

An Introduction to CTIP & Pediatric Innovation



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Current State of Pediatric Medical Devices (PMD)

- The availability and sophistication of PMDs lags behind adult devices by as much as 10 years
- Children experience innovation differently than adults
- PMD innovation represents a significant health inequity, with the majority of device development targeting adult populations
- This gap is greatest for young children, and for high-risk, life saving devices

Current State of Pediatric Medical Devices (PMD)

- Most pediatric use of devices is off-label, with little or no safety data
- Children are exposed to inconsistent benefit-risk profiles from the necessary off-label use of devices.
- Devices designed, evaluated, and labelled for children improve safety profiles and health equity.

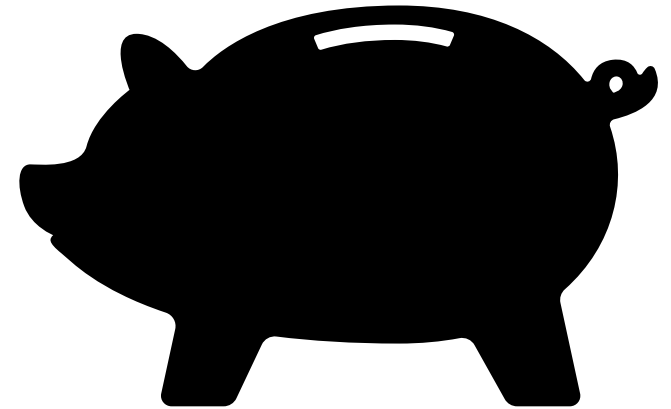
How We Got Here

- Scientific and engineering challenges
- Ethical challenges
- Regulatory challenges
- Financial challenges



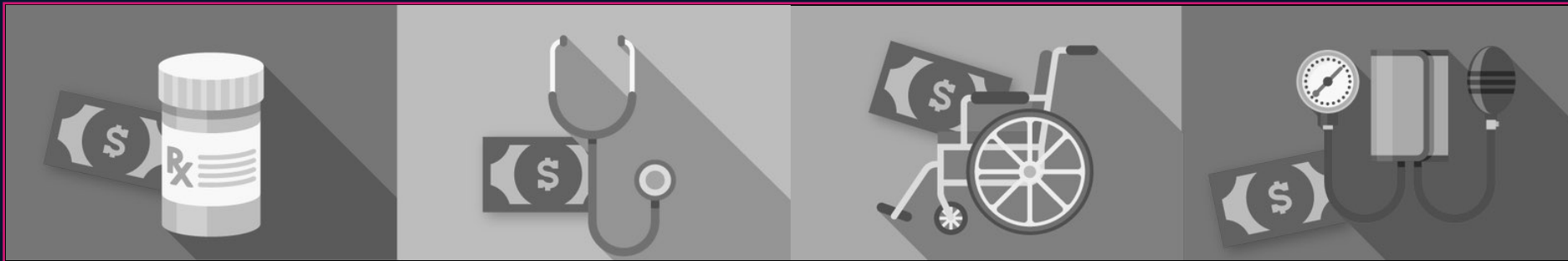
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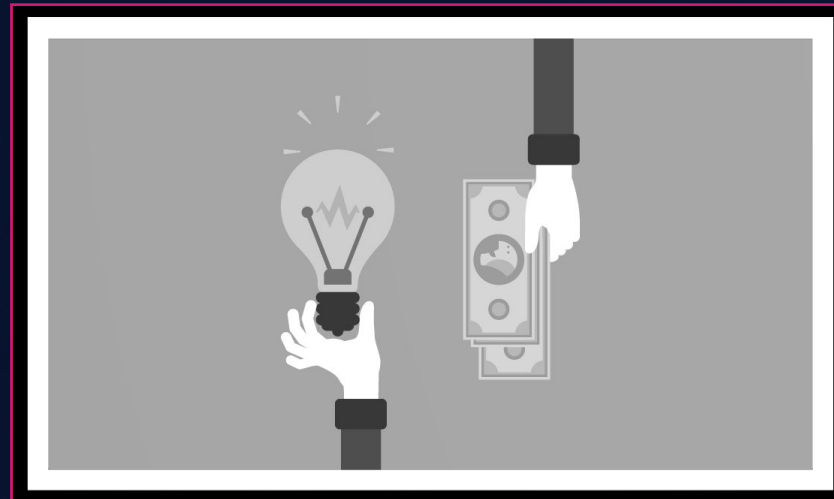
How We Got Here

