

## Digital Medicine 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 System and module requirement specification Interface mock-ups 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 and pathway Preliminary indications for use Preliminary risk and hazard analysis	Preliminary system & software architecture Key module PoC prototypes Demonstration results 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 Secure Access to Core IP	Draft essential requirements checklist Draft product claims Draft instructions for use Institutional approval request(s) Cyber security plan Submission pathway defined	Product Requirement Document (PRD) Software & hardware architecture "Works Like" prototypes Essential experiment results Risk mitigation & interoperability plan Provisional IP filing & initial FTO review 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+ users</li> <li>Feedback from 5+ KOLs</li> <li>Medical advisory board</li> <li>Clinical pilot</li> <li>Clinical trial endpoints</li> </ul>	<ul style="list-style-type: none"> <li>Incorporation &amp; Founder's agreement</li> <li>Key management team committed</li> <li>Investor ready business plan</li> <li>Feedback from 10+ economic buyers</li> <li>Initial seed investment</li> <li>Key relationships formalized</li> </ul>	<ul style="list-style-type: none"> <li>Essential requirements checklist</li> <li>Application to regulatory authority submitted</li> <li>Clinical Investigation approval(s)</li> <li>Protected Health Information (ePHI) plans</li> </ul>	<ul style="list-style-type: none"> <li>"Works Like, Looks Like" prototypes</li> <li>Essential technical experiments results</li> <li>Interoperability validation</li> <li>IP search report</li> <li>Key in-sourcing requirements committed</li> <li>cGMP compliant pilot medical software &amp; production environment(s)</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 Feasibility clinical trials</li> <li>Demo feedback from 20+ users</li> <li>Peer reviewed publication(s) submitted</li> </ul>	<ul style="list-style-type: none"> <li>Value quantification</li> <li>Feedback from 20+ 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>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)	Institutional and regulatory approval received and sales launch	<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 production environment</li> <li>Regionalization requirements</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>Regionalization implemented</li> <li>Improvement plan</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>