Pediatric Congenital Heart Disease (CHD) Landscape

Osprey Intel Deep Dive

Osprey Intel LLC

Pediatric Congenital Heart Disease (CHD)

- Pediatric Congenital Heart Disease is an umbrella term for structural heart defects present at birth, along with related complications, arrhythmias, and syndromes.
- CHD can affect various parts of the heart, including the valves, the walls of the heart, or the blood vessels surrounding the heart
- **CHD is the most common birth defect, occurring in about 1 in 100 babies.**
- The severity of these heart defects varies widely: some may cause no symptoms or problems, while others can be critical and life-threatening, requiring early intervention such as surgery
- While there is no cure for CHD, advancements in diagnosis, medical care, and surgical treatments have significantly improved the survival and quality of life for children born with these conditions; many children with CHD now live into adulthood with specialized ongoing care.

Sources: American Heart Association, Centers for Disease Control and Prevention (CDC)

There are many types of pediatric CHDs

Common types:

American Heart Association.

- Aortic Valve Stenosis (AVS)
- Atrial Septal Defect (ASD)
- Coarctation of the Aorta (CoA)
- Complete Atrioventricular Canal defect (CAVC)
- d-Transposition of the Great Arteries
- Ebstein's Anomaly
- Hypoplastic Left Heart Syndrome
- l-Transposition of the Great Arteries
- Patent Ductus Arteriosus (PDA)
- Pulmonary Atresia
- Pulmonary Valve Stenosis
- Single Ventricle Defects
- Tetralogy of Fallot
- Total Anomalous Pulmonary Venous Connection (TAPVC)
- Tricuspid Atresia
- Truncus Arteriosus
- Ventricular Septal Defect (VSD)

CDC U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

- Atrial Septal Defect
- Atrioventricular Septal Defect
- Coarctation of the Aorta*
- Double-outlet Right Ventricle*
- d-Transposition of the Great Arteries*
- Ebstein Anomaly*
- Hypoplastic Left Heart Syndrome*
- Interrupted Aortic Arch*
- Pulmonary Atresia*
- Single Ventricle*
- Tetralogy of Fallot*
- Total Anomalous Pulmonary Venous Return*
- Tricuspid Atresia*
- Truncus Arteriosus*

The types marked with a star (*) are considered critical

MAYO CLINIC

- Atrial septal defect (ASD)
- Atrioventricular canal defect
- Bicuspid aortic valve
- Coarctation of the aorta
- Congenital mitral valve anomalies
- Double-outlet right ventricle
- Ebstein anomaly
- Hypoplastic left heart syndrome
- Partial anomalous pulmonary venous return
- Patent ductus arteriosus (PDA)
- Patent foramen ovale
- Pulmonary atresia
  - ***-with intact ventricular septum***
  - ***-with ventricular septal defect***
- Pulmonary valve stenosis
- Tetralogy of Fallot
- Total anomalous pulmonary venous return (TAPVR)
- Transposition of the great arteries
- Tricuspid atresia
- Truncus arteriosus
- Vascular rings
- Ventricular septal defect (VSD)

Sources: American Heart Association, U.S. Centers for Disease Control and Prevention (CDC), Mayo Clinic

They fall into the general categories described below

A. Septal Defects ("holes")

- Atrial Septal Defect (ASD)
- Ventricular Septal Defect (VSD)
- Atrioventricular Septal Defect (AVSD)

(MedlinePlus: "septal defects," NHLBI: "simple," AHA core)

B. Valve Defects

- Pulmonary Stenosis / Pulmonary Atresia
- Aortic Stenosis / Bicuspid Aortic Valve
- Tricuspid Atresia / Ebstein's Anomaly
- Congenital Mitral Valve anomalies

(Mayo Clinic: "congenital valve problems," MedlinePlus: "valve defects")

C. Defects in Major Vessels

- Coarctation of the Aorta
- Interrupted Aortic Arch
- Patent Ductus Arteriosus (PDA)
- Vascular Rings

(MedlinePlus: "large vessel defects")

D. Abnormal Connections / Mixing Defects

- d-Transposition of the Great Arteries (d-TGA)
- l-Transposition of the Great Arteries (l-TGA)
- Truncus Arteriosus
- Total / Partial Anomalous Pulmonary Venous Return (TAPVR/PAPVR)
- Double-Outlet Right Ventricle (DORV)

(Mayo Clinic: "changes in connections," MedlinePlus: "defects in large blood vessels")

E. Complex / Single Ventricle Syndromes

•Hypoplastic Left Heart Syndrome (HLHS)
•Single Ventricle defects
•Tetralogy of Fallot (TOF)
•Eisenmenger syndrome (secondary)

(NHLBI: "complex/critical"; Mayo: "combination defects")

F. Other / Overlapping Conditions

•Patent Foramen Ovale (PFO) – often incidental
•Eisenmenger syndrome – acquired complication of untreated shunt defects
•Kawasaki disease, Long QT, WPW – not strictly CHDs, but listed by Mayo due to cardiac impact

Sources: National Heart, Lung, and Blood Institute (NHLBI), MedlinePlus, American Heart Association, MedlinePlus, Mayo Clinic

Beyond type, CHDs span a spectrum from mild to life-threatening

VSD overwhelmingly dominates CHD presentations, while ASD and PDA form a secondary tier of frequency. More complex lesions like TOF, AVSD, TGA, and CoA occur far less often, each at well under 1 per 1,000 U.S. births.

Simple

(often mild / asymptomatic)

- Atrial Septal Defect (ASD)
- ***Ventricular Septal Defect (VSD, small/moderate)***
- Patent Ductus Arteriosus (PDA)

Across registries, VSD is the most common CHD (~30–45%), followed by ASD (~8–13%), PDA (~7–10%),

Complex

(cyanotic, abnormal mixing; require repair)

- Tetralogy of Fallot (TOF)
- Transposition of the Great Arteries (TGA)
- Truncus Arteriosus

TOF (~3–7%) and AVSD (~3–5%) less frequent

Critical

(life-threatening in infancy; urgent surgery required)

- Hypoplastic Left Heart Syndrome (HLHS)
- Severe Coarctation of the Aorta (CoA)
- Complete Atrioventricular Septal Defect (AVSD)

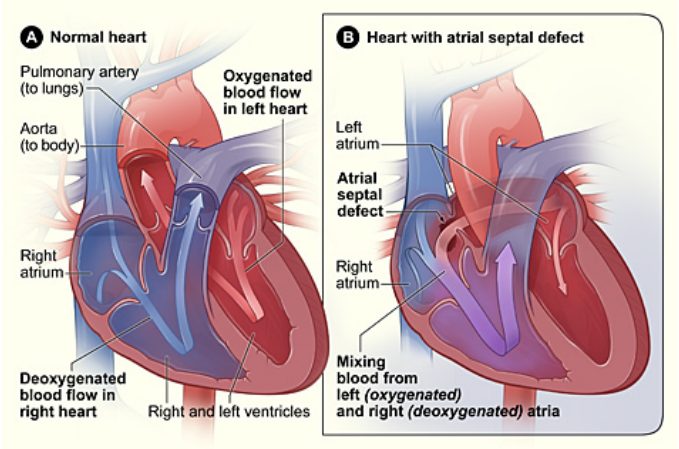
Sources: National Heart, Lung, and Blood Institute (NHLBI), MedlinePlus, American Heart Association

