

2025 PICS, Chicago
CCISC Meeting
August 27, 2026
Grand Horizon Ballroom C – Level 4



Update on CCISC Projects

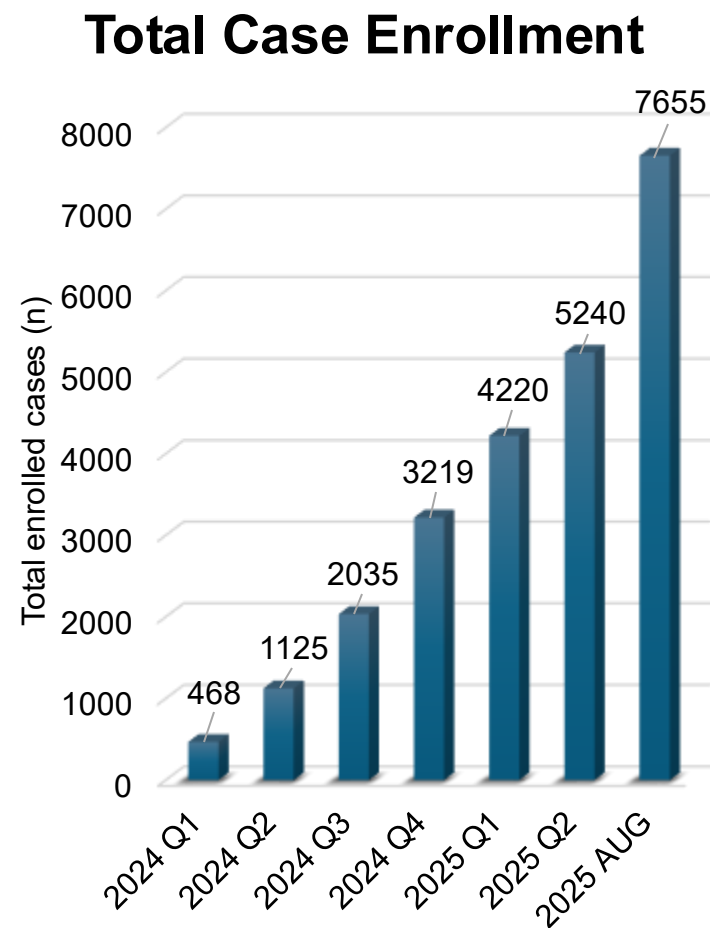
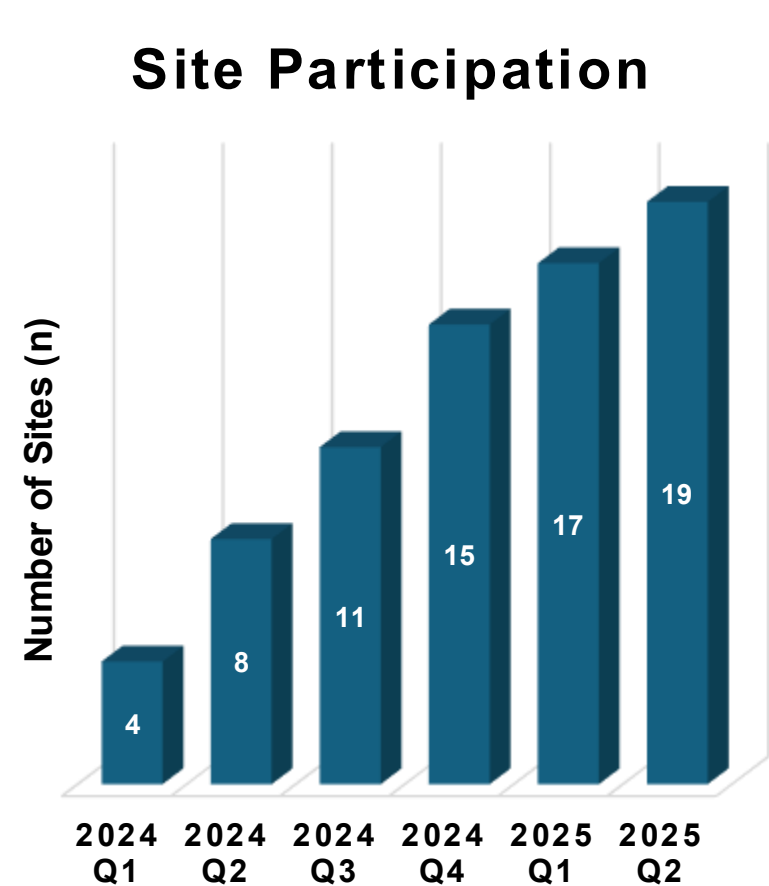
Daisuke Kobayashi, MD, MPH, MHA
Professor of Pediatrics, Washington University in St. Louis
Director, Cardiac Catheterization Laboratory,
St. Louis Children's Hospital



