



CDISC Submission Data Standards (SDS) Team Team Charter

<p><u>Leadership Team</u> Dan Godoy & Barrie Nelson (Co-Leads) Diane Wold Wayne Kubick Fred Wood Amy Palmer</p> <hr/> <p><u>SDTM Area Leads</u></p> <p>Findings NEC Randall Austin & Jan Hess Interventions, Events and FA VACANT Lab Findings Joyce Hernandez & VACANT Oncology Barrie Nelson, Melanie Paules & Amy Adyanthaya Questionnaires Gary Cunningham & Steve Kopko Special Purpose Trial Design & IE Tom Guinter & VACANT Diane Wold & VACANT</p> <hr/> <p><u>SDTM Experts</u> Gail Stoner Madhavi Vemuri Gary Walker</p> <p><u>Cross-Team Liaisons</u> FDA Ron Fitzmartin & Helena Sviglin SDS Volunteers Naveed Khaja Controlled Terminology Bernice Yost Devices Carey Smoak</p>	<p style="text-align: center;"><u>Team Mission</u></p> <p>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.</p> <hr/> <p style="text-align: center;"><u>Scope</u></p> <p>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).</p> <p>The SDS team maintains the SDTM, SDTMIG, SDTMIG-PGx, 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.</p> <p>The SDS Team is also looking to directly support C-FAST Therapeutic Area Standards products.</p> <hr/> <p style="text-align: center;"><u>2014 Product Goals</u></p> <p>The SDS Team will agree and implement its 2014 SDS Team - Project Delivery Plan, targeting to deliver:</p> <ul style="list-style-type: none"> ➤ An update to the Study Data Tabulation Model (SDTM v 1.5) ➤ An update to the Study Data Tabulation Model Implementation Guide (SDTMIG v3.3) ➤ An update to the Metadata Submission Guideline (MSG v1.0) ➤ The SDTM Implementation Guide: Pharmacogenomics/Genomics (SDTMIG-PGx v1.0) ➤ The SDTMIG Rules Guidance (v1.0) <hr/> <p style="text-align: center;"><u>Other Major Project(s)</u></p> <p>The SDS Team will begin a project to load SDTM content into SHARE in 2014, 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.</p> <p>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.</p>	<p style="text-align: center;"><u>Stakeholders/Constituency</u></p> <ul style="list-style-type: none"> ➤ Regulatory Authorities ➤ Standards Development Organizations ➤ Pharmaceutical Sponsors ➤ Medical Devices, Diagnostics ➤ Contract Research Organizations & Consultants <hr/> <p style="text-align: center;"><u>Collaborations</u></p> <p>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</p> <hr/> <p style="text-align: center;"><u>Operating Model & Meetings</u></p> <ul style="list-style-type: none"> ➤ Full team is divided into sub-teams to deliver one or more components from the 2014 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 SDTM Area 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 2014 SDS Team - Project Delivery Plan ➤ Key meetings on Mondays 11am-12:30pm EDT <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
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