

Alberta Innovates Client Journey and Health Innovation Checklist

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.	<input type="checkbox"/> Unmet clinical need identified and validated through secondary research.			<input type="checkbox"/> State of the art summarized
AICE CONCEPTS	2. Ideating Potential solutions to unmet need described, evaluated, and selected.	<input type="checkbox"/> Target clinical population identified and characterized. <input type="checkbox"/> Current clinical care pathway and workflow described. <input type="checkbox"/> Feedback from ≥5 clinicians or consumers.	<input type="checkbox"/> Target market identified and characterized. <input type="checkbox"/> Key stakeholders identified. <input type="checkbox"/> Envisioned benefit statements for patients, payers, and providers.	<input type="checkbox"/> Familiarization with local regulatory requirements and processes.	<input type="checkbox"/> Idea screening & selection completed. <input type="checkbox"/> Hypothesis and experimental design completed.
	3. Conceptualizing Key component concepts validated in models and value proposition tested.	<input type="checkbox"/> Technology-adjusted care pathway and workflow described. <input type="checkbox"/> Quantifiable health outcome targets developed. <input type="checkbox"/> Feedback from clinicians or consumers in ≥ 5 different settings.	<input type="checkbox"/> Competitive analysis and competitive positioning completed. <input type="checkbox"/> Path to payment plan or reimbursement described. <input type="checkbox"/> Stakeholder management plan developed. <input type="checkbox"/> Proposed Business Model. <input type="checkbox"/> Foundational business agreements drafted (i.e., initial ownership and rights).	<input type="checkbox"/> Comparable / predicates identified as necessary. <input type="checkbox"/> Preliminary intended / indications for use drafted. <input type="checkbox"/> Regulatory categorization and class determination <input type="checkbox"/> Hazard and risk analysis.	<input type="checkbox"/> Key Proof-of-Concept features documented. <input type="checkbox"/> Proof-of-concept and mechanistic action experiments completed. <input type="checkbox"/> Intellectual property strategy drafted and IP disclosure filed as needed. <input type="checkbox"/> 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.	<input type="checkbox"/> Technology-adjusted care pathway and workflow updated. Use-case scenario developed. <input type="checkbox"/> Clinical Advisory team formed. <input type="checkbox"/> Feedback from clinicians or consumers in ≥10 settings.	<input type="checkbox"/> Feedback from ≥5 economic buyers. <input type="checkbox"/> Revised Business Model. <input type="checkbox"/> Business Mentorship Circle formed. <input type="checkbox"/> Foundational business agreements executed (i.e., initial ownership and rights).	<input type="checkbox"/> “Essential Requirements” checklist drafted and pre-submission meeting complete. <input type="checkbox"/> Instructions for Use drafted. <input type="checkbox"/> Cyber security plan drafted.	<input type="checkbox"/> “Looks Like” prototype drafted. <input type="checkbox"/> “Works-Like” experiments initiated. <input type="checkbox"/> Software architecture, usability assessment, and interoperability plan developed for digital components. <input type="checkbox"/> 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.	<input type="checkbox"/> Feedback from clinicians or consumers in ≥20 settings. <input type="checkbox"/> Feedback from ≥3 Key Opinion Leaders. <input type="checkbox"/> Peer reviewed experimental results published.	<input type="checkbox"/> Investor-ready business plan completed, including costing for manufacturing. <input type="checkbox"/> Path to payment plan or reimbursement revised. <input type="checkbox"/> Advisory Board development plan completed. <input type="checkbox"/> Key team members committed. <input type="checkbox"/> Pre-seed investment secured. <input type="checkbox"/> Feedback from ≥10 economic buyers received.	<input type="checkbox"/> Necessary regulatory approvals granted to move into clinical trials. <input type="checkbox"/> Institutional Review Board (IRB) documents for clinical investigations drafted. <input type="checkbox"/> Draft product claims <input type="checkbox"/> Cyber security plan drafted (i.e., HIPAA, GDPR). <input type="checkbox"/> Preliminary manufacturing plan (GMP).	<input type="checkbox"/> “Works-like” pre-clinical experiments completed, and performance specifications documented. <input type="checkbox"/> “Looks-like” prototype available and product requirement document drafted (design freeze). <input type="checkbox"/> Full IP protection strategy enabled (IP applications as necessary). <input type="checkbox"/> Software architecture, usability assessment and interoperability plan validated.
