



“Sustainable Development Goals in Real-world data collection”

Lessons learned from using registry data for approval applications

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Introduction

- This presentation does not reflect a consensus of Nipro Corporation.
- This presentation is based on information until NIPRO Corporation got approval of HeartMate3™ as Designated Marketing Authorization Holder for foreign-manufactured medical devices (DMAH) in April 2019.
- Currently, approval of HeartMate3™ in Japan is held by Abbott, and Abbott Medical Japan is registered as DMAH in Japan.

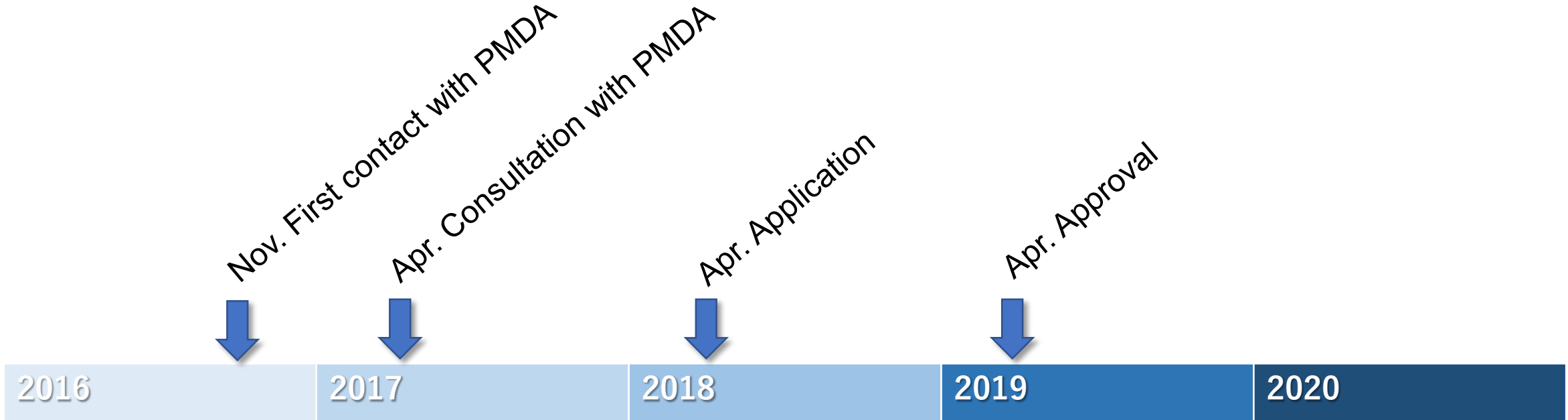
HeartMate 3™

Implantable
Left Ventricular
Assist Device
(LVAD)



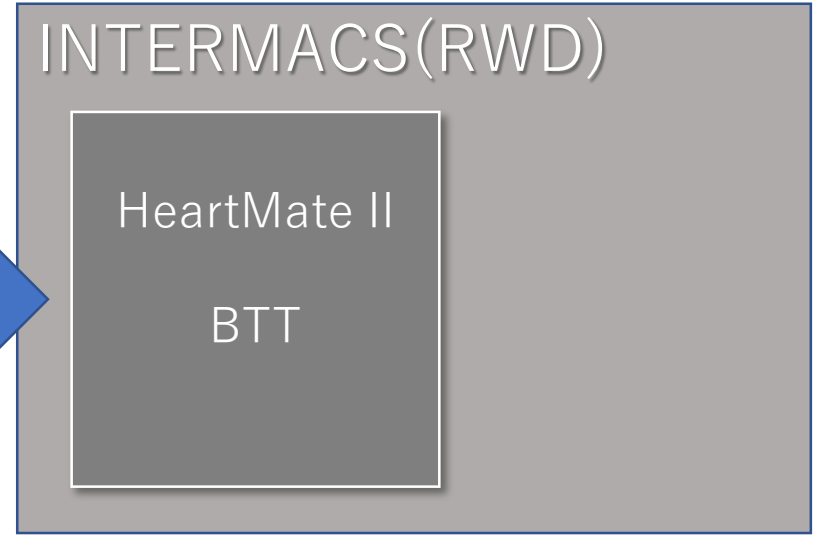
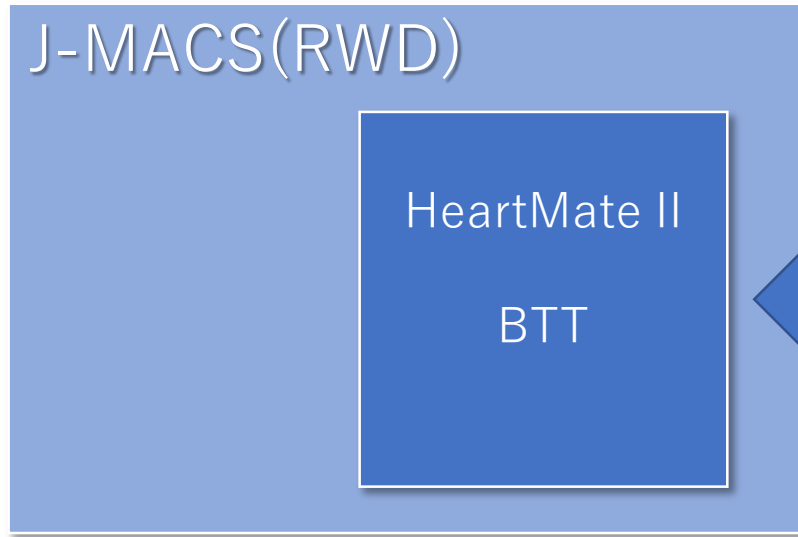