Overview

1. CRISP Registry
2. Occlutech ASD Occluder Module
3. PFR Registry
4. CRIPS/PFR Registry Webinar
5. MHS IT Upgrade and Cordis REALPASS
6. Future and Ongoing Projects

1. CRISP Registry - Site Participation



No.	Site	IRB	Contract
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	Children's Hospital of New Orleans	✓	✓
7	University of Minnesota Fairview	✓	✓
8	Children's Hospital Colorado	✓	✓
9	Atrium Health Levine Children's Hp	✓	✓
10	Duke University	✓	✓
11	Inova Fairfax Children's Hospital	✓	✓
12	Children's Mercy Hospital Kansas City	✓	✓
13	Nicklaus Children's Hp Miami	✓	✓
14	Central Michigan University Detroit	✓	✓
15	Wolfson Children's Hospital Jacksonville	✓	✓
16	Helen DeVos Children's Hospital	✓	✓
17	University of Virginia	✓	✓
18	Advocate Children's Hospital	✓	✓
19	St. Louis Children's Hospital WashU	✓	✓
20	University of Iowa	✓	
21	St. Joseph Children's Hospital Tampa	✓	✓
22	Children's Medical Center Dallas UTSW	✓	
23	UCSF	✓	
24	Children's Memorial Hermann Hospital	✓	
25	University of Texas at Austin Dell Children's	✓	
26	OSF Healthcare University of Illinois, Peoria		
27	Loma Linda University		
28	Medical City Dallas - HCA		
29	Methodist Hospital, San Antonio - HCA		
30	Ochsner Children's Hospital		
31	Rocky Mountain Hospital for Children - HCA		
32	St. Christopher's Hospital for Children Drexel		
33	Sunrise Hospital Medical Center - HCA		
34	University of Oklahoma		
35	West Virginia University		
36	Arkansas Children's Hospital		
37	Valley Children's Hospital		
38	Seattle Children's Hospital		

CRISP Registry Site Map

August 2025



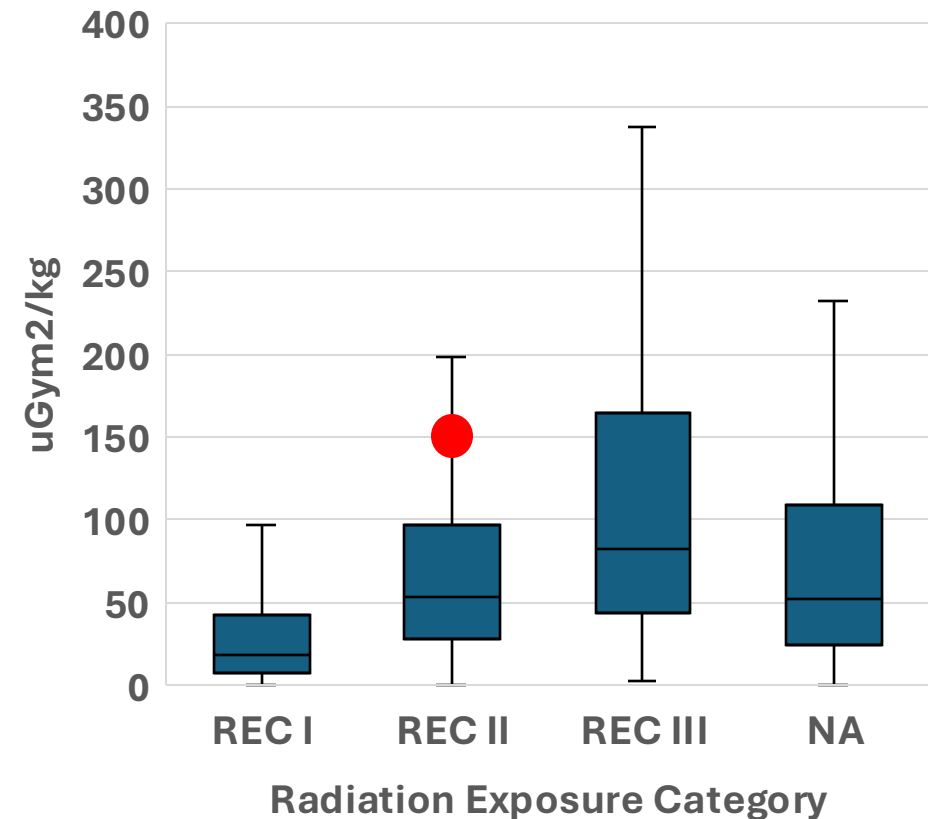
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CRISP Registry

