Cytel

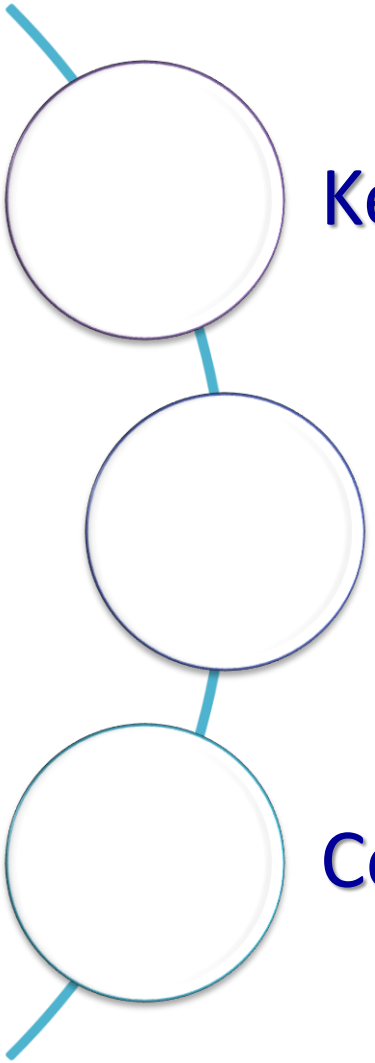
Shaping the Future of
Drug Development

Submission Experience (with FDA)

Laura Phelan, Cytel Inc.

GUF CDISC - Genève / 04 December 2018

Agenda



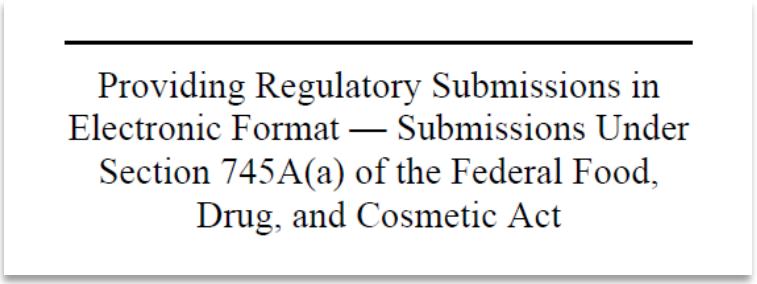
Key Requirements

Our Submission Experience

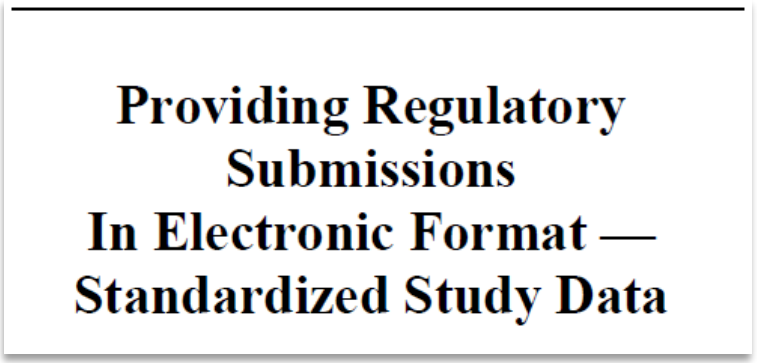
(& what the requirements don't say)

Conclusions

Key Requirements


Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

Electronic not paper submission


Providing Regulatory Submissions In Electronic Format — Standardized Study Data

Must use data standards


STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

How to submit using standards

Key Requirements

FDA Data Standards Catalog

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Supported Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Statutory, Regulatory, or Guidance Authority	Information Sources
Documents	PDF	PDF	Adobe	1.7	N/A	CBER, CDER, CDRH	11.20.2012					For CDRH only: eCopy Program for Medical Device Submissions
Clinical and Non-Clinical study data sets - Transport	SAS (XPORT)	XPT	SAS	5	SAS Technical Support TS-140	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]		Standardized Study Data	For CDER and CBER only: Technical Conformance Guide
Clinical and Non-Clinical study data sets - Transport	SAS XPORT	XPT	SAS	5	SAS Technical Support TS-140	CDRH, CFSAN, CVM	Ongoing				Standardized Study Data	For CDRH only: eCopy Program for Medical Device Submissions

Instr. & Column Descriptions | **Submission Data Exchange Stds** | SubmissionTerminology Stds | Change History

Terminology Standard	Terminology Standards Development and/or Maintenance Organization	Version(s)	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Examples of Use	Statutory, Regulatory, or Guidance Authority	Information Sources	
Medical Dictionary for Regulatory Activities (MedDRA)	Maintenance and Support Services Organization (MSSO)	8 or earlier	CBER, CDER	Ongoing	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]	CDISC AE Domain	Standardized Study Data	MedDRA.org	Study Data Technical Conformance Guide
MedDRA	MSSO	Current Version	CBER, CDER	08/31/2017		03/15/2019 [1] 03/15/2020 [2]		CDISC AE Domain	Standardized Study Data	MedDRA.org	Study Data Technical Conformance Guide

