Validation of simple, isolated one-off programs
- a pragmatic approach.

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Contents

What is a simple, isolated one-off program?

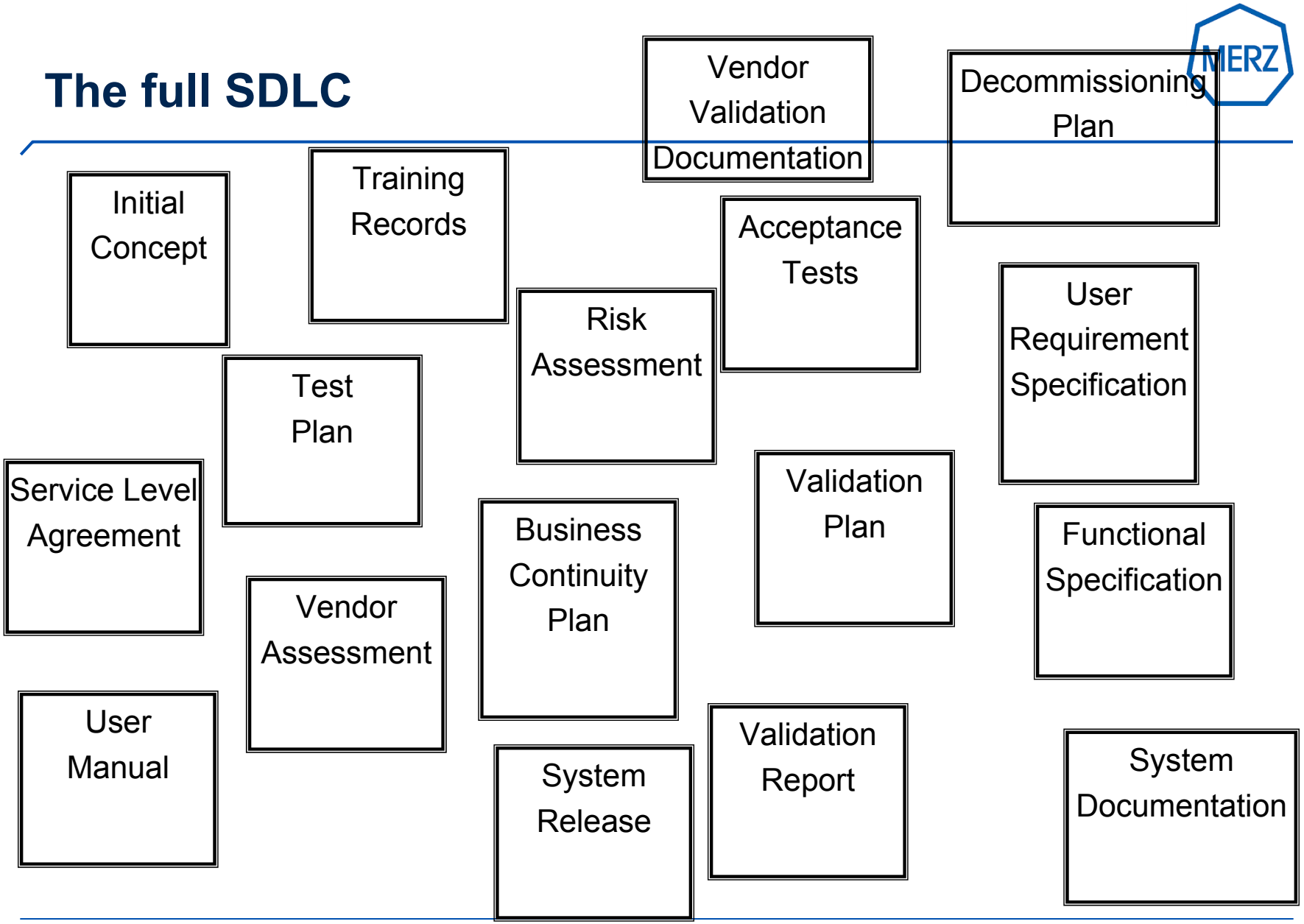
Examples

- Conversion of data sent by external vendors into SAS-CDASH format (safety lab, pharmacogenetics, ECG, …)
- Subject profiles for Medical Review and other manual review listings
- Edit checks outside the Clinical Data Management System (CDMS)
- SAE reconciliation, Status reports, …

Not applicable to

- conversion of CDASH to SDTM to ADaM
- creation of tables, listings, figures
- edit checks in the CDMS
- standard macros

The full SDLC



What are the essentials of a validation?

- What is to be validated?
- What are the (user) requirement/ required functionality?
- Who is responsible for what?
- What was tested?
- What is the outcome of the test?

