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This demonstration shows how legacy data (in any format) is converted to SDTM datasets. Clivax does the job for you - divided in five simple conversion steps:

- 

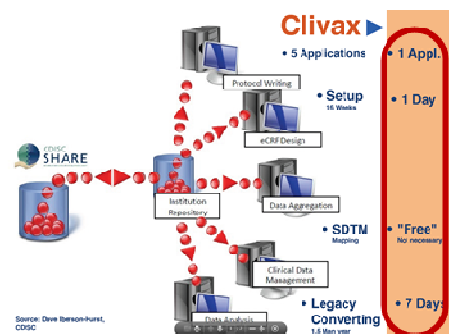
The presentation will be finished with an overview of the built-in power of Clivax. See how the setup of a study can be made within 4 hours - the SDTM submission included. Clivax offers you the ultimate way to take advantage of the compliance with the CDISC / SDTM standard and get SDTM submission for free.

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 has accepted SDTM datasets since 2004. The Center for Drug Evaluation and Research (CDER) has in the document "CDER Common Data Standards Issues Document" from May 2011 taken the opportunity to give feedback and recommendations regarding the submission of standardized datasets.

By the help of the right Software you are helped dramatically in order to be able to generate and submit SDTM datasets. Clivax makes it possible to setup a study within 4 hours - the SDTM submission included. And Clivax is even able to import "Legacy studies" and export the SDTM datasets. Clivax demonstrates that SDTM datasets can be done easy, simple and fast. And you save a lot of time and money. It is the most cost concerned way to produce SDTM datasets.

Clivax is the full service Software for Clinical Trials. Instead of using a multiple number of software with Clivax you cover the process from the very beginning to the Submission. (End to End Solution).

- One Application instead of five
- Setup of new study in one day
- SDTM already included
- Legacy Converting (express over night)



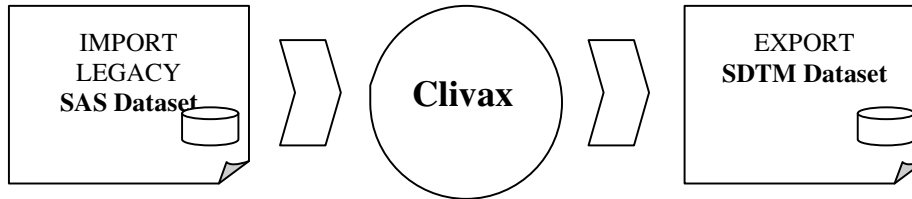
Clivax is designed for submission as SDTM datasets. Without additional programming work you design your SDTM datasets – hit the button and receive your SDTM datasets. Without any additional costs – included in the Clivax software package.

SDTM
submission for
free

PhUSE 2011

4. LEGACY STUDIES

The simple concept of Clivax makes it possible in a extremely simplified process to:



5. DEMONSTRATIONS

For you we have chosen to demonstrate the software live. The most illustrative way is to let it happen in front of your eyes. The JavaScript has been prepared. I can show you following steps:

6. FIVE CONVERSION STEPS

The five simple conversion steps are:

- 1) Import of the “raw” data into the system.
- 2) Assign critical issues with the help of drag and drop.
- 3) Integrate the assigned data into the system.
- 4) Activate the SHARE library and supplement your own SDTM Domains as needed.
- 5) Export the SDTM.

And before we start the automatic running JavaScript I make a resume

6.1 “RAW” DATA IMPORT

Use the Data from your source - Oracle Clinical etc.

ae.sas7bdat	SAS Data Set	785 KB	29.04.2011 12:03
cm.sas7bdat	SAS Data Set	1'041 KB	29.04.2011 12:03
co01co.sas7bdat	SAS Data Set	17 KB	29.04.2011 12:03
dm.sas7bdat	SAS Data Set	17 KB	29.04.2011 12:03
ds01ds.sas7bdat	SAS Data Set	49 KB	29.04.2011 12:03
ds02ds.sas7bdat	SAS Data Set	17 KB	29.04.2011 12:03
eg01eg.sas7bdat	SAS Data Set	417 KB	29.04.2011 12:03
ex01ex.sas7bdat	SAS Data Set	33 KB	29.04.2011 12:03
ex02ex.sas7bdat	SAS Data Set	33 KB	29.04.2011 12:03
ex03ex.sas7bdat	SAS Data Set	33 KB	29.04.2011 12:03
ex04ex.sas7bdat	SAS Data Set	33 KB	29.04.2011 12:03

