WHAT WE CAN SAY NOW BASED ON OUR EXPERIENCE IN OBTAINING APPROVAL IN JAPAN AND THE U.S

HBD EAST
THINK TANK MEETING 2023

DECEMBER 14, 2023

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Further, Together

POTENTIAL CONFLICTS OF INTEREST

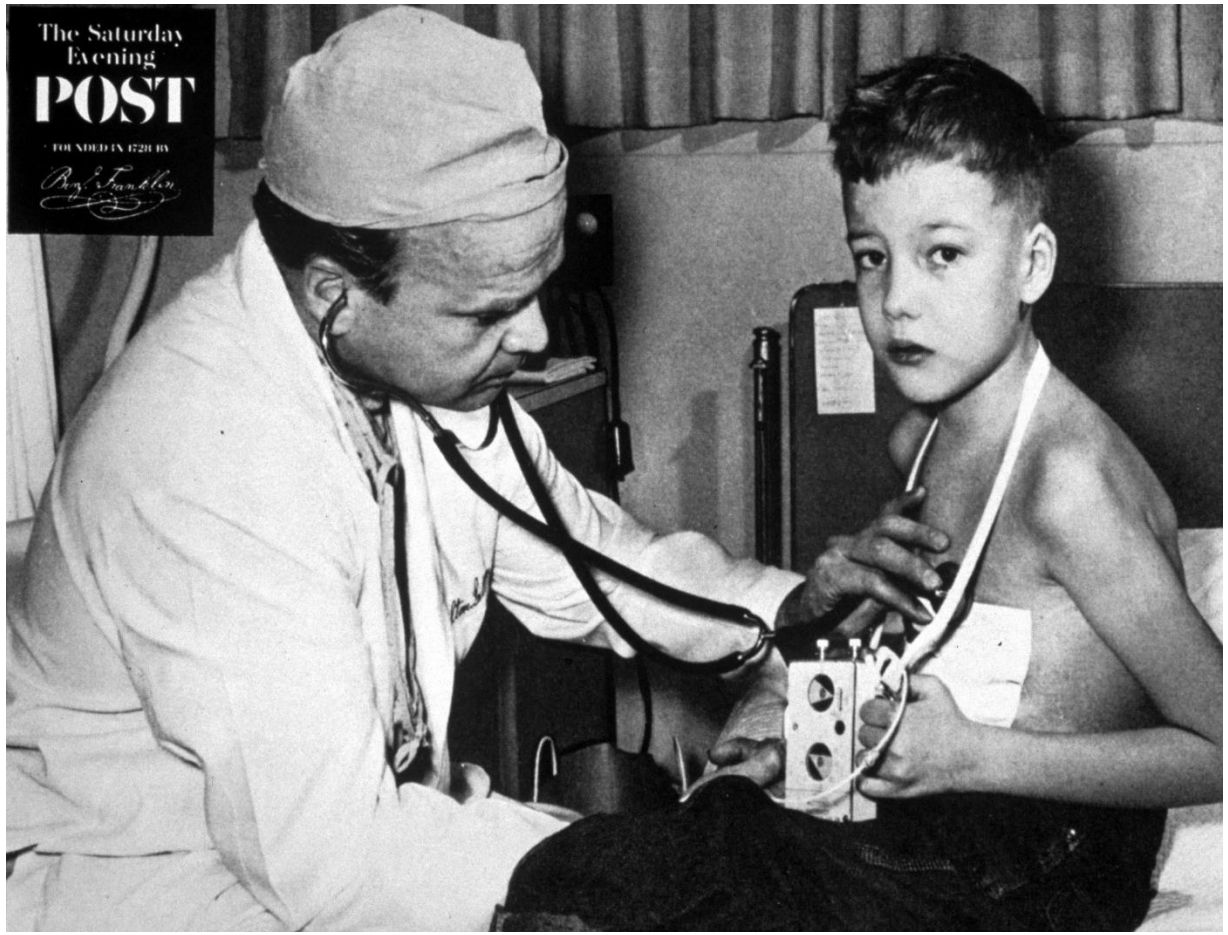
Speaker's name: Daiki Yasuhara

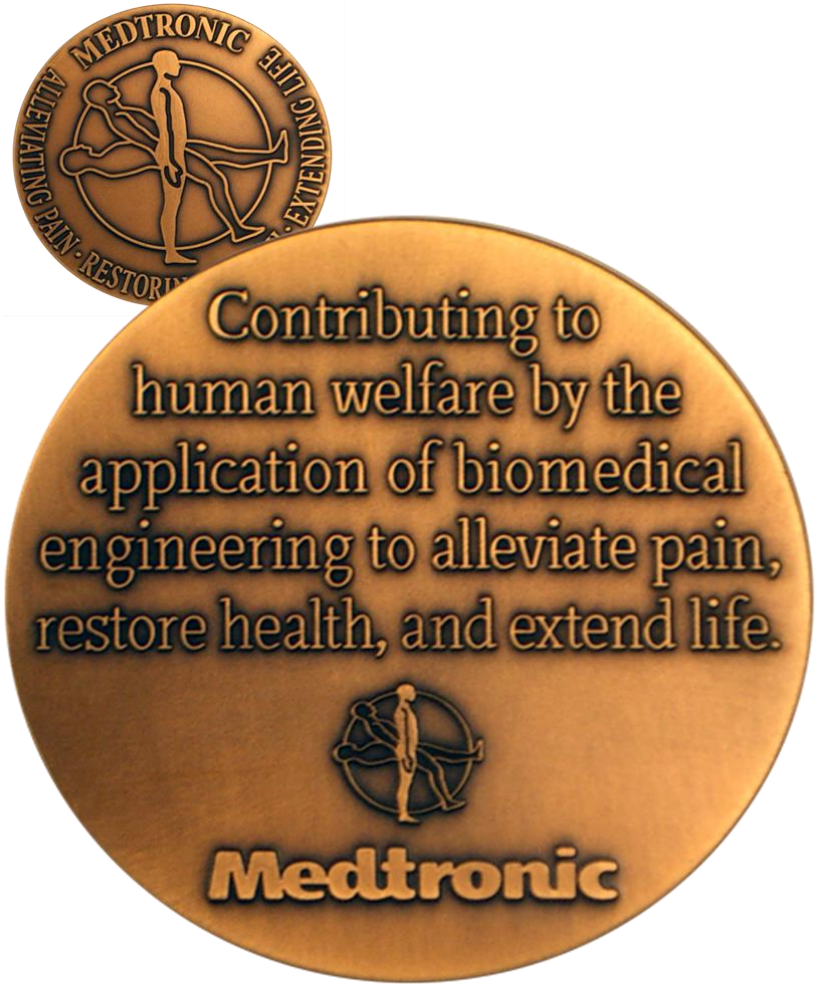
- ❑ **I have the following potential conflicts of interest to report:**

