PhUSE US Connect 2019: SD02

Mapping Programs
Written by MDR

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Agenda

- Mapping Specifications – Background
- Technology
- Reporting Overview
- Program Code Generation
- Demo
- Q&A
Motivation

- Outsourcing to CROs on the rise

Cost Cutting to Drive 12% Growth in CRO Outsourcing Through 2021, New Study Finds

Apr 11, 2018  By Pharmaceutical Technology Editors

While pharma industry growth has slowed from double to single digit levels recently, demand for contract research organization (CRO) services is growing rapidly, according to the Business Research Company’s (BRC’s) 2018 CRO Global Market Report.

http://www.pharmtech.com/cost-cutting-drive-12-growth-cro-outsourcing-through-2021-new-study-finds
• **Communication is key**
  - Global organizations
  - Sponsor “flavors” of standards e.g. SDTM
  - Project / study structure metadata

• **Specifications for data transformations**
  - To SDTM
  - To ADaM
  - Reproducible
  - Universal format
MDR characteristics

- **Fully model agnostic**
  - Repository for all kinds of standards
  - Structure metadata (CDISC, EDC, proprietary, interim)
  - Controlled terminology
  - Algorithms, value level metadata
  - Reporting metadata (headers, footers)
  - Any other

- **Inheritance concept**
  - Support for global, project, study level
  - More levels by configuration
  - Reduced maintenance effort, enhanced performance
MDR Reports

- Mapping specifications
  - Two formats: Excel and define.xml
  - Define.xml by design ensures traceability
  - Both formats widely used and understood

- Relations Report
  - Track metadata relationships across data models
  - Hyperlinks
  - Highlighting missing algorithms
One step beyond

- **Convert MDR information into code**
  - Collect metadata and algorithms
  - Bring into GUI
  - Review and edit assignments of variables
  - On-the-fly reporting
  - Generate validated SAS code
- **Purely metadata driven**
  - Uses MDR or metadata derived from data
  - Multiple steps supported
  - Conditions, joins and where clauses
  - Validated SAS code
• Demo Video
Questions and Answers