A Clinical Research and Implementation Plan

Aura of Intelligence Dementia Care System: A Proof of Concept in Queensland

This is a First Draft including the use of Content by Luke Hayes and LLM GenAI Google Gemini

Part I: Foundational Clinical Framework for the 'Aura of Intelligence'

The successful transition of the 'Aura of Intelligence' (A.o.I) system from a technologically advanced concept to a clinically integrated tool requires a foundational framework that is both innovative and rigorously aligned with established medical practice. The system's core value proposition lies in its deep, person-centered approach to dementia care, as outlined in its planning documents.[1] However, for this system to be adopted within the Australian healthcare landscape, particularly in a proof-of-concept trial in Queensland, its novel data collection methods must be translated into a language understood and trusted by clinicians, regulators, and funding bodies. This foundational part of the plan details the systematic process of re-engineering the A.o.I's conceptual features—'Persona Mapping' and 'Behavior Modeling'—into a clinically robust framework. It addresses the critical challenge of bridging the gap between A.o.I's rich, narrative-driven design and the structured, evidence-based requirements of Australian clinical guidelines and assessment protocols.[2] The objective is to create a system that not only captures the essence of the individual but also generates data that is valid, reliable, and profoundly meaningful for improving dementia care outcomes.

Section 1: Translating 'Persona Mapping' into a Validated Clinical Profile

The 'Persona Mapping' module is the cornerstone of the A.o.I system, designed to create a comprehensive, dynamic profile of the individual by capturing their life story, values, and preferences.[1] This aligns seamlessly with the principle of person-centered care, which is the standard for dementia care in Australia.[3] To achieve clinical validation, this module must be enhanced to not only preserve its narrative richness but also to structure its outputs in a way that informs and correlates with established clinical assessment tools. This section details the strategy for this translation, ensuring A.o.i can be integrated into existing clinical workflows.

1.1 The Duality of Persona Mapping: Narrative Richness and Clinical Rigor

The A.o.I. system's 'Persona Mapping' captures a deep, empathetic understanding of the individual through historical data, value assessments, and preference analysis.[1] This approach is not merely a feature but a philosophical alignment with the highest standards of care, which recognize that

understanding the person is paramount.[3] However, for this rich qualitative data to be useful in a clinical context, it must be structured to inform quantitative assessments and track changes over time in a measurable way.

To achieve this, the A.o.I. system must be architected with a dual-layer data structure. The first layer, the **user-facing narrative interface**, will remain as designed—an engaging and intuitive platform for the person with dementia, their family, and carers to input stories, photos, preferences, and memories.[1] This layer promotes therapeutic activities such as reminiscence and life story work, which are recommended non-pharmacological interventions.[5]

The second layer, a **clinical-facing structured database**, will operate in the background. This layer will be the engine of clinical translation. As qualitative data is entered into the narrative interface, the system's AI will parse, tag, and map this information to predefined clinical domains. For example, a family member sharing a story about the user recently getting lost on a familiar route would be captured as a narrative moment. Simultaneously, the system would tag this event as a potential indicator of declining visuospatial ability and episodic memory, domains that are formally assessed in clinical evaluations.[7] This dual-layer approach preserves the humanistic front-end experience while generating the structured, analyzable data required for clinical validation.

1.2 Mapping A.o.I Data to Dementia Outcomes Measurement Suite (DOMS)

For the A.o.I system to be accepted in a Queensland-based trial, its outputs must align with the Dementia Outcomes Measurement Suite (DOMS). DOMS is a compendium of validated assessment tools commissioned by the Australian government to create a "common language" for dementia assessment among clinicians.[2] By mapping A.o.I's data collection to DOMS instruments, the system's outputs become immediately relevant and comprehensible to Australian healthcare professionals. The following table outlines this critical mapping process.

Table 1: Mapping A.o.I 'Persona' Data to Clinical Assessment Tools

AoI Feature	AoI Data Point	Clinical Domain	Corresponding DOMS Tool/Guideline	Relevance/Justification
Historical Persona Data Collection	Recollections of life events, ability to recall names, dates, and locations from personal history [1]	**Cognition (Memory & Orientation)**	Rowland Universal Dementia Assessment Scale (RUDAS) [7], General Practitioner Assessment of Cognition (GPCOG) [7], Mini-Mental State Examination (MMSE) [7]	AoI's narrative collection directly probes episodic and semantic memory. Mapping these to RUDAS/GPCOG items provides a longitudinal, real-world measure of cognitive status, complementing point-in-time clinical tests.

