Implementing CDISC LAB, ODM and SDTM in a Clinical Data Capture and Management System:

« How we did it »

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[i-clinics]

Who are we?

- [i-clinics] is a software company specialized in image-based solutions for the acquisition and management of clinical trials data

- ClinCAPT is a CDMS offering an integrated system for all modes of acquisition: paper, fax and EDC

- XML4Pharma is a consultancy and Information Technology company specializing in XML for the Pharma industry

Timelines for CDISC Integration

- Preliminary analysis of standards: Q2 2003
- Decision for implementation: Q1 2005
- Selection of partner: Q2 2005
- LAB implementation: Q3 2005
- ODM implementation: Q4 2005
- SDTM implementation: Q1 2006

LAB Implementation

Goal:

Import CDISC LAB-1.0.1 data files into ClinCAPT

Background:

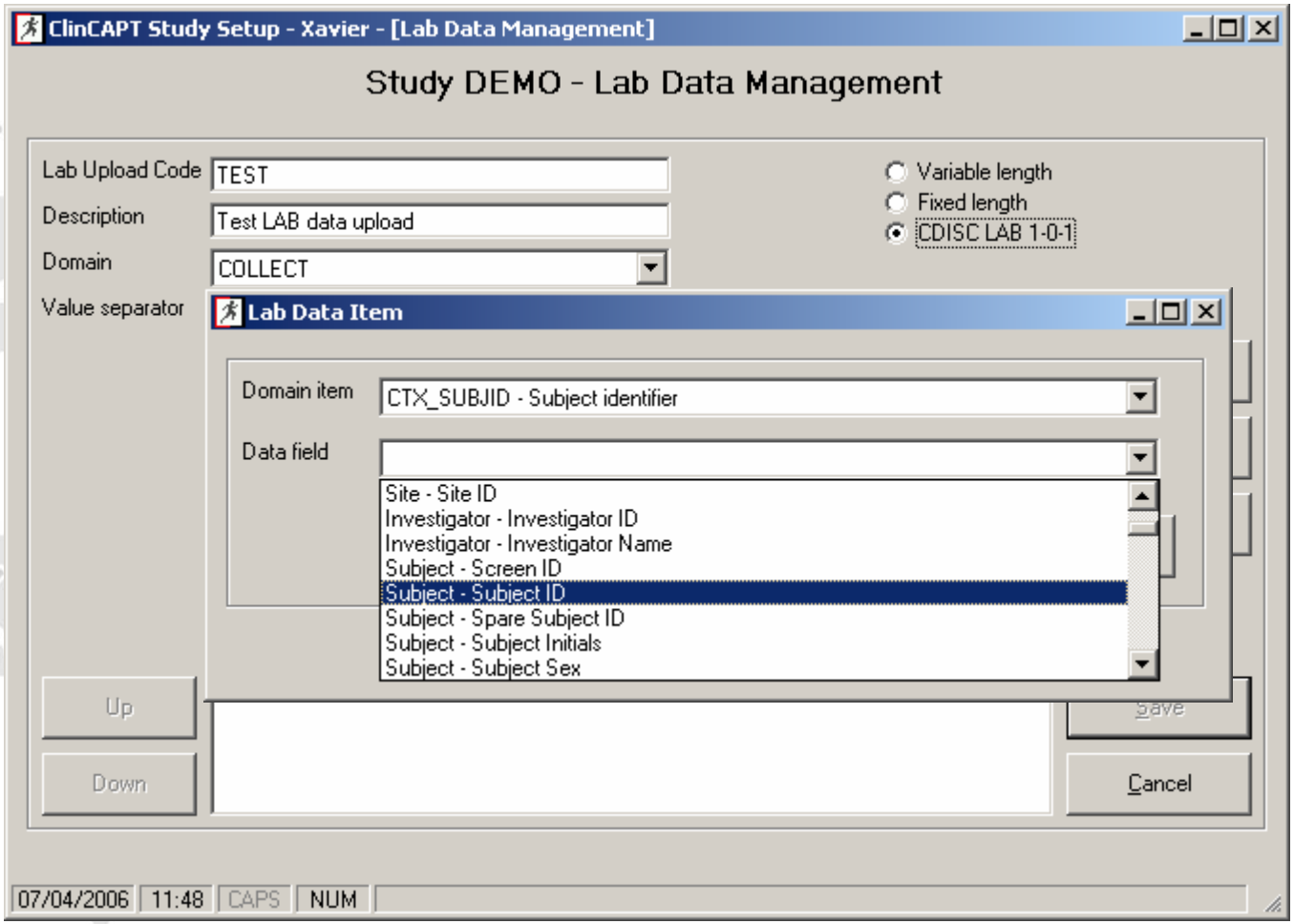
ClinCAPT already included functions to import lab data files in ASCII format:

- Variable length (for instance CSV)
- Fixed length

Scope:

- Flat file only
- Insert & Update, but not Remove

LAB Implementation



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ODM Implementation

Goal:

- Export study metadata to ODM 1.2 format
- Import study data from ODM 1.2 format

Analysis:

Help needed for:

- ODM expertise
- XML expertise
- Conversion Oracle DB <-> XML

Joined Development:

- XSL, DB scripts, Process UI: XML4Pharma
- Main UI, Pre- & Post-processing: [i-clinics]

ODM Implementation

Project tasks:

- Construct a mapping between ClinCAPT database structure and the ODM
- Write the necessary PL/SQL scripts to export Study setup in ODM format
- Develop software / scripts to import clinical data in ODM format into ClinCAPT

ODM Implementation

Mapping between ClinCAPT and ODM:

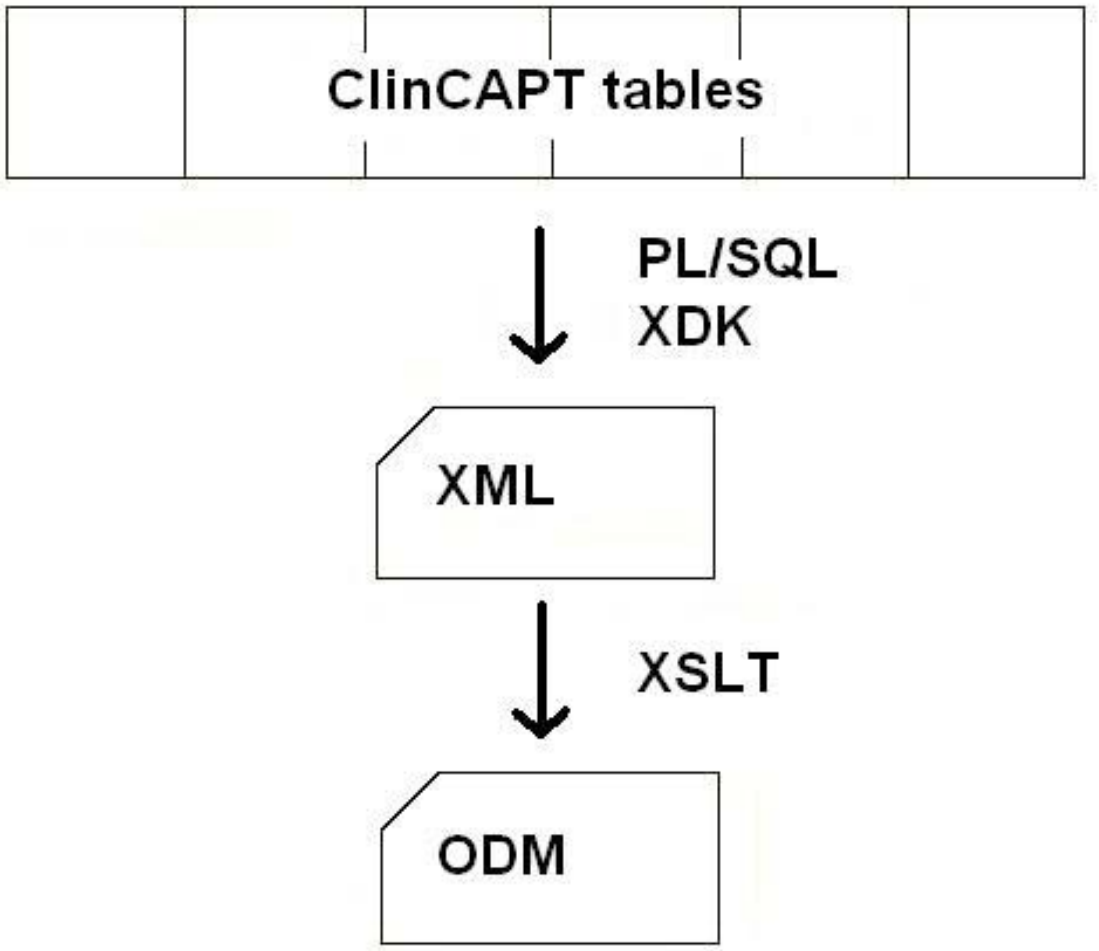
- Study the database structure
- Communicate with the ClinCAPT specialist
- Result: 18-page document describing the mapping

