

INTERPRETING CDISC ADaM IG THROUGH USERS INTERPRETATION

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Interpreting CDISC ADaM IG through Users Interpretation

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Introduction

- **2004** Statistical Analysis Dataset Model General Considerations
- **2008** IG Draft for Public Comment
- **2009** December IG Final
- **9 years later** we have an IG (v1.0), a new model (v2.1), two new models, Validation Checks and a new Pilot

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Document / Guidance

Analysis Data Model (ADaM), Version 2.1

Analysis Data Model (ADaM), Implementation Guidance, Version 1.0

CDISC ADaM Validation Checks, Version 1.2

Analysis Data Model (ADaM), Examples in commonly used Statistical Analysis Methods

Analysis Data Model (ADaM), Data Structure for Adverse Event Analysis (ADAE), Version 1.0

The ADaM Basic Data Structure for Time-to-Event Analyses (ADTTE), Version 1.0

IG compliance update of CDISC-FDA Pilot 1

Interpreting CDISC ADaM IG through Users Interpretation

Introduction

- FDA SDTM based submission in 2010 → **23%**
- FDA SDTM based submission in 2011 → **39%** and **32%** ADaM based
- ADaM is also adopted by the sponsors as a standard regardless of submission

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The Question

Are ADaM IG and all developed models enough?

What is the gray area and where IG leaves more space for interpretations?

How different users (sponsor) have interpreted such a gray area?

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- There is still space for further development for the CDISC ADaM team.
- Feedback from users experience will inform the CDISC ADaM team on what needs to be clarified and/or added/changed.
- One idea could be to launch a survey among the CDISC users to see what they would like to see in next IG.
 - SAS Institute use the same approach since 1976 with the SASware Ballot for the release of new versions / new functionalities (<http://support.sas.com/community/ballot/>).

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- It is the opinion of some users that some rules can be challenged
 - Having PARCATx classifying PARAM would be useful when same parameters can be «measured» with different approaches or on different locations
 - When AVALC contains categorical results (e.g. a scale) and AVAL contains summary patient information (e.g. Average) then the one-to-one relationship rule does not apply
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- Always check the 'reviewer preferences'
- Each sponsor should have its own Implementation Guidance and Governance Team
 - Further interpretation of the CDISC IG
 - Identify gray area of ADaM and 'take a position'
 - Policy for non-standard analysis datasets

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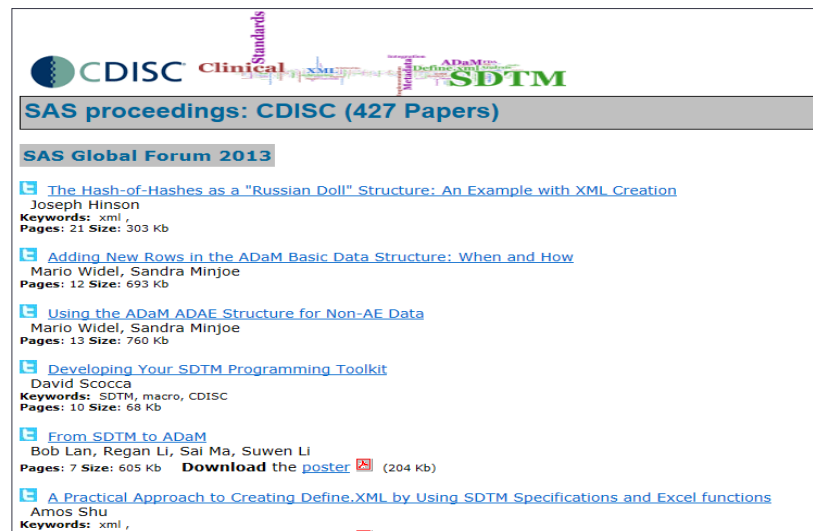
- Conduct a systematic review of what has been «published» so far. It is a common approach used in Medicine (see A gentle introduction to Meta-analysis, PhUSE 2007)
- Similar previous published work
 - SAS Programmer Resources on the web Experiences Acquired Surfing the Net, PhUSE 2006
 - A systematic review of PhUSE, PhUSE 2007

