

The Elusive Goal of Automation in SDTM Mapping

A CRO perspective

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Ephicity

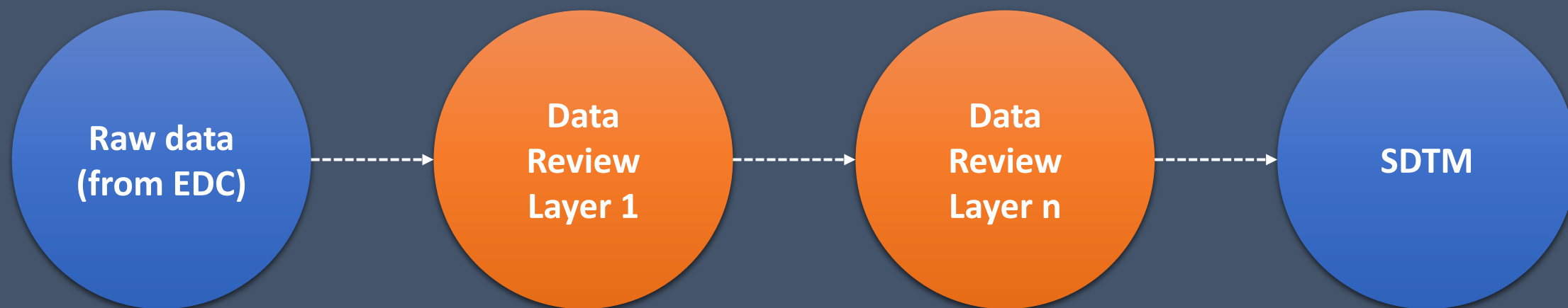
Agenda

- The grind of manually-mapping SDTMs
- The CRO perspective
- Approaching automation
- Conclusion

Typical SDTM Mapping



Typical SDTM Mapping



Why is it time-consuming

- Too many components
- Ever-evolving standards
- Varying study designs limit re-use
- Study-specific adhoc requests
- **Data review takes time**

Raw data

Intermediate data
layer

Specifications

aCRF

SDTM

Additional challenges for CROs

- Limited scope of work based on type of contract with sponsor
- Quick turn-around time
- Different possible inputs (input data from EDC or intermediate layer)
- One solution for one type of project will not extend to others

Scope for automation – what is out there

- Rule-based mapping (If-This-Then-That systems)
- Metadata-based mapping
- Machine/Deep learning based mapping
- Proprietary systems

