

Metadata Design for Analysis & Reporting



PRAHEALTHSCIENCES

DATE
Oct 12 – 15, 2014

PRESENTED BY
Giri Balasubramanian
Gopinath Viswanathan



Abstract

- PRA Health Sciences, based on its understanding of implementation guide published by CDISC for trial data, was able to convert them into metadata form in its flagship system EXACT. The metadata captured in EXACT was then organized to meet the needs of PRA's internal standards and also able to import sponsor specific metadata information as part of its process within EXACT or extend the PRA's metadata too based on business needs. Using it's metadata repository named 'Global Metadata Repository' PRA was able to generate reports with consistent quality in less time
- This presentation is supported by demonstration of EXACT on how the metadata is extended to generate the mock shells for SAP preparation by statisticians?, and then generate TFLs either using mock shells or adhoc generation and finally promoting the generated output as mock shell for future re-use. This feature is supplemented with search capability within EXACT in order to re-use from similar studies



Agenda

- To detail the importance of metadata in performing Analysis & Reporting across therapeutics and thereby how it increases productivity of the team?
- Purpose & Evolution of TFL metadata in Analysis & Reporting
- What are different types of metadata in TFL?
- Use of metadata in TFL Generation – a demonstration
- Benefits



Purpose & Evolution of metadata in Analysis & Reporting

- Metadata in Clinical Trials lead to standardization
- Demonstrated & put to use through standardization of submission meta data aiding regulatory reviewers
- How to extend it for Analysis & Reporting ?
 - Using Analysis Metadata model (ADaM)
 - Continuous metadata build-up and review for therapeutics



What are different types of metadata in TFL ?

- Classification based on Report Layout Structure
- Types of metadata identified
 - Header & Footer Metadata
 - Variable Level Metadata
 - Descriptive Statistics (Continuous/Categorical/Hypothesis) Metadata
 - Format Metadata
 - Mock shells (TFL) Metadata
 - Study/Analysis Metadata



Table Mock shells – Metadata

xxxxxxx

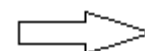
<Compound><Study> Statistical Output

CONFIDENTIAL

<DRY RUN/DRAFT/FINAL>

15 Feb 2013

Page 65 of 179



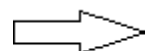
Header Metadata

Variable Level Metadata

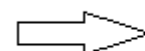
ADLB

Table 4.6.xⁱ
Quantitative Clinical Laboratory Results by Treatment Group: <Laboratory Categoryⁱ>
(<Analysis Set³>)

