

## 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	2 <sup>nd</sup> 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