Rule-based mapping



“If-This-Then-That”
Rules

Rule-based mapping

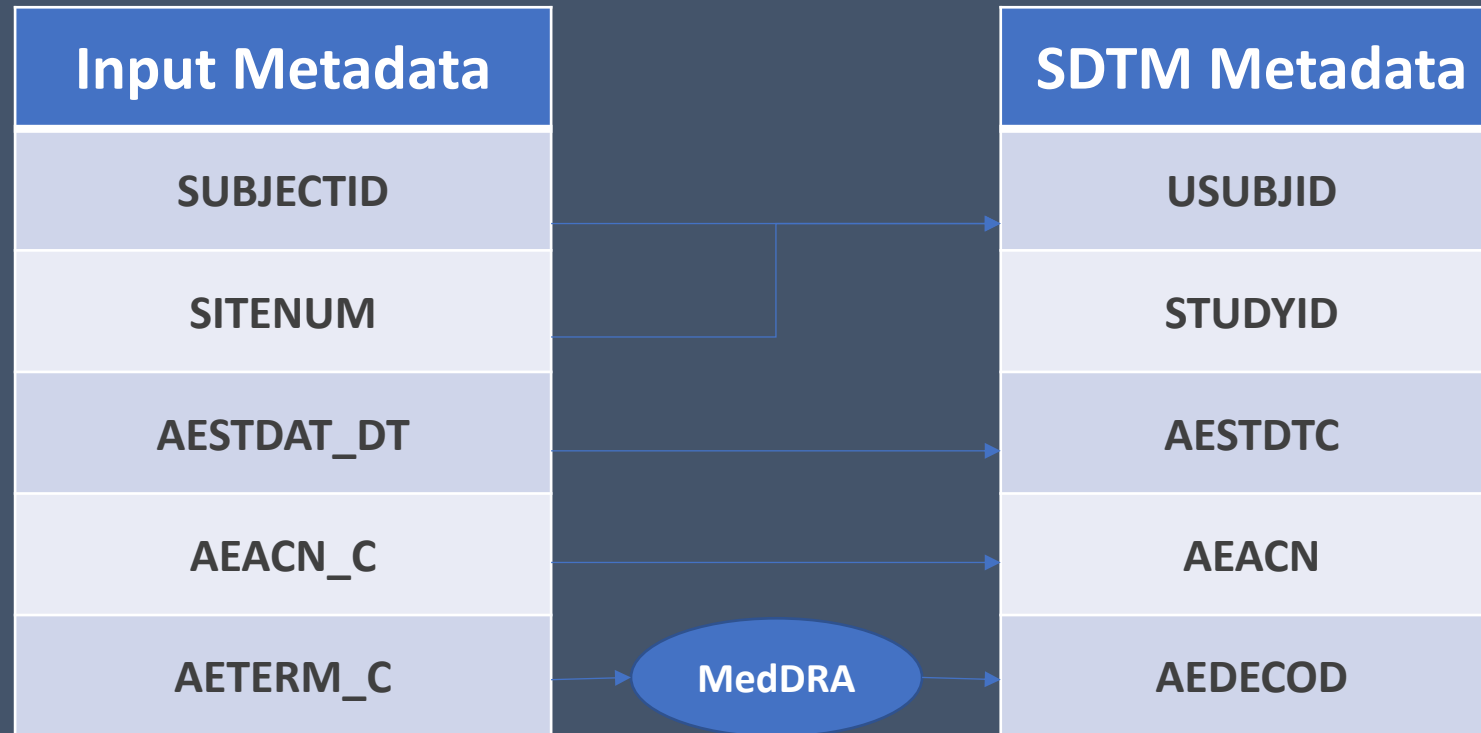
- Independent of standards
- Can work with legacy/proprietary data
- Works well for known repeatable inputs
- New study design/CRF/CRF field results in null output
- Requires constant updates to the rule database

