



SD07 SDTM Automation by Using Metadata

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* This body of work was done while Krishna was at Saama Inc

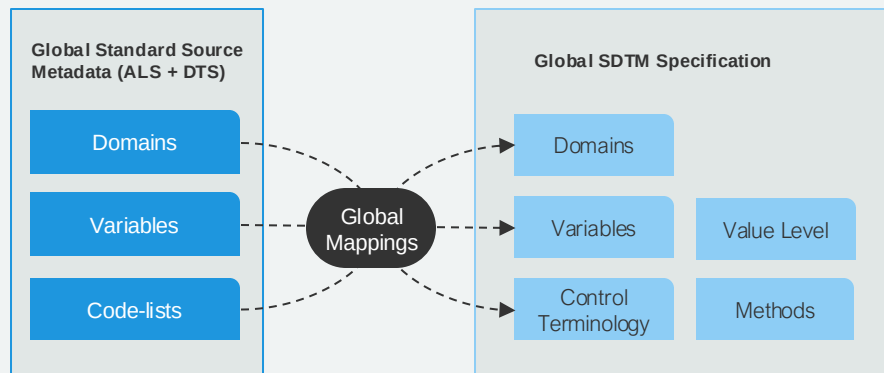
Approach for Managing Global SDTM Standards and Mappings

Key Features:

- Tiered standard mappings
- Multiple versions of standards
- Multiple versions of Control terminology, including Sponsor control terminology
- Management of “Value level” metadata
- Standard transformation maps included out-of-the-box
- Custom transformation maps creation and management

Global (TA-level context)

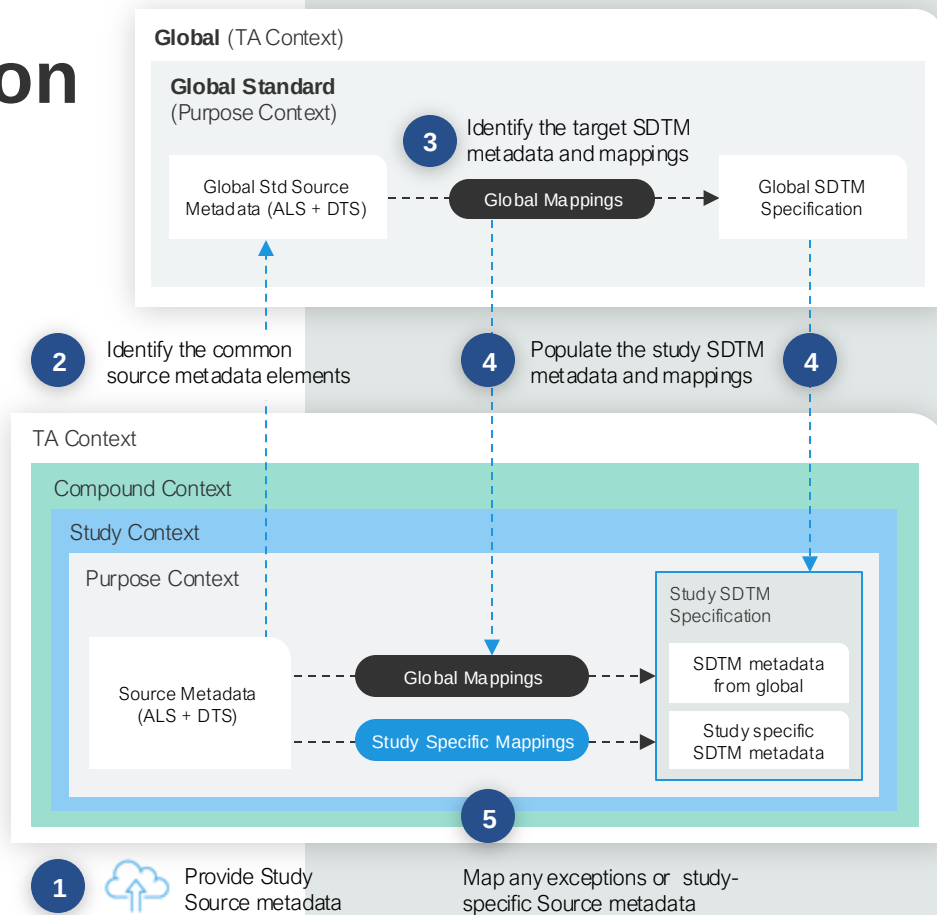
Global Standard (Purpose-level context)



