



Anticipate. Innovate. Deliver.

Clinical Metadata Management (CLMM) System

End to End Metadata management

Challenges

Multiple eCRF Standards (EDC)

- Multiple consumers of EDC data need to be aware of what standards are used in a trial for their data consumption needs
- No standardized terminology or semantics across eCRF trial elements
- No centralized metadata repository for analysis of standards

Complex transformations

- Data flow from one system to another undergoes complex transformation, typically these transformations are done directly in code and maintained in requirements documents. No centralized machine readable electronic storage
- Change in data standards and therefore impact assessment to the downstream systems becomes very difficult

Integrated Development Platform

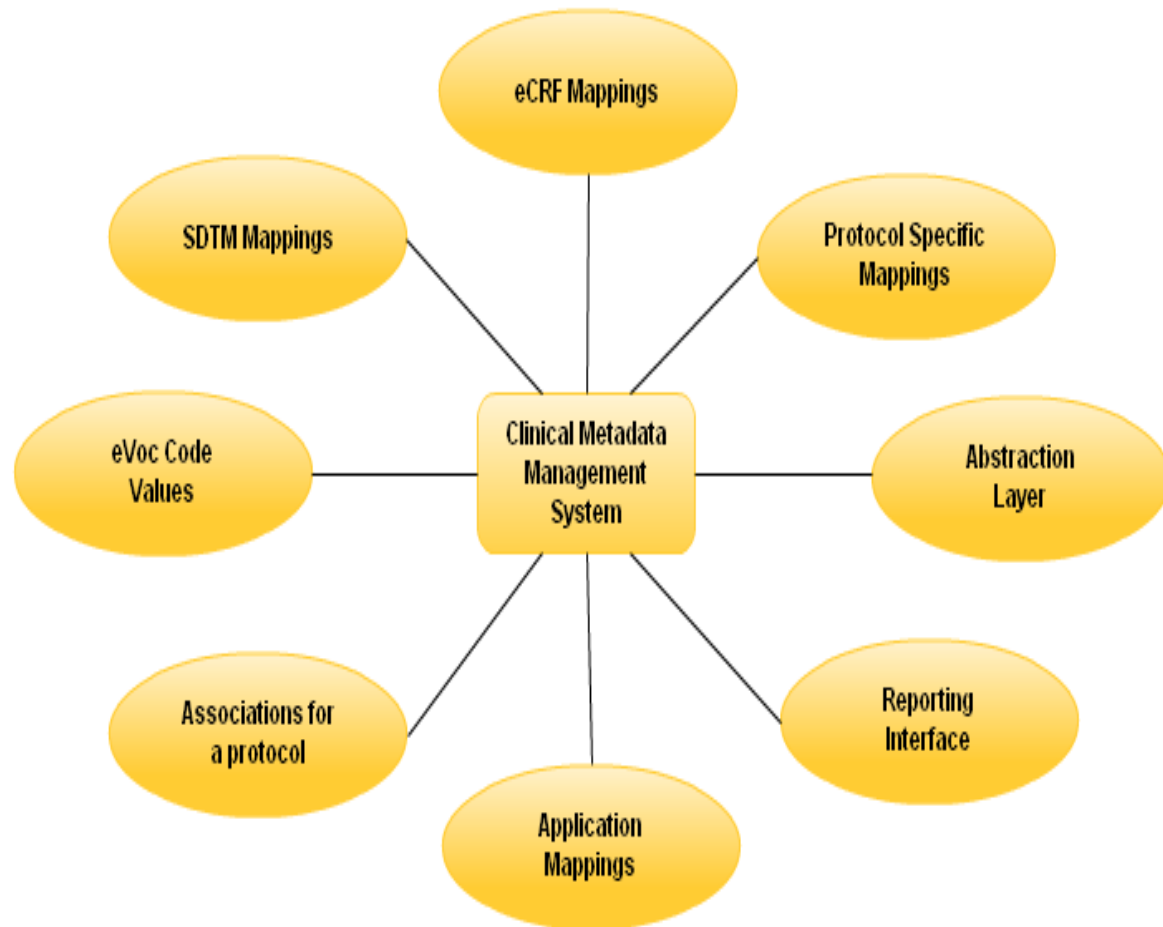
- Metadata is available within or across systems of a particular domain, not across the entire clinical development
- No End to end metadata definition capability currently exists

End to End visibility

- Due to the lack of metadata repository, data traceability to the source data becomes challenging
- Data integrity checks becomes more manual, time consuming, error prone and less effective

Overview of Clinical Metadata Management System

- ❑ The system is built based on **ISO/IEC 11179** Information Technology Metadata registries (MDR) standards.
 - ❖ Partial Implementation
 - ❖ Datasets, Value sets, Elements, Groups, Attributes, Association, transformation, Abstraction and DB Specification
- ❑ Mappings and associations required for subscribing applications.
- ❑ Data Abstractions required for subscribing applications through API's.
- ❑ Provides a holistic view of clinical data elements & standards.
- ❑ Provides reporting interface to review metadata mappings, abstractions and associations
- ❑ Implemented using Oracle DB, Java and Semantics technologies.



