



**2025**  
*Washington,*  
*D.C.* MAY 1-3

**Scientific Sessions**

Date/Time: May 2, 2025, 5pm

Room: 145AB

# CCISC Meeting

**Daisuke Kobayashi, MD, MPH, MHA**

Professor of Pediatrics, Washington University in St. Louis, St. Louis Children's Hospital

**Thomas Forbes, MD**

Chief of Cardiology, Joe DiMaggio Children's Hospital

**Lee Benson, MD**

Professor of Pediatrics, University of Toronto, The Hospital for Sick Children in Toronto



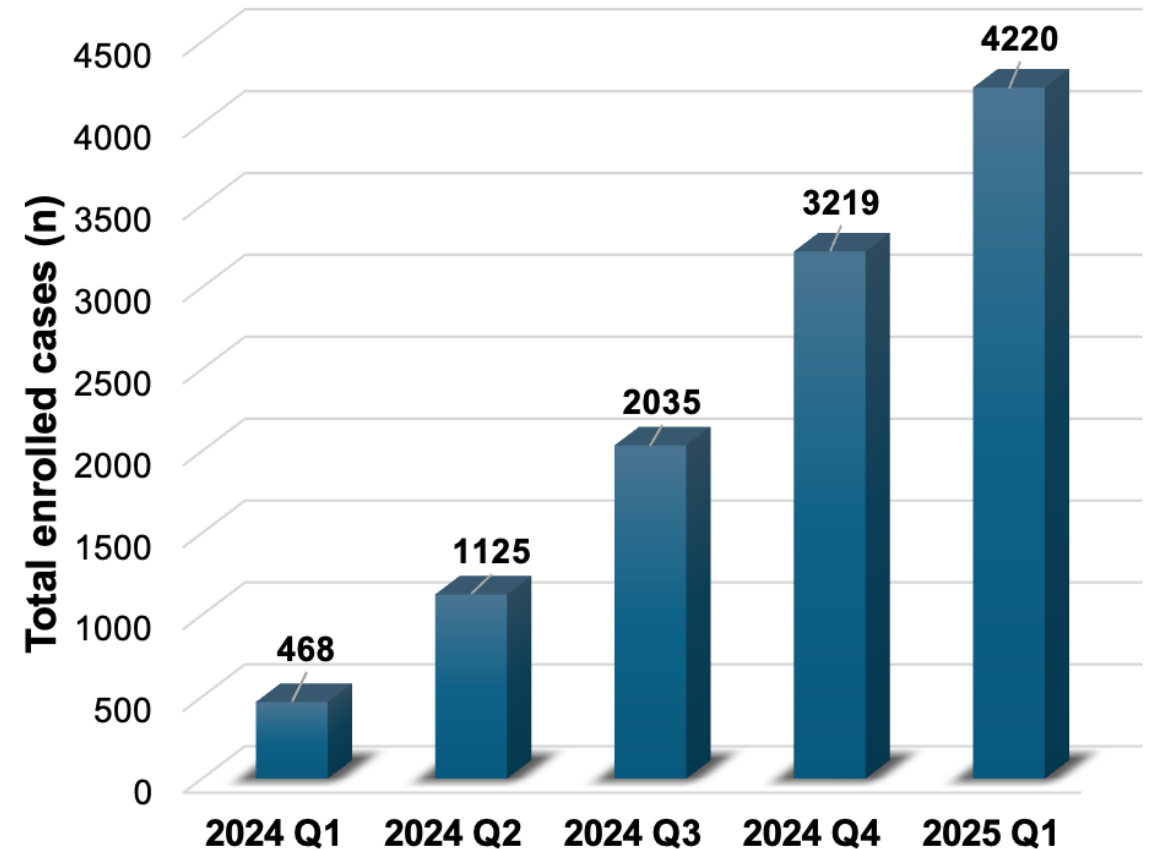
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# 1. CRISP Registry

- Re-launched in late 2023
- Currently, **17** institutions are contributing, with **20** more undergoing IRB/DUA approval
- Total case enrollment has surpassed **4,400**