The history we get approval with RWD





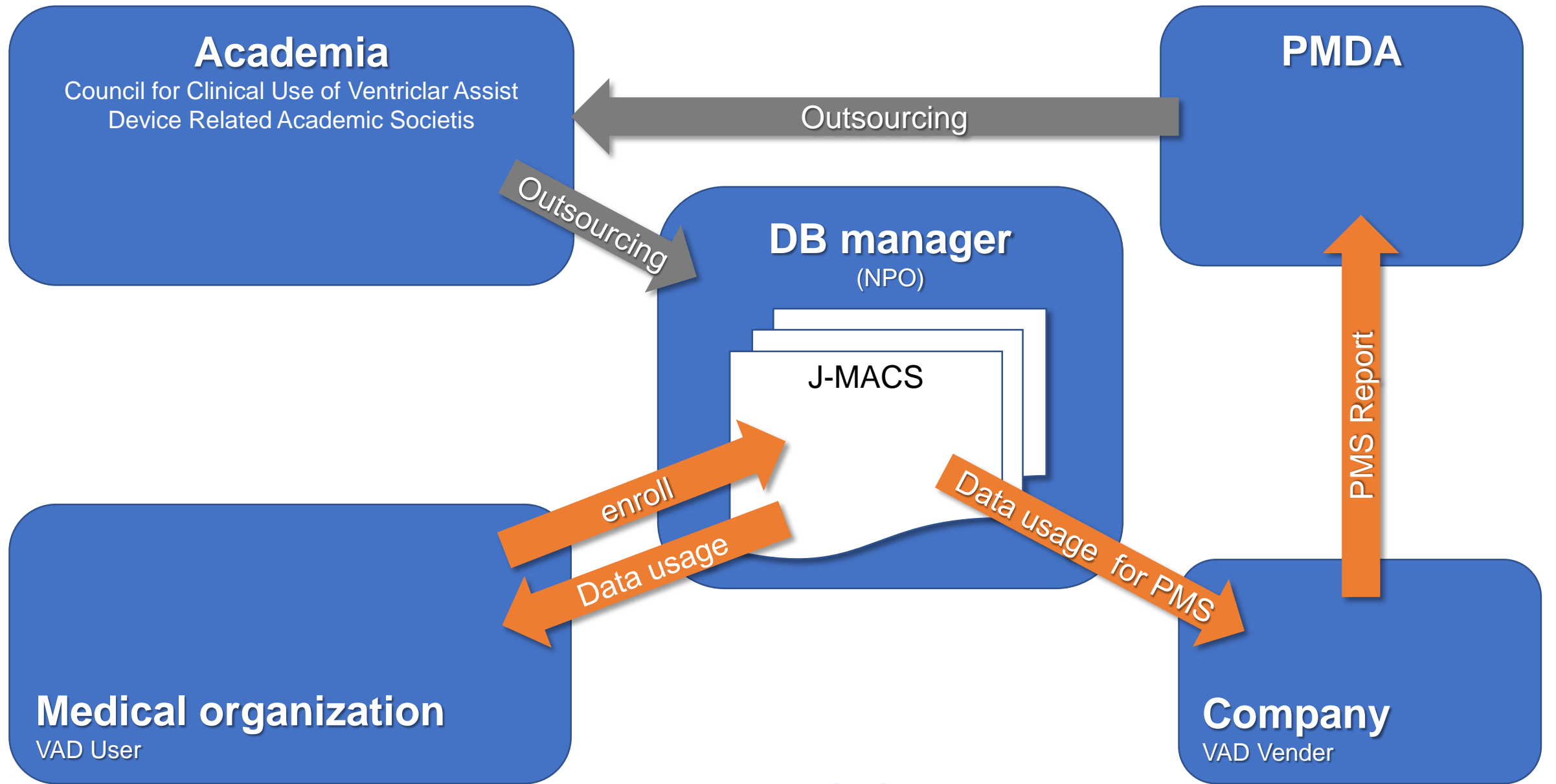
Step1





Merit of RWD usage

- Save cost for clinical trial
- Save time until approval
- Faster Access to new device



J-MACS

Japanese registry for Mechanically Assisted Circulatory Support



Issues of RWD

- RWD in other countries is difficult to use for application
 - Background
 - Cultural & Ethnic variations
- No incentives for data entry by doctors and co-medicals
 - Registration is voluntary
 - Incomplete registration
 - RWD with the low quality can't be used for application
- Who is beneficiary of RWD ?
 - Approved device is property of national and public
 - Shouldn't RWD be covered by government funding?



Conclusion

- By using RWD to obtain approval for the HeartMate 3™, Nipro and Abbott could get an approval more than a year earlier than by conducting a clinical trial. From a corporate standpoint, we welcome applications using RWD.
- Quality is important when using RWD for application, but it is difficult to secure it. The human burden of data input is also a problem. The beneficiaries of the RWD are the entire nation. Enhancing RWD through government funding will improve accessibility to new devices and further benefit the public.
- In order for RWD to become a sustainable goal, it is essential for the government to intervene to improve input accuracy and reduce the burden on input user.