Appendix 1: HealthTech Innovation Readiness (HIR) Level Deliverables

Level/ Name	Overall Description	Innovation Maturity Level Descriptors (Deliverables)			
		Clinical	Market/Business	Technology	Regulatory
1. Need	Insights into unmet clinical needs and available solutions	Unmet need is articulated based on clinical experience	Deficiency in existing solutions identified	Available solutions identified and new technologies searched	NA
2. Idea	Potential solution described to unmet need	Clinical workflow scenario description	Competitive landscape and preliminary reimbursement review	"Paper Prototype" and initial institutional "Idea" (IP) disclosure and review Hypothesis experimental designs for addressing the technical issues of key components	Preliminary solution classification and predicates identified
3. Proof of Concept (PoC)	Key component concepts validated in models and value proposition articulated	Positive feedback from clinicians in other settings (>5)	Preliminary "Value Proposition" and "Path to Payment" plan	Experiments validate key components hypotheses. (In vivo, in silica, and maybe in vitro) Refined institutional IP disclosure	Solution classification and preliminary regulatory pathway defined
4. Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	Positive feedback from (Total ≥ 20) other clinicians in target settings	Positive feedback from economic buyers (>5) Preliminary business model and plan (including reimbursement path)	"Looks Like" and "Works Like" prototypes FTO review and provisional IP filing Killer technical experiment (e.g. initiation of animal model development for desired indication)	Submission pathway defined IRB approvals
5. Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated (initial commercial investment)	Positive feedback from other clinicians (≥ 50) and KOLs Animal/first in man experiments Peer reviewed publication(s)	Investor ready business plan Positive feedback from economic buyers (≥50) Key management team identified and seed investment (NewCo or project)	"Works Like, Looks Like" prototypes of MVP with product IFU Manufacturing plan and costing Full IP application Killer technical experiment (e.g. non-GLP animal studies for regulatory filing)	Submission data package defined
6. Initial Clinical Trails (ICT)	Regulated production of prototypes and collection of clinical and economic data	Conduct phase 0 and/or 1 clinical trial(s) to determine the safety and effectiveness of the solution	Collection of economic data compared to SoC (e.g. validating beachhead market) 1st round of institutional investment	Manufacture GMP-compliant pilot lots	Preliminary FDA guidance (not a meeting necessarily) and data package assembled
7. Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	Clinical efficacy trials (e.g., phase 2 and 3), and/or expanded clinical safety trials Training materials established	Purchasing intent from lead users 2nd round of institutional investment	Initiation of GMP process validation	Submission
8. Approval & Launch (A&L)	Institutional and regulatory approval received and sales launch	Specialty medical groups review	Initial sales Reimbursement code	Finalized GMP manufacturing process	Registration and listing
9. Clinical Use (Use)	The solution is used successfully in day-to-day clinical practice	Included in practice guidelines	Profitable sales	US IP issued; improvements under development	Monitoring/ inspections
10. Standard of Care (SoC)	The solution is recognized as the standard of care	Recommended practice by medical specialty	Dominant market share	Int'l IP issued; next generation under development	NA