Congenital Cardiovascular Interventional Study Consortium

CRISP Registry - 2025 Annual Report (Benchmark)

7,103	19	3.3%	6.4%
cases submitted in 2025	contributing centers	CMAE rate (95% CI 2.9–3.7)	any adverse event

Executive Summary

The CRISP Registry captured 7,103 catheterization cases across 19 participating centers during calendar year 2025, more than double the 3,193 cases contributed in 2024. Clinically meaningful adverse events (CMAE, defined as adverse event level 3b, 3c, 4 or 5) occurred in 233 cases, a rate of 3.3% (95% CI 2.9–3.7). An adverse event of any severity was recorded in 457 cases (6.4%).

The central finding of this reporting period is stability. Across the eight quarters spanning 2024 and 2025, the quarterly CMAE rate remained within a narrow band of 3.0% to 3.6%, and the confidence interval for every quarter contained the pooled rate. This flat trajectory occurred while the network expanded from 4 centers to 19 and quarterly case volume grew from 427 to 1,869. That the pooled safety signal did not deteriorate as heterogeneous new centers joined is the most meaningful quality observation available from these data.

Risk gradients behaved as expected and support the continued use of the CRISP and CRISA classification systems. CMAE rose monotonically across CRISP strata, from 1.8% in CRISP 1 to 17.7% in CRISP 5 — a roughly tenfold gradient. The CRISA scale showed the same ordering, from 0% in CRISA 1 to 9.7% in CRISA 4. Patient-level risk factors were similarly consistent with clinical expectation: neonates under 30 days (6.7%), patients weighing under 2.5 kg (6.1%), patients receiving prostaglandin (7.7%), ICU inpatients (5.8%) and emergent procedures (8.1%) all carried CMAE rates roughly double the cohort average, whereas elective procedures (2.7%), outpatients (2.6%) and transplant biopsies (0.8%) fell well below it.

Radiation exposure, indexed as dose–area product per kilogram, varied approximately twenty-fold across radiation exposure categories — from a median of 3.2 μGy·m^2/kg for biopsy-only procedures to 70.4 μGy·m^2/kg for high-complexity interventions — confirming that REC stratification is a prerequisite for any valid dose comparison between centers. Quarterly median doses were broadly stable within each category, with the notable exception of diagnostic catheterization, where the median fell from 37.6 μGy·m^2/kg in 2024 Q1 to 19.3 μGy·m^2/kg in 2025 Q4, a reduction of roughly half.

How to read this report

This report presents pooled network-level benchmarks. It is intended to let a participating center locate its own performance within the distribution of contributing centers — not to rank centers against one another.

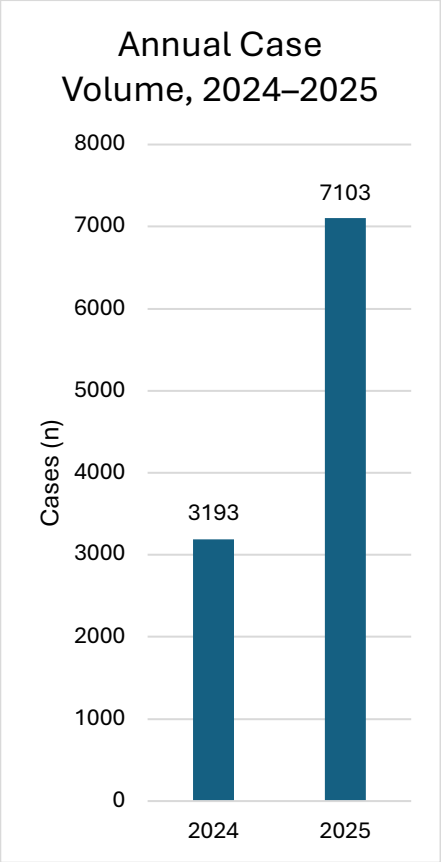
1. Network Participation and Case Accrual

Nineteen centers contributed data by the close of 2025, up from four at the start of 2024. The table below records, by quarter, which centers had a complete dataset and which had initiated case enrollment.

