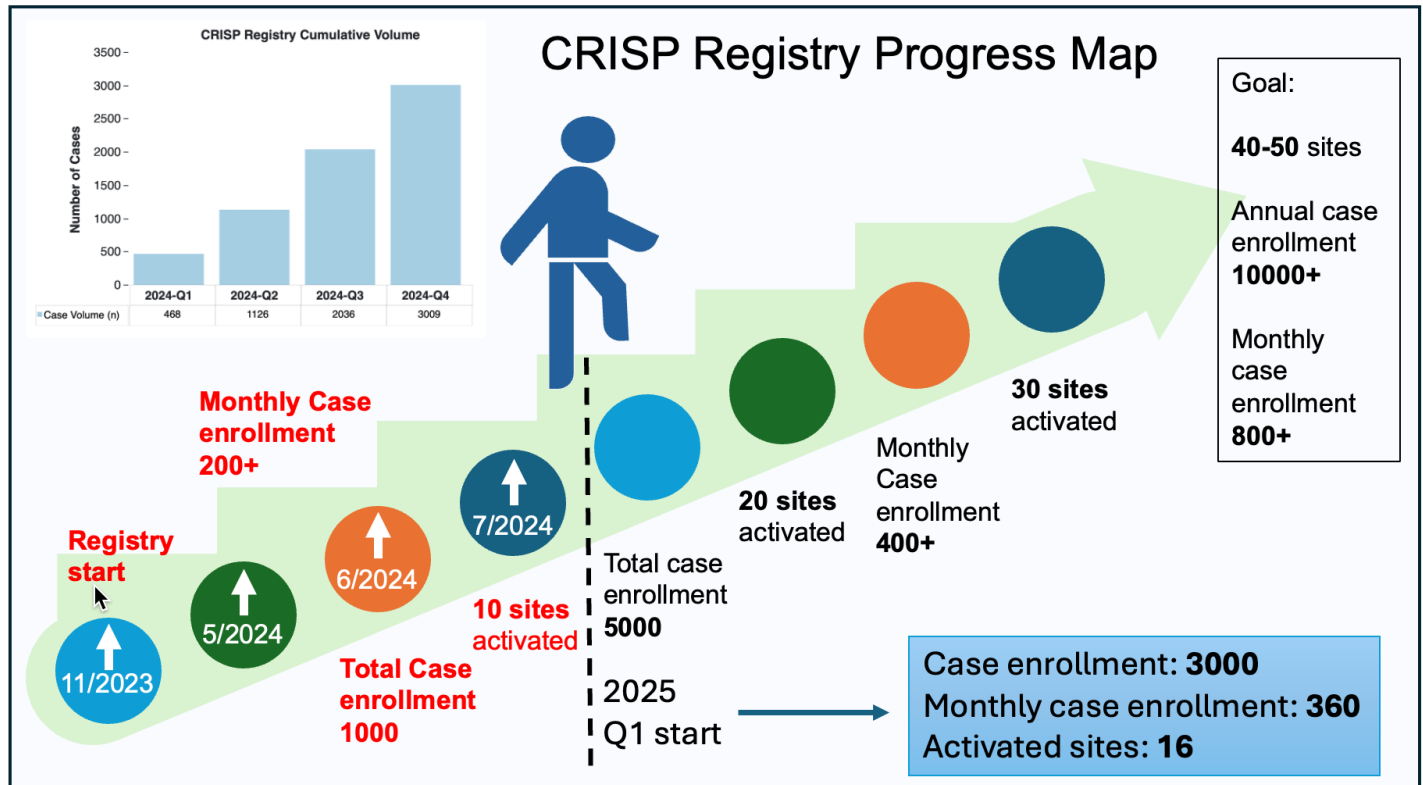# CRISP Registry Newsletter

Congenital Registry for Interventional and Diagnostic Study Procedures Ver. 3.2

Highlights

- **CRISP Registry Version 3**: The registry has enrolled approximately 3,000 cases across 15 activated sites. An additional 10 sites have IRB approval, and 18 more are considering participation.
- **Occlutech ASD Module**: Our first real-world surveillance study in collaboration with Occlutech is underway, with 8 cases enrolled across 4 sites. Efforts to strengthen this partnership are ongoing—stay tuned for updates.
- **Collaboration with FDA and PICS Society**: The registry is working with the FDA and PICS Society to expand indications for use of key devices, including the IntraStent LD stent (for PA stenosis and CoA) and the Formula 418 stent (for PA stenosis), among others.
- **Post-Approval Study for Palmaz Mullins XD Pulmonary Stent (Genesis XD Stent):** Discussions are ongoing regarding the CRISP registry's involvement in this critical post-approval study.
- **Real-World Surveillance Data Studies**: Plans are underway to expand real-world surveillance to include various devices, such as ASD closure devices, PDA closure devices, and transcatheter pulmonary valve stents.