## Cumulative Case Enrollment



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★ Active  
★ Pending



★ **Current 17 activated institutions**

- Joe DiMaggio Children's Hospital
- Children's Minnesota
- University of Mississippi
- Ann Lurie Children's Hospital
- Arnold Palmer Hospital for Children
- Children's Hospital of New Orleans
- University of Minnesota
- Children's Hospital Colorado
- Atrium Health Levine Children's Hp
- Duke University
- Inova Fairfax Children's Hospital
- Children's Mercy Hospital Kansas City
- Nicklaus Children's Hp Miami
- Central Michigan University | Detroit
- Wolfson Children's Hospital | Jacksonville
- Helen DeVos Children's Hospital
- University of Virginia

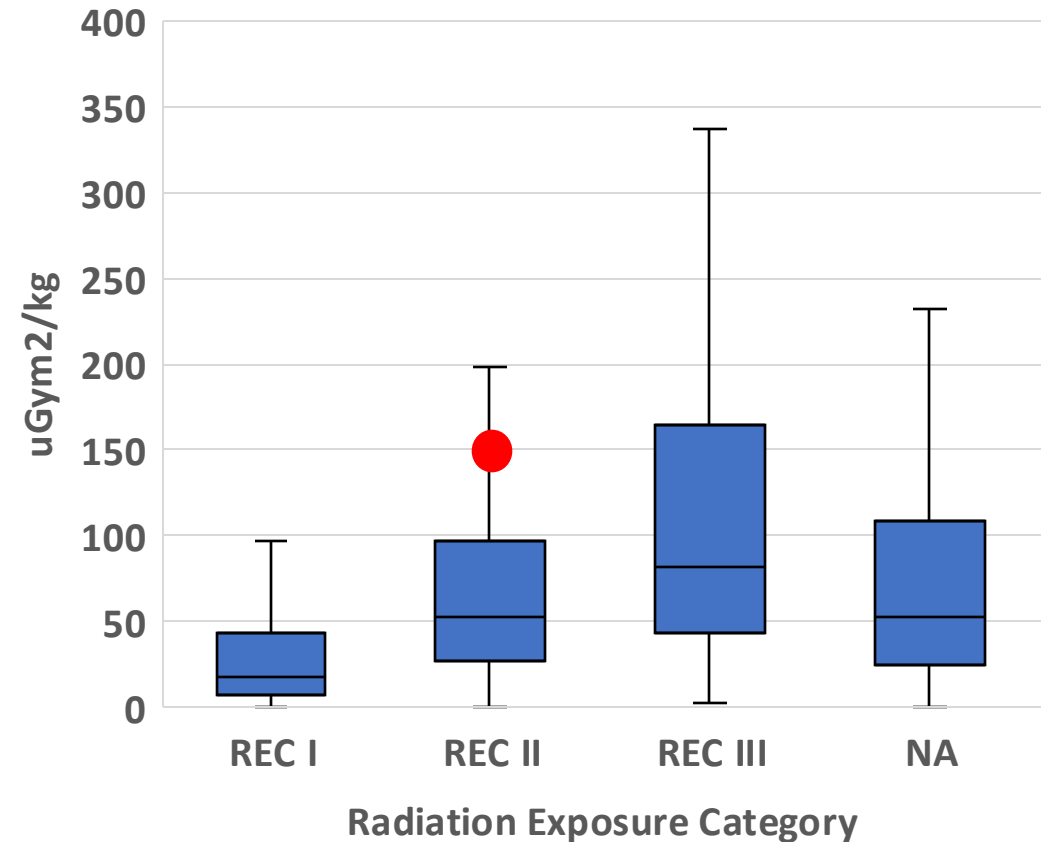
★ **20 institutions - pending**

- Advocate Children's Hospital
- University of Iowa
- St. Louis Children's Hospital | WashU
- St. Joseph Children's Hospital | Tampa
- Children's Medical Center Dallas | UTSW
- UCSF
- Children's Memorial Hermann Hospital
- Loma Linda University
- Medical City Dallas
- Methodist Hospital, San Antonio
- Ochsner Children's Hospital
- Rocky Mountain Hospital for Children
- St. Christopher's Hospital for Children | Drexel
- Sunrise Hospital Medical Center
- University of Oklahoma
- University of Texas at Austin | Dell Children's
- West Virginia University
- Arkansas Children's Hospital
- Valley Children's Hospital