ODM Implementation

Export study metadata to ODM

- Written as a set of PL/SQL scripts
- Uses Oracle XDK technology
  - XML-SQL Utility for PL/SQL
  - XMLDOM package
- Usage of XSLT stylesheets

ODM Implementation



ODM Implementation

Importing ODM Clinical data into ClinCAPT - Strategy

- Split ODM input document into XML structures that correspond to ClinCAPT table structure
- Load XML structures into Oracle tables using Oracle's XML-SQL Utility

ODM Implementation

Importing ODM Clinical data into ClinCAPT - Workflow

- Load ODM file
- Connect to study database
- Verify Country, Investigator, Location against information in database
- Verify Visit ID, Form ID, ItemGroups, Items against database tables
- If all OK, split ODM in XML structures corresponding to database table structures
- Upload XML data using XML-SQL Utility

ODM Implementation

Importing ODM Clinical data into ClinCAPT - Technology

- To split XML documents, we need XSLT2
  - Or write complicated software
- Oracle's 9i XSLT engine does not support XSLT2
- So, a Java GUI was developed
  - Using SAXON as XSLT2 engine
- An XSLT stylesheet was developed to do the transformations

ODM Implementation

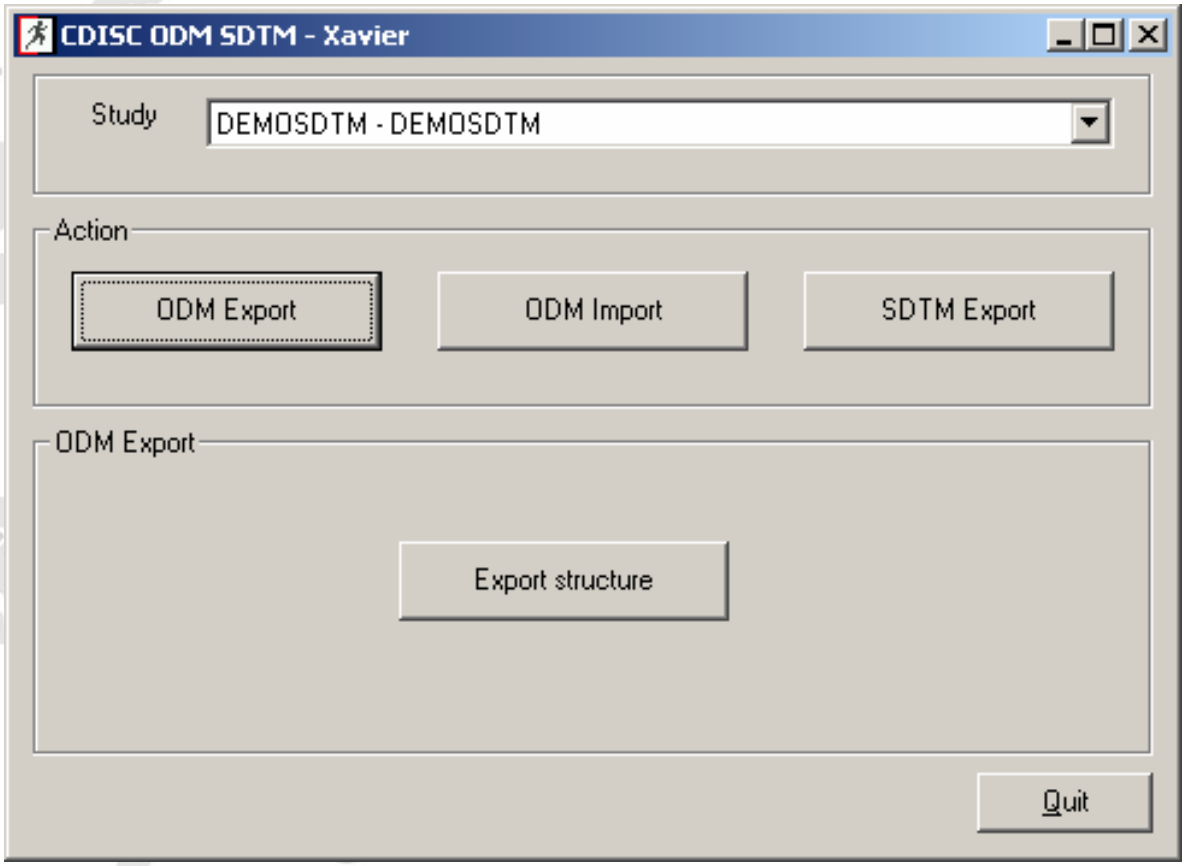
Making a CDMS ODM-compliant
view of a CDISC consultant

- Learn to understand the database structure
- Communicate a lot with your customer
- Use tools and utilities that come with the database as much as possible

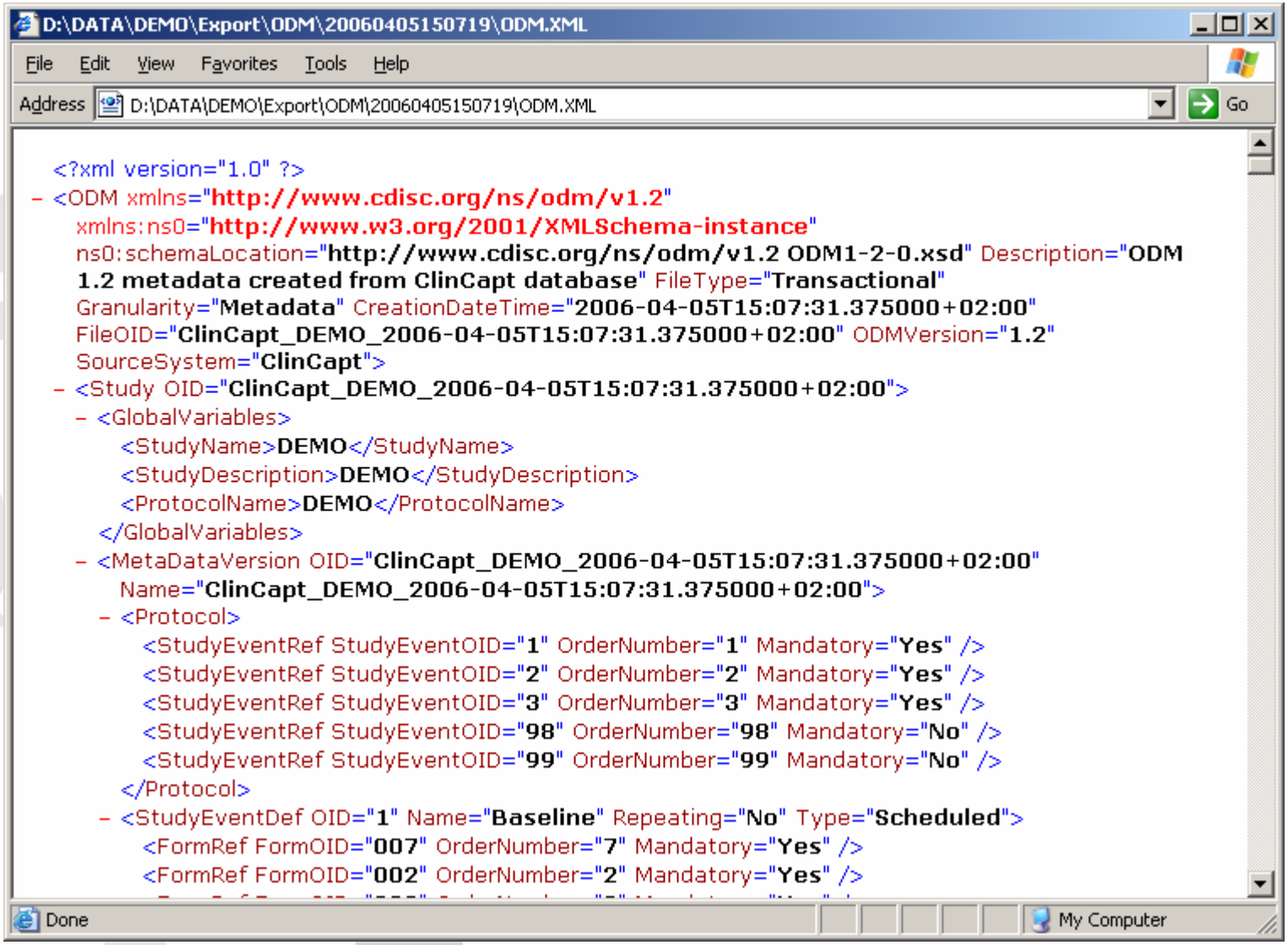
- Making a CDMS CDISC-ODM compliant is easy ...

