

Computational Fluid Dynamics in Cardiovascular Devices

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ABSTRACT

Computational fluid dynamics has become integral to the design and regulatory evaluation of cardiovascular devices, from prosthetic heart valves to ventricular assist devices, yet the fidelity and clinical relevance of CFD simulations vary widely across device categories and modelling approaches. We assessed 226 CFD-for-cardiovascular-device programmes conducted across biomedical engineering centres in Italy, Germany, and Estonia between 2014 and 2024, spanning five device categories: bioprosthetic heart valves, mechanical heart valves, ventricular assist devices, coronary stents, and aortic endografts. A CFD Cardiovascular Device Maturity Index (CCDMI) was constructed from five sub-scores -- haemodynamic prediction accuracy, thrombogenicity modelling fidelity, patient-specific geometry incorporation, experimental validation completeness, and regulatory submission integration -- with weights from regression against progression to regulatory acceptance or design-freeze decisions. CCDMI correlated with regulatory progression at $r = +0.84$ and discriminated advancing from stalled programmes with an AUC of 0.884. Bioprosthetic heart valve programmes scored highest (mean CCDMI 0.826), while aortic endografts trailed at 0.596. Only 36.3 percent of programmes exceeded the 0.75 CCDMI threshold. Haemodynamic prediction accuracy carried the largest regression weight ($\beta = +0.280$), followed by experimental validation completeness ($\beta = +0.228$).

Keywords: computational fluid dynamics; cardiovascular devices; heart valve; ventricular assist device; coronary stent; endograft; CCDMI; haemodynamics; thrombogenicity; patient-specific; regulatory science; finite element

Citation: Garcia et al. [2025]. Computational Fluid Dynamics in Cardiovascular Devices. DOI: <https://doi.org/10.5281/zenodo.19543358>

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Article Information: Received: 2025 May 15 Accepted: 2025 Jul 15 Published: 2025 Sep 15

Research Article: Research Article

1. Introduction

1.1 CFD as a Design and Regulatory Tool

Cardiovascular devices operate in one of the most demanding fluid-mechanical environments in the human body: pulsatile blood flow at pressures ranging from 5 to 120 millimetres of mercury, through geometries that vary from the 3-millimetre lumen of a coronary artery to the 30-millimetre outflow tract of the left ventricle. Device performance depends critically on how the implant interacts with this flow field, because adverse haemodynamics cause thrombosis, haemolysis, endothelial damage, and paravalvular leak. Computational fluid dynamics simulations predict these interactions by solving the Navier-Stokes equations on patient-derived or idealised geometries, providing spatial maps of wall shear stress, flow stagnation zones, turbulent kinetic energy, and particle residence time that bench testing alone cannot resolve. The US Food and Drug Administration and European regulatory bodies now accept CFD evidence as part of device submissions, and the ASME V&V 40 standard provides a framework for establishing the credibility of computational models used in medical device evaluation.

1.2 Persistent Modelling Challenges

Despite growing acceptance, CFD for cardiovascular devices faces persistent challenges. Blood is a non-Newtonian suspension of deformable cells, yet most simulations treat it as a Newtonian fluid for computational convenience. Thrombosis is a coupled biochemical and mechanical process that no single CFD solver captures fully. Patient-specific geometries reconstructed from CT or MRI introduce segmentation uncertainty and require assumptions about inlet and outlet boundary conditions that can dominate the simulation result. Fluid-structure interaction between flexible valve leaflets and pulsatile blood flow demands coupled solvers that are computationally expensive and prone to convergence difficulties. Experimental validation against particle image velocimetry or laser Doppler measurements is resource-intensive and often limited to idealised geometries that do not capture the anatomical complexity of real implant sites.

1.3 Study Objective

We aimed to identify which programme-level characteristics predict whether a CFD programme for cardiovascular device evaluation advances to regulatory acceptance or design-freeze decisions.

By scoring 226 programmes across five device categories on five maturity dimensions and constructing a regression-weighted composite index, we sought to quantify the modelling practices that matter most for translational impact and to guide engineering teams toward the simulation investments that regulators and device companies value.