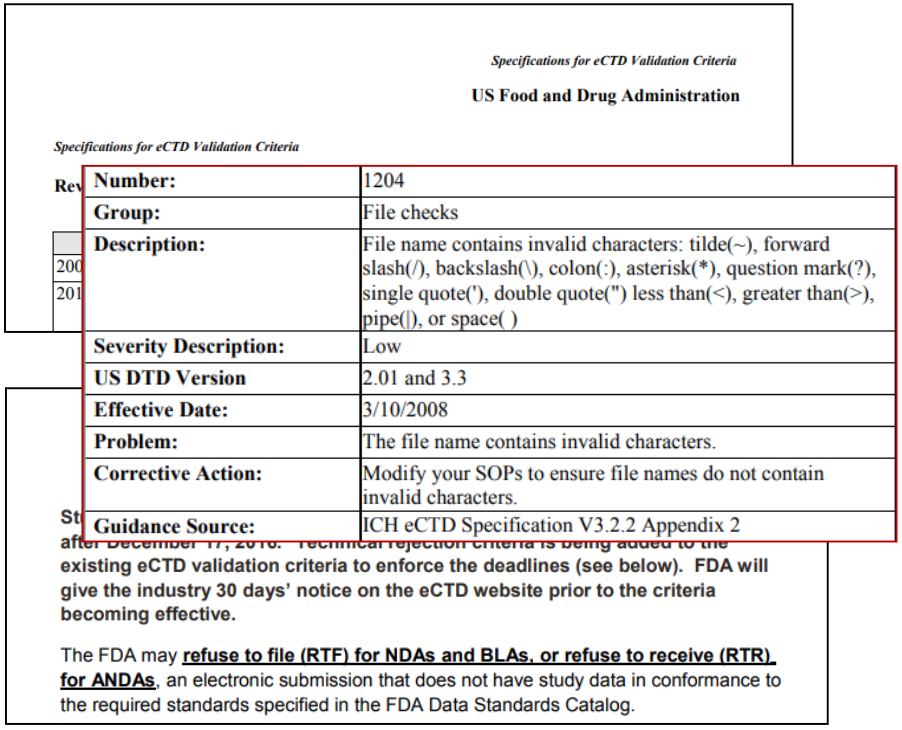
Instr. & Column Descriptions | Submission Data Exchange Stds | **SubmissionTerminology Stds** | Change History

Key Requirements….*and do not forget*

PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS

Technical Specifications Document

"…optimize PDF for fast web view…"



Specifications for eCTD Validation Criteria

US Food and Drug Administration

Specifications for eCTD Validation Criteria

Number:	1204
Group:	File checks
Description:	File name contains invalid characters: tilde(~), forward slash(/), backslash(\), colon(:), asterisk(*), question mark(?), single quote('), double quote(") less than(<), greater than(>), pipe(|), or space( )
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The file name contains invalid characters.
Corrective Action:	Modify your SOPs to ensure file names do not contain invalid characters.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2

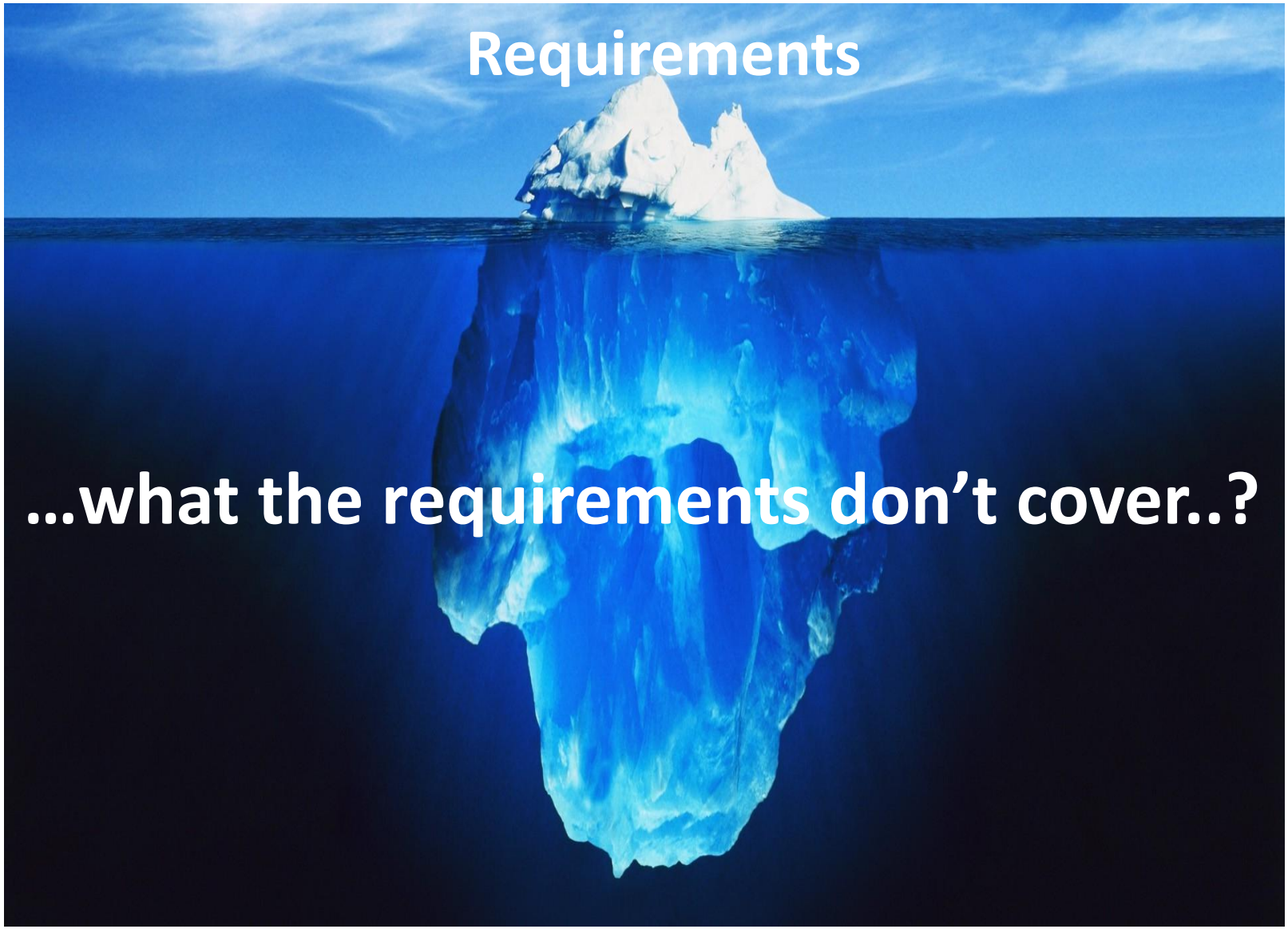
existing eCTD validation criteria to enforce the deadlines (see below). FDA will give the industry 30 days' notice on the eCTD website prior to the criteria becoming effective.

