



Support to fully expand the value from the standards



Assistance with technical tasks post-implementation



Assistance with metadata readiness and implementation

**Expertise and resources to maximize the value of the MDR**

## Standards

### Standards Governance Design in MDR

- Translate existing governance processes into an MDR environment
- Leverage opportunities within the tool to facilitate governance improvement

### Standards Governance Enhancement

- Assess current state of standards governance by SME
- Solve process problems for existing governance
- Establish appropriate levels of initial governance where absent

### Governance as a Service (GaaS)

- Perform well-defined standards governance tasks within the MDR that involve non-proprietary activities
- Implement a “governance starter kit” within the MDR

### Standards Growth Appraisal

- Quickly assess current state in adoption of standards, governance, and metadata management
- Produce high-level report that demonstrates where the organization is on the path to standards and an MDR

### Data Standards Assessment

- Assess an organization’s application of CDISC standards in CDASH, SDTM, and ADaM
- Produce report that identifies remediation and opportunities for greater value from the standards

## MDR Implementation

### Roadmap for Readiness for an MDR

- Assess an organization’s metadata at high-level vs industry best practices
- Recommend incremental steps towards the goal of effective metadata management in an MDR

### Metadata Analysis Inventory

- Analyze an organization’s metadata in a deep dive to determine alignment with best practice usage of an MDR
- Link analysis to the actual MDR implementation

### Business Requirements Authoring

- Generate MDR business requirements based on an organization’s relevant use cases
- Provide strategic guidance to align MDR business requirements with industry best practices

### Test Scripts Authoring

- Generate MDR test scripts in conjunction with the MDR implementation

## MDR Supplement

### Terminology Updates

- Manage the technological updates for the CDISC terminology within the MDR tool
- Deliver as an ongoing activity at designated periodic intervals