CONSUMING YOUR METADATA FOR A HEALTHY MAPPING

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AGENDA

• Introduction
• Using the metadata
• Generating pattern code
• Executing pattern code
• Consistency checking and governance
• A worked example
• Conclusion
INTRODUCTION - I

MANAGEMENT OF DATA STANDARDS

MANAGEMENT OF STUDY INSTANCE METADATA

HUB & SPOKES

Study Design (SDTM TDM) Visit Schedule with T&E

EDC IVRS ePRO Lab

Macro Library Statistical Computing Environment

Protocol Optimization Data Surveillance Clinical Data Repository
INTRODUCTION - II

- **ISO 21090 BASED CLINICAL RECOGNIZABLE CONCEPTS**
- **DATA IS MAPPED TO AND FROM A HUB**
- **USABLE FOR CDISC AND OTHER DATA MODELS**

- Mapping by declaration to concepts
- Allows End to End (E2E) data flow dry-run without data
- Study teams worry about the what not the how
USING THE METADATA

PAREXEL® CLINICAL MDR

DATA COLLECTION INSTRUMENTS (DCI)
ELECTRONIC CASE REPORT FORM (ECRF)

GLOBAL MACRO LIBRARY (GML)
PATTERN CODE GENERATION
PATTERN CODE EXECUTION

CONSISTENCY CHECKS
METADATA
DATA

GLOBAL MACRO LIBRARY (GML)
PATTERN CODE GENERATION
PATTERN CODE EXECUTION

RAW DATA
SDTM
ADAM
GENERATING AND EXECUTING PATTERN CODE

Generating Pattern Code

- For each pattern defined in the MDR
- Corresponding algorithm to translate the pattern metadata connectivity and input data into output data
- Executable pattern code generated

Executing Pattern Code

- Once pattern code is generated
- Code is executed together with the input data (e.g. raw data for an SDTM execution)
- Output data generated
CONSISTENCY CHECKING AND GOVERNANCE

Performed at both pattern code generation and pattern code execution

During pattern code generation

• Checks performed on the metadata
• Check each variable in the metadata is accounted for

During pattern code execution

• Checks performed on the metadata
• Checks performed on the data
• Check individual metadata is consistent between the study instance metadata; metadata in pattern code generated; structural metadata and raw data content
A WORKED EXAMPLE - I

PAREXEL® CLINICAL MDR

AEACNOTH
CODED ITEM

DISPLAYNAME

TRANSLATION.
DISPLAYNAME

GROUP.
DISPLAYNAME

CONTROLLED TERMINOLOGY

NONE
CONCOMITANT MEDICATION
HOSPITALIZATION OR PROLONGATION
OF HOSPITALIZATION
THERAPEUTIC OR DIAGNOSTIC
PROCEDURE

PATTERN CODE
GENERATION

CONSISTENCY
CHECKS
METADATA

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A WORKED EXAMPLE - II

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PATTERN CODE EXECUTION

ADAM
CONCLUSION

By defining algorithms that relate to each pattern applied in the PAREXEL® Clinical MDR, we can automate the majority of tabulation and analysis dataset mappings and associated population.

PAREXEL® Clinical MDR and patterns facilitate

SIMULTANEOUS

CONSISTENT

EFFICIENCY
THANK YOU

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