Metadata-based mapping



Rules based on input
and output standards

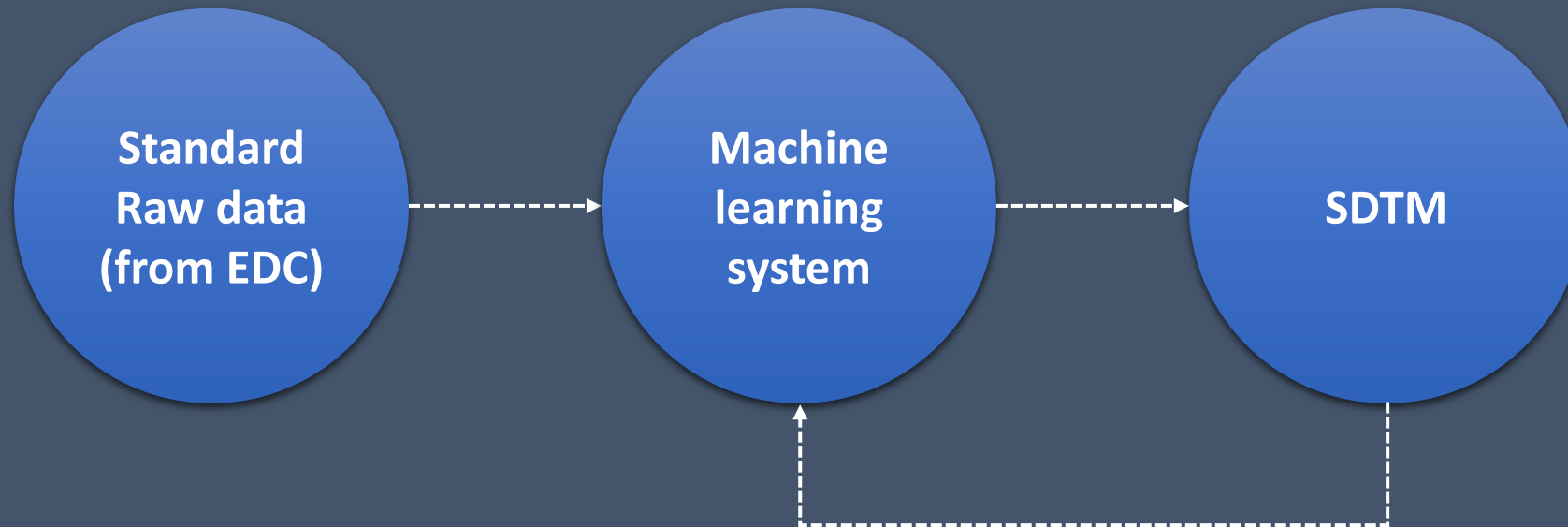
Metadata-based mapping



Metadata-based mapping

- Works well for a given CRF library
- New CRF pages can expand the mapping database
- Can be implemented with macros and set of metadata
- Study specific changes still need manual intervention
- Complex study design scenarios need manual intervention

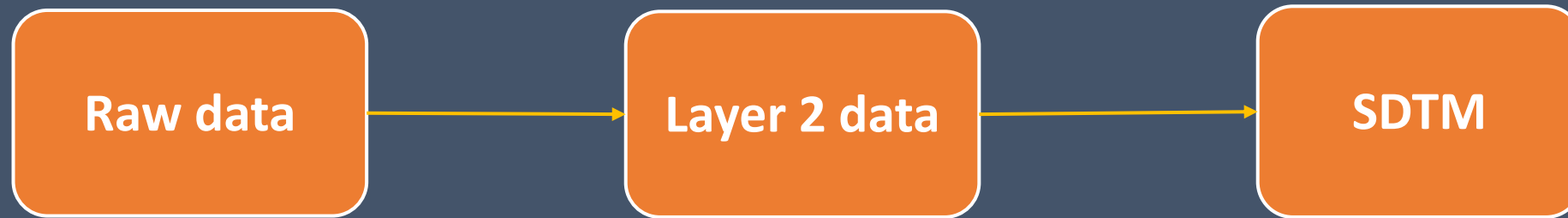
Machine learning for SDTM Mapping



Machine learning for SDTM mapping

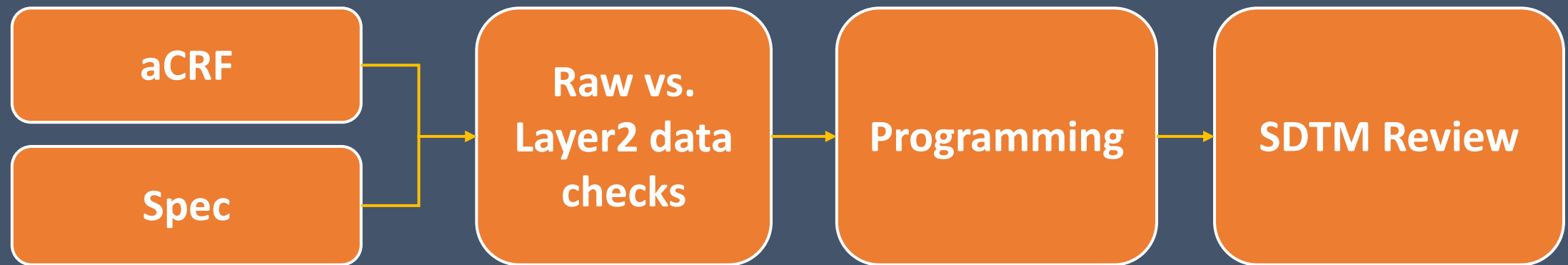
- Train the system with a set of inputs
- Analyse the output for standard inputs
- Expand the system to self-learn
- Requires a significant amount of R&D and review of outputs