Not all CHDs need intervention. Some simple ones resolve naturally, with no symptoms

Examples of common simple heart defects

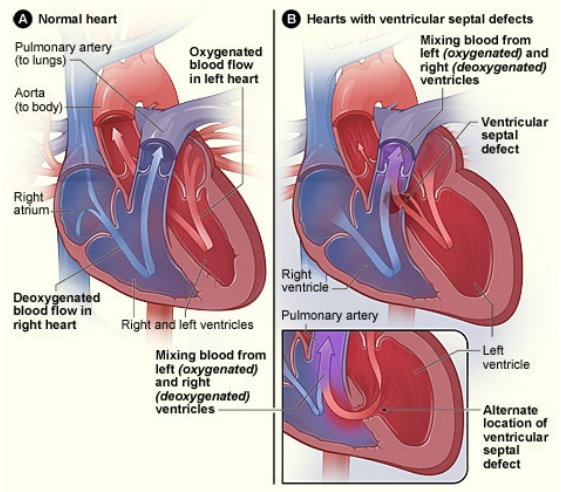
Atrial septal defect

An atrial septal defect is a hole in the wall of the heart between the left and right atria, which are the two upper chambers of the heart. The hole causes blood to flow from the left atrium and mix with the right atrium, instead of going to the rest of the body.
An atrial septal defect is considered a simple congenital heart defect because the hole may close on its own as the heart grows during childhood.



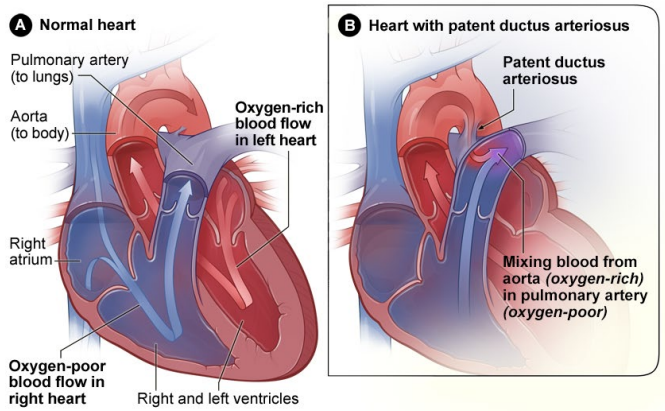
Ventricular septal defect

A ventricular septal defect is a hole in the wall between the left and right ventricles, which are the two lower chambers of the heart. Blood may flow from the left ventricle and mix with blood in the right ventricle, instead of going to the rest of the body. If the hole is large, the heart and lungs may need to work harder to pump blood. In addition, it may cause fluid to build up in the lungs



Patent ductus arteriosus

This common type of simple congenital heart defect occurs when a connection between the heart's two major arteries, the aorta and the pulmonary artery, does not close properly after birth. This leaves an opening through which blood can flow when it should not. In many cases, small openings may close on their own.



Sources: NIH, National Heart, Lung, and Blood Institute (NHLBI), Osprey Intel research and analysis

Complex and critical defects may demand immediate intervention, multiple surgeries, and ongoing management

COMPLEX DEFECTS:

ASSOCIATED WITH CYANOSIS, REQUIRE PLANNED SURGICAL CORRECTION.

- Tetralogy of Fallot (TOF)
  - Causes cyanosis; requires surgical repair
- Transposition of the Great Arteries (TGA)
  - Severe cyanosis, life-threatening without intervention
- Truncus Arteriosus
  - Mixing of blood, heart failure, surgical repair needed

CRITICAL DEFECTS:

LIFE-THREATENING; URGENT NEONATAL SURGICAL INTERVENTION IS NEEDED.

- Hypoplastic Left Heart Syndrome (HLHS)
  - Underdeveloped left heart; fatal without immediate surgical intervention.
- Severe Coarctation of the Aorta (CoA)
  - Leads to heart failure or shock in infants; needs urgent repair
- Complete Atrioventricular Septal Defect (AVSD)
  - Large septal defect with valve clefts, often in Down syndrome; requires surgery

Sources: Mayo Clinic, Cleveland Clinic, National Heart, Lung, and Blood Institute (NHLBI), Osprey Intel research and analysis

Pediatric CHD Standard of Care

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Standard of care in pediatric CHD is early diagnosis, timely intervention, and lifelong follow-up, with ongoing surveillance and transition to adult care

Simple

(often mild in presentation; may resolve spontaneously or require a single intervention)

- Small ASDs often observed; secundum ASDs closed percutaneously; surgery for unsuitable anatomy
- Many monitored; surgery for significant lesions; device closure limited to select muscular VSDs
- Patent Ductus Arteriosus (PDA) Preemies: drug closure; older children: device closure preferred; surgery if unsuitable

Complex

(cyanotic physiology; generally, require early definitive repair)

- Repaired in infancy with VSD closure and RVOT relief; cath interventions as bridge or reintervention
- Neonatal arterial switch is standard; balloon septostomy may stabilize before surgery
- Early repair with VSD closure and RV-PA conduit; conduit replacement expected over time

Critical

(ductal-dependent or life-threatening; require urgent staged or definitive intervention)

- Staged palliation (Norwood → Glenn → Fontan); PGE1 pre-op to maintain ductal patency
- Neonates stabilized with PGE1; surgical repair in neonates, balloon angioplasty/stent in older infants or some neonatal centers
- Early surgical repair in infancy; medical therapy for heart failure as bridge

Sources: National Heart, Lung, and Blood Institute (NHLBI), MedlinePlus, American Heart Association

Treatment modalities in pediatric CHD are medical stabilization, catheter-based therapies, and surgical repair, with staged palliation and transplant in select cases

Simple

(often mild in presentation; may resolve spontaneously or require a single intervention)

- Transcatheter device closure is the preferred method for suitable secundum ASDs, as it avoids open-heart surgery. Many ASDs can be closed percutaneously with an occluder device, which has a high success rate and fewer complications than surgery
- Large VSDs: surgical patch repair (≈1% mortality without PH) to prevent pulmonary vascular disease; device closure only for select muscular/perimembranous VSDs in older infants/children
- PDA: transcatheter closure first-line; surgery if not feasible; 6-month endocarditis prophylaxis

Complex

(cyanotic physiology; generally, require early definitive repair)

- TOF complete repair: VSD patch + RVOT relief (often transannular), typically in infancy; restores oxygenation and relieves RV pressure, with expected chronic pulmonary regurgitation
- TGA: Start PGE1 and perform balloon atrial septostomy to stabilize; definitive neonatal arterial switch (ASO) within 1–2 weeks is standard, with rare alternatives (e.g., Rastelli if ASO contraindicated)
- Truncus arteriosus: neonatal/early-infant one-stage repair (VSD closure + RV-PA conduit); good long-term survival, but predictable conduit/valve reinterventions and lifelong ACHD follow-up.

