

Efficiency and Delivery Driven by Metadata

Magnus Mengelbier
Director

Topics

- Housekeeping (definitions)
- Process
- Standards
- Rules
- Driven by metadata
- Summary

Metadata

- Information, details and attributes that describe data or deliverables
 - High level metadata
 - ❑ Project
 - ❑ Protocol
 - ❑ Study
 - ❑ Analysis
 - ❑ Titles
 - ❑ Footnotes
 - ❑ Formats
 - ❑ Data set structure
 - Low level metadata
 - ❑ Origin / Source
 - ❑ Code List
 - ❑ Methods / Algorithms
 - ❑ Statistic
 - ❑ Summary section
 - ❑ Semantics

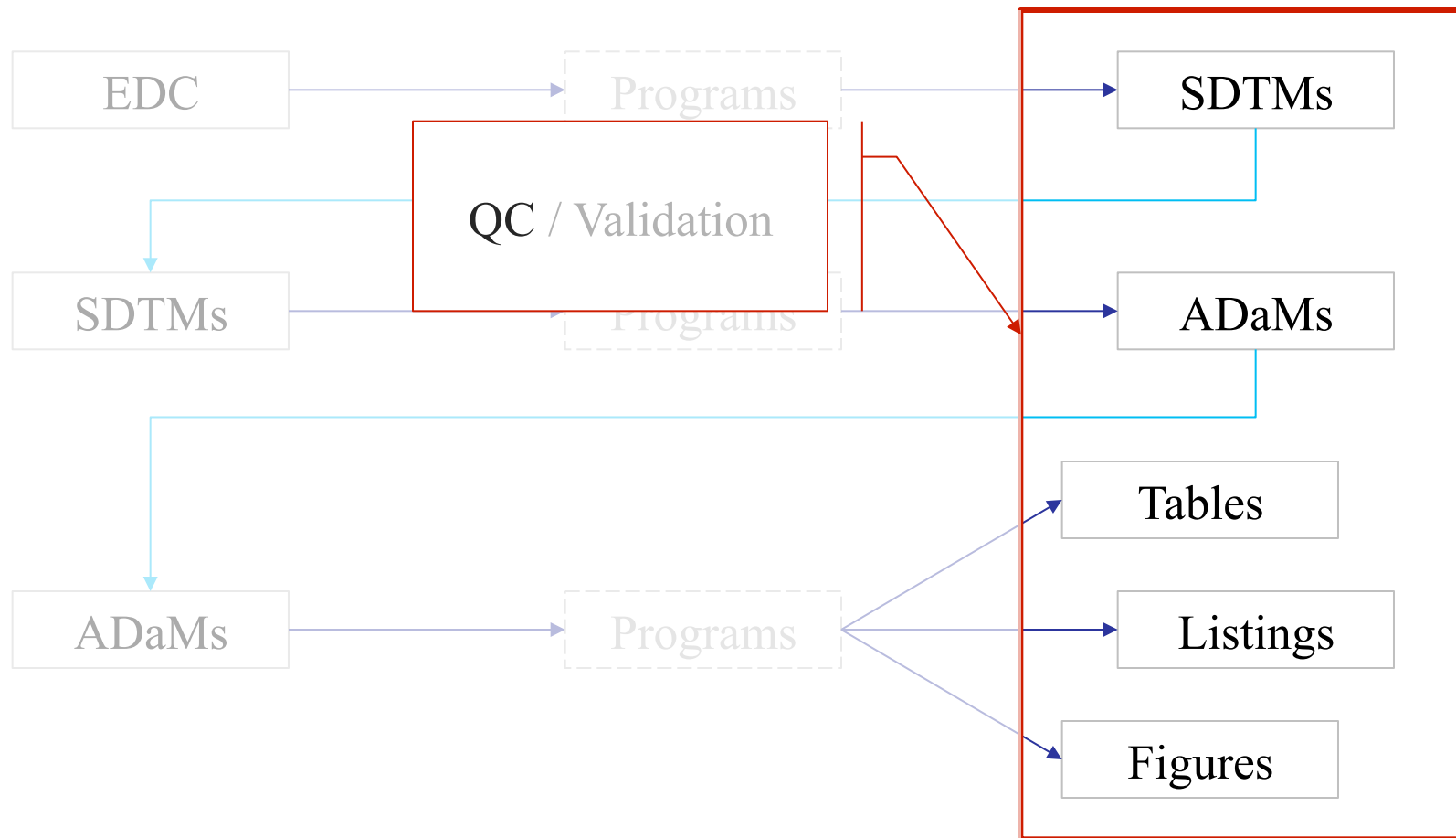
Context & Structure

Content

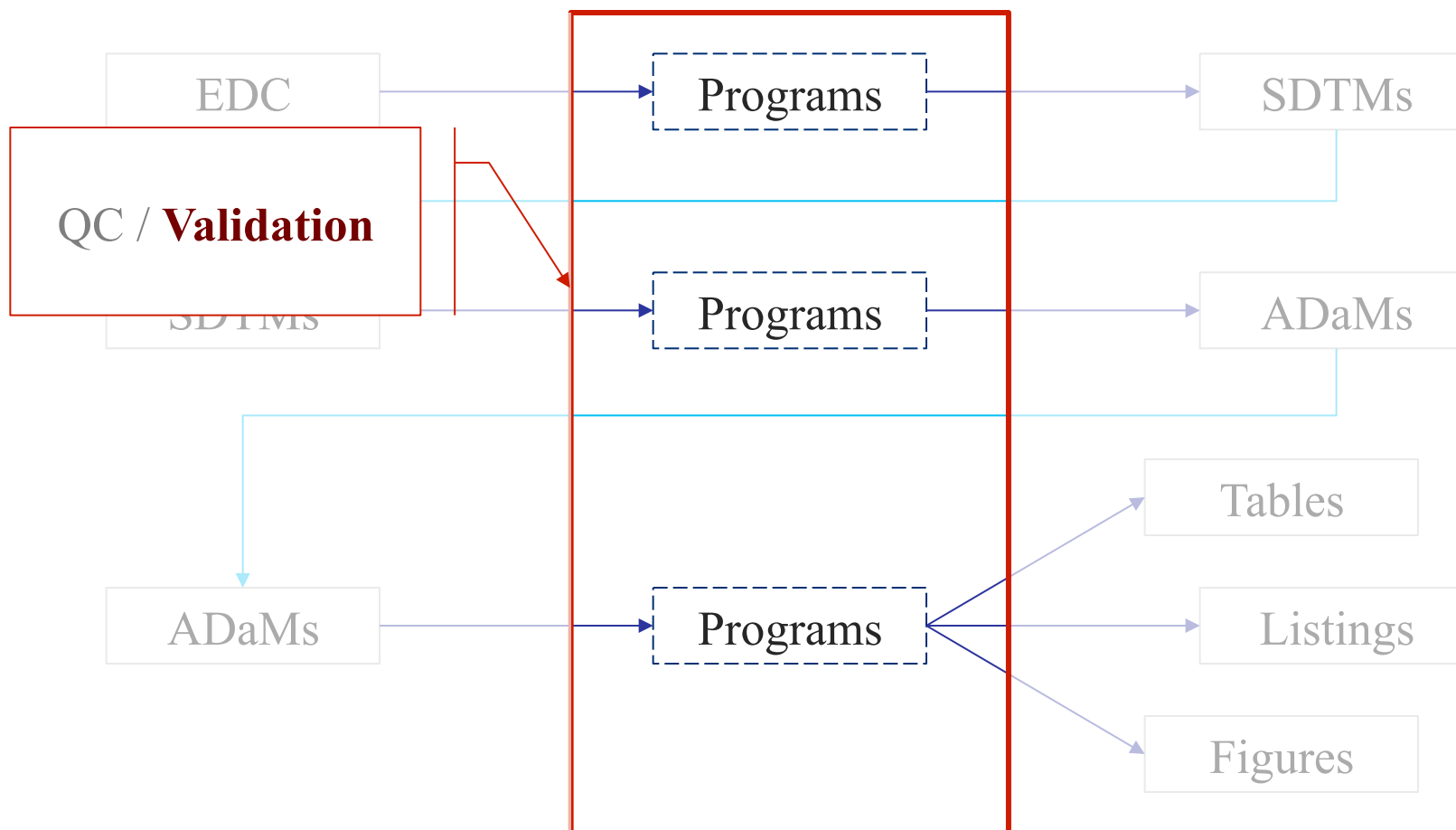
QC versus Validation

- Quality Check / Quality Control / QC
 - Assert that a *deliverable* is correct
 - Performed when the end result is available
- Validation
 - Assert that a program creating a deliverable will create the deliverable correctly
 - Performed prior to production use, e.g. before the final inputs and end result is available

