



Last Mile Problem to manage Data Transformation for Analysis & Reporting

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Agenda

1. Motivation
2. Conventional Production
3. Automated Production
4. Architecture
5. Benefits

Motivation

Motivation - EU based company SDTM Conversion, ADaM & TLF Creation

Client Situation: CDISC Standardization

Outcomes:

- Efficiency gains in the range of 30-40% for SDTM (reduction of time, hence costs)
- Efficiency gains in the range of 35-40% for ADaM and TLFs (reduction of time, hence costs)

68

Macros Developed

Documentation 68/68
Completed PLUS Environment
Set-Up

10 Macros for Literate
Programming

3 Analysis Macros;
3 Graph Macros;
3 Reporting Macros
including Data listings;

2 Set up Macros

7/7 ADaM

11/11 SDTM

28 Utility Macros

Benefits:

- Standardized macros with documentation
- Optimal resource utilization
- Standardization of other Analysis and Reporting documents e.g. Mock shells, Programming Specs
- Statistics Report Automation reducing the processing time by almost 40% post DBL

C-ART Cognizant - Analysis and Reporting Tool

Industry Challenges

- Paucity of skilled resources needed for successful delivery – High attrition among Senior Biostatistics and Statistical Programming resources.
- SDTM, ADaM, and TLFs conversion / creation needs specialist associates, as it is complex with lot of domain centricity.
- Medical writers spend significant effort in writing patient narratives for each patient.
- There is a constant struggle of hiring, retaining, training, and attrition.