- Signed, dated, credible, identifiable documentation

The document

- … meets all essentials
- … is only one document
- … is stored as template for the most common programs
- … is easily adaptable to other programs
- … **is auditproof**

- Obvious discussion points which were no findings
  - No strong proven chronology of requirements – test plan – test performance
  - No documentation of findings, only the last, successful test is documented
  - No strong separation of roles author – reviewer – approver
  - …

The document – Table of Contents

1. Objective
2. Requirements/ Functionality
3. Responsibilities
4. Test items and results
5. Validation result

The document - Objective

1 Objective

This document describes the validation of the following SAS program:

File name:	SubjectProfiles.sas	
Path:	\\ntsrv808\biomet\...	
Last change:	01-Jan-2012, 23:78	
Include files:	InclSubjectProfiles-AE.sas	05-Sep-2012, 17:23
	InclSubjectProfiles-ConMed (Phase1).sas	06-Sep-2012, 13:21
	InclSubjectProfiles-ConMed (Phase2-4).sas	06-Sep-2012, 15:30
	InclSubjectProfiles-ConTherapy.sas	06-Sep-2012, 13:42
	InclSubjectProfiles-EOS.sas	06-Sep-2012, 13:49
	InclSubjectProfiles-Figure.sas	06-Sep-2012, 14:36
	InclSubjectProfiles-Lab.sas	06-Sep-2012, 15:18
	InclSubjectProfiles-MHx.sas	06-Sep-2012, 14:52
	InclSubjectProfiles-VisitDates.sas	06-Sep-2012, 14:57

- … names the exact program, incl. time stamp
- … includes (all) files influencing the program which are not part of standard settings
- Red: most likely to be adapted

The document – Revision history

Revision history

The original SAS program, i.e. the SAS program before each revision, should be stored with a different file name/ folder name keeping the original date/time of last change.

Reason for Revision	Version	Date
First version	1.0	<DD-MMM-YYYY>

- … has an revision index, in case a validated version is revised

The document - Requirements

2 Requirements/ Functionality

The SAS program converts files with safety laboratory data delivered by the CRO xxx acc. to the file specification below into CDASH conformant SAS data sets.

File specification of the delivered data:

\\ntsrv808\biomet\....

CDASH definition:

G:\Documents\CDISC\CDASH\Merz-CDASH-Definitions\v2.0-20120622\Merz-CDASH-v2.0-20120622.xls

The name of the input file contains the date of delivery. The current file name is specified within the text file CurrentLabFile.txt in the same directory as the SAS program.

The output is written to the directory \\ntsrv808\biomet\....\

<In addition to restructuring, the following data changes are necessary:

1. If an observation has the values VISITNUM=0 and VISIT='Screening' in the input file then set VISITNUM / VISIT to
    - 10 / 'Screening' for cohort 1-8, and
    - 2 / 'Screening (Day -21 to Day -10)' for cohort 9.
2. Delete leading 0 from SITEID.>

- Short explanation why the program exists
- Links to external files needed
- Name of external initialisation file
- Output
- Additional tasks if necessary (should be numbered for the test section)

The document - Responsibilities

3 Responsibilities

Activity	Name
Author of this document	Dörte Becker
Reviewer of this document	Stefan Beimel
Programming	Stefan Beimel
Test execution *	Dörte Becker

* If Source Code Review is performed, the reviewer must not be the programmer.

- … must be more than one person, usually 2 people involved
- … all activities must be done
- restriction 1: author of document ≠ reviewer of document
- restriction 2: see * above

The document – Test items and results

4 Test items and results

Test No.	Test item	Test method/ description (all attached documents must be clearly identifiable [at least by study number], signed and dated)	Test passed
1	Current programming header used and adapted	Compare standard programming header from process drive with header in SAS program. Check all items to be adapted.	☐
2	All items from standards modules are displayed as in example on process drive	Visual comparison of resp. modules in example with profile of a complete subject (<E1>)	☐
3	All data from standard modules are displayed	Compare with data from complete subject E1	☐

- Predefined for special types of program, which are available as template
- **Test No.:** can be referenced on attached pages or screen shots
- **Test item** may refer to the number in section 2 'Requirements/ functionality'
- **Test method:** Attached pages should also give a back reference to this document and test item (a blank document with resp. header could be used for all pages, screen shots, ..)
- **Test passed:** No 'Test failed' tick box

The document – Validation result

5 Validation result

The SAS program is correctly described, and the test items are adequate.

The results are comprehensibly documented and all items are passed.

All persons mentioned in section 3 (Responsibilities) should sign below:

printed name		signature		date

printed name		signature		date

Test cases

Some predefined test cases

- Program header used and adapted?
- Log date after date of program?
- No ERRORS, WARNING, and suspicious notes in log?
- If program templates are used:
  Are all items mentioned in manual adequately adapted? (1 test case per item)
- Source code review if the program is very simple
- Programmatically check data set structure against a reference
- Specials on listings

For each additional requirement there should be at least one test.

Currently no case of double programming.

Test cases – Specials on listings

4 Test items and results

Test No.	Test item	Test method/ description (all attached documents must be clearly identifiable [at least by study number], signed and dated)	Test passed
		Vital Signs	
	All required variables are displayed and data are correct	Comparison with data from complete subject E1	☐
	layout of module	Visual inspection of layout w.r.t • title correct and in table of contents • correct labels • meaning full sorting • duplicate hiding • no truncated text • correct units • no typing errors	☐

Test cases – Additional requirements

4 Test items and results

Test No.	Test item	Test method/ description (all attached documents must be clearly identifiable [at least by study number], signed and dated)	Test passed
<5>	Renaming VISIT (see section 2.1)	Screenshot before/ after	☐
< 6 >	Deleting leading 0 (see section 2.2)	Screenshot before/ after	☐

Since we have this document

- Everybody in the data management group knows how to validate a SAS program.

- The error rate decreased.

- We got rid of the nightmare question during an inspection:

  “Show me the validation docs of the lab import program.”

The End