Complete the initial phase of participation process by **the end of 2025**

# CRISP Registry Interval Updates

- March 27, 2025: Refinement of **SAE** Definition
- April 1, 2025: Version **3.2** Launch – new variables (patient location and disposition)
- April 1, 2025: Radiation Dosage **Self-Auditing** and Awareness Function
- April 25, 2025: Guidelines for **Research** and Publications



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# Site Audit in 2025 - Maintain High Quality Data

- **Round 1:** Sites joined in 2024Q1/Q2
- **Round 2:** Sites joined in 2024 Q3/Q4
- **Round 3:** Sites joined in 2025 Q1/Q2

Site participation timing		2024				2025		Audit Rounds		
No	Site	Q1	Q2	Q3	Q4	Q1	Q2	Round 1	Round 2	Round 3
1	Joe DiMaggio Children's Hospital	●	●	●	●	●		★		
2	Children's Minnesota	●	●	●	●	●		★		
3	University of Mississippi	●	●	●	●	●		★		
4	Ann Lurie Children's Hospital	●	●	●	●	●		★		
5	Arnold Palmer Hospital for Children		●	●	●	●		★		
6	Inova Fairfax Children's Hospital		●	●	●	●		★		
7	Atrium Health Levine Children's Hp		○	●	●	●		★		
8	Duke University			○	●	●			★	
9	University of Minnesota			○	●	●			★	
10	Children's Mercy Hospital Kansas City			○	●	●			★	
11	Wolfson Children's Hospital				●	●			★	
12	Children's Hospital Colorado				○	●			★	
13	Nicklaus Children's Hospital				○	●			★	
14	Central Michigan University, Detroit				○	●			★	
15	Helen DeVos Children's Hospital					○				★
16	University of Virginia					○				★
17	Children's Hospital of New Orleans									★

● complete dataset in the quarter | ○ case enrollment initiated in the quarter

[Group 1]

- 5/7 (Wed): Atrium Health
- 5/7 (Wed): INOVA Health
- 5/15 (Thu): Joe DiMaggio
- 5/16 (Fri): Clinics of Minnesota
- 5/19 (Mon): Uni of Mississippi
- 5/29 (Thu): Arnold Palmer

[Group 2]

July to August

# Join the CRISP Registry!

- The registry is open to any U.S. institutions.
- Annual participation fee is **\$3,500**
- To participate, a site need a local IRB approval and DUA.
- Please contact with the organizers
  - Thomas Forbes: [thforbes@mhs.net](mailto:thforbes@mhs.net)
  - Daisuke Kobayashi: [daisuke@wustl.edu](mailto:daisuke@wustl.edu)
  - Nancy Sullivan: [NSullivan@mhs.net](mailto:NSullivan@mhs.net)

Please scan to go to [ccsisc.net](http://ccsisc.net)