Example RawData (SAS format)

	NAME	STATUS	ENDOK	MT	PAGE	SUBPAGE	DOI	RECONT	RECHAD	RECHV	RECHP	RECHD	RECHT	RECHC	RECHT	RECHC
1	Testatut	AE	03	05	6	39	1	1	1	HEADACHE	0	0	31AUG2010	31AUG2010	13.15	
2	Testatut	AE	05	09	6	39	1	1	1	1	1	1	08SEP2010	08SEP2010	17.25	
3	Testatut	AE	07	09	6	39	1	1	1	1	1	1	30AUG2010	03SEP2010		
4	Testatut	AE	08	09	6	39	1	1	1	1	1	1	29AUG2010	31AUG2010		
5	Testatut	AE	09	09	6	39	1	1	1	1	1	1	27AUG2010	06SEP2010	9.00	

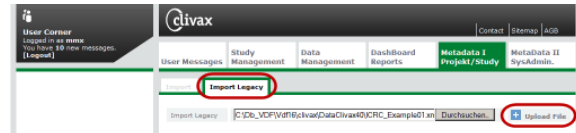
The same
example in
XML format

```
<AE>
<STUDYID>TESTSTUDY</STUDYID>
<DOMAIN>AE</DOMAIN>
<USUBJID>12345</USUBJID>
<EPOCH>6</EPOCH>
<DYNO>DT</DYNO>
<PAGE>39</PAGE>
<SUBVEV>1</SUBVEV>
<SEQ>1</SEQ>
<AECONTR>1</AECONTR>
<AETERM>HEADACHE</AETERM>
<AESD0>0</AESD0>
<AESD09</AESD09>
<AESTD>2010-08-31</AESTD>
<AESTDC />
<AENDD>2010-08-31</AENDD>
<AENDC />
<AESTT>13:15:00</AESTT>
<AESTIC />
<AESTT2>14:15:00</AESTT2>
<AEENTC />
<AECADU>1</AECADU>
<AECACN>0</AECACN>
<AECACNU />
<AECONU>2</AECONU>
<AESGND>2010-09-06</AESGND>
<AESGND1 />
<LLT C>10019211</LLT C>
<LLT C>Headache</LLT C>
<PT C>10019211</PT C>
```

PhUSE 2011

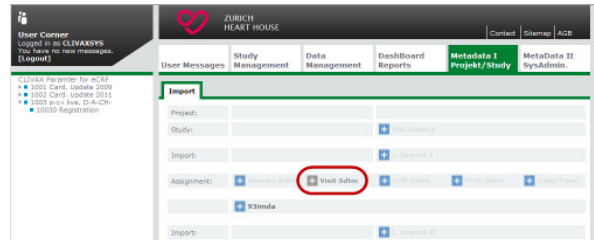
Upload Legacy

Any critical issue is automatically filtered out and prepared for a "handling".

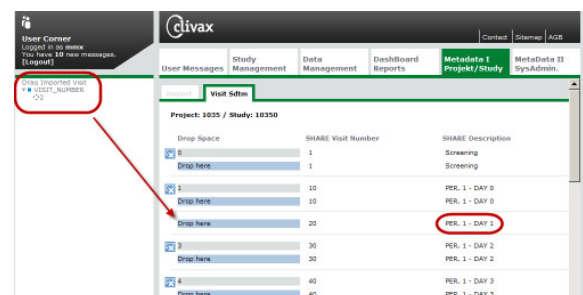


6.2. ASSIGN CRITICAL ISSUES. (DRAG AND DROP)

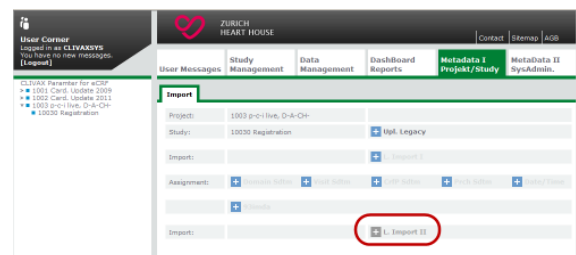
The total critical issues / questions are illustrated and the assignment can be done directly - by using "drag and drop"



