



EFS EXPRESS

Edition 6 • July 10, 2019

EFS Symposium Recap: Implementation Strategies for Early Feasibility Studies

By David R. Holmes, Jr., MD | Mayo Clinic

Last month at the TVT Structural Heart Summit in Chicago, MDIC partnered with the Cardiovascular Research Foundation (CRF), to host an EFS symposium focused on best practices among clinicians for patient screening and enrollment in Early Feasibility Studies. This successful event was attended by clinicians, industry sponsors, site coordinators, and a representative of the FDA. In March, MDIC held a meeting on best practices for EFS administrative issues. This stimulated and helped curate the following topics for the June EFS symposium:

1. Identification of relevant patient population/Patient screening
2. Patient consent issues
3. Procedural and clinical follow-up issues

Attendees heard from institutional physicians from Oregon Health Sciences University, Northwestern University, and Columbia University – as they provided presentations on a case-based approach on the specific topics. Representatives from Boston Scientific, Edwards Lifesciences, and Conformal Medical, were also part of the presentation, providing industry comments while physicians from Penn Medicine, Medstar, Baylor Scott & White, University of Virginia, and a representative of the FDA contributed to the robust, freewheeling panel discussion.

Highlights of the Symposium include new approaches to physician-to-physician referral and the importance of communication/collaboration, during the Patient Screening presentation. The session on Patient Consent focused on managing expectations of the patient and family and the role of the PI in this conversation, while attendees learned of the many scheduling and coordination challenges that should be jointly managed by both sponsor and site during the session on Procedural and Clinical follow-up.

As Chair of the Symposium, I want to thank all of the supporters who made this event possible. In addition to making the presentations available, we anticipate hosting future webinars to share some of the information that was discussed last month. In the meantime, I welcome you to access [MDIC's event page](#) where you can view the EFS Symposium: Implementation Strategies for Early Feasibility Studies agenda and presentations at your own leisure.

Editor's Note: The previous edition of the EFS Express contained a misspelling of Andy Farb's last name. We apologize for this error.

Looking for more information?

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

Follow on [Twitter](#). [Connect on LinkedIn](#). [Forward to Friend](#)

Copyright © All rights reserved.

Our mailing address is:
1501 Wilson Blvd., Suite 910 Arlington, VA 22209

No longer wanting to receive these emails? Feel free to [update subscription preferences](#) so we only send you what you want to see.