

## MedTech Innovation Cycle Checklist

Solution Name: \_\_\_\_\_

Not Done

Proposed

Completed

Date: \_\_\_\_\_

IML	Overall Description	Clinical	Business	Regulatory	Technology
1. Need	Insights into unmet medical 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 Comparables identified	Idea screening and selection Paper prototype Hypothesis and experimental design 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 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 from clinical stakeholders 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 Submission pathway defined Draft product claims Draft instructions for use Institutional approval request(s)	Product Requirement Document (PRD) "Works Like" and "Looks Like" prototypes Essential experiment results Provisional IP filing & initial FTO review Manufacturing/QMS plan Key in-sourcing plans

5. Proof of Value (POV)	The potential of the solution to work and create value for stakeholders is demonstrated	<ul style="list-style-type: none"> <li>Feedback from 100+ clinical stakeholders</li> <li>Feedback from 5+ KOLs</li> <li>Animal/first in/with man experiments</li> <li>Medical advisory board</li> <li>Clinical trial endpoints</li> </ul>	<ul style="list-style-type: none"> <li>Key management team committed</li> <li>Investor ready business plan</li> <li>Feedback from 20+ economic buyers</li> <li>Initial seed investment</li> <li>Incorporation &amp; Founders Agreement</li> <li>Key relationships formalized</li> </ul>	<ul style="list-style-type: none"> <li>Essential requirements checklist</li> <li>Application form to competent authority submitted</li> <li>Clinical Investigation approval(s)</li> </ul>	<ul style="list-style-type: none"> <li>"Works Like, Looks Like" prototypes</li> <li>Essential technical experiments results</li> <li>IP search report</li> <li>Key in-sourcing requirements committed</li> <li>cGMP compliant pilot manufacturing process</li> </ul>
6. Initial Clinical Trials	Regulated production of prototypes and collection of clinical and economic data	<ul style="list-style-type: none"> <li>Endpoints achieved in pilot clinical trials</li> <li>Demo feedback from 50+ clinical stakeholders</li> <li>Peer reviewed publication(s) submitted</li> </ul>	<ul style="list-style-type: none"> <li>Value quantification</li> <li>Feedback from 50+ economic buyers</li> <li>1st Institutional Investment</li> </ul>	<ul style="list-style-type: none"> <li>GDPR/HIPAA compliance</li> <li>Security and vulnerability certifications</li> <li>Data requirements confirmation</li> <li>Pre-submission sent</li> </ul>	<ul style="list-style-type: none"> <li>cGMPs compliant manufacturing process</li> <li>Updated specification &amp; experimental validation</li> <li>All in-sourcing requirements achieved</li> <li>Full IP application</li> </ul>
7. Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	<ul style="list-style-type: none"> <li>Endpoints achieved in pivotal clinical trials</li> <li>Peer reviewed publication(s) accepted</li> </ul>	<ul style="list-style-type: none"> <li>Purchasing intent from 10+ buyers</li> <li>Second round of institutional investment</li> </ul>	<ul style="list-style-type: none"> <li>Submission of Technical file to regulatory body</li> </ul>	<ul style="list-style-type: none"> <li>Quality assured process validation (cGMP)</li> <li>Updated specification &amp; experimental validation</li> </ul>
8. Approval & Launch (A&L)	The solution is shown to be effective and its value to all stakeholders is validated	<ul style="list-style-type: none"> <li>Training materials &amp; Support established</li> <li>Specialty medical groups review in place</li> </ul>	<ul style="list-style-type: none"> <li>Initial sales</li> <li>Regionalization plans</li> </ul>	<ul style="list-style-type: none"> <li>Registration and listing</li> <li>CMS/Public Coverage and CPT/DRG code determination</li> </ul>	<ul style="list-style-type: none"> <li>Finalized cGMP manufacturing process</li> <li>IP for improvements filed</li> </ul>
9. Clinical Use (Use)	The solution is used successfully in day-to-day clinical practice	<ul style="list-style-type: none"> <li>Included in local practice guidelines</li> <li>Peer reviewed publications</li> </ul>	<ul style="list-style-type: none"> <li>Profitable sales</li> <li>New markets launched</li> </ul>	<ul style="list-style-type: none"> <li>Monitoring/ inspections</li> </ul>	<ul style="list-style-type: none"> <li>Improvement plan</li> <li>Key patents issued</li> </ul>
10. Standard of Care (SoC)	The solution is recognized as the standard of care	<ul style="list-style-type: none"> <li>Recommended practice by medical specialty</li> </ul>	<ul style="list-style-type: none"> <li>Dominant market share</li> <li>Health economics study</li> </ul>	<ul style="list-style-type: none"> <li>Product Obsolescence Plan</li> </ul>	<ul style="list-style-type: none"> <li>Component Obsolescence Plan</li> </ul>