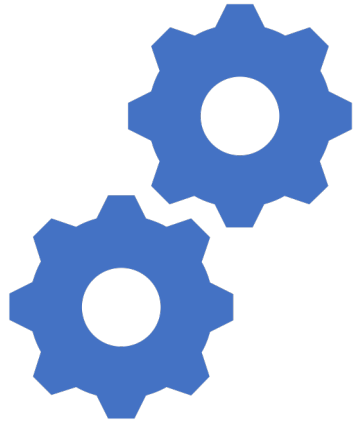
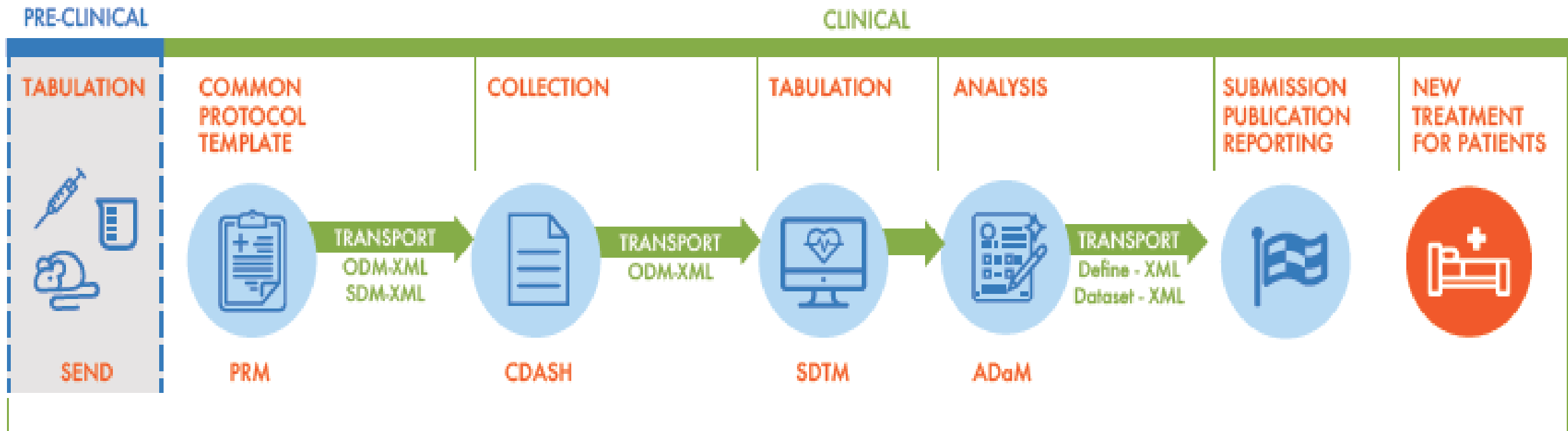




Commissioning MDR System: Next-generation of standards implementation

Abhinav Jain, Ephicacy Consulting Group, USA

CDISC Landscape



Challenges with Standards Implementation

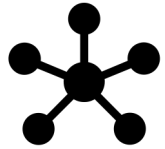


- Standards are implemented in silos.
- Data definitions vary from study to study
- Data definitions in different data models are not linked
- Spreadsheets are used for metadata management
- Manual processes for content management, change control, versioning and distribution of metadata
- Inconsistent implementation of standards between organization teams
- For large organizations having investigational drugs in various therapeutic areas, maintaining global and therapeutic area standards is an enormous task
- With version releases in the standards, organizations struggle with maintaining multiple versions of the standard



MDR System: End-to-End Standards Implementation

MDR System



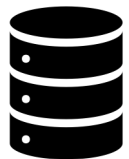
Metadata Repository (MDR)

