Key Insights from the 3D EFS MDIC Symposium

The virtual 3D and MDIC EFS Symposium held on April 21, 2021, featured representatives of FDA, CMS, device companies and venture capital firms, as well as clinical investigators and consultants who shared their experience and insights on Early Feasibility Studies (EFS) in the United States.

Overall Key Insights

Collaboration is key.

- Close collaboration between sponsors and FDA as well as with sites is central to a successful EFS Program.
- Lack of interaction with FDA is the most common sponsor mistake. Sponsors should discuss the unknowns and problems with FDA and work together to address gaps and mitigate risks.

The clinical pathway is more efficient, collaborative, and predictable in the U.S. than in Europe.

- The FDA EFS Program has made it easier to conduct EFS in the U.S.
- The EU MDR transition has made the European clinical pathway more difficult.

Master clinical trial agreements such as MDIC's EFS Master Clinical Trial Agreement are crucial but flexibility is needed due to the many unknowns in the EFS space.

- Early discussions between sponsors and sites about contracts save time.
- Indemnification, liability, and publication rights are challenging.
- Flexibility is necessary to deal with the study changes based on lessons learned from each procedure.

Key Issues and Stumbling Blocks

The cost of U.S. EFS and lack of reimbursement are key problems.

- Higher costs and lack of reimbursement in the U.S. force many device companies, especially startups, to conduct EFS outside the U.S.
- Providing CMS coverage for the device and routine costs will enable more companies to conduct EFS in the U.S.
- Providing a means to bring clarity to CMS coverage *prior* to study initiation is important to the ongoing success of the EFS Program

Expanding EFS beyond Structural Heart

Opportunities for neurovascular EFS in the U.S. are strong

- Innovation is ongoing in the neurovascular space.
- The FDA looks forward to expanding U.S. EFS into the neurovascular space.
- The neurovascular EFS pathway should be able to leverage many of the learnings from the experience in the cardiovascular space.

Implications of the EU MDD to MDR Transition on EFS

The transition to MDR is negatively influencing the ability to perform EFS in Europe.

- Uncertainty, increased clinical requirements, and longer timelines for CE marking are major challenges in Europe.
- Notified bodies may not have the capacity to work with small medtech companies.

Qualities of Successful EFS Sites

A physician champion who can:

- Help the company develop a better product by providing open feedback to the development team
- Facilitate acceptance of EFS at her/his institution by working closely with the IRB and administration

Quality and speed

- Extensive clinical trial experience
- Timeliness
- Use of an external IRB
- Good communication
- A high-volume of relevant procedures

U.S. EFS by the Numbers

FDA Metrics

- Over 200 EFS studies
- Over 2,500 subjects
- 80% of EFS approved on the first cycle (FY 2020)

MDIC Metrics

Significant improvements in EFS:

- Time to first enrollment
- Median time for IDE, IRB, and contracting and budgeting approval

Time to first enrollment

- 2017: 187 days
- 2019: 88 days

Median time for IDE, IRB, and contracting and budgeting approval

- 2017: About 320 days
- 2019: 252 days

About the EFS Symposium

The 3D EFS MDIC Symposium, hosted by the 3D Dartmouth Device Development Symposium and MDIC's Clinical Science Initiative, highlighted experience to date with U.S. EFS and:

- Issues and stumbling blocks in U.S. EFS
- Expanding EFS beyond structural heart, and
- Implications of the EU MDD to 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.