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- CDISC papers presented at SAS conferences were selected through [Lex Jansen website](http://lexjansen.com) (lexjansen.com):
 - SAS Global Forum
 - PharmaSUG
 - PhUSE including single day events
 - Other local area SAS user groups

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- Additional information from the CDISC interchange conferences (Worldwide, Europe, Regional), discussions/blogs (<http://www.cdisc.org/public-discussion-forum>)



CDISC Strength Through Collaboration

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Discussion Forum

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SDTM: Frequently Received Answers to Questions

Forum name	Threads	Messages	Last post
SDTM: Frequently Received Answers to Questions  This forum is hosted by CDISC with content provided by the PhRMA Study Data Tabulation Model Best Review Practices Group. DISCLAIMER: Information posted on this website is volunteered by those submitting data via the SDTM standard to the FDA. The information provided on this site is for informational purposes only. It does not represent FDA policy or CDISC endorsement. Each sponsor is encouraged to have appropriate communications with the FDA.	12	12	 Implementing SDTM in the Clinical D... > 2009-08-10 12:51 PM by jpevans

Active Discussions

Forum name	Threads	Messages	Last post
 General Issues Issues spanning topics.	321	912	 CDASH Team Projects - E2B > 2013-04-29 1:58 PM by syousef
 SDTM IG V3.1.3 Final Comments, questions, ideas, issues and suggestions about the Study Data Tabulation Model Implementation Guide Version 3.1.3 Final	5	13	 hogan rebel > 2013-04-26 2:38 AM by liuhaohan

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- Linkedin CDISC Groups (CDISC, CDISC ADaM, CDISC Advocates).

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- An excel file tracking all CDISC presentations

Title, Author, Company, Conference, Year					My Comment/ Notes	Keywords identifying contents									
	A	C	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	Title	Company	Year	Conference	Final Comment	CRO/Pharma	SD	AD	IG	Application	Definition	Validation	Results Metadata	CT	Generic
256	Building Flexible ADaM Analysis Variable Metadata	K & L Consulting Services, Celgene	2012	PharmaSUG		CRO PHARMA									
259	Derivation and Traceability in ADaM: Examples	Malley Research programming Inc	2012	CDSIC UG Washington DC		CRO		Traceability							
262	Multiple Applications of ADaM Time-to-Event Datasets	MSD	2012	PharmaSUG	Time in ADTTE. ?? Check how traceability is done compared to IG	PHARMA		TTE							
267	ADaM Implications from the "CDER Data Standards Common Issues" and SDTM Amendment 1 Documents	Octagon	2012	PharmaSUG	CDER SDS impact on AdAM, imputation in ADaM not in SDTM, submission should only includes ADSL and key AD (AE and main endpoints), ADSL plus other key variables, SDTM --DY vs ADAM, CDER requires variables that are permissible in SDTM, carefully review SDTM 'derived' variables if copied and used in ADAM (eg --BL variables)	CRO	SDSim pact	SDSim pact							
274	CDISC ADaM Application: Does All One-Record-per-Subject Data Belong in ADSL?	Octagon	2012	PharmaSUG	Traceability for ADSL, BDS for other ADSL info, ADSL used to produce which table, multivariate and BDS	CRO		ADSL BDS Traceability							
276	Automate Validation of CDISC ADaM Variable Label Compliance	Octagon	2012	PharmaSUG	Check of variable labels.	CRO		Yes		Macro		YesLabel			
279	SDTM and AdAM: Metadata Playing Together Nicely	Octagon Omnicare	2012	PhUSE CDSIC UG		CRO	Yes								