	6. Validating (phase 2) Validation of the solution begins with clinical and economic evidence generation and the regulated production of prototypes.	<input type="checkbox"/> Safety/efficacy validation trial(s) conducted, and endpoints achieved. <input type="checkbox"/> Demo feedback from ≥25 users.	<input type="checkbox"/> Advisory Board in place. <input type="checkbox"/> Feedback from ≥20 economic buyers and purchasing expression of interests from >1 buyer. <input type="checkbox"/> Further funding secured (2 nd pre-seed or Series A).	<input type="checkbox"/> IRBs documents for clinical investigations submitted and approved at ≥1 institution. <input type="checkbox"/> Data requirements for regulatory approval reviewed and confirmed. <input type="checkbox"/> GMP-compliance achieved, and pilot lot produced. <input type="checkbox"/> Cyber security certifications obtained.	<input type="checkbox"/> “Works-like” clinical experiments completed, and performance and safety specifications updated. <input type="checkbox"/> “Feels-like” usability data collected.
AICE MARKET ACCESS	7 Validating (phase 3) Solution is shown to be effective and its value to all stakeholders validated.	<input type="checkbox"/> Efficacy trials conducted. <input type="checkbox"/> Peer reviewed data from safety/efficacy trials published.	<input type="checkbox"/> Purchasing intent from ≥10 buyers obtained. <input type="checkbox"/> 2 nd round of institutional investment secured. <input type="checkbox"/> Reimbursement path finalized.	<input type="checkbox"/> Submission package (“Technical File”) completed and submitted. <input type="checkbox"/> Quality System Plan for (c)GMP-manufacturing process drafted finalized.	<input type="checkbox"/> “Works-like” clinical experiments completed, and performance and safety specifications updated. <input type="checkbox"/> “Feels-like” usability data collected.
	8. Scaling Institutional and regulatory approval received, and sales launched.	<input type="checkbox"/> Real-world trial conducted and validated economic data and endpoints achieved. <input type="checkbox"/> Training materials & support established. <input type="checkbox"/> Peer reviewed data from efficacy trials published.	<input type="checkbox"/> Series A investment secured. <input type="checkbox"/> Sales and support team established <input type="checkbox"/> First-buyer secured. <input type="checkbox"/> Reimbursement for associated product and/or services listed.	<input type="checkbox"/> Company registered with applicable regulatory agencies. <input type="checkbox"/> Quality System documentation completed for GMP-manufacturing processes.	<input type="checkbox"/> “Looks-like” “Works-like” “Feels-like” product finalized. <input type="checkbox"/> Patents issued.
	9. Establishing The solution is used successfully in day-to-day clinical practice.	<input type="checkbox"/> Solution included in local clinical practice guidelines <input type="checkbox"/> Peer reviewed data from real-world trials published.	<input type="checkbox"/> Series B investment secured <input type="checkbox"/> Profitable business venture with sustainable sales funnel and recurring revenue. <input type="checkbox"/> Scale-up plan in place and new markets launched.	<input type="checkbox"/> Regulatory agency monitoring and inspections conducted.	<input type="checkbox"/> Improvement plan based on feedback from stakeholders drafted.
	10. Leading The solution is recognized as the Standard of Care.	<input type="checkbox"/> Recommended practice by medical specialty supported by peer-reviewed data.	<input type="checkbox"/> Dominant market share (≥30%).	<input type="checkbox"/> Obsolescence planning.	<input type="checkbox"/> Obsolescence planning.