Historical Persona Data Collection	Descriptions of difficulty with planning events, managing finances, or multi-step tasks (e.g., cooking a meal) [1]	**Cognition (Executive Function)**	Frontal Assessment Battery (FAB) [9], Dementia Australia Warning Signs [7]	Captures real-world examples of executive dysfunction, a core diagnostic feature of many dementias, providing richer context than standardized tests alone.
Daily Routines Observation	Logging ability to perform daily and instrumental activities (e.g., dressing, preparing meals, using the phone) [1]	**Function (ADLs & IADLs)**	Disability Assessment for Dementia (DAD) [11], Lawton IADL Scale [12], Blessed Dementia Scale (BDS) [2]	Directly measures the impact of cognitive impairment on independence, a key criterion for dementia diagnosis and staging.[11] AoI provides continuous functional data, unlike infrequent clinical assessments.
Social Connection Facilitation	Frequency and quality of social interactions logged via 'Circles of Support' and automated greetings [1]	**Quality of Life (Social Domain)**	Dementia Quality of Life Scale (DEMQOL) [2], Quality of life in late-stage dementia (QUALID) [2]	Measures social engagement, a key component of subjective well-being. This allows the trial to assess AoI's impact on a primary goal of dementia care: improving quality of life.[5]
Behavior Modeling	Carer-reported instances of agitation, apathy, depression, or anxiety, including triggers and successful interventions [1]	**Behavioural/Psychological (BPSD)**	Neuropsychiatric Inventory (NPI) [2], Cornell Scale for Depression in Dementia (CSDD) [2], Rating Anxiety In Dementia (RAID) [2]	Provides a structured, longitudinal record of BPSD, enabling analysis of patterns and the effectiveness of non-pharmacological interventions, a key focus of Australian guidelines.[3]
Circles of Sup	Carer-reported data on their own stress, time spent on	**Carer Wellbeing**	Carer Burden Scale [12], Geriatric Depression Scale (GDS) [2]	Measures the impact of the AoI system on the carer, a critical outcome measure for demonstrating holistic value to

port	care, and emotional state [1]			funding bodies and support services like Carers Queensland.[13]
Values & Preference Analysis	User's expressed wishes, values, and preferences for care and daily life [1]	**Person-Centred Care & Advance Care Planning**	Clinical Practice Guidelines for Dementia [3]	Documents the user's preferences, which is fundamental to person-centred care and can inform advance care planning discussions, a key recommendation in Australian guidelines.[7]

This mapping strategy transforms AoI's features into powerful clinical data-gathering instruments. For instance, the 'Daily Routines Observation' module [1] will be enhanced beyond simple activity logging. It will be programmed to periodically prompt the user or their carer with specific questions derived from the Disability Assessment for Dementia (DAD) scale, such as, "Did you need any help with preparing your breakfast today?" or "Were you able to use the telephone without assistance?".[11] This provides structured, validated data on functional independence over time.

Similarly, the 'Social Connection Facilitation' module [1] will be used to track not just the existence of a social network but the frequency and quality of interactions. This data, combined with periodic, integrated prompts based on the DEMQOL scale, will provide a robust, longitudinal measure of the participant's quality of life.[2]

A pivotal element of this approach is the creation of a "clinical wrapper." The most viable path to clinical acceptance for AoI is not to replace existing, trusted assessment tools but to augment them. Clinicians are time-poor and trained to rely on validated instruments like the GPCOG or RUDAS.[2] Presenting them with an entirely new, unvalidated system creates a significant barrier to adoption. The "clinical wrapper" strategy circumvents this by using AoI's key technological advantage—continuous, longitudinal data collection—to generate reports in a format that clinicians already know and trust.

The process would work as follows:

1. The AoI system continuously and passively collects data through user and carer engagement, as detailed in the mapping table.
2. At specified intervals (e.g., quarterly), the system's AI synthesizes this vast dataset.
3. It then generates a report formatted to resemble a standard clinical assessment, for example, an "AoI-Generated GPCOG Report." This report would present a score and highlight the specific data points from the preceding three months that contributed to it (e.g., "Noted three instances of difficulty recalling recent conversations," "Successfully managed personal finances on 10 of 12 occasions").
4. The clinician receives the information they need in a familiar format, but it is backed by a far richer dataset than a single, 5-minute, point-in-time test could ever provide.