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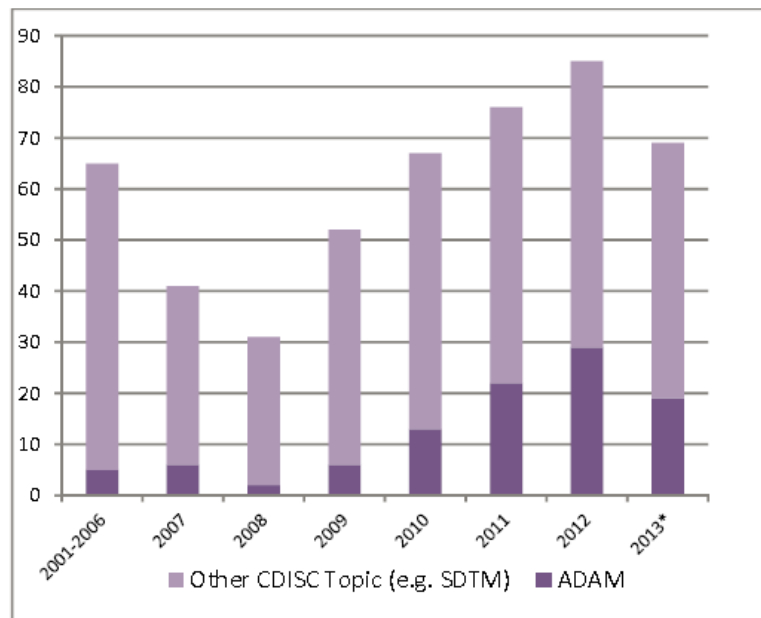
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Quantitative Results

- 482 papers discussing CDISC topics were found
- 102 were focusing on the implementation of ADaM
- ADaM was most discussed at PharmaSUG and PhUSE (with respectively 50% and 28%)
- Authors were prevalent from CROs with 58% of the presentations (Pharma: 32%).



BDS Define.xml Pooling

Governance **Validation**

Traceability Derived Observations Analysis Ready

Controlled Terminology

Flags PARAM OpenCDISC SAS Macro Metadata

Applications

ADTTE ADAE ADSL ADLB

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Qualitative Results

- Generic topics
 - The obvious rules
 - Traceability
 - non-ADaM Analysis Datasets
 - Analysis-Ready
 - ADaM does not support listings
 - CDER SDS impact
 - Validation
- ADSL topics
 - One or several subject-level datasets
 - Use of TRTxSDT/TRTxEDT in oncology studies
- BDS topics
 - Misuse of Indicator Variables
 - Deriving rows or adding columns
 - PARCATy cannot split PARAM
 - How to populate TRTP/TRTA in BDS
 - ADLB and how to represent / classify AVAL
- Other topics
 - Use of ADAE and ADTTE
 - Pooling (ISS/ISE strategy)
 - Governance

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The obvious rules

- ADXXX Naming conventions
- SAS XPT v5 rules
- AD split
 - E.g. ADLBH, ADLBC, ADLBU
- Meaningfull AD Label
 - E.g. Efficacy AD containing primary endpoint should be clearly identifiable
- SDTM fragment can be used to create new variable when ADaM rules do not apply

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Traceability

Traceability makes possible to understand the full data flow from data collection to reporting

- Traceability in the ADaM Standard; PharmaSUG 2013
- Derivations and traceability in ADaM: examples; CDSIC UG Washington DC; 2012
- Examples of Building Traceability in CDISC ADaM Datasets for FDA Submission; PharmaSUG 2012
- When to use xxSEQ vs SRCDOM/SRCVAR/SRCSEQ
- Keeping SDTM variables
- PARAMTYP and DTYPE in BDS Structure
- Use of ANLxxFL and CRITx
- Metadata, especially when traceability is complex (e.g. complex algorithm)
- Use of Intermediate Analysis Datasets

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Non-ADaM Analysis Datasets

Not all Analysis Datasets are ADaM

- Common Misunderstanding about ADaM Implementation; PharmaSUG 2010
- Class should be 'Other'
- Keep SDTM structure
- Key variables from ADSL
- Use ADaM principles when creating new variables
- Use ADaM principles when creating new observations
- Use BDS variables if applicable (e.g. TRTx, CRITx)

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Analysis Ready

- "Analysis ready" - Considerations, Implementations, and Real World Applications; PharmaSUG 2012
- Laboratory Analysis Dataset (ADLB): a real-life experience; CDISC Europe Interchange 2013
- LinkedIn ADaM Group Discussion http://www.linkedin.com/groupItem?view=&gid=3092582&type=member&item=245409684&qid=379c7b1b-df19-4772-acf1-3d279ef5b245&trk=group_most_popular-0-b-ttl&goback=%2Egmp_3092582&_mSplash=1

■ As per ADaM IG

Analysis datasets have a structure and content that allows statistical analysis to be performed with minimal programming

→ one-proc-away

- Output programs should only focus on selecting (and extracting) the statistical models and «eventually» improving the standard statistical outputs template
- It is preferable to have complex derivation in the derived (and fully validated) analysis datasets

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Analysis Ready (cont.)

