

# DIGITAL HEALTH MILESTONES FRAMEWORK

| Innovation Maturity Level |                            |  | Innovation Maturity Level Milestones  |  |  |   |
|---------------------------|----------------------------|--|---|--|--|---|
| Maturity Level            | Name                       | Overall Description  | Clinical  | Market/Business  | Regulatory   | Technology  |
| 1                         | Need                       | Insights into unmet clinical needs and available solutions                             | <ul style="list-style-type: none"> <li><input type="checkbox"/> Unmet need statement</li> <li><input type="checkbox"/> Disease state characterization</li> </ul>  | <ul style="list-style-type: none"> <li><input type="checkbox"/> Needs screening &amp; selection</li> <li><input type="checkbox"/> Existing solutions characterization</li> </ul>   | <ul style="list-style-type: none"> <li><input type="checkbox"/> Regulatory familiarization</li> </ul>  | <ul style="list-style-type: none"> <li><input type="checkbox"/> State-of-the-Art summary</li> </ul>   |
| 2                         | Idea                       | Potential solution to unmet need described, evaluated and selected                     | <ul style="list-style-type: none"> <li><input type="checkbox"/> Workflow scenario</li> <li><input type="checkbox"/> Updated need statement</li> <li><input type="checkbox"/> Envisioned benefit statement</li> <li><input type="checkbox"/> Feedback from 5+ clinical stakeholders</li> </ul> | <ul style="list-style-type: none"> <li><input type="checkbox"/> Competitive landscape</li> <li><input type="checkbox"/> Envisioned Value Proposition</li> <li><input type="checkbox"/> Key stakeholders identified</li> <li><input type="checkbox"/> Reimbursement familiarization</li> </ul>  | <ul style="list-style-type: none"> <li><input type="checkbox"/> Medical device determination (MDR in EU)</li> <li><input type="checkbox"/> Comparable identified</li> </ul>  | <ul style="list-style-type: none"> <li><input type="checkbox"/> Idea screening and selection</li> <li><input type="checkbox"/> System and module requirement specification</li> <li><input type="checkbox"/> Interface mock-ups</li> <li><input type="checkbox"/> Institutional IP disclosure</li> </ul>  |
| 3                         | Proof of Concept (PoC)     | Key component concepts validated in models and value proposition tested                | <ul style="list-style-type: none"> <li><input type="checkbox"/> Feedback from clinical stakeholders in 5+ settings</li> <li><input type="checkbox"/> Updated need statement and workflow scenario</li> <li><input type="checkbox"/> Target outcomes</li> </ul>                                | <ul style="list-style-type: none"> <li><input type="checkbox"/> Competing solutions characterization</li> <li><input type="checkbox"/> Preliminary value proposition</li> <li><input type="checkbox"/> Path-to-Payment plan</li> <li><input type="checkbox"/> Stakeholder map</li> <li><input type="checkbox"/> Business protection model</li> </ul> | <ul style="list-style-type: none"> <li><input type="checkbox"/> Preliminary regulatory classification</li> <li><input type="checkbox"/> Preliminary regulatory pathway</li> <li><input type="checkbox"/> Preliminary intended /indications for use</li> <li><input type="checkbox"/> Preliminary risk and hazard analysis</li> </ul>   | <ul style="list-style-type: none"> <li><input type="checkbox"/> Preliminary system and software architecture</li> <li><input type="checkbox"/> Key module PoC prototypes</li> <li><input type="checkbox"/> Demonstration results</li> <li><input type="checkbox"/> Updated institutional IP disclosure</li> <li><input type="checkbox"/> Key in-sourcing requirements</li> </ul>  |
| 4                         | Proof of Feasibility (PoF) | Feasibility of whole solution demonstrated in models and in feedback from stakeholders | <ul style="list-style-type: none"> <li><input type="checkbox"/> Feedback on users in 20+ settings</li> <li><input type="checkbox"/> Updated need statement and Use Case scenario/workflow</li> <li><input type="checkbox"/> Updated target outcomes</li> </ul>                                | <ul style="list-style-type: none"> <li><input type="checkbox"/> Feedback from 5+ economic buyers</li> <li><input type="checkbox"/> Preliminary business model</li> <li><input type="checkbox"/> Development plan</li> <li><input type="checkbox"/> Key relationships identified</li> <li><input type="checkbox"/> Business advisory board</li> </ul> | <ul style="list-style-type: none"> <li><input type="checkbox"/> Draft essential requirements checklist</li> <li><input type="checkbox"/> Draft product claims</li> <li><input type="checkbox"/> Draft instructions for use</li> <li><input type="checkbox"/> Institutional approval request(s)</li> <li><input type="checkbox"/> Cyber security plan</li> <li><input type="checkbox"/> Submission pathway defined</li> </ul> | <ul style="list-style-type: none"> <li><input type="checkbox"/> Product Requirement Document (PRD)</li> <li><input type="checkbox"/> Software and hardware architecture</li> <li><input type="checkbox"/> "Works Like" prototype</li> <li><input type="checkbox"/> Essential experiment results</li> <li><input type="checkbox"/> Provisional IP filing &amp; initial FTO review</li> <li><input type="checkbox"/> Key in-sourcing plans</li> <li><input type="checkbox"/> Risk mitigation and interoperability plan</li> </ul> |
| 5                         | Proof of Value             | The potential of the solution to work and create value for all                         | <ul style="list-style-type: none"> <li><input type="checkbox"/> Feedback from 100+ users</li> <li><input type="checkbox"/> Feedback from 5+ KOLs</li> </ul>   | <ul style="list-style-type: none"> <li><input type="checkbox"/> Key management team committed</li> <li><input checked="" type="checkbox"/> <b>Investor ready business plan</b></li> </ul>  | <ul style="list-style-type: none"> <li><input type="checkbox"/> Essential requirements checklist</li> </ul>  | <ul style="list-style-type: none"> <li><input type="checkbox"/> "Works Like, Looks Like, prototypes</li> <li><input type="checkbox"/> Essential technical experiments results</li> </ul>  |