If you know how

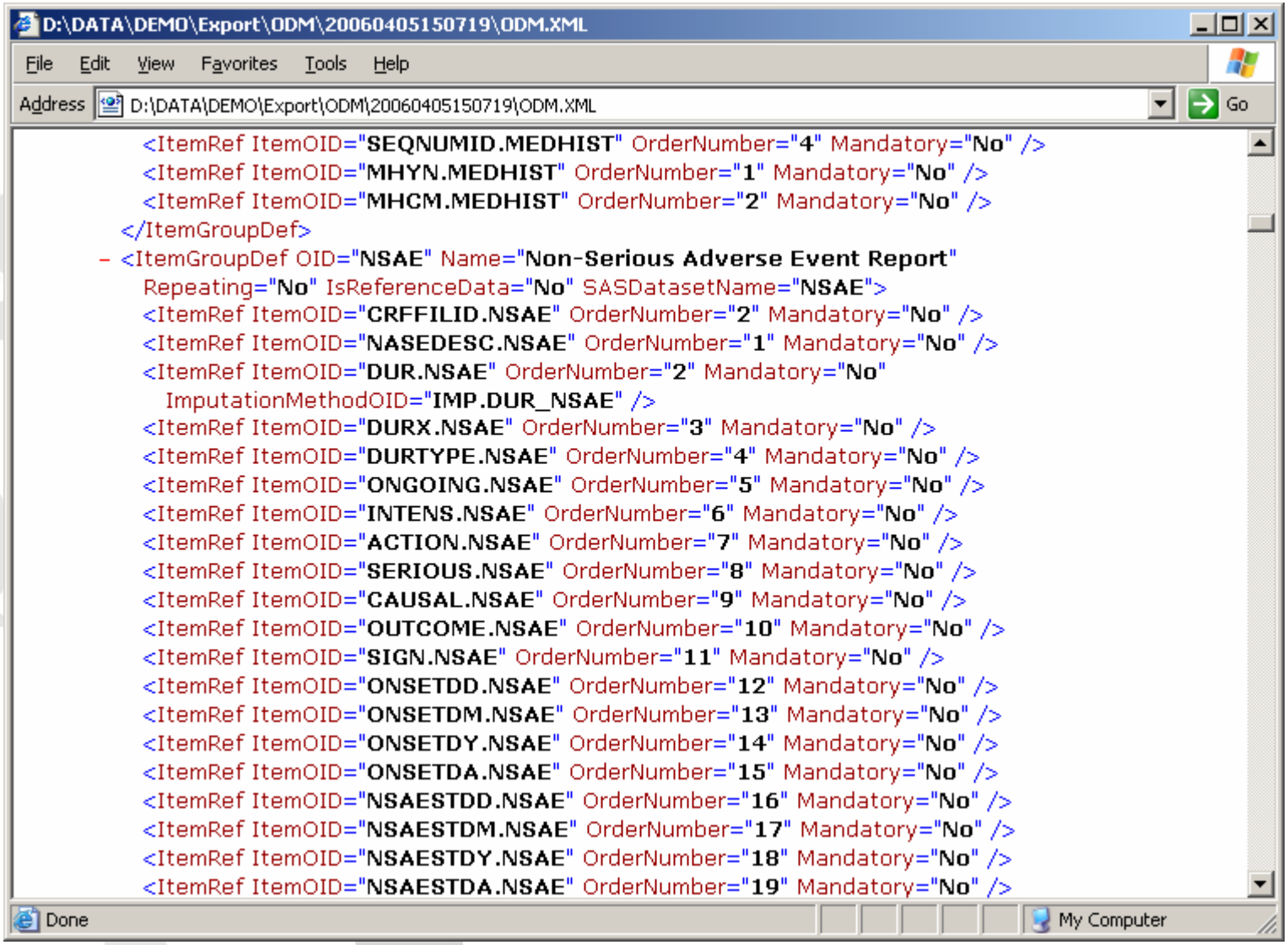
ODM Implementation



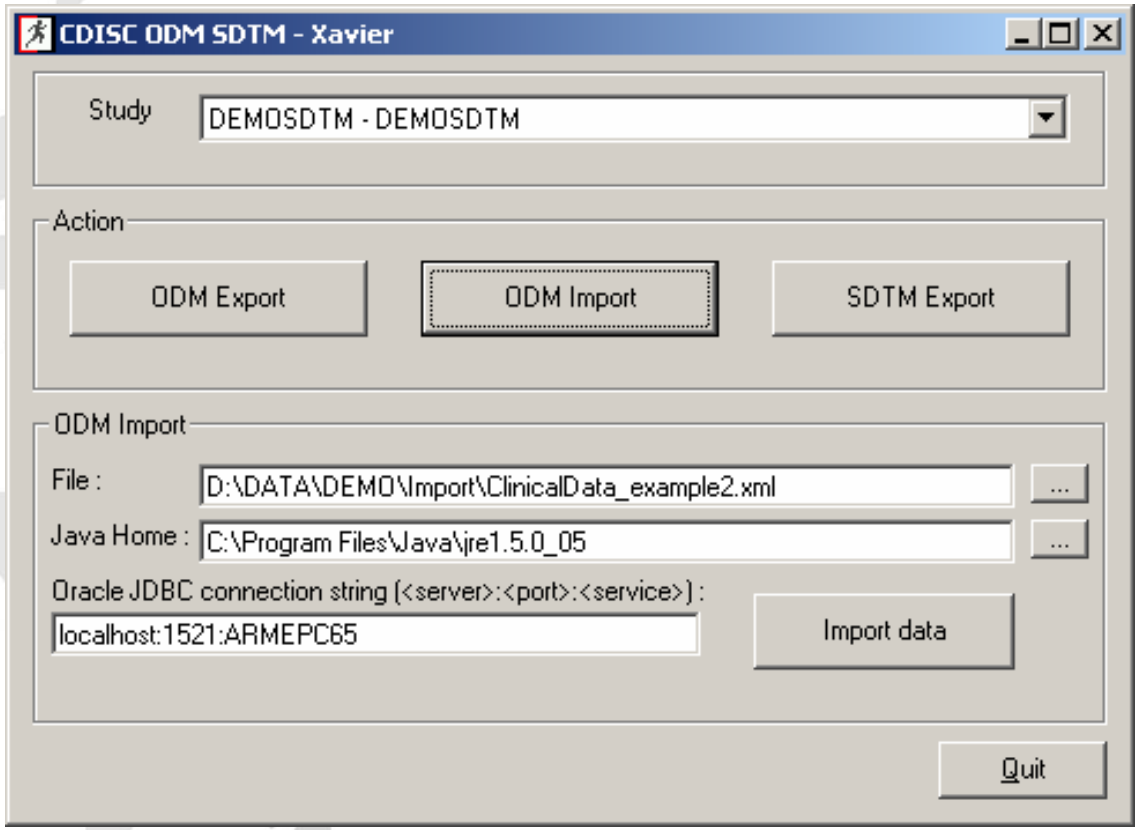
ODM Implementation



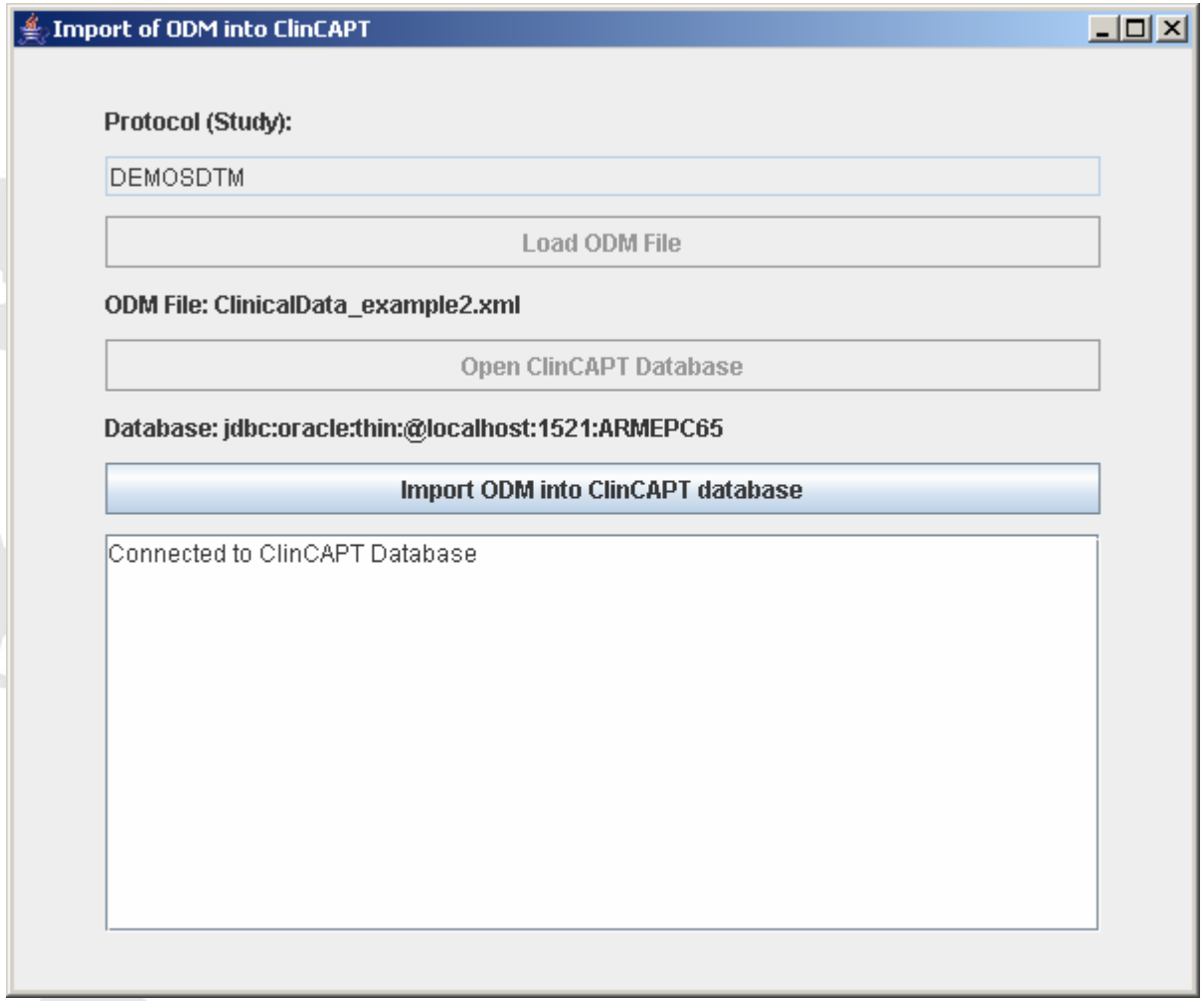
ODM Implementation



ODM Implementation



ODM Implementation



SDTM Implementation

Goal:

Export study data to SDTM 3.1.1 format (SAS and XML)

Background:

Pre-existing SAS XPT export module

Analysis:

- Help needed for crucial decision: SDTM compliance within ClinCAPT or post-processing at export time?
