



What else is needed to advance pediatric medical device development?

Renata Medical Industry Perspective



History of Pediatric Devices

- In the last 35 years, only 3.8% of cardiovascular devices have been approved specifically for pediatrics
- In the Japan, the frequency of CHD is 10.6 per 1,000 people, accounting for about 1% of the population
- In a 2019 survey of the Japanese Society of Pediatric Cardiology and Cardiac Surgery council:
 - 90% believed that difficulties in development existed
 - 70% were dissatisfied with the pediatric medical devices currently available in Japan
- Among many factors, the high risk and low ROI has led to a lack of development and innovation for pediatrics



Overview

1. Deep Collaboration with the Pediatric Community
2. Early Engagement and Partnership with Regulatory Bodies
3. Support of socioeconomic costs of treating a young child



1. Deep Collaboration with the Pediatric Community

- Publications help us learn what is needed in the medical field and how devices are being used off label
- Collaboration with Physicians help us develop new devices that better support their patients and clinical needs
- Physician testing during development helps us improve devices
- Community support allows industry to bring it to market
- Community adoption allows industry to continue to adopt develop for this space



2. Early Engagement and Partnership with Regulatory Bodies

- Synergistic Trial Development
- ARC harmonizing definitions
- Support through submission hurdles
- Collaboration early and often through movements like HBD
- Lowered Costs for Pediatric Devices



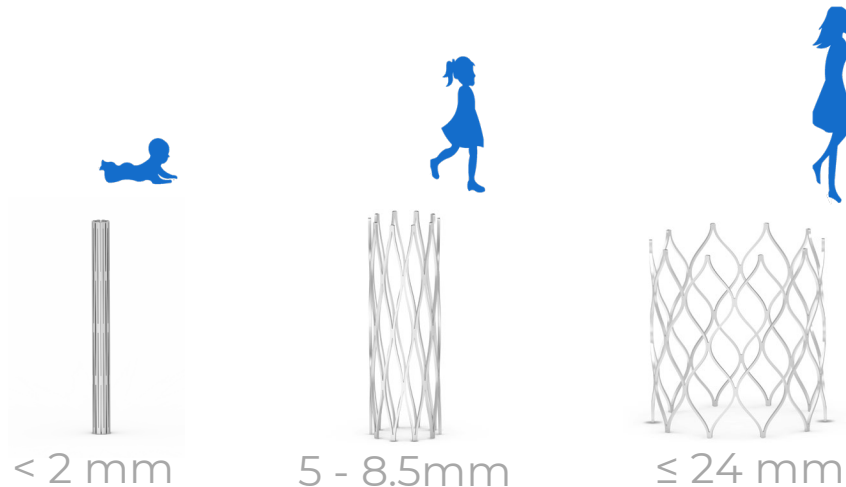
3. Support of Socioeconomic Costs of Treating a Young Child

- On average, bringing a device to market costs \$94 Million Dollars and takes 9 years
- Small market size requires a higher cost to be able sustainable
- Government support to lessening the economic barrier to adoption
- Investing in patients who have their whole lives ahead of them that need devices that will serve them for their lifetime



Renata Medical is Committed to Innovating in the Pediatric Cardiovascular Space

Minima Stent:



- Founded in 2019, Renata Medical specializes in transformative pediatric cardiovascular solutions
- **Only FDA approved stent for neonates, infants, and small children**
- Pre-mounted stent and system suitable for vessel access in neonates, infants, and small children
- Implantable diameters tailored for pediatric vessels
- Designed for planned re-expansion to adult vessels



Thank you/Questions

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