

1. [SDS Home on the CDISC Website](#)
2. [SDS Home on the CDISC Wiki](#) (Access may be restricted to SDS Team Members)

<u>Leadership Team</u>
<ol style="list-style-type: none"> 1. Janet Reich 2. Mike Hamidi 3. Christine Connolly
<u>SDTM Area / Project Leads</u>
Interventions, Events and FA
Janet Reich & Madhavi Vemuri
PGx
Joyce Hernandez
Oncology
Barrie Nelson, Melanie Paules & Amy Adyanthaya
QRS
Gary Cunningham & Steve Kopko, Bess LeRoy, Jon Neville
RESPONC
Mike Hamidi & Richard Lewis
Business Rules
Stetson Line
<u>Cross-Team Liaisons</u>
FDA: TBD & Helena Sviglin
Controlled Terminology: TBD
Devices: Kit Howard

<u>Team Mission</u>
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.
<u>Scope</u>
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 (<i>SDTM</i>), as well as its drug- and biologics-focused Implementation Guide (<i>SDTMIG</i>).
The SDS team maintains the <i>SDTMIG</i> , <i>Metadata Submission Guideline</i> , and <i>SDTMIG-AP</i> , 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.
<u>2017 Product Goals</u>
The SDS Team will agree and implement its <i>2017 SDS Team - Project Delivery Plan</i> , targeting to deliver:
<ul style="list-style-type: none"> • 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 (eg, 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
<u>Other Major Project(s)</u>
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.

<u>Stakeholders/Constituency</u>
<ul style="list-style-type: none"> • Regulatory Authorities • Standards Development Organizations • Pharmaceutical Sponsors • Medical Devices, Diagnostics
Contract Research Organizations & Consultants
<u>Collaborations</u>
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
<u>Operating Model & Meetings</u>
<ul style="list-style-type: none"> • 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 <i>SDTM</i>, <i>SDTMIG</i>, and <i>SDTMIG-AP</i> • 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 <ul style="list-style-type: none"> • 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