Objective: To demonstrate the process flow and applications used at Novartis to develop, utilize and govern clinical data and reporting/submission standards.

Path to a Metadata-Driven Standards Environment – Collection to Submission

How does metadata impact...

**Clinical Data Management System**
- Consistency and reliability of standard data elements, leading to efficiencies in database development
- Increases data mining capabilities based on metadata
- Single source of clinical data for cross-functional use (safety, modeling, PK)
- Effective integration of data to support timely decision-making (before, during and after submission)

**Data Warehouse**
- Reporting system based on reusable metadata vs. study/project level
- Streamlines downstream analysis and reporting processes

**Governance Board (meets weekly)**
- Act as the expert team on all matters concerning data standards; provide consultancy to stakeholders as needed or requested
- Provide consistent oversight of data collection and reporting standards to ensure alignment with all applicable internal clinical trial policies and procedures, health authority requirements, industry, best practices, and industry data submission standards (e.g. Study Data Tabulation Model (SDTM))
- Recommend and oversee implementation of business processes which will allow for the definition, adoption and enforcement of these standards
- Requests for standards approval managed via service requests in an incident management system

**Membership**
Senior representatives with a background in Clinical Science, Biostatistics, Statistical Reporting and/or Data Management. Representatives from the Global Library, Reporting Operations, and Data Warehouse Operations. Extended team representation: Imaging, Pharmacometrics, Biomarkers, Drug Safety and Epidemiology, and Clinical Quality Assurance.

**Lessons Learned**
- Designing quality checks is an evolving process – and it’s best that this is incorporated into system entry as much as possible
- Proactively manage expectations around defining fields in the MDR
- Avoid creating a lot of metadata fields that are not used
- Accept that you will want to add more metadata fields as your strategy evolves
- The definition of fields in the MDR is critical – make sure everyone has the same understanding
- Need to allow time for people to get used to reading and interpreting metadata
- Create a versioning strategy and methodology for each type of metadata stored upstream
- Consider business requirements vs. theoretical when defining this strategy
- Maintaining an MDR that is not fully integrated with the systems that consume the metadata leads to sizeable efforts in keeping them consistent
- Have a technical solution for holding, defining, editing, searching the metadata

**Data Domains**

**Metadata Repository**

**Data Collection Metadata (i.e. CDASH standards)**

**Clinical Data Management System**

**3rd Party Data**

**Clinical Study Report**