CRISP Registry Progress Map

CRISP Registry Study Contacts:

Principal Investigator: **Thomas J. Forbes**, MD Joe DiMaggio Children's Hospital; (954) 265-3437; ThForbes@mhs.net	Project Manager: **Nancy M. Sullivan**, MS, CCRC Joe DiMaggio Children's Hospital; (313) 303-4634; Nsullivan@mhs.net
Co-Investigator: **Daisuke Kobayashi**, MD, MPH, MHA Washington University in St. Louis; (314)454-6095; daisuke@wustl.edu	Business Intelligence Developer; **Jonathan Forbes** Joe DiMaggio Children's Hospital; (954) 265-3437; JForbes@mhs.net
Study Advisor: **David G. Nykanen**, MD Arnold Palmer Hospital for Children; (407)649-6907; david.nykanen@orlandohealth.com	

Overall Site Progress

No.	Site	IRB	Contract	Invoice	Active	v3.2	Occlutech ASD module
1	Joe DiMaggio Children's Hospital	✓	✓	✓	✓	✓	10/31/2024
2	Children's Minnesota	✓	✓	✓	✓	✓	No
3	University of Mississippi	✓	✓	✓	✓		Yes
4	Ann Lurie Children's Hospital	✓	✓	✓	✓	✓	10/31/2024
5	Arnold Palmer Hospital for Children	✓	✓	✓	✓	✓	Yes
6	Children's Hospital of New Orleans	✓	✓	✓	✓		Yes
7	University of Minnesota	✓	✓	✓	✓	✓	12/4/2024
8	Children's Hospital Colorado	✓	✓	✓	✓	✓	Yes
9	Atrium Health Levine Children's Hp	✓	✓	✓	✓	✓	12/11/2024
10	Duke University	✓	✓	✓	✓	✓	Yes
11	Inova Fairfax Children's Hospital	✓	✓	✓	✓	✓	Yes
12	Children's Mercy Hospital Kansas City	✓	✓	✓	✓	✓	Yes
13	Nicklaus Children's Hp Miami	✓	✓	✓	✓	✓	Yes
14	Central Michigan University | Detroit	✓	✓	✓	✓	✓	Yes
15	Wolfson Children's Hospital | Jacksonville	✓	✓	✓	✓	✓	Yes
16	Helen DeVos Children's Hospital	✓	✓				
17	St. Joseph Children's Hospital | Tampa	✓					
18	University of Virginia	✓		✓		✓	
19	Advocate Children's Hospital	✓				✓	No
20	Children's Medical Center Dallas | UTSW	✓				✓	
21	St. Louis Children's Hospital | WashU	✓				✓	
22	Mayo Clinic	(✓)				✓	
23	University of Iowa	✓					
24	UCSF	✓				✓	Yes
25	Children's Memorial Hermann Hospital	✓				✓	

[Participation consideration]
- Medical City, Dallas
- Methodist Hospital, San Antonio
- Loma Linda University
- Ochsner Medical Center
- Rocky Mountain Hospital for Children
- St. Christopher's Hospital for Children (Drexel)
- Sunrise Hospital and Medical Center
- University of Oklahoma
- University of Texas at Austin
- West Virginia University
- Arkansas Children's Hospital
- Cardinal Glennon Children's
- Cleveland Clinic
- University of Alabama
- University of Wisconsin
- Tulane University
- Valley Children's Hospital
- University of New Mexico

Site Contribution to CRISP Registry Cohort

	Site	2024 Q1 (Jan-Mar)	2024 Q2 (Apr-Jun)	2024 Q3 (Jun-Sep)	2024 Q4 (Oct-Dec)
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	Children's Hospital of New Orleans	○			

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