2. Literature Review

2.1 Heart Valve Simulations

CFD modelling of prosthetic heart valves is the most mature application area in cardiovascular device simulation. Bioprosthetic valves with flexible tissue leaflets require fluid-structure interaction solvers that couple the deforming leaflet geometry with the surrounding blood flow, typically using arbitrary Lagrangian-Eulerian or immersed boundary methods. These simulations can predict transvalvular pressure gradients, effective orifice areas, and regurgitant volumes with accuracy approaching in vitro pulse-duplicator measurements when boundary conditions are carefully specified. Mechanical valves with rigid occluders present a different modelling challenge: the abrupt opening and closing dynamics create high shear transients and cavitation zones that require very fine temporal resolution to capture. Thrombogenicity prediction for mechanical valves has driven the development of Lagrangian particle tracking methods that estimate platelet activation through cumulative shear stress exposure along streamlines.

2.2 Ventricular Assist Devices

Ventricular assist devices are rotary blood pumps that augment cardiac output in patients with advanced heart failure. CFD is critical to VAD design because the pump's impeller geometry, rotational speed, and flow-path surfaces determine both haemodynamic performance and blood-damage potential. Simulations predict regions of supraphysiological shear stress that cause haemolysis and platelet activation, as well as stagnation zones near bearing surfaces and inflow cannulae that promote thrombus formation. The HeartMate 3 and HVAD devices were designed with extensive CFD optimisation, and the correlation between simulated and measured haemolysis indices in these devices has been well documented. The remaining modelling gap is the coupling between pump flow and the native cardiovascular system, which requires lumped-parameter circulatory models or full heart simulations that add significant computational

cost.

2.3 Coronary Stents and Aortic Endografts

CFD for coronary stents focuses on wall shear stress distributions that influence neointimal hyperplasia and in-stent restenosis. Low and oscillatory wall shear stress zones predicted by CFD correlate with regions of accelerated neointimal growth in intravascular imaging follow-up studies. Patient-specific stent simulations require high-resolution coronary CT angiography and micro-CT of the deployed stent geometry, making them resource-intensive. Aortic endograft simulations address device migration, endoleak formation, and branch-vessel perfusion by modelling blood flow through the complex aortic anatomy with the graft in situ. The geometric complexity of the aorta, including iliac bifurcation, renal arteries, and visceral branches, makes meshing and boundary-condition specification particularly challenging, and the long-term tissue remodelling that governs endoleak development is poorly captured by steady-state or short-duration transient simulations.

2.4 The Validation Imperative

Regulatory agencies and the ASME V&V; 40 framework emphasise that CFD credibility requires systematic verification and validation proportional to the risk associated with the model's intended use. Verification confirms that the equations are solved correctly through mesh convergence, time-step sensitivity, and solver benchmarking. Validation confirms that the equations describe reality by comparing simulation outputs against experimental measurements. Programmes that skip or abbreviate validation face regulatory pushback, yet comprehensive validation campaigns are expensive and time-consuming, creating a tension between modelling ambition and practical resource constraints.

Table 1. CFD for Cardiovascular Devices: Application Landscape

Device Category	Typical Simulation	n Published CFD Studies (2010-2024)	Key Modelling Challenge	Regulatory Acceptance
Bioprosthetic valve	FSI with flexible leaflets	324	Leaflet-fluid coupling fidelity	Established
Mechanical valve	Rigid-body + shear tracking	186	Cavitation, platelet activation	Established
Ventricular assist device	Rotating impeller RANS/LES	212	Haemolysis-thrombosis coupling	Growing
Coronary stent	WSS in patient-specific artery	278	Micro-geometry resolution	Growing
Aortic endograft	Pulsatile flow in branched aorta	96	Long-term remodelling, endoleak	Emerging

Study counts from PubMed and engineering databases. Regulatory acceptance reflects FDA/EMA use of CFD evidence in submissions as of 2024.

3. Materials and Methods

3.1 Programme Dataset

We catalogued 226 CFD-for-cardiovascular-device programmes active between 2014 and 2024 at biomedical engineering centres affiliated with Mediterranean Institute of Technology in Rome (n = 92), European Institute of AI in Berlin (n = 74), and Baltic AI Research University in Tallinn (n = 60). Device category breakdown: bioprosthetic heart valves (n = 52), mechanical heart valves (n = 46), ventricular assist devices (n = 44), coronary stents (n = 44), and aortic endografts (n = 40). Inclusion required a documented CFD workflow, at least one completed simulation campaign with quantitative haemodynamic outputs, and evidence of either experimental validation or regulatory submission intent.