The FDA may **refuse to file (RTF) for NDAs and BLAs, or refuse to receive (RTR) for ANDAs**, an electronic submission that does not have study data in conformance to the required standards specified in the FDA Data Standards Catalog.

"File name exceeds max. length (64 chars)…"

"A Trial Summary (TS) dataset must be present …"

Our submission experience



Our submission experience

Indication 1 SDTM Ig 3.2, ADaM 1.0, define 2.0	Indication 2 SDTM Ig 3.1.3, ADaM 1.0, define 1.0
6 SDTMs	10 SDTMs
	5 ADaMs
ISE (3) & ISS (6) ~1100 subjects	ISS (10) ~2400 subjects
Cytel : CDISC migration & Pooling - Advise	
Sponsor: final package & FDA interaction - Decide	

Our submission experience

- Results metadata – to submit or not submit?
- External References – where, how?
- Mock Submission – feedback and what's negotiable?
- Screening failures - include?
- BIMO who?
- Epoch – how complex to make SE domain?
- Medical dictionaries – upversioning from SDTM to ADaM?
- Special characters – which can stay?

Results Metadata (ARM)

- To submit or not submit?
  - Not mandatory (yet)
  - Requires define v2.0
  - Indic 1: details in adrg
- Submit ARM, reviewer likes it

7. Submission of Programs

All programs used to derive the ADaM datasets are part of the submission, and available upon request. Output programs are also part of the submission, and available upon request.

All submitted programs will execute on a PC environment running Windows and SAS version 9.2 or later.

The intent is to give the reviewer the possibility to review how derivations has been done and models used in the analysis; however the programs have some macro and environment dependencies so they are not executable without making ad-hoc modifications.

Program Name	Output	Inputs+	Macro Used*
adsl.sas	adsl	adefbase, dm, suppdm, ds, vs, qs, mg, zg, ex, suppex, zr, suppzr, sv, ae, cm, lb, zs, yg, suppyg	
adoa.sas	adoa	adsl mh (where MHPRESP='Y' and MHTERM='OSTEOARTHRITIS OF THE KNEE') or (MHCAT="PRIMARY DIAGNOSIS" and mhscat = "OSTEOARTHRITIS IN OTHER LOCATIONS") suppmh (where qnam in ("MHACRA","MHACRS","MHACRC","MHACRKP","	

External References

- When, where, how?
  - Xml limited 1000 chars*

Value Level Metadata (ValueList.ADXMSUM.PARAMCD)

Value	Label	Type	Controlled Terms or Format	Comment
FRACT2	Active T2 Lesions Free Status	text	YN	Derive per subject/parameter. Equals Y if subject has no Lesions/Subject/Scan, equals 'N' otherwise using the non-imputed lesions/subject/scan (where ANL01FI='Y'.) For Unknown lesion free status, impute as: a) Call the proportion of subjects with known free status, i.e., number of subject with AVALC = 'Y'/ (number of subjects with (AVALC 'Y' or 'N') across all treatment groups, 'p'. b) Call the number of subjects in each treatment with AVALC='UNK' , 'n1', n2' and 'n3' respectively. c) Multiple 'n1', n2' and 'n3' by 'p' call the results 'r1', 'r2' and 'r3'. Round 'r1', 'r2' and 'r3' to the nearest integer, call the results 's1', 's2' and 's3'. d) Randomly assign 's1' of the 'n1' subjects to AVAL= 1 (AVALC='Y') and the remainder to AVAL = 0 ('AVALC='N'). Repeat for the other treatment arms. How to randomly assign: Generate 'n1' numbers between 0 and 1 using RANUNI and sort 1000 ranks from 1 to n1. Assign the lowest s1 ranks the others 0 as per SAP Sections 8.4 and 9.5.1.

ok

the others 0 as per SAP Sections 8.4 and 9.5.1.

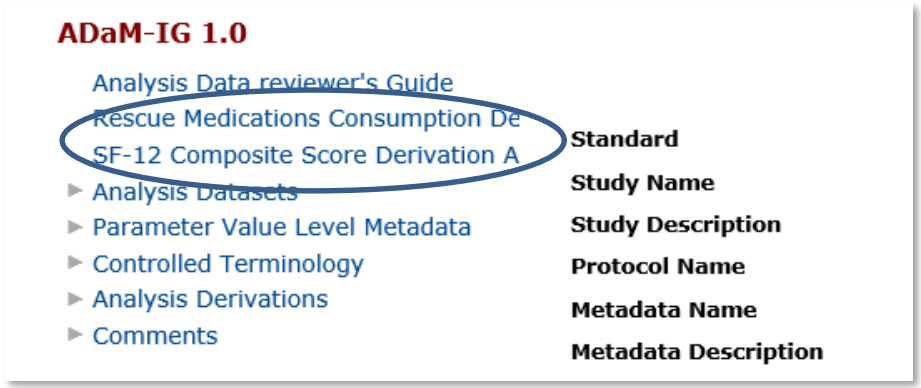
Value Level Metadata (ValueList.ADMSQOL.PARAMCD)

Value	Label	Type	Controlled Terms or Format	Comment
				Derived from QS.QSSTRESN as per SAP, reference 8: 'Vickrey BG, Hays RD, Harooni R, Myers LW, Ellison GW. A health-related quality of life measure for multiple sclerosis. Qual Life Res 1995 Jun;4(3):187-206.'.

