To develop and maintain a standard model and implementation guides that support more consistent and effective integration, aggregation, and submission of tabulation data from human clinical trials to facilitate FDA reviews and increase the value of collected research data.

Scope
The SDS Team develops standards for the submission of tabulation data from human clinical trials. Since its inception, the SDS Team has worked to develop data domain models to support the Safety Domains listed in the 1999 FDA Guidance Documents from CDER & CBER, and continues to develop new or enhanced domain models through Study Data Tabulation Model (SDTM), as well as its drug- and biologics-focused Implementation Guide (SDTMIG).

The SDS team maintains the SDTMIG, Metadata Submission Guideline, and SDTMIG-AP in alignment with the CDISC Strategy, by organizing its constituent members into relevant sub-teams to deliver domain models that meet growing data standardization needs from FDA, as well as key therapeutic-area-focused and collaborative organizations such as TransCelerate BioPharma.

The SDS Team is also looking to directly support C-FAST Therapeutic Area Standards products.

2017 Product Goals
The SDS Team will agree and implement its 2017 SDS Team - Project Delivery Plan, targeting to deliver:

- Update to the Study Data Tabulation Model (SDTM v1.7)
- Update to the Study Data Tabulation Model Implementation Guide (SDTMIG v3.3)
- Conformance Rules update for SDTM v1.7/SDTMIG v3.3
- Update to the Metadata Submission Guideline (MSG v1.0)
- The SDTMIG Rules Guidance (v1.0)
- Intermediate provisional domain models (more to be defined)
- Cascade CDISC values and develop SDTM modeling principles to facilitate decision making.
- Improve CDISC wiki organization (e.g., from team site and charter, to cross-team sites/charters, to CDISC Technical Plan).
- Develop a library of examples, concept maps, decision trees as supplemental documents for user community reference.
- White Paper on Race & Ethnicity

Other Major Projects
The SDS Team will begin a project to load SDTM content into SHARE in 2015, and will also initiate the creation and implementation of several new domains, enhancements, and/or corrections to previously published sections, and other incremental content targeted for inclusion on the next release of the SDTMIG (v 3.3). Domains may be released in batches for review and provisional use prior to 3.3.

These updates may be originated from previously existing plans, or as a direct result of Therapeutic Area Project needs. Calls for volunteers will be issued to create SDTM Domain Development sub-teams.

Stakeholders/Constituency
- Regulatory Authorities
- Standards Development Organizations
- Pharmaceutical Sponsors
- Medical Devices, Diagnostics

Contract Research Organizations & Consultants

Collaborations
The SDS Team works closely with CDISC Teams who utilize or leverage the SDTM standard to develop their own IGs (e.g., SDTM Governance, SEND, ADaM, Devices, CDASH, PGx, XML Technologies).

The SDS Team is also a strong contributor to BRIDG, SHARE, and TA Project Teams

Operating Model & Meetings
- Full team is divided into sub-teams to deliver one or more components from the 2016 SDS Team - Project Delivery Plan to effectively maintain the SDTM, SDTMIG, and SDTMIG-AP
- Sub-teams set own meeting schedule, and mechanism to report progress through their Lead(s)
- SDTM Area Leads ensure consistency across SDTM Sections/domains under their care, and report maintenance progress up to SDS LT
- SDS LT regularly engages with SDTM Area Leads to share CDISC Updates & Review deliverables against agreed 2015 SDS Team - Project Delivery Plan
- Key meetings on Mondays 11am-12:30pm Eastern US Time
  - 1st & 3rd Monday SDS LT
  - 2nd & 4th Monday – SDS LT, SDTM Area Leads & SDTM Experts and Liaisons

Quarterly meetings w/ full SDS Team, including volunteers