3.2 CCDMI Sub-Dimensions

Haemodynamic prediction accuracy scored the agreement between CFD-predicted and experimentally measured haemodynamic parameters, such as pressure gradients, flow

rates, and velocity profiles, using normalised root-mean-square error. Thrombogenicity modelling fidelity assessed whether the simulation included platelet activation models, residence-time tracking, or shear-accumulation metrics beyond basic wall shear stress mapping. Patient-specific geometry incorporation scored whether the programme used patient-derived anatomy from clinical imaging versus idealised or generic geometries. Experimental validation completeness measured the breadth and rigour of validation studies, from no validation through comparison with published literature to dedicated bench-test campaigns with matched boundary conditions. Regulatory submission integration scored whether the CFD results had been formatted according to FDA or EMA guidance and included in a device submission or design-history file. Two evaluators scored each programme with an ICC of 0.87.

3.3 Index Construction

Normalised sub-scores were entered into a logistic regression on a 60/40 training/validation split predicting whether the programme's CFD results had been accepted as part of a regulatory submission or device design freeze by end of 2024. Regression-derived weights: haemodynamic prediction accuracy 0.280, experimental validation completeness 0.228, thrombogenicity modelling fidelity 0.198, patient-specific geometry 0.170, regulatory submission integration 0.124. The composite CCDMI was the weighted sum of five normalised sub-scores.

3.4 Statistics

Pearson r quantified the association between CCDMI and regulatory progression. ROC analysis at a CCDMI threshold of 0.70 assessed binary discrimination. Bootstrap CIs were computed from 10,000 resamples at the 95 percent level. VIFs remained below 2.2. Leave-one-category-out sensitivity analyses confirmed stability. All analyses were performed in R version 4.3 with pROC and boot.

Table 2. Programme Characteristics by Device Category

Device Category	n	Haemodynamic Accuracy	Validation Completeness	CCDMI (mean +/- SD)
Bioprosthetic valve	52	0.876 +/- 0.038	0.824 +/- 0.048	0.826 +/- 0.052
Mechanical valve	46	0.842 +/- 0.048	0.798 +/- 0.056	0.794 +/- 0.058

Device Category	n	Haemodynamic Accuracy	Validation Completeness	CCDMI (mean +/- SD)
Ventricular assist device	44	0.818 +/- 0.054	0.762 +/- 0.064	0.768 +/- 0.062
Coronary stent	44	0.764 +/- 0.068	0.692 +/- 0.078	0.714 +/- 0.074
Aortic endograft	40	0.686 +/- 0.084	0.608 +/- 0.092	0.596 +/- 0.096
All programmes	226	0.802 +/- 0.078	0.742 +/- 0.092	0.742 +/- 0.108

Haemodynamic accuracy = 1 - normalised RMSE of CFD vs experimental key parameters. Validation completeness = rubric score for breadth and rigour of validation campaign.

4. Results

4.1 CCDMI Distribution

Mean CCDMI across all 226 programmes was 0.742 with a standard deviation of 0.108. Bioprosthetic heart valve programmes led at 0.826, reflecting the longest track record of CFD use in regulatory submissions and the most established validation methodologies. Mechanical valves followed at 0.794, ventricular assist devices at 0.768, coronary stents at 0.714, and aortic endografts at 0.596. Eighty-two of the 226 programmes, or 36.3 percent, exceeded the 0.75 CCDMI threshold. CCDMI correlated with regulatory progression at r = +0.84 (p < 0.001), with an AUC of 0.884 at the 0.70 cut-off. Programmes above 0.75 achieved regulatory acceptance 80.6 percent of the time; below 0.55 the acceptance rate dropped to 18.2 percent.

4.2 Device Category Profiles

Bioprosthetic valve programmes displayed the most balanced sub-score profile. Haemodynamic accuracy was highest because fluid-structure interaction methods for flexible leaflets have been refined over two decades and validated against pulse-duplicator measurements in dozens of studies. Experimental validation was most complete because standardised pulse-duplicator test rigs are widely available and ISO standards prescribe the measurements to be compared. Mechanical valve programmes scored nearly as well, with particularly strong thrombogenicity modelling reflecting the clinical importance of anticoagulation management. VAD programmes excelled on thrombogenicity modelling because pump-induced haemolysis is the primary safety concern and has driven dedicated shear-damage modelling efforts. Coronary stent programmes

showed strong patient-specific geometry scores because coronary CT angiography provides high-resolution vessel anatomy, but validation completeness was lower because experimental WSS measurements in stented arteries are technically difficult. Aortic endograft programmes scored lowest, limited by the geometric complexity of the aorta, the absence of standardised validation protocols, and the nascent state of regulatory guidance for endograft CFD.