Case Study: A CRO perspective



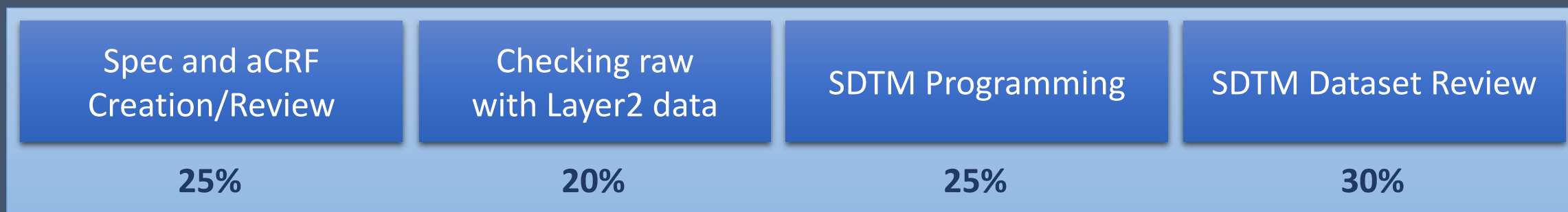
Data flow

Case Study: A CRO perspective



Task flow

Case Study: A CRO perspective

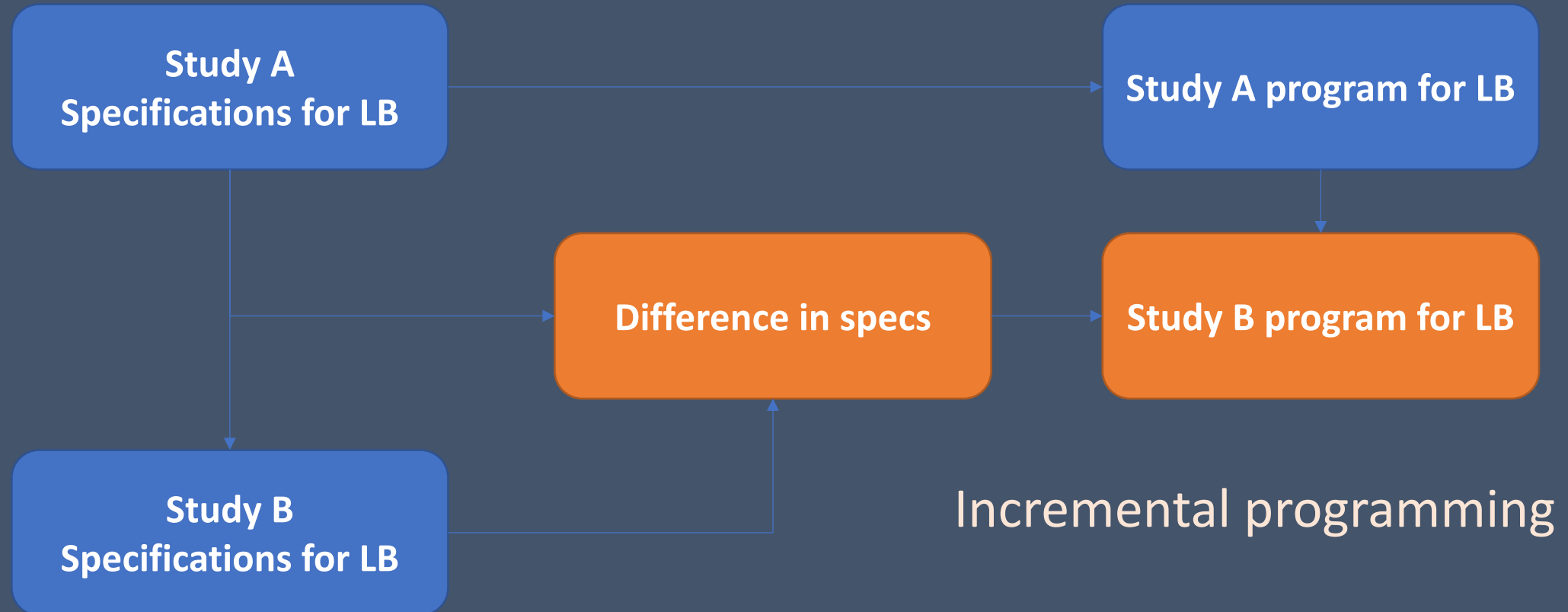


Time-wise Break up
per domain

Case Study: A CRO perspective

- Quick turn around expected – no scope for exploration
- Sponsor-supplied half-automated macro libraries
- In-built metadata mapping
- Optimize the process - Differential/Incremental programming

Case Study: A CRO perspective



Incremental programming

Conclusion

- Plug-and-play solution needed, especially for CROs
- Needs a system that is well-integrated with standards
- SDTM Mapping sounds simple but is complex to execute
- 100% automation is a fantasy

Thank you