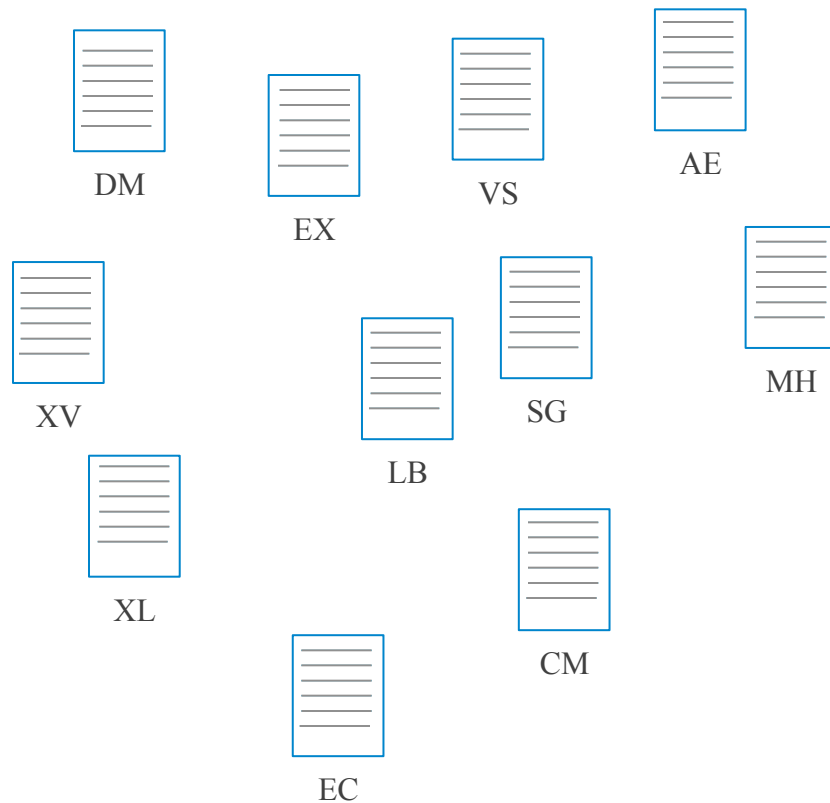
Process



Metadata Driven Process



The beginning

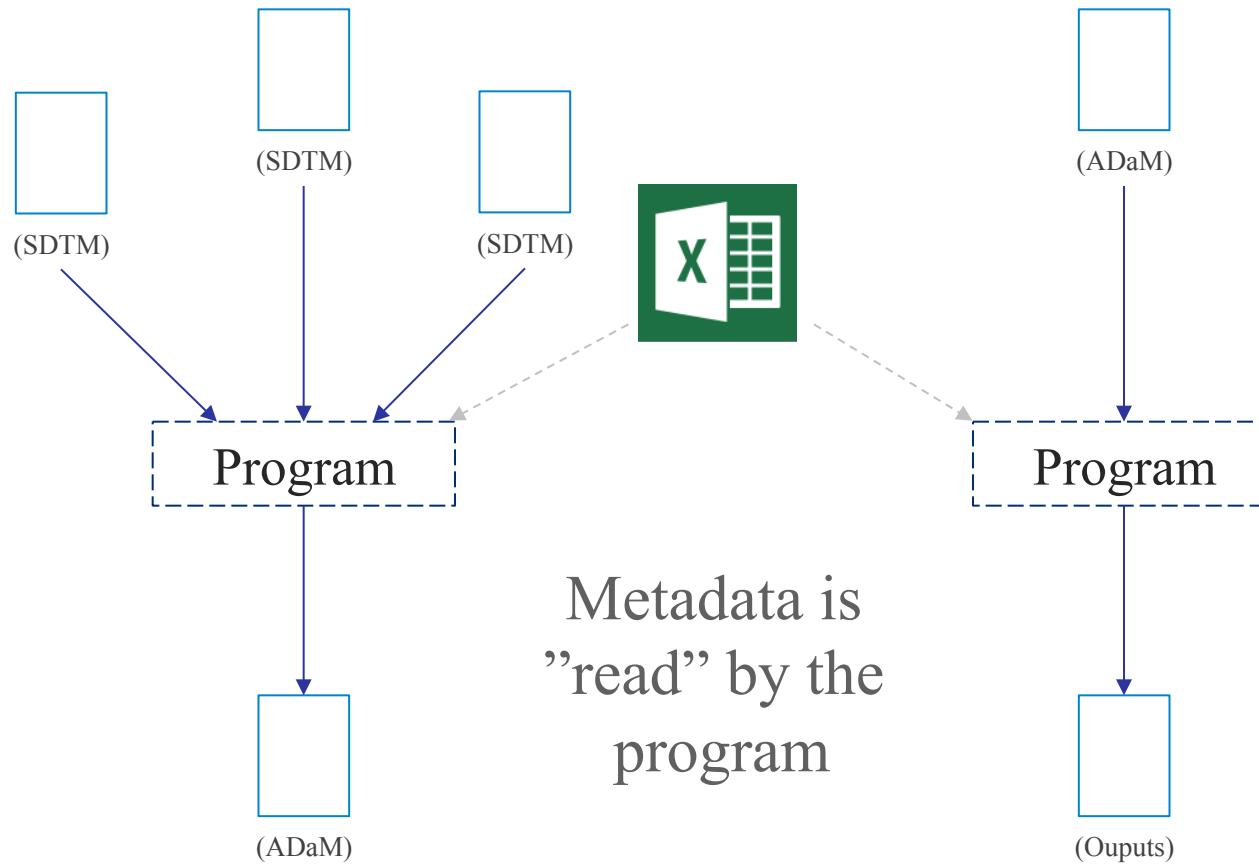


Standard



Study Specific

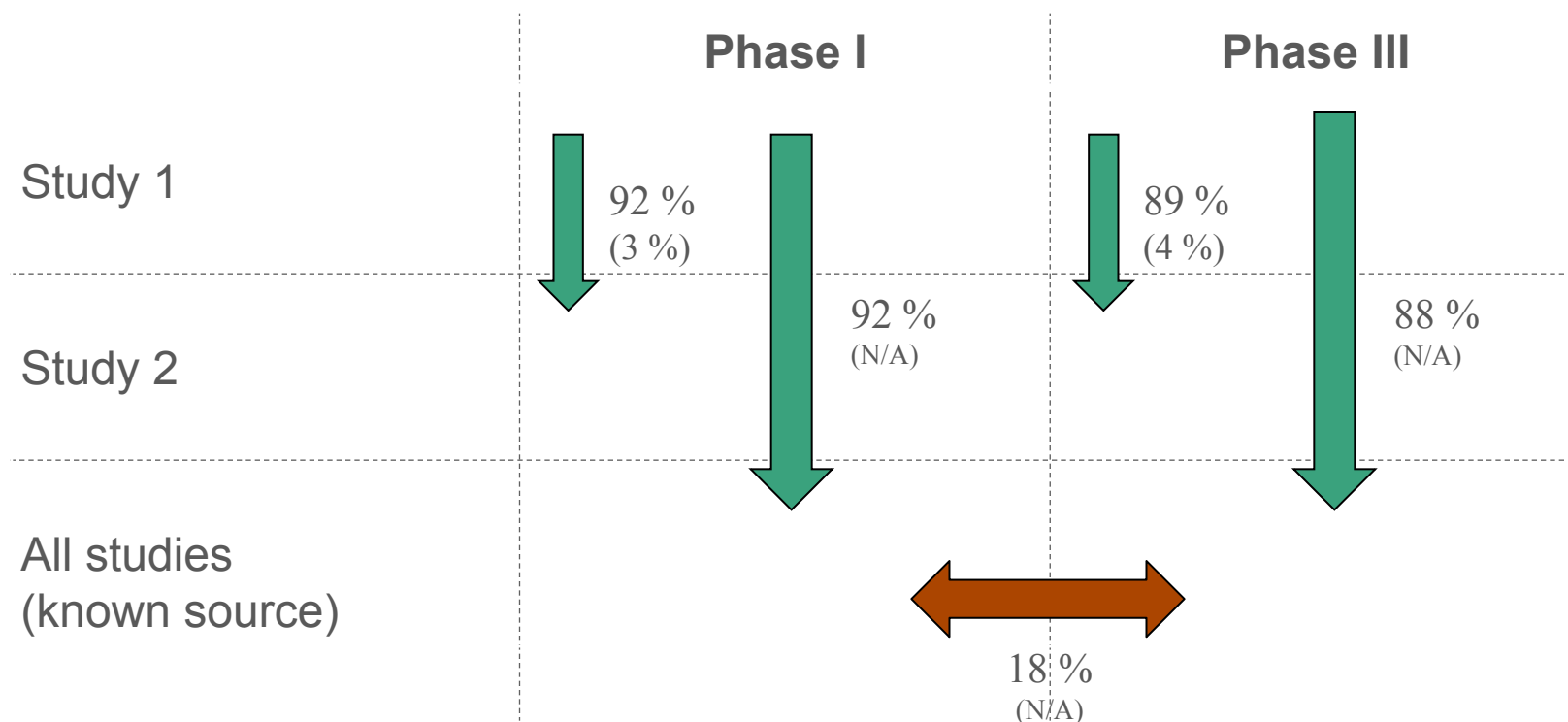
Metadata in Process