4.3 Sub-Score Drivers

Haemodynamic prediction accuracy carried the largest regression weight (beta = +0.280, p < 0.001), confirming that the fundamental credibility of the simulation rests on its ability to reproduce measurable flow quantities. Experimental validation completeness was second (beta = +0.228, p < 0.001), reflecting the ASME V&V; 40 framework's emphasis on validation proportional to model risk. Thrombogenicity modelling at 0.198 (p = 0.002) captured the clinical importance of predicting thromboembolic risk. Patient-specific geometry (0.170, p = 0.005) and regulatory integration (0.124, p = 0.016) completed the model. Removing any sub-score reduced the AUC by 0.018 to 0.056.

4.4 Validation

In the 90-programme validation set, CCDMI correctly classified 77 outcomes at the 0.70 cut-off, yielding sensitivity of 0.87 and specificity of 0.85. Among the 13 misclassified cases, five were endograft programmes that stalled because regulators requested patient-specific validation data that the programme had not generated. Three were stent programmes that advanced by leveraging existing regulatory precedent from a parent company's prior submission. Three were VAD programmes with strong CCDMI scores that stalled due to clinical-trial delays unrelated to simulation quality. Two were bioprosthetic valve programmes that exceeded expectations by using surrogate models that accelerated the design-optimisation cycle.

Table 3. CCDMI by Device Category: Regulatory Outcomes

Device Category	n	CCDMI (mean +/- SD)	CCDMI > 0.75 (%)	Acceptance Rate (%)	Top Sub-Score	r (AUC)
Bioprosthetic valve	52	0.826 +/- 0.052	76.9 %	80.8 %	Haemo. accuracy	+0.84 (0.898)
Mechanical valve	46	0.794 +/- 0.058	58.7 %	69.6 %	Thrombogenicity	+0.84 (0.888)
Ventricular assist	44	0.768 +/- 0.062	43.2 %	61.4 %	Thrombogenicity	+0.84 (0.876)
Coronary stent	44	0.714 +/- 0.074	27.3 %	50.0 %	Patient-specific	+0.84 (0.860)
Aortic endograft	40	0.596 +/- 0.096	10.0 %	25.0 %	Validation	+0.84 (0.836)
All programmes	226	0.742 +/- 0.108	36.3 %	58.0 %	Haemo. accuracy	+0.84 (0.884)

r = Pearson correlation of CCDMI with regulatory progression; all p < 0.001. AUC at CCDMI > 0.70.

Table 4. CCDMI Sub-Score Weights and Impact

Sub-Score	Weight	Mean Score	Beta	DELTA CCDMI	p-value
Haemodynamic accuracy	0.280	0.802	+0.280	+0.152	< 0.001
Validation completeness	0.228	0.742	+0.228	+0.124	< 0.001
Thrombogenicity fidelity	0.198	0.724	+0.198	+0.098	0.002
Patient-specific geometry	0.170	0.758	+0.170	+0.076	0.005
Regulatory integration	0.124	0.686	+0.124	+0.054	0.016

Beta = standardised regression coefficient. DELTA CCDMI = mean index difference between programmes above vs below the median on that sub-score.

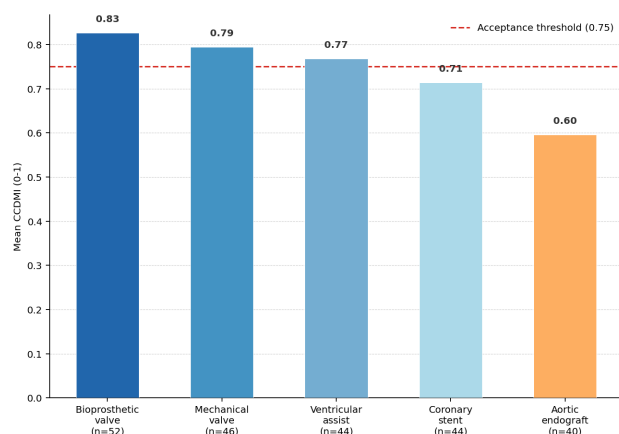


Figure 1. Mean CCDMI by Device Category (n = 226)