Employee: Medtronic

MEDTRONIC FOUNDED 1949

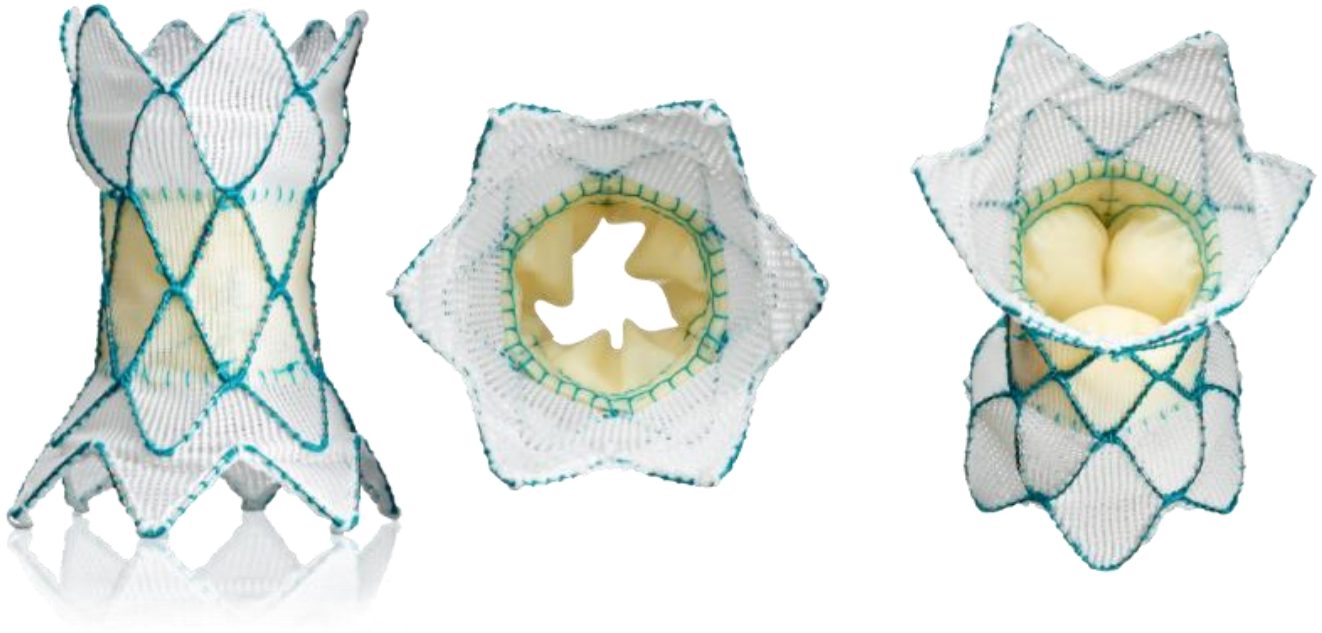
EARLY INSPIRATION IN SERVING PEDIATRIC PATIENTS

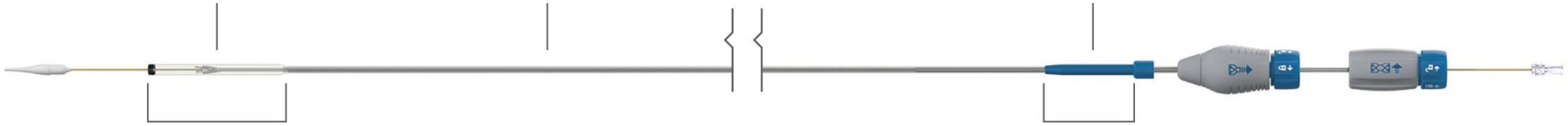




HARMONY™ TRANSCATHETER PULMONARY VALVE SYSTEM

- Harmony™ TPV provides a non surgical alternative to restore pulmonary valve function in subjects with pulmonary regurgitation following CHD surgical repair





