Introduction

For every Pharmaceutical Organization, there is a need to standardize heterogeneous Clinical Data for Cross-study analysis and foster 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 Stand-alone framework, but, CDMS 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 Submissions framework”.

Key Considerations for Clinical Data Standardization

- Should bring all Legacy/Ongoing and Planned trials in scope.
- Share-List Target Standard (CDISC/Provider Defined).
- Should select appropriate Technologies and Technologies for setting up the Standardization Framework.
- Integration of Standardization Framework with the Analysis system.

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

End to End Clinical Trial processes with Standardized Framework

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

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 and Analyze Datasets.
- Generalized algorithms for Clinical Data Analysis and automatic provision of generating other Deliverables like Patient Profiles, Define.xml etc. through the same framework.

Conclusion

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

- Efficient Data Transformation
- Effective Data Analysis
- Improved Data Quality
- Data Accuracy
- Enhanced Process Efficiency
- Standardized Data Reporting
- Cost Efficient Data Management

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