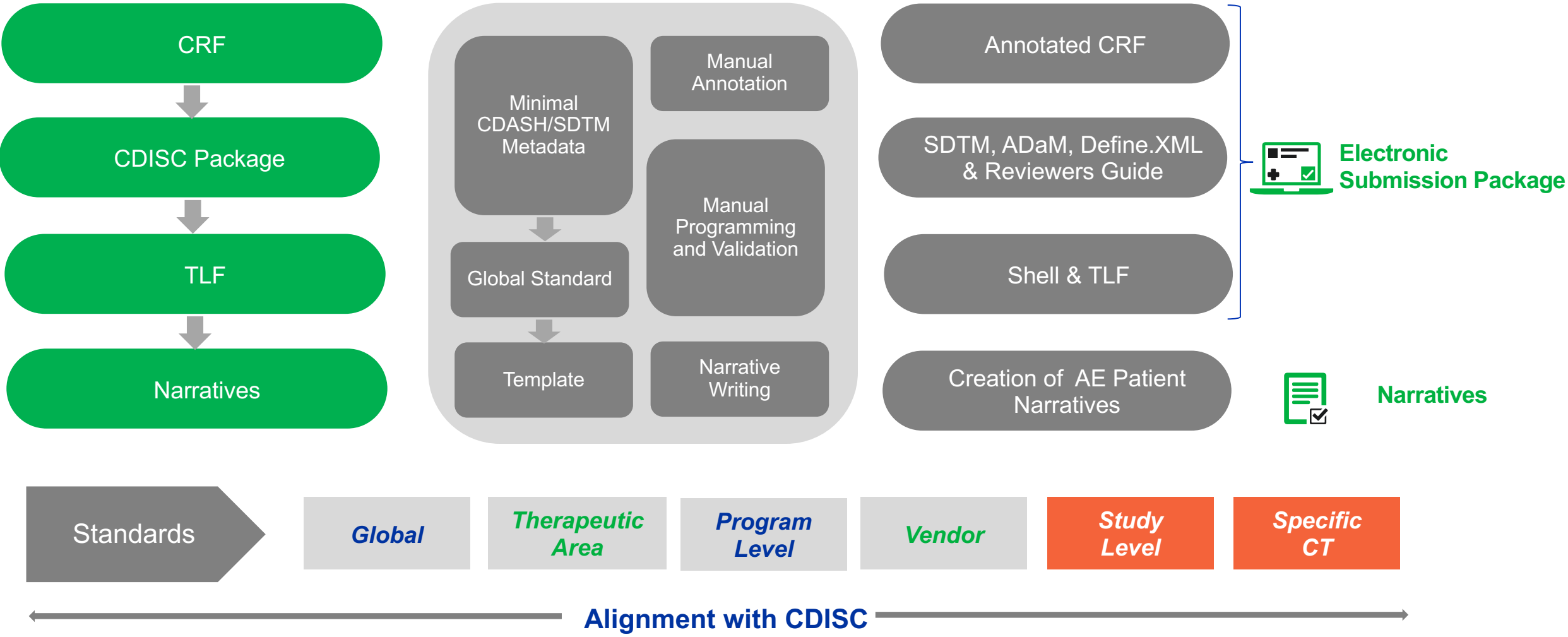


C-ART – Tool to Automate Biostatistical Analysis Processes

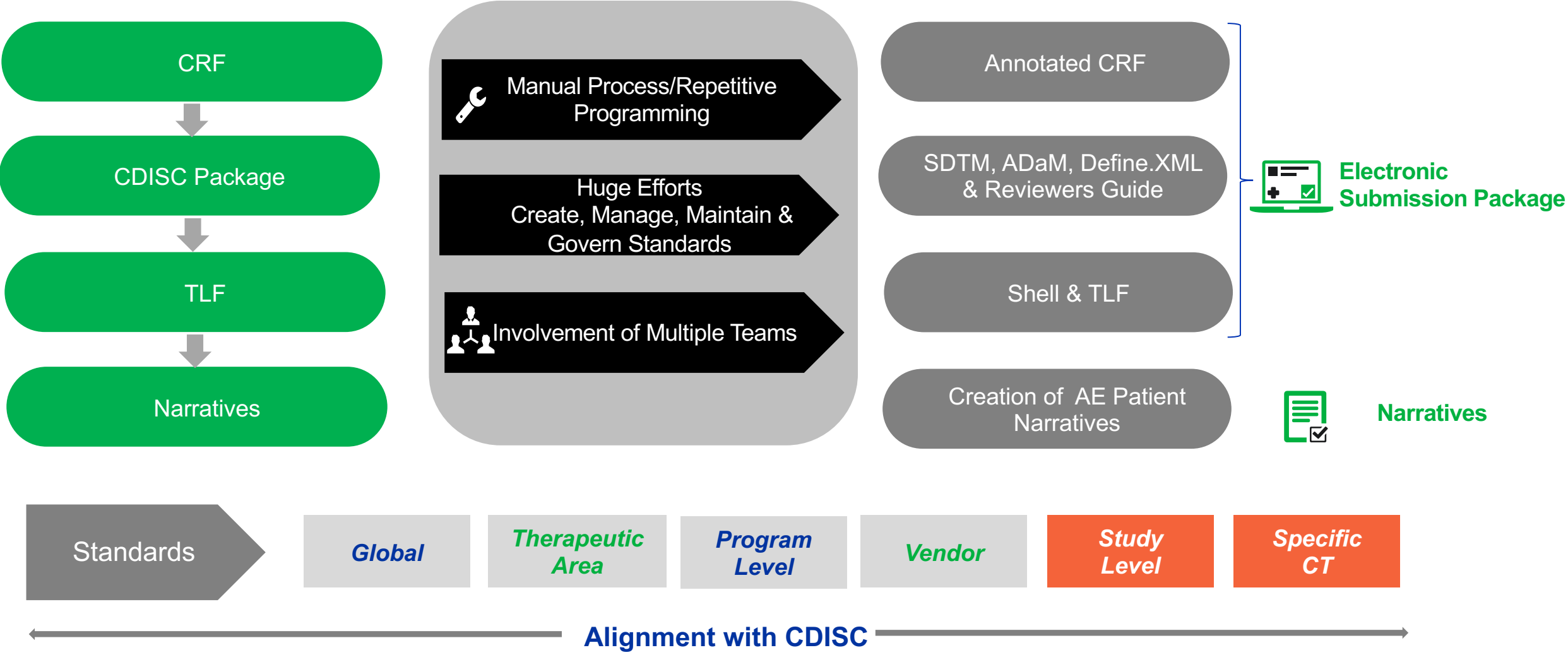
- Allows for automated conversion of study data to SDTM, ADaM creation, and TLF creation
- **Promotes re-use of macros thru global libraries (one time setup, repeated use)**
 - Customizable as per need for standards – external or internal specific
 - Audit trail capabilities
- Validated environment that can be rolled out and setup for different clients.
- Stand alone application, should be able to connect to various CDM systems/repositories such as: RAVE, Inform
- Allow the Metadata to drive the process supporting the integration of the CDM and statistical Analysis processes
- Automated documentation for reporting, compliance and submission

