Early Feasibility Study: Expectation from Japanese Physicians

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Do Japanese Patients & Doctors Want EFS: Academic View

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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?

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• 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?

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• 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?

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- 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?

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• 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

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- 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.