



## Cdisc Sdtm Internship

Various approaches where Internship candidates will be exposed under CDISC, SDTM, and ADaM standards:

### **Standardizing Data Collection**

Implementing CDISC standards for consistent and standardized data collection across clinical trials.

2.

### **Compliance Assessments**

Regularly assessing compliance with CDISC standards to ensure data accuracy and consistency.

4.

### **Data Mapping and Transformation**

Mapping existing data to CDISC standards and developing transformation processes for smooth transition.

6.

### **Version Control**

Implementing version control systems to track changes and updates in CDISC standards and datasets.

8.

### **Quality Control Checks**

Conducting regular quality control checks to identify and rectify discrepancies in CDISC compliant datasets.

10.

## **Customizing CDISC Standards**

Customizing CDISC standards to meet specific trial requirements while maintaining compliance.

12.

## **External Vendor Collaboration**

Collaborating with external vendors to align their data formats with CDISC standards for seamless integration.

14.

## **Implementing CDASH Standards**

Utilizing Clinical Data Acquisition Standards Harmonization (CDASH) for consistent data collection.

16.

## **Continuous Improvement**

Continuously evaluating and improving CDISC implementation processes based on feedback and lessons learned.

18.

## **Risk-Based Monitoring**

Applying risk-based monitoring techniques to identify potential issues in CDISC compliant datasets early on.

20.

## **SDTM Dataset Creation**

Creating SDTM datasets based on collected clinical trial data for regulatory submission.

2.

## **Metadata Standardization**

Standardizing metadata across SDTM and ADaM datasets for consistency.

4.

## **ADaM Mapping and Validation**

Mapping SDTM datasets to ADaM datasets and performing validation checks.

6.

## **Dataset Specifications**

Developing detailed specifications for SDTM and ADaM datasets.

8.

## **Data Traceability**

Ensuring traceability of data elements from source to SDTM to ADaM datasets.

10.

## **ADaM Interim Analysis Datasets**

Creating interim analysis datasets based on ADaM standards for ongoing trial assessment.

12.

## **Data Integration**

Integrating SDTM and ADaM datasets with other databases and systems for comprehensive analysis.

14.

## **Protocol Deviations Handling**

Implementing protocols for handling and documenting protocol deviations in SDTM and ADaM datasets.

16.

## **Data Submission Preparation**

Preparing SDTM and ADaM datasets for regulatory submission in the required format.

18.

## **Data Reconciliation**

Reconciling data between SDTM, ADaM, and other clinical trial databases to ensure consistency.