Conventional

Conventional CDISC & TLFs Production

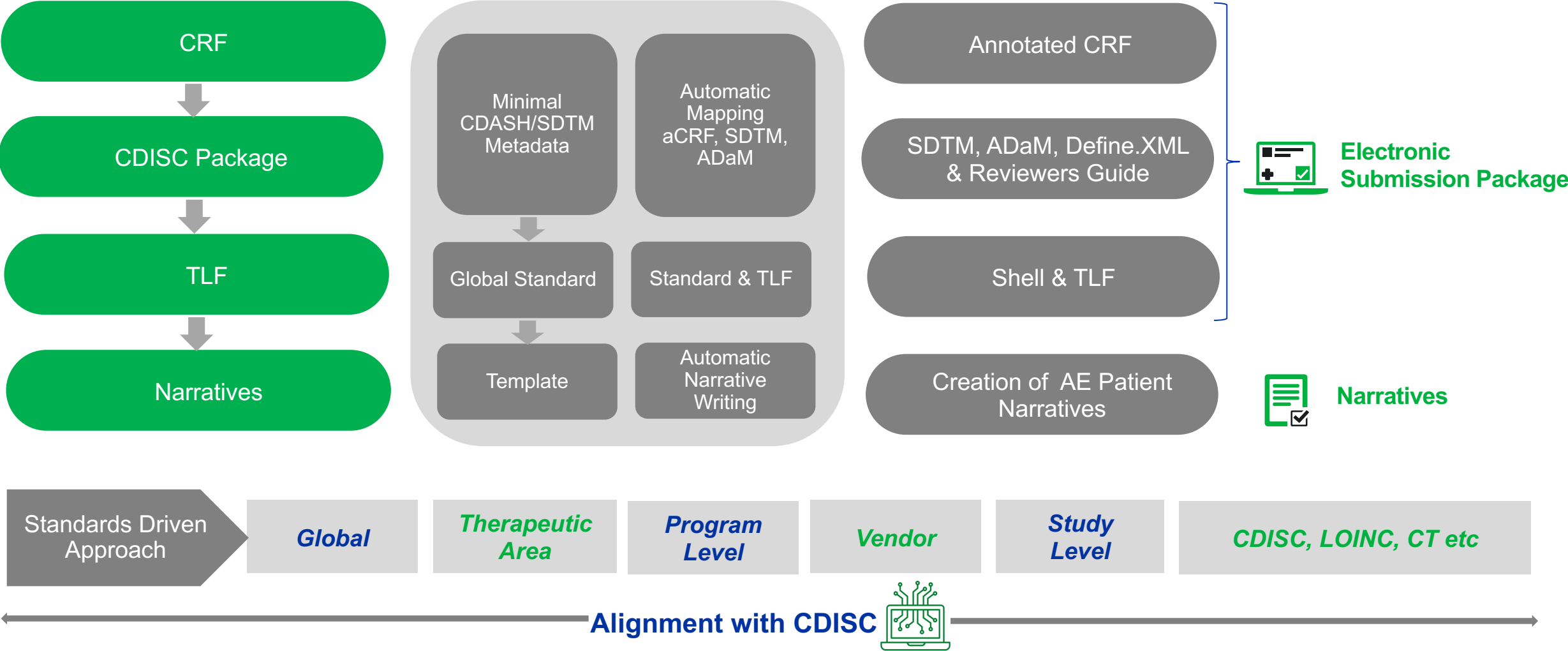


Conventional CDISC & TLFs Production

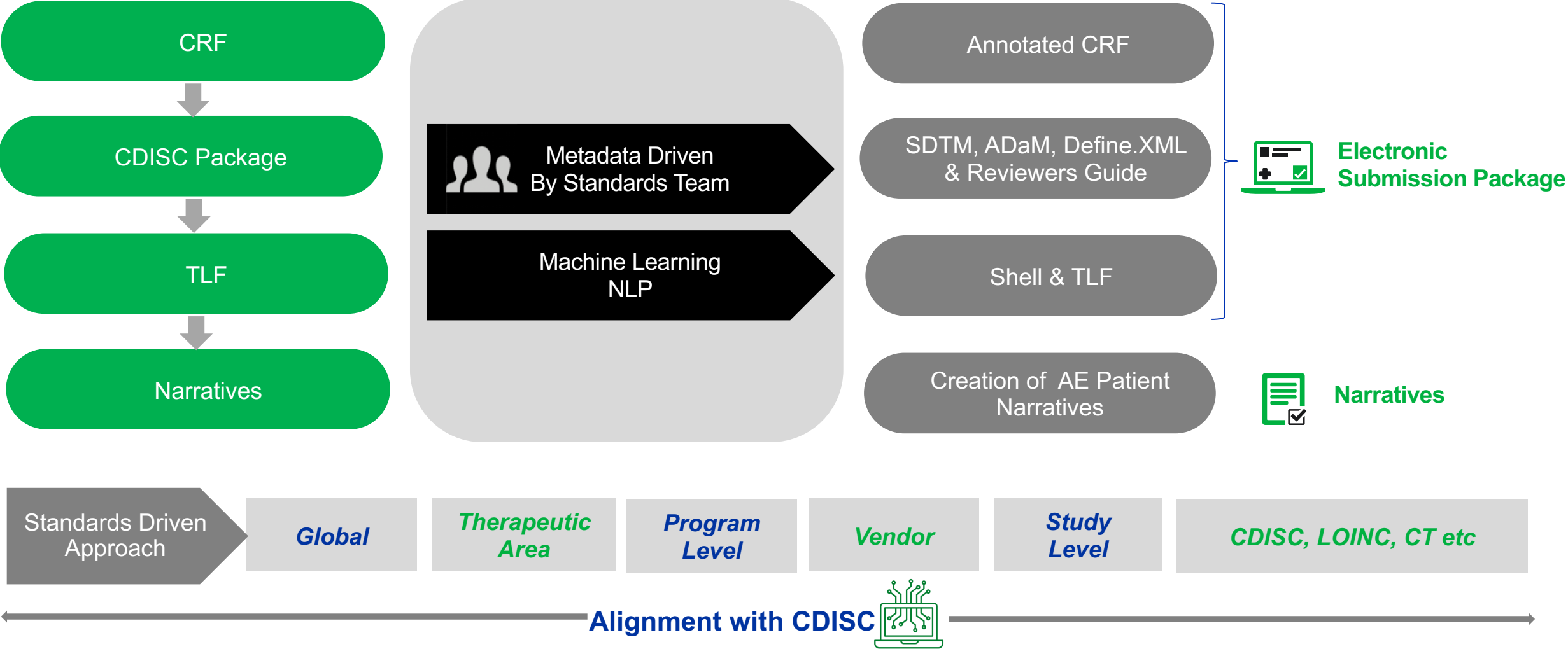


Automated

Automated CDISC & TLFs Production

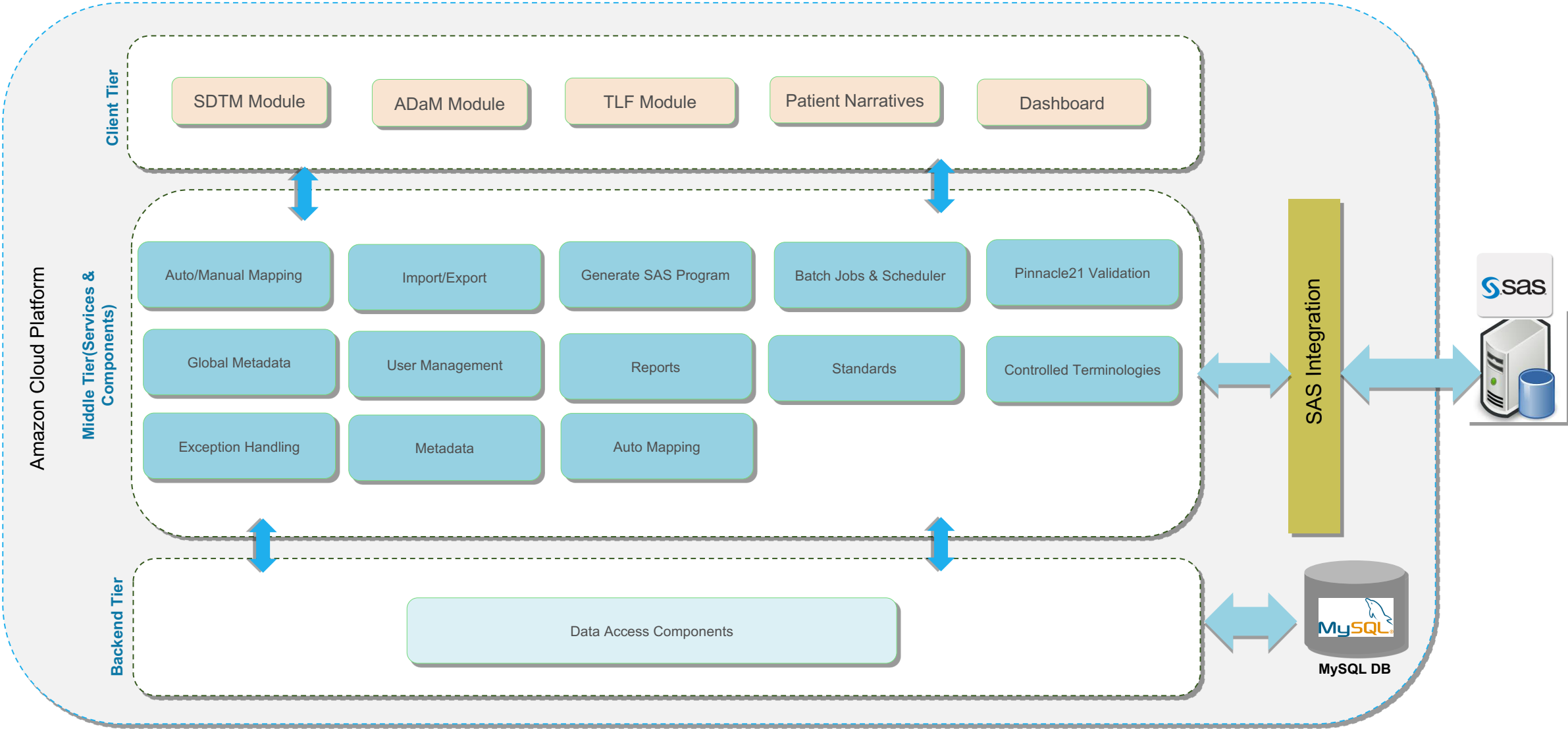


Automated CDISC & TLFs Production



Architecture

C-ART Application Architecture



Benefits

Benefits of C-ART

QUALITY

- Ensuring “Quality First”
- Elimination of human errors