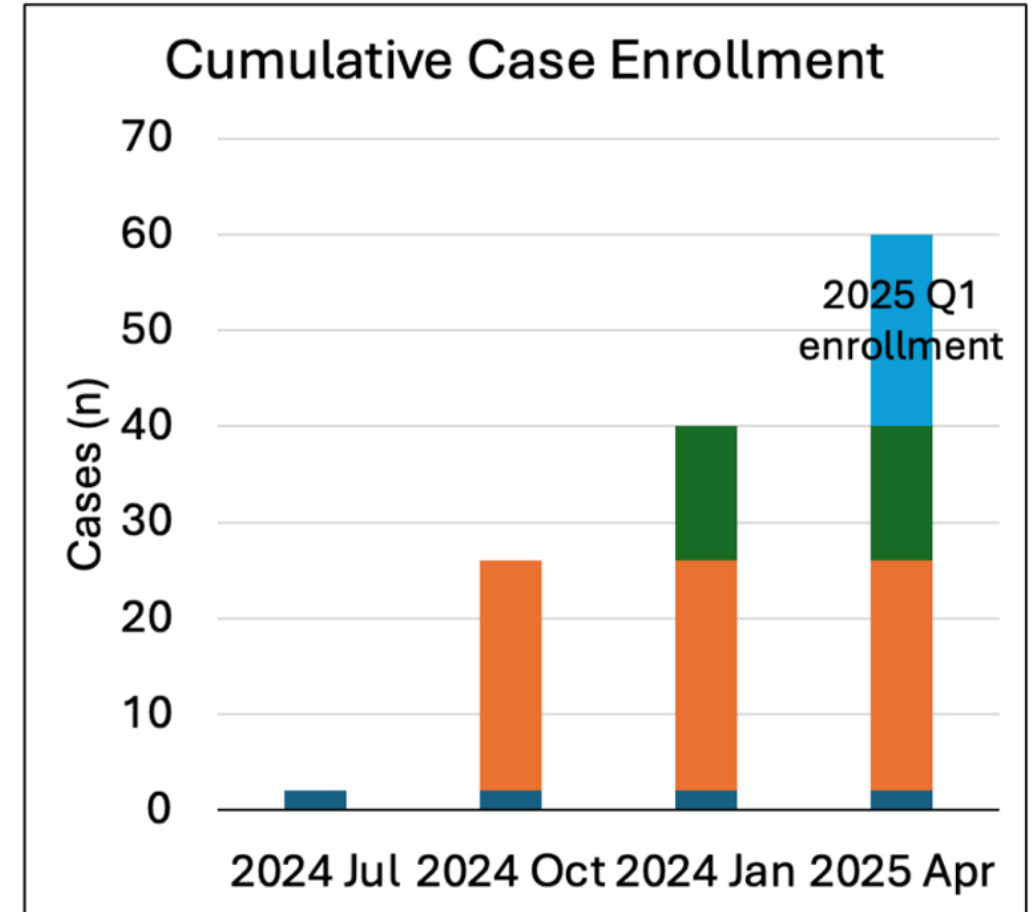


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## 2. PFR Registry

- PFR Registry was launched in late 2024.
- Total cases enrolled: **61**
- Participating sites: **13**
- The registry plans to present its first abstract upon reaching **100** enrolled cases.



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# PFR Registry Webinar

– June 12, 2025 | 5pm CST / 6pm EST



Case Presenter:  
**Dr. Stephen Clark**  
(University of Alabama)



Moderator:  
**Dr. David Balzer**  
(WashU)

**REGISTER at CCISC Website**  
**ccisc.net**

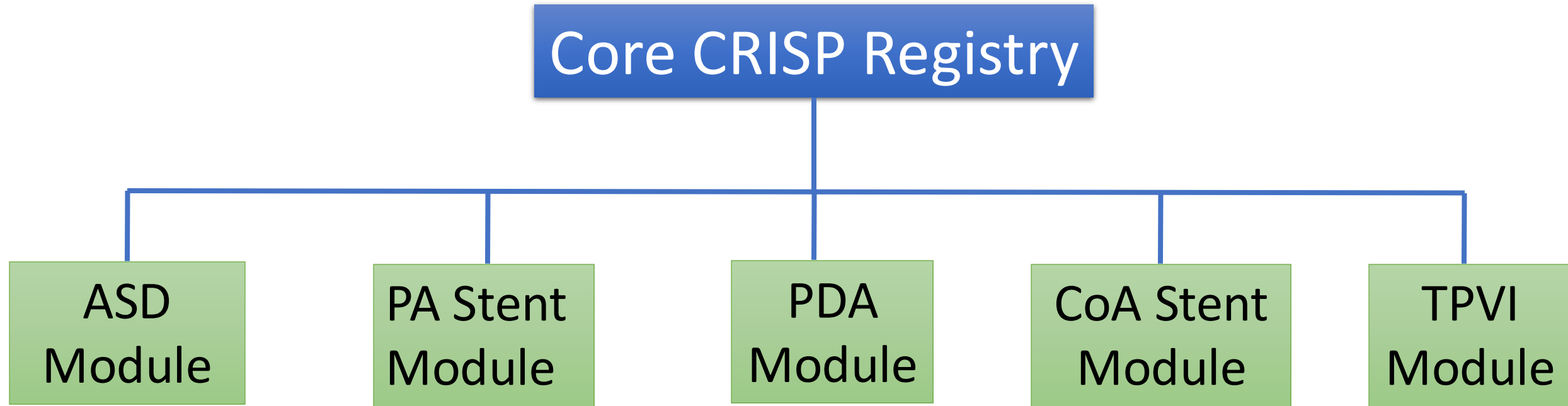


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### 3. CRISP Registry – Device Module Design (Registry-Based Real World Use Surveillance)

