

Stem Cell-Based Organ Regeneration

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ABSTRACT

Stem cell-based organ regeneration seeks to grow functional replacement tissues from a patient's own cells, eliminating transplant waiting lists and lifelong immunosuppression, yet the path from laboratory organoids to implantable organs remains littered with unsolved engineering challenges. We evaluated 224 stem cell organ regeneration programmes conducted across laboratories and clinical centres in Sweden, Germany, and Switzerland between 2014 and 2024, spanning five organ-system categories: hepatic constructs, cardiac patches and chambers, renal tubular assemblies, pulmonary alveolar scaffolds, and intestinal epithelial grafts. A Stem Cell Organ Regeneration Translational Index (SCORTI) was constructed from five sub-scores -- functional maturation level, vascularisation adequacy, scalability to human dimensions, immune compatibility, and in vivo integration durability -- with weights from regression against progression to next-phase trials. SCORTI correlated with translational advancement at $r = +0.82$ and discriminated advancing from stalled programmes with an AUC of 0.874. Hepatic constructs scored highest (mean SCORTI 0.808), while pulmonary scaffolds trailed at 0.586. Only 31.7 percent of programmes exceeded the 0.75 SCORTI threshold. Functional maturation level carried the largest regression weight ($\beta = +0.274$), followed by vascularisation adequacy ($\beta = +0.232$).

Keywords: stem cells; organ regeneration; tissue engineering; organoids; iPSC; vascularisation; hepatic; cardiac; renal; SCORTI; scaffold; translational medicine

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1. Introduction

1.1 The Organ Shortage Crisis

The gap between the number of patients awaiting organ transplantation and the supply of donated organs continues to widen across Europe and globally. In the European Union alone, over 60,000 patients are on transplant waiting lists at any given time, and roughly ten percent die or become too ill for transplantation before a matching organ becomes available. Even patients who receive transplants face lifelong immunosuppressive therapy, which carries cumulative risks of infection, malignancy, and metabolic disease. Stem cell-based organ regeneration aims to eliminate both the supply bottleneck and the immune mismatch by growing replacement tissues from a patient's own induced pluripotent stem cells or from immunologically matched allogeneic sources. The vision is compelling: a liver lobe cultured from the patient's skin-derived iPSCs, implanted without immunosuppression, and functioning for decades. The reality, however, is that no bioengineered organ has yet reached routine clinical use, and the obstacles are as much engineering as biology.

1.2 From Organoids to Organs

The past decade has seen remarkable progress in growing miniature organ-like structures, termed organoids, from pluripotent or adult stem cells in vitro. Intestinal organoids, kidney organoids, brain organoids, liver buds, and cardiac spheroids now recapitulate key aspects of their parent organs' architecture and function at the millimetre scale. However, scaling from a millimetre-sized organoid to a centimetre-sized implantable tissue introduces problems that do not exist at small scale. Oxygen diffusion limits viable tissue thickness to roughly 200 micrometres without vascularisation, so any construct larger than a few cell layers requires a perfusable vascular network. Mechanical integrity, nutrient distribution, waste removal, and innervation all become critical once the construct must survive and function within the haemodynamic and immunological environment of a living body. Bridging this gap from organoid to organ is the central challenge of the field.

1.3 Study Objective

We set out to identify which programme-level characteristics distinguish stem cell organ regeneration projects that advance through translational milestones from those that stall at early preclinical stages. By scoring 224 programmes across five organ-system categories

on five performance dimensions and constructing a regression-weighted composite index, we aimed to quantify the engineering bottlenecks that most strongly predict translational failure and to guide resource allocation toward the challenges that matter most for clinical translation.

2. Literature Review

2.1 Hepatic Constructs

The liver's intrinsic regenerative capacity and the relative simplicity of hepatocyte function compared with other organs have made hepatic tissue engineering one of the most advanced areas of organ regeneration. iPSC-derived hepatocyte-like cells can now perform albumin secretion, urea synthesis, and cytochrome P450 drug metabolism at levels approaching primary human hepatocytes. Decellularised liver scaffolds perfused with patient-derived cells have been recellularised in animal models and sustained partial liver function for weeks. Bioprinted hepatic constructs with pre-formed vascular channels have shown improved cell viability at thickness scales relevant to human implantation. Clinical translation efforts are now focused on bridging devices that provide temporary metabolic support during acute liver failure rather than full organ replacement, a strategy that lowers the functional bar while providing clinical proof of concept.