- Complex derivations for exposure

ADEXSUM derived from ADEX

SITEID	SUBJID	PARAMCD	PARAM	AVAL	AVALCAT1
0102	0004	NADM	Nr. of Administrations	3	
0102	0004	OVERD	Nr. of Overdoses	0	
0102	0004	RDI	Relative Dose Intensity (%)	123.52941176	>110%
0102	0004	TDUR	Treatment Duration (months)	1.6755646817	

Table 15.3.15.1 Treatment Exposure - Safety Analysis Set

Characteristics Statistics		Placebo (N=60)	75 mg q3w + SoC (N=58)	150 mg q3w + SoC (N=60)
Last initiated administration (Number of adm.)				
Min		1	1	1
Q1		4.0	4.0	4.0
Median	AVAL where	6.0	6.0	6.0
Q3	PARAMCD=NADM	9.0	8.0	10.0
Max		24	25	24
Relative Dose Intensity (%)				
N		0	58	60
Missing		60	0	0
Mean	AVAL where PARAMCD=RDI	-	99.01	97.45
SD		-	4.561	7.958
Min		-	85.7	66.7
Median		-	100.00	100.00
Max		-	123.5	123.5
<=75%		N (%)	0	3 (5.0)
>75%-<=90%	AVALCAT1 where	N (%)	2 (3.4)	2 (3.3)
>90%-<=110%	PARAMCD=RDI	N (%)	55 (94.8)	54 (90.0)
>110%		N (%)	1 (1.7)	1 (1.7)

- Look-up Dataset supporting Outputs Production

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Validation

- SDTM, ADaM and define.xml with OpenCDISC; PharmaSUG 2013
- Interpreting ADaM standards with OpenCDISC; PhUSE 2012
- OpenCDISC is commonly accepted
- Opportunity for Improvement is on the tool outputs
 - That's why some companies have also developed their own internal tool

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In some instances when validation rules fail IG might require revisions

Character Tests with AVAL/AVALC and deriving rows

■ Common Misunderstanding about ADaM Implementation; PharmaSUG 2010

AVISIT	PARAMCD	QSORRES	QSSTRESC	QSSTRESN	AVAL	AVALC	DTYPE
Week 12	QS1	VERY BAD	1	1	1	VERY BAD	
Week 12	QS1	BAD	2	2	2	BAD	
Week 12	QS1	GOOD	4	4	4	GOOD	
Week 12	QS1				2.333		AVERAGE

Same name, Same Value, Same Metadata.....but it should be meaningful

→ «End of Study Reason» in ADSL, ESREAS or DSDECOD ?

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ADaM does not support listings

- An Evaluation of the ADaM Implementation Guide v1.0 and the Analysis Data Model v2.1; PhUSE 2009
- Considerations for CSR Output Production from ADaM Datasets; PhUSE 2012
- The focus of CDISC as well as ADaM is submission
- A lot of derivations are also required for listings production indicating that such derivations should be done by using ADs
- «Derivations» can then be removed if ADs are part of submission

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CDER Common SDS Issues Document

- ADaM Implications from the “CDER Data Standards Common Issues” and SDTM Amendment 1 Documents; PharmaSUG 2012
- USUBJID consistency
- Linear CDISC Implementation is suggested
- ADaM should not rely on SDTM derived variables (e.g. flags)
- Do not forget SUPPQUALs
- When submitted to FDA ADaM should at the minimum support key analysis

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ADSL - One or several subject-level datasets

- CDISC ADaM Application: Does All One-Record-per-Subject Data Belong in ADSL?; PharmaSUG 2012
- Designing and Tuning ADaM Datasets; PharmaSUG 2013
- ADaM on a Diet: Preventing Wide and Heavy Analysis Datasets; PhUSE 2011
- ADSL core information driven by the SAP
- Other ADSL-like can be added e.g. ADBASE

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TRTxxSDT/TRTxxEDT vs TRT01P: The Oncology fight for mapping cycles date information