Critical

(ductal-dependent or life-threatening; require urgent staged or definitive intervention)

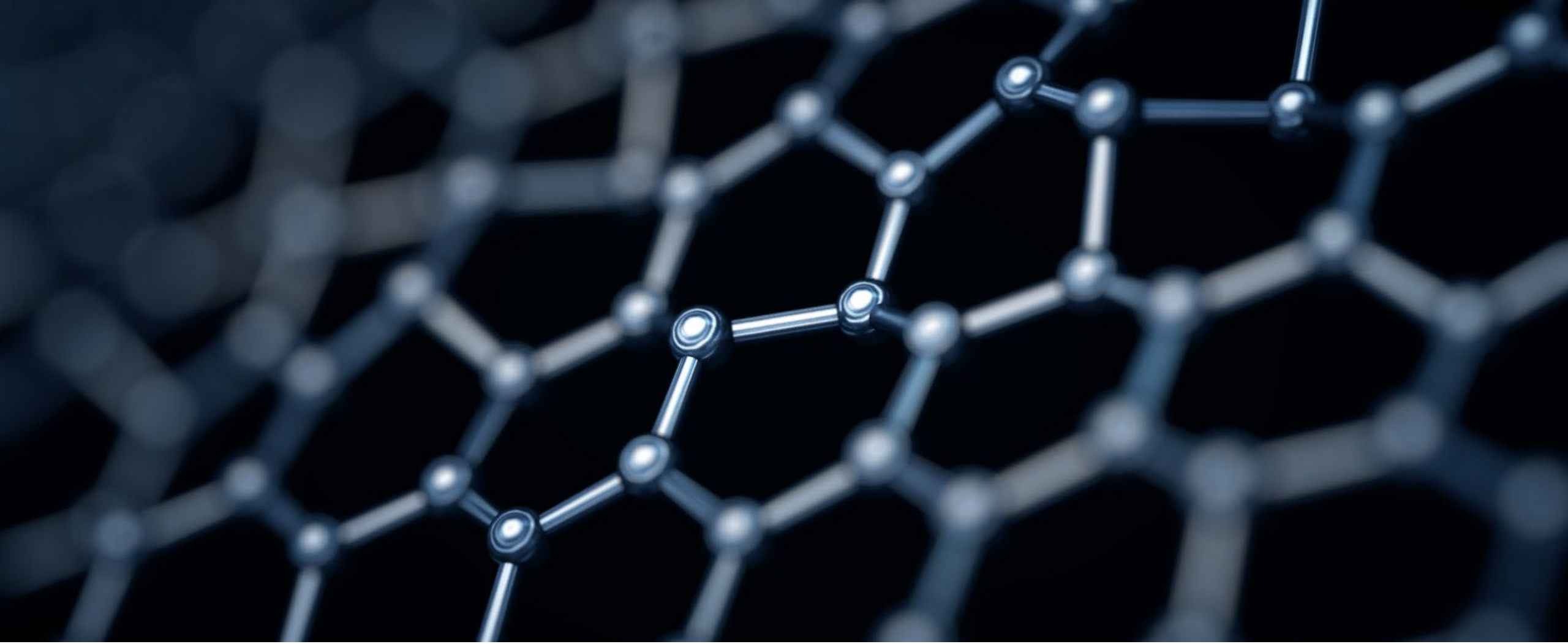
- HLHS treatment: staged palliation – Norwood → Glenn → Fontan (with pre-op PGE1); hybrid Stage I for high-risk neonates; heart transplant if palliation isn't feasible
- Pediatric coarctation: neonatal primary surgical repair; balloon angioplasty for discrete or recurrent lesions in older infants and children
- Complete AVSD treatment: early complete repair in infancy (3–6 months, earlier in Down syndrome); bridge with heart failure medications

Sources: National Heart, Lung, and Blood Institute (NHLBI), MedlinePlus, American Heart Association

Technology & IP Landscape

Osprey Deep Dive

August 18th, 2025



Pediatric CHD Technologies in Development

Osprey Intel Deep Dive

This report outlines the landscape of pediatric CHD, analyzes the current standard of care, and identifies key areas ripe for technological disruption

Our analysis points to three primary investment theses:

1. **Minimally Invasive Devices:** The expansion of transcatheter therapies to treat younger and smaller patients, including novel valve replacement systems and neonatal-specific devices.

2. **Regenerative & Bioresorbable Materials:** The development of implants (stents, valves, grafts) that can be resorbed by the body after guiding tissue regeneration, eliminating the need for future replacement.

3. **Advanced Imaging & AI:** The use of artificial intelligence, 3D modeling, and virtual reality to improve diagnostic accuracy, personalize surgical planning, and predict outcomes.

The pediatric CHD market, while smaller than adult cardiology sectors, is characterized by a high unmet need, dedicated clinical communities, and opportunities for breakthrough innovations that can command premium pricing and capture lifelong patient value.

Clinical Trial analysis reveals three distinct innovation tracks across CHD severity spectrum

Research Methodology

- We analyzed 575 congenital heart disease clinical trials from the ClinicalTrials.gov database as of August 16, 2025
- Using artificial intelligence and natural language processing tools, we categorized these trials based on the type of heart defect being studied, the severity of the condition, the treatment approach, and the stage of research development. Each trial can be verified through its unique government registry number (NCT ID)
    - Among the 176 trials targeting specific heart defects, 43% address simple defects, 33% focus on complex conditions, and 24% tackle critical cases
    - The remaining 399 trials develop platform technologies applicable across multiple defect types rather than single conditions

Simple **ASD/VSD/PDA** (76 case studies, 43%)	• Minimally invasive closures dominate: Transcatheter devices now seal common defects (ASD/VSD/PDA) without open surgery, with bioabsorbable options dissolving after healing complete • AI-enhanced precision: Advanced ultrasound guidance and artificial intelligence tools optimize patient selection and real-time device placement for improved outcomes • Strong safety profile established: Multiple post-market studies confirm long-term effectiveness, driving adoption of catheter-based approaches as first-line therapy
Complex **TOF/TGA/Truncus** (58 case studies, 33%)	• Valve preservation priority: New surgical techniques avoid prosthetic replacements in Tetralogy of Fallot and Transposition cases, eliminating lifelong anticoagulation needs • Hybrid procedures expand options: Combined catheter-surgical approaches stabilize high-risk patients and enable staged repairs with reduced mortality • 3D planning transforms outcomes: CT/MRI fusion imaging creates patient-specific surgical roadmaps, reducing operative time and improving repair durability
Critical **HLHS/CoA /AVSD** (42 case studies, 24%)	• Multi-stage palliation refined: Hybrid Stage I procedures combining stents and surgery improve survival for single-ventricle patients like Hypoplastic Left Heart Syndrome • Regenerative medicine breakthrough potential: Stem cell trials show promising early results for strengthening underdeveloped heart muscle in HLHS patients • Lymphatic interventions address complications: Novel treatments target protein-losing enteropathy and plastic bronchitis in post-Fontan patients, improving quality of life

Sources: ClinicalTrials.gov, Osprey Intel research and analysis

CHD trial pipeline is imaging-led, device-driven, digitally stacked, with near-term approvals concentrated on MedTech rather than drugs

Heart Defects, Congenital (575 studies)

