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EFS Symposium Highlights Progress, Issues, and Next Steps for Bringing New Technology to the U.S. First

The U.S. now offers a more favorable environment for conducting EFS studies, thanks to the FDA's EFS Program and the European Union Medical Device Regulation of 2017 (EU MDR), noted presenters at the 3D EFS MDIC Symposium on April 21, 2021, co-sponsored by the 3D Dartmouth Device Development Symposium and MDIC.

Representatives of FDA, CMS, device companies, and venture capital firms, as well as clinical investigators and consultants, provided insights on:

- Issues and stumbling blocks in U.S. EFS
- Expanding EFS beyond structural heart, and
- Implications of the European Union Medical Device Directive (EU MDD) to Medical Device Regulation (MDR) transition on EFS.

More than 250 members of the medical device ecosystem attended the symposium, which consisted of three roundtable conversations and four interviews.

In the last seven years, the FDA has approved over 200 EFS studies involving over 2,500 subjects. Metrics collected by MDIC show significant improvements from 2017 to 2019 in time to first enrollment in U.S. EFS and median time for IDE, IRB, and contracting and budgeting approval for U.S. EFS.

"Kudos to the FDA for creating the EFS Program. It's been a lifesaver for industry and has created incredible value for U.S. patients by giving them access to devices much earlier," says Rick Geoffrion, President and CEO of Cyrano Therapeutics, Inc.

[Key insights from the symposium](#) include:

- Collaboration between sponsors and the FDA as well as with sites is key
- All stakeholders must be flexible
- The clinical pathway is more efficient, more collaborative, and more predictable in the U.S. than in Europe
- But the cost of U.S. EFS and lack of reimbursement is a key stumbling block, especially for start-up companies, who must conduct EFS outside the U.S.
- The FDA looks forward to expanding U.S. EFS beyond the cardiovascular space into the neurovascular space
- Opportunities for neurovascular EFS in the U.S. are strong

Successful EFS sites:

- Have a physician champion
- Have investigators who can help the company develop a better product by providing open feedback to the development team
- Offer quality and speed

Key words and concepts for the medical device ecosystem include: collaboration, communication, partnership, learning, reinventing, personal involvement, passion, patients, preparedness, practice, and perspicacity.

"We will continue to gather strength and apostles and to work towards the goal of optimizing care for patients," says David Holmes, MD, Scripps Professor in Cardiovascular Medicine at Mayo Clinic.

Learn more

Watch the [3D EFS MDIC Symposium](#).

MDIC thanks all of the presenters in the EFS Symposium.

Have an EFS success story? In support of our Strategic Priorities, we want to publish success stories to help further the mission and vision of this project. If you would like to share, please send us an e-mail at efspilot@mdic.org with your contact information and a 2-3 sentence summary of your project/story and we will contact you to set up a time to discuss further. Success stories may be written up and published in the EFS Express and across general MDIC channels and industry channels.

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