



EFS EXPRESS

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EFS Master Clinical Trial Agreement – 2019 Virtual Legal Roundtable Recap

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On July 9, 2019, the Medical Device Innovation Consortium (MDIC) collaborated with Baylor Scott & White Research Institute (BSWSRI) to host a virtual legal roundtable to facilitate additional discussion and further refinement of the [EFS Master Clinical Trial Agreement \(MCTA\)](#) template. The initial draft of the EFS MCTA Template, version 1, resulted from the in-person legal roundtable held by MDIC at BSWRI in February 2018. Feedback on the in-person legal roundtable was extremely positive. Therefore, MDIC sought additional feedback from a broader audience to make the MCTA even more effective for sponsors and sites conducting early feasibility studies. As with the in-person legal roundtable, the goal is to (1) have an MCTA that balances sponsor and site concerns, (2) have a starting point for negotiation with agreement on a significant portion of the MCTA's provisions, and (3) allow for both parties to focus legal resources on a small number of non-agreed provisions of the MCTA.

This year's virtual legal roundtable was a webinar with about 50 attendees, which included a mix of representatives from sites and sponsors as well as an FDA representative. To prepare for the roundtable, participants were asked to provide comments and suggested improvements to the MCTA prior to the webinar. This feedback was used to begin a version 2 draft of the MCTA. During the webinar, there was a panel-led discussion of the provisions that were identified as potential negotiating chokepoints as well as provisions that feedback suggested should be revisited. In response to the panel-led discussion, real time feedback and questions were gathered and recorded. This information will be analyzed and used to finalize version 2 of the MCTA.

The webinar panel included representatives from BSWRI, Northwestern University, and Main Line Health, Inc. Modifications to the following sections were discussed during the webinar: Study Device, Disclaimer, Record Retention, Inventions, Confidentiality, Reimbursements of Medical Expenses.

MDIC would like to thank all supporters and participants of the 2019 MCTA Virtual Legal Roundtable. We anticipate hosting future legal 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 2019 MCTA Virtual Legal Roundtable agenda, presentation, and recording at your leisure.

Looking for more information?

Interested in participating as a sponsor or site? Visit our [website](#) for more information or [email us](#) today.

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