Leading Intervention Types

- Diagnostic/Imaging leads the taxonomy (≈414 records): echo/CT/MRI protocols and peri-op imaging dominate evidence generation
- Devices and procedures are the next tier (≈228 devices; ≈208 surgical/hybrid), centered on occluders, stents, transcatheter valves, and neonatal delivery systems
- Drug/biologic trials are a minority (≈98), typically peri-op adjuncts or physiology support rather than primary therapy

Trial Phases Distribution

- Phases are frequently "N/A" for devices/observational studies (≈200+), reflecting the medtech/digital tilt of the pipeline
- Where phases apply (drugs/biologics), activity clusters in Phase 2–3 (~27 vs ~25), with a smaller Phase 1/Early tail (~20 combined) and limited Phase 4 (~16)
- **Implication:** Near-term approvals will skew device-side; drug programs show thinner late-phase activity

Geographic Site Leadership

- U.S. hosts the largest share (≈185 studies with listed sites), followed by China (≈59) and EU hubs (France 56, Italy 49, Germany 32, UK 34); Canada 49
- Trials are predominantly multicenter and transatlantic; pivotal MedTech programs concentrate in U.S.–EU KOL networks

Technology Modalities in Trials

- Imaging/diagnostics dominate (≈414), with AI/digital/remote rapidly rising (≈273), especially for interstage monitoring and decision support
- Medtech remains robust (≈228 devices; ≈208 surgical/hybrid), aligned to structural lesion repair/reintervention
- Modalities are often stacked (imaging + device + digital), enabling faster evidence cycles and payer-relevant endpoints (readmissions, LOS, reinterventions avoided)

NIH National Library of Medicine
National Center for Biotechnology Information

Search Results

Viewing 101-200 out of 575 studies

Showing results for: **Heart Defects,Congenital | Not yet recruiting, Recruiting, Active, not recruiting studies**

— Synonyms of conditions or disease (35)

heart ; Cardiac ; coronary ; Hearts ; Heart structure ; Cardiac structure

heart defects congenital ; Congenital Heart Disease ; Congenital Heart Defects ; Congenital Heart Defect ; Congenital Heart Diseases ; cardiac anomaly ; congenital cardiac defect ; Heart malformations ; Congenital cardiac defects ; cardiac congenital defects ; Cardiac anomalies ; Malformation Of Heart ; Congenital cardiac anomalies ; heart anomaly

defects congenital ; Abnormalities ; Congenital Abnormalities ; dysgenesis ; Deformities ; anomaly ; malformation ; CONGENITAL ANOMALIES ; Birth Defects ; Congenital malformation ; Birth Defect ; Congenital Defects ; Deformity ; congenital malformations ; dysmorphism ; fetal anomaly ; Congenital anomaly

congenital ; Congenita

Selected | Download | Save

Study Title	NCT Number	Status	Conditions	Interventions
Electronic Archive of Patients With Diagnosis and Suspected Prenatal Diagnosis of Aortic Coarctation	NCT06759103	Recruiting	• Aortic Coarctation	
Value of MRI in **Congenital Heart Disease**	NCT06752187	Not yet recruiting	• **Congenital Heart Disease**	
A Comparison of Multidetector CT and TE in the Diagnosis of **Congenital** Cyanotic **Heart** Diseases	NCT06749548	Active, not recruiting	• **Congenital Heart Disease**	• Radiation: Group 1
AI-enabled Screening and Diagnosis of Cardiomyopathies Using **Coronary** CTA	NCT06748261	Not yet recruiting	• Cardiovascular Diseases • Hypertrophic Cardio	• Diagnostic Test: CCTAI model

Notes: Dataset = ClinicalTrials.gov ("Heart Defects, Congenital"), open statuses; 575 records; JSON analyzed 8/16/2025, Counts are non-exclusive ("stacked") across 575 studies; many trials span multiple categories. Severity mix uses a lesion-explicit subset (N=176); remainder are cross-cutting or multi-lesion.

Pediatric CHD trials: early-stage drugs & process-heavy; near-term traction in devices, imaging, and surgical–digital hybrids

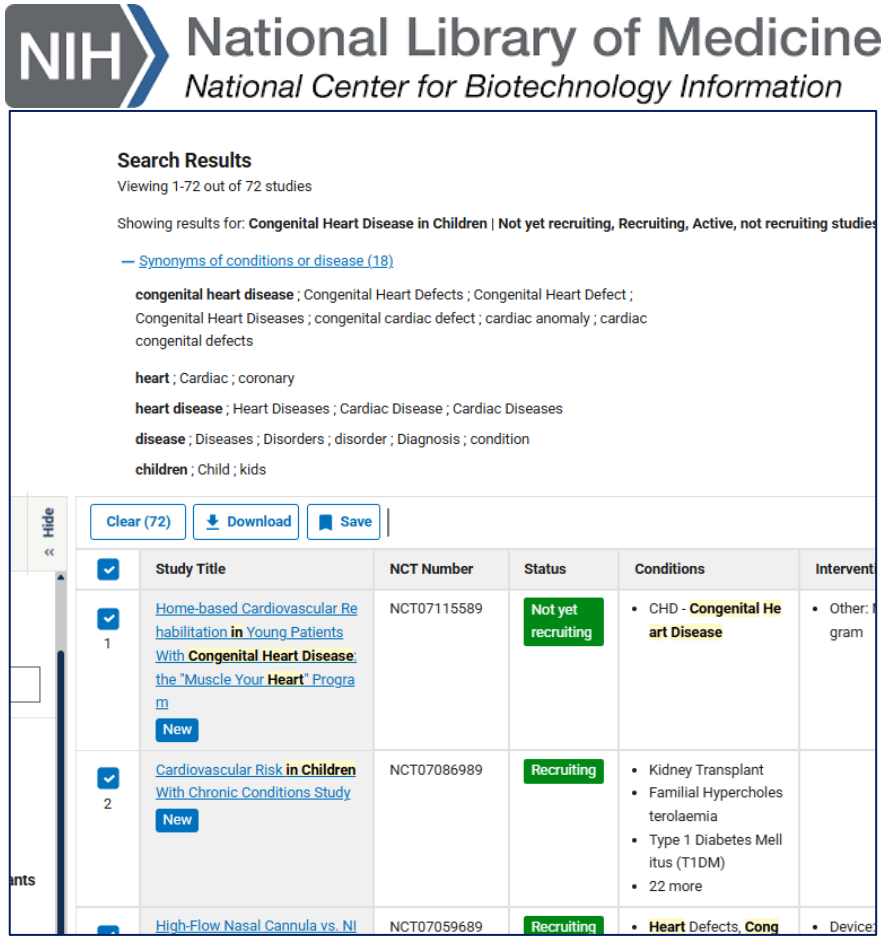
Congenital Heart Disease in Children (72 studies)

Leading Intervention Types
- Interventional 40 (56%) vs Observational 32 (44%) → active treatment/evaluation dominates
- Top mentions: Drug 24, Behavioral 13, Device 10, Diagnostic test 9 (CT.gov "Other" 25 = care-path/process trials)
- Implication: Pediatric CHD "open" pipeline tilts to process/drug over brand-new devices in this narrow query