Standard Programs

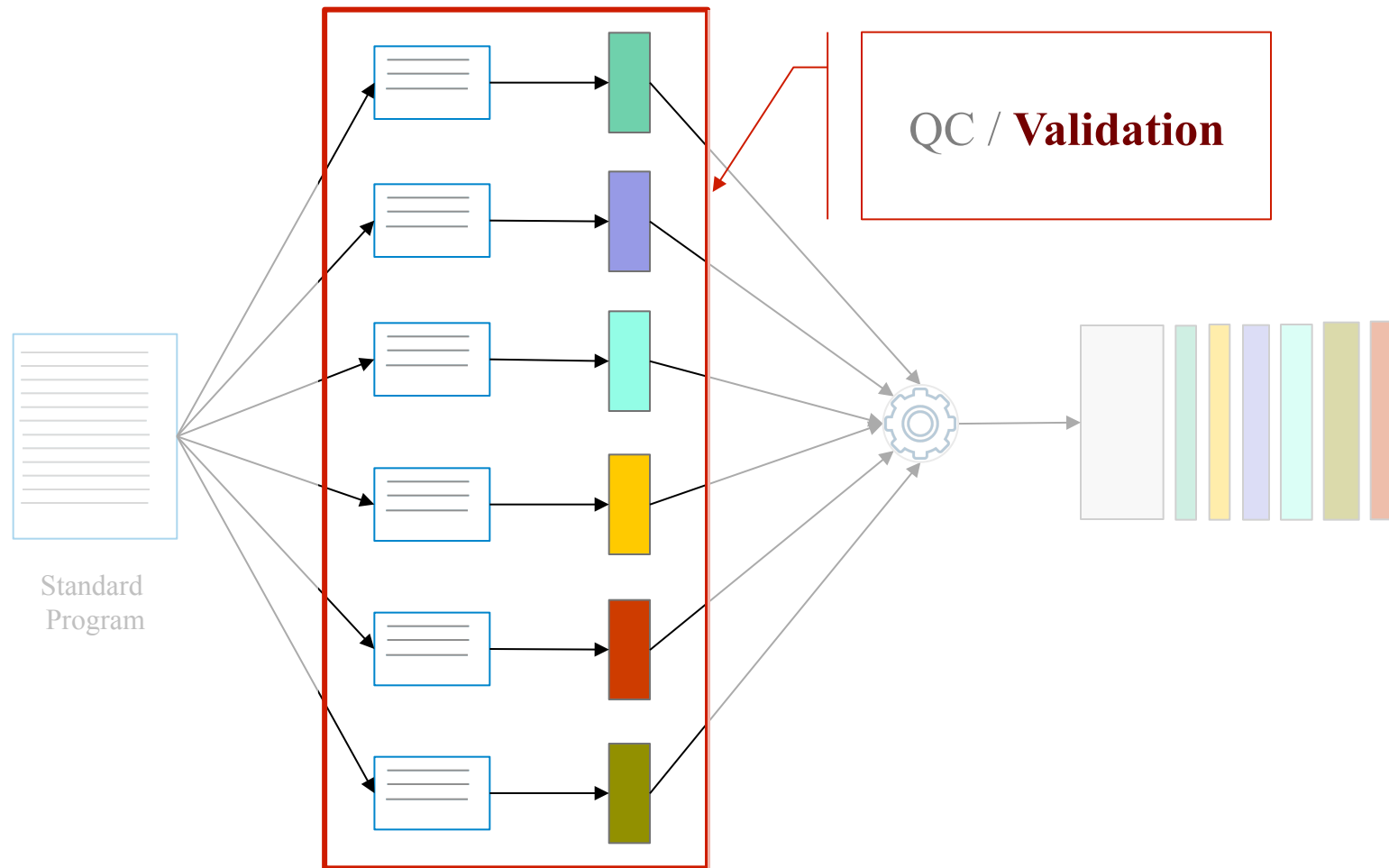
- Standard SDTMs and ADaMs
 - Standard eCRF pages
 - Standard EDC extracts
 - Pre-defined set of SDTMs and ADaMs
 - One SDTM/ADaM domain equal to one program
 - Metadata defines options
- Company standards 1.0
 - Use standard when possible
 - Study specific when a standard does not meet requirements
- Company standards 2.0
 - Use standard when one exists
 - Study specific when a standard does not exist

