FDA Considerations for Early Feasibility Studies

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2017 Harmonization by Doing Think Tank East
December 7, 2017 – Tokyo, Japan
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
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
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

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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！