Slightly better

*at the time of these submissions

External References



← Top left define.xml

ADT	Analysis Date		integer	DATE9		Derived: Numeric SAS date part from SDTM YR.YRDTC when from IVRS reported rescue medications (PARAMCD='RMEDIVRS'). When rescue medications consumption is derived from the concomitant medications page (PARAMCD='RMEDCM'), the date is derived by using the date in the range of star (CM.CMSTDTC) and end of medication (CM.CMENDTC). More details can be found in the Rescue Medications Consumption Derivation document. Rescue Medications Consumption Derivation Page 1

Documentation

See more details about in the Analysis Reviewer Guide

Analysis Data reviewer's Guide Page 23

← Link specific adrg page

Much better

Mock Submission feedback

- FDA says «Jump!» – how high?
  - Associated Persons domains
    - Feedback: *«stick to the model»*
    - Negotiated *: a waiver*
  - Define version 1.0 vs 2.0

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Supported Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)
Study data definition	Define	XML	CDISC	1.0	N/A	CDER, CBER	Ongoing	03.15.2018

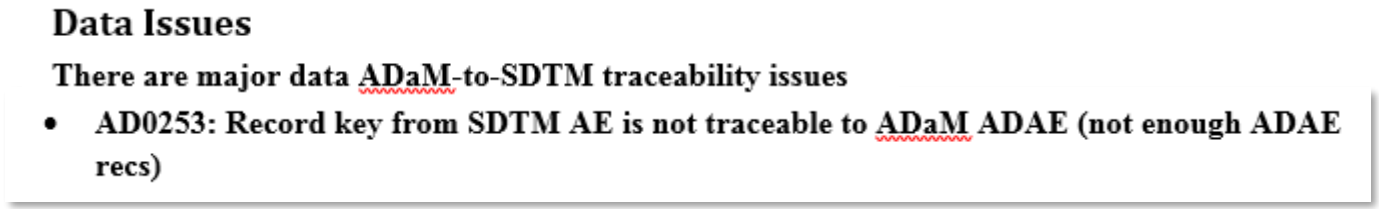
Define.xml

Outdated version of Define-XML standard

- Support for Define-XML v1.0 is ending by 2018-03-18 [3]

Mock Submission feedback

- Other findings



Data Issues

There are major data ADaM-to-SDTM traceability issues

- **AD0253: Record key from SDTM AE is not traceable to ADaM ADAE (not enough ADAE recs)**

  - Originally kept ADAE.SAFFL='Y'
    - Bad idea – keep all AEs.
    - *OCCDS v1.0: "one record per record in SDTM domain"*

  - Recommendation:
    - **Include AE, DM, EX in Pinnacle validation of ADaM**

(based on) Mock Submission feedback

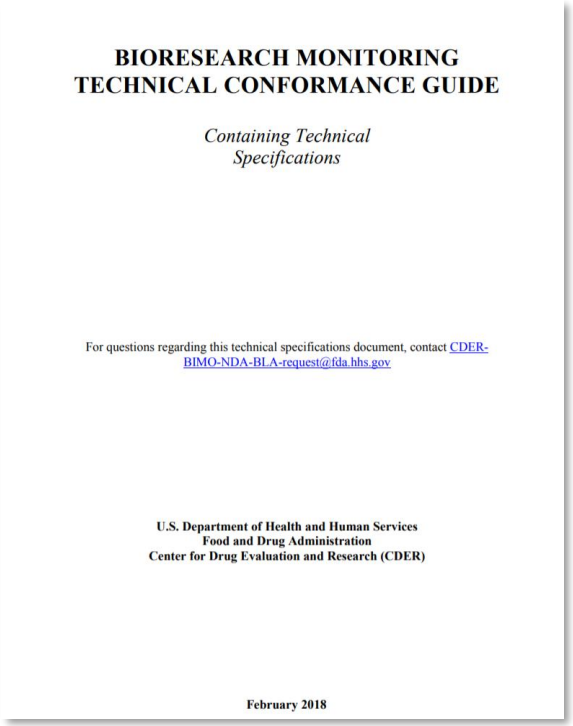
- ISS STUDYID
  - ADSL.STUDYID=«STUDY 1»
  - Non-ADSL.STUDYID=«STUDY1», «STUDY2» or «STUDY3»
    - "AD0256: USUBJID value does not exist in the ADaM ADSL domain"
    - "AD0196: Required STUDYID value is null"
  - Pi messages imply lack of integrity
    - Replaced non-ADSL.STUDYID with ASTUDYID (traceability)
    - Non-ADSL.STUDYID =ADSL.STUDYID

Screening Failures

- Include in SDTM?
  - Indic. 2 – Yes, needed for ADaM
  - Indic. 1 – No
    - FDA asked for it later
- Our recommendation: keep in SDTM

BIMO who?

- **Bi**oresearch **Mo**nitoring
  - Advises FDA on site selection for inspection



BIORESEARCH MONITORING
TECHNICAL CONFORMANCE GUIDE

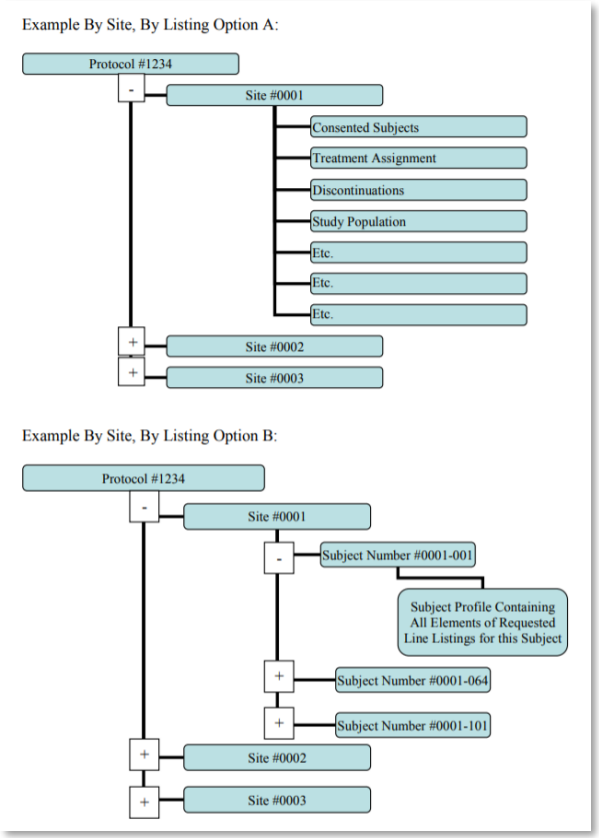
Containing Technical Specifications

For questions regarding this technical specifications document, contact CDER-BIMO-NDA-BLA-request@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

February 2018

READ it !