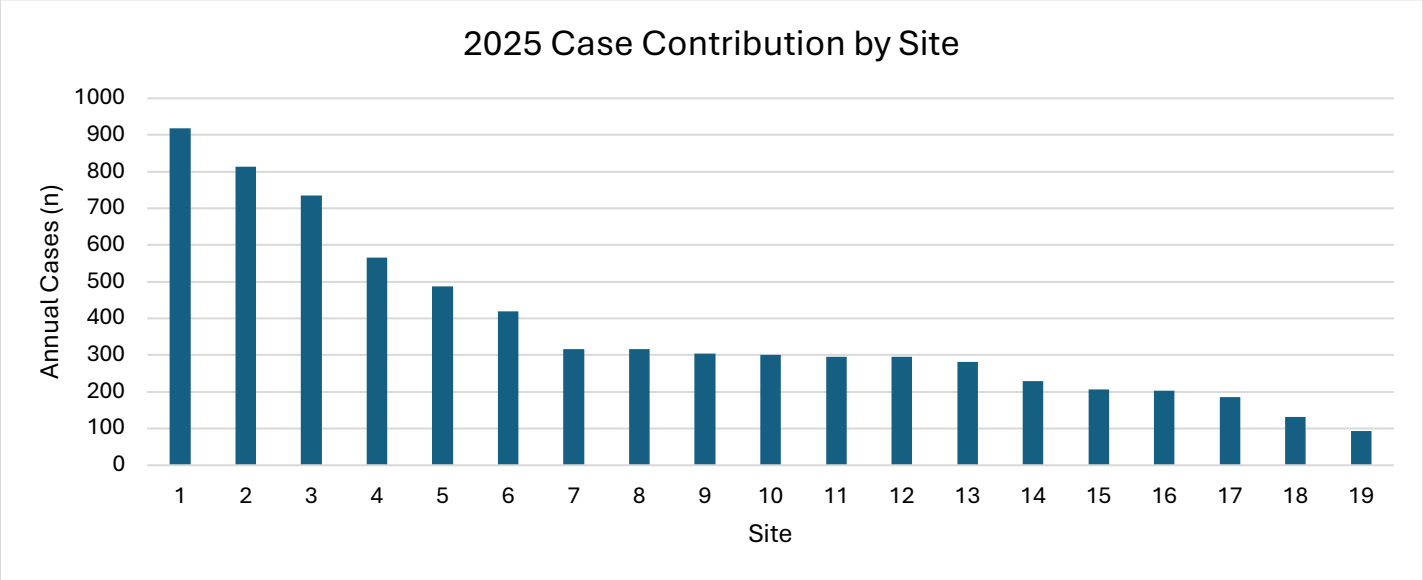
Site Contribution 2024–2025

	2024				2025			
Site	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Joe DiMaggio Children's Hospital	◉	◉	◉	◉	◉	◉	◉	◉
Children's Minnesota	◉	◉	◉	◉	◉	◉	◉	◉
University of Mississippi	◉	◉	◉	◉	◉	◉	◉	◉
Ann Lurie Children's Hospital	◉	◉	◉	◉	◉	◉	◉	◉
Arnold Palmer Hospital for Children		◉	◉	◉	◉	◉	◉	◉
Inova Fairfax Children's Hospital		◉	◉	◉	◉	◉	◉	◉
Atrium Health Levine Children's Hp		○	◉	◉	◉	◉	◉	◉
Duke University			○	◉	◉	◉	◉	◉
University of Minnesota			○	◉	◉	◉	◉	◉
Children's Mercy Hospital Kansas City			○	◉	◉	◉	◉	◉
Wolfson Children's Hospital				◉	◉	◉	◉	◉
Children's Hospital Colorado				○	◉	◉	◉	◉
Nicklaus Children's Hospital				○	◉	◉	◉	◉
Central Michigan University, Detroit				○	◉	◉	◉	◉
Helen DeVos Children's Hospital					○	◉	◉	◉
University of Virginia					○	◉	◉	◉
Advocate Children's Hospital						○	◉	◉
St. Louis Children's Hospital						○	◉	◉
Children's Hospital of New Orleans							◉	◉
Centers with completed data	4	6	7	11	14	16	19	19
Cases submitted (n)	427	670	907	1189	1387	1807	2040	1869