INDUSTRY CHALLENGES

COMMERCIALIZING PEDIATRIC DEVICES IS A TOUGH DECISION

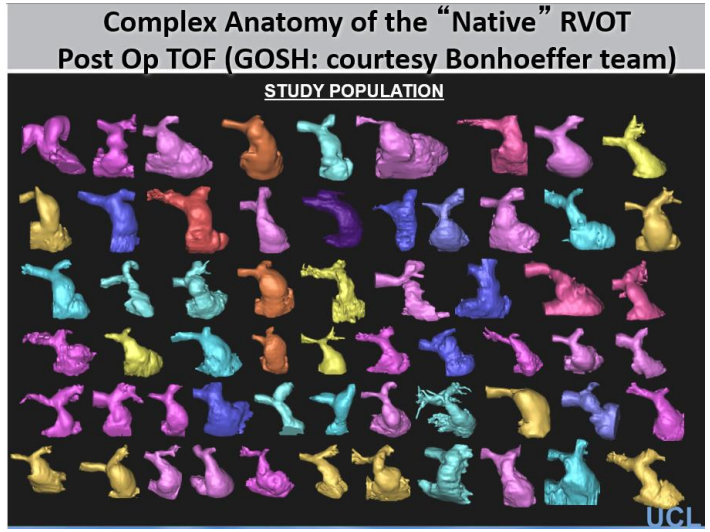
Patient Population Fundamentals

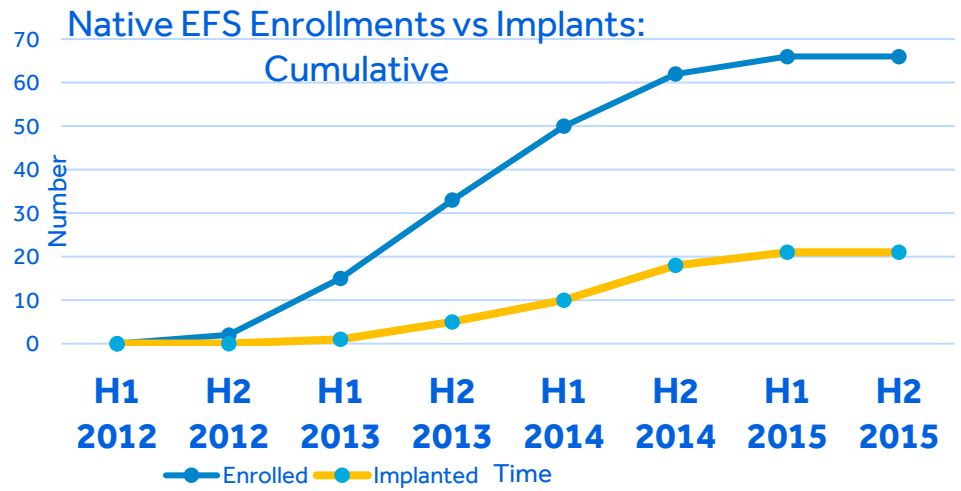
- Small, heterogenous patient population globally
- Patients widely dispersed, difficult to accrue sufficient numbers in a manageable number of sites
- Treatment practices vary depending on region

Clearing Regulatory Hurdles

- Limited alignment amongst global regulators
- Established test methods may not be applicable for novel technologies
- Reimbursement challenges

Potential Solution should be "HBD"