A Few Metrics

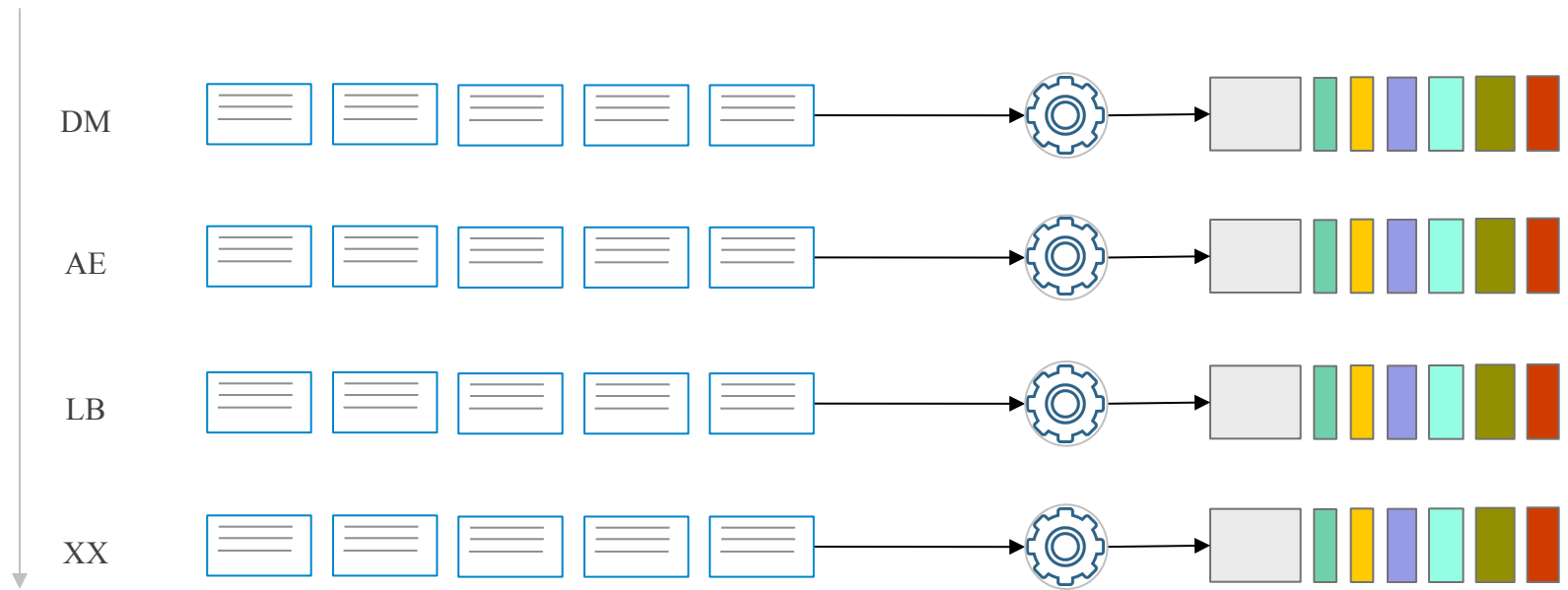


- SDTM and ADaM programs
 - Program naming convention consistent
 - High fidelity output – Detailed specifications
 - Organisational SDTM and ADaM standards applied to both Ph I and III

