

## 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	<b>Key mechanism of action validated</b>  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	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

<b>6. Initial Clinical Trials (ICT)</b>	<b>Regulated production of prototypes and collection of clinical and economic data</b>	<b>Endpoints achieved in Feasibility clinical trials</b>  Peer reviewed publication(s) submitted	Value quantification Feedback from 25+ economic buyers <b>1st institutional investment</b>	Data requirements confirmation Pre-submission filed	cGMPs compliant manufacturing process Updated TPP & experimental validation All in-sourcing licensing requirements achieved <b>Full IP application</b>
<b>7. Validation of Solution (VoS)</b>	<b>The solution is shown to be effective and its value to all stakeholders is validated</b>	<b>Endpoints achieved in pivotal clinical trials</b>  Peer reviewed publication(s) accepted	Purchasing intent from 10+ buyers <b>2nd round of institutional investment</b>	Submission of Technical file to regulatory body	Quality assured process validation (cGMP) Updated TPP & experimental validation
<b>8. Approval &amp; Launch (A&amp;L)</b>	<b>Institutional and regulatory approval received and sales launch</b>	Training materials & support established Specialty medical groups review in place	<b>Initial sales</b> Regionalization plans	<b>Registration and listing CMS/Public Coverage and CPT/DRG code determination</b>	Finalized cGMP production environment IP for improvements filed
<b>9. Clinical Use (Use)</b>	<b>The solution is used successfully in day-to-day clinical practice</b>	Included in local practice guidelines Peer reviewed publications	<b>Profitable sales</b> New markets launched	Monitoring/ inspections	Improvement plan Key patents issued
<b>10. Standard of Care (SoC)</b>	<b>The solution is recognised as the standard of care</b>	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://cimit.net/web/biomarker-diagnostic/guidance>