- Children (under 21) represent ~25% of the US population
- <10% of US Healthcare dollars are spent in pediatrics
- Pediatric care is reimbursed at 50-70% of the same or comparable service for adults
- There are almost no national coverage policies for pediatric healthcare



How We Got Here

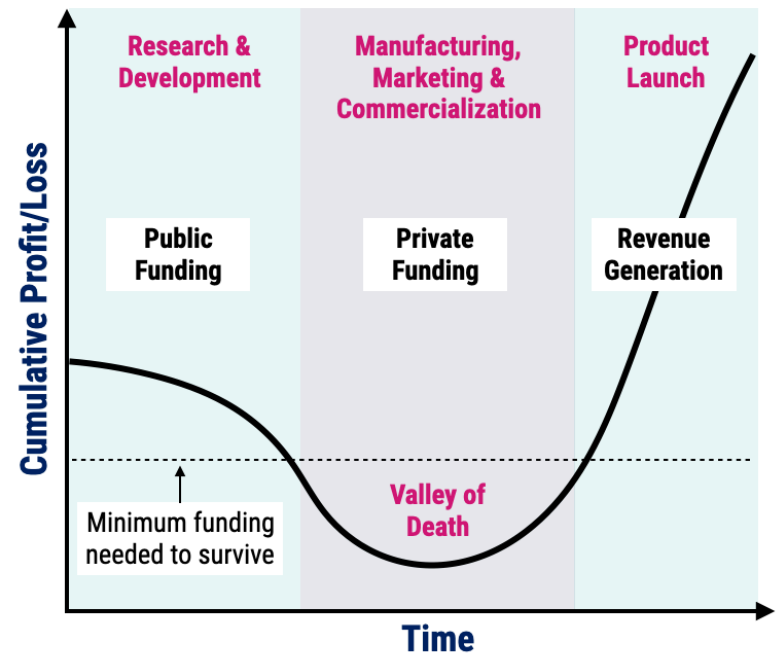
- Other areas are equally underinvested
 - Research: 12% of the NIH budget is pediatric research
 - Investors: 1% - 4% of health tech deals are related to pediatrics (if you include digital health)



How We Got Here

- Medical devices are expensive to develop (\$30 million to \$200 million)
- Long journey to market (3 to 10 years)
- Pediatric market can be heterogenous & unpredictable in terms of revenue generation

Medical device innovation “Valley of Death”



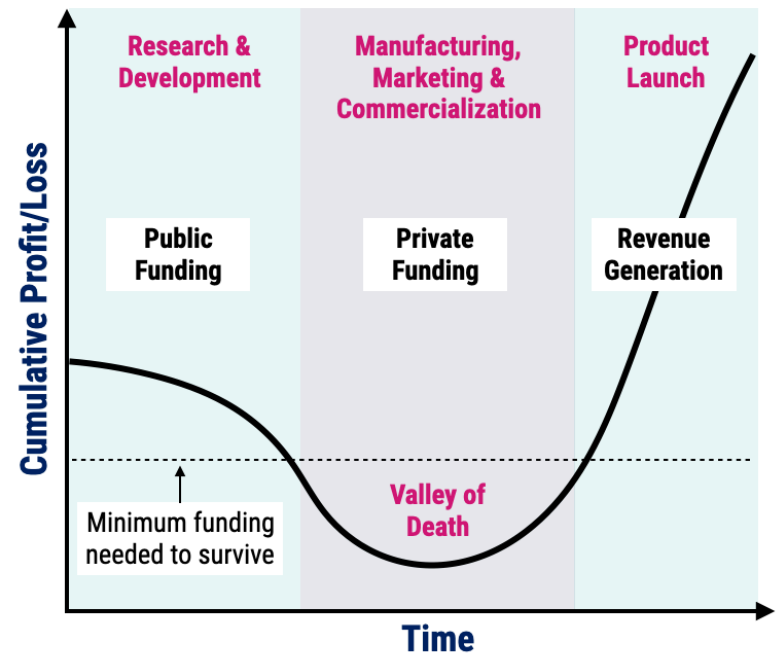
How Do We Turn This Around?



