

VB-310

HeartTwin — Digital Heart Twin

Virelion Biotech | Platform scientific dossier | v0.2 | 03 September 2026

Program Status

Stage: Active development. VB-310 (HeartTwin) has moved beyond a pure discovery blueprint into an active software-platform build. Public domain engines and cardiac-state libraries are under continuous development across the Virelion-Biotech GitHub organization, with **Virelion-HeartTwin** as the primary user-facing entrypoint.

This remains a **research computational platform**, not a clinically validated model, diagnostic, therapeutic decision system, or regulatory digital twin. No proprietary patient dataset, wet-lab efficacy claim, prospective clinical validation, or reported model performance is asserted by this dossier.

1. Target Product Profile

Field	VB-310 target
Purpose	Quantify and simulate myocardial repair/regeneration states from multimodal biological data via an integrated digital heart twin stack.
Primary biological question	What molecular, cellular, spatial, and functional states distinguish regenerative repair from adverse post-MI remodeling, and which transitions are computationally predictable?
Core inputs	sc/snRNA-seq, spatial transcriptomics when available, curated bulk RNA-seq, histology/image features, ECG/mechanics summaries, structured literature/knowledge layers.
Core outputs	Regenerative state scores; transition probabilities; fibrosis/remodeling burden; pathway activity; uncertainty and OOD flags; ranked experimental hypotheses.
Intended use	Research hypothesis prioritization, dataset harmonization, experimental design support, and open computational methods development.
Not intended for	Clinical diagnosis, treatment selection, patient-specific therapy, or any regulated medical-device claim.
Public entrypoint	https://github.com/Virelion-Biotech/Virelion-HeartTwin

2. Architecture (current build)

HeartTwin is implemented as a composition of public Virelion repositories rather than a single monolithic model:

- **Domain engines:** CardiAtlas (knowledge), ElectroTrace (ECG), MyoTrace (mechanics video), OptiCell (microscopy QC).
- **Cardiac state engine:** CardiLearn, CardiSim, CardiBench, CardiEval, CardiTrace, CardiBridge, CardiStudio, CardiAgent, CardiVex, DCCP.
- **Workflow loop:** Observe → Predict → Simulate → Intervene → Validate.

Software maturity varies by component. Several libraries are substantially engineered (contracts, CI, provenance hooks) while empirical performance on locked public benchmarks remains data-dependent and must not be over-claimed.

3. Modeling layers (L0–L6)

The multiscale layer plan from v0.1 remains the scientific scaffold: evidence/knowledge (L0), molecular cell state (L1), spatial tissue context (L2–L3), repair-state dynamics (L4), functional coupling (L5), and uncertainty/OOD (L6). Layers are being realized incrementally through the stack above; L5–L6 and cross-layer fusion are active development priorities, not finished products.

4. What changed since v0.1

- Status updated from **Discovery** to **Active development** to reflect an implemented multi-repo platform under public build.
- Framing updated from a generic computational regeneration model to **HeartTwin** as the user-facing digital heart twin program (VB-310).
- Public engines catalogued and linked; browser demos exist for selected components (research illustrations only).
- Scientific guardrails retained: no clinical twin claim, no efficacy claim, no IND/clinical-stage claim.

5. Validation discipline

Evaluation remains leakage-aware and provenance-bound (CardiBench / CardiEval / CardiTrace contracts). GO criteria require locked public or prospectively registered benchmarks, held-out biological units, calibration reporting, and explicit separation of software completeness from scientific validation. NO-GO applies to causal/therapeutic language driven by study, species, developmental stage, or assay confounds.

6. Risks (unchanged in kind)

- Dataset heterogeneity / batch effects — mitigate with study-level splits and robust normalization.
- Label leakage and overconfident OOD predictions — mitigate with group-safe splits and uncertainty layers.
- Confounding regeneration with species/development — treat as covariates; test cross-domain transfer.
- Overclaiming causality or clinical readiness — keep association/prediction/hypothesis language until experimentally tested.

7. Website-ready description

VB-310 (HeartTwin) is Virelion's actively developed digital heart twin platform for myocardial repair research. Public domain engines feed a cardiac state stack used to observe, predict, simulate, intervene, and validate regenerative versus maladaptive trajectories. Primary public entryptpoint: Virelion-HeartTwin. Research platform only — not a clinical digital twin.

8. Disclaimer

This dossier is a scientific and engineering status note for collaborators and internal alignment. It does not constitute regulatory advice, clinical guidance, or an offer of a medical device or software as a medical device (SaMD). Supersedes VB-310 Discovery Dossier v0.1 for program-status language.