innovative health initiative

HEU EFS

HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

EFS Advantages in Device Development

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Disclaimer/Disclosure Statement

Within the past 12 months, I or my spouse/partner have had a financial interest/ arrangement or affiliation with the organization(s) listed below

AFFILIATION/FINANCIAL RELATIONSHIP	COMPANY
• Employee	• Edwards Lifesciences, LLC

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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.

Complements of A. Farb (FDA)

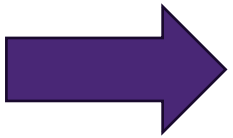
FDA's EFS IDE Background

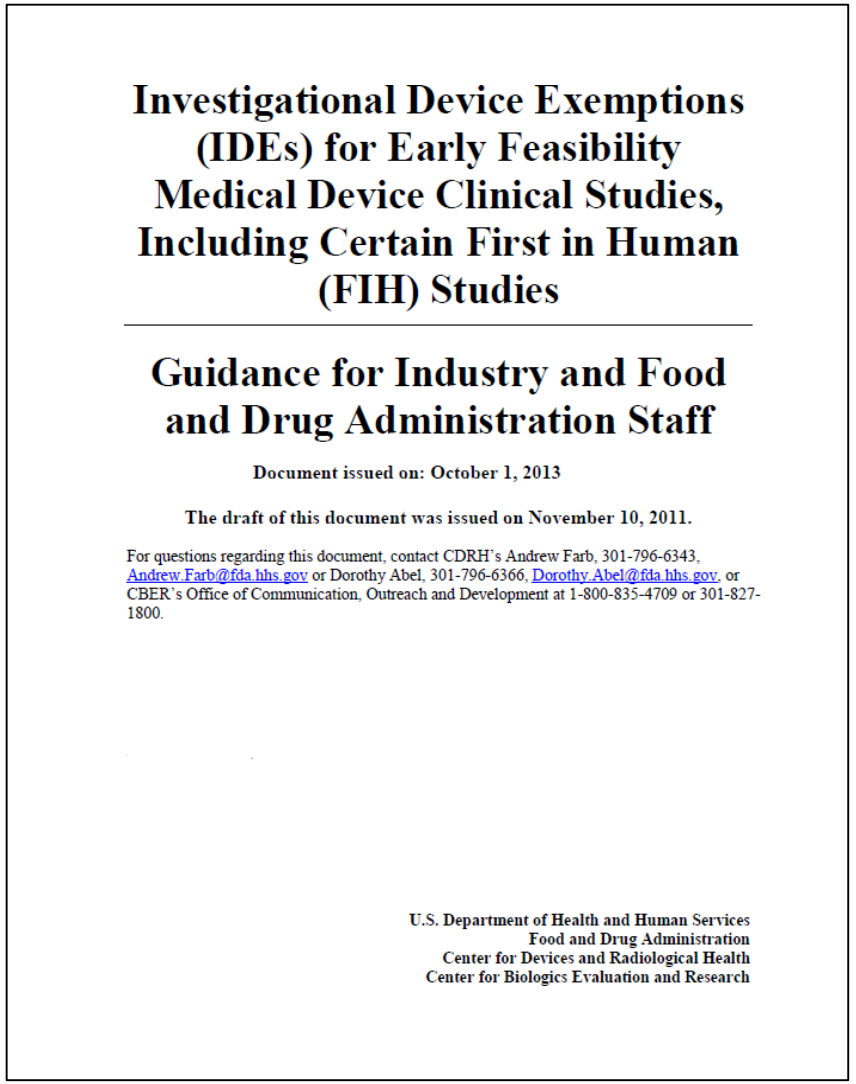
Pilot Phase 2011 – 2013

~ 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.

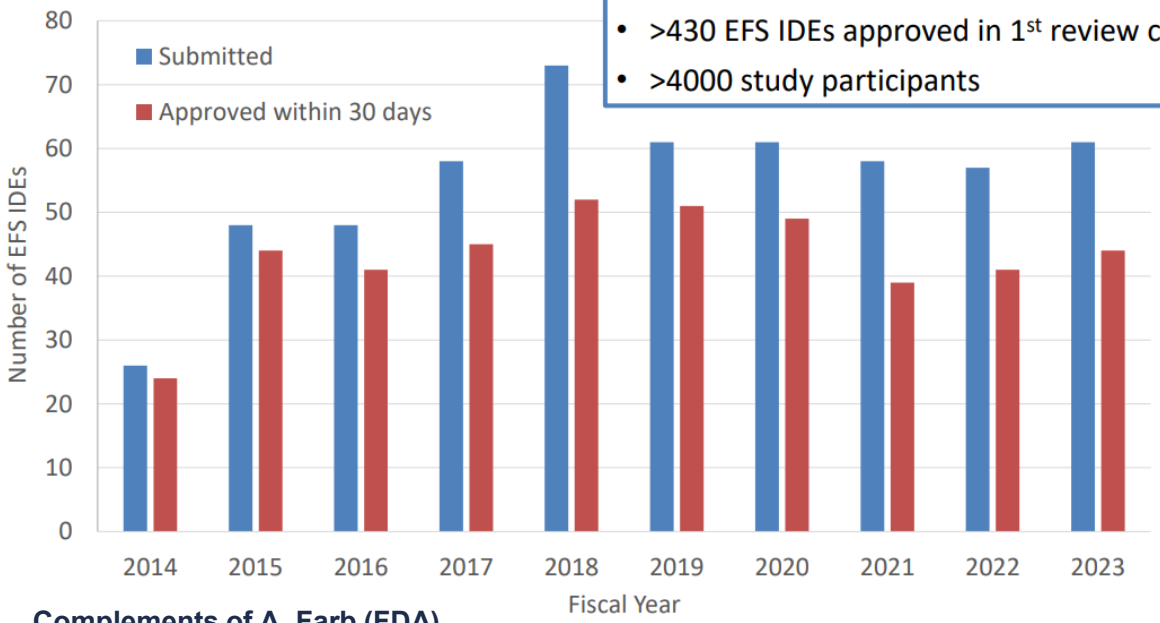
For questions regarding this document, contact CDRH's Andrew Farb, 301-796-6343, Andrew.Farb@fda.hhs.gov or Dorothy Abel, 301-796-6366, Dorothy.Abel@fda.hhs.gov, or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

