integrate Assigned Data in System
5. Use Share, Domain

Export SDTM



4. Integrate Assigned Data in System

The screenshot displays the Clivax web application interface. The top navigation bar includes the Clivax logo, a 'User Corner' section with login details for 'CLIVAXSYS2', and links for 'Contact', 'Sitemap', and 'AGB'. The main navigation menu features 'User Messages', 'Study Management', 'Data Management', 'DashBoard Reports', 'Metadata I Projekt/Study' (highlighted), and 'MetaData II SysAdmin.'. The 'Import' sub-menu is active, showing a 'Project:' field set to '1001 PHUSE'. A list of import options is visible, including 'Upl. Legacy', 'L. Import I', 'CrfP Sdtm', 'Prch Sdtm', 'Date/Time', and 'L. Import II' (highlighted with a red circle). A modal message box is open, displaying 'Import02 started...' (circled in red) and an 'OK' button.

User Corner
Logged in as **CLIVAXSYS2**
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.**

Import

Project: 1001 PHUSE

+ Upl. Legacy

+ L. Import I

+ CrfP Sdtm | + Prch Sdtm | + Date/Time

+ L. Import II

Message [X]

Import02 started...

OK

Legacy Data

5 Conversion Steps (Without Programming)

Study Structure Analysis

1. Define Study
2. Import Raw Data
3. Assign Issues
4. Integrate Assigned Data in System

5. Use Share, Domain

Export SDTM



5.1 Use Share, SDTM Domain Structure

User Corner
Logged in as **CLIVAXSYS2**
You have no new messages.
[Logout]

clivax

User Messages Study Management Data Management DashBoard Reports

CLIVAX/SDTM Param.for eCRF Sdtm

Project 1001 PHUSE / Study 10010 PHUSE01 / Domain AE Adverse E

Drag from list below

- 01 Common Identifier
 - DOMAIN (S)
 - INVID (S)
 - RDMAIN (P)
 - SITEID (S)
 - SPONSOR (S)
 - STUDYID (S)**
 - SUBJID (S)
 - USUBJID (S)
- 02 Common Timing Var
- AE Adverse Event (18)
 - AEACN (P)
 - AEACNOTH (P)
 - AEBODSYS (P)
 - AECONTRT (P)
 - AEDECOD (P)
 - AEENDC (P)
 - AEENDC_EXC (P)
 - AEENDTC (P)
 - AEENRF (P)
 - AEENTC (P)
 - AEENTC_EXC (P)
 - AELLT (P)
 - AELLTCD (P)
 - AEOTACN1 (P)
 - AEOTACN2 (P)
 - AEOTACN3 (P)
 - AEOTACN4 (P)
 - AEOTAEFRO (P)
 - AEOTENDC (P)
 - AEOTRESULT (P)
 - AEOTRSLT1 (P)

Drop Variable:

STUDYID (S)

SDTM Tags:
< STUDYID > VALUE </ STUDYID >

Delete SDTM Tag

Drop Variable:

SDTM Tags:
< DOMAIN > VALUE </ DOMAIN >

Delete SDTM Tag

```

- <EG>
<STUDYID>PHUSE01</STUDYID>
<DOMAIN>EG</DOMAIN>
<USUBJID>PHUSE01.001</USUBJID>
<EGSEQ>2</EGSEQ>
<EGTESTCD>INTP</EGTESTCD>
<EGTEST/>
<EGCAT/>
<EGPOS/>
<EGORRES>ABNORMAL, NOT CLINICALLY S
<EGORRESU/>
<EGSTRESC>ABNORMAL, NOT CLINICALLY
<EGSTRESN>ABNORMAL, NOT CLINICALLY
<EGSTRESU/>
<EGSTAT/>
<EGREASND/>
<EGMETHOD/>
<EGBLFL/>
<EGDRVFL/>
<EGEVAL/>
<VISITNUM>0</VISITNUM>
<VISIT>SCREENING</VISIT>
<EGDTC>2010-11-30T09:10</EGDTC>
<EGTPT/>
<EGTPTNUM>0</EGTPTNUM>
</EG>
  
