MEDTECH MILESTONES FRAMEWORK

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			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**	❑ 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 ❑ Paper Prototype ❑ 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 ❑ Preliminary risk and hazard analysis	❑ Key component PoC prototypes ❑ Demonstration results ❑ 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	❑ Product Requirement Document (PRD) ❑ "Works Like" and "Looks Like" 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**	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs	❑ Key management team committed ❑ Investor ready business plan	❑ Essential requirements checklist ❑ Application form to competent authority submitted	❑ "Works Like, Looks Like, Made Like" prototypes ❑ Essential technical experiments results

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		stakeholders is demonstrated	❑ Use Case/ scenarios testing with 10+ users ❑ **Animal/first in/with man experiments** ❑ Medical advisory board ❑ Clinical trial endpoints	❑ Feedback from 20+ economic buyers ❑ **Initial Seed Investment** ❑ Key relationships formalized ❑ Incorporation & Founders agreement	❑ Clinical Investigation approval(s)	❑ IP search report ❑ GMP compliant pilot manufacturing process ❑ Key in-sourcing requirements committed
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	☐ **Endpoints achieved in Feasibility clinical trials** ☐ Demo feedback from 25+ users ☐ Peer reviewed publication(s) submitted	☐ Value quantification ☐ Feedback from 25+ economic buyers ☐ **1st institutional investment**	☐ GDPR/HIPAA compliance ☐ Security and vulnerability certifications ☐ Data requirements confirmation ☐ Pre-submission filed	☐ cGMPs compliant manufacturing process ☐ Updated specification & 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 specification & 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 the specific meaning of each of the milestones you can access:
https://gaits.org/web/medtech/guidance

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