



EFS Advantages in Device Development

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FDA's EFS IDE Background

Innovative Medical Device Evaluation in the US *The Past*

- Migration of initial clinical testing of novel devices overseas
- Time lag in the access to beneficial medical devices for US patients
- Delay in physician experience with new products



US was the 42nd nation to approve a transcatheter aortic valve replacement device

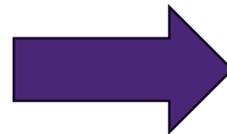


Many clinical trial ecosystem factors contributed to these trends including FDA's requirements for non-clinical testing prior to initiating clinical studies of new devices.

FDA's EFS IDE Background



Pilot Phase 2011 – 2013
~ 9 Programs
Sponsor Experience
FDA Experience



Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 1, 2013

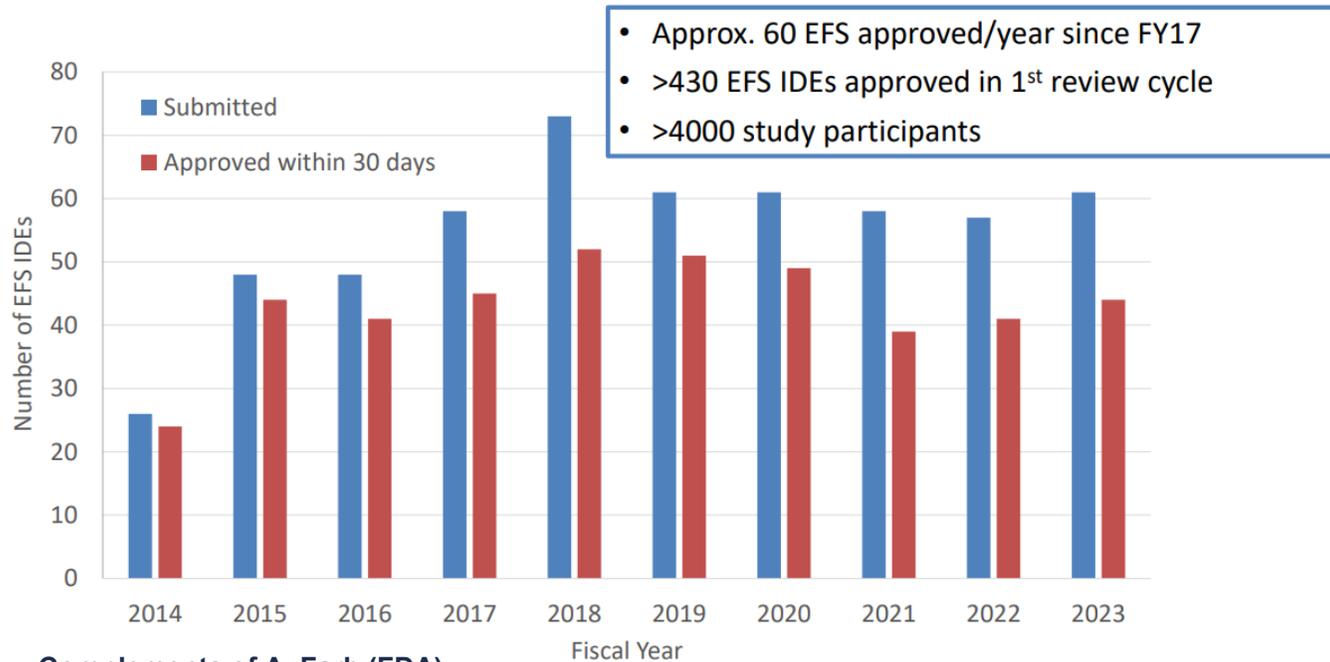
The draft of this document was issued on November 10, 2011.

For questions regarding this document, contact CDRH's Andrew Farb, 301-796-6343, Andrew.Farb@fda.hhs.gov or Dorothy Abel, 301-796-6366, Dorothy.Abel@fda.hhs.gov, or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

EFS IDE Roll-Out

EFS Program Snapshot



- Approx. 60 EFS approved/year since FY17
- >430 EFS IDEs approved in 1st review cycle
- >4000 study participants

Complements of A. Farb (FDA)

8

MDIC EFS Support Activities

- Accelerate EFS Toolkit
- EFS Site Best Practice Workshops
- Clinical Science Alliance

MDIC.org

**Blueprint for Early Feasibility Study Success:
A report of the Early Feasibility Study
working group of the Medical Device
Innovation Consortium (MDIC)**