- Help needed to identify hurdles

Scope:

Provide SDTM datasets for statistical analysis

SDTM Implementation

The decision was made to build SDTM compliance within ClinCAPT

Advantages:

- Data model consistency
- Immediate availability of SDTM datasets
- No complex data mapping at export time

Disadvantages:

- SDTM incurs rigid constraints for data model

SDTM Implementation

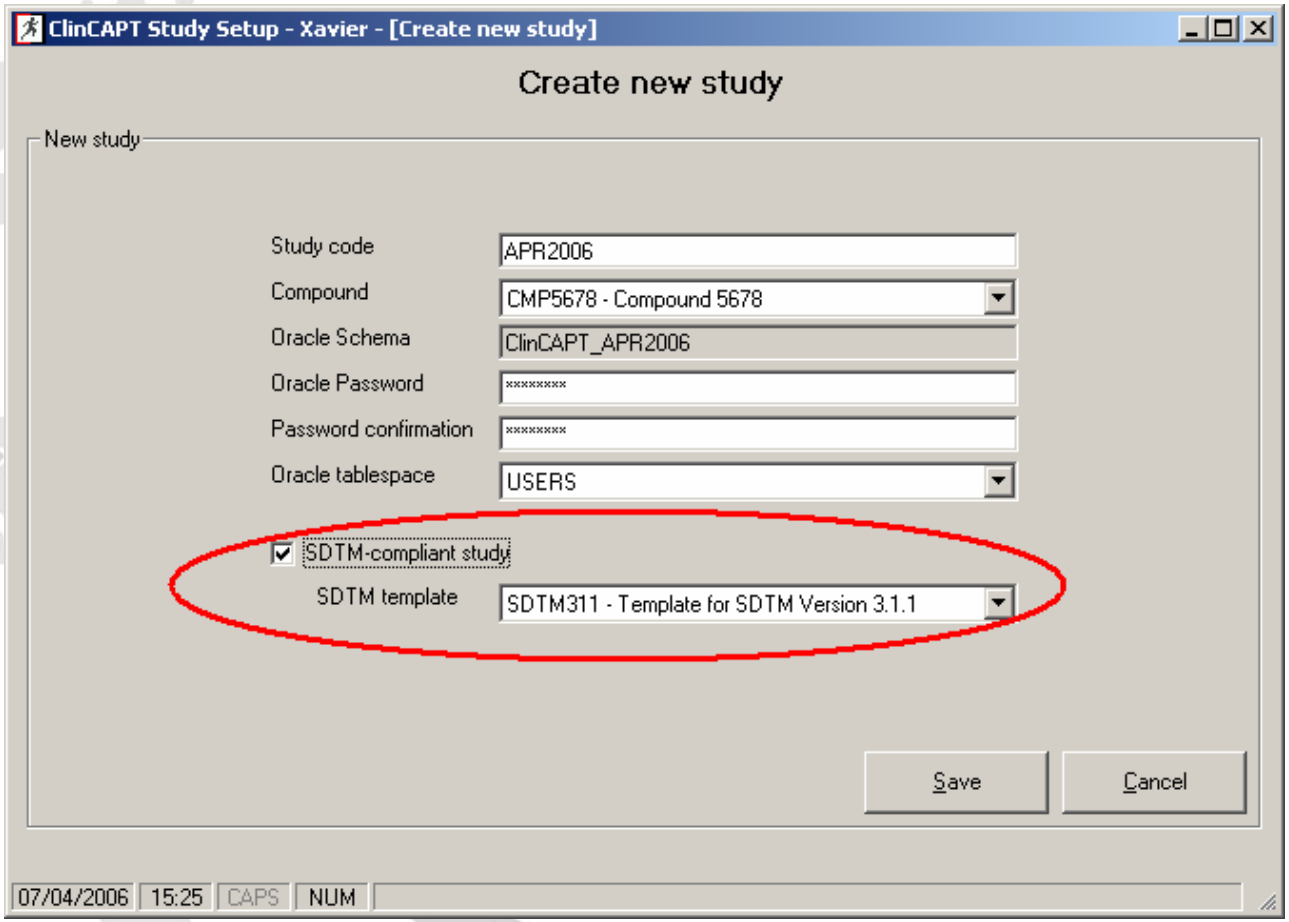
ClinCAPT is delivered with an SDTM library based on SDTM version 3.1.1:

- Codelists (controlled terminologies)
- Valuelists (identifiers)
- Domains & domain items

The library is adapted to the specific requirements of the application, in particular for date handling.

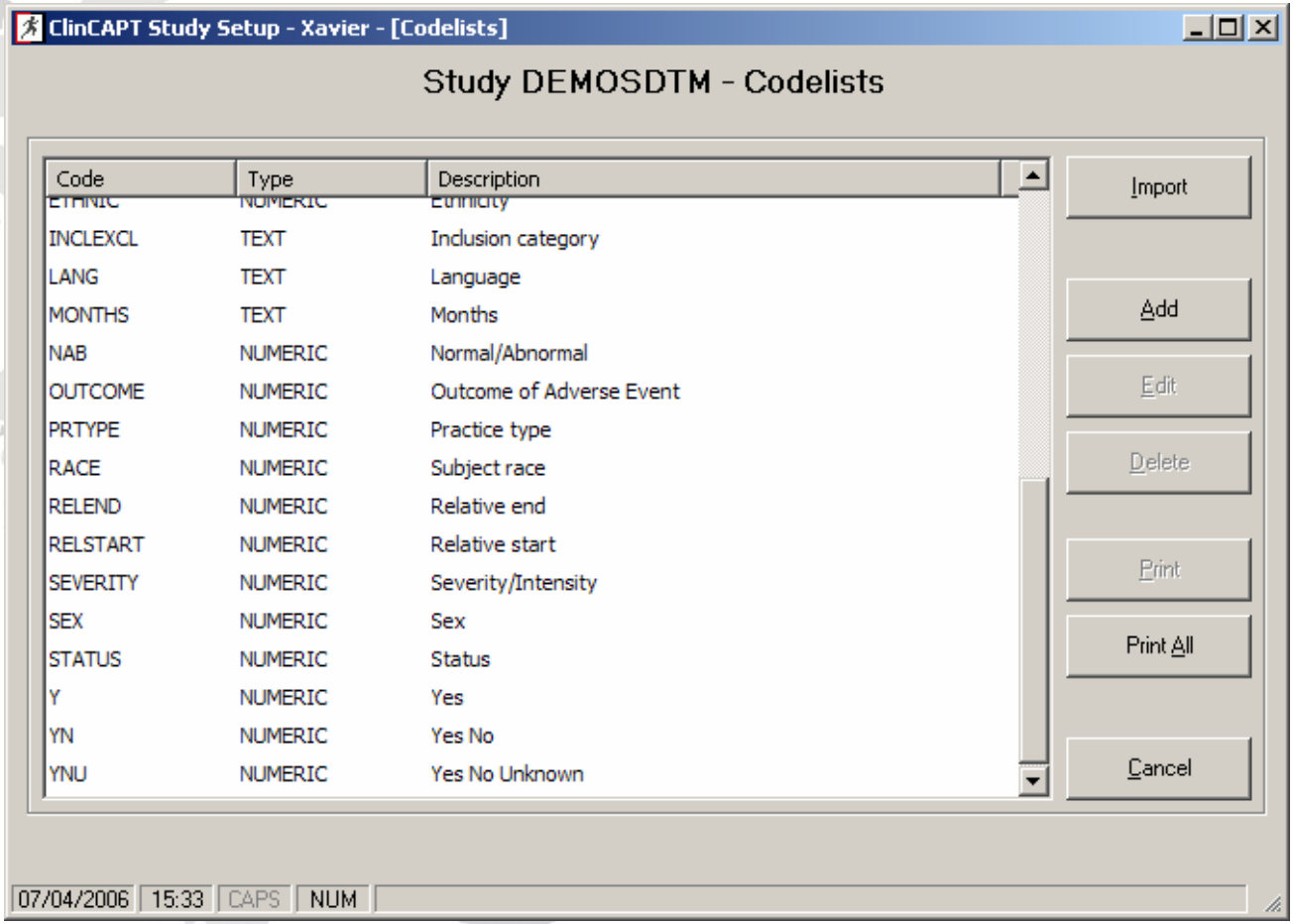
SDTM Implementation

SDTM compliance must be defined when a New study is created:



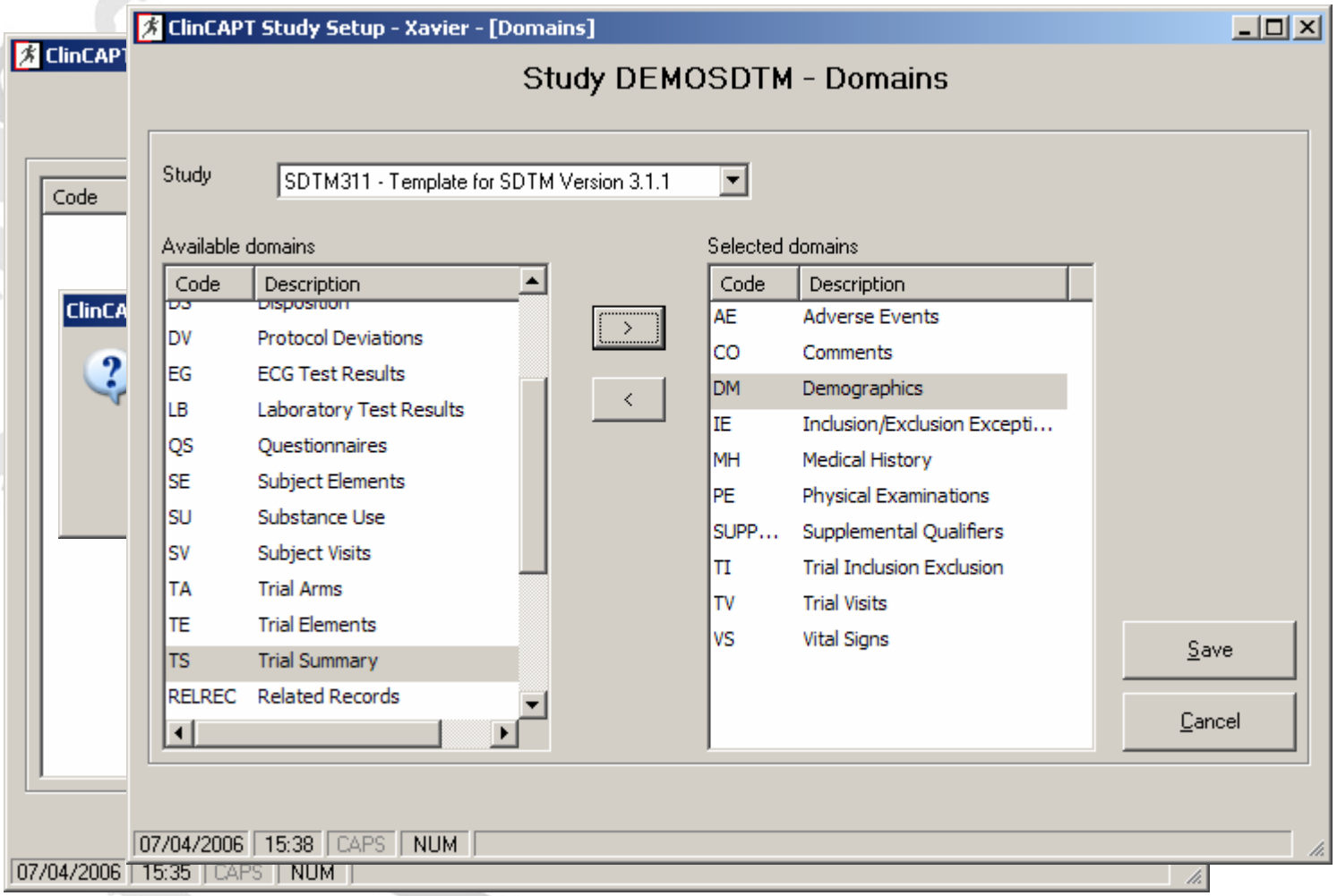
SDTM Implementation

All codelists defined in the library are automatically created:



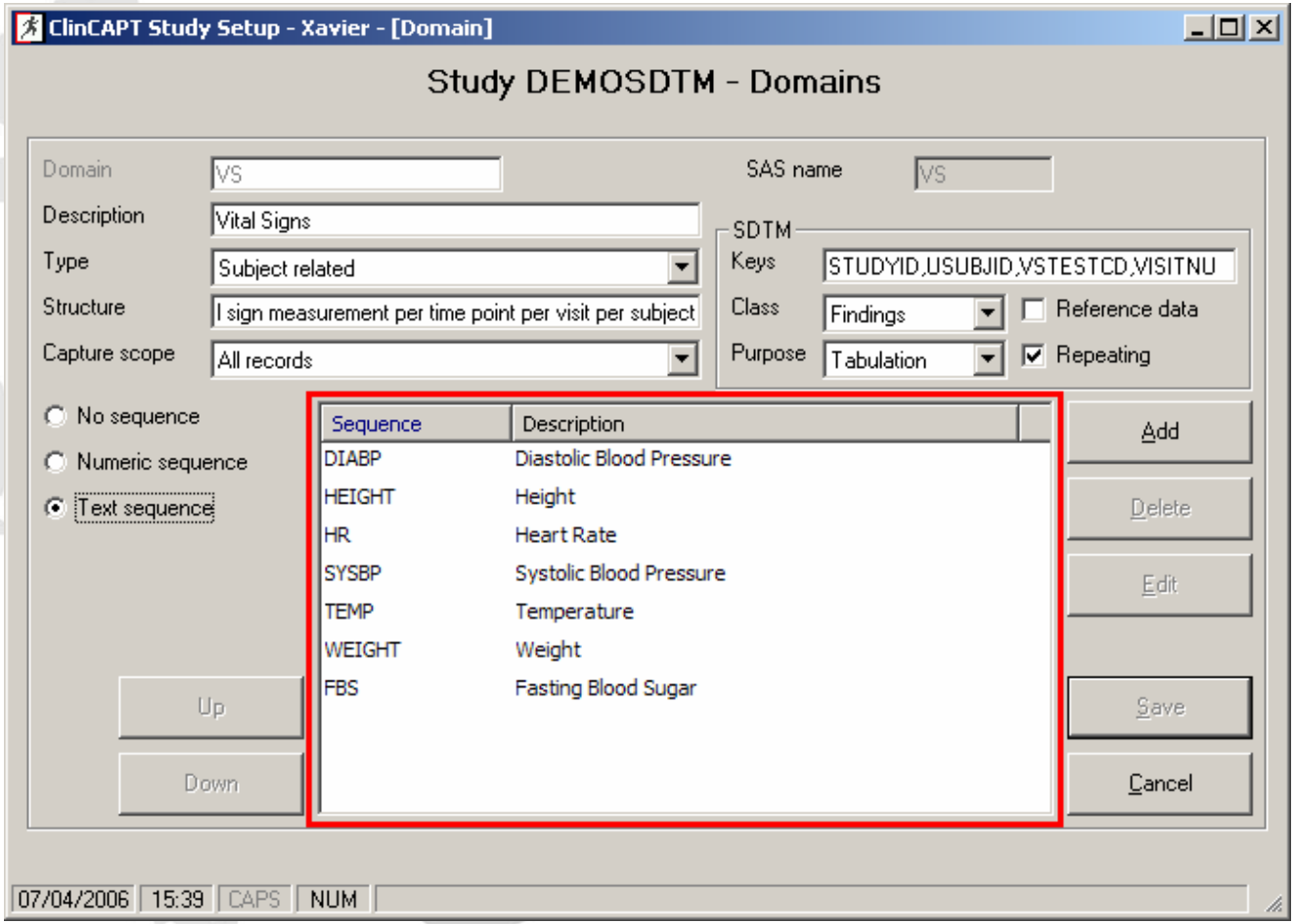
SDTM Implementation

Panels are imported from the library:



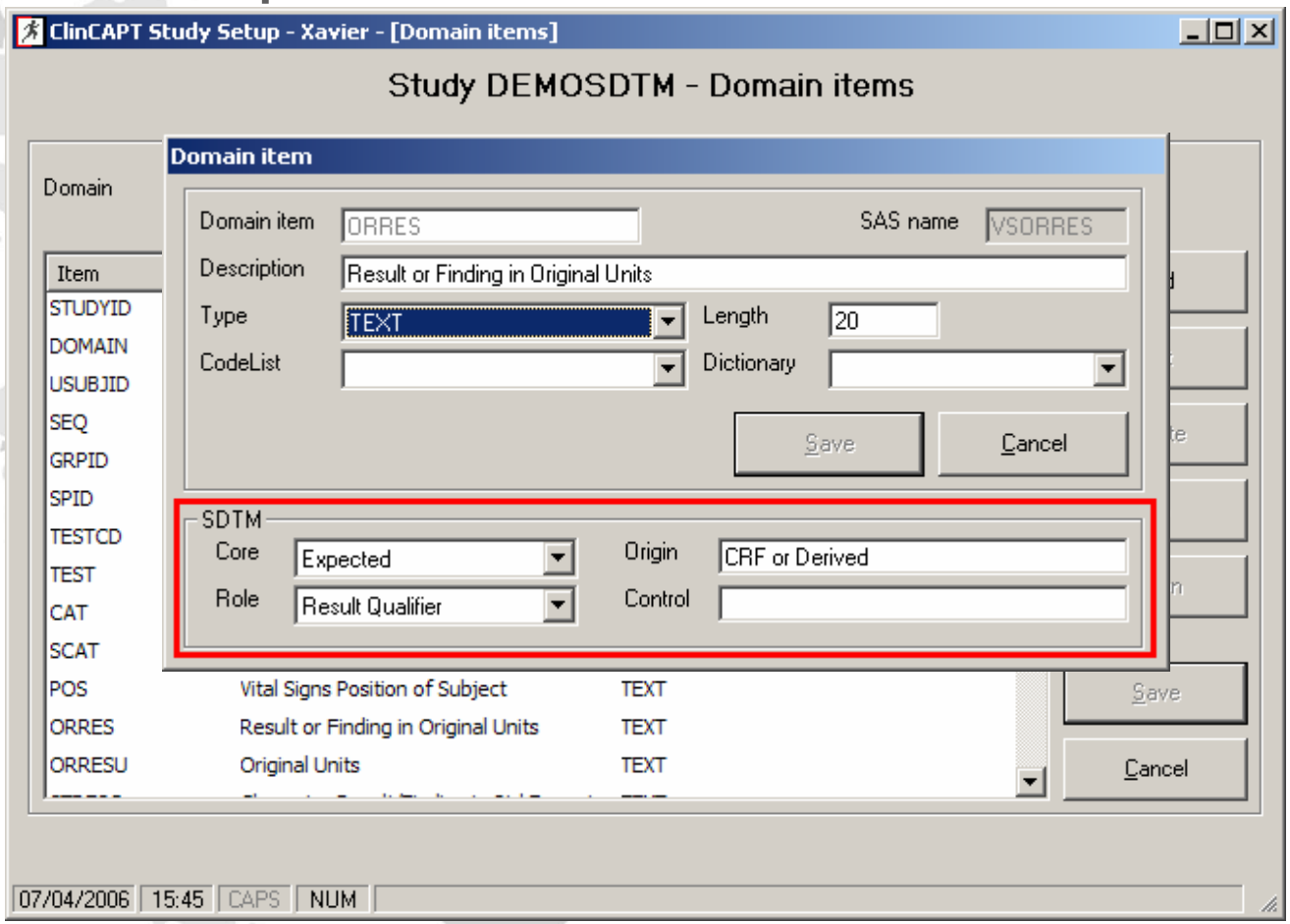
SDTM Implementation

SDTM-specific attributes and identifiers are imported from the library:



SDTM Implementation

Items are imported from the library with SDTM-specific attributes & default data types:



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SDTM Implementation

Main difficulties encountered during the implementation:

Date handling in ClinCAPT

STDTCDD (day)	STDTCDM (month)	STDTCDY (year)	STDTCDA (derived date)	STDTCDH (hour)	STDTCDI (minute)	STDTCDT (derived datetime)
09	MAY	2005	2005-05-09 00:00:00	23	28	2005-05-09 23:28:00
08	MAY	2005	2005-05-08 00:00:00	23		
	APR	2005				
	MAY	2005		23	28	

Date handling in SDTM dataset (ISO 8601)

STDTC
2005-05-09T23:28
2005-05-08T23
2005-04
2005-05

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SDTM Implementation

Main difficulties encountered during the implementation:

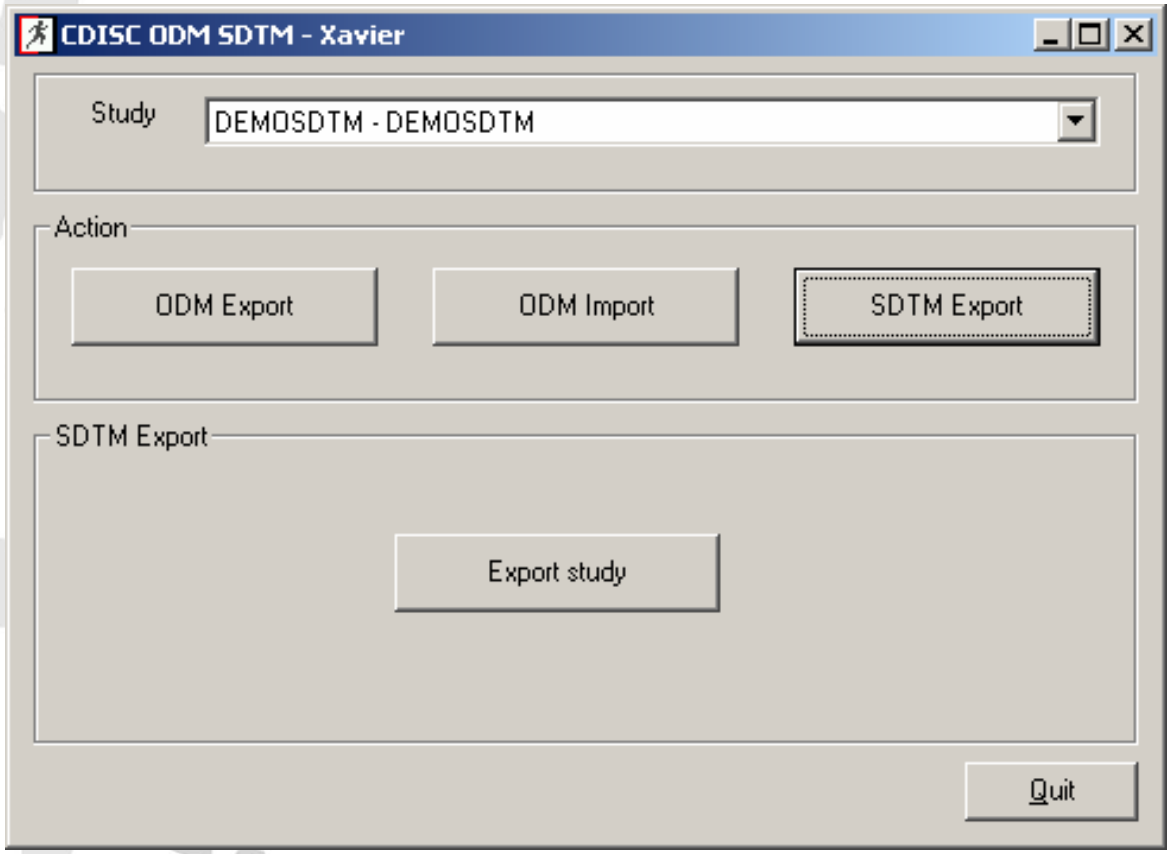
Inclusion/exclusion criteria in ClinCAPT