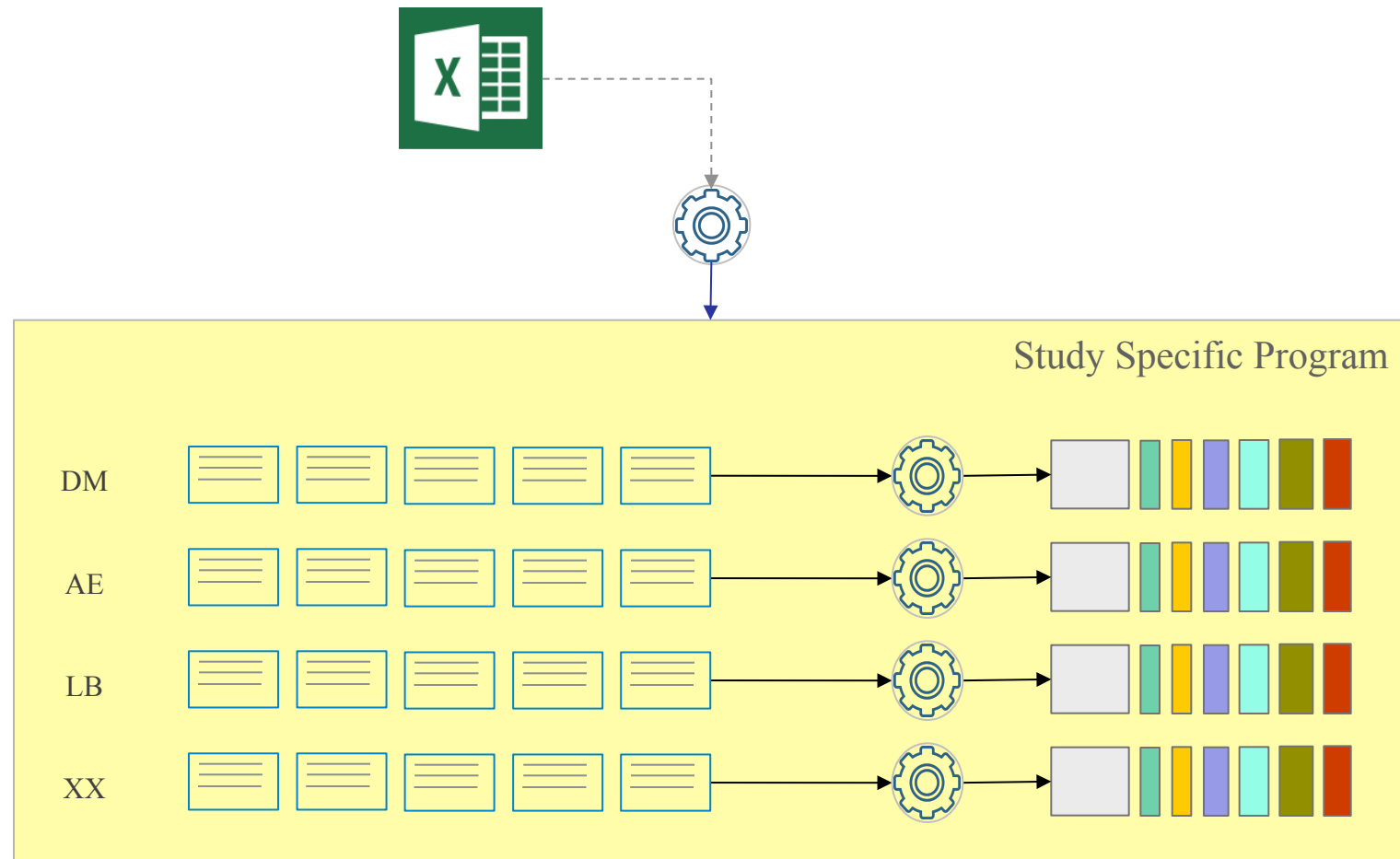
Rules: Back to Basics



Metadata Driven



Metadata Driven Process



Summary

- Metadata in standard programs creates complexity
- Complexity key driver to inefficiency
 - Documentation
 - Programming
 - Testing and validation
 - Support and maintenance
- Rule-based approach can avoid complexity
- Simple rules add transparency
- Metadata driven process can use existing tools and skills
- Efficiency is transparency and lack of complexity

Contact Details

- Housekeeping (definitions)
- Process
- Standards
- Rules
- Driven by metadata
- Summary

Magnus Mengelbier

mmr@limelogic.com

Limelogic AB
 Jungmansgatan 12
 211 19 Malmö
 Sweden

+46 40 685 1480