Centralized metadata governance platform



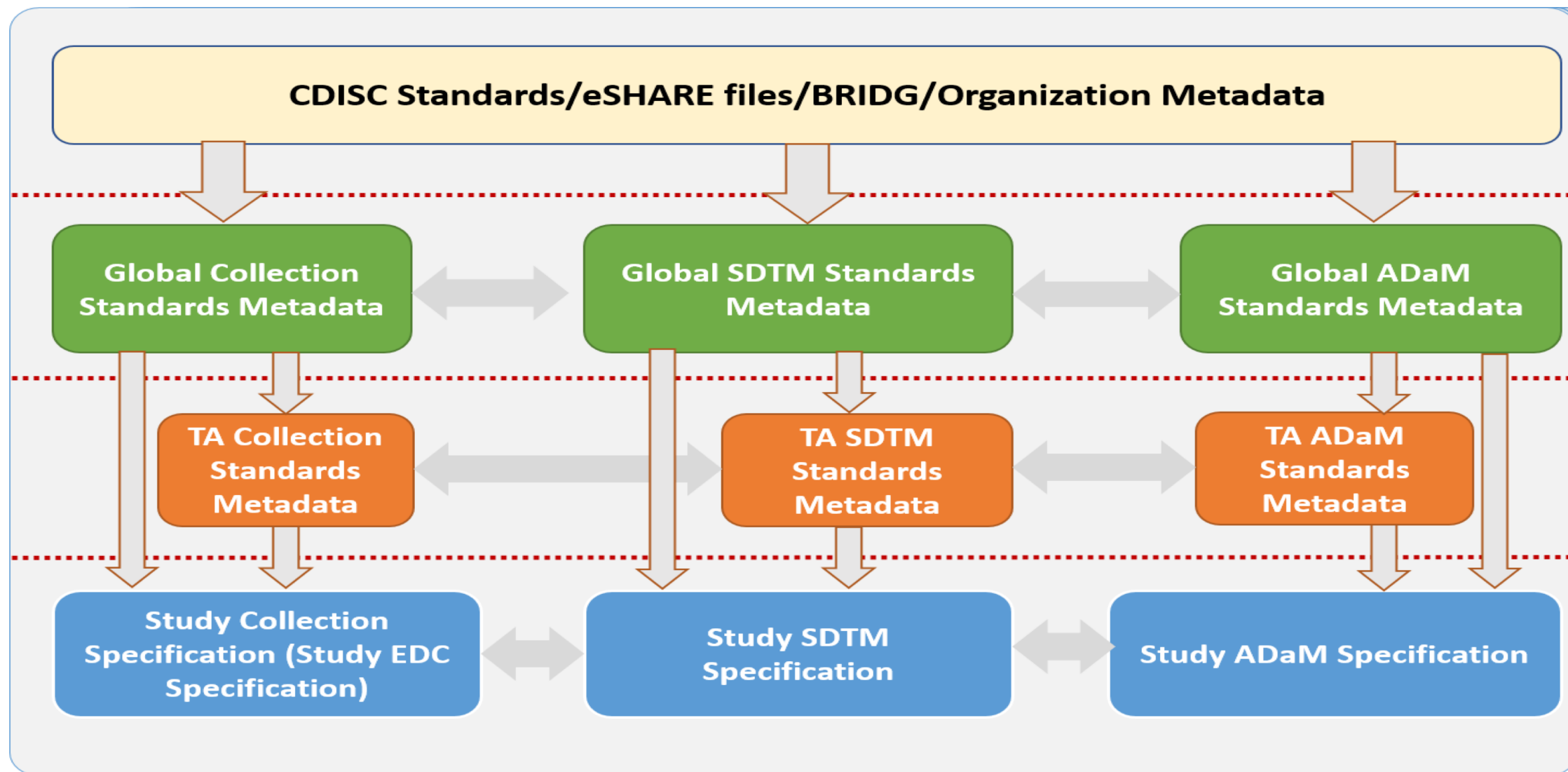
Cloud-based application with

Interactive Graphic User Interface (GUI)



Inventory of metadata components for data artifact: forms, fields, domains, variables, mapping algorithms, controlled terminology, codelists