Example Visits

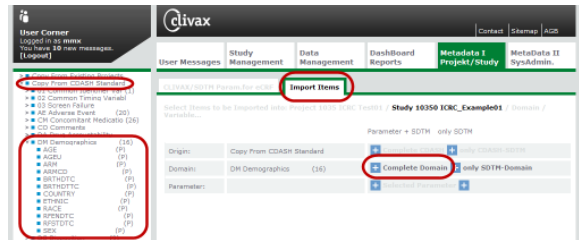


6.3. INTEGRATE THE ASSIGNED DATA INTO THE SYSTEM.



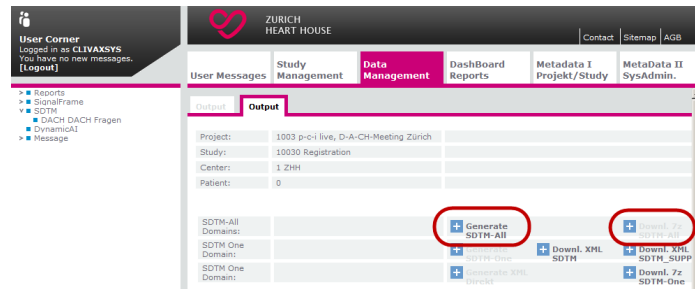
6.4. ACTIVATE THE SHARE LIBRARY

Activate the CDISC/SDTM structures. Use the built in "SHARE" and supplement your own SDTM Domains as needed.



6.5. EXPORT THE SDTM

Export of the SDTM.



The Domain (AE) and the SUPP-Domain (SUPPAE). You choose XML format or SAS format

```
<SUPPAE>
<STUDYID>CDISC01</STUDYID>
<RDOMAIN>AE</RDOMAIN>
<USUBJID>CDISC01.100014</USUBJID>
<IDVAR>AESEQ</IDVAR>
<IDVARVAL>1</IDVARVAL>
<QNAM>LIT</QNAM>
<QLABEL>Lowest Level Term</QLABEL>
<QVAL>Diarrhea</QVAL>
<QORIG>DERIVED</QORIG>
<QEVAL>SPONSOR</QEVAL>
</SUPPAE>
```

```
<AE>
<STUDYID>CDISC01</STUDYID>
<DOMAIN>AE</DOMAIN>
<USUBJID>CDISC01.100014</USUBJID>
<AESEQ>1</AESEQ>
<AETERM>DIARRHEA</AETERM>
<AEMODIFY />
<AEDECOD>Diarrhoea</AEDECOD>
<AEBODSYS>Gastrointestinal disorders</AEBODSYS>
<AESEV>MILD</AESEV>
<AESER>N</AESER>
<AEACN>DOSE NOT CHANGED</AEACN>
<AEREL>NOT RELATED</AEREL>
<AESTDTC>2004-01-06</AESTDTC>
<AEENDTC />
<AESTDY>84</AESTDY>
<AEENDY>0</AEENDY>
<AEENRF>AFTER</AEENRF>
</AE>
```

7. AUTOMATIC RUNNING DEMO

For this we will use the prepared FuncUnit scripts.

1. Phuse_Demo01.js
2. Phuse_Demo02.js
3. Phuse_Demo03.js
4. Phuse_Demo04.js
5. Phuse_Demo05.js

8. "OVERNIGHT"

Just use the latest version of your data to get the actual SDTM version of your data. The process is ready for you - express delivered "overnight"

Name	Größe	Änderungsdatum	Typ
SUPPVS_XML_2011-06-21T10_05_20.xml	3 KB	21.06.2011 10:11	XML-Dokument
SUPPVS_XML_2011-06-21T10_05_20.xml	164 KB	21.06.2011 10:11	XML-Dokument
10010_79_2011-06-21-79	57 KB	21.06.2011 02:26	7Z-Datei
SUPPVS_XML_2011-06-21-79	19 KB	21.06.2011 02:26	XML-Dokument
SV_XML_2011-06-21.xml	132 KB	21.06.2011 02:26	XML-Dokument
KA_XML_2011-06-21.xml	30 KB	21.06.2011 02:26	XML-Dokument
VS_XML_2011-06-21.xml	164 KB	21.06.2011 02:26	XML-Dokument

9. DEFINE.XML

Clivax is able to automatically create a first version of define.xml.

