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)