MDIC
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Regulatory Roundtable Recap

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On October 2nd and 3rd, the Medical Device Innovation Consortium (MDIC) collaborated with Baylor Scott & White Research Institute (BSWSRI) to host an Early Feasibility Studies (EFS) regulatory roundtable. This event was a continuation of the work begun by MDIC in 2017. After preparing the initial legal library tools, it was determined that it would be helpful to continue this work with a focus on assisting participants with regulatory issues associated with the startup of early feasibility device trials. The regulatory roundtable event was structured as a walkthrough of some of the most frequently discussed provisions of the research subject informed consent form (ICF). Comments were solicited by all participants on proposed updates to the ICF template prior to the event. With this preparation as the backdrop for the event, individual speakers were assigned to review proposed comments and lead the discussion on specific sections of the ICF template. All remaining sections were considered by the entire group of participants. Feedback and comments regarding all sections were recorded for later consideration and further development of the ICF template.

There were 39 participants at the event. The foregoing discussions and exercises were led by BSWRI, MDIC, Intermountain Medical Center, Cedars Sinai Medical Center, Northwestern University, Columbia University Medical Center, Advarra and Boston Scientific, the FDA, and Clinical Trial Transformation Initiative.

A revised draft consent form template was created for further review by the FDA as well as other member organizations of MDIC. At the conclusion of the meeting, select attendees volunteered to create small working groups for the purpose of making further enhancements to the template ICF and developing additional tools to facilitate efficient regulatory review and approval of EFS studies.

MDIC and BSWRI would like to thank all supporters and participants of the 2019 Regulatory Round Table. We anticipate hosting future regulatory roundtables to share additional information obtained from this year's event and continue discussions on the topic. In the meantime, you are welcome to access MDIC's event page where you can view the agenda and presentations at your leisure.

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