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)

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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)

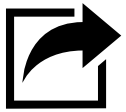
MDIC

September 2016
www.mdic.org

EFS IDE Benefits

Early FDA engagement/partnership

Just in time testing approach



Avoid export permits/notifications

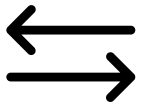
Avoid language barriers

Reduced travel expense

EFS IDE Benefits

Ability to leverage data

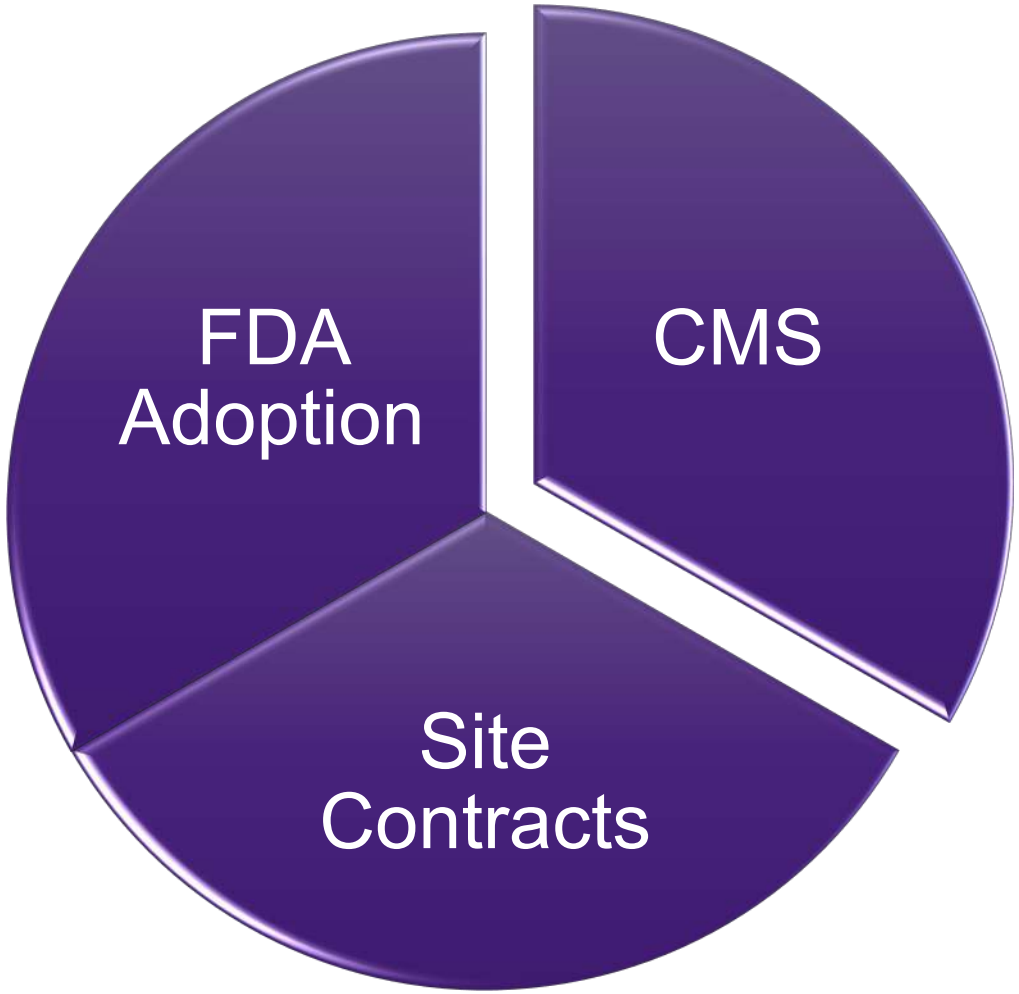
Network of sites familiar with the EFS program



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!!!

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

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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innovative health initiative COCIR efpia EuropaBio MedTech Europe Vaccines Europe Co-funded by the European Union