# Leadership Team

- Kit Howard (CDISC)
- Carey Smoak (S-Cubed)
- Fred Wood (TalentMine)

# Additional Key Contributors

The Device team includes representatives from other CDISC Foundational Teams and a set of subteams representing different facets of the CDISC Device standards.

Other key contributors include:

- Paul Franson, Medtronic
- Priya Gopal, Theorem Clinical
- Julia Yang, Medtronic
- Henry Friend II, Abbott Diabetes
- John Neville, CDISC
- Donna Sattler, J&J

# Team Mission

To define data collection, submission and analysis standards for research involving medical devices.

# Scope

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).

# Collaborations

- SDTM, CDASH, ADaM, NCI EVS, Therapeutic Area Teams, FDA (CDRH)

# Operating Model & Meetings

The Device leadership team meets the first and third Thursday of each month at 1 pm EST.

Team meetings are being reevaluated and rescheduled. Please check back soon.

Project documents are stored on the CDISC Wiki at [Medical Devices Home](#)