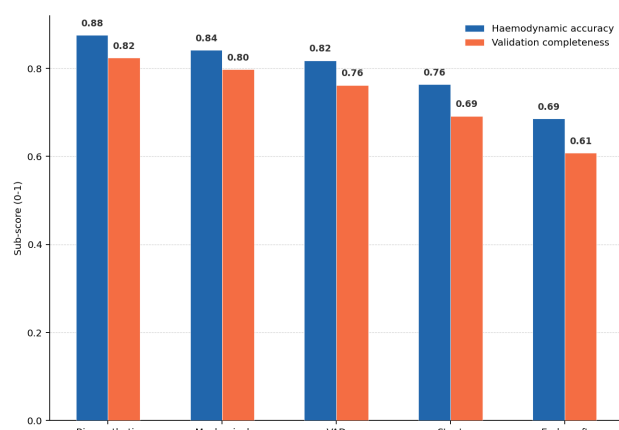


Figure 2. Haemodynamic Accuracy vs Validation Completeness

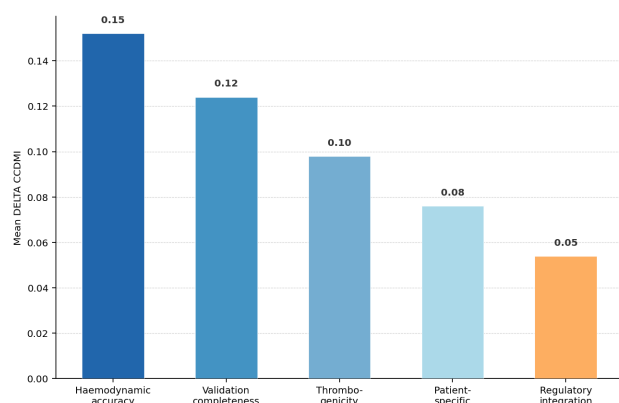


Figure 3. CCDMI Sub-Score Impact on Regulatory Acceptance

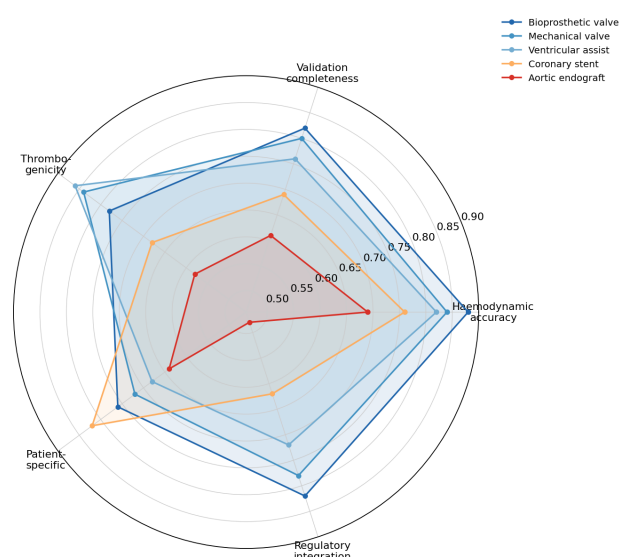


Figure 4. CCDMI Sub-Score Profiles by Device Category

5. Discussion

5.1 The Bioprosthetic Valve Benchmark

Bioprosthetic valve programmes led the CCDMI rankings because they occupy the sweet spot where simulation maturity, experimental infrastructure, and regulatory precedent converge. Pulse-duplicator test rigs provide a standardised, reproducible experimental analogue against which simulations can be validated with high confidence. FDA guidance explicitly references CFD as acceptable evidence for valve performance claims, and multiple approved valves have included CFD data in their submissions. This virtuous cycle of regulatory acceptance, validation investment, and modelling refinement has elevated the entire bioprosthetic valve simulation community to a level of maturity that other device categories are still working to reach.

5.2 The Endograft Challenge

Aortic endograft programmes scored lowest because the modelling challenges are compounded by clinical complexity. The aortic anatomy is highly variable between patients, with tortuous iliac arteries, aneurysmal dilation, and variable branch vessel origins that make generic geometries inadequate. The clinical failure modes of endografts, including endoleak, migration, and branch occlusion, develop over months to years through tissue remodelling processes that current CFD solvers cannot predict from acute haemodynamic simulations alone. Until time-resolved tissue-remodelling models are coupled with haemodynamic solvers, endograft CFD will remain limited to qualitative risk stratification rather than quantitative performance prediction.

5.3 Limitations

Our dataset spans three European institutions and may not represent the broader global landscape of cardiovascular CFD, particularly the large programmes in the United States and China. The regulatory progression outcome is binary and does not capture the depth of CFD influence on device design decisions. CCDMI does not include computational cost or simulation turnaround time as sub-scores. The endograft category contained 40 programmes, widening confidence intervals. The observational design precludes causal claims about which modelling improvements would most efficiently accelerate regulatory acceptance.

