Clinical Data Standards

Accelerated efforts through the Coalition for Accelerating Standards & Therapies (CFAST) to establish therapeutic area (efficacy) data standards

Initiative Status
Last Update: September 2018

Explore  Design  Deliver  Maintain  Closed

Deliverables:
✓ The Clinical Data Standards team supported the delivery of 20+ Therapeutic Area Data Standards.

These therapeutic area standards are freely available on the CDISC website

Value for Stakeholders

This initiative assisted CDISC in the development of data standards by supporting the review of Therapeutic Area User Guides (TAUGs) that, when implemented, enable data aggregation, cross study analysis and end to end data flow. Collectively, these activities provided benefits such as:

• Enabled the combining of data from disparate sources for analyses to plan new studies & enhanced medical and scientific insights, thus enhancing disease management
• Enabled operational efficiencies in data management and analysis
• Facilitated the demonstration of traceability of data
• Enabled more efficient regulatory reviews
• Provided a Foundation for interoperability as stated in FDA Guidance on electronic regulatory submissions Enabling future integration of clinical studies with Electronic Health Record (EHR) or Electronic Medical Record (EMR)