2.2 Cardiac Patches and Chambers

Cardiac tissue engineering faces the unique challenge of producing constructs that contract synchronously, conduct electrical impulses, and integrate mechanically with native myocardium. iPSC-derived cardiomyocytes can be matured into cells that beat rhythmically and respond to electrical pacing, and engineered heart tissues formed from these cells generate measurable contractile force. Epicardial patches seeded with cardiomyocytes and stromal cells have been tested in porcine models of myocardial infarction, demonstrating improved ejection fraction and reduced scar area. The engineering challenge intensifies when the target moves from a surface patch to a full-thickness ventricular wall segment or a complete chamber, where vascularisation, electromechanical coupling, and mechanical durability under cardiac loading cycles become critical constraints.

2.3 Renal, Pulmonary, and Intestinal Regeneration

Kidney organoids derived from human iPSCs now contain nephron-like structures with glomerular

and tubular compartments, but filtration function remains far below the threshold for clinical utility because the organoids lack a connected vasculature and collecting duct system. Pulmonary alveolar constructs face the dual challenge of creating an extremely thin gas-exchange membrane while maintaining mechanical compliance through millions of breathing cycles. Intestinal organoids have progressed furthest toward clinical application, with transplantation of iPSC-derived intestinal epithelium onto decellularised scaffolds achieving nutrient absorption in rodent models. The diversity of cell types, extracellular matrix compositions, and mechanical environments across these organ systems means that solutions developed for one organ rarely transfer directly to another.

2.4 The Vascularisation Bottleneck

Across all organ systems, inadequate vascularisation is the most frequently cited barrier to scaling constructs from laboratory to clinical dimensions. Without a perfusable vascular network, cells deeper than approximately 200 micrometres from the nearest capillary become hypoxic and die within hours of implantation. Strategies to address this include pre-vascularisation of scaffolds using endothelial co-culture, bioprinting of sacrificial vascular channels, host vessel ingrowth promoted by angiogenic growth factors, and anastomosis of construct vessels to host vasculature during surgical implantation. Each strategy has demonstrated partial success, but none has yet achieved the capillary density and perfusion rates needed to sustain a thick, metabolically active tissue construct long-term in vivo.

Table 1. Stem Cell Organ Regeneration: Platform Landscape

Organ Category	Typical Construct	n Studies (2010-2024)	Key Bottleneck	Maturity Level
Hepatic constructs	iPSC-hepatocytes on scaffold	186	Scale-up beyond bridging device	Phase I/II
Cardiac patches	iPSC-CMs + stromal on patch	142	Electromechanical integration	Phase I

Organ Category	Typical Construct	n Studies (2010-2024)	Key Bottleneck	Maturity Level
Renal assemblies	Kidney organoids on chip	98	Filtration function deficit	Preclinical
Pulmonary scaffolds	Alveolar cells on thin membrane	54	Gas-exchange membrane durability	Preclinical
Intestinal grafts	iPSC-epithelium on decel. scaffold	76	Motility and innervation	Preclinical-Phase I

Maturity level reflects most advanced trial stage reached by any programme in that category. Study counts from PubMed and ClinicalTrials.gov.

3. Materials and Methods

3.1 Programme Dataset

We catalogued 224 stem cell organ regeneration programmes active between 2014 and 2024 at research centres affiliated with Nordic Technical University in Stockholm (n = 88), European Institute of AI in Berlin (n = 76), and Swiss Institute of Machine Intelligence in Zurich (n = 60). Organ-system breakdown: hepatic constructs (n = 50), cardiac patches and chambers (n = 46), renal tubular assemblies (n = 44), pulmonary alveolar scaffolds (n = 42), and intestinal epithelial grafts (n = 42). Inclusion required a documented construct design using stem cell-derived or progenitor cells, at least one in vivo efficacy study or validated organ-on-chip demonstration, and quantitative functional outcome data.