- Data Accuracy, Consistency and Audit

- Data audit was conducted in Spring 2025 → **96% accuracy** in key variables
- All the AE entries are adjudicated
 - Provide consistent and fair AE grading
 - Provide the guidance and feedback through the “Message Board”
- Radiation dosage verification
 - Registry adjudicates cases with high DAP/kg above 95%tile
 - Self-Auditing and Awareness Function



CRISP Registry

- Radiation Exposure Category



JSCAI 

The official journal of the Society for
Cardiovascular Angiography & Interventions

Original Research

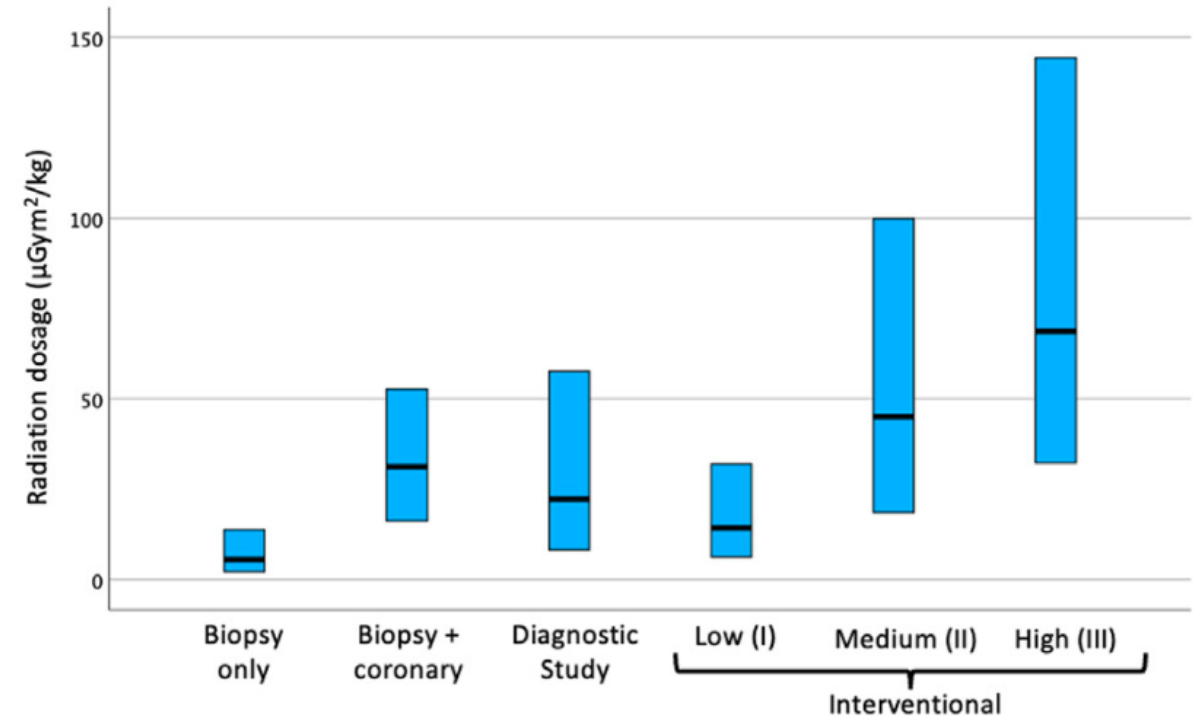
Trends in Radiation Exposure With the Refinement of Radiation Exposure Categories in Congenital Cardiac Catheterization: Insights From the CRISP Registry