Opportunities to Advance PMDs

- **We can change the shape of the curve**
 - More public funding
 - Incentives for private funding
 - Reduce the cost of the valley of death
 - Shorten the time in the valley of death
 - Increase revenue generation opportunities

Medical device innovation “Valley of Death”



Opportunities to Advance PMDs

- Regulatory and legislative innovation
- Increase research funding
- Robust and reliable value generation mechanisms
- Real world evidence
- Industry support
- Pediatric Device Consortia
- PMD-PPP



The Pediatric Device Consortia



Pediatric Device
Consortia Grants Program



The Pediatric Device Consortia

2009

The Michigan Pediatric Device Consortium (A)
University of California, San Francisco Pediatric Device Consortium (B)
The MISTRAL Device Consortium (C)
The Pediatric Cardiovascular Device Consortium (D)

2011

University of Michigan MPED & PMDI Pediatric Medical Device Consortium (A)
University of California, San Francisco Pediatric Device Consortium (B)
Atlanta Pediatric Device Consortium (E)

2013

University of Michigan Pediatric Device Consortium (A)
Boston Pediatric Device Consortium (D)
Atlantic Pediatric Device Consortium (E)
National Capital Consortium for Pediatric Device Innovation (F)
New England Pediatric Device Consortium (G)
Southern California Center for Technology and Innovation in Pediatrics (H)
Philadelphia Regional Pediatric Medical Device Consortium (I)