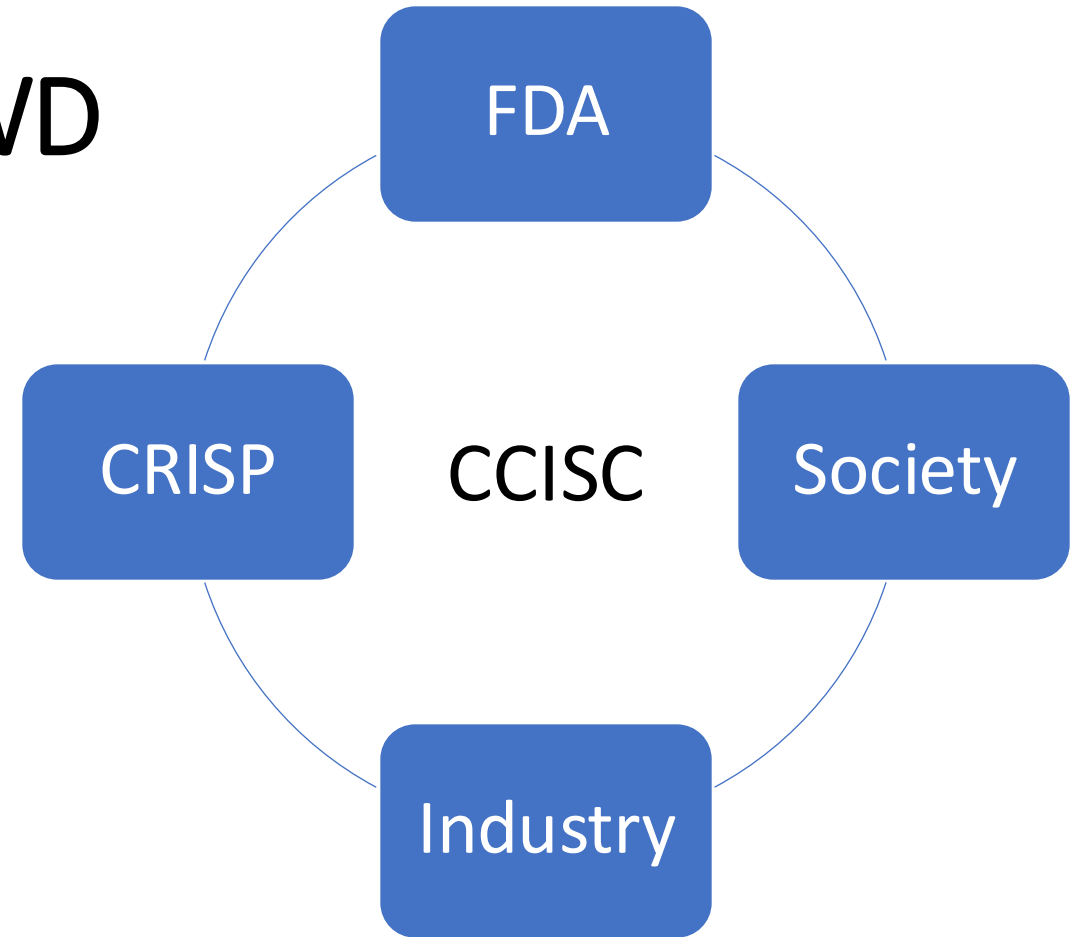


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# Framework to Build RWE utilizing CRISP Registry RWD

1. Obtain appropriate labeling to expand IFU  
→ Conduct a retrospective study for **PMA application**
2. Show the device performance in a real-world post-market setting  
→ Conduit a **Registry-Based Real-World Use Surveillance Study** to replace "Traditional Post-Approval Study"



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# Success: A retrospective study for PMA application

## **PALMAZ MULLINS XD Pulmonary Stent P220004**

Approval Date: July 21, 2023



PMA was granted based on a multicenter retrospective data (108 patients in 11 sites, organized by CCISC)