```

User Corner
Logged in as **CLIVAXSYS2**
You have no new messages.
[\[Logout\]](#)

clivax

Contact | Sitemap | AG

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

CLIVAX Paramter for eCRF

- 1001 PHUSE
 - 10010 PHUSE01
 - 01 Common Identifier
 - DOMAIN (S)
 - INVID (S)
 - RDOMAIN (P)
 - SITEID (S)
 - STUDYID (S)**
 - Category
 - Sub Category
 - SDTM Variable
 - Question Title
 - Instructions
 - Prompt
 - Help Text
 - CDASH Core
 - Parameter Type
 - Formula
 - Chart / Yes
 - Validation /
 - Adverse Even
 - SUBJID (S)
 - USUBID (S)

CLIVAX/SDTM Param.for eCRF

Variable

Domain [XX] 01

Categorie [XXCAT]

Sub Categorie [XXSCAT]

[XXDECOD]

Variable [XXTESTCD] STUDYID

[QNAM]

Status Active

CDASH STUDYID

SDTM [XXOCCUR] STUDYID

[XXORRES]

[XXSTRESC]

[QVAL]

CLIVAX/SDTM Param.for eCRF

Edit ParameterType

Variable STUDYID Question Title What is the study identifier?

Specifications

Parameter Type ASCII

Choice Type 0 none [Create New Choice](#)

Formula

cd11stud.title_01

5.2 Assign SDTM Parameters

5.3 Assign SDTM Parameters II

Tead ID:

Domain:

Clivax Variable:

Term:

Term	Target01	Target02	Value01	Factor
INTP	EGCAT	EGCAT		0.00000
INTP	EGEVAL	EGEVAL	INVESTIGATOR	0.00000
INTP	EGMETHOD	EGMETHOD		0.00000
INTP	EGORRES	EGORRES	cd14pati.value01	0.00000
INTP	EGORRESU	EGORRESU		0.00000
INTP	EGPOS	EGPOS		0.00000
INTP	EGSTRESC	EGSTRESC	cd14pati.value01	0.00000
INTP	EGSTRESN	EGSTRESN	cd14pati.value01	0.00000
INTP	EGSTRESU	EGSTRESU		0.00000
INTP	EGTEST	EGTEST		0.00000
INTP	QEVAL	QEVAL	INVESTIGATOR	0.00000
INTP	QLABEL	QLABEL	Clinical Significant	0.00000

```

- <EG>
  <STUDYID>PHUSE01</STUDYID>
  <DOMAIN>EG</DOMAIN>
  <USUBJID>PHUSE01.001</USUBJID>
  <EGSEQ>2</EGSEQ>
  <EGTESTCD>INTP</EGTESTCD>
  <EGTEST/>
  <EGCAT/>
  <EGPOS/>
  <EGORRES>ABNORMAL, NOT C
  <EGORRESU/>
  <EGSTRESC>ABNORMAL, NOT C
  <EGSTRESN>ABNORMAL, NOT C
  <EGSTRESU/>
  <EGSTAT/>
  <EGREASND/>
  <EGMETHOD/>
  <EGBLFL/>
  <EGDRVFL/>
  <EGEVAL/>
  <VISITNUM>0</VISITNUM>
  <VISIT>SCREENING</VISIT>
  <EGDTC>2010-11-30T09:10</EGDTC>
  <EGTPT/>
  <EGTPTNUM>0</EGTPTNUM>
</EG>
  
```

5.4 SDTM / Supplement Domain - Bind

```

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<RDOMAIN>EG</RDOMAIN>
<USUBJID>PHUSE01.001</USUBJID>
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<IDVARVAL>2</IDVARVAL>
<QNAM>INTP</QNAM>
<QLABEL>Clinical Significant</QLABEL>
<QVAL>N</QVAL>
<QORIG>CRF</QORIG>
<QEVAL>INVESTIGATOR</QEVAL>
</SUPPEG>
  
```

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:	1001 PHUSE	+ Tead		
Study:	10010 PHUSE01	+ Message Amin.	+ Tran. Choice	+ Imp. Items
Domain:	EG ECG Test Results	+ Edit Domain	+ New Domain	+ SDTM
Category:				
Sub Category:	2			
Variable [XXTESTCD] [QNAM]	INTP (P)	+ Edit Variable	+ New Variable	
SDTM [XXOCCUR] [XXORRES] [XXSTRESC] [QVAL]	EGORRES	+ Bind Supp		