BIMO who?

- By site listings
  - Raw + some derived variables
  - «by subject» or «by site»

- CLINSITE dataset
  - define
  - adrg (optional)
    - *" If the applicant is submitting a Reviewer's Guide"*

Variable Index	Variable Name	Variable Label	Type	Controlled Terms or Format	Notes or Description	Sample Value
13	SCREEN	Number of Subjects Screened	Num	Integer	Total number of subjects screened (consented) at a given site. When a subject has transferred from one site to another, the applicant should handle reporting of such subjects consistently across sites and include the reporting convention used in the define file or the BIMO Reviewer's Guide (if provided). The applicant may opt to further explain the reasons subjects transferred between sites in the BIMO Reviewer's Guide, if provided.	100
14	DISCSTUD	Number of Subject Discons from Study	Num	Integer	Number of subjects in the safety population who discontinued from the study.	5
15	DISCTRT	Number of Subject Discons from Study Treatment	Num	Integer	Number of subjects in the safety population who discontinued from the study treatment.	10
16	ENDPOINT	Primary Endpoint	Char	String	Plain text label used to describe the primary endpoint as described in the Define file included with each application (limit 200 characters).	Average increase in blood pressure
17	ENDPTYPE	Primary Endpoint Type	Char	String	Variable type of the primary endpoint (i.e., continuous, discrete, time to event, or other).	Continuous
18	TRTEFFR	Treatment Efficacy Result	Num	Floating Point	Summary statistic for each primary efficacy endpoint by treatment arm at a given site.	0, 0.25, 1, 100
19	TRTEFFS	Treatment Efficacy Result Standard Deviation	Num	Floating Point	Standard deviation of the efficacy result (TRTEFFR) for each primary efficacy endpoint by treatment arm at a given site. If N=1, set to "0".	0.065
20	SITEEFFE	Site-Specific Treatment Effect	Num	Floating Point	Site-specific treatment effect reported using the same representation as reported for the primary efficacy analysis.	0, 0.25, 1, 100

Analysis Datasets for BIMO

Dataset	Description	Class	Structure	Purpose	Keys	Location
CLINSITE	Summary-level clinical site data	ADAM OTHER	One record per site ID per planned treatment arm	Analysis	SITEID, ARM	clinsite.xpt

EPOCH (TA & SE)

- How complex?
  - If lucky…

STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
EX3	TA	AA	A-Open A	1	SCRN	Screen	Randomized to Treatment A		Screen
EX3	TA	AA	A-Open A	2	DBA	Treatment A	Assigned to Open Drug A on basis of response evaluation		Double Blind
EX3	TA	AA	A-Open A	3	OA	Open DRUG A			Open Label

  - Probably get this…

DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
TA	CHD	High Dose	1	PRE	SCREENING	Randomized to High Dose		Screening
TA	CHD	High Dose	2	CTRT	TREATMENT CYCLE			1st Treatment
TA	CHD	High Dose	3	CTRT	TREATMENT CYCLE			1st Treatment
TA	CHD	High Dose	4	CTRT	TREATMENT CYCLE			1st Treatment
TA	CHD	High Dose	5	CTRT	TREATMENT CYCLE			1st Treatment
TA	CHD	High Dose	6	FUP	FOLLOW-UP		If not assigned at End of Follow-Up to Re-Treatment subject immediately starts with Follow-Up Re-Treatment Epoch	Follow-Up
TA	CHD	High Dose	7	CTRT	TREATMENT CYCLE			Re-Treatment
TA	CHD	High Dose	8	CTRT	TREATMENT CYCLE			Re-Treatment
TA	CHD	High Dose	9	FUPRT	FOLLOW-UP RE-TREATMENT			Follow-Up Re-Treatment
TA	CHD	High Dose	10	ITPTERM	INITIAL TREATMENT PERIOD FINAL VISIT/ET		1) If converted to CDMS go to Element OLMPWSH (TAETORD 20); 2) If converted to McDonald MS go to Element LTFUTRT (TAETORD 13)	End of Initial Treatment Period
TA	CHD	High Dose	11	LTFU	LONG-TERM FOLLOW-UP		1) switch to LTFU Treat (TAETORD 13) if McDonald Conversion; 2) switch to OLMPWSH (TAETORD 20) if CDMS conversion	Long-Term Follow-Up
TA	CHD	High Dose	12	LTFUTERM	LONG TERM FOLLOW-UP FINAL VISIT/ET		Switch to STERM (TAETORD 23) Element at end of this Element	End Long Term Follow-Up
TA	CHD	High Dose	13	LTFUTRT	LTFU TREATMENT CYCLE		If subject converts to CDMS MS switch to OLMPWSH (TAETORD 20) Element immediately	LTFU Treatment
TA	CHD	High Dose	14	LTFUTRT	LTFU TREATMENT CYCLE		If subject converts to CDMS MS switch to OLMPWSH (TAETORD 20) Element immediately	LTFU Treatment
TA	CHD	High Dose	15	LTFUFUP	LTFU TREATMENT FOLLOW-UP		If not assigned at End of Follow-Up to LTFU Re-Treatment (TAETORD 16) switch immediately to LTFURFUP (TAETORD 18); If subject converts to CDMS MS switch to OLMPWSH (TAETORD 20) Element immediately	LTFU Follow-Up Treatment
TA	CHD	High Dose	16	LTFUTRT	LTFU TREATMENT CYCLE		If subject converts to CDMS MS switch to OLMPWSH (TAETORD 20) Element immediately	LTFU Re-Treatment
TA	CHD	High Dose	17	LTFUTRT	LTFU TREATMENT CYCLE		If subject converts to CDMS MS switch to OLMPWSH (TAETORD 20) Element immediately	LTFU Re-Treatment
TA	CHD	High Dose	18	LTFURFUP	LTFU RE-TREATMENT FOLLOW-UP		If subject converts to CDMS MS switch to OLMPWSH (TAETORD 20) Element immediately	LTFU Follow-Up Re-Treatment
TA	CHD	High Dose	19	LTFTTERM	LTFU TREATMENT FINAL VISIT/ET		Switch to STERM (TAETORD 23) Element at end of this Element	End Long Term Follow-Up Treatment
TA	CHD	High Dose	20	OLMPWSH	OPEN LABEL MAINTENANCE WASHOUT PERIOD			Maintenance Washout
TA	CHD	High Dose	21	OLMPTRT	OPEN LABEL MAINTENANCE TREATMENT PERIOD			Open Label Maintenance
TA	CHD	High Dose	22	OLMPTERM	OLMP TREATMENT FINAL VISIT/ET			End of Open Label Maintenance Period
TA	CHD	High Dose	23	STERM	FINAL STUDY VISIT			End of Study