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## 4. Occlutech ASD Occluder RWU Surveillance Study (CRISP Registry Module)

- Study name: Registry-Based Real-World Use Surveillance of **Occlutech ASD Occluder** for Ostium Secundum ASD
- CCISC/CRISP Registry collaborates with **Occlutech** to conduct Real-World Use Surveillance Post-Market Study utilizing the CRISP registry RWD.
- Objective: Evaluate the safety and effectiveness in the post-market setting.
- Sample size: **500** cases
- Follow-up period **7 years** post-implant



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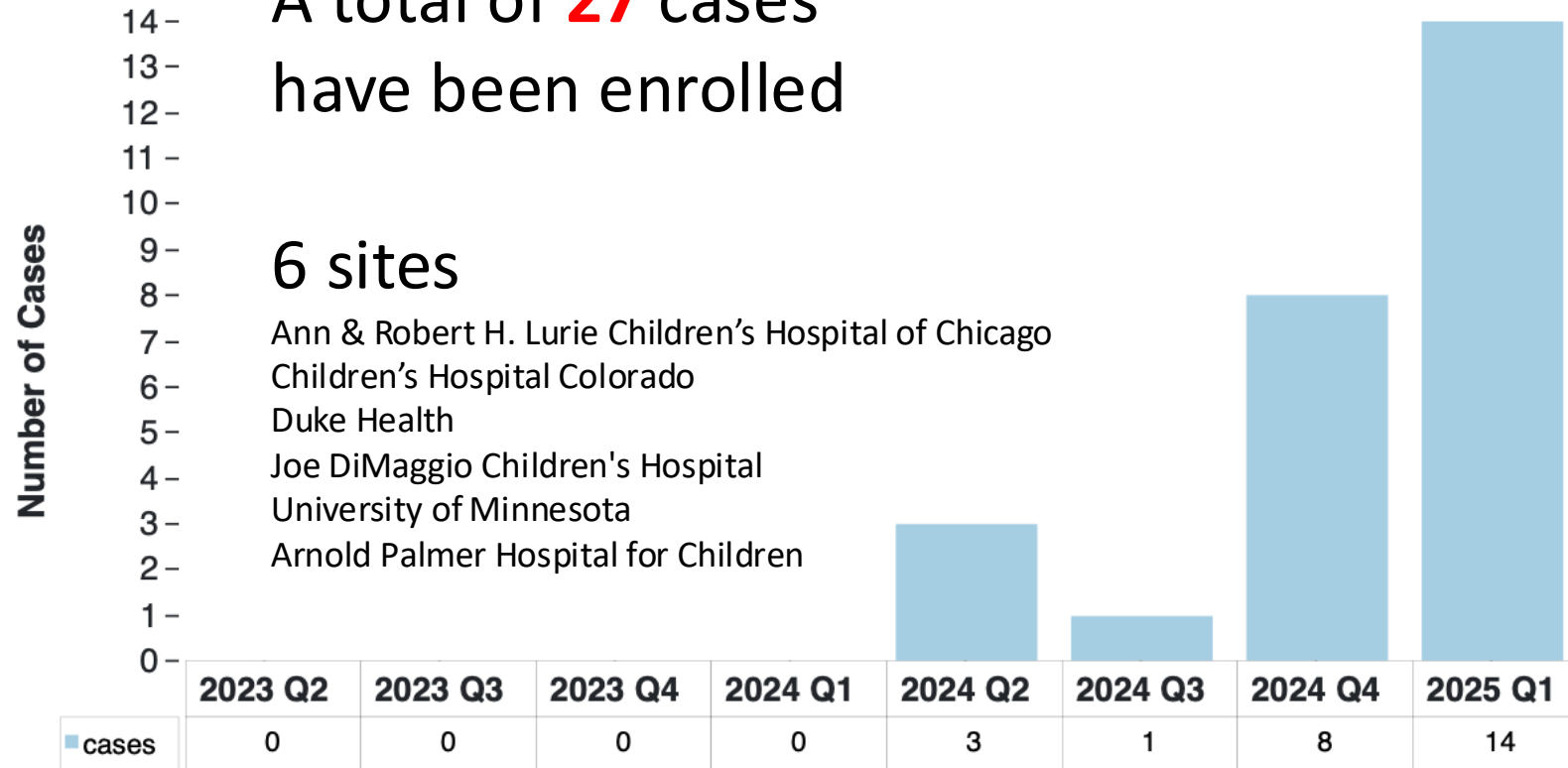
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# Occlutech Module has been launched

