Client Journey and AICE Program Mapping

Program	AI Client Journey Description	Product-Market Fit	Business Readiness	Regulatory Compliance	Product Development
	1. Discovering 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
AICE CONCEPTS	**2. Ideating** 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.
	3. Conceptualizing 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).
AICE VALIDATE	**4. Committing** 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.
	5. Validating (phase 1) 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. ☐ 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.
AICE MARKET ACCESS	**6. Validating (phase 2)** Validation of the solution begins with clinical and economic evidence generation and the regulated production of prototypes.	☐ Safety/efficacy validation trial(s) conducted, and 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.
	7 Validating (phase 3) Solution is shown to be effective and its value to all stakeholders validated.	☐ Efficacy trials conducted. ☐ Peer reviewed data from safety/efficacy trials published.	☐ 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.
	8. Scaling Institutional and regulatory approval received, and sales launched.	☐ Real-world 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.
	9. Establishing 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.
	10. Leading 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.

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