Trial Design: TA and EPOCH

- Prepare Trial Design
  - Based on «reality» data checks vs protocol(s)
  - with, or before, aCRF
  - SE.EPOCH

Due to overlaps in the SV domain, visits which slot into one or more EPOCHs are assigned using priority rule:

EPOCH	Priority
Pre-Study	4th
1st Treatment	1st
Follow-up	3rd
Re-Treatment	2nd
Follow-Up Re-Treatment	3rd
End of Study	5th

  - NEW!!! SDTM Ig 3.3

4.1.3.1 EPOCH Variable Guidance

Sponsors should not impute EPOCH values, but should, where possible, assign EPOCH values on the basis of CRF instructions and structure, even ifEPOCH was not directly collected and date/time data was not collected with sufficient precision to permit assignment of an observation to an EPOCH on the basis of date/time data alone. If it is not possible to determine theEPOCH of an observation, then EPOCH should be null. Methods for assigning EPOCH values can be described in the Define-XML document.

Medical Dictionaries

- Study MedDRA 11.0 & 17.1 – 2 versions ?
  - Reconciled AEs *after* DB lock
  - Use AEPV?
    - Pi split domains – errors!!

Issue Summary					
Source	Pinnacle 21 ID	Publisher ID	Message	Severity	Found
AE					
	CT2001	FDAC340	AEACN value not found in 'Action Taken with Study Treatment' non-extensible codelist	Error	4
	SD0005	FDAC044	Duplicate value for AESEQ variable	Error	4883
	SD0008	FDAC346	Value for AEDECOD not found in MedDRA dictionary	Error	95
	SD0080	FDAC208	AE start date is after the latest Disposition date	Error	16
	SD1095	FDAC072	Invalid dataset name for split domain	Error	1

  - ZA (custom)

3.3.18. ZA – Adverse Events Pharmacovigilance Reconc.

The ZA domain represents Adverse Events which have been reconciled with the Pharmacovigilance AE database after the study was closed and events in ZA are coded using MedDRA v17.1. Included are all adverse events as available in the domain AE, and with the same legacy mapping, however

Controlled Terminology (External Dictionaries)	
AEDICT2_F, Reference Name (AEDICT2_F)	
External Dictionary	Dictionary Version
MedDRA	17.1
AEDICT_F, Reference Name (AEDICT_F)	
External Dictionary	Dictionary Version
MedDRA	11.0

Medical Dictionaries

- Upversioning from SDTM to ADaM?
  - v20.0 in ISS
  - Traceability AEBODSYS
    - Use ABODSYS, ADECOD

ADAEA, ADAEP, ADAEM, ADAED, ADAEC, ADAEO	AD0047: Required variable is not present	Error	30	AEBODSYS, AEDECOD, AETERM, AESER and AESEQ are not present as they are displayed as ABODSYS, ADECOD, ATERM, ASER and ASEQ respectively. As data is a pool of multiple SDTM domains (AE, CE and ZA domains), in order to have all records in one variable, Axxx variables have been used instead of AExxx.

  - Pi Error explained

Special characters

- Requirements:
  - *"..restricted to ASCII ..(printable values below 128)"*

- In practice:
  - Replaced 0-31
    - «WARNING: Non-ASCII Char Removed: PDTEXT=compliance less than 70%"