Trial Phases Distribution
- N/A (device/observational): ~60/72 → many studies don't use drug phases
- Drugs are thin in late stage: Ph2 = 5, Ph3 = 5, EP1 = 2, P1 = 1, P4 = 1
- Implication: Near-term approvals skew device/diagnostic; pharmacotherapy is earlier-stage

Geographic Site Leadership
- United States 20, Canada 8, France 7, China 6, Korea 5, Germany 5, Netherlands 5
- Multicenter 29%; multicountry 12%
- Recency: 92% last updated 2024–25; Enrollment: median 125 (IQR 80–300); Top sponsors: Assiut Univ (4), Stanford (3), Seoul Nat'l Univ Hosp (3), China NCCVD (3), Boston Children's (3)

Technology Modalities in Trials
- Surgical/Hybrid 35, Drug/Bio 17, Imaging 15, Device 11, AI/Digital 8
- Implication: Modalities are stacked (procedure + imaging + digital), favoring shorter evidence cycles



Notes: Dataset = ClinicalTrials.gov query "Congenital Heart Disease in Children" (open studies), 72 records; JSON analyzed 8/18/2025, counts are non-exclusive ('stacked') across 72 studies; many trials span multiple categories

Market Sizing & Forecasts

Osprey Deep Dive

August 18th, 2025

Global incident-year, device-only CHD market is ~$0.5B–$5.3B (base ≈ $2.4B), patches dominate spend; occluders and conduits are secondary, with figures anchored on conservative price floors

A Incidence (Population Baseline) CHD incidence: ~1% of live births globally (WHO/CDC).

- Example: U.S. ~3.6M births/year → ~36,000 infants with CHD annually.EU (~4.0M births/year → ~40,000 cases).Israel (~180k births/year → ~1,800 cases).

B Severity split: Critical 25%, Moderate 35%, Mild 40%.

- Intervention rates: Critical ~100%; Moderate 30–40%; Mild 5–15%.
  - Critical: 330,000 cases → ~330,000 device-treatable
  - Moderate: 462,000 cases → ~138,600 to 184,800 device-treatable
  - Mild: 528,000 cases → ~26,400 to 79,200 device-treatable
- Total device-treatable (annual incident): ~495,000 to 594,000 Share of incident CHD device-treatable: ~37.5% to 45%

C Device price bands (AU Prescribed List–anchored floors)*

- Septal occluders (ASD/PFO/VSD): ~$4,500–$6,500
- Pulmonary valve conduits (surgical; pediatric sizes): ~$4,000–$6,000
- Patches (VSD/ASD): ~$399–$6,509
- Mechanical valves (<21 mm): ~$3,200–$5,500

D Calculation Example (U.S, incident-yr., device-only.)36,000 new CHD births

- Device-treatable share: 37.5–45% → 13,500–16,200 treated infants
- Procedures per treated infant (year 1): 1.05–1.20 → ~14,175–19,440 device procedures. Blended device price floor: $5,000 (stress-test $6,000)Incident-year device spend: ~$71–$97M @ $5k (or ~$85–$117M @ $6k)

Step A. Incidence (Population Baseline)

Annual births (global)		CHD Incidence		New CHD cases/year
~132 million	✖	**~1%**	=	**~1.3 million**

Step B. Severity split and intervention rates

Critical	Moderate	Mild
100% require intervention = 330k cases/yr	**30-40% require intervention = 139-185k cases/yr**	**5-15% require intervention = 26-79k cases/yr**

Step C. Device price bands (AU Prescribed List–anchored floors)*

Septal occluders	Pulmonary valve conduits	Patches	Mechanical valves (<21 mm)
~$4.5k–$6.5k	**~$4k–$6k**	**~$399–$6.5k**	**~$3.2k–$5.5k**

Step D. Calculation Example (Global)

Critical	Moderate	Mild
Critical ($243.3M to $3.1B)	**Moderate ($189M to $1.6B)**	**Mild ($74M to $619M)**

Notes: *Device-only hospital acquisition price floors anchored on Australia's Prescribed List (Jul-2024) and cross-checked with US VA FSS contractor price lists (NAC Catalog) and NHS Supply Chain frameworks/NPMs; excludes procedural costs and hospital markups. Use as conservative floors, not ASPs. Critical CHD is ~25% of CHD and generally requires surgery or catheter intervention in the first year (treated here as ~100% intervention for incident modeling).

A

Global & Regional Birth Estimates with CHD Incidence (2024)

Global TAM baseline: ~132M births in 2024 → ~1.3M new CHD cases per year

SAM (U.S./EU/Israel): ~73k new CHD cases annually (36k U.S. + ~35k EU + 1.8k Israel)

EU 2024 births: Estimated at ~3.53M (range: 3.49–3.56M), applying a moderated decline assumption (–2% to –3%). Official Eurostat 2024 release expected in 2026

Consensus across epidemiology and public health agencies (WHO, CDC, NIH) and peer-reviewed meta-analyses supports using **~1% incidence of CHD per live birth as the global baseline***

Prevalence impact: >2M living with CHD in the U.S. alone — interventions are not limited to newborns

Consistency: This incidence-driven baseline anchors TAM → SAM → SOM modeling, ready for Step B (intervention rates) and Step C (device prices)

Region / Metric	2023 Estimate	2024 Estimate	CHD Incidence (~1%)	Sources
Global Births	~131M (UN WPP 2023)	~132M	**~1.3M new CHD cases/year**	UN WPP; Our World in Data; Database.earth
U.S. Births	3,596,017	3,628,934 (+1%)	~36,000 new CHD cases/year	CDC FastStats; NCHS DB 507 & 535
EU Births (EU-27)	3.67M	~3.53M (estimated, –2% to –3% decline from 2023)	~35,000 new CHD cases/year	Eurostat; Brussels Times; ScienceAlert (AFP)
Israel Births	~178,000	~181,000	~1,800 new CHD cases/year	Israel National News; JFeed; CBS
CHD Prevalence (U.S.)	>2M living with CHD	>2M (stable)	n/a	CDC; AHA Bethesda; CDC 2010

Sources: WHO/CDC/EUROCAT/EUROlinkCAT for incidence + severity + intervention, AU Prescribed List (with VA FSS/NHS) for prices, and registry/literature for re-intervention

B

From Incidence to Intervention – How Critical, Moderate, and Mild Cases Convert to Device Demand

Severity split and intervention rates

- **Critical CHD ≈ 25% → ~100% intervention (first year)**
  • CDC: ~1 in 4 babies with CHD have *critical* CHD and generally need surgery or other procedures in the first year of life. (CDC Congenital Heart Defects – Data & Statistics)

- **Moderate CHD → 30–40% intervention by childhood (conservative)**
  • EUROCAT (pan-European): For the common "non-severe" cluster (VSD/ASD/PVS), less than 10% required surgery in early life; overall ~1 in 6 liveborn CHD cases ultimately required surgery. This sets a surgery-only floor. (EUROCAT Special Report: CHD in Europe 2000–2005)
  • Modern practice adds catheter interventions (e.g., ASD device closure, balloon valvuloplasty for PS), raising the treated share beyond surgery alone; ACC/ESC guidance reflects widespread percutaneous use in appropriate lesions. (ACC pediatric pulmonary stenosis algorithm; ESC adult congenital guidance)
  • EUROlinkCAT (multi-region) reports wide *regional variation* in proportions of children with less-severe CHD undergoing surgical/interventional correction through childhood – supports using ranges rather than a single point estimate.

