# Clinical data interchange standards consortium: A bridge to overcome data standardisation

Perception is a utility, which is stamped and has a barcode meets the standard requirement and is an appropriate utility, which is derived or manufactured as per standards. It is important that the utility or product is validated. In clinical research data standardisation has been advanced to a certain level. The complexity of data types, data formats and modes by which the data collection takes place, makes the process a bit complex. When we consider data related to patients or health cases there are various organisation that are playing a key role in creating and enhancing data specifications/standards. Clinical data interchange standards consortium (CDISC), critical path institute (C-Path) health level seven are units, which are non-profit standards developing organization. They are very much active in developing global standards to streamline medical research.

It is very important to decide as to which time point of the study the standards are implemented. Is it implemented within the clinical data management system (CDMS)? Or is it programmed as a function when data is extracted out from CDMS? However, it is recommended that a combination of both the approaches is considered. When CDISC standards are defined at a domain level, it helps to setup studies and project, which further provides uniformity in data standards, structure and also helps extracting data in the required format. This also ensures that the database tables are defined in CDISC, which further will facilitate format in which the data is analyzed and reported. Implementing the CDISC standards at the "back-end" as part of the management of the data in analysis and reporting has benefits and drawbacks as there is no direct involvement of database management system (DBMS).[1] Most of the organization who owned

legacy system and process though their functionality and performance was good they had to be developed or modify the data standards to meet the needs of food and drug administration (FDA) and international conference on harmonisation (ICH).

As a next step the FDA, CDISC, and C-Path are further working on helping to put together and develop therapeutic area wise standards. This further facilitated to have evolution of coalitions for accelerating standards and therapies (CFAST), which is called as Coalitions for Accelerating Standards and Therapies. This standard is an effective initiative, which will allow the industry to produce new therapies for patients in several ways. However, the biggest challenge faced by leading contract research organization (CRO's) is due to the way their clients are interpreting these standards as well as the presence of their own level of standards, which poses a challenge/difficulty in having a full proof concept of standardisation. Hence before interpretation of CDISC standards it is important that the type of interpretation should be considered. It is important that interpretation is accurate, which will help to facilitate in having compliant standards.

Domains within the CDISC are very well-defined; hence mapping the same with the already existing standards within the organization causes some difficulty and might lead to a timely affair when it comes to correlating and redefining the same. Other challenges faced while mapping in case of specialized data, which is uncommon and also for the data, which is common, but the date for the same is collected in an unusual manner. The child bearing potential can be an example as this information is collected at multiple times during the trial as this information is part of subject characteristic domain. Limitation of this domain is that it will not allow for characteristic information at multiple visits, which is not acceptable to place it there. Once it is determined that where and until what depth the standards are implemented, it is equally important as to who performs implementation. Raw data source is considered as input; hence this helps establishing a relationship between study data tabulation model (SDTM)

and analysis data model (ADaM). Preferred practice would be to create SDTM domains from the raw dataset and then implement ADaM using the SDTM. Training is an important consideration although planning implementation of CDISC.

It is important during planning and strategising implementation of CDISC to use the existing tools with some minor alteration (if required) and run a pilot. It is suggested that external vendors are finalized along with various mapping tools such as XML generators, data conversion utilities, etc., Data review tools such as Integrated Review™ (iReview) or jReview™ are helpful tools, though not required commonly. CDISC specific review tools exists such as WebSDM™, which provides mechanisms to verify the structure of the data sets and also help in reviewing contents as well.

It is clear that steps for implementing CDISC standards are systematic, but its execution may not be. It is imperative and critical is to define the objectives for the organization. The setting of standards requires high-level objectives such as training internal expert or by an external vendor experienced in CDISC structures. Standards must be part of managing the data extracted from the DBMS. Hence, Interpretation of the standards by database programmers for SDTM, SAS programmers for ADaM and members associated with submission experience is a must. Systematic approach for implementation of SDTM and ADaM models is surely the need of the hour. Tools such as SAS will help articulating and aligning the format as per the standards.

Moving forward as the CDISC standards are defined, there is better visibility as we submit these in the required format and systems are able to easily recognise and read pre-clinical and clinical data based on protocols, designs, and plans. Health data basically consists/represent diagnosis, procedures and observations. It

mainly focuses on observations such as Direct primary patient, Meta-observations, Context observations, Analysis observations etc., Hence, it is imperative for developed/updated SDTM and ADaM views (perhaps as operational data model [ODM]), which will be required for submission readiness that will support clinical review and its analysis. It is important that we understand that CDISC data structures will eventually bridge the gap from the raw data to structured clinical trial views of the clinical data. The gap will be bridged as various sources of data collection to analysis and reporting through regulatory submission and electronic data archive are controlled using the SDTM, ADaM, ODM, laboratory data model, Protocol Representation, trial design model, Case Report Tabulation Data Definition Specification – (define.xml), standard for exchange of nonclinical data and the clinical data acquisition standards harmonization. This is a continuous process and surely these developments will benefit the standardization between the health-care record and the clinical trial data.

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## REFERENCE

1. Stemplinger RT, Lane J. Considerations for CDISC Implementation; PhUSE 2007; Paper RA10 Available from: http://www.phusewiki.org/docs/2007/PAPERS/_RA10.pdf. [Last accessed on 2013 Apr 30]

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