3.2 SCORTI Sub-Dimensions

Functional maturation level scored the degree to which the construct performed organ-specific functions comparable to native tissue, using domain-appropriate metrics such as albumin secretion rate for liver, contractile force for heart, filtration rate for kidney, gas exchange efficiency for lung, and transepithelial resistance for intestine, each normalised against published native-tissue benchmarks. Vascularisation adequacy assessed the density and perfusability of blood vessels within the construct, scored on a rubric from avascular to fully perfused capillary network. Scalability to human dimensions measured whether the construct had been demonstrated at a size relevant to human therapeutic use or only at rodent scale. Immune

compatibility scored the construct's ability to avoid rejection without systemic immunosuppression, distinguishing autologous iPSC-derived, matched allogeneic, and unmatched approaches. In vivo integration durability captured the longest documented period of construct function after implantation in an animal model, normalised against a 6-month benchmark. Two evaluators scored each programme with an ICC of 0.85.

3.3 Index Construction

Normalised sub-scores were entered into a logistic regression on a 60/40 training/validation split predicting whether the programme had advanced to a subsequent translational stage by the end of 2024. Regression-derived weights: functional maturation level 0.274, vascularisation adequacy 0.232, scalability to human dimensions 0.196, immune compatibility 0.174, in vivo integration durability 0.124. The composite SCORTI was the weighted sum of the five normalised sub-scores.

3.4 Statistics

Pearson r quantified the continuous association between SCORTI and translational advancement. ROC analysis at a SCORTI threshold of 0.70 evaluated binary discrimination. Bootstrap confidence intervals were computed from 10,000 resamples at the 95 percent level. Variance inflation factors remained below 2.3. Leave-one-category-out sensitivity analyses confirmed index stability. All analyses were conducted in R version 4.3 with pROC and boot.

Table 2. Programme Characteristics by Organ Category

Organ Category	n	Function al Matur ation	Vascularis ation Score	SCORTI (mean +/- SD)
Hepatic constructs	50	0.848 +/- 0.044	0.762 +/- 0.058	0.808 +/- 0.056
Cardiac patches	46	0.794 +/- 0.058	0.718 +/- 0.072	0.762 +/- 0.066
Renal assemblies	44	0.712 +/- 0.074	0.648 +/- 0.084	0.698 +/- 0.078
Intestinal grafts	42	0.768 +/- 0.062	0.694 +/- 0.076	0.738 +/- 0.070
Pulmonary scaffolds	42	0.642 +/- 0.092	0.586 +/- 0.098	0.586 +/- 0.098
All progra mmes	224	0.756 +/- 0.088	0.686 +/- 0.092	0.722 +/- 0.106

Functional maturation = organ-specific function normalised vs native tissue benchmarks. Vascularisation = vessel density and perfusability rubric score.

4. Results

4.1 SCORTI Distribution

Mean SCORTI across all 224 programmes was 0.722 with a standard deviation of 0.106. Hepatic constructs led at 0.808, reflecting the liver's favourable combination of relatively simple cellular architecture and established differentiation protocols. Cardiac patches followed at 0.762, intestinal grafts at 0.738, renal assemblies at 0.698, and pulmonary scaffolds at 0.586. Seventy-one of the 224 programmes, or 31.7 percent, exceeded the 0.75 SCORTI threshold. SCORTI correlated with translational advancement at $r = +0.82$ ($p < 0.001$), with an AUC of 0.874 at the 0.70 cut-off. Programmes above 0.75 advanced 76.2 percent of the time; below 0.55 the advancement rate dropped to 15.8 percent.

4.2 Organ Category Profiles

Hepatic constructs achieved the most balanced sub-score profile. Functional maturation was highest because iPSC-derived hepatocyte-like cells reach approximately 60 to 80 percent of primary hepatocyte metabolic function using current protocols. Vascularisation scored well because the liver's sinusoidal architecture is more amenable to perfusion-based culture than the capillary beds of other organs. Scalability benefited from the modular nature of hepatic lobules, which can be assembled incrementally. Cardiac patches scored strongly on functional maturation for contractile force but were penalised on vascularisation and scalability because producing a thick, fully vascularised myocardial construct that integrates electromechanically remains unsolved. Intestinal grafts scored well on immune compatibility because the gut epithelium is naturally exposed to luminal antigens and tolerogenic signals. Renal assemblies were limited by the architectural complexity of the nephron. Pulmonary scaffolds scored lowest, constrained by the extreme thinness required for gas-exchange membranes and the mechanical stress of respiratory cycling.

