FDA Considerations for Early Feasibility Studies

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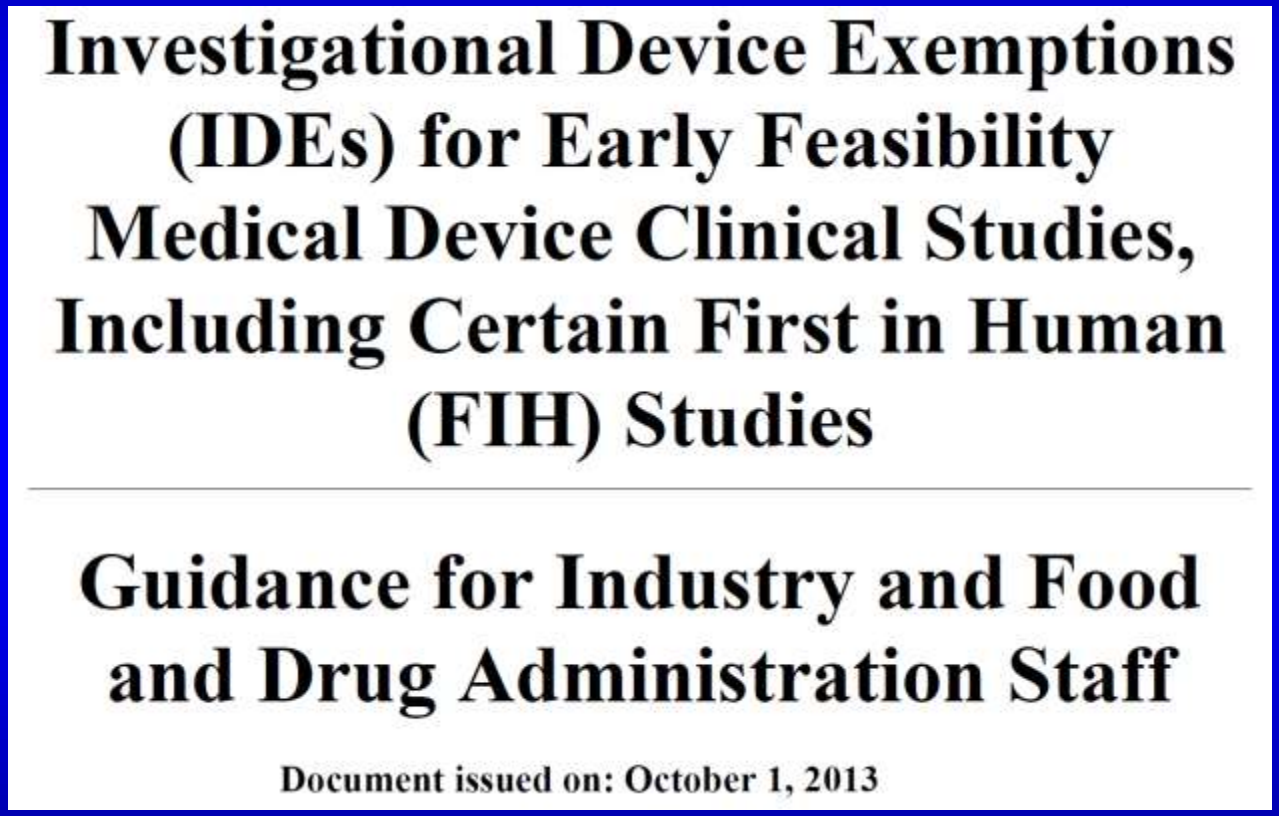
Why EFS?

- Increase early-stage clinical research in the US
- Evaluate device proof of concept when further non-clinical testing is not possible or meaningful
- Use this clinical information to:
  - Improve final device design
  - Inform design of next-phase study
  - Optimize physician training

CDRH Review of EFS



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

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Guidance for Industry and Food and Drug Administration Staff

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Risk Analysis and Mitigation

- Indicated disease/patient population
  - What are available alternative treatments?

- Informed consent
  - Do patients know what the alternatives are and what is known/unknown about the EFS device?

- Follow-up assessments
  - Is more follow-up warranted due to greater uncertainty?

Device Evaluation

- What non-clinical testing is needed to start EFS, vs. what can be provided later?
- Consider:
  - Most likely and clinically significant device failure modes
  - Which clinical protection measures are in place
- Some device/protocol changes can be made during the study without prior FDA approval

Benefits of EFS

- Earlier potential clinical benefit to US patients
- More effective incorporation of device modifications or protocol improvements in pivotal study
- Increasing application of EFS concepts (benefit-risk, device testing strategy) in review of later-phase clinical studies and marketing submissions

Non-Regulatory Considerations

- Risk tolerance
  - IRBs
  - Manufacturers
  - Patients
- Reimbursement
- Study costs
- ??

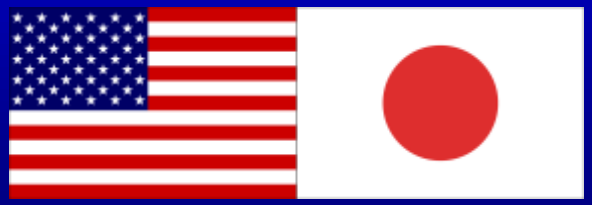
International Considerations

- Leveraging EFS data from outside the US?
- “Global” EFS?

- Need to consider:
  - Device differences
  - Physician experience
  - Training program
  - Patient characteristics
  - Quality/reliability of collected data

What About Japan and US?

- Japan and US are similar in many ways:
  - Large medical device markets
  - Strict regulatory systems
  - Comparable levels of clinical care
- History of successful clinical/regulatory collaborations
- Recent focus on improving the environment for medical device development and access



How Can HBD Help Advance EFS?

- Share EFS-related experiences and perspectives
- Greater ability to accept data from non-domestic EFS
- Learn about differences in EFS environment in both countries
  - Regulatory and non-regulatory
- ??

Conclusions

- The EFS program has helped to increase early-stage clinical research in the US and consideration of benefits/risks in regulatory decision-making
- Challenges and opportunities for further optimizing EFS use still exist
- HBD represents a uniquely valuable opportunity to promote and enhance EFS on an international level

Thank you!

ご清聴ありがとうございます！