10. ADaM (ANALYSIS DATA MODEL)

If demanded the Clivax structure makes it possible extend the SDTM export with a ADaM export.

11. CLIVAX AND CDISC SHARE IN ACTION - DEMONSTRATION

Demonstration of how you setup a new study within 4 hours. SHARE and Clivax does the job for you and your additional bonus is: **SDTM for free**

The demonstration shows how you make a new study - fast and simple without any programmers or programming work involved.

And generate the corresponding SDTM structure without additional work.

Print the annotated BlankCRF.pdf out as help for a optimization of the eCRF-Design.

Fill in test data in the eCRF and print the SDTM for control.

You have the total SDTM work done for you without additional work.

All based on the "state of the art" web technology.

From anywhere and on any device including your iPad.

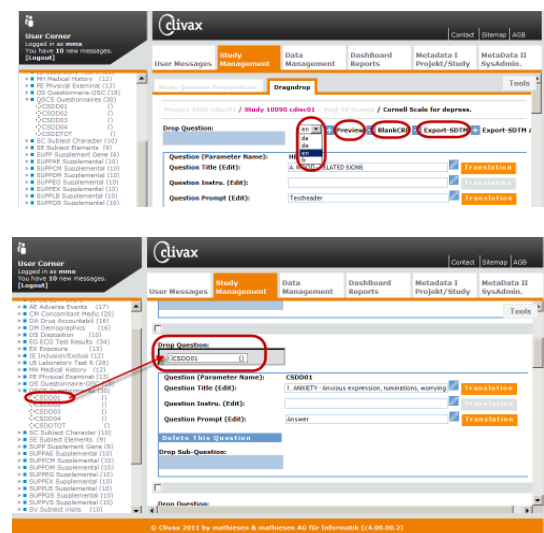
11.1 DESIGN TOOLS (eCRF)

"Drag and drop" your Clinical Trial Input Form

In any Language

And before any data is filled in make the comprehensive test:

- Check immediately the design and functionalities (Preview)
- Print the BlankCRF.pdf for approval by the colleges
- Check the SDTM export. No adaptations are necessary



11.2 eCRF PREVIEW

eCRF Preview

Project: 1000 v01-01 / Study: 10000 v01-01 / Center: 1 / Patient: 1941 / Visit: 10 26.09.2010 /

Cornell Scale for depress.

A. MOOD - RELATED SIGNS

1. ANXIETY - Anxious expression, rumination, worrying

Answer: ☐ Absent ☒ Mild or intermittent ☐ Severe OK

2. SADNESS - Sad expression, and voice, tearfulness

Answer: ☒ Absent ☐ Mild or intermittent ☐ Severe OK

3. LACK OF REACTIVITY TO PLEASANT EVENTS

Answer: ☐ Absent ☐ Mild or intermittent ☒ Severe OK

4. IRRITABILITY - Easily annoyed, short tempered

Answer: ☒ Absent ☐ Mild or intermittent ☐ Severe OK

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11.3 BlankCRF (ANNOTATED)

BlankCRF

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Cornell Scale for depress.

A. MOOD - RELATED SIGNS

OSCS - Questionnaire Cornell Scale

1. ANXIETY - Anxious expression, rumination, worrying

Answer: ☐ Absent ☐ Mild or intermittent ☐ Severe OSCS when OSCSTESTCD = CSD001

2. SADNESS - Sad expression, and voice, tearfulness

Answer: ☐ Absent ☐ Mild or intermittent ☐ Severe OSCS when OSCSTESTCD = CSD002

3. LACK OF REACTIVITY TO PLEASANT EVENTS

Answer: ☐ Absent ☐ Mild or intermittent ☐ Severe OSCS when OSCSTESTCD = CSD003

11.4 eCRF TRANSLATIONS

eCRF Translations

Translation

Translate: **Date of Birth**

Danish Fødselsdag

German Geburtsdatum

English Date of Birth

French Date de naissance

PhUSE 2011

11.5 DATA MANAGEMENT

Data Management



12. COMPLIANT TO FDA 21 CFR PART 11

Clivax comply to FDA 21 CFR Part 11

CONTACT INFORMATION

Your comments and questions are valued and encouraged.

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