

PhUSE EU Connect 2018: SD03

Mapping Programs Written by MDR

Jörn Bilow



Jörn Bilow has more than 20 years of experience in the pharmaceutical and biotech industry and has worked for several enterprise software providers in the pre-clinical and clinical pharma R&D process. Since 2012 he has been Sales Manager at Entimo in Berlin, Germany, focusing on regulatory-compliant enterprise solutions for standards governance, metadata management, biostatistical analysis and clinical data warehousing. Jörn holds a PhD in chemistry from the Free University Berlin.

- Mapping Specifications – Background
- Technology
- Reporting Overview
- Program Code Generation
- Demo
- Q&A

- **Outsourcing to CROs on the rise**



Cost Cutting to Drive 12% Growth in CRO Outsourcing Through 2021, New Study Finds

Apr 11, 2018 By Pharmaceutical Technology Editors

While pharma industry growth has slowed from double to single digit levels recently, demand for contract research organization (CRO) services is growing rapidly, according to the [Business Research Company's](https://www.thebusinessresearchcompany.com/report/contract-research-organizations-global-market-report-2018) (BRC's) 2018 CRO Global Market Report.

<http://www.pharmtech.com/cost-cutting-drive-12-growth-cro-outsourcing-through-2021-new-study-finds>
<https://www.thebusinessresearchcompany.com/report/contract-research-organizations-global-market-report-2018>

- **Communication is key**
 - Global organizations
 - Sponsor “flavors” of standards e.g. SDTM
 - Project / study structure metadata
- **Specifications for data transformations**
 - To SDTM
 - To ADaM
 - Reproducible
 - Universal format

- **Fully model agnostic**

- Repository for all kinds of standards
- Structure metadata (CDISC, EDC, proprietary, interim)
- Controlled terminology
- Algorithms, value level metadata
- Reporting metadata (headers, footers)
- Any other

- **Inheritance concept**

- Support for global, project, study level
- More levels by configuration
- Reduced maintenance effort, enhanced performance

■ Relations Report

- Track metadata relationships across data models
- Hyperlinks
- Highlighting missing algorithms

■ Mapping specifications

- Two formats: Excel and define.xml
- Define.xml by design ensures traceability
- Both formats widely used and understood

Datasets for Study test (Specification test SDTM_3.2 to ADAM_1.2)

Dataset	Description	Class	Structure	Purpose	Keys
adsl	ADaM Subject Level	Analysis	One record per subject	Analysis	STUDYID, USUBJID
dm	Demographics	Special Purpose	One record per subject	Tabulation	STUDYID, DOMAIN, USUBJID
sv	Subject Visits	Special-Purpose	One record per subject per actual visit	Tabulation	STUDYID, DOMAIN, USUBJID, VISITNUM
ex	Exposure	Interventions	One record per constant dosing interval per subject	Tabulation	STUDYID, DOMAIN, USUBJID, EXSEQ
qs	Questionnaire	Findings	One record per questionnaire per question per time point per visit per subject	Tabulation	STUDYID, DOMAIN, USUBJID, QSSEQ
vs	Vital Signs	Findings	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, DOMAIN, USUBJID, VSSEQ
ds	Disposition	Events	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, DOMAIN, USUBJID, DSSEQ

Name	Label	Type (Length)	Format	Comment
STUDYID	Study Identifier	C (100)		Unique identifier for a study.
	referenced by adsl.STUDYID (adam_1.2)			
	based on available dm_studyidkey (rave_1.0)			method(STUDYID): Assign DM_STUDYIDKEY
	based on available DM_STUDYIDKEY (rave_1.0)			
DOMAIN	Domain Abbreviation	C (2)	DOMAIN	DM
				method(DOMAIN): Set to DM
USUBJID	Unique Subject Identifier	C (100)		method(USUBJID): Concat_STUDYIDKEY and_SUBJECTKEY(delimited by _)
	referenced by adsl.USUBJID (adam_1.2)			
	based on not available dmUSUBJID (rave_1.0)			
	based on available DM_STUDYIDKEY (rave_1.0)			
	based on available DM_SUBJECTKEY (rave_1.0)			
SUBJID	Subject Identifier for the Study	C (100)		method(SUBJID): Assign DM_SUBJECTKEY
	referenced by adsl.SUBJID (adam_1.2)			
	based on available DM_SUBJECTKEY (rave_1.0)			
	based on not available dmSUBJID (rave_1.0)			
SITEID	Study Site Identifier	C (100)		method(SITEID): Assign SUBJ_INFO.SITEID
	referenced by adsl.SITEID (adam_1.2)			

- **Convert MDR information into code**
 - Collect metadata and algorithms
 - Bring into GUI
 - Review and edit assignments of variables
 - On-the-fly reporting
 - Generate validated SAS code

■ Purely metadata driven

- Uses MDR or metadata derived from data
- Multiple steps supported
- Conditions, joins and where clauses
- Validated SAS code

```

52 *****
53 *** Begin step 1: RAVE_1.0 to SDTM_3.2.DM [1] (Quick-Join Task)
54 *****
55 *** Reads dataset(s): S.&S_DM
56 ***                      S.&S_SUBJ_INFO
57 *** Writes dataset(s): T.&T_DM
58 *****
59 %put ;
60 %put NOTE: *** Begin step 1: RAVE_1.0 to SDTM_3.2.DM [1] (Quick-
61
62 /* Service Macro Variables, that can be used by the programmer */
63 %local _mapping_task_no _mapping_task_name;
64 %let _mapping_task_no = 1;
65 %let _mapping_task_name = RAVE_1.0 to SDTM_3.2.DM [1];
66 %let _mapping_rc = 0;
67
68 /* Check existence of source datasets */
69 %if %sysfunc(exist(S.&S_DM)) ne 1 and
70 %sysfunc(exist(S.&S_DM,view)) ne 1 %then %do;
71 %put ERR%str(OR:) &msg_pref.Source dataset S.&S_DM for task 1
72 %let _mapping_rc = 1;
73 %end;
74
75 %if %sysfunc(exist(S.&S_SUBJ_INFO)) ne 1 and
76 %sysfunc(exist(S.&S_SUBJ_INFO,view)) ne 1 %then %do;
77 %put ERR%str(OR:) &msg_pref.Source dataset S.&S_SUBJ_INFO for
78 %let mapping rc = 1;
    
```

Basic Settings

Name: dm

Description:

Generate Report Check Consistency Update Codelists

Generate SAS Program

Output path: root/operations_template/Project_drugabc/S_2017_002/dev/program

☐ Include macro code in generated program

Set SAS Program Path Generate SAS Program

Tasks

1: RAVE_1.0 to SDTM_3.2.DM [1]

Up Down New Edit Remove Template

Available Datasets

Available DataSet(s)

- S.DM (MV &S_DM)
 - 1: RAVE_1.0 to SDTM_3.2.DM [1] - as Source
- S.SUBJ_INFO (MV &S_SUBJ_INFO)
 - 1: RAVE_1.0 to SDTM_3.2.DM [1] - as Source
- T.DM (MV &T_DM)
 - 1: RAVE_1.0 to SDTM_3.2.DM [1] - as Target

Task Details: RAVE_1.0 to SDTM_3.2.DM [1]

Target Datasets and Attributes

T.DM (1)

Source Datasets and Attributes

S.DM

S.SUBJ_INFO

Assign ...

by name by name/type by rules

Use Copy Create Derive

- Demo Video
- 1. Mapping Specification define-like
- 2. Relationship Report
- 3. Mapping Program written by MDR

Questions and Answers