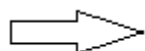
TRTP



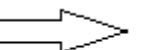
Reporting Header Metadata



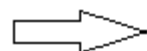
Column header Metadata



Descriptive Statistics



Reporting Footnote Metadata



Footer Metadata

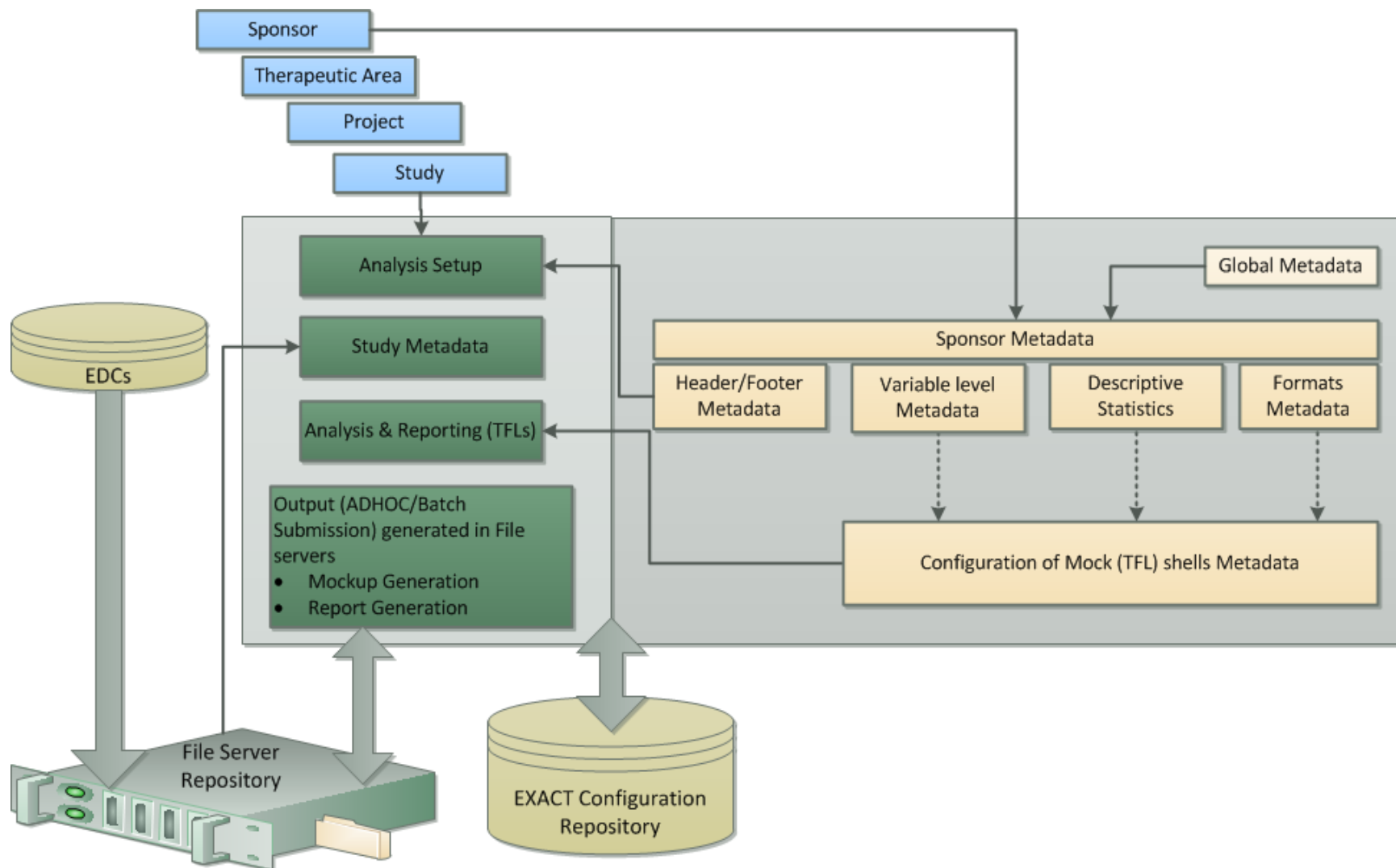
Parameter Visit	PARAM AVISIT	Statistic	Placebo (N ² =xx)		Shire Drug ⁱ (N ² =xx)		Active Comparator (N ² =xx)	
			AVAL	CHG	AVAL	CHG	AVAL	CHG
			Change from Baseline		Change from Baseline		Change from Baseline	
Parameter 1 (<units>)								
Baseline	ABLFL='Y'		xx		xx		xx	
		Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
		Median	xx.x		xx.x		xx.x	
		Min, Max	xx, xx		xx, xx		xx, xx	
<add rows for each visit as specified in the SAP>			xx		xx		xx	
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Parameter n (<units>)								
Baseline			xx	xx	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
<add rows for each visit as specified in the SAP>			xx	xx	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Cross-reference: Listing xxx <Provide reference to supporting listing>

Program: xxxxxxx.sas, Output: xxxxxxx.rtf, Generated on: DDMMYYYY xx:xx Page x of y



TFLs Metadata in EXACT - Organization





Use of metadata in TFL Generation – a demonstration

- Video clip on how PRA implemented metadata in TFL Generation



Benefits

- Creation of TFL repository across studies
- Re-usability, Process In-place
- Enhance the analysis skillset of statisticians
- IMPROVES PRODUCTIVITY
- A step towards extending CDISC SHARE (or Other) for TFL Metadata



- Your comments and questions are valued and encouraged. Contact the author at:
- Author Name – Giri Balasubramanian & Gopinath Viswanathan
 - Company – PRA Health Sciences
 - Address – 40 2nd Main Road, R.A.Puram
 - City / Postcode – Chennai - 600028
 - Work Phone: +914445535341
 - Fax: +914445535343
- Email: BalasubramanianGiri@prahs.com
ViswanathanGopinath@prahs.com
- Web: <http://www.prahs.com/>



PRAHEALTHSCIENCES

THE FUTURE OF CLINICAL DEVELOPMENT