Gurumurthy Hiremath, MD^a, Juan Carlos Samayoa, MD^a, Alexander Javois, MD^b, Osamah Aldoss, MBBS, MD^c, Ryan Leahy, MD, MA^d, Reid Chamberlain, MD, MSCI^e, Elena Amin, MD^f, Marko Vezmar, MD^g, Makram Ebeid, MD^h, Shyam Sathanandam, MDⁱ, David Nykanen, MD^j, Thomas Forbes, MD^k, Christopher Curzon, MD^l, Martin Bocks, MD^m, Daisuke Kobayashi, MD, MPH, MHA^{n,*}

*CRISP REC separated from Low REC

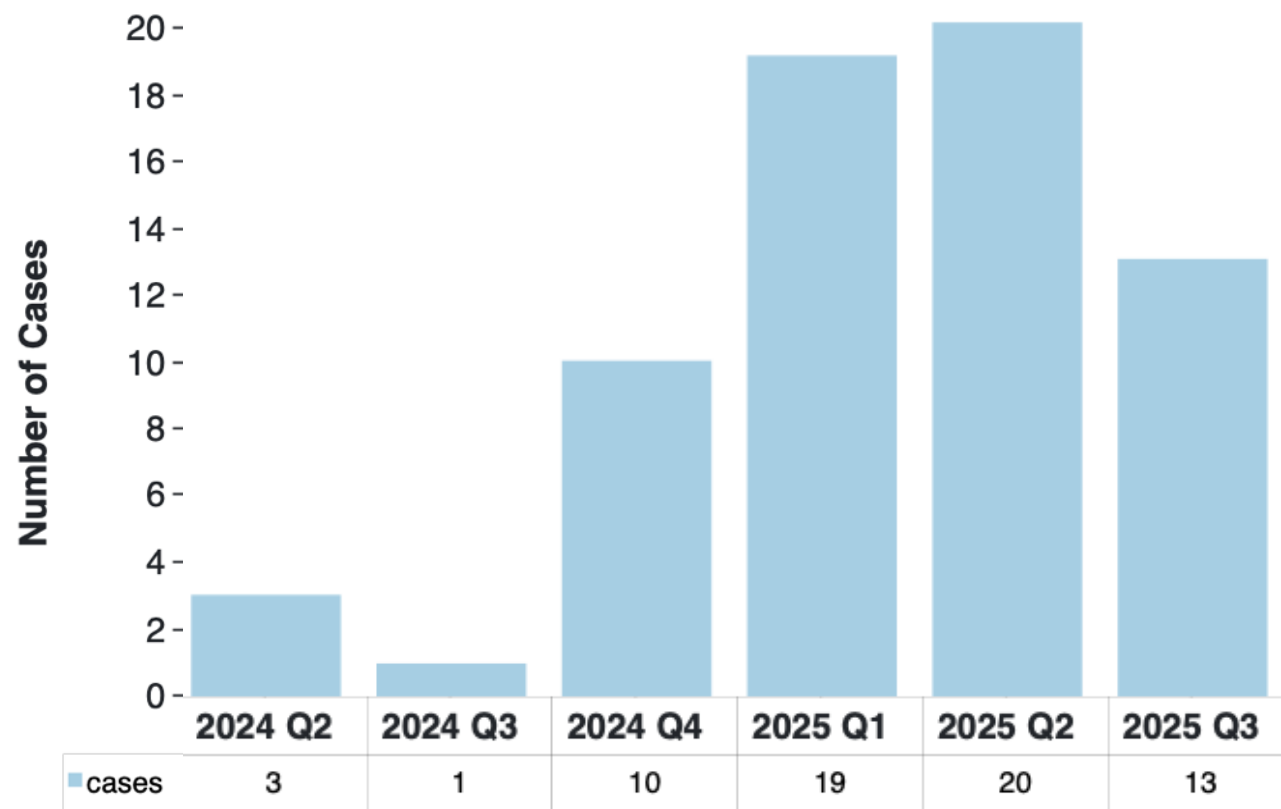
- Biopsy only
- Biopsy + coronary
- Diagnostic Study

