

Metadata Design for Analysis & Reporting

Giri Balasubramanian, PRA Health Sciences, Chennai, India
Gopinath Viswanathan, PRA Health Sciences, Chennai, India

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 its metadata repository named Global Metadata Repository, PRA was able to generate reports with consistent quality in less time.

The presentation would detail the importance of metadata in performing Analysis & Reporting across therapeutics and thereby how it increases productivity of the team?

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.

INTRODUCTION

The scope of this presentation is to detail the importance of metadata in performing Analysis & Reporting across therapeutics and thereby how it increases productivity of the team?

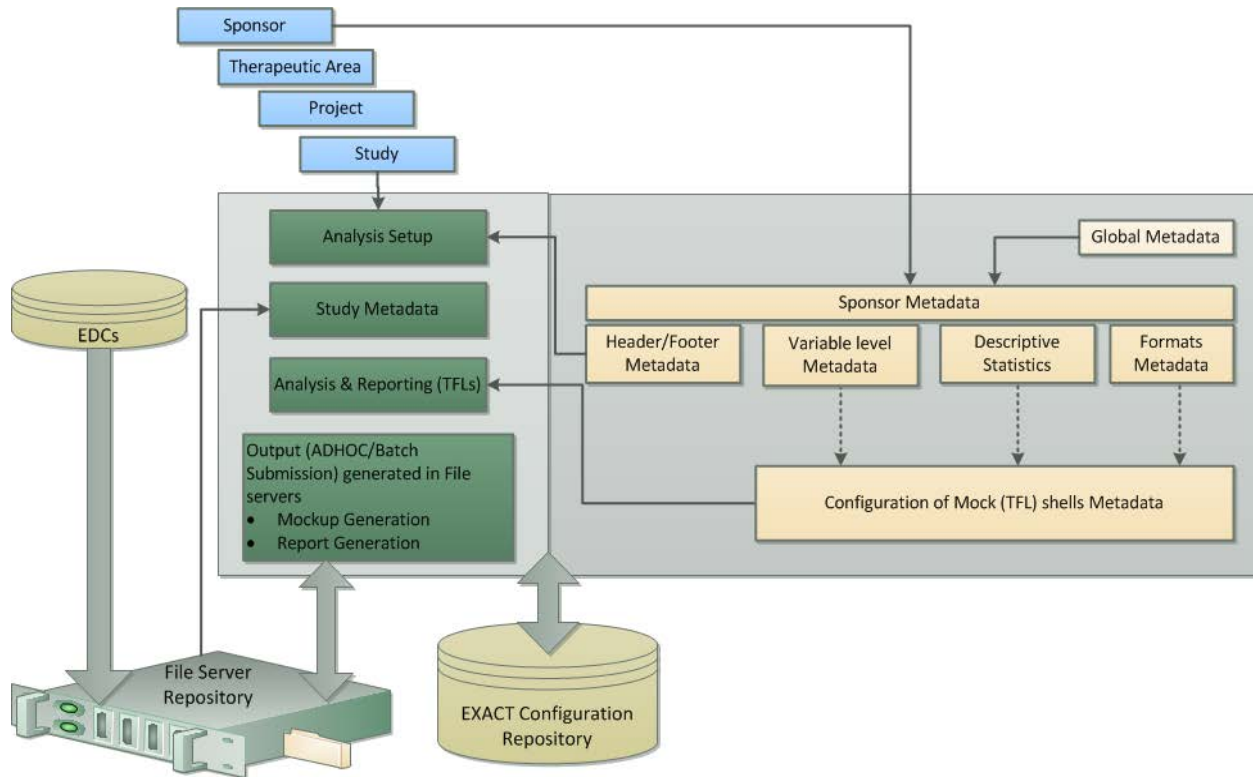
PURPOSE & EVOLUTION OF METADATA IN ANALYSIS & REPORTING

- 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

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

TFLS METADATA IN EXACT - ORGANIZATION



CONCLUSION

The presentation shares the below 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

CONTACT INFORMATION

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/>

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