

1. [Medical Devices Home on the CDISC Wiki](#) (Access may be restricted to Medical Devices Team Members)

<p style="text-align: center;"><u>Leadership Team</u></p> <ul style="list-style-type: none">• Kit Howard (CDISC)• Carey Smoak (S-Cubed)• Fred Wood (TalentMine)
<p style="text-align: center;"><u>Additional Key Contributors</u></p> <p>The Device team includes representatives from other CDISC Foundational Teams and a set of subteams representing different facets of the CDISC Device standards.</p> <p>Other key contributors include:</p> <ul style="list-style-type: none">• Paul Franson, Medtronic• Priya Gopal, Theorem Clinical• Julia Yang, Medtronic• Henry Friend II, Abbott Diabetes• John Neville, CDISC• Donna Sattler, J&J

<p style="text-align: center;"><u>Team Mission</u></p> <p>To define data collection, submission and analysis standards for research involving medical devices.</p>
<p style="text-align: center;"><u>Scope</u></p> <p>This project is developing collection (CDASH), submission (SDTM) and analysis (ADaM) standards with associated controlled terminology to support electronic submission of PMAs, 510(k)s and Biologics License Applications (BLAs). It also supports implementation of CDISC standards for drug/device combination products, and the use of devices in non-device studies (e.g., Therapeutic Area studies).</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 companies• Contract Research Organizations, Technology Vendors & Consultants• Other organizations conducting or supporting device-related research (e.g., universities)

<p style="text-align: center;"><u>Collaborations</u></p> <p>SDTM, CDASH, ADaM, NCI EVS, Therapeutic Area Teams, FDA (CDRH)</p>
<p style="text-align: center;"><u>Operating Model & Meetings</u></p> <p>The Device leadership team meets the first and third Thursday of each month at 1 pm EST.</p> <p>Team meetings are being reevaluated and rescheduled. Please check back soon.</p> <p>Project documents are stored on the CDISC Wiki at Medical Devices Home</p>