CRISP REC



2. Occlutech ASD Module (n=65)

- Real World Surveillance Registry Study

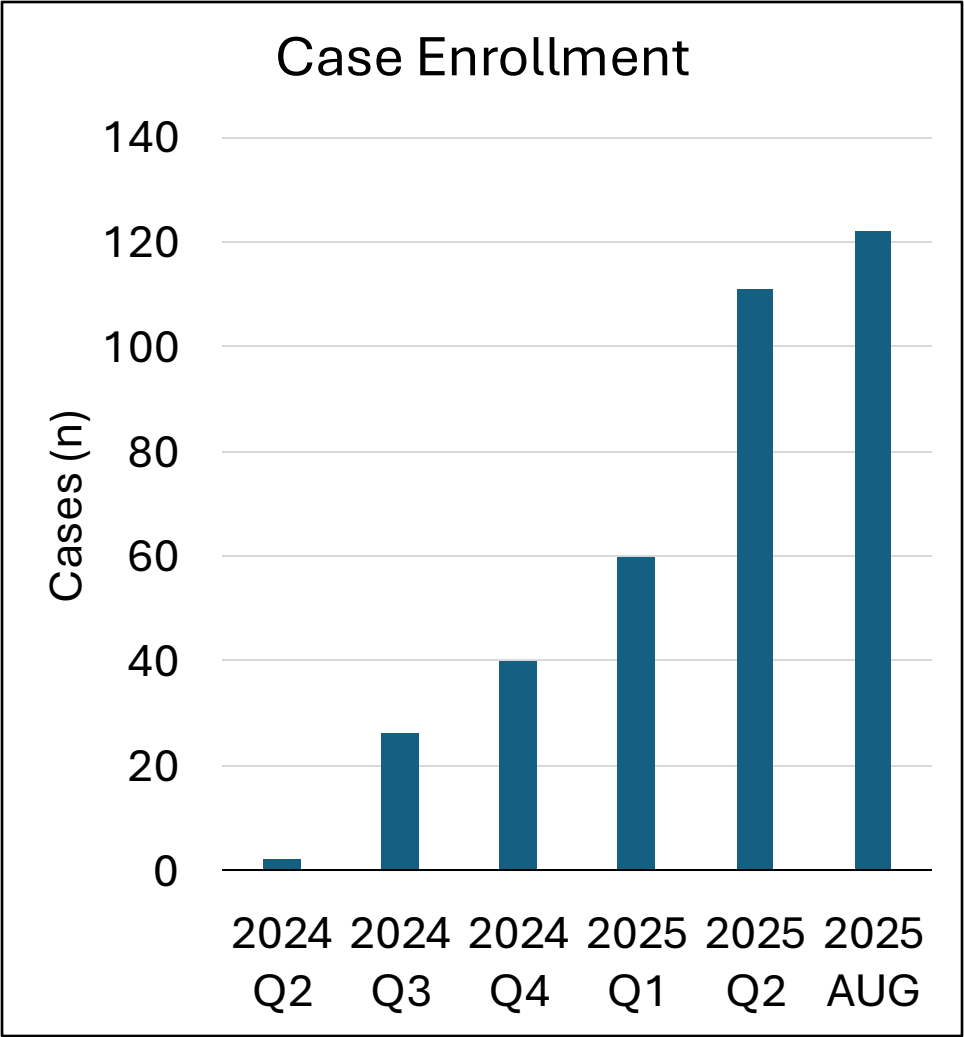
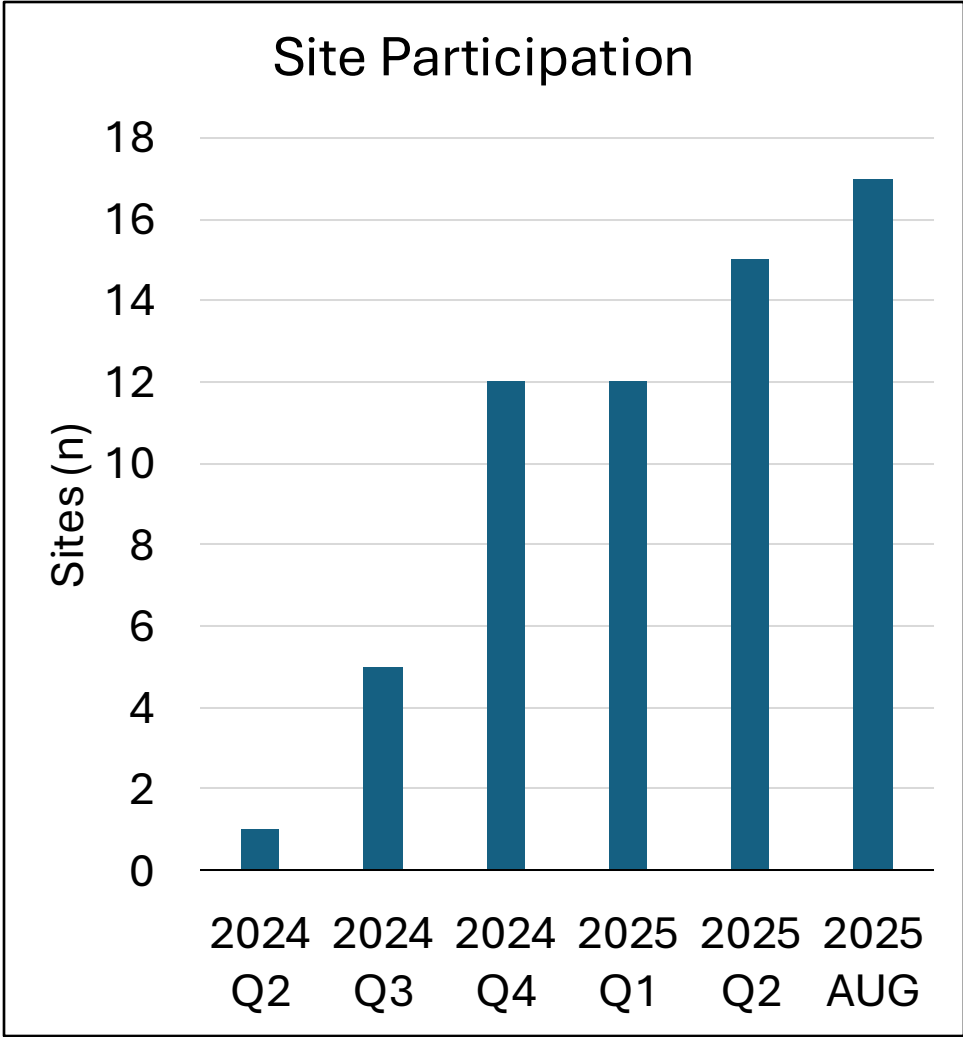