CLIVAX/SDTM Param.for eCRF | **Bind Supp**

Project:	1001 PHUSE	
Study:	10010 PHUSE01	
Domain:	EG ECG Test Results	
Parameter:	INTP P	
Connected Parameters	INTP INTP (SUPP)	+ Remove this Connection
Clivax Variable	INTP (P)	+ Bind Supp to Parameter

5.5 SDTM / Interpretation - QVAL

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

Variable **INTP** Question Title **INTP**

Specifications

Parameter Type **DERIVED with a calculation**

Choice Type **INTP** **INTP** **Create New Choice**

Formula

cd12tead.value01

Create Parameter Choice Selections

PrCh_id **INTP**

Title **INTP**

SuppDomain:
Positive = Y
Negative = N

Ranking	CodedValue	Description	STRESC	Visible
0	ABNORMAL, CLINIC	ABNORMAL CLINICALLY SIGNIFICANT	1	Y
0	ABNORMAL, NOT CLINICALLY SIGNIFICANT	ABNORMAL NOT CLINICALLY SIGNIFICANT	-1	Y
0	NORMAL	NORMAL	0	Y
0			0	Y

<SUPPEG>

<STUDYID>PHUSE01</STUDYID>

<RDOMAIN>EG</RDOMAIN>

<USUBJID>PHUSE01.001</USUBJID>

<IDVAR>EGSEQ</IDVAR>

<IDVARVAL>2</IDVARVAL>

<QNAM>INTP</QNAM>

<OLABEL>Clinical Significant</OLABEL>

<QVAL>N</QVAL>

<QORIG>CRF</QORIG>

<QEVAL>INVESTIGATOR</QEVAL>

</SUPPEG>

5.6 SDTM / QLABEL, QORIG, QEVAL

CLIVAX/SDTM Param.for eCRF

Tead

Tools

Tead ID

59

Domain

EG

Clivax Variable

EGCLSIG

Term

INVSIGN

Term	Target01	Target02	Value01	F
INVSIGN	QEVAL	INVSIGN	INVESTIGATOR	
INVSIGN	QLABEL	INVSIGN	SUBJECT ELIGIBILITY	
INVSIGN	QORIG	INVSIGN	CRF	

<SUPPEG>

<STUDYID>PHUSE01</STUDYID>

<RDOMAIN>EG</RDOMAIN>

<USUBJID>PHUSE01.001</USUBJID>

<IDVAR>EGSEQ</IDVAR>

<IDVARVAL>2</IDVARVAL>

<ONAM>INTP</QNAM>

<QLABEL>Clinical Significant</QLABEL>

<QVAL>N</QVAL>

<QORIG>CRF</QORIG>

<QEVAL>INVESTIGATOR</QEVAL>

</SUPPEG>

Legacy Data

5 Conversion Steps (Without Programming)

Study Structure Analysis

1. Define Study
2. Import Raw Data
3. Assign Issues
4. Integrate Assigned Data in System
5. Use Share, Domain

Export SDTM



6.1 SDTM Deliver / Export

User Corner
Logged in as CLIVAXSYS2
You have no new messages. [Logout]

Project/Patient
▼ 1001 PHUSE
▼ 10010 PHUSE01
> 1

clivax Contact Sitemap AGB

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

Data Capture

Project:	1001 PHUSE	Managm. Merge Recipients	+ Output
Study:	10010 PHUSE01	Time Mgmt. SD/SN	+ Output
Center:		Reports Exports	+ Output

```
-<EG>
<STUDYID>PHUSE01</STUDYID>
<DOMAIN>EG</DOMAIN>
<USUBJID>PHUSE01.001</USUBJID>
<EGSEQ>2</EGSEQ>
<EGTESTCD>INTP</EGTESTCD>
<EGTEST/>
<EGCAT/>
<EGPOS/>
<EGORRES>ABNORMAL, NOT CLINICALLY SIGNI
<EGORRESU/>
<EGSTRESC>ABNORMAL, NOT CLINICALLY SIGNI
<EGSTRESN>ABNORMAL, NOT CLINICALLY SIGNI
<EGSTRESU/>
<EGSTAT/>
<EGREASND/>
<EGMETHOD/>
<EGBLFL/>
<EGDRVFL/>
<EGEVAL/>
<VISITNUM>0</VISITNUM>
<VISIT>SCREENING</VISIT>
<EGDTC>2010-11-30T09:10</EGDTC>
<EGTPT/>
<EGTPTNUM>0</EGTPTNUM>
</EG>
```