- **Mild CHD → 5–15% intervention (conservative)**
  • CDC notes milder defects are increasingly detected but are less likely to require intervention; a small subset (e.g., hemodynamically significant PDA/ASD, select monitoring devices) remains device-addressable.
- *Context:* UK NICOR congenital audit tracks sustained high catheter activity alongside surgery; used here as system-capacity context rather than to anchor a specific crossover year.

1

Lifetime Interventions per Patient
- Average 2–3 device interventions per patient over a lifetime.
- Repeat interventions are common due to growth, device degradation, or complications.
- Some subsegments (e.g., valves, conduits) require multiple replacements as the child grows.

2

Spectrum of Device Use
- **Structural repair devices:** septal occluders, patches.
- **Valve/conduit replacements:** pulmonary valve conduits, mechanical/biologic valves.
- **Catheter-based adjuncts**: stents, shunts, balloons.
- **Digital health / monitoring**: implantable monitoring systems, remote telemetry.

Sources: WHO/CDC/EUROCAT/EUROlinkCAT for incidence + severity + intervention, AU Prescribed List (with VA FSS/NHS) for prices, and registry/literature for re-intervention

B

Devices don’t grow; durability is finite; stents need upsizing, so many CHD patients require ~2–3 device procedures by adolescence. Valves/conduits and PA stents drive most repeats

1

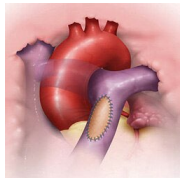
Lifetime interventions per patient

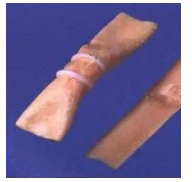
Key drivers of repeat interventions

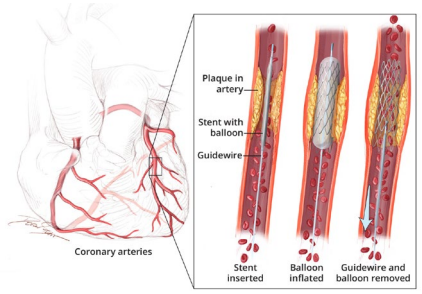
1. **Transcatheter pulmonary valve (TPV) durability → repeat procedures:**
   - Long-term Melody TPV follow-up shows freedom from reintervention ~60% at 10 years (i.e., ~40% require another transcatheter or surgical intervention by 10 years), reflecting finite durability and complications such as stent fracture/endocarditis**. This underpins multiple valve/conduit procedures over a patient’s course**
2. **RVOT conduits don’t grow and degenerate over time → multiple replacements:**
   - Reviews of valved conduits (homograft, Contegra, PTFE) emphasize lack of growth and structural degeneration as “major limitations,” leading to reintervention/replacement as children grow. Pediatric series specifically analyze risk factors for earlier explant/reintervention.
   - Together, these establish the expectation of **serial conduit/valve replacements** (often ≥2 over childhood–young adulthood)
3. **Serial stent management in growing children:**
   - Classic and contemporary literature on pulmonary artery (PA) stents documents planned serial (re)dilations to accommodate somatic growth, plus occasional redilation for restenosis – i.e., repeat catheter procedures are part of standard longitudinal care

High-activity subsegments requiring repeat interventions

1. **Transcatheter pulmonary valves:** Real-world longitudinal data show **meaningful reintervention rates by 8–10 years**, consistent with the need for **multiple lifetime valve procedures**.
2. **Pulmonary valves & RVOT conduits:** Lack of somatic growth and durability limits → **planned replacements/reinterventions** over time. (Homograft/xenograft/PTFE reviews; pediatric JTCVS analyses.)
3. **Branch PA stents: Re-dilation/expansion** to keep pace with vessel growth is a routine part of follow-up in children. (JACC/Heart studies; interventional reviews.)







Sources: WHO/CDC/EUROCAT/EUROlinkCAT for incidence + severity + intervention, AU Prescribed List (with VA FSS/NHS) for prices, and registry/literature for re-intervention

C

Intervention Stack: Occluders • Conduits • Adjuncts • Monitoring

2 *Spectrum of Device Use*

Structural Repair Devices

- **Transcatheter ASD Occluders:** Amplatzer Septal Occluder, high success rates, standard for secundum ASD closure
- **VSD Occluders:** Lifetech KONAR-MF™ multifunctional occluder successfully deployed in infants and children
- **PDA Closure Devices:** Amplatzer Piccolo Occluder FDA-approved for premature infants

Valve / Conduit Replacements

- **RVOT and Pulmonary Valved Conduits:** Conduits inevitably require replacement as children grow
- **Transcatheter Pulmonary Valves (Melody Valve):** Long-term follow-up shows significant reintervention rates by 8–10 years

Catheter-Based Adjuncts (Stents, Shunts, Balloons)

- **Stents in Pediatric CHD**: Revolutionized treatment for congenital vessel stenoses
- **Pediatric Stent (“Minima”)**: FDA-approved for infants; expandable into adulthood
- **Balloon and Hybrid Procedures**: Case reports highlight catheter closure of CHD lesions without open surgery

Digital Health / Monitoring (Implantable & Remote)

- **CIED Remote Monitoring**: >80% compliance in pediatric CHD patients, integral to long-term management
- **Implantable Cardiac Monitors**: Used for rhythm surveillance in CHD patients
- **Wearable Biosensors**: Armband/wearable technology enables at-home monitoring

Sources: WHO/CDC/EUROCAT/EUROlinkCAT for incidence + severity + intervention, AU Prescribed List (with VA FSS/NHS) for prices, and registry/literature for re-intervention

D

Modeling the 330k critical cases → device mix (first-year incident only)

C

Device counts (by scenario) ***Spend***

Device	Conservative	Base	Aggressive	Prices (USD) (L/M/H)	Low	Base	High
Pulmonary valved conduits	26,400	39,600	49,500	**$4k/$5k/$6k**	$106M	$198M	$297M
Patches *(patients × patches/patient)*	198,000 × 1.3 = **257,400**	231,000 × 1.4 = **323,400**	247,500 × 1.6 = **396,000**	**$399/$3.5k/$6.5k**	$103M	$1.1B	$2.6B
Septal occluders	6,600	16,500	26,400	**$4.5k/$5.5k/$6.5k**	$30M	$91M	$172M
Mechanical valves (<21 mm)	1,650	3,300	6,600	**$3.2k/$4.4k/$5.5k**	$5.3M	$14.4M	$36M
Totals	**-**	**-**	**-**	**-**	**$243.3M**	**$1.42B**	**$3.1B**

- **Pulmonary valved conduits (surgical)** – used for RVOT reconstructions (e.g., **truncus, PA+VSD, TOF variants**). Penetration varies by lesion mix and center practice → **8% / 12% / 15%** of critical CHD. 1 conduit per treated patient
- **Patches** – ubiquitous across complex repairs; many patients get **>1** patch → **60% / 70% / 75%** penetration with **1.3 / 1.4 / 1.6** patches per treated patient
- **Septal occluders** – limited role in neonatal "critical" presentations (more common for secundum ASDs/PFO later); assume small first-year use for residual defects/staged strategies → **2% / 5% / 8%**; **1** per treated patient
- **Mechanical valves (<21 mm)** – **rare** in infants; used when repair isn't feasible → **0.5% / 1% / 2%**; **1** per treated patient

Sources: Counts from CDC/EUROCAT/STS/NCDR/NICOR + FDA; spend from AU Prescribed List floors, cross-checked VA FSS/NHS; device-only, floors not ASPs.

