End-to-End Clinical Study MetaData-Driven Process and Intelligence CDISC and Submission Flow
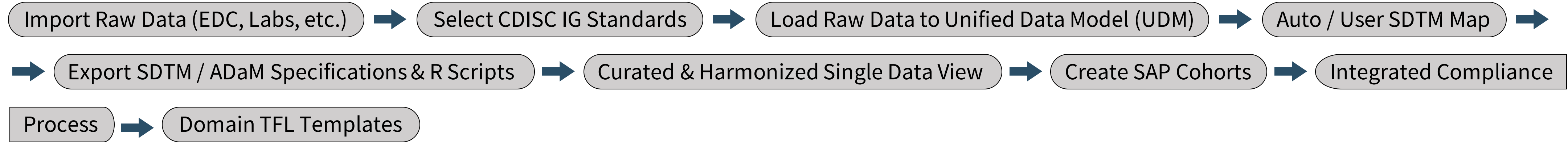
POINT CROSS

CDISC – 360 Metadata Artifacts: Setup Configuration [Study: Protocol (**PRM**), Design, Workflow, Visits, Parameters], Standards Selection (**CDISC IG**), Data Collection [Raw Data, CRF, **CDASH**], **Control Terminology**, **MedDRA**, Tabulation (**SDTM IG**), Analysis (**ADaM IG**, BDS), **ARM**, **Define.xml**

PROCESS

Import Raw Data (EDC, Labs, etc.) → Select CDISC IG Standards → Load Raw Data to Unified Data Model (UDM) → Auto / User SDTM Map →

→ Export SDTM / ADaM Specifications & R Scripts → Curated & Harmonized Single Data View → Create SAP Cohorts → Integrated Compliance

Process → Domain TFL Templates

GOALS Project Management, Documentation, Standards, Automation (Low Coding), Quality, Productivity (Fewer Resources), Budget (Less Expensive)
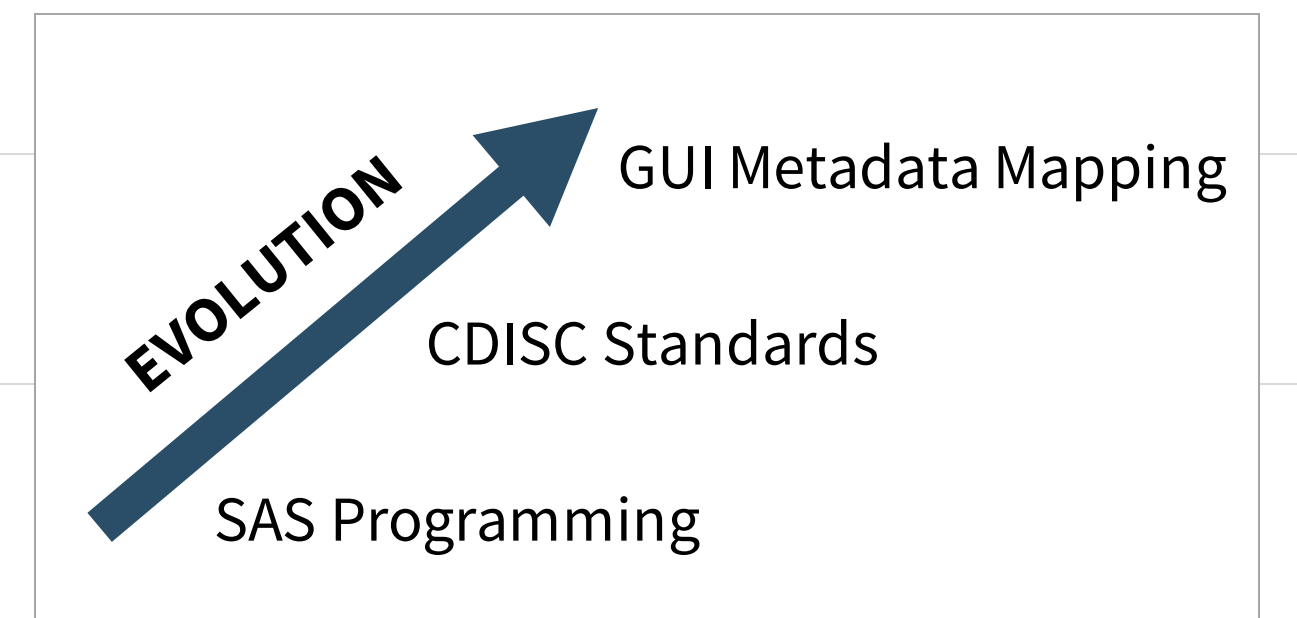
REASONS Project Complexity, CDISC Compliance Requirement, Traceability / Audit Trail, Enforce Hundreds of Rules

INTELLIGENCE DESIGN Machine Readable / Learning (Decision Tree Process / Pattern Recognition / Consistency)

CROSS-REFERENCE Directories, Structure / Transpose, Study / Project, Datasets (BDS), Variables, Order, Required, Value-Level, Control Terminology, CDISC IG Rules, Results, Links, Name, Type (Numeric, Character), Length, Label, Format, Units, Descriptive Stats, Codelists (Unique, Missing, Range, Keys, Max Length)

EVOLUTION → GUI Metadata Mapping / CDISC Standards / SAS Programming

EDC / Labs / CRF	Metadata / CDISC Deliverables			Study Documentation Define.xml	Regulatory Compliance eDV / SDRG / ADRG
	SDTMs	ADAMs	TFLs		
DATA: Raw Codelists	Standard Domains Standard Variables Standard Terminology Codelists	Safety / Efficacy Derived Variables Codelists	SAP	Documentation Control Terminology Value-Level Metadata Raw / Derived Variables	Documentation Data Issues Compliance Issues
METADATA / **CDASH** SPECIFICATIONS: Attributes, Structure, **PRM**	**SDTM IG Rules** **Control Term IG Rules** **MedDRA** Export Specifications	**ADAM IG Rules** **Control Term IG Rules** (Optional) Export Specifications	**ARMs** BDS Independent of ADaMs	Define.xml IG Rules SDTMs / ADaMs Snapshot Integrated Links to CRF pages User-Interface Edits	Snapshots / Links
USER INTERFACE MACHINE LEARNING PRODUCTIVITY:	Joins / Transpose Auto / User Mapping Templates Drop-down lists	SAP Mapping Auto / User Mapping SAP Cohorts Drop-down lists	SAP Cohorts Domain Templates Drop-Down Lists	IG Mapping Templates	Template Mapping PhUSE Templates
TRADITIONAL PROGRAMMING PRODUCTIVITY:	Attribute Macros Variable Macros	Attribute Macros Variable Macros	Reporting Macros	Source / QC — Separate Tool Out-of-Sync	Separate Tool Manual Updates