User Corner
Logged in as CLIVAXSYS2
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
 DM Demographics
 DS Disposition
 EG ECG Test Results
 EX Exposure
 LB Laboratory Test Results
 MH Medical History
 ML ML Test
 PE Physical Examination
 QS Questionnaires
 SC Subject Characteristics
 SU Substance Use
 SUPP Supplement General Para
 SV Subject Visits
 VS Vital Signs
 XA XA Test
> DynamicAI
> Message
> Connections

clivax Contact S

User Messages Study Management **Data Management** DashBoard Reports Metadata I Projekt/Study S

Data Capture **Output**

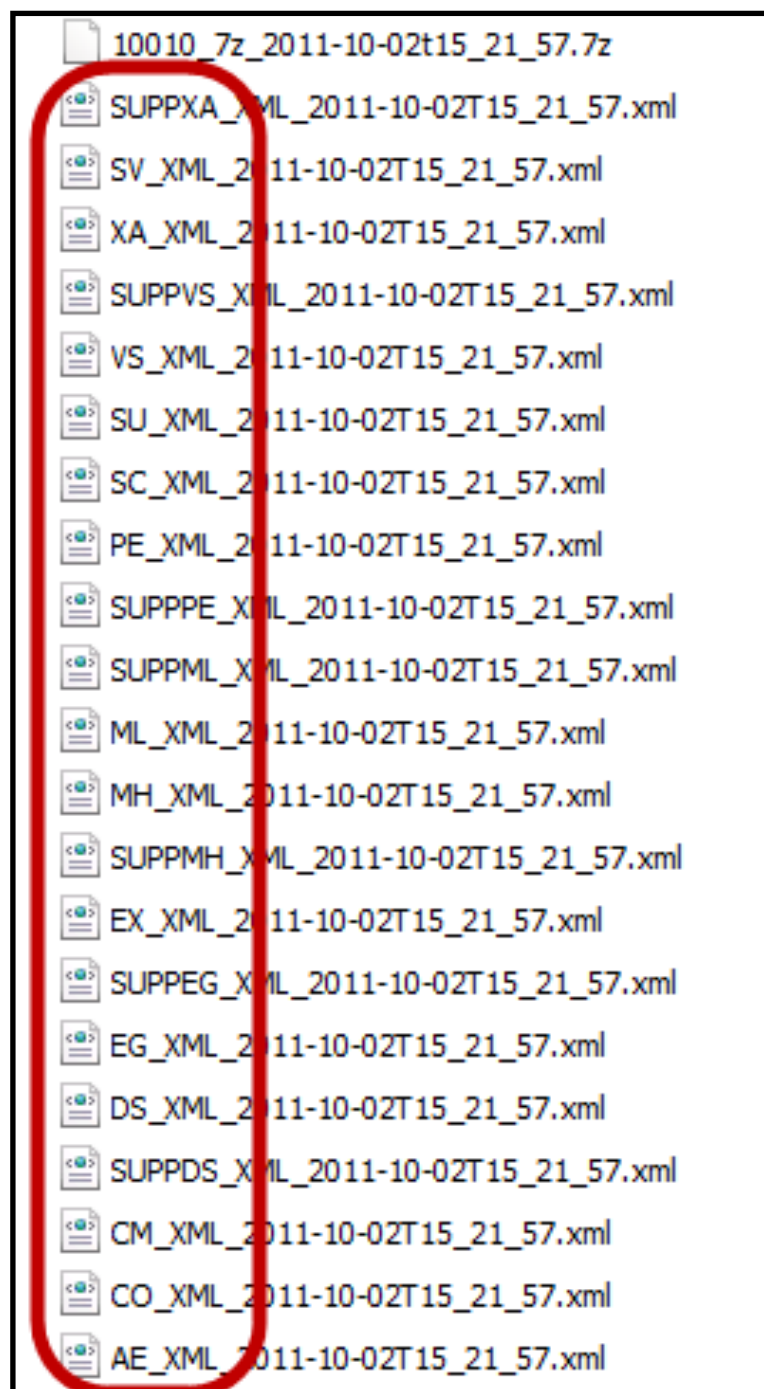
Project:	1001 PHUSE	
Study:	10010 PHUSE01	
Center:	0	
Patient:	0	