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



Case contribution was uneven across the 19 centers, ranging from approximately 90 to 920 cases (median 300, mean 373). Three high-volume centers each exceeded 700 cases and together accounted for 35% of the registry; the top six accounted for 55%. Seven centers clustered narrowly between 280 and 320 cases, and the remaining six each contributed fewer than 250, together representing 15% of the cohort.



Centers joining mid-year contributed for part of 2025 only; the lowest-volume bars reflect duration of participation rather than program size.

2. Patient and Procedural Characteristics, 2025

	CRISP Registry Benchmark, 2025 (N = 7,103)	
	N (%)	CMAE, N (%)
Patient Location (n=5967)		
Outpatient	3987 (67%)	105 (2.6%)
Inpatient floor	457 (8%)	11 (2.4%)
Inpatient ICU	1523 (26%)	88 (5.8%)
Age group		
<30 days	608 (9%)	41 (6.7%)
30 days to <1 year	1640 (23%)	72 (4.4%)
1 to <18 years	3671 (52%)	78 (2.1%)
≥18 years	1184 (17%)	42 (3.5%)
Weight <2.5 kg	344 (5%)	21 (6.1%)
Weight ≥2.5 kg	6759 (95%)	212 (3.1%)
Single ventricle	1738 (25%)	70 (4.0%)
Biventricle	5365 (75%)	163 (3.0%)
Genetic syndrome, yes	1313 (18%)	48 (3.7%)
Genetic syndrome, no	5790 (82%)	185 (3.2%)
Any comorbidities, yes	3108 (44%)	117 (3.8%)
Any comorbidities, no	3995 (56%)	116 (2.9%)
Systemic illness		
No/mild	5473 (77%)	163 (3.0%)
Moderate	1393 (20%)	60 (4.3%)
Severe	237 (3%)	10 (4.2%)
PGE, yes	365 (5%)	28 (7.7%)
PGE, no	6738 (95%)	205 (3.0%)
Procedure status		
Elective	5771 (81%)	158 (2.7%)
Urgent	1066 (15%)	54 (5.1%)
Emergent	248 (4%)	20 (8.1%)
Salvage	18 (0.3%)	1 (5.6%)
Pre-cath procedure type		
Diagnostic	1752 (25%)	34 (1.9%)
Interventional	4231 (60%)	189 (4.5%)
Transplant biopsy	1106 (16%)	9 (0.8%)
Hybrid	14 (0.2%)	1 (7.1%)
CRISP Category		
CRISP 1	656 (11%)	12 (1.8%)
CRISP 2	2441 (41%)	38 (1.6%)
CRISP 3	1997 (34%)	84 (4.2%)
CRISP 4	720 (12%)	40 (5.6%)
CRISP 5	96 (2%)	17 (17.7%)
CRISA Category		
CRISA 1	97 (8%)	0 (0%)
CRISA 2	572 (48%)	11 (1.9%)
CRISA 3	297 (25%)	10 (3.4%)
CRISA 4	216 (18%)	21 (9.7%)

Patient location was introduced as a data element mid-2025; percentages are computed on the 5,967 cases with location recorded.