A total of **27** cases  
have been enrolled

6 sites

Ann & Robert H. Lurie Children's Hospital of Chicago  
Children's Hospital Colorado  
Duke Health  
Joe DiMaggio Children's Hospital  
University of Minnesota  
Arnold Palmer Hospital for Children



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# 5. REALPASS

(A Post-Approval Evaluation of the PALMAZ MULLINS XD™ Pulmonary Stent in the Treatment of Pulmonary Artery Stenosis)

- **Sponsor:** Cordis
- **Study Design:** Prospective, single-arm, multi-center, post-approval study
- **Purpose:** To characterize clinical outcomes and assess the real-world use of the commercially available PALMAZ MULLINS XD Pulmonary Stent
- **Sample Size:** 35–75 subjects across up to 11 sites
- **Follow-Up:** Through hospital discharge
- **Planned Launch:** Summer 2025
- **Data Management:** [EDC/database provided by JDCH/MHS](#)



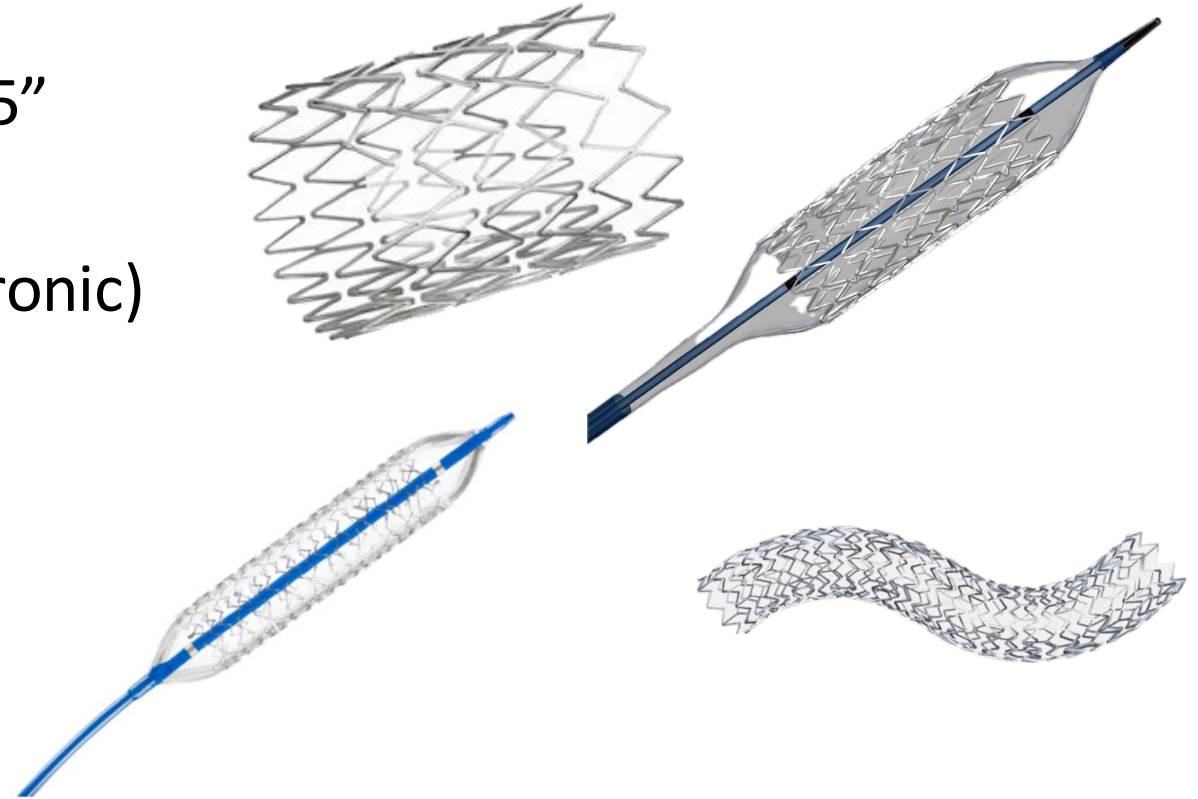
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## 6. Expand indication for use for Off-Label Use of Stents