	Total	2024	2025
Ann & Robert H. Lurie Children's Hospital of Chicago	3	3	0
Childrens Hospital Colorado	7	1	6
Duke Health	3	2	1
Joe DiMaggio Children's Hospital	14	2	12
St. Louis Children's Hospital	12	3	9
University of Minnesota	9	3	6
Arnold Palmer Hospital for Children	5	0	5
Children's Hospital New Orleans	2	0	2
Inova Health Care	1	0	1
Nicklaus Childrens Hospital	8	0	8
The University of Virginia	2	0	2
Total	66	14	52

May 2025 SCAI: N=26, 6 sites → Aug 2025 PICS: N=65, 11 sites

Goal: Sample size: **500 cases**, 20-25 sites
F/p period: **7 years** post-implant

3. PFR Registry (n=122, 17 sites)



No.	Site
1	Children's Hospital of Colorado
2	Joe DiMaggio Children's Hospital
3	Children's of Alabama at Birmingham
4	Children's Minnesota
5	Children's Hospital of Los Angeles
6	University of Minnesota
7	University of Texas Memorial Hermann
8	Vanderbilt University
9	OSF Healthcare Children's Hospital of Illinois
10	Wolfson Children's Hospital
11	Arnold Palmer Hospital for Children
12	Columbia Presbyterian Hospital
13	St. Louis Children's Hospital / WashU
14	Phoenix Children's Hospital
15	Central Michigan University Detroit
16	Ann & Robert H. Lurie Children's Hospital
17	West Virginia University Children's Hospital
18	Medical City Dallas
19	INOVA Fairfax
20	Advent Health for Children
21	Advocate Children's Hospital
22	Atrium Health
23	Children's Hospital of the King's Daughters
24	UPMC Children's Hospital of Pittsburgh
25	Children's Hospital of Richmond/VCU
26	Children's Mercy Hospital, Kansas City
27	Cincinnati Children's Hospital
28	Cleveland Clinic
29	Cohen Children's Medical Center of NY
30	Duke University
31	Johns Hopkins All Children's Hospital
32	LeBonheur Children's Hospital
33	Mayo Clinic
34	Nationwide Children's Hospital
35	Nemours Children's Hospital
36	Nicklaus Children's Hospital
37	University of North Carolina, Chapel Hill
38	Ochsner Children's Hospital
39	Rady Children's Hospital
40	Seattle Children's Hospital
41	Texas Children's Hospital
42	UC Davis
43	UCSF
44	University of Arizona Health Sciences Center
45	University of Oklahoma
46	University of Wisconsin, Madison
47	Valley Children's Hospital

PFR Registry – Successful 1st Webinar



June 12, 2025 at 5pm CST / 6pm EST

PFR REGISTRY WEBINAR

Pulmonary Flow Restrictor Registry



Dr. Stephen Clark
Uni of Alabama



Dr. David Balzer
Washington Un in St. Louis



Dr. Frank Ing
UC Davis
Children's Hp



Dr. Joseph Graziano
Phoenix
Children's Hp



Dr. Shyam Sathanandam
Nicklaus
Children's Hp



Dr. Mariel Turner
NY-Presbyterian Morgan
Stanley Children's Hp

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4. CRISP / PFR Registry Webinar

- **Semiannual** webinars for each registry
- Provide **CME credit** for attendance
- The webinar delivers the registry updates and presentation by invited speakers
- Funded by **Medtronic grant**
- **Next WEBINARS**
 - ***CRISP Registry: October 2025***
 - ***PFR Registry: December 2025***



[Next invited speaker
for PFR registry webinar]
Nicola Maschietto, MD, PhD
Boston Children's Hospital

5. MHS IT Upgrade and Cordis REALPASS

To meet FDA and industry standards

- **Electronic signatures (DocuSign):** secure digital approvals
- **Standard Operating Procedures (SOPs):** clear rules for consistency
- **Peer review of code:** every change checked by another expert
- **Automated testing:** system automatically re-checks old and new functions
- **Formal change tracking:** every system change recorded and approved



Post-Approval Study of PALMAZ
MULLINS XD in Treating
Pulmonary Artery Stenosis
(**REALPASS**)

6. Future and Ongoing Projects



- **CRISP Registry**

- Next Protocol ver3.3 coming (IRB submission in Sep-Oct 2025)
 - Integrate new Modules: TPVI, Premie PDA Closure, Renata Minima
- Interface update
 - predicted procedural time on weekly dashboard
 - CRISP REC and center comparison of radiation dosage
- PA stent module coming

- **PFR Registry**

- Data presentation in PDA stent symposium in San Diego (Oct 2025)

- **IntraStent LD Mega/Max (Medtronic)**

- Expand indication for use for PA and CoA stenting

- **Real-world surveillance study with potential collaboration with industries**

- Edwards, Medtronic, Abbott, Merit

New

12Y

Biopsy only (transplant)

● CRISP: 2/5

Kobayashi

20 min (IQR 15-25 min)



Thank you

CCISC/CRISP/PFR

Please contact with

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- Thomas Forbes: tforbes@mhs.edu
- Nancy Sullivan: Nsullivan@mhs.edu