3. Adverse Events by Severity, 2025

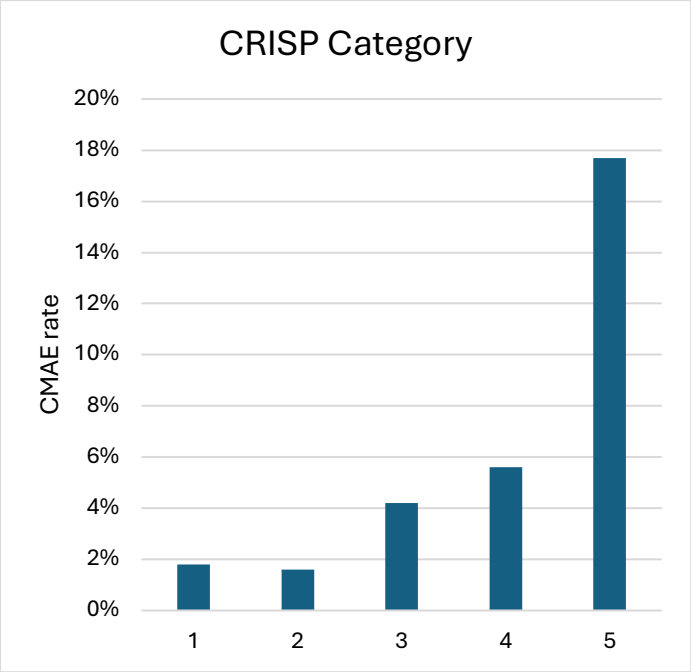
An adverse event of any severity was recorded in 457 of 7,103 cases (6.4%, 95% CI 5.9 – 7.0). The distribution by highest severity level attained is shown below.

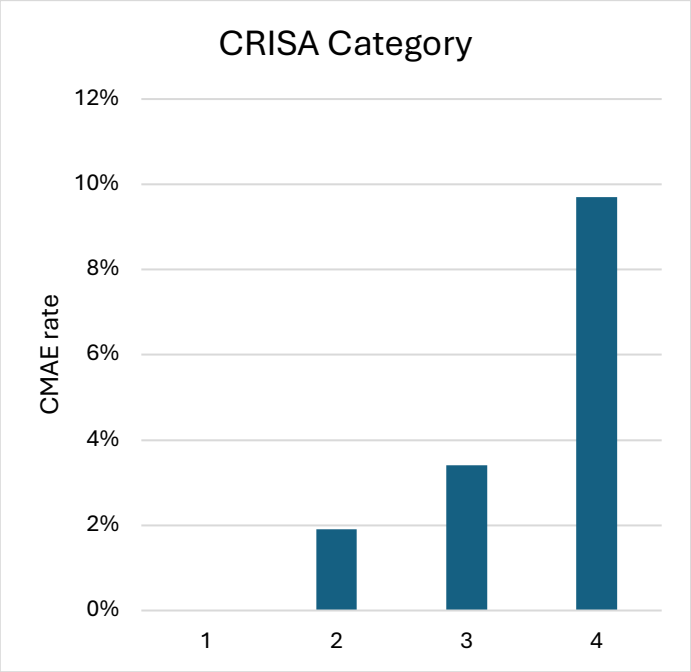
Adverse event severity	n	% of all cases	95% CI
Any adverse event	**457**	**6.4%**	5.9 – 7.0
Level 1 — no therapy, no consequence	12	0.2%	0.1 – 0.3
Level 2 — minor therapy, no consequence	100	1.4%	1.2 – 1.7
Level 3a — moderate, no lasting sequelae	112	1.6%	1.3 – 1.9
Level 3b — moderate, escalation of care	107	1.5%	1.2 – 1.8
Level 3c — moderate, major escalation	64	0.9%	0.7 – 1.1
Level 4 — major, life-threatening	57	0.8%	0.6 – 1.0
Level 5 — catastrophic / death	5	0.1%	0.03 – 0.2
CMAE (levels 3b, 3c, 4 and 5)	**233**	**3.3%**	2.9 – 3.7

4. CRISP and CRISA Risk Prediction Performance, 2025

The observed CMAE gradient supports both instruments. CMAE rose from 1.8% in CRISP 1 to 17.7% in CRISP 5, and from 0% in CRISA 1 to 9.7% in CRISA 4, with each successive stratum carrying a higher rate than the last.