■ [Linkedin ADaM Group Discussion
http://www.linkedin.com/groupItem?view=&qid=3092582&type=member&item=228552283&qid=2742e47e-d7cd-44a5-9fc6-083901aa2f76&trk=group_items_see_more-0-b-ttl&mSplash=1]

- Cycle $\neq$ Period
- Use exposure analysis dataset

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BDS - PARCATy cannot split PARAM

- Designing and Tuning ADaM Datasets; PharmaSUG 2013
- ADaM Implementation Guide Status Update; CDISC UG Atlantic 2013
- PARCATy can be not used as a qualifier of PARAM

USUBJID	PARCAT1	PARAMN	PARAM	AVALC
01010001	Investigator	1	Best Overall Response	SD
01010001	Reviewer	1	Best Overall Response	PR

USUBJID	PARAMN	PARAM	AVALC
01010001	1	Best Overall Response (Investigator)	SD
01010001	2	Best Overall Response (Reviewer)	PR

????? Can the CDISC ADaM team change this rule ?????

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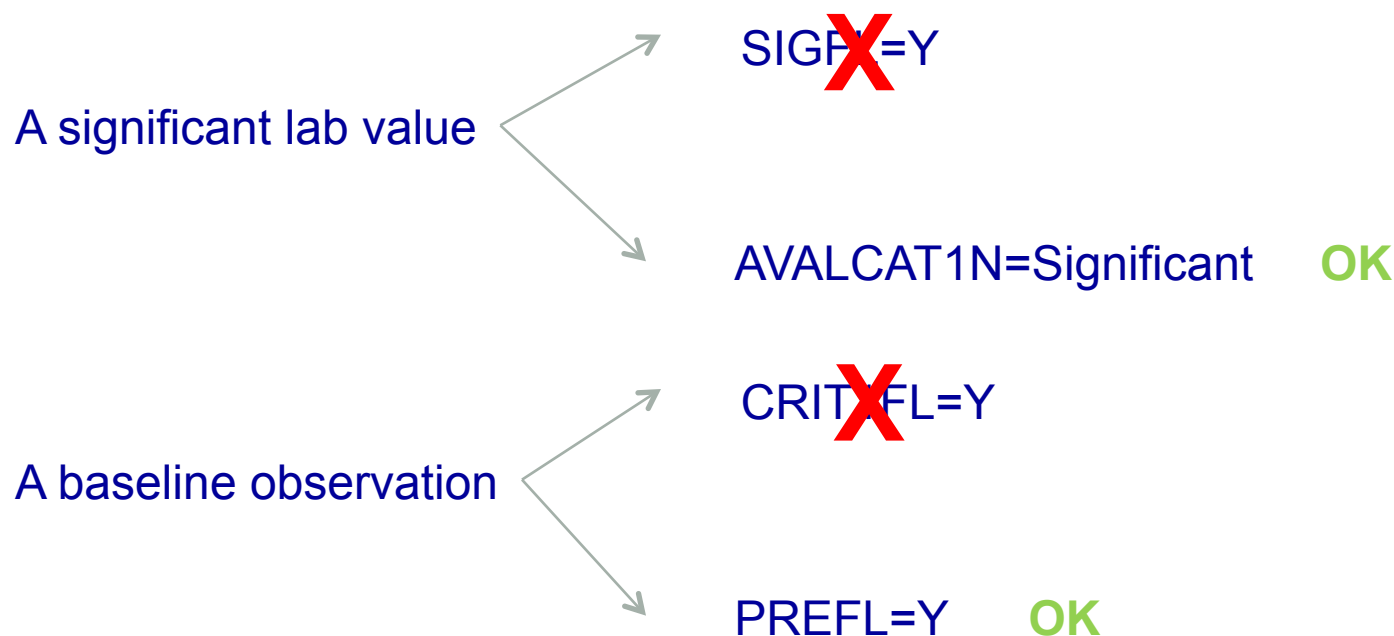
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BDS - Misuse of Indicator Variables and Criteria Variables

- Common Misunderstanding about ADaM Implementation; PharmaSUG 2012
- Flags for Facilitating Statistical Analysis Using CDISC Analysis Data Model; PharmaSUG 2013

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BDS - Deriving Rows or Adding Columns?

