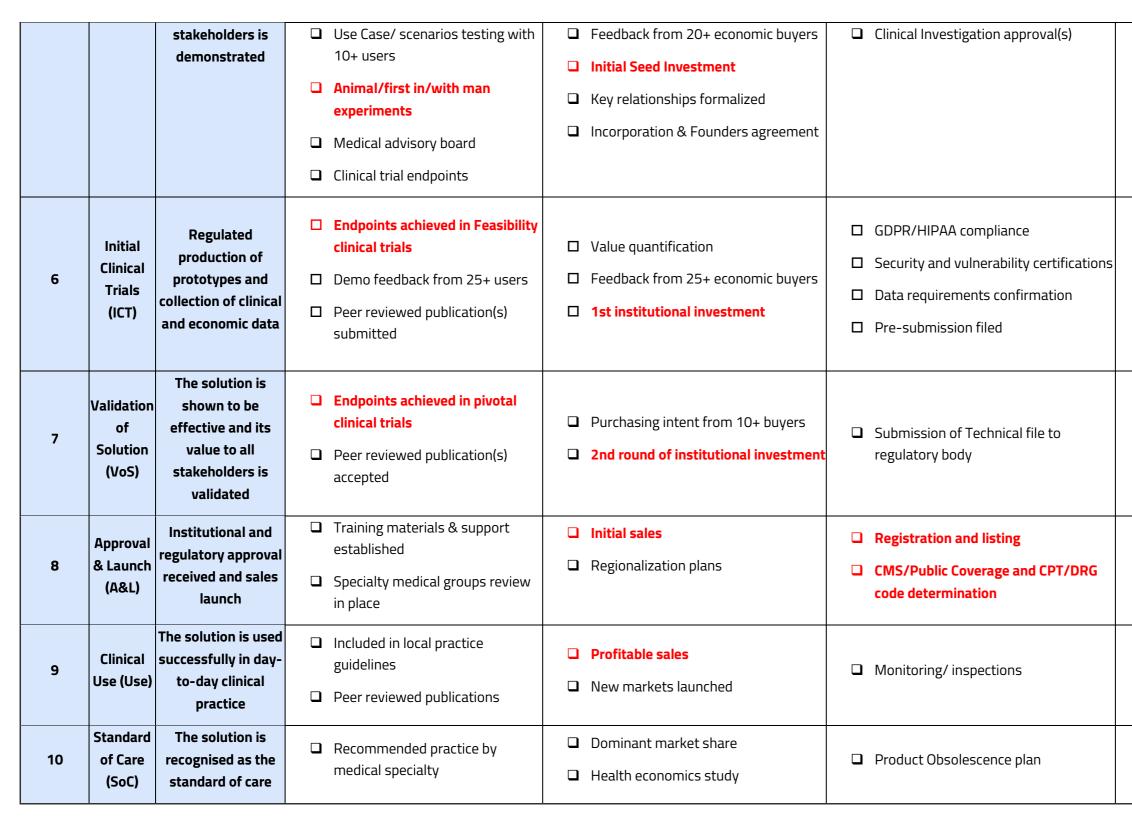


MEDTECH MILESTONES FRAMEWORK

Innovation		o		Innovation Mat	turity Level Milestones	
Maturity Level	Name	Overall Description	Clinical	Market/Business	Regulatory	
1	Need	Insights into unmet clinical needs and available solutions	Unmet need statementDisease state characterization	Needs screening & selectionExisting solutions characterization	Regulatory familiarization	(
2	ldea	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 	((
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 	
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 	(((((
5	Proof of Value (PoV)	The potential of the solution to work and create value for all		 Key management team committed Investor ready business plan 	 Essential requirements checklist Application form to competent authority submitted 	(

Technology
State-of-the-Art summary
Idea screening and selection
Paper Prototype
Institutional IP disclosure
Key component PoC prototypes
Demonstration results
Preliminary Freedom to Operate (FTO) Assessment
Updated institutional IP disclosure
Key in-sourcing requirements
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
"Works Like, Looks Like, Made Like" prototypes
Essential technical experiments results



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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IP search report
GMP compliant pilot manufacturing process
Key in-sourcing requirements committed
cGMPs compliant manufacturing process
Updated specification & experimental validation
All in-sourcing licensing requirements achieved
Full IP application
Quality assured process validation (cGMP)
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Updated specification & experimental
Updated specification & experimental validation
Updated specification & experimental validation Finalized cGMP production environment
 Updated specification & experimental validation
Updated specification & experimental validation Finalized cGMP production environment IP for improvements filed
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