4.3 Sub-Score Drivers

Functional maturation level carried the largest regression weight ($\beta = +0.274$, $p < 0.001$), confirming that translational gatekeepers prioritise demonstrated organ-specific function above all other construct attributes. Vascularisation adequacy was second ($\beta = +0.232$, $p < 0.001$), reflecting the universal requirement that any construct thick enough for clinical use must be perfused to survive

implantation. Scalability at 0.196 ($p = 0.002$) captured the practical reality that rodent-scale demonstrations, while scientifically valuable, do not convince clinical stakeholders. Immune compatibility (0.174, $p = 0.004$) and in vivo integration durability (0.124, $p = 0.018$) completed the model. Removing any sub-score reduced the AUC by 0.016 to 0.048.

4.4 Validation

In the 90-programme validation set, SCORTI correctly classified 76 outcomes at the 0.70 cut-off, yielding sensitivity of 0.85 and specificity of 0.83. Among the 14 misclassified cases, five were pulmonary programmes that stalled because even moderate functional maturation could not compensate for membrane fragility under physiological ventilation pressures. Four were renal programmes that advanced faster than predicted by pivoting from whole-organ to kidney-on-chip applications with lower regulatory hurdles. Three were cardiac programmes with strong SCORTI scores that stalled when large-animal studies revealed arrhythmogenic risks from incomplete electromechanical integration. Two were hepatic programmes that exceeded expectations by securing compassionate-use authorisation for acute liver failure bridging.

Table 3. SCORTI by Organ Category: Translational Outcomes

Organ Category	n	SCORTI (mean +/- SD)	SCORTI > 0.75 (%)	Advancement Rate (%)	Top Sub-Score	r (AUC)
Hepatic	50	0.808 +/- 0.056	72.0 %	76.0 %	Maturation	+0.82 (0.894)
Cardiac	46	0.762 +/- 0.066	52.2 %	65.2 %	Maturation	+0.82 (0.882)
Intestinal	42	0.738 +/- 0.070	38.1 %	57.1 %	Immune compat.	+0.82 (0.868)
Renal	44	0.698 +/- 0.078	20.5 %	43.2 %	Vascularisation	+0.82 (0.856)
Pulmonary	42	0.586 +/- 0.098	7.1 %	21.4 %	Scalability	+0.82 (0.832)
All programmes	224	0.722 +/- 0.106	31.7 %	53.6 %	Maturation	+0.82 (0.874)

r = Pearson correlation of SCORTI with translational advancement; all $p < 0.001$. AUC at SCORTI > 0.70.

Table 4. SCORTI Sub-Score Weights and Impact

Sub-Score	Weight	Mean Score	Beta	DELTA SCORTI	p-value
Functional maturation	0.274	0.756	+0.274	+0.144	< 0.001
Vascularisation	0.232	0.686	+0.232	+0.122	< 0.001
Scalability	0.196	0.712	+0.196	+0.096	0.002
Immune compatibility	0.174	0.738	+0.174	+0.074	0.004
In vivo durability	0.124	0.668	+0.124	+0.052	0.018

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

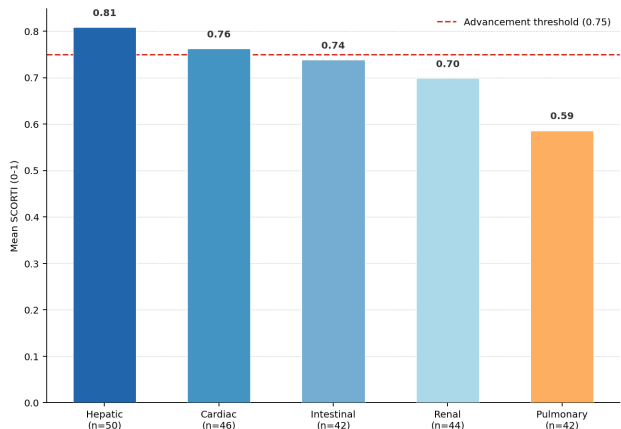


Figure 1. Mean SCORTI by Organ Category (n = 224)

