IVD Innovation Cycle Checklist

Solution Name: _____ ☐ Not Done ⊞ Partial ☑ Completed **Date**:_____

IML	Overall Description	Clinical	Business	Regulatory	Technology
1. Need	Insights into unmet needs and available solutions	☐ Unmet need statement ☐ Disease state characterization	☐ Needs screening & selection ☐ Existing solutions characterized	☐ Regulatory familiarization	☐ State-of-the-Art Summary
2. Idea	Potential solution to unmet need described, evaluated, and selected	☐ Envisioned benefit statement ☐ Feedback from 5+ clinical stakeholders ☐ Identify appropriate target(s) to be detected ☐ Workflow scenario	☐ Competitive landscape ☐ Envisioned Value Proposition ☐ Key stakeholders identified ☐ Market map & segmentation ☐ Reimbursement familiarization	☐ Comparables identified ☐ Medical device determination	☐ Core components of kit/reagents identified ☐ Hypothesis and experimental design ☐ Idea screening and selection ☐ Institutional IP disclosure ☐ Paper prototype
3. Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	☐ Feedback from clinical stakeholders in 5+ settings ☐ Target outcomes ☐ Updated need statement and workflow scenario	☐ Business protection model ☐ Competing solutions characterized ☐ Preliminary Path-to-Payment plan ☐ Preliminary value proposition Stakeholder map	☐ Design control system in place ☐ Preliminary indications for use ☐ Preliminary regulatory classification ☐ Preliminary regulatory pathway(LDT or device) ☐ Preliminary risk and hazard analysis	☐ Demonstration results ☐ Key assay components identified ☐ Key hardware/device component PoC prototypes ☐ Preliminary Freedom to Operate (FTO) Assessment ☐ Updated institutional IP disclosure
4. Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	☐ Feedback users in 20+ settings ☐ Updated need and workflow descriptions ☐ Updated target outcomes	☐ Business advisory board ☐ Development plan ☐ Feedback from 5+ economic buyers ☐ Key relationships identified ☐ Preliminary business model ☐ Preliminary supply chain strategy ☐ Secure Access to Core IP	☐ Draft essential requirements checklist ☐ Draft instructions for use ☐ Draft product claims ☐ Institutional approval request(s) ☐ Submission pathway defined	☐ Essential experiment results ☐ Intellectual property assessment ☐ Key in-sourcing plans ☐ Preliminary BOM and Manufacturing-QMS Plan ☐ Provisional IP filing ☐ User/Product requirement document (URD/PRD) ☐ “Works Like” and “Looks Like” prototypes

5. Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated	☐ Animal/first in/with man experiments ☐ Clinical trial endpoints ☐ Feedback from 5+ KOLs ☐ Feedback from 50+ clinical stakeholders ☐ Medical advisory board	☐ Feedback from 10+ economic buyers ☐ Incorporation & founders agreement ☐ Initial seed investment ☐ Investor ready business plan ☐ Key management team committed ☐ Key relationships formalized	☐ Application regulatory authority submitted ☐ Clinical Investigation approval(s) ☐ Electronic Protected Health Information (ePHI) plans ☐ Essential requirements checklist ☐ Quick reference guide	☐ cGMP compliant pilot manufacturing process ☐ Essential technical experiments results ☐ IP search report ☐ Key in-sourcing requirements committed ☐ "Works-like, Looks-like. Made-like" prototypes
6. Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	☐ Demo feedback from 20+ clinical stakeholders ☐ Endpoints achieved in pilot clinical trials	☐ 1st Institutional Investment ☐ Business resumption plan ☐ Feedback from 20+ economic buyers ☐ Value quantification	☐ Data requirements confirmation ☐ GDPR/HIPAA compliance ☐ Pre-submission filed ☐ Security and vulnerability certifications	☐ All in-sourcing requirements achieved ☐ cGMPs compliant manufacturing plan ☐ Full IP application ☐ Updated PRD & experimental validation
7. Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	☐ Endpoints achieved in pivotal clinical trials ☐ Peer reviewed publication(s) accepted	☐ 2nd round of institutional investment ☐ Purchasing intent from 10+ buyers	☐ Submission of Technical file to regulatory body	☐ cGMPs compliant manufacturing process ☐ Quality assured process validation (cGMP) ☐ Scale-up verification and validation
8. Approval & Launch (A&L)	Institutional and regulatory approval received and sales launch	☐ Specialty medical groups review in place ☐ Training materials & Support established	☐ Initial sales ☐ Regionalization plans	☐ Registration and listing ☐ Public coverage and code determination	☐ Finalized cGMP manufacturing process ☐ IP update
9. Clinical Use (Use)	The solution is used successfully in day-to-day clinical practice	☐ Included in local practice guidelines ☐ Peer reviewed publications	☐ New markets launched ☐ Profitable sales	☐ Monitoring/ inspections	☐ Improvement plan ☐ Key patents issued
10. Standard of Care (SoC)	The solution is recognised as the standard of care	☐ Recommended by medical specialty	☐ Dominant market share ☐ Health economics study	☐ Product Obsolescence Plan	☐ Component Obsolescence Plan