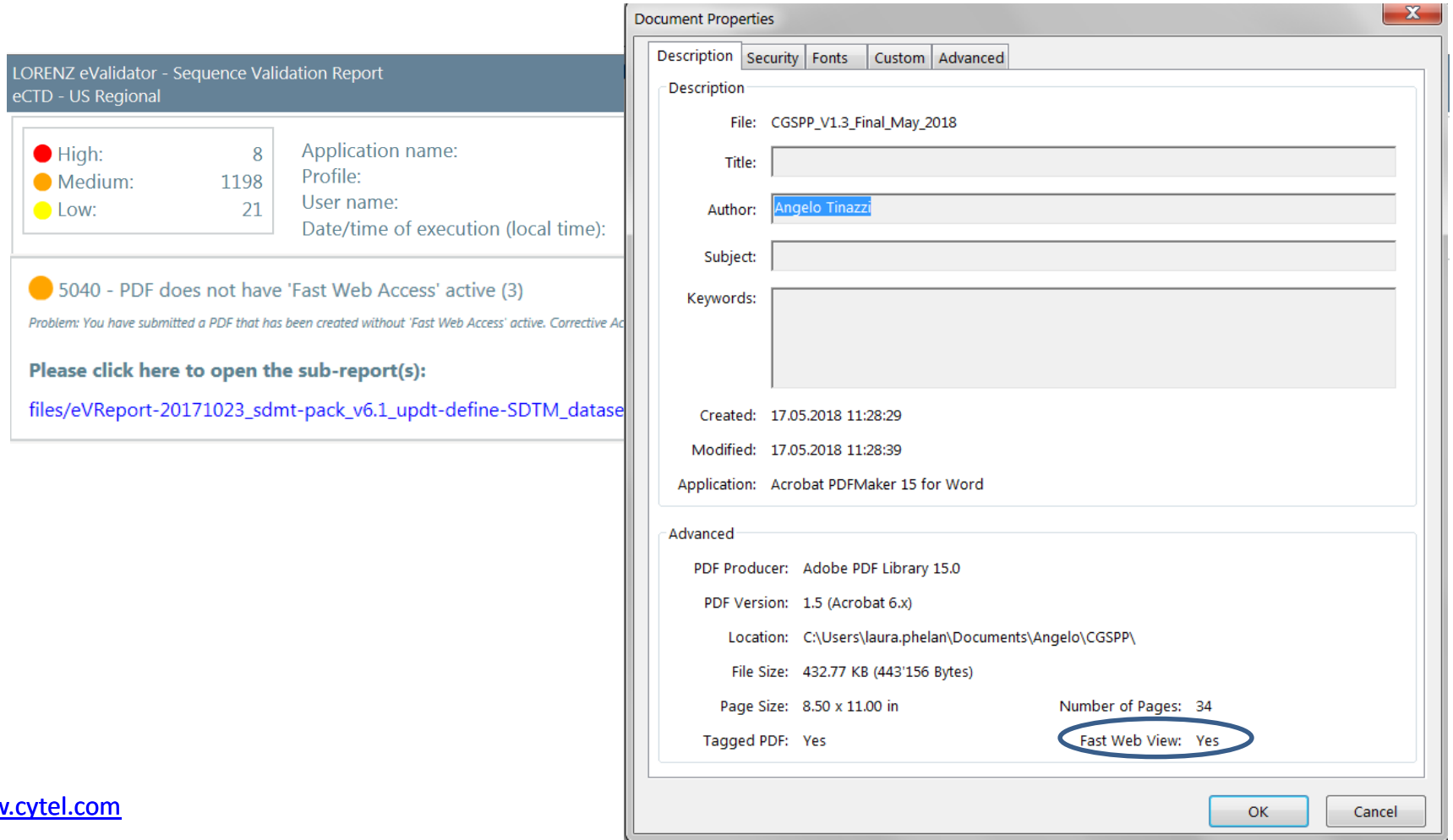
> Special non-ascii characters (bytes 1 to 32) were replaced in the DV domain with a blank which did not change the text but allowed for full readability.

  - But not 32-128

Pinnacle 21 ID	Publisher ID	Message	Description	Category	Severity
SD1029	FDAC214	Non-ASCII or non-printable characters in variable	Variables value must not include non-ASCII or non-printable characters (outside of 32-126 ASCII code range), limited to variables which values may be converted into new variable name or label (--TEST, --TESTCD, --PARM, --PARMCD, QLABEL, QNAM).	Format	Error

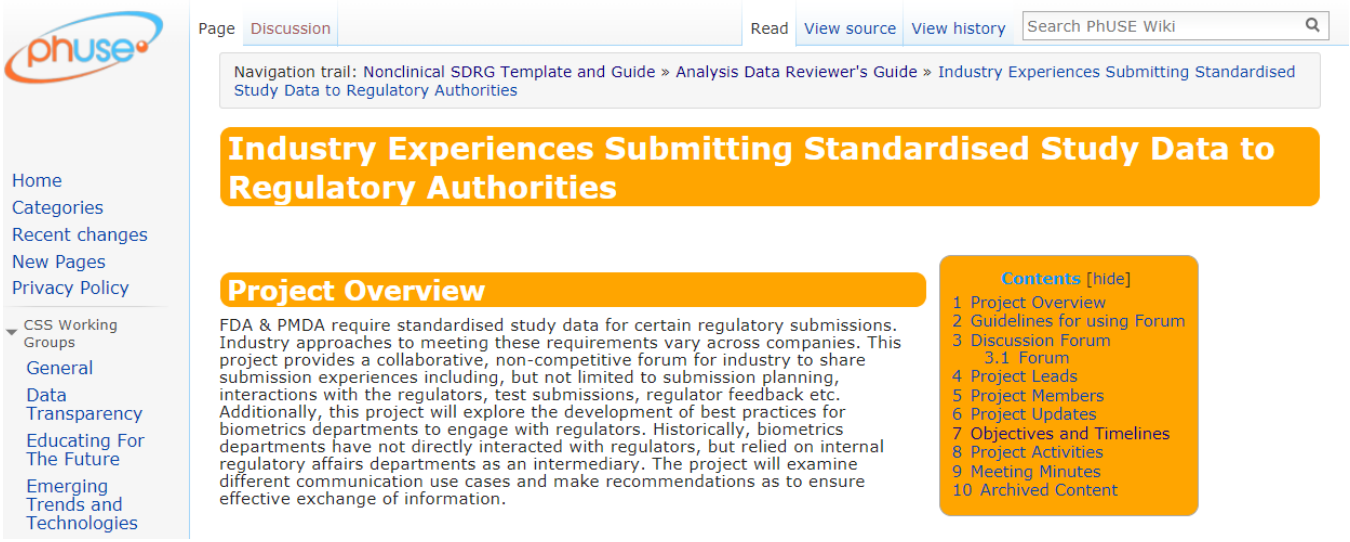
Lorenz Validator

- Further from the PDF Specs
  - Lorenz eValidator (http://www.lorenz.cc/index.cfm). (free!)



Conclusion

- Important to share experiences
  - Phuse Working group :
    - “Industry Experiences Submitting Standardized Study Data to Regulatory Authorities”



- Merci
- Des questions?