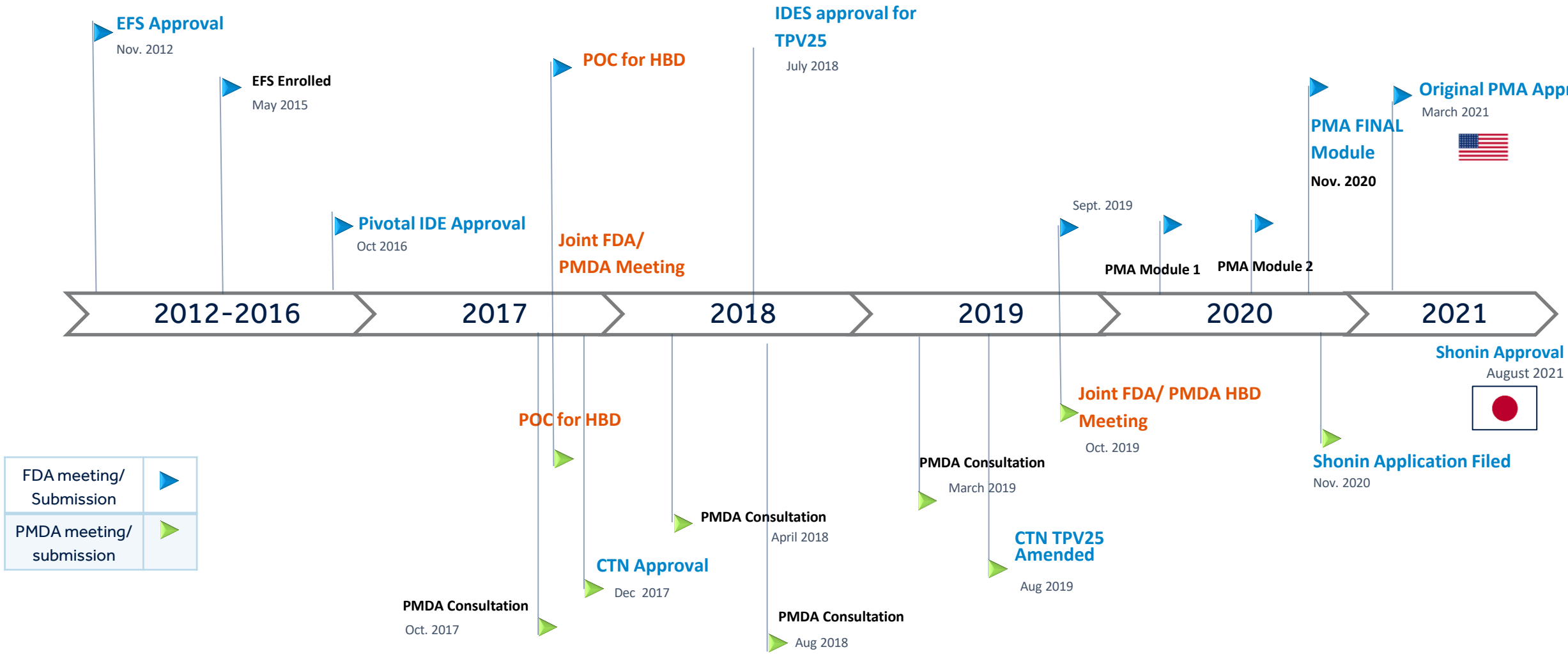


HUMANIZATION BY DOING

HARMONIZATION OF CLINICAL AND REGULATORY APPROACHES IN THE US AND JAPAN

- Co-operative effort, promoted by academia, industry, FDA and PMDA since 2003
- Discuss issues and solutions in implementing global clinical trials and in promoting harmonization between the medical device regulations of both countries, putting emphasis on practice
- Resolving “device lag” through collaboration, such as conducting global clinical trials, mainly in the field of cardiovascular medical devices
- Similarities in the medical device regulations of the US and Japan
- HBD for Children established in 2016 with a primary focus on the development of pediatric devices as the development of medical devices for pediatric use lags behind that of medical devices for adults in both countries

HISTORY OF INTERACTIONS



HBD EXPERIENCE
WHAT WORKED WELL

- Practical solutions to several challenges typical of pediatric programs
  - Achievable pivotal study design & sample size determined based on target patient population
  - Ability to iterate during study

- Agency prioritization and cooperation
  - Joint agency interaction
  - Interactive review – facilitate innovation & accelerated review
  - Breakthrough Design Designation (US)
  - Orphan product (Japan)

RECOMMENDATION/NEXT CHAPTER

- Discuss any differences in medical practice proactively and jointly with both agencies
  - A priori agreement of:
    - patient population
    - Indication
    - Patient selection criteria
    - Preoperative assessment methods
- Reduction in burden continues to be important e.g., interactive review, pre-approval inspection
- PMDA & FDA collaboration on GCP inspection
- PMDA & FDA collaboration on RWD usage
- Expand HBD to include other regions

CONCLUSION

- Practical mechanism to expand the market by pursuing effective harmonized multiregional regulatory & clinical strategy
- Global regulatory agency cooperation with academia and industry can reduce development time and time to market for pediatric products
- Program would not have succeeded without Academia, PMDA & FDA support

HARMONY TPV COMMERCIALIZATION

SINCE COMMERCIALIZATION – AS OF OCTOBER 2023

patients treated	countries	hospitals	HCPs trained	hospitals with a solo implanter	CT scans reviewed
1,300+	6	122	333	65	3,300+

THANK YOU

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