MDR Architecture



Features of MDR System

Hierarchical Metadata Management

Role Based Access

Interconnected Data Models

Version Control and Audit trail

Impact Analysis

Generate Study Artifacts

Integrated Workflows

Integration with external systems

Change Control System

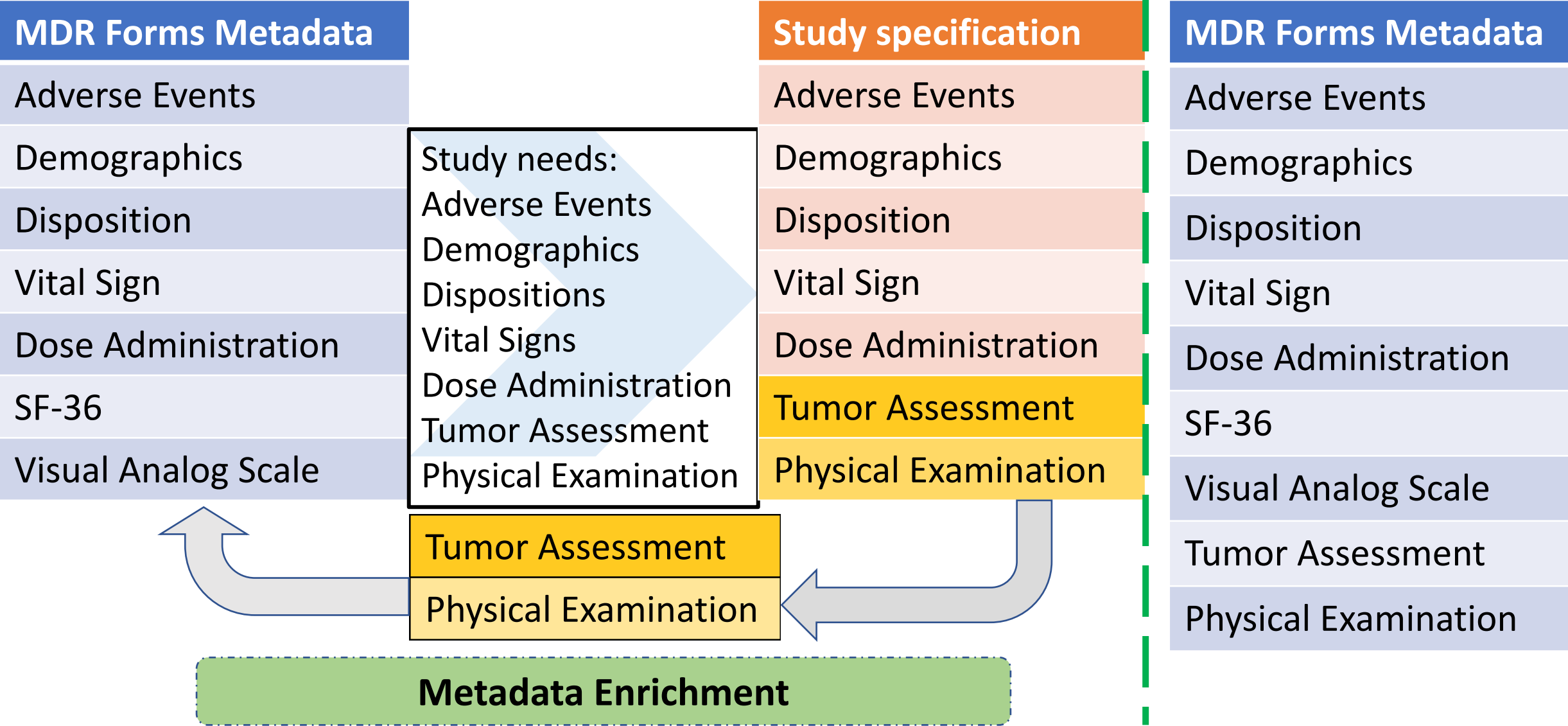
Metadata Quality Control

Collection Metadata Management with MDR



- Metadata management in organization EDC configuration (Rave, OC)
- Metadata components from eCRF like forms, fields, data and unit dictionaries
- Standards codelist and codelist terms consistently used across all trials
- Grab and Go approach to Study EDC specification generation
- Study DM team designs the study EDC specification using Global and TA-level collection Standards
- Specification generated by MDR system can be plugged into EDC system
- Maintains the version history of study EDC specifications
- Study teams can request updates/enhancements to the standard items via change request system
- Study-level items are adjudicated to enrich the standards metadata to be available for future studies

Study Collection Metadata with MDR System



Management of SDTM Metadata with MDR System

- Inventory of all SDTM metadata components: Domain, Variable, ValueLevel, WhereClause, Methods, Comments, Codelists (Cterms)
- Preserves the mapping relationship between source EDC fields with target SDTM variables
- Eliminates the excel spreadsheets for managing SDTM specification
- Ensures implementation of consistent coding values and derivation rules
- Generates draft study specification by comparing the study EDC specification with EDC-SDTM mappings
- Workflow based creation, review and approval of study specifications
- Maintains the version history of study specifications
- Integration with Pinnacle21 for SDTM Validation

Metadata Driver Transformation

EDC Form	EDC Field	Mapping Relationship	Target SDTM Domain	Target SDTM Variable
DM_V01	RACE	COPY	DM	RACE
DM_V01	BRTHDTC_YY, BRTHDTC_MM BRTHDTC_DD	DATE_TRANSFORM	DM	BRTHDTC



Based upon the study forms and fields list of target SDTM domains and variables.



Confirmation if a optional SDTM variables is required for the study.
Confirmation if all the collected fields are mapped



Auto-generated SDTM Programs.
Generation of SDTM artifacts like SDTM Specs, Define.xml

10 Reasons to commission MDR System



Centralized managements of standards and study metadata



Consistent Implementation of Business Rules



Substantial Reduction in DB-built time



Improved operations by advanced Comparison and Collaboration tools



Reusability and automation of DM, SDTM and ADaM Processes



Content management



Captures data models metadata with mapping relationships



Quality control of metadata



Metadata driven transformation



Significant improvement in the data handling capabilities of the organization

Questions?