|    |                               |  |   |  |  |   |
|----|-------------------------------|--|---|--|--|---|
|    | (PoV)                         | stakeholders is demonstrated   | <input type="checkbox"/> Medical advisory board<br><input type="checkbox"/> Clinical pilot<br><input type="checkbox"/> Clinical trial endpoints   | <input type="checkbox"/> Feedback from 20+ economic buyers<br><input type="checkbox"/> Initial Seed Investment<br><input type="checkbox"/> Key relationships formalized<br><input type="checkbox"/> Incorporation & Founders agreement | <input type="checkbox"/> Application form to competent authority submitted<br><input type="checkbox"/> Clinical Investigation approval(s)<br><input type="checkbox"/> Protected Health Information (ePHI) plans                  | <input type="checkbox"/> Interoperability validation<br><input type="checkbox"/> cGMP medical software and production environments (s)<br><input type="checkbox"/> Key in-sourcing requirements committed |
| 6  | Initial Clinical Trials (ICT) | Regulated production of prototypes and collection of clinical and economic data      | <input type="checkbox"/> <b>Endpoints achieved in Feasibility clinical trials</b><br><input type="checkbox"/> Demo feedback from 25+ users<br><input type="checkbox"/> Peer reviewed publication(s) submitted | <input type="checkbox"/> Value quantification<br><input type="checkbox"/> Feedback from 25+ economic buyers<br><input type="checkbox"/> <b>1st institutional investment</b>  | <input type="checkbox"/> GDPR/HIPAA compliance<br><input type="checkbox"/> Security and vulnerability certifications<br><input type="checkbox"/> Data requirements confirmation<br><input type="checkbox"/> Pre-submission filed | <input type="checkbox"/> Updated specification & experimental validation<br><input type="checkbox"/> All in-sourcing licensing requirements achieved<br><input type="checkbox"/> Full IP application      |
| 7  | Validation of Solution (VoS)  | The solution is shown to be effective and its value to all stakeholders is validated | <input type="checkbox"/> <b>Endpoints achieved in pivotal clinical trials</b><br><input type="checkbox"/> Peer reviewed publication(s) accepted   | <input type="checkbox"/> Purchasing intent from 10+ buyers<br><input type="checkbox"/> <b>2nd round of institutional investment</b>  | <input type="checkbox"/> Submission of Technical file to regulatory body   | <input type="checkbox"/> Quality assured process validation (cGMP)<br><input type="checkbox"/> Updated specification & experimental validation  |
| 8  | Approval & Launch (A&L)       | Institutional and regulatory approval received and sales launch                      | <input type="checkbox"/> Training materials & support established<br><input type="checkbox"/> Specialty medical groups review in place  | <input type="checkbox"/> Initial sales/deployment<br><input type="checkbox"/> Regionalization plans  | <input type="checkbox"/> <b>Registration and listing</b><br><input type="checkbox"/> <b>CMS/Public Coverage and CPT/DRG code determination</b>   | <input type="checkbox"/> Finalized cGMP production environment<br><input type="checkbox"/> Regionalization requirements   |
| 9  | Clinical Use (Use)            | The solution is used successfully in day-to-day clinical practice                    | <input type="checkbox"/> Included in local practice guidelines<br><input type="checkbox"/> Peer reviewed publications   | <input type="checkbox"/> <b>Profitable sales</b><br><input type="checkbox"/> New markets launched  | <input type="checkbox"/> Monitoring/ inspections   | <input type="checkbox"/> Improvement plan<br><input type="checkbox"/> Regionalization implemented   |
| 10 | Standard of Care (SoC)        | The solution is recognised as the standard of care                                   | <input type="checkbox"/> Recommended practice by medical specialty  | <input type="checkbox"/> Dominant market share<br><input type="checkbox"/> Health economics study  | <input type="checkbox"/> Product Obsolescence plan   | <input type="checkbox"/> Component Obsolescence plan  |

For more information on the specific meaning of each of the milestones you can access: <https://gait.org/web/-digital-medicine/guidance>