D

Moderate Severity – Incident Device Spend (30–40% intervention; 138,600–184,800 Pts)

C

Device counts (by scenario) ***Spend***

Device	Conservative	Base	Aggressive	Prices (USD) (L/M/H)	Low	Base	High
Pulmonary valved conduits	1,386	3,234	5,544	**$4k/$5k/$6k**	$5.6M	$16M	$33.3M
Patches *(patients × patches/patient units)*	66,528	105,105	155,059	**$399/$3.5k/$6.5k**	$27M	$363M	$1B
Septal occluders	36,450	56,595	83,160	**$4.5k/$5.5k/$6.5k**	$156M	$311M	$541M
Mechanical valves (<21 mm)	277	809	1,848	**$3.2k/$4.4k/$5.5k**	$0.9M	$3.5M	$10M
Totals	-	-	-	-	**$189M**	**$694M**	**$1.6B**

- **Pulmonary valved conduits:** far less common than in critical; **1% / 2% / 3%** penetration; 1 per treated patient.
- **Patches:** widely used but less intense than critical; **40% / 50% / 60%** penetration with **1.2 / 1.3 / 1.4** patches/patient.
- **Septal occluders:** more prominent here; **25% / 35% / 45%** penetration; 1 per treated patient.
- **Mechanical valves:** rare; **0.2% / 0.5% / 1.0%**.
- **Scope:** incident-year only; device-only (no procedural costs); excludes transcatheter pulmonary valves.

Sources: Counts from CDC/EUROCAT/STS/NCDR/NICOR + FDA; spend from AU Prescribed List floors, cross-checked VA FSS/NHS; device-only, floors not ASPs.

D

Mild Severity – Incident Device Spend (5–15% Intervention; 26,400–79,200 Pts)

C

Device counts (by scenario) ***Spend***

Device	Conservative	Base	Aggressive	Prices (USD) (L/M/H)	Low	Base	High
Pulmonary valved conduits	0	264	792	**$4k/$5k/$6k**	-	$1.3M	$4.8M
Patches *(patients × patches/patient units)*	5,808	15,840	30,888	**$399/$3.5k/$6.5k**	$2.3M	$55M	$201M
Septal occluders	15,840	36,960	63,360	**$4.5k/$5.5k/$6.5k**	$72M	$203M	$412M
Mechanical valves (<21 mm)	0	53	158	**$3.2k/$4.4k/$5.5k**	-	$231K	$869K
Totals	**-**	**-**	**-**	**-**	**$74M**	**$260M**	**$619M**

- **Septal occluders: 60% / 70% / 80%** penetration; **1** per patient.
- **Patches: 20% / 25% / 30%**; **1.1 / 1.2 / 1.3** patches per patient.
- **Pulmonary valved conduits: 0% / 0.5% / 1%** (rare in mild).
- **Mechanical valves: 0% / 0.1% / 0.2%** (very rare).
- Scope stays the same: **incident-year, device-only**, AU Prescribed List–anchored floors; excludes transcatheter PV systems and all procedural costs/markups.

Sources: Counts from CDC/EUROCAT/STS/NCDR/NICOR + FDA; spend from AU Prescribed List floors, cross-checked VA FSS/NHS; device-only, floors not ASPs.

Regulatory & Policy Context

Custom interactive AI dashboard: global regulatory landscape for pediatric CHD devices

Osprey Deep Dive

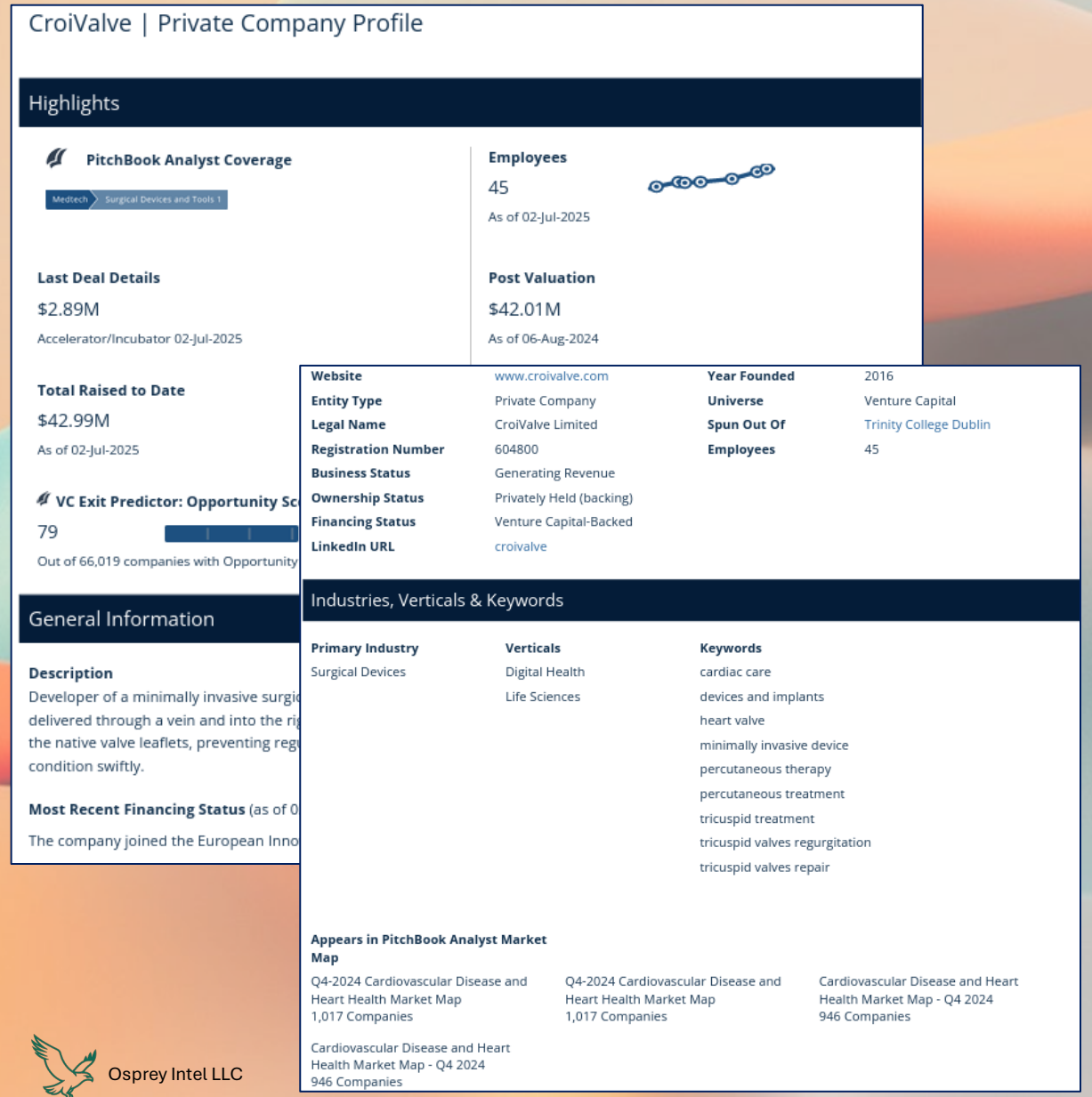
August 18th, 2025

Strategic Positioning & White Space

[Custom interactive AI dashboard: pediatric CHD investment white space analysis]