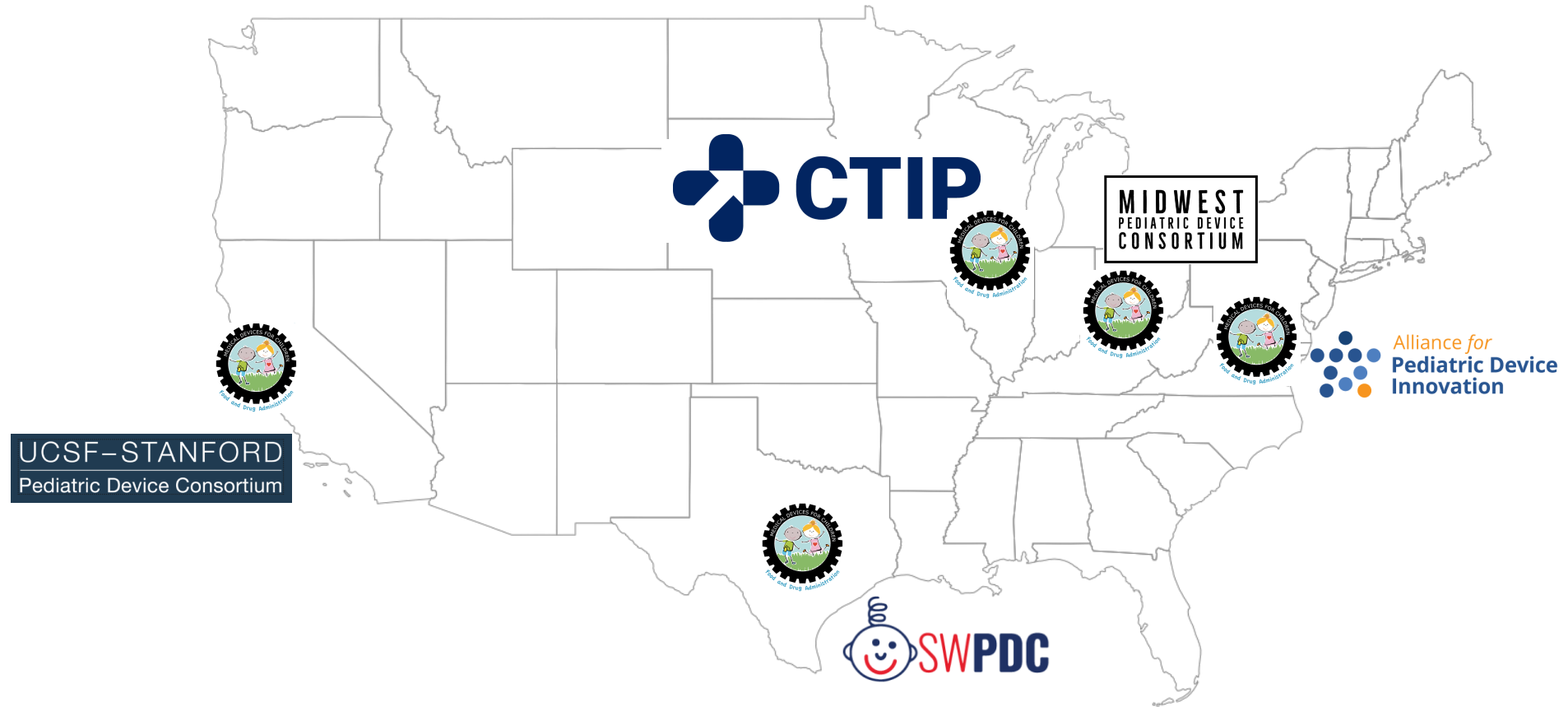
2018

UCSF-Stanford Pediatric Device Consortium (B+C)
National Capital Consortium for Pediatric Device Innovation 2.0 (F)
The West Coast Consortium for Technology & Innovation in Pediatrics (H)
Pennsylvania Pediatric Medical Device Consortium (I)
Southwest National Pediatric Device Innovation Consortium (J)



- 14 years
- 4 grant cycles
- 20 awards
- 10 institutions

The 2023- 2028 PDCs



The Consortium for Technology & Innovation in Pediatrics

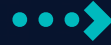
2011

- CTIP established at CHLA+USC



2013

- CTIP first funded by FDA
- \$2.2M Fund I
- Southern California focus



2018

- CTIP refunded by FDA
- \$6.6M Fund II
- Expands across the West Coast: California, Oregon, and Washington