“Lost access to Valeo Stent in early 2025”

- IntraStent Mega/Max LD Stent (Medtronic)
- Formula 418 Stent (Cook)
- Visi-Pro Stent (Medtronic)
- Express LD Stent (Boston Scientific)



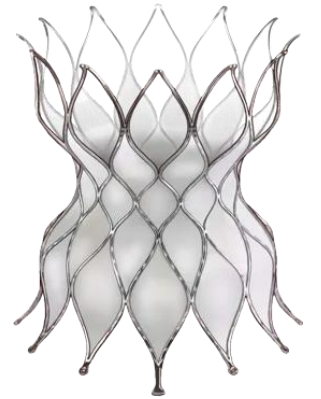
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# 7. Future Potential Modules (CRISP Registry based Real-World Use Surveillance)

- **Bloom Occluder**
  - Consider after PMA based on PREEMIE study
- **Renata Minima Stent**
  - Already PMA granted and commercialized
- **TPVI for new and current valve stent**



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# Power of the CRISP Registry for Cardiac Device Module

- **Seamless Enrollment**
  - Capture all consecutive cases, ensuring complete device module enrollment
- **Integrated Interface**
  - Automatically links device use to the correct module, eliminating extra steps
- **User-Friendly Design**
  - Streamlines, user-friendly interface for efficient data entry
- **Collaborative Infrastructure**
  - Built on strong collaboration with industry, FDA and societies.
  - Only registry-based real-work surveillance platform at present
- **Cost-Effective & Impactful**
  - Reduces post—market study costs by replacing traditional trials
  - Delivers timely, “real-world evidence” to support device evaluation



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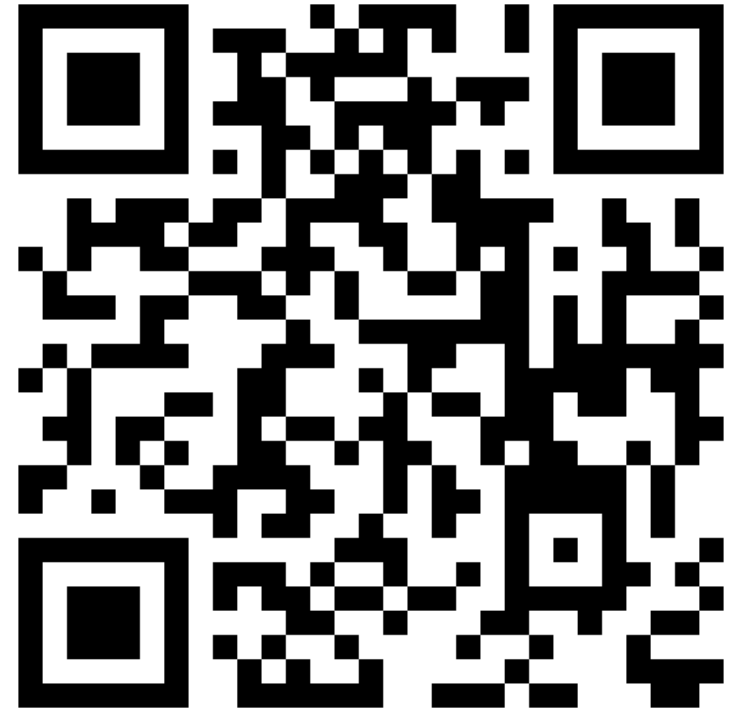
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# Q&A

## CCISC/CRISP/PFR

Please contact with

- Daisuke Kobayashi: [daisuke@wustl.edu](mailto:daisuke@wustl.edu)
- Thomas Forbes: [tforbes@mhs.edu](mailto:tforbes@mhs.edu)
- Nancy Sullivan: [Nsullivan@mhs.edu](mailto:Nsullivan@mhs.edu)



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