Osprey Deep Dive

August 18th, 2025



CroiValve | Private Company Profile

Highlights

PitchBook Analyst Coverage

Medtech › Surgical Devices and Tools 1

Employees

45

As of 02-Jul-2025

Last Deal Details

$2.89M

Accelerator/Incubator 02-Jul-2025

Post Valuation

$42.01M

As of 06-Aug-2024

Total Raised to Date

$42.99M

As of 02-Jul-2025

VC Exit Predictor: Opportunity Sc

79

Out of 66,019 companies with Opportunity

Website	www.croivalve.com	Year Founded	2016
Entity Type	Private Company	Universe	Venture Capital
Legal Name	CroiValve Limited	Spun Out Of	Trinity College Dublin
Registration Number	604800	Employees	45
Business Status	Generating Revenue		
Ownership Status	Privately Held (backing)		
Financing Status	Venture Capital-Backed		
LinkedIn URL	croivalve		

General Information

Description

Developer of a minimally invasive surgi
delivered through a vein and into the ri
the native valve leaflets, preventing reg
condition swiftly.

Most Recent Financing Status (as of 0

The company joined the European Inno

Industries, Verticals & Keywords

Primary Industry	Verticals	Keywords
Surgical Devices	Digital Health	cardiac care
	Life Sciences	devices and implants
		heart valve
		minimally invasive device
		percutaneous therapy
		percutaneous treatment
		tricuspid treatment
		tricuspid valves regurgitation
		tricuspid valves repair

Appears in PitchBook Analyst Market Map

Q4-2024 Cardiovascular Disease and Heart Health Market Map
1,017 Companies

Q4-2024 Cardiovascular Disease and Heart Health Market Map
1,017 Companies

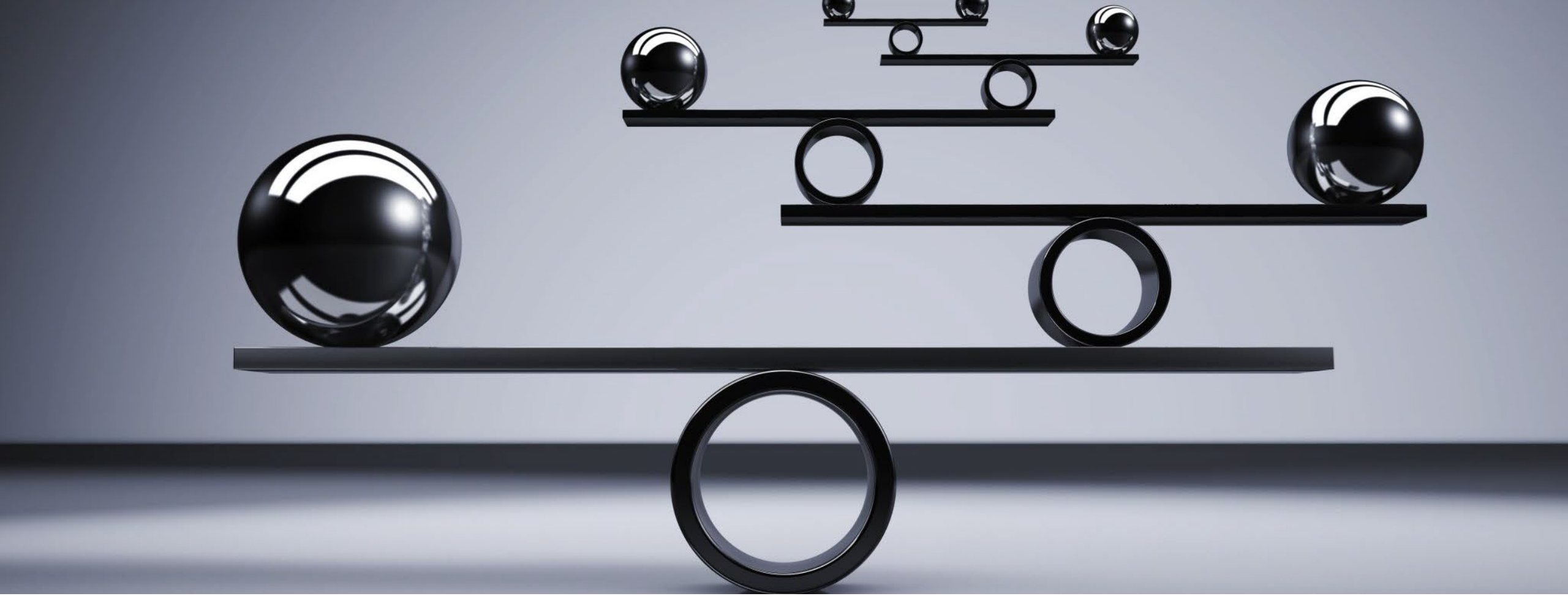
Cardiovascular Disease and Heart Health Market Map - Q4 2024
946 Companies

Cardiovascular Disease and Heart Health Market Map - Q4 2024
946 Companies

CroiValve

Industries, Verticals & Keywords

- Primary Industry
  - Surgical Devices
- Verticals
  - Digital Health
  - Life Sciences
- Keywords
  - cardiac care
  - devices and implants
  - heart valve
  - minimally invasive device
  - percutaneous therapy
  - percutaneous treatment
  - tricuspid treatment
  - tricuspid valves regurgitation
  - tricuspid valves repair



Sources

Health authorities & NGOs
•World Health Organization (WHO)
•U.S. Food & Drug Administration (FDA)
•National Institutes of Health (NIH)
•U.S. Centers for Disease Control and Prevention (CDC)
•United Nations Data (UN Data)

Professional societies & journals
•American Heart Association (AHA)
•Journal of the American Heart Association

Medical & academic institutions
•Mayo Clinic
•Johns Hopkins Medicine

Private markets & investor intelligence
•PitchBook
•WSJ Pro VC/PE

Companies (industry)
•Medtronic

Market research & business information
•IBISWorld
•Technavio
•BCC Research
•MarketLine Advantage
•Statista

Scholarly literature platforms & indexes
•PubMed
•ScienceDirect
•Scopus
•Web of Science

Clinical trials registry
•ClinicalTrials.gov

AI Tools

•ChatGPT 5
•Claude Opus 4.1
•Gemini 2.5 Pro