Laura Phelan
Cytel Inc.
Email: Laura.Phelan@cytel.com
Web: www.Cytel.com

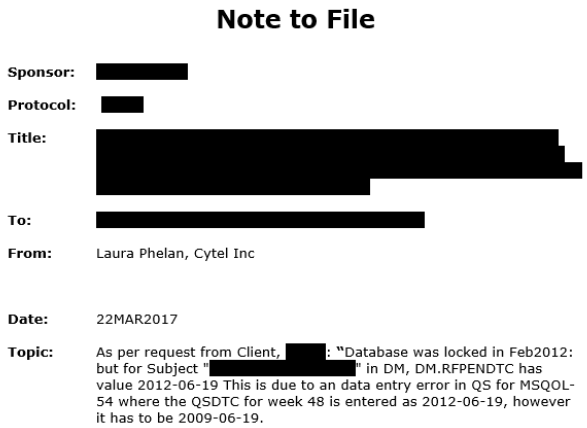
- **BACK UP SLIDES**

Gap Analysis

- Why?
  - Do you have everything?
  - Protocol(s) vs raw & external data
  - External data – is there DST for all?
  - If legacy CSR, have all data to reproduce?

DB Issues

- Closed legacy studies?
- Example:
  - DB lock Feb2012
  - Subject X last date (RFPENDTC) June 2012
    - uncorrected data entry error
- Result:
  - Hardcoding
  - NTF



Note to File

Sponsor: [redacted]

Protocol: [redacted]

Title: [redacted]

To: [redacted]

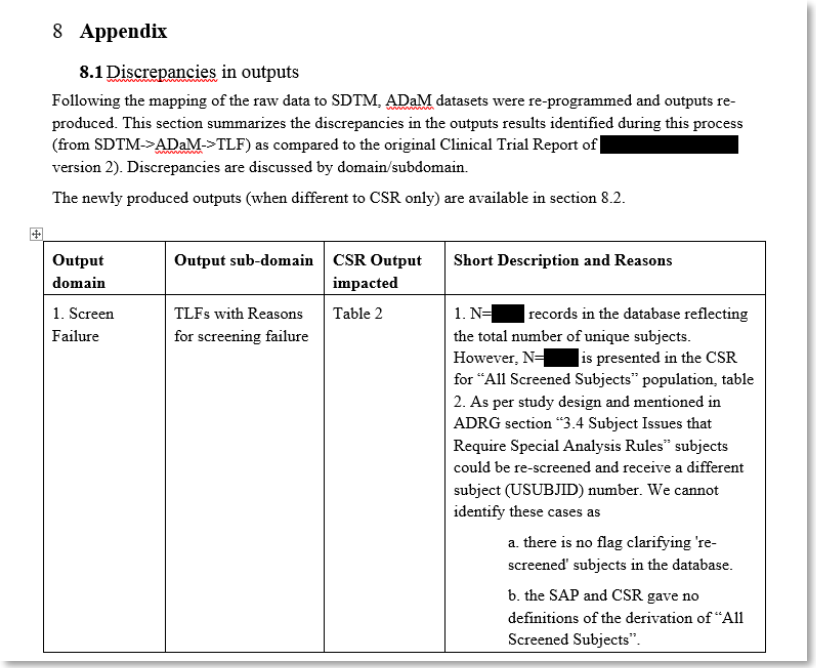
From: Laura Phelan, Cytel Inc

Date: 22MAR2017

Topic: As per request from Client, [redacted]: "Database was locked in Feb2012: but for Subject "[redacted]" in DM, DM.RFPENDTC has value 2012-06-19 This is due to an data entry error in QS for MSQOL-54 where the QSDTC for week 48 is entered as 2012-06-19, however it has to be 2009-06-19.

Legacy CSR Discrepancies

- What if we don't match?
  - Discrepancies
    - Determine cause
    - Describe in ADRG



8 **Appendix**

8.1 Discrepancies in outputs

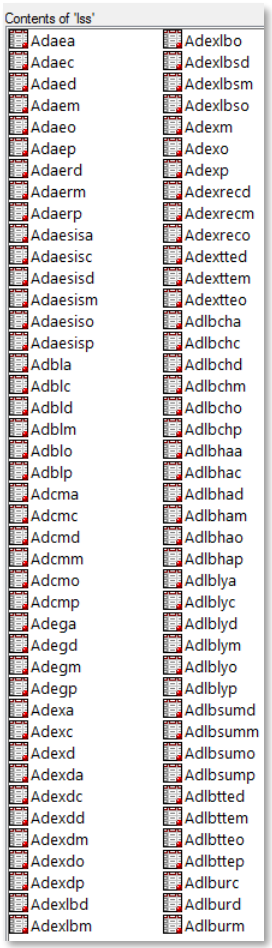
Following the mapping of the raw data to SDTM, ADaM datasets were re-programmed and outputs re-produced. This section summarizes the discrepancies in the outputs results identified during this process (from SDTM->ADaM->TLF) as compared to the original Clinical Trial Report of [redacted] version 2). Discrepancies are discussed by domain/subdomain.

The newly produced outputs (when different to CSR only) are available in section 8.2.

Output domain	Output sub-domain	CSR Output impacted	Short Description and Reasons
1. Screen Failure	TLFs with Reasons for screening failure	Table 2	1. N=[redacted] records in the database reflecting the total number of unique subjects. However, N=[redacted] is presented in the CSR for "All Screened Subjects" population, table 2. As per study design and mentioned in ADRG section "3.4 Subject Issues that Require Special Analysis Rules" subjects could be re-screened and receive a different subject (USUBJID) number. We cannot identify these cases as a. there is no flag clarifying 're-screened' subjects in the database. b. the SAP and CSR gave no definitions of the derivation of "All Screened Subjects".

ISS cohorts

- Pooling cohorts in 1 ADaM complex?
  - 6 cohorts
    - Option 1: 1 ADaM all cohorts?
    - **Option 2: split** =ADAEA/ADAEC/ADAED/ADAEO….
  - Pi – not recognize ADAEx



6.1 Conformance Inputs

- Pinnacle configuration file has been adjusted in order to be able to run the checks on ADAEx datasets. In fact, datasets are not strictly named ADAE, but the naming convention used in the ISS is ADAE concatenated with the cohort suffix (see section 2.2). ADAE checks were not running on it, so we had to adjust the configuration file to have proper checks applied on it.

Level of detail in csdrg, adrg

- How much is too much?
  - We were asked to include reason : only need QNAM /description as per template