"I was brought up to believe that the only thing worth doing was to add to the sum of accurate information in the world."

- Margaret Mead

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Hello,

As a member of the CDISC leadership of the medical device standards subteam, I am pleased to announce the first draft of the Devices Supplement to the Study Data Tabulation Model Implementation Guide (SDTMIG) has been completed and is available for public review. This has been a long term cooperative effort between FDA, industry and members of the CDISC CDASH/SDS teams, with the goal of developing collection and submission standards to support electronic submission of PMAs, 510(k), and BLAs.

Being able to share information electronically with FDA and other regulatory agencies is a goal we all aspire to in the medical device industry, as we know it will promote efficiency and faster pathways to market approval. Therefore, I encourage you to visit the **CDISC website** where you can learn more about the Device Supplement, download it, and make comments back to the team. For those of you unfamiliar with CDISC and SDTM, there is a lot of great information on the website, along with ways to get training if you choose.

BSI is a member of CDISC and has experience in SDTM and AdaM dataset creation for your submissions. We have also designed our **rED Cap software** with CDISC in mind, using the ODM model. To learn more about BSI, visit our **website**or **contact us** directly from this newsletter.