CRISP and CRISA Risk Prediction Performance, 2025





5. Procedure Time and Radiation Dose by CRISP Radiation Exposure Category, 2025

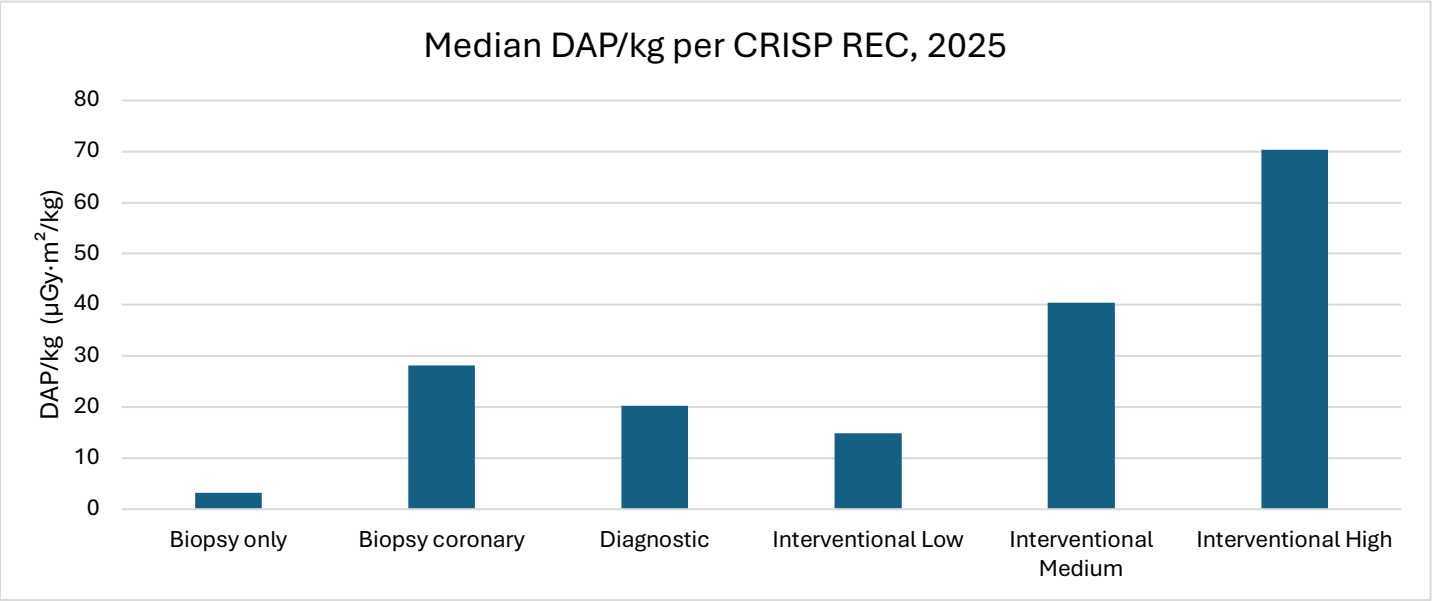
Radiation dose is reported as dose–area product indexed to body weight (DAP/kg, μGy·m^2/kg). All values are medians with interquartile range. The approximately twenty-fold spread in median dose across categories means that comparison of radiation dose between centers is only meaningful within a radiation exposure category.

