

Paper PP25
Enhancing Research Through Clinical Data Standardization

- **Introduction**

For every Pharmaceutical Organization, there is a need to standardize heterogeneous Clinical Data for Cross study analysis and faster regulatory submissions. In this poster we provide a Clinical Data Standardization Methodology (CDSM) to help Organizations in building their own Metadata oriented Standardization framework for streamlining the Clinical Trial Process.

Data Standardization framework has largely been considered as a Standalone framework, but CDSM also focuses on integrating it with the existing Analysis and Reporting system of any Organization.

This can be considered as an approach which focuses on integrating (co-locating) all the Clinical Data Management, reporting, analytics and Transformation tools which can be called as a "Clinical End to End Submission framework".

- **Designing the Clinical Data Standardization Framework**

2.1 Key Considerations for Clinical Data Standardization

- Should bring all Legacy/Ongoing and planned trials in scope.
- Short-list Target Standard (CDISC/Sponsor Defined).
- Should select appropriate Techniques and Technologies for setting up the Standardization Framework.
- Integration of Standardization Framework with the Analysis system.

Taking the above considerations in scope, CDSM will help the Organizations in building their own Clinical Data Standardization Framework.

The standardization solution revolves around three key Process Steps namely Metadata set-up, creation of an effective and user friendly GUI and integration with other Analytics applications.

The standardization approach can be applied to Legacy, On-going (post completion) as well as Future Trials (directly into the new standard).

- **End to End Clinical Trial processes with Standardized Framework**

The Standardize framework forms the base of all the Clinical Data Processes and hence should cover the entire scope of Study Life cycle.

3.1 Key Considerations governing the End to End Framework

- Across all the trials, should use generalized CRFs covering all the Therapeutic areas.
- CRFs should also be in sync with the Standard defined in the Standardized framework.
- Parameter based generalized codes for handling the Non uniform source Data variables and then validating the source Data with the Standardized Analysis Datasets.
- Generalized algorithms for Clinical Data Analysis and automatic provision of generating other Deliverables like Patient Profiles, Define.xml etc. through the same framework.

The integrated approach of the Standardization Framework and the Existing Clinical Trial Data Process systems can be best depicted in the below pictorial diagram showing its applicability and coverage.

- **Conclusion:**

Integrating the Clinical Trial Data Processing systems with the Standardization Framework can help us in availing the benefits shown below:

- **Acknowledgement:**

Thanks to the TCS Team for the support and valuable inputs.

- **Contact Details:**

Pankaj Bhandari (pankaj.bhandari@tcs.com)

Tata Consultancy Services, India