**PP21: One Approach to a Metadata and Data Standards Repository**

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**Define**

Anyone using data standards is already using metadata. Metadata defines data standards, how data is structured and proprietary. Some are simple, others can be complex and need to be managed. Standards such as CDISC (CDISC Study Data Tabulation Model (SDTM), Standard for Tabular Clinical Data (SDTM), and Common Data Elements (CDE)) are protocols for data management across studies. CDASH (Common Data Architecture for Statistical Analysis) is a methodology for managing data that is already in use. The selection of metadata that can appropriately be applied to a study or project such as SDTM, CDASH, or Adachi can be represented in various ways, and they have different technical specifications. A template statistical analysis plan can define all or added study design elements designating collected data elements and even CRF template standardization. SAS Clinical Data Integration can signifi- cally impact metadata management for SDTM and Adachi.

**Manage**

During the implementation of the metadata, the following steps are recommended: Managing metadata begins by mapping data to a metadata standard and identifying the elements that are needed and not used. Metadata and data standards should change over time. Ensure that there is a change control mechanism and processes in place. Questions to answer are:

- What will be a contractor or a single owner?
- How will changes be communicated? Will you integrate?
- How will the business process with the change be defined and enforced?
- Will there be automatic verification of changes to supported formats for review?
- Changes can be modified by the author that changes will be tested on the tool and not on a template.