September 2016
www.mdic.org



EFS IDE Benefits



Early FDA engagement/partnership



Just in time testing approach



Avoid export permits/notifications



Avoid language barriers



Reduced travel expense



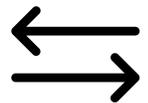
EFS IDE Benefits



Ability to leverage data



Network of sites familiar with the EFS program



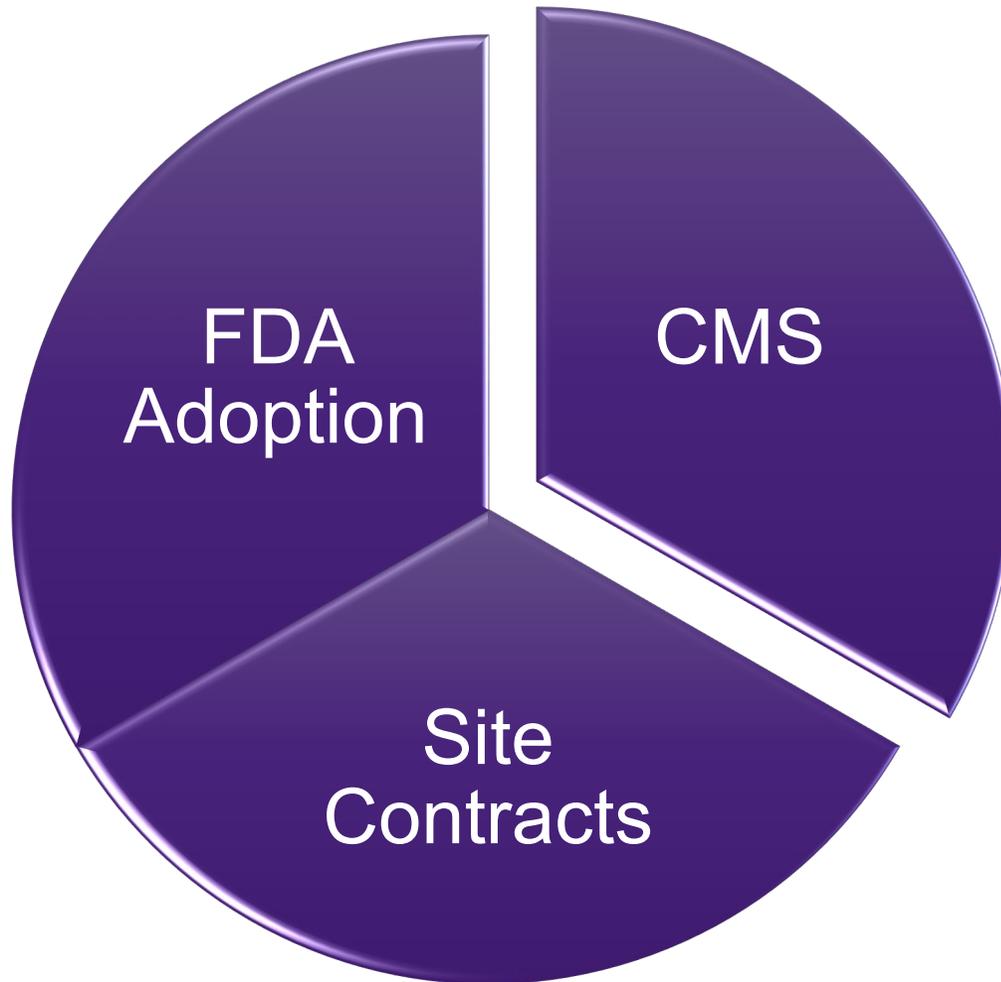
Ability to change/modify/react real time



Ties in nicely with Breakthrough Device Designation Program



EFS IDE Areas for Improvement



CMS Example

FDA Designates CMS Category

CMS Application

IRB/REB approval

Clinical Experience (e.g., 5 pts, 90-days)



Problem

- CMS Requests Clinical Experience
- Sites Desire CMS Approval Prior to Enrolling Patients



Solution

OUS Feasibility Study or
Compassionate Use?

Tips for EFS IDE Studies



- ✓ Talk to FDA early
 - ✓ Informally for general topics
 - ✓ Q-submission for specific or directed questions
- ✓ Keep the sample size small (# of patients, # of sites)
- ✓ Use sites that are familiar with the EFS concept
- ✓ Expand the trial when appropriate
 - ✓ New patient populations
 - ✓ Post design iteration
- ✓ Enhance patient protection measures
 - ✓ More frequent follow-up
 - ✓ DSMB oversight



Conclusions

- EFS IDE Program is the gold standard
- FDA program based on collaboration & communication
- Benefit – Risk position is critical to success
- Success can look differently → discontinue, modify or proceed
- Areas for optimization are available!!!



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Edwards EVOQUE Tricuspid Valve Replacement System

- EFS IDE
- BTDD
- Pivotal
- FDA PMA Approval



One of the 1st



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Thank you!

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