Radiation exposure category	Cases (n)	% of cohort	Procedure duration (min)	Fluoroscopy time (min)	DAP/kg (μGy·m^2/kg)
Biopsy only	464	6.5%	25 [19, 33]	5.2 [3.5, 7.5]	3.2 [1.7, 7.5]
Biopsy with coronary	551	7.8%	48 [38, 64]	11.4 [9.0, 16.6]	28.1 [16.4, 48.3]
Diagnostic	1,791	25.2%	58 [39, 84]	13.1 [7.2, 22.5]	20.3 [8.1, 47.6]
Interventional, low	1,666	23.5%	55 [38, 81]	12.2 [7.0, 21.3]	14.8 [7.6, 30.6]
Interventional, medium	1,103	15.5%	99 [73, 135]	27.6 [18.0, 41.9]	40.4 [19.8, 79.9]
Interventional, high	564	7.9%	124 [90, 179]	35.0 [24.8, 55.4]	70.4 [37.7, 138.2]
Unclassified	964	13.6%	102 [67, 148]	27.5 [16.0, 44.0]	42.4 [19.7, 87.5]
Total	**7,103**	**100%**	—	—	—

All values are median [interquartile range].

Median DAP/kg spanned a 22-fold range across radiation exposure categories, from 3.2 μGy·m^2/kg for biopsy-only procedures to 70.4 μGy·m^2/kg for high-complexity interventions. This spread far exceeds the corresponding variation in fluoroscopy time (6.7-fold) and procedure duration (5.0-fold), indicating that radiation dose is driven substantially by acquisition mode rather than by procedure length alone. The effect is clearest in biopsy with coronary angiography, which delivered 2.5 μGy·m^2/kg per minute of fluoroscopy — the highest dose intensity of any category — and consequently carried a higher median dose (28.1) than both diagnostic catheterization (20.3) and low-complexity intervention (14.8) despite being the shorter procedure.

Interquartile ranges spanned three- to six-fold within each category and overlapped between adjacent ones, so centers should benchmark against the category IQR rather than the median — exceeding the median is common, falling outside the IQR warrants review.



6. Trends in CMAE and Radiation Dose, 2024–2025

6.1 Clinically meaningful adverse events by quarter

	2024 Q1	2024 Q2	2024 Q3	2024 Q4	2025 Q1	2025 Q2	2025 Q3	2025 Q4
Cases (n)	427	670	907	1,189	1,387	1,807	2,040	1,869
CMAE (n)	14	24	27	38	45	61	67	60
CMAE rate	**3.3%**	**3.6%**	**3.0%**	**3.2%**	**3.2%**	**3.4%**	**3.3%**	**3.2%**
95% CI	2.0–5.4	2.4–5.3	2.1–4.3	2.3–4.4	2.4–4.3	2.6–4.3	2.6–4.1	2.5–4.1

Pooled 2024–2025 CMAE rate: 336 / 10,296 = 3.3% (95% CI 2.9 – 3.6). Quarterly rates ranged only from 3.0% to 3.6%, and the confidence interval for every quarter contained the pooled rate — no change in CMAE over the period, despite growth in the network from 4 to 19 centers and a more than fourfold increase in quarterly case volume.

6.2 Median radiation dose (DAP/kg, μGy·m^2/kg) by quarter

	2024 Q1	2024 Q2	2024 Q3	2024 Q4	2025 Q1	2025 Q2	2025 Q3	2025 Q4
Biopsy only	2.8	3.4	3.4	2.8	3.4	2.9	3.5	3.2
Biopsy with coronary	23.6	27.9	24.5	23.8	31.5	26.5	25.9	28.8
Diagnostic	37.6	34.0	25.6	19.4	18.1	20.5	22.0	19.3
Interventional, low	17.1	18.2	15.7	13.7	17.0	14.0	14.2	14.5
Interventional, medium	45.3	57.7	47.4	48.7	39.0	41.1	42.7	36.8
Interventional, high	66.5	89.4	112.2	79.1	80.5	68.8	67.6	71.7

Median dose was broadly stable within most categories. The exception is diagnostic catheterization, where the median fell from 37.6 μGy·m^2/kg in 2024 Q1 to 19.3 μGy·m^2/kg in 2025 Q4 — a reduction of roughly half, sustained across six consecutive quarters. Whether this reflects genuine dose-reduction practice or a shift in the case mix contributed by newly joined centers cannot be determined from these data.