

# Early Feasibility Study: Expectation from Japanese Physicians

**Shigeru SAITO, MD, FACC**  
**Kamakura, JAPAN**

HBD East 2017 Think Tank Meeting

At National Institute of Global Health and Medicine

Tokyo, Japan: December 7, 2017

0

# **Do Japanese Patients & Doctors Want EFS: Academic View**

***Shigeru SAITO, MD, FACC***  
***Kamakura, JAPAN***

## **Disclosure Statement of Financial Interest**

**I, Shigeru SAITO, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation**

# **Why EFS may be difficult in comparison to RCT?**

**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

<https://www.fda.gov/downloads/medicaldevices/.../ucm279103>

# Early Feasibility Study (EFS)

- **EFS:**
  - *A limited clinical investigation of a device early in development*, typically before the device design has been finalized, for a specific indication (e.g., innovative device for a new or established intended use, marketed device for a novel clinical application). It may be used to evaluate the device design concept with respect to initial clinical safety and device functionality in a small number of subjects (generally fewer than 10 initial subjects) when this information cannot practically be provided through additional nonclinical assessments or appropriate nonclinical tests are unavailable.
- **First in Human (FIH or FIM):**
- **Traditional Feasibility Study**

# Will patients and doctors randomized?

*2007/JAN/10-11 HBD West, Durham, North Carolina, USA*

- **The principles:**
  - **Doctors try to do their best in treating the patients based on:**
    - #1 the scientific evidence
    - #2 personal experiences
    - #3 his belief.
  - **Patients and their family want to receive the treatment, which the attending doctors recommend, if they are really trusted.**

# Will patients and doctors randomized?

*2007/JAN/10-11 HBD West, Durham, North Carolina, USA*

- **Doctors will randomize, if:**
  - **Doctors are not happy for current situation.**
  - **New treatment may solve the problems.**
  - **FIM results look significantly good.**

# Will patients and doctors randomized?

*2007/JAN/10-11 HBD West, Durham, North Carolina, USA*

- **Patients will accept the randomization:**
  - If the attending doctor really believes that the new treatment might provide better results to them.
  - If the physician's daily practice is satisfactory and trustable.
  - If the patient's care in that hospital is satisfactory and trustable.



# Will patients and doctors randomized?

*2007/JAN/10-11 HBD West, Durham, North Carolina, USA*

- **We are ready to randomize.**
- **However, we have questions:**
  - **When the regulatory authorities require the randomization?**
  - **When the regulatory authorities do not require the randomization?**

# Now we have finished enrollment for many DES trials

*2007/JAN/10-11 HBD West, Durham, North Carolina, USA*

- Resolute
- *NOBORI*
- *Century*
- Century-SV

***Now we are ready to  
start FIM for DES in  
Japan!***

- DEB-ISR
- DEB-SV
- *BVS*
- *COMBO*

# **Will patients and doctors are ready for EFS?**

- **Doctors are ready, if:**
  - **Doctors are not happy for current situation.**
  - **There are enough reasons to believe that new treatment may solve the problems.**

# **Will patients and doctors are ready for EFS?**

- **Patients will accept EFS, if:**
  - the attending doctor really believes that the new treatment might provide better results to them.
  - the physician's daily practice is satisfactory and trustable.
  - the patient's care in that hospital is satisfactory and trustable.

# Do Japanese Patients & Doctors Want EFS?

- **Yes, Japanese doctors strongly wish for EFS.**
  - There are still many unmet needs.
  - Many doctors have unique ideas.
  - Study infrastructures have matured than before.
- **Yes, Japanese patients strongly wait for EFS.**
  - They trust in Japanese as well as US technologies.
  - We have sincere and good relationship between doctors and patients.