HEALTH INNOVATION CYCLE[[1]](#footnote-2)

**The Status of the Innovation:** The objective of this section is to characterize the current state of commercialization across 4 key domains of health innovation to determine the best program fit for the project. Please check all milestones completed to date

| **AI Client** **Journey** | **Milestone** | **Overall Description** | **Product-Market Fit** | **Business Readiness** | **Regulatory Compliance** | **Product Development** |
| --- | --- | --- | --- | --- | --- | --- |
| **Discovering** | 1. Need Identification
 | Insights into unmet health need and state of the art solutions. | [ ] Unmet clinical need identified and validated through secondary research. |  |  | [ ] State of the art summarized |
| **Ideating** | 1. Idea

Generation | Potential solutions to unmet need described, evaluated and selected.  | [ ] Target clinical population identified and characterized.[ ] Current clinical care pathway and workflow described.[ ] Feedback from ≥5 clinicians or consumers.  | [ ] Target market identified and characterized.[ ] Key stakeholders identified.[ ] Envisioned benefit statements for patients, payers, and providers.  | [ ] Familiarization with local regulatory requirements and processes.  | [ ] Idea screening & selection completed.[ ] Hypothesis and experimental design completed.  |
| **Conceptualizing** | 1. Proof of

Concept | Key component concepts validated in models and value proposition tested. | [ ] Technology-adjusted care pathway and workflow described. [ ] Quantifiable health outcome targets developed.[ ] Feedback from clinicians or consumers in ≥ 5 different settings. | [ ] Competitive analysis and competitive positioning completed.[ ] Path to payment plan or reimbursement described.[ ] Stakeholder management plan developed. [ ] Proposed Business Model.[ ] Foundational business agreements drafted (i.e., initial ownership and rights)  | [ ] Comparable / predicates identified as necessary.[ ] Preliminary intended / indications for use drafted.[ ] Regulatory categorization and class determination[ ] Hazard and risk analysis.  | [ ] Key Proof-of-Concept features documented. [ ] Proof-of-concept and mechanistic action experiments completed. [ ] Intellectual property strategy drafted, and IP disclosure filed as needed. [ ] Functional requirements document drafted (i.e., system, module, interface, performance specifications). |
| **Committing** | 1. Proof of Feasibility
 | Feasibility of whole solution demonstrated in models and in feedback from stakeholders. | [ ] Technology-adjusted care pathway and workflow updated. [ ] Use-case scenario developed. [ ] Clinical Advisory team formed[ ] Feedback from clinicians or consumers in ≥10 settings. | [ ] Feedback from ≥5 economic buyers.[ ] Revised Business Model. [ ] Business Mentorship Circle formed. [ ] Foundational business agreements executed (i.e., initial ownership and rights).  | [ ] “Essential Requirements” checklist drafted and pre-submission meeting complete.[ ] Instructions for Use drafted.[ ] Cyber security plan drafted. | [ ] “Looks Like” prototype drafted. [ ] “Works-Like” experiments initiated. [ ] Software architecture, usability assessment, and interoperability plan developed for digital components. [ ] Provisional IP filed & Freedom-to-Operate assessment completed. |
| **Validating** | 1. Demonstrating

Value | The potential of the solution to work and create value for all stakeholders is demonstrated. | [ ] Feedback from clinicians or consumers in ≥20 settings. [ ] Feedback from ≥3 Key Opinion Leaders.[ ] Peer reviewed experimental results published.  | [ ] Investor-ready business plan completed, including costing for manufacturing.[ ] Economic modelling completed, comparing to current standards of care.[ ] Path to payment plan or reimbursement revised.[ ] Advisory Board development plan completed.[ ] Key team members committed.[ ] Pre-seed investment secured.[ ] Feedback from ≥10 economic buyers received. | [ ] Necessary regulatory approvals granted to move into clinical trials. [ ] Institutional Review Board (IRB) documents for clinical investigations drafted.[ ] Draft product claims[ ] Cyber security plan drafted (i.e., HIPAA, GDPR).[ ] Preliminary manufacturing plan (GMP). | [ ] “Works-like” pre-clinical experiments completed, and performance specifications documented. [ ] “Looks-like” prototype available and product requirement document drafted (design freeze). [ ] Full IP protection strategy enabled (IP applications as necessary).[ ] Software architecture, usability assessment and interoperability plan validated.  |
| 1. Clinical and

End-user Safety and Feasibility | Clinical, end-user and economic data collected, and endpoints achieved through initial trials. . | [ ] Initial validation trial(s) conducted, and safety and feasibility endpoints achieved. [ ] Demo feedback from ≥25 users | [ ] Advisory Board in place. [ ] Feedback from ≥20 economic buyers and purchasing expression of interests from >1 buyer. [ ] Further funding secured (2nd pre-seed or Series A).  | [ ] IRBs documents for clinical investigations submitted and approved at ≥1 institution.[ ] Data requirements for regulatory approval reviewed and confirmed.[ ] GMP-compliance achieved, and pilot lot produced. [ ] Cyber security certifications obtained. | [ ] “Works-like” clinical experiments completed, and performance and safety specifications updated.[ ] “Feels-like” usability data collected.  |
| 1. Clinical and

End-User Efficacy  | Clinical, end-user and economic data collected, and efficacy endpoints achieved through pivotal trials. | [ ] Larger scale efficacy trials conducted. [ ] Peer reviewed data from initial trials published. | [ ] Economic model updated and assumptions validated with trial data. [ ] Purchasing intent from ≥10 buyers obtained.[ ] 2nd round of institutional investment secured.[ ] Reimbursement path finalized.  | [ ] Submission package (“Technical File”) completed and submitted. [ ] Quality System Plan for (c)GMP-manufacturing process drafted finalized.  | [ ] “Works-like” clinical experiments completed, and performance and safety specifications updated.[ ] “Feels-like” usability data collected. |
| **Scaling** | 1. Real-world

Implementation | Institutional and regulatory approval received, and sales launched. | [ ] Real-world implementation trial conducted and validated economic data and endpoints achieved. [ ] Training materials & support established.[ ] Peer reviewed data from efficacy trials published. | [ ] Series A investment secured. [ ] Sales and support team established [ ] First-buyer secured. [ ] Reimbursement for associated product and/or services listed. | [ ] Company registered with applicable regulatory agencies.[ ] Quality System documentation completed for GMP-manufacturing processes. | [ ] “Looks-like” “Works-like” “Feels-like” product finalized. [ ] Patents issued.  |
| **Establishing** | 1. Clinical Use
 | The solution is used successfully in day-to-day clinical practice. | [ ] Solution included in local clinical practice guidelines[ ] Peer reviewed data from real-world trials published.  | [ ] Series B investment secured[ ] Profitable business venture with sustainable sales funnel and recurring revenue.[ ] Scale-up plan in place and new markets launched. | [ ] Regulatory agency monitoring and inspections conducted. | [ ] Improvement plan based on feedback from stakeholders drafted. |
| **Leading** | 1. Standard of Care
 | The solution is recognized as the Standard of Care. | [ ] Recommended practice by medical specialty supported by peer-reviewed data. | [ ] Dominant market share (≥30%). | [ ] Obsolescence planning. | [ ] Obsolescence planning. |

**Notes / Comments:**

Please provide any notes for context or explanation. E.g. - If a given milestone is left blank because it is not applicable as opposed to incomplete.

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1. Adapted from the Consortia for Improving Medicine with Innovation & Technology’s Guidance and Impact Tracking System. https://www.gaits.org/ja/. [↑](#footnote-ref-2)