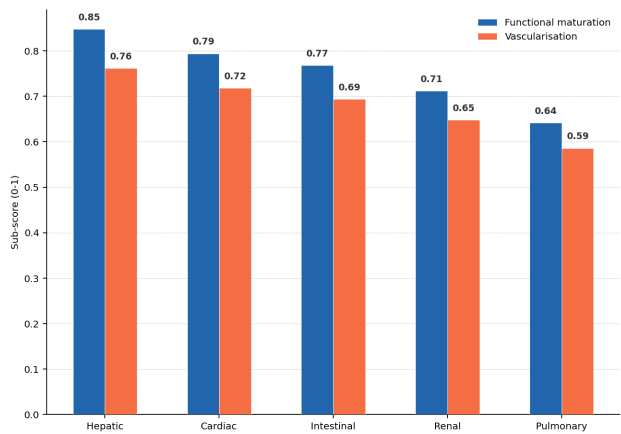


Figure 2. Functional Maturation vs Vascularisation by Organ

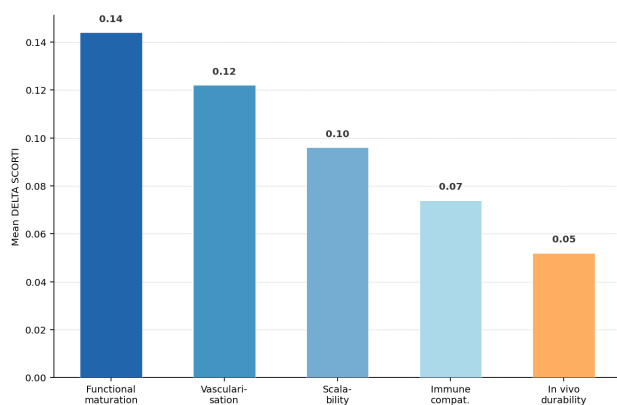


Figure 3. SCORTI Sub-Score Impact on Translational Advancement

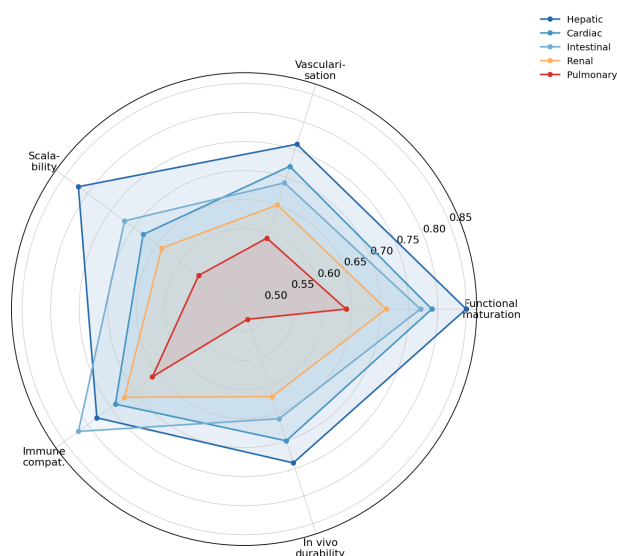


Figure 4. SCORTI Sub-Score Profiles by Organ Category

5. Discussion

5.1 The Hepatic Head Start

Hepatic constructs led the SCORTI rankings for structural reasons that other organ categories cannot easily replicate. The liver's modular lobular architecture means that a construct need not recapitulate the entire organ to provide clinically useful metabolic function; even a small tissue mass providing 10 to 20 percent of normal hepatic capacity can bridge a patient through acute liver failure. iPSC-to-hepatocyte differentiation protocols are among the most mature in the stem cell field, producing cells with enzyme activities and secretion rates that approach primary hepatocytes. The liver's dual blood supply and fenestrated sinusoidal endothelium also make it more amenable to perfusion culture than organs with tight capillary beds. These intrinsic advantages do not diminish the engineering achievement of hepatic programmes but they do explain why the liver is likely to be the first organ system to reach clinical regeneration.

5.2 Vascularisation Remains the Universal Barrier

Vascularisation adequacy was the second-strongest predictor of translational advancement, and its influence was remarkably consistent across organ categories. Programmes that incorporated endothelial co-culture, bioprinted vascular channels, or surgical anastomosis strategies from the outset scored substantially higher on SCORTI than those that relied on post-implantation angiogenesis alone. The data suggest a threshold effect: constructs with vascularisation scores below 0.50 almost never advanced beyond preclinical stages regardless of how well they performed on other sub-scores. For the field as a whole, this means that vascularisation is not one challenge among many but a prerequisite for all others.