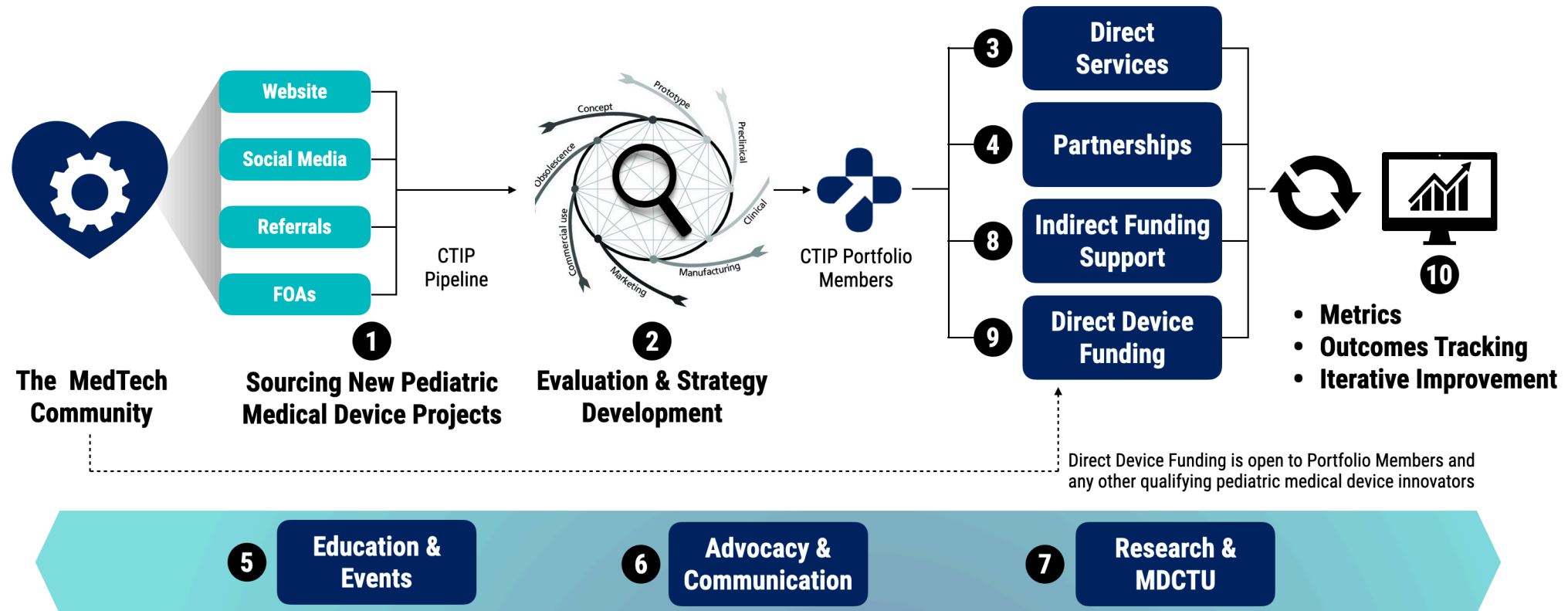
2023

- CTIP moved to Lurie
- CTIP refunded by FDA
- \$5.8M Fund III
- Expands to 26 organizations across 8 states

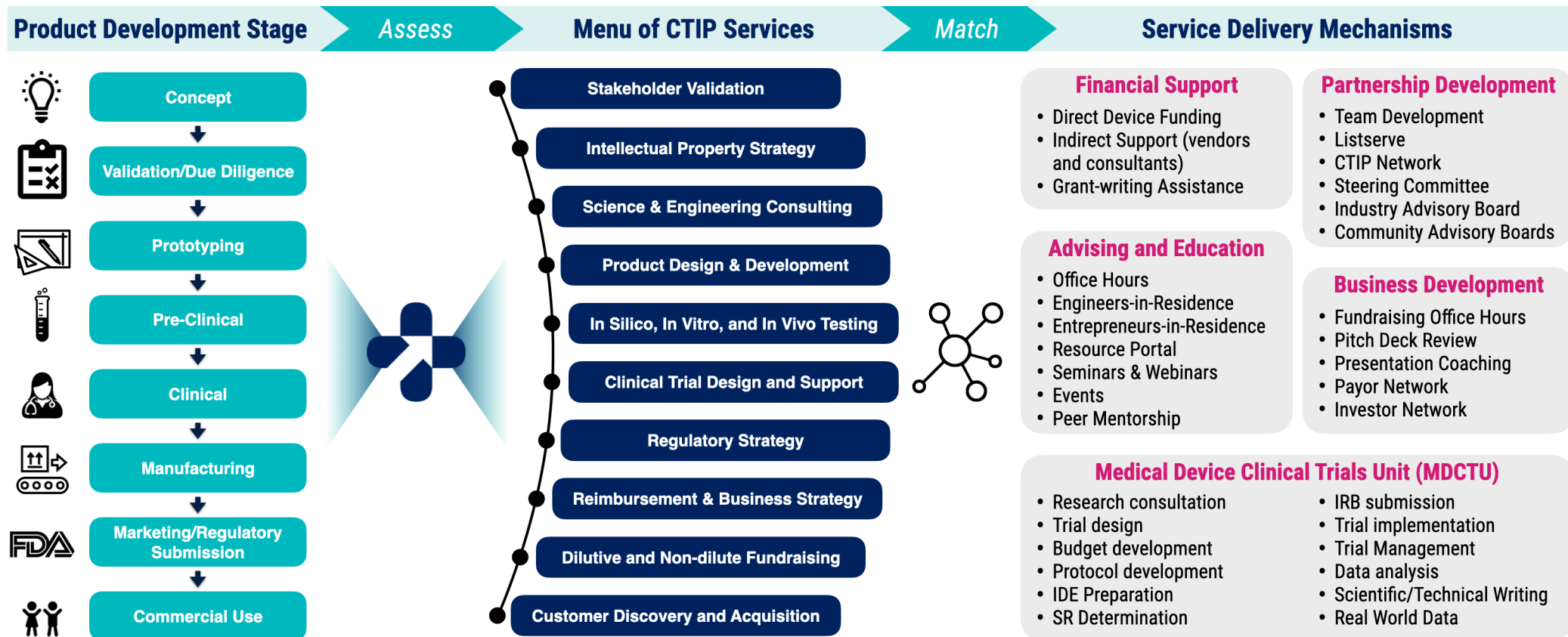
The Consortium for Technology & Innovation in Pediatrics

- Our goal is to advance pediatric medical devices along the path from concept to commercialization
- We work with innovators and entrepreneurs at any stage (concept, prototype, etc.)
- CTIP does NOT take any stake, IP, or ownership