SDTM-All Domains:	EG ECG Test Results	+ Generate
SDTM One Domain:		+ Generate SDTM-One
SDTM One Domain:		+ Generate XML Direkt

Domain	Total Patients	Total Rows	Patient Counter	cd11xmld Counter	cd12xmld Counter	Time	xml
EG	20	500	3	0	14	0:0:3:32	

```
-<SUPPEG>
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<RDOMAIN>EG</RDOMAIN>
<USUBJID>PHUSE01.001</USUBJID>
<IDVAR>EGSEQ</IDVAR>
<IDVARVAL>2</IDVARVAL>
<QNAM>INTP</QNAM>
<QLABEL>Clinical Significant</QLABEL>
<QVAL>N</QVAL>
<QORIG>CR</QORIG>
<QEVAL>INVESTIGATOR</QEVAL>
</SUPPEG>
```

6.2 SDTM Deliver / Export



```
- <EG>
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  <DOMAIN>EG</DOMAIN>
  <USUBJID>PHUSE01.001</USUBJID>
  <EGSEQ>2</EGSEQ>
  <EGTESTCD>INTP</EGTESTCD>
  <EGTEST/>
  <EGCAT/>
  <EGPOS/>
  <EGORRES>ABNORMAL, NOT CLINICALLY SIGNIFICANT</EGORRES>
  <EGORRESU/>
  <EGSTRESC>ABNORMAL, NOT CLINICALLY SIGNIFICANT</EGSTRESC>
  <EGSTRESN>ABNORMAL, NOT CLINICALLY SIGNIFICANT</EGSTRESN>
  <EGSTRESU/>
  <EGSTAT/>
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  <VISITNUM>0</VISITNUM>
  <VISIT>SCREENING</VISIT>
  <EGDTC>2010-11-30T09:10</EGDTC>
  <EGTPT/>
  <EGTPTNUM>0</EGTPTNUM>
</EG>
```

```
- <SUPPEG>
  <STUDYID>PHUSE01</STUDYID>
  <RDOMAIN>EG</RDOMAIN>
  <USUBJID>PHUSE01.001</USUBJID>
  <IDVAR>EGSEQ</IDVAR>
  <IDVARVAL>2</IDVARVAL>
  <QNAM>INTP</QNAM>
  <QLABEL>Clinical Significant</QLABEL>
  <QVAL>N</QVAL>
  <QORIG>CRU</QORIG>
  <QEVAL>INVESTIGATOR</QEVAL>
</SUPPEG>
```

Experience / Optimizing

Legacy Data



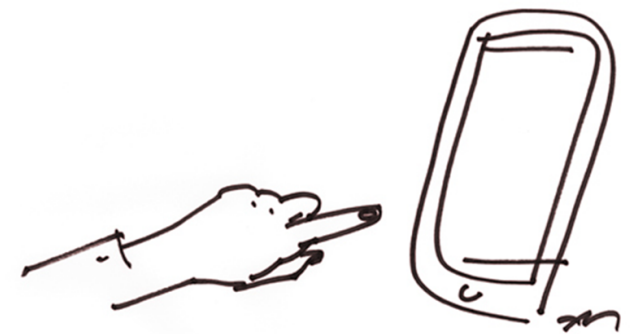
SDTM

Data obtained as "native" as possible
(from the eCRF structure retained)

Data cleaning from a high quality

Unique parameter names makes life easier
(according to the CDISC philosophy)

Source of related data from the same SAS table
(avoid mixing domains)



Clivax delivers SDTM

Legacy Data  **SDTM ("Overnight")**

1. **Speed up the Clinical Trial Process**
2. **SDTM ready before "Start" of Data Input**
3. **SDTM always "Included" and "Free" of charge**
4. **All managed by your Clinical Trial team**
5. **Without IT Specialists**

Questions and Contact

mathiesen & mathiesen
AG für informatik

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+41 61 271 69 42



You will find us at

Stand Number 17