- One record per criterion per subject

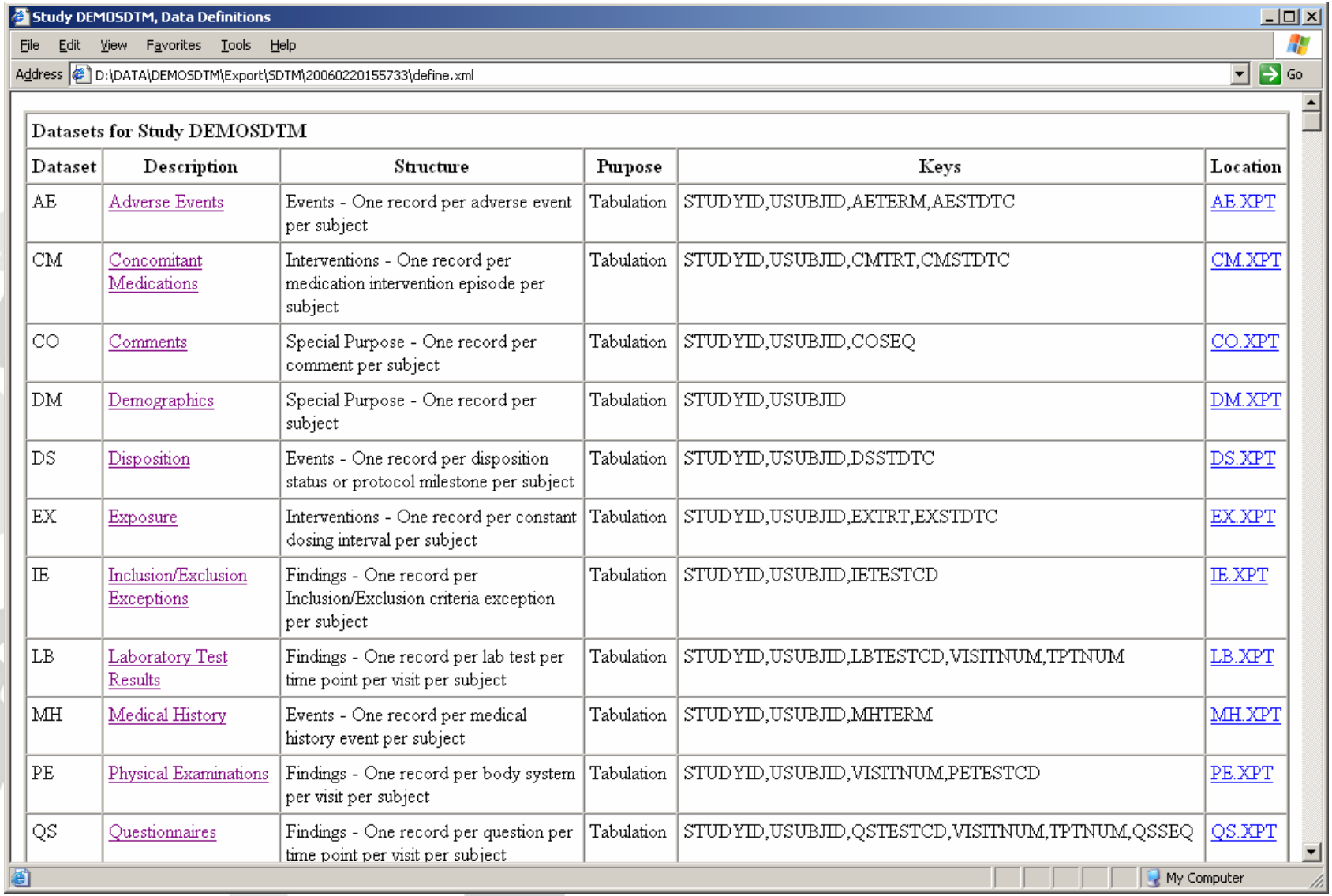
Inclusion/exclusion criteria in SDTM

- One record per criterion exception per subject

SDTM Implementation



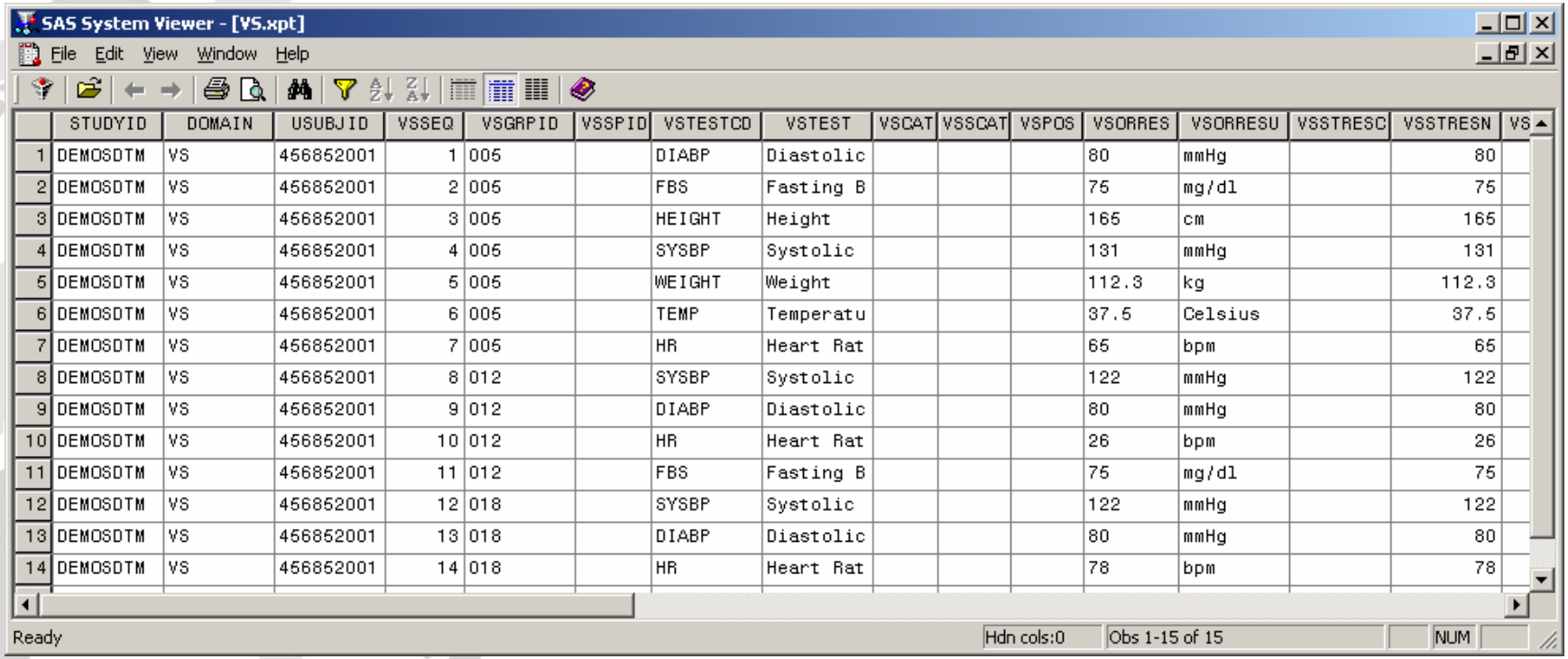
SDTM Implementation



Datasets for Study DEMOSDTM

Dataset	Description	Structure	Purpose	Keys	Location
AE	Adverse Events	Events - One record per adverse event per subject	Tabulation	STUDYID,USUBJID,AETERM,AESTDTC	AE.XPT
CM	Concomitant Medications	Interventions - One record per medication intervention episode per subject	Tabulation	STUDYID,USUBJID,CMTRT,CMSTDTC	CM.XPT
CO	Comments	Special Purpose - One record per comment per subject	Tabulation	STUDYID,USUBJID,COSEQ	CO.XPT
DM	Demographics	Special Purpose - One record per subject	Tabulation	STUDYID,USUBJID	DM.XPT
DS	Disposition	Events - One record per disposition status or protocol milestone per subject	Tabulation	STUDYID,USUBJID,DSSTDTC	DS.XPT
EX	Exposure	Interventions - One record per constant dosing interval per subject	Tabulation	STUDYID,USUBJID,EXTRT,EXSTDTC	EX.XPT
IE	Inclusion/Exclusion Exceptions	Findings - One record per Inclusion/Exclusion criteria exception per subject	Tabulation	STUDYID,USUBJID,IETESTCD	IE.XPT
LB	Laboratory Test Results	Findings - One record per lab test per time point per visit per subject	Tabulation	STUDYID,USUBJID,LBTESTCD,VISITNUM,TPTNUM	LB.XPT
MH	Medical History	Events - One record per medical history event per subject	Tabulation	STUDYID,USUBJID,MHTERM	MH.XPT
PE	Physical Examinations	Findings - One record per body system per visit per subject	Tabulation	STUDYID,USUBJID,VISITNUM,PETESTCD	PE.XPT
QS	Questionnaires	Findings - One record per question per time point per visit per subject	Tabulation	STUDYID,USUBJID,QSTESTCD,VISITNUM,TPTNUM,QSSEQ	QS.XPT

SDTM Implementation


SAS System Viewer - [VS.xpt]

File Edit View Window Help

	STUDYID	DOMAIN	USUBJID	VSSEQ	VSGRPID	VSSPID	VSTESTCD	VSTEST	VSCAT	VSSCAT	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VS
1	DEMOSDTM	VS	456852001	1	005		DIABP	Diastolic				80	mmHg		80	
2	DEMOSDTM	VS	456852001	2	005		FBS	Fasting B				75	mg/dl		75	
3	DEMOSDTM	VS	456852001	3	005		HEIGHT	Height				165	cm		165	
4	DEMOSDTM	VS	456852001	4	005		SYSBP	Systolic				131	mmHg		131	
5	DEMOSDTM	VS	456852001	5	005		WEIGHT	Weight				112.3	kg		112.3	
6	DEMOSDTM	VS	456852001	6	005		TEMP	Temperatu				37.5	Celsius		37.5	
7	DEMOSDTM	VS	456852001	7	005		HR	Heart Rat				65	bpm		65	
8	DEMOSDTM	VS	456852001	8	012		SYSBP	Systolic				122	mmHg		122	
9	DEMOSDTM	VS	456852001	9	012		DIABP	Diastolic				80	mmHg		80	
10	DEMOSDTM	VS	456852001	10	012		HR	Heart Rat				26	bpm		26	
11	DEMOSDTM	VS	456852001	11	012		FBS	Fasting B				75	mg/dl		75	
12	DEMOSDTM	VS	456852001	12	018		SYSBP	Systolic				122	mmHg		122	
13	DEMOSDTM	VS	456852001	13	018		DIABP	Diastolic				80	mmHg		80	
14	DEMOSDTM	VS	456852001	14	018		HR	Heart Rat				78	bpm		78	

Ready Hdn cols:0 Obs 1-15 of 15 NUM

« Thank you for your attention »

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