The Consortium for Technology & Innovation in Pediatrics



The Consortium for Technology & Innovation in Pediatrics



The Consortium for Technology & Innovation in Pediatrics

2018 - 2023

Portfolio Metrics

500+ Projects Evaluated
146 Portfolio Members

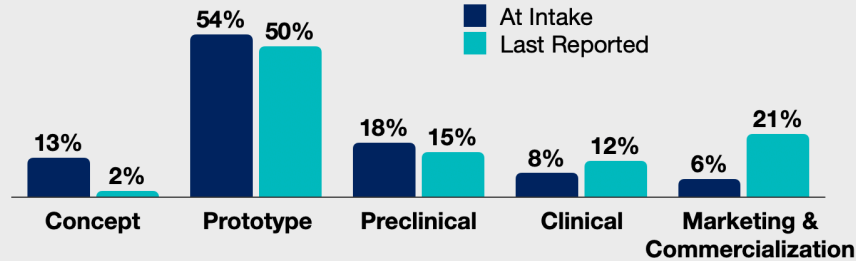
Anticipated Device Class

Class I	32 (22%)
Class II	84 (58%)
510k	62 (43%)
De Novo	16 (11%)
Exempt	6 (4%)
Class III	10 (7%)
Combination Product	3 (2%)
To be determined	15 (10%)

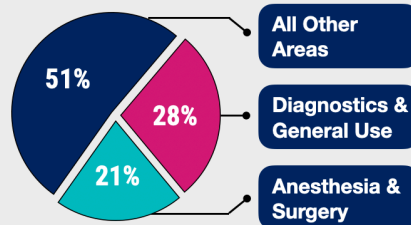
Intended Pediatric Subpopulation

Neonates	61 (42%)
Infants	76 (53%)
Children	107 (74%)
Adolescents	105 (73%)

Product Development Stage



Clinical Areas



Diverse & Inclusive Portfolio

Out of 108 Portfolio Members self-reporting their identity, they identified as:



Fundraising

Total Funds Raised

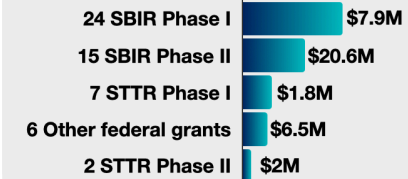
By all CTIP Portfolio Members:

\$210.2 Million Before joining CTIP
+
\$422.7 Million Since joining CTIP

\$632.9 Million Total raised

Federal Grant Funding

51 Grants **31 Recipients**



\$38.8 Million Awarded

Clinical Research

56 Portfolio members initiated clinical research including first-in-human, pilots, and clinical trials

16 Projects supported by CTIP Medical Device Clinical Trials Unit over a 12-month period

Marketing & Commercialization

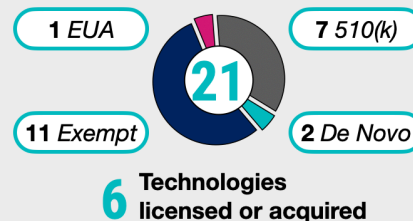
Breakthrough Device

7 Granted
1 In review

STeP Program

3 Granted
2 In progress

Devices on Market



Publications

CTIP Team

28 Academic Publications
12 RWE Publications

417 Other Presentations, Publications & Media Appearances

Portfolio Members

35 Academic Publications
42 Poster Presentations

The Consortium for Technology & Innovation in Pediatrics



Juan Espinoza, MD | Executive Director

Melissa Bent, MD | Co-Director

Yaniv Bar-Cohen, MD | Co-Director



Bianca Riello, MEng | Managing Director

Kathryne Cooper, MBA | Investment Advisor

Salima Jamal, MBA | Program Manager



Greg Zapotoczny, PhD | Regulatory Lead & MDCTU Director

Madison Christmas, BS | Program Associate, Investment & Growth

Nadine Afari, MS | Program Associate, Research & Education



Jordan Cashwell, MPH | Program Coordinator

Rachel Spencer, BA | Communications Coordinator

Tamara Lambert, PhD | CobiCure MedTech Innovation Fellow

2025 Pediatric Device Innovation Symposium



Friday, August 15th
11am-6pm
SQBRC Lobby

Registration:



<https://bit.ly/ctip2025>