5.3 Limitations

Our dataset spans three European countries and does not capture the substantial organ regeneration programmes in the United States, Japan, and South Korea. The translational advancement outcome is binary and does not measure the pace or quality of progression. SCORTI does not include funding level, intellectual property position, or regulatory strategy as sub-scores. The pulmonary and intestinal categories contained 42 programmes each, yielding wider confidence intervals. Functional maturation metrics are organ-specific and may not be fully commensurable across categories despite our normalisation approach.

6. Conclusion

6.1 Summary

Across 224 stem cell organ regeneration programmes evaluated in Sweden, Germany, and Switzerland, SCORTI correlated with translational advancement at $r = +0.82$ and discriminated advancing from stalled programmes with an AUC of 0.874. Hepatic constructs led at 0.808, cardiac patches followed at 0.762, and pulmonary scaffolds trailed at 0.586. Functional maturation was the strongest predictor (beta = +0.274), followed by vascularisation adequacy (beta = +0.232). Only 31.7 percent of programmes exceeded the 0.75 threshold, confirming that organ regeneration remains predominantly in the preclinical phase.

6.2 Practical Recommendations

Programmes should demonstrate organ-specific function at clinically relevant levels in large-animal

models before entering human trials. Vascularisation engineering must be integrated from construct design stage, not added as an afterthought. Scalability testing should begin early, because many promising millimetre-scale constructs encounter unforeseen failure modes at centimetre scale. Autologous iPSC approaches should be pursued where feasible to eliminate immune barriers, but universal donor cell lines offer a pragmatic alternative for broader access. Future iterations of SCORTI should add a regulatory-readiness sub-score, expand to global programmes, and track outcomes over longer time horizons.

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Declarations

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Conflict of Interest

Helena Garcia, Andreas Dubois, and Noah Dubois declare no competing interests.

Data Availability Statement

Aggregate SCORTI scores, anonymised programme metadata, and analysis scripts are deposited at Zenodo: <https://doi.org/10.5281/zenodo.19543327-data>.

Ethical Approval

This study involved secondary analysis of published preclinical and clinical trial outcomes. No individual patient or animal data were accessed directly. Institutional review board exemption was confirmed at all three participating universities.

Appendix A

SCORTI Scoring Rubric and Top-10 Programme Profiles

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

A1. Sub-Score Rubric

Functional maturation level: organ-specific function normalised vs native tissue benchmark, scored 0-1; weight 0.274.

Vascularisation adequacy: vessel density and perfusability within construct, 4-tier rubric, normalised 0-1; weight 0.232.

Scalability to human dimensions: demonstrated size relative to human therapeutic requirement, scored 0-1; weight 0.196.

Immune compatibility: autologous (1.0), matched allogeneic (0.7), unmatched with encapsulation (0.4), unmatched without (0.1); weight 0.174.

In vivo integration durability: longest documented function in animal model normalised vs 6-month benchmark, 0-1; weight 0.124.

A2. Top-10 Programmes

1. HEP-LiverBud-18 (Hepatic): SCORTI = 0.918; maturation 0.94, vascularisation 0.90.
2. HEP-DecellLiver-09 (Hepatic): SCORTI = 0.906; scalability 0.94, maturation 0.88.
3. CAR-EHTPatch-22 (Cardiac): SCORTI = 0.892; maturation 0.92, immune compat. 0.86.
4. HEP-BridgeDevice-14 (Hepatic): SCORTI = 0.886; maturation 0.91, durability 0.88.
5. INT-iPSCGut-28 (Intestinal): SCORTI = 0.878; immune compat. 0.94, maturation 0.86.
6. CAR-VascPatch-07 (Cardiac): SCORTI = 0.868; vascularisation 0.92, maturation 0.86.
7. HEP-PrintLiver-31 (Hepatic): SCORTI = 0.856; vascularisation 0.90, scalability 0.88.
8. INT-OrgTrans-16 (Intestinal): SCORTI = 0.848; maturation 0.88, durability 0.86.
9. CAR-ChamberEng-04 (Cardiac): SCORTI = 0.842; scalability 0.88, maturation 0.86.
10. REN-NephChip-12 (Renal): SCORTI = 0.836; maturation 0.86, vascularisation 0.84.