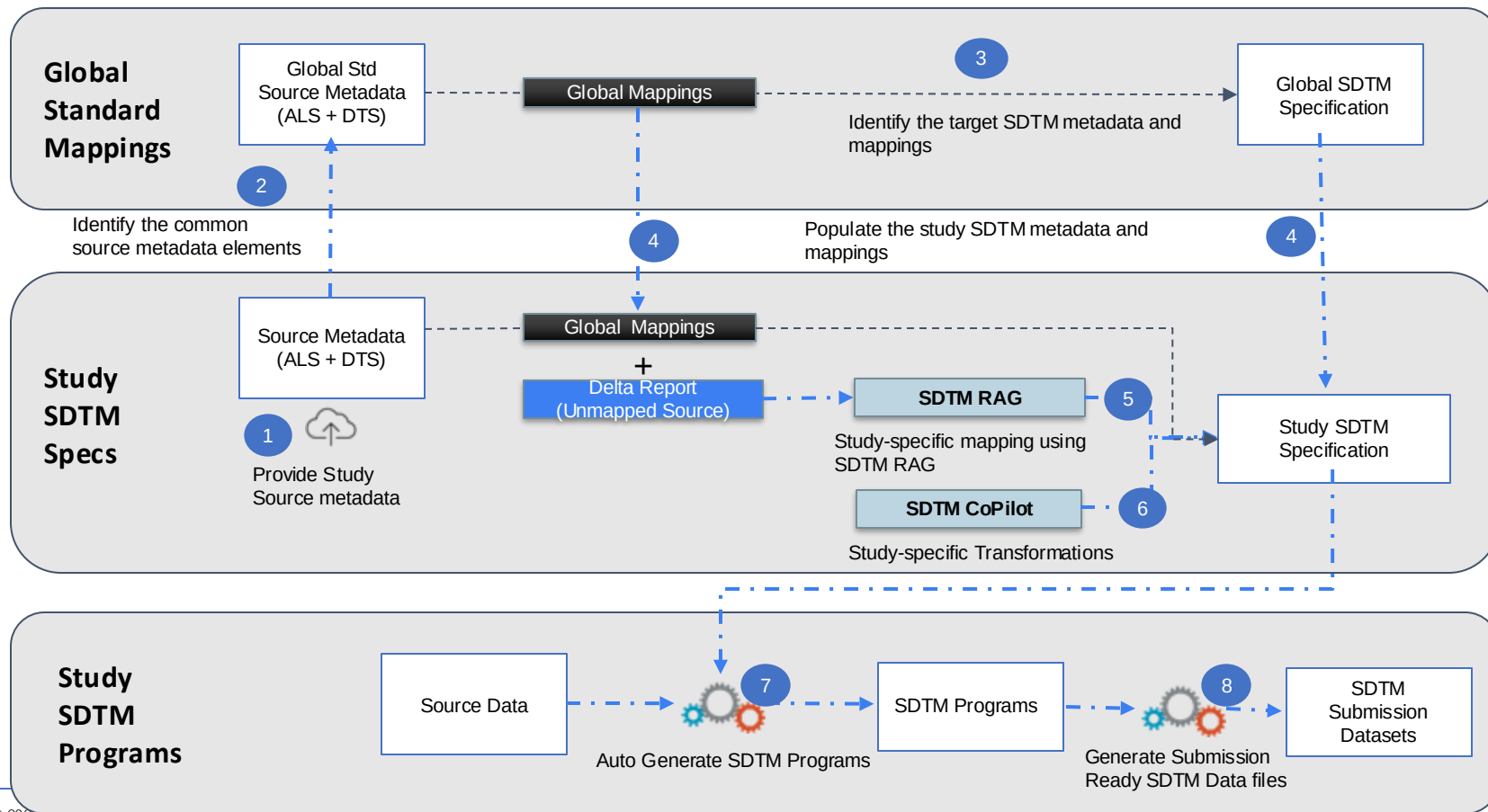
Approach for Automation of Study SDTM Spec and Mapping

Key Features:

- Auto-generation of Study SDTM spec using mappings
- Support for Define.xml V 2.1
- Support study-specific Value-level metadata, CT, Methods ...
- Study specific mappings and transformation functions can be created
- Maintains a standalone code package so that outputs can be reproduced easily
- R-code generation for individual SDTM domain outputs
- Auto creation of submission ready SDTM XPT files.
- Integration with P21E for Define.xml generation



GEN AI based Automation of Study SDTM Spec and Mapping





Demo

<https://www.loom.com/share/f46f075fffcf41598cb37f76265d3417?sid=ae1e5e0e-b0f8-456b-9b61-d031a00b331f>



BRAIN - SDTM: Key Business Outcomes

SDTM automation in BRAIN typically achieves 50% reduction in effort and 69% reduction in timelines for generation of outputs per study

Spec Creation and
Approval Timeline

Typical Industry Metric

26 Days

Programming / QC
effort for first
SDTM output
generation

200 Hours

- 8 hours avg per domain x 25 domains
- For typical standards based studies

Outcomes with BRAIN - SDTM

13 Days

50%



62 Hours

69%



- 2.5 hours avg per domain x 25 domains
- For typical standards based studies





Thank you