PROCESS

- Highly efficient process
- Significant reductions in cycle time for the data transformations and reporting
- Increased probability for detecting safety & efficacy signals

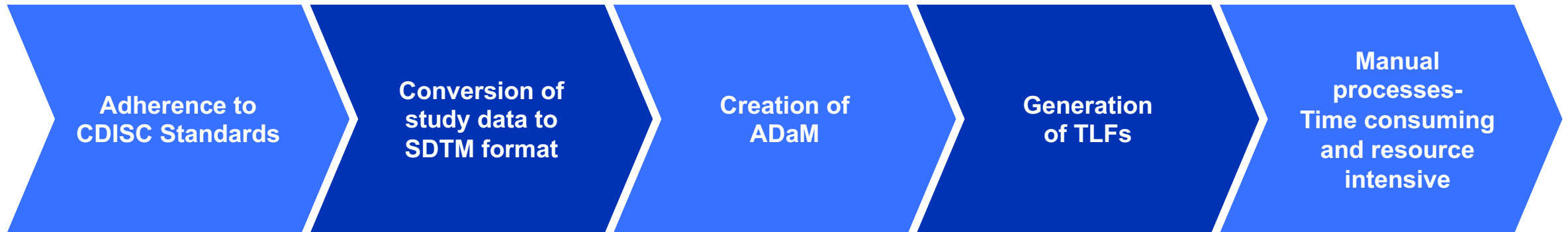


COMPLIANCE

- Audit trail allowing for traceability & reproducibility
- Automated standardized reporting adhering to CDISC standards



C-ART – Digitize and Accelerate the Bio-statistical and Statistical Programming processes - Highlights



EXPLORE-C-ART

- Single platform to:
 - Convert raw study data to SDTM
 - Create ADaM
 - Create TLFs
- Standard libraries promote reuse
- One time setup, repeated use, process in place
- Improves productivity

OUTCOMES

- Significant efficiencies and quality enhancements
- Accelerate Study Data conversion to SDTM
- Accelerate ADaM creation
- Accelerate TLF generation

Cognizant

Thank you

