



EFS EXPRESS

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EFS Innovator Solves COVID-19 Challenges to Help More Patients

Site: Baylor Scott & White Research Institute
Site type: Academic medical center
Device Type: Cardiovascular devices

This is Part 2 of a 3-part series on the impact of COVID-19 on US EFS. Read [Part 1](#).

The [Baylor Scott & White Research Institute](#) has been conducting EFS in the cardiovascular space since the program's inception. When the COVID-19 pandemic struck in March 2020, elective procedures were discontinued and the cardiovascular research team was assigned to COVID-19 studies. Work on three transcatheter valve EFS were suspended and the start of a new EFS to study an artificial heart was delayed.

MDIC discussions enabled FDA, sponsors, and investigators to discuss overarching issues in conducting EFS during the pandemic. Informal discussions among the stakeholders about individual studies led to changes that enabled EFS to continue with fewer missing data and more compliance.

These changes included collection of fewer data, fewer study visits, and use of remote technologies, such as study visits by telehealth, point of care diagnostic devices, and remote proctoring. Proctoring, supervision by a physician who is familiar with the new device, is required by the FDA or the sponsor.

"The pandemic accelerated the changes that needed to happen," says Michael J. Mack, MD, director of the Cardiovascular Service line, Baylor Scott & White Health System and president and chairman, Baylor Scott & White Research Institute. [Read more](#) about advances in the EFS process that came out of the pandemic.

When EFS studies resumed in August, the Baylor Scott & White Research Institute made EFS studies the priority. "These patients were most desperately in need of devices that were being studied in EFS trials," says Dr. Mack.

Still, challenges remained. Telehealth and remote diagnostics weren't sufficient for monitoring participants who had received an EFS device and collecting data or evaluating potential candidates for an EFS. Patients were reluctant to come into the hospital.

Also, the sponsor support needed for EFS procedures was limited. Usually, five or six experts are present during procedures. Only two were allowed in the hospital during the pandemic.

By February 2021, Baylor Scott & White Research Institute's EFS program was close to normal. "The major issue is the travel of sponsor personnel for procedures and getting the devices into the U.S.," says Dr. Mack. For example, the EFS on the artificial heart was delayed because the device is made by a French company.

The FDA EFS program is "a significant advantage in the pandemic environment," says Dr. Mack. "If this was 5 or 10 years ago and everything had to be done in Europe or South America, things would be totally shut down." Also, most EFS device companies are in the United States and domestic travel is easier than international travel. Dr. Mack expects research to be "relatively normal" once herd immunity is achieved this summer.

MDIC thanks Dr. Michael J. Mack, director of the Cardiovascular Service line, Baylor Scott & White Health System and president and chairman, Baylor Scott & White Research Institute for sharing his EFS Story.

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