

Subject: Site Virtual Audit Process in 2025

Dear CRISP Registry Participants,

We are excited to announce **the first site audit** for the CRISP registry. As part of our ongoing commitment to data accuracy, consistency, and continuous improvement, **the virtual audit process** provides an opportunity to evaluate and enhance our collective efforts in maintaining high-quality data. This audit will also serve as a valuable opportunity for us to engage in dialogue and gather feedback from the sites to support your data entry efforts. Because this is our first audit trial during the registry's launching phase, we make this audit process **simple** and **straightforward**. Expected time for the site audit is **<1 hour**.

Audit Purpose and Objectives

The primary goals of the site audit are:

- 1. Verify Data Accuracy
- 2. Review SAE Adjudication Result
- 3. Confirm the site-specific DAP unit

Audit Process

The audit will focus on **3-5** randomly selected cases from your site. The registry will focus on several key variables to ensure the quality of the data captured: Age, weight, primary cardiac diagnosis, primary procedure type, fluoroscopy time, radiation dosage, Qp:Qs, adverse event.

Next Step

- 1. Please respond to a request scheduling the auditing virtual meeting.
- 2. You will receive the CRISP ID of audited cases. Please prepare the requested documentation (cath report, discharge summary if appliable) in advance of the audit date.
- 3. The registry organizer will send the list of adverse events including SAE adjudication result to the site. The site will kindly review it before the audit.

Appendix

Sites will be grouped into audit Rounds depending on when they joined the registry. We will begin with Round 1 (early participating sites), followed by Rounds 2 and 3 in order of site activation.

- 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		0	•	•	•		*		
8	Duke University			0	•	•			*	
9	University of Minnesota			0	•	•			*	
10	Children's Mercy Hospital Kansas City			0	•	•			*	
11	Wolfson Children's Hospital				•	•			*	
12	Children's Hospital Colorado				0	•			*	
13	Nicklaus Children's Hospital				0	•			*	
14	Central Michigan University, Detroit				0	•			*	
15	Helen DeVos Children's Hospital					0				*
16	University of Virginia					0				*
17	Children's Hospital of New Orleans									*

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