


Regulatory Perspective



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FDA's Role

- Facilitate discussion to address need for clinical module that can be used to evaluate pediatric neurological and neurocognitive and quality of life
- Important because devices must demonstrate clinical benefit (safety and effectiveness or probable benefit)



How did we get here?

- Clinical need for pediatric devices
- NHLBI recognized need for MCSD and is currently supporting development of pediatric circulatory support devices
- FDA also recognized need for clinical evaluation of safety and benefit— funding provided by CDRH Pediatric Steering Committee



Workshop Objectives

	Pre-Implant	On Device	Post-Implant
Imaging			
Neurological Exam			
Neurocognitive/ Functional Capacity			
Quality of Life			

≥ 24 months, < 24 months, unconscious, conscious



Challenges

- Limited relationships between adult and pediatric assessments
- Clinical challenges are different from adults
 - Limited ability or no ability communicate
 - Smaller number of patients to obtain data to validate measures
- Lack of registries to collect data
- Direct applicability of existing measures may or may not exist – may need additional validation

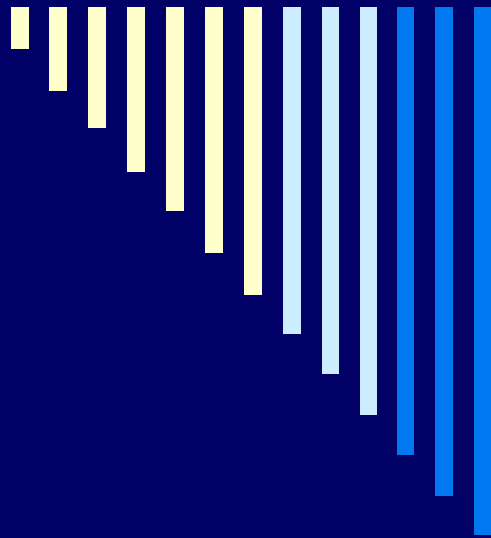


Expected Outcomes

- Development of acceptable neurological/health status evaluation for pediatric patients

- Consensus paper from this meeting/workshop

- Encourage collection of data via in registries
 - Are there existing registries that can be leveraged?
 - Who will fund?



Regulatory Considerations – How do you get your device to market?



FDA Applications

- Pre-IDE (early interaction with FDA, not binding)
- IDE – Investigational Device Exemption (clinical study, pre-specified endpoints)
- Marketing Applications
 - PMA – Pre-market Application
 - HDE - Humanitarian Device Exemption (must obtain Humanitarian Use Designation from Office of Orphan Products)



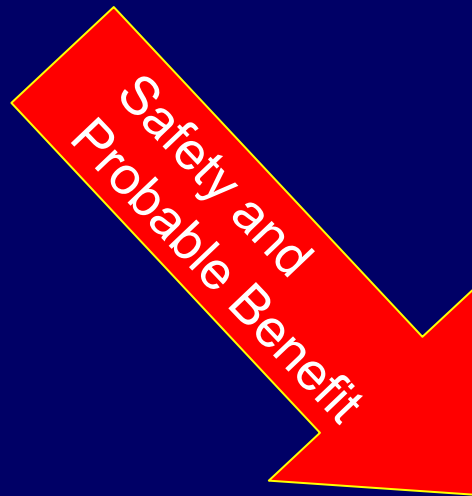
Possible Paths to Market

- Humanitarian Device Exemption (HDE)

- Few patients (<4000)
- Limited clinical data

- Pre-Market Application (PMA)

- Abundant patients
- Convincing clinical data



Market



Thank You

- Circulatory Support and Prosthetics Branch

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