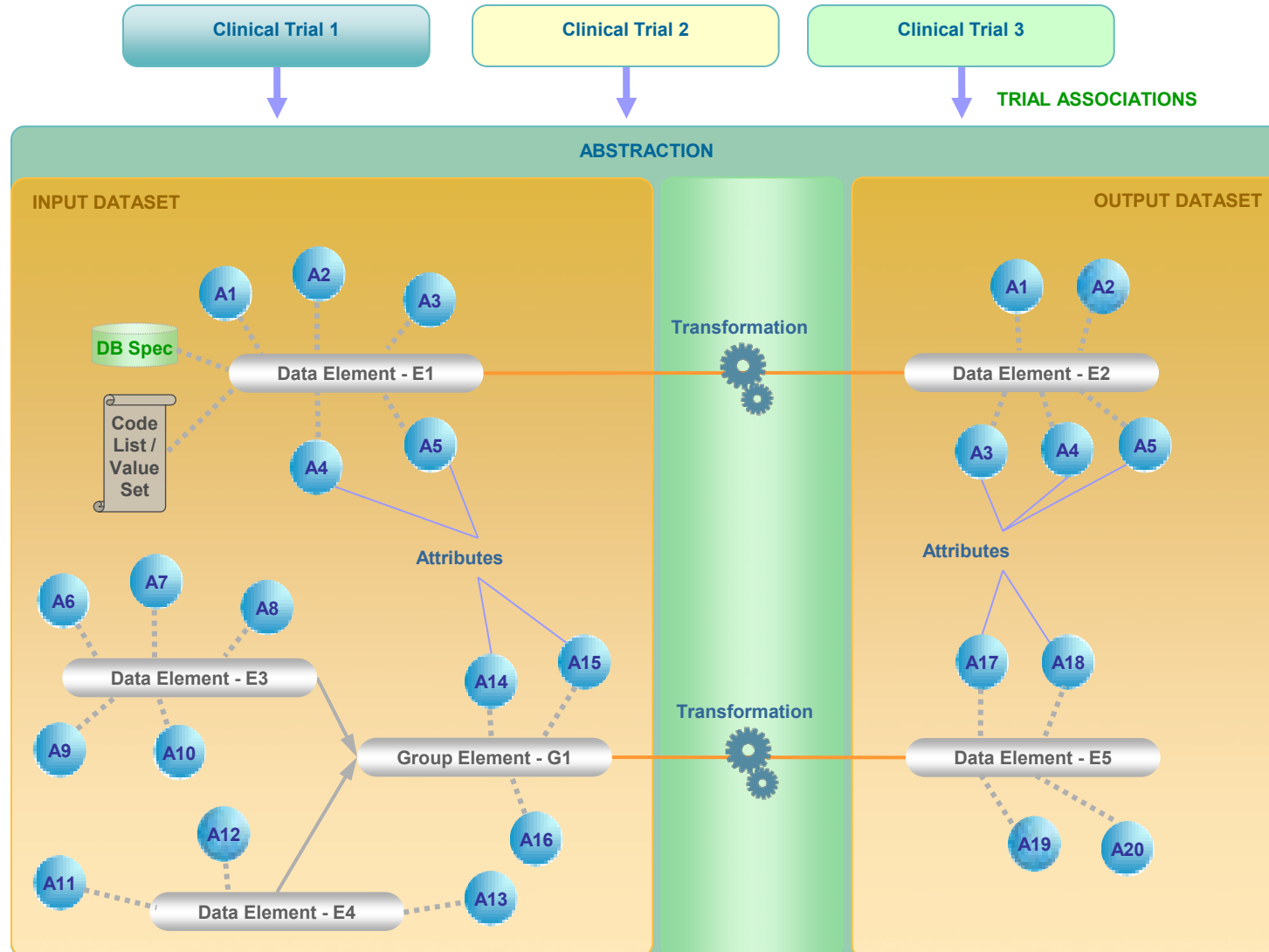
CLMM Components

- ❑ Data Element
 - ❖ unit of data for which the definition, identification, representation and permissible values are specified by means of a set of attributes
- ❑ Grouped data elements
 - ❖ Set of data elements grouped based on certain business rules for abstraction
- ❑ Data set
 - ❖ Set of Grouped data elements / Data elements grouped to represent an abstraction
- ❑ Value Sets (Domain)
 - ❖ Set of permissible values, this can be instantiated or a link to an external system
- ❑ Attributes
 - ❖ Characteristics of an data element or grouped data element
 - ❖ A data element can have multiple attributes
- ❑ Association
 - ❖ Mechanism to link multiple data sets
 - ❖ Data sets are associated at the element level
 - ❖ Linking of data elements can be one-one, one-many, many-many, many-one

