

| SDS Leadership Team   |
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| <ul style="list-style-type: none"> <li>• Mike Hamidi (<i>Advisor</i>)</li> <li>• Christine Connolly</li> <li>• Kristin Kelly</li> <li>• Dana Booth (<i>Project Manager</i>)</li> </ul>  |
| SDS Sub-team Leaders  |
| Team leaders are listed in the <a href="#">SDS Subteam Tracker</a> .  |
| SDS Team Liaisons to the GGG  |
| <ul style="list-style-type: none"> <li>• Gary Walker</li> <li>• Ellina Babouchkina</li> <li>• Richard Phillips</li> </ul>   |
| Deliverables  |
| <ul style="list-style-type: none"> <li>• Study Data Tabulation Model Implementation Guide (SDTMIG): Human Clinical Trials</li> <li>• SDTMIG Conformance Rules</li> <li>• SDTMIG for Associated Persons (AP)</li> <li>• SDTMIG for Medical Devices (MD)</li> <li>• SDTMIG for Pharmacogenomic /genetics (PGx)</li> <li>• Metadata Submission Guidelines (MSG) for SDTMIG</li> <li>• Oncology Supplements</li> <li>• Questionnaires, Ratings, Scales (QRS) Supplements</li> </ul> |

| Team Mission   |
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| The SDS team develops and maintains standards for representing study data from human clinical trials and other research collaborations. The SDS team seeks continuous improvement and strives to increase the value of standardized study data for greater interoperability and accessibility by academic researchers, healthcare organizations, sponsors, and global health authorities.  |
| Scope  |
| The SDS team scope focuses on SDTM implementation guides for human clinical trial data. Each implementation guide (and its associated SDTM) describes the organization, structure, and format of the standardized data to support use by academic researchers, healthcare organizations, sponsors, and/or global health authorities.   |
| Operating Model  |
| <ul style="list-style-type: none"> <li>• Working meetings to plan for future projects and content for industry stakeholders</li> <li>• A predictable and open forum for SDS team members to raise concerns /issues, provide feedback, identify cross-standard discrepancies (e.g., CDASH, CT), propose solutions, support development of content, and aid in the review and disposition of content for publication</li> <li>• Communicate across and manage all associated SDS sub-teams</li> <li>• Provide the Global Governance Group (GGG) updates to the wider SDS team members</li> <li>• Aid in on-boarding and mentoring SDS volunteers by providing a transparent and inclusive development culture</li> </ul> |

| Stakeholders   |
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| <ul style="list-style-type: none"> <li>• Regulatory Authorities (e.g., U.S. FDA, PMDA)</li> <li>• Standards &amp; Related Organizations (e.g., HL7, LOINC, WHO, UMC, PhUSE)</li> <li>• Pharmaceutical/Biotech, Medical Devices, etc.</li> <li>• Contract Research Organizations (CROs)</li> <li>• Technology Vendors</li> <li>• Consultants, Programmers, Statisticians, and other related Subject Matter Experts</li> <li>• Academic and Scientific Communities</li> <li>• Healthcare Institutions</li> </ul> |
| Cross-Team Collaborations  |
| The SDS team works closely across CDISC teams to ensure consistency, clarity, and to support development requirements of SDS deliverables.   |
| A list of cross-team collaborations (and SDS subteams) are listed on the <a href="#">SDS Home page</a> .   |
| Additional Resources   |
| <ul style="list-style-type: none"> <li>• CDISC Website <ul style="list-style-type: none"> <li>• <a href="#">SDTM, SDTMIG, QRS Supps., PG xIG</a></li> </ul> </li> <li>• CDISC Wiki <ul style="list-style-type: none"> <li>• <a href="#">Global Governance Group Home*</a></li> <li>• <a href="#">Standards Updates Table*</a></li> <li>• <a href="#">Navigating the CDISC Standards Development Process*</a></li> </ul> </li> </ul>  |
| *Links are accessible to CDISC Volunteers only.  |