Biomarkers Diagnostic Milestone Checklist

Solution Name: _____ ☐ Not Done ☐+ Proposed ☐√ Completed **Date:** _____

IML	Overall Description	Innovation Maturity Level Milestone			
		Clinical	**Market/Business**	**Regulatory**	**Technology**
1. Need	**Insights into unmet clinical needs and available solutions**	☐ Unmet need statement ☐ Disease state characterization	☐ Needs screening & selection ☐ Existing solutions characterization	☐ Regulatory familiarization	☐ State-of-the-Art summary
2. Idea	**Potential solution to unmet need described, evaluated and selected**	☐ Clinical Workflow scenario ☐ Updated need statement ☐ Envisioned benefit statement ☐ Feedback from 5+ clinical stakeholders	☐ Competitive landscape ☐ Envisioned Value Proposition ☐ Key stakeholders identified ☐ Reimbursement familiarization	☐ Medical device determination (MDR in EU) ☐ Comparable identified	☐ Idea screening and selection ☐ Preliminary Target Product Profile (TPP) ☐ Biological mechanism of action Identified Institutional ☐ IP disclosure
3. Proof of Concept (PoC)	**Key component concepts validated in models and value proposition tested**	☐ Feedback from clinical stakeholders in 5+ settings ☐ Updated need statement and workflow scenario ☐ Target outcomes	☐ Competing solutions characterization ☐ Preliminary value proposition ☐ Path-to-Payment plan ☐ Stakeholder map ☐ Business protection model	☐ Preliminary regulatory classification ☐ Preliminary regulatory pathway ☐ Preliminary intended /indications for use	☐ **Key mechanism of action validated** ☐ Updated Target Product Profile (TPP) ☐ Preliminary Freedom to Operate (FTO) Assessment ☐ Updated institutional IP disclosure ☐ Key in-sourcing requirements
4. Proof of Feasibility (PoF)	**Feasibility of whole solution demonstrated in models and in feedback from stakeholders**	☐ Feedback on users in 20+ settings ☐ Updated need statement and Use Case scenario/workflow ☐ Updated target outcomes	☐ Feedback from 5+ economic buyers ☐ Preliminary business model ☐ Development plan ☐ Key relationships identified ☐ Business advisory board ☐ Secure Access to Core IP	☐ Draft essential requirements checklist ☐ Draft product claims ☐ Draft instructions for use ☐ Institutional approval request(s) ☐ Submission pathway defined	☐ Updated Target Product Profile (TPP) ☐ “Works Like” and “Looks Like” packaging prototypes ☐ Essential experiment results ☐ Provisional IP filing & initial FTO review ☐ Key in-sourcing plans ☐ Manufacturing/QMS plan
5. Proof of Value (PoV)	**The potential of the solution to work and create value for all stakeholders is demonstrated**	☐ Feedback from 100+ users ☐ Feedback from 5+ KOLs ☐ Animal/first in/with man experiments ☐ Medical advisory board ☐ Clinical trial endpoints	☐ Key management team committed ☐ Investor ready business plan ☐ Feedback from 20+ economic buyers ☐ Initial Seed Investment ☐ Key relationships formalized ☐ Incorporation & Founders agreement	☐ Essential requirements checklist ☐ Application form to competent authority submitted ☐ Clinical Investigation approval(s)	☐ "Works Like, Looks Like, Made Like” prototypes ☐ Updated TPP & Essential technical experiments results ☐ IP search report ☐ cGMP compliant pilot manufacturing process ☐ Key in-sourcing requirements committed ☐ Conference/poster session/paper submitted

6. Initial Clinical Trials (ICT)	**Regulated production of prototypes and collection of clinical and economic data**	☐ **Endpoints achieved in Feasibility clinical trials** ☐ Peer reviewed publication(s) submitted	☐ Value quantification ☐ Feedback from 25+ economic buyers ☐ **1st institutional investment**	☐ Data requirements confirmation ☐ Pre-submission filed	☐ cGMPs compliant manufacturing process ☐ Updated TPP & experimental validation ☐ All in-sourcing licensing requirements achieved ☐ **Full IP application**
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	☐ Purchasing intent from 10+ buyers ☐ **2nd round of institutional investment**	☐ Submission of Technical file to regulatory body	☐ Quality assured process validation (cGMP) ☐ Updated TPP & experimental validation
8. Approval & Launch (A&L)	**Institutional and regulatory approval received and sales launch**	☐ Training materials & support established ☐ Specialty medical groups review in place	☐ **Initial sales** ☐ Regionalization plans	☐ **Registration and listing** ☐ **CMS/Public Coverage and CPT/ DRG code determination**	☐ Finalized cGMP production environment ☐ IP for improvements filed
9. Clinical Use (Use)	**The solution is used successfully in day-to-day clinical practice**	☐ Included in local practice guidelines ☐ Peer reviewed publications	☐ **Profitable sales** New ☐ markets launched	☐ Monitoring/ inspections	☐ Improvement plan ☐ Key patents issued
10. Standard of Care (SoC)	**The solution is recognised as the standard of care**	☐ Recommended practice by medical specialty	☐ Dominant market share ☐ Health economics study	☐ Product Obsolescence plan	☐ Component Obsolescence plan

For more information on specific milestones visit: https://www.gaits.org/web/biomarker-diagnostic/guidance