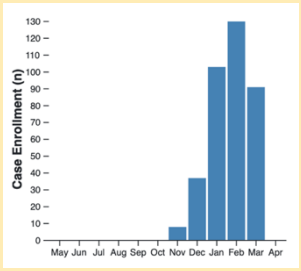
April 2024 | Issue 2

Congenital Cardiovascular Interventional Study Consortium (CCISC)
www.new.ccisc.net

CRISP Registry Newsletter

Congenital Registry for Interventional and Diagnostic Study Procedures Ver. 3.1

Highlights



- CRISP registry has made significant strides in the site participation process since last newsletter (Jan).
  - **10** sites have completed the site activation meeting.
  - Another **6** sites will join the registry in a coming month.
  - **13** sites are working on the application / considering participation.
- Case enrollment is **increasing** (n=360, April 2024).
- **Off-label device study**: Through collaboration with the FDA, CCISC organizes various studies utilizing the CRISP registry. We successfully obtained the FDA approval for the first PA stent (**PALMAZ MULLINS XD Pulmonary Stent**, July 2023) using exclusive retrospective data collection. We currently study the **KA Micro Plug** use for PDA closure in premature infants.

Overall Site Progress

No.	Site	IRB approval	DUA Contract	Invoice payment	Site Activation Meeting	Activated
1	Joe DiMaggio Children's Hospital	✓	✓	✓	11/21/2023	✓
2	Children's Minnesota	✓	✓	✓	12/8/2023	✓
3	University of Mississippi	✓	✓	✓	1/8/2024	✓
4	Ann Lurie Children's Hospital	✓	✓	✓	1/9/2024	✓
5	Arnold Palmer Hospital for Children	✓	✓	✓	2/22/2024	✓
6	Children's Hospital of New Orleans	✓	✓	✓	2/27/2024	✓
7	University of Minnesota	✓			3/18/2024	
8	Children's Hospital of Michigan				3/20/2024	
9	University of Virginia	✓			3/20/2024	
10	Children's Hospital Colorado	✓	✓		4/1/2024	
11	Children's Mercy Hospital Kansas City	✓			4/12/2024	
12	Sanger Heart & Vascular institute (Atrium)	✓	✓			
13	Children's Medical Center Dallas - UTSW	✓				
14	University of Iowa	✓				
15	Duke University	✓				
16	DeVos Children's Hospital		✓			

IRB/DUA/Contract process submitted:
- Children's Memorial Hermann Hp - UTX
- Inova Fairfax Children's Hospital
- Sanger Heart and Vascular institute (Atrium)
- St. Joseph Children's Hospital Tampa
- Nicklaus Children's Hospital Miami
- St. Louis Children's Hospital / Washington University

Sites with preview meeting performed:
- Johns Hopkins All Children's Hp (11/30/23)
- Medical City, Dallas (12/14/23)
- Driscoll Children's Hospital (3/7/2024)
- UCSF (1/19/24)

Sites with participation consideration
- Advocate Children's Hospital
- University of Texas at Austin
- Wolfson Children's Hospital
- Mayo clinic

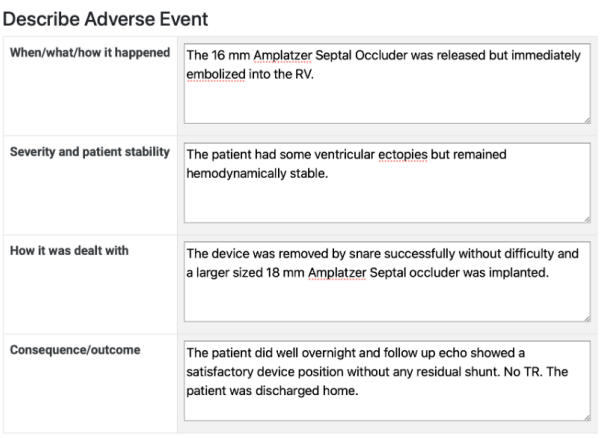
What's New?

- Real-time "**Radiation Dosage Reporting**" function will become available soon. The CRISP registry utilizes the "Radiation Exposure Category (REC) – Low, Medium, High" that was proposed by the C3PO registry (Quinn BP 2019 Pediatric Cardiology). Procedure types are assigned to 40 unique REC case types that are categorized to Low (case type 1-13), Medium (14-29), High (30-40).
- **"Training Materials"** will become available soon. The CRISP registry organizers are working on series of training slides to explain the registry interface, add patients, and many more functions.
- The CRISP registry aims to achieve **20+** site participation by Summer 2024 and **30+** site participation by End of 2024.

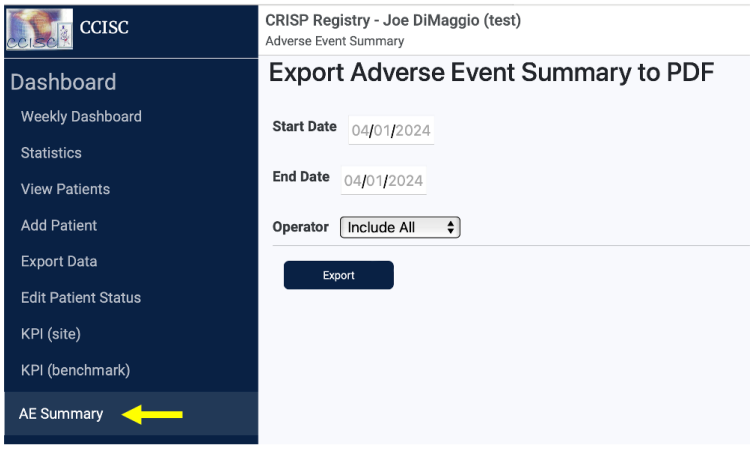
Registry Tips

Adverse Event section: Please include the detail description in the narrative section. This will be shown in the "**AE Summary**" for your local QI activity. Example is shown below.

[Adverse event – narrative section]



[AE Summary download]



[AE Summary Output]

CRISP ID	Date Of Cath	Operator	Adverse Event	Severity
2024-01-0013	2024-04-29	Test Operator	Closure device/coil	3a. Moderate

Case Type: Interventional - Closure / ASD
Diagnosis: Coarcation of aorta
Age: 3 Years
Procedural Time (mins): 103

AE: Closure device/coil

Description: The 16 mm Amplatzer Septal Occluder was released but immediately embolized into the RV. The patient had some ventricular ectopies but remained hemodynamically stable. The device was removed by snare successfully without difficulty and a larger sized 18 mm Amplatzer Septal occluder was implanted. The patient did well overnight and follow up echo showed a satisfactory device position without any residual shunt. No TR. The patient was discharged home.

CRISP Registry Study Contacts:

Principal Investigator: **Thomas J. Forbes**, MD Joe DiMaggio Children's Hospital 1005 Joe DiMaggio Dr, Hollywood, FL 33021 (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 One Children's Place, St. Louis, MO 63110 (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 1222 S. Orange Ave. 2nd floor, Orlando, FL 32806 (407)649-6907; david.nykanen@orlandohealth.com	