- Designing and Tuning ADaM Datasets; PharmaSUG 2013
- Common Misunderstanding about ADaM Implementation; PharmaSUG 2012
- Adding new Rows in the ADaM Basic Data Structure. When and How; SAS Global Forum 2013
- Derived observations and associated variables in ADaM datasets; PharmaSUG 2013
- Section 4.2 of IG illustrates the 6 rules for the creation of rows vs columns
- All rules except one, require the creation of a new records
 - «A parameter invariant function of AVAL and BASE on the same row that does not involve a transformation of BASE should be added as a new column»
 - Adding a new column is restricted to available BDS variables
 - a.g. CHG=AVAL-BASE

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BDS - Deriving Rows or Adding Columns? (cont.)

- E.g. how to identify the worst post baseline observation (minimum)

USUBJID	VISIT	PARAM	AVAL	WORST
01010001	Week 1	XXXXXX	80	75
01010001	Week 2	XXXXXX	78	75
01010001	Week 3	XXXXXX	75	75

- IG section 4.5.3 Identification of Post-Baseline Conceptual Timepoint Rows

USUBJID	VISIT	AVISIT	PARAM	AVAL	DTYPE
01010001	Week 1	Week 1	XXXXXX	80	
01010001	Week 2	Week 2	XXXXXX	78	
01010001	Week 3	Week 3	XXXXXX	75	
01010001		Post-Baseline Minimum	XXXXXX	75	MINIMUM

→ Or flag worst post-baseline record (ANL01FL=Y)

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BDS – Mixed Questions

How to populate TRTP and TRTA in BDS

TRTA is a record-level identifier that represents the actual treatment attributed to a record for analysis purposes. TRTA indicates how treatment varies by record within a subject and enables analysis of crossover and other multi-period designs. TRTxxA (copied from ADSL) may also be needed for some analysis purposes, and may be useful for traceability and to provide context. TRTA is required when there is an analysis of data as treated and at least one subject has any data associated with a treatment other than the planned treatment.

ADLB and Outputs Production

- Producing Clinical Laboratory Shift Tables From ADaM Data; PharmaSUG 2011
- Using the ADaM ADAE Structure for Non-AE Data; SAS Global Forum 2013

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Pooling: ISS/ISE Strategy

- Approaches to Creating ADaM Subject-Level Analysis Datasets (ADSL) for Integrated Analyses; PhUSE 2012
- ADaM or SDTM? A Comparison of Pooling Strategies for Integrated Analyses in the Age of CDISC; PhUSE 2012
- ADaM in a Pool! A Concept on how to Create Integrated ADaM Datasets; PhUSE 2012
- ADaM Implications from the "CDER Data Standards Common Issues" and SDTM Amendment 1 Documents; PharmaSUG 2012
- Strategies for Implementing SDTM and ADaM Standards; PharmaSUG 2005
- An hot topic fearly supported by the IG
- Pooling in SDTM or in ADaM?
- An ADaM sub-team is working on developping a process

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Implementing ADaM in your Organization, Governance and CRO Surveillance

- Defining the Governance and Process of Implementing ADaM across an Organization]; PhUSE 2011
- The 5 Biggest Challenges of ADaM; NESUG 2010
- «Start small and build iteratively different levels of standards and refining the standards and process along the way»
 - Make your own interpretation and standardise it (Sponsor IG)
 - Develop and manage your standards (governance)
 - Support your team
- Having in place the sponsor's IG and standards will set clear expectations on what and how CRO will deliver

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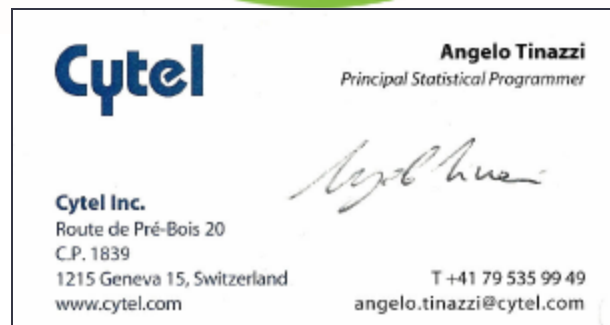


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