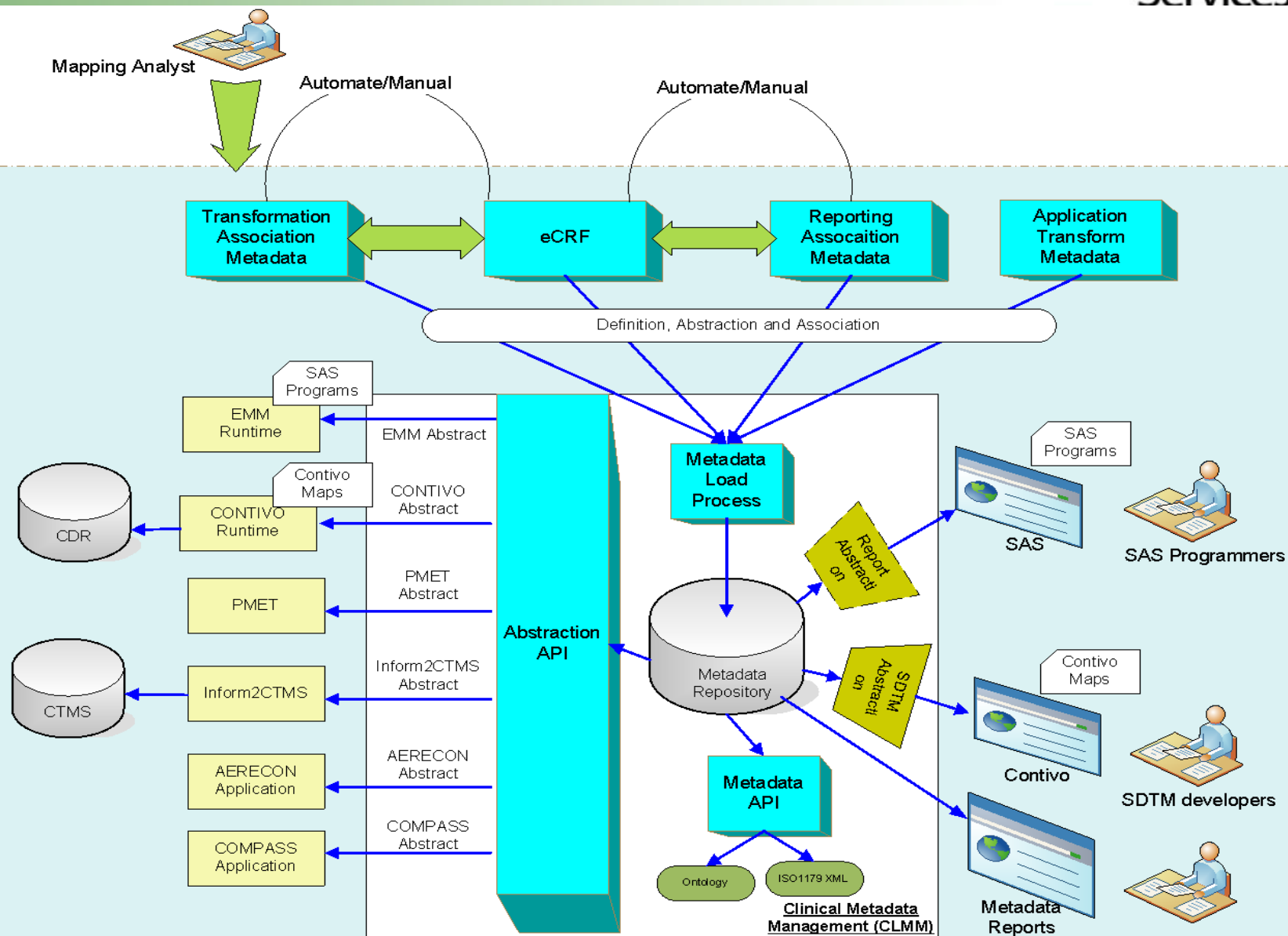
CLMM Components

- ☐ Transformation
 - ❖ Any rules governing the association
- ☐ Abstraction
 - ❖ Abstract view representation of data sets
- ☐ DB Specification
 - ❖ Descriptor of the data source for a data element

CLMM Components Hierarchy



Architecture (Conceptual)



❑ Metadata Management

- ❖ Create and manage Metadata standards
- ❖ Create and Manage Data abstractions
- ❖ Validate Mappings
- ❖ Standard's validation and promotion process

❑ Metadata API's

- ❖ ISO11179 XML feed
- ❖ Ontology

❑ Abstraction API's

- ❖ Views
- ❖ SAS Datasets
- ❖ Web Services

❑ Reporting

- ❖ Reporting criteria definitions
- ❖ View Report
- ❖ Export Report

❑ Administration

- ❖ Create and Manage users
- ❖ Create and Manage Roles and privileges

Questions ?