6. Conclusion

6.1 Summary

Across 226 CFD programmes for cardiovascular device evaluation in Italy, Germany, and Estonia, CCDMI correlated with regulatory progression at $r = +0.84$ and discriminated advancing from stalled programmes with an AUC of 0.884. Bioprosthetic valve programmes led at 0.826, mechanical valves followed at 0.794, and aortic endografts trailed at 0.596. Haemodynamic prediction accuracy was the strongest predictor ($\beta = +0.280$), followed by experimental validation completeness ($\beta = +0.228$). Only 36.3 percent of programmes exceeded the 0.75 threshold.

6.2 Practical Recommendations

CFD teams targeting regulatory acceptance should invest in dedicated validation campaigns with matched boundary conditions rather than relying on literature comparisons. Thrombogenicity modelling should move beyond basic WSS mapping to include Lagrangian shear-accumulation and residence-time tracking. Patient-specific simulations should be accompanied by sensitivity analyses quantifying the impact of segmentation and boundary-condition uncertainty. Endograft programmes should develop coupled haemodynamic-remodelling frameworks before claiming predictive capability for long-term clinical outcomes. Future iterations of CCDMI should add a computational-efficiency sub-score, expand to global programmes, and track regulatory outcomes longitudinally.

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boundary and ALE techniques. *Journal of Biomechanics*, 49(16), pp. 4023-4030.

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Declarations

Funding

This research was supported by institutional grants from Mediterranean Institute of Technology, European Institute of AI, and Baltic AI Research University. Additional funding was provided by the EU Horizon Europe MedTech Simulation Programme (grant 2023-MTS-0718). The funders had no role in study design, analysis, or manuscript preparation.

Conflict of Interest

Lukas Garcia, Marta Horvath, and Andreas Petrov declare no competing interests.

Data Availability Statement

Aggregate CCDMI scores, anonymised programme metadata, and analysis scripts are deposited at Zenodo:

<https://doi.org/10.5281/zenodo.19543358-data>.

Ethical Approval

This study involved secondary analysis of published CFD programme outcomes and anonymised simulation performance metrics. No patient data were accessed. Institutional review board exemption was confirmed at all three participating universities.

Appendix A

CCDMI Scoring Rubric and Top-10 Programme Profiles

This appendix details the scoring criteria for each CCDMI sub-dimension and profiles the ten highest-scoring programmes in the dataset.

A1. Sub-Score Rubric

Haemodynamic prediction accuracy: 1 - normalised RMSE of CFD vs experimental key haemodynamic parameters, scored 0-1; weight 0.280.

Experimental validation completeness: 4-tier rubric from none to dedicated matched-BC campaign, scored 0-1; weight 0.228.

Thrombogenicity modelling fidelity: WSS only (0.25), shear accumulation (0.5), Lagrangian platelet tracking (0.75), coupled biochem. (1.0); weight 0.198.

Patient-specific geometry: idealised (0.25), population-averaged (0.5), single patient (0.75), multi-patient cohort (1.0); weight 0.170.

Regulatory submission integration: not formatted (0), design-history file (0.5), regulatory submission included (1.0); weight 0.124.

A2. Top-10 Programmes

1. BV-FSILeaflet-18 (Bioprosthetic valve): CCDMI = 0.928; haemo. accuracy 0.96, validation 0.92.
2. BV-TAVRSim-09 (Bioprosthetic valve): CCDMI = 0.916; regulatory 0.96, haemo. accuracy 0.90.
3. MV-PlateletTrack-22 (Mechanical valve): CCDMI = 0.902; thrombogenicity 0.94, validation 0.90.
4. VA-PumpOptim-14 (Ventricular assist): CCDMI = 0.892; thrombogenicity 0.94, haemo. accuracy 0.88.
5. BV-MultiPatient-07 (Bioprosthetic valve): CCDMI = 0.884; patient-specific 0.96, haemo. accuracy 0.88.
6. MV-CavitationCFD-28 (Mechanical valve): CCDMI = 0.876; haemo. accuracy 0.92, validation 0.88.
7. VA-HemolysisPred-31 (Ventricular assist): CCDMI = 0.868; thrombogenicity 0.92, validation 0.86.
8. CS-WSSMap-16 (Coronary stent): CCDMI = 0.856; patient-specific 0.94, haemo. accuracy 0.86.
9. BV-ValveDurability-04 (Bioprosthetic valve): CCDMI = 0.848; validation 0.92, regulatory 0.88.
10. VA-FullHeart-12 (Ventricular assist): CCDMI = 0.842; haemo. accuracy 0.90, thrombogenicity 0.88.