The proof-of-concept trial will be essential to validate this approach. A key outcome will be to measure the correlation between the AoI-generated score and a score from the same instrument administered in the traditional way by a clinician. Demonstrating a high correlation will prove the reliability and validity of the AoI system as a clinical assessment tool.

Section 2: Aligning 'Behavior Modeling' with Clinical Best Practice

The 'Behavior Modeling' feature of the AoI system, with its capacity for pattern recognition and trigger identification, represents a significant technological asset.[1] To maximize its clinical utility, this feature must be explicitly reframed as a tool for the assessment and management of Behavioural and Psychological Symptoms of Dementia (BPSD). BPSD, such as agitation, apathy, and depression, are a major source of distress for both the person with dementia and their carers, and their management is a primary focus of Australian clinical guidelines.[14]

2.1 From Activity Logging to BPSD Analysis

Current Australian best practice for BPSD management emphasizes understanding the underlying causes of behaviour before resorting to medication.[3] A key framework used by services like Dementia Support Australia is the

CAUSEd model, which prompts carers to consider Communication, Activity, Unwell/unmet needs, Story, Environment, and Dementia as potential triggers.[14]

The AoI system's 'Behavior Modeling' module will be redesigned to directly operationalize this clinical model. The 'Potential Trigger Identification' feature [1] will be structured to guide carers through the CAUSEd framework. When a carer logs a behaviour of concern, such as an episode of agitation, the AoI interface will present a structured questionnaire based on the CAUSEd acronym:

- **Communication:** "What might the person have been trying to communicate with their behaviour?"
- **Activity:** "What activity were they engaged in? Was it too complex, or were they bored?"
- **Unwell/Unmet Needs:** "Could they be in pain, hungry, thirsty, or need to use the toilet?"
- **Story:** "Is there something from their personal history or values that might explain this behaviour?" (This links directly back to the 'Persona Mapping' data).
- **Environment:** "Was the environment too noisy, crowded, or unfamiliar?"

This structured input transforms a simple log into a clinical assessment. The system's 'Behavioral Pattern Recognition' algorithms [1] can then analyze these structured inputs over time to identify correlations that a human might miss. For example, the system could generate an insight such as: "Analysis indicates that episodes of agitation are 70% more likely to occur on days when the user has not had outdoor activity and when background noise levels are high." This provides an evidence-based foundation for creating a personalized behaviour support plan, directly aligning with the 'ABC' (Antecedent, Behaviour, Consequence) assessment method used in formal tools like the Behavioural Assessment Form (BAF).[17]

2.2 Integrating Non-Pharmacological Interventions

The Australian guidelines for dementia care strongly advocate for the use of tailored, non-pharmacological interventions as the first-line response to BPSD.[3] The AoI system will be developed to move beyond passive monitoring to become an active therapeutic partner that recommends these evidence-based strategies.

The system will leverage its integrated understanding of the user's persona and real-time state to suggest appropriate interventions:

- If the 'Behavior Modeling' module detects patterns indicative of anxiety (e.g., restlessness, specific vocal tones), it can proactively suggest a 'Moment Sharing' session. This feature, which constitutes a form of **reminiscence therapy**, would use photos and videos from a known calming period in the person's life, as identified during 'Persona Mapping'.[1]
- If the system detects apathy or withdrawal, it could recommend playing a personalized playlist of the user's favorite music (**music therapy**) or suggest a simple, enjoyable activity based on their cataloged interests and passions, such as looking at a digital scrapbook of their gardening achievements.[1]
- This functionality transforms AoI from a data collection device into an interactive intervention platform. It directly supports the principles of restorative care and re-enablement that underpin Australian aged care funding models, by actively promoting engagement and well-being.[6]

This reframing positions AoI as a critical tool for both proactive BPSD prevention and real-time de-escalation support. This capability directly addresses the core mission of specialist services like Queensland's Dementia Behaviour Management Advisory Service (DBMAS), which provides clinical support to carers managing impactful behaviours.[13] The system can generate proactive alerts for carers, such as, "John often becomes restless in the late afternoon. A 'Moment Sharing' session with his wedding photos has been effective at promoting calm in the past. Would you like to start one now?" This is proactive prevention.

Furthermore, in a moment of acute distress, a carer could activate a "Calm" or "S.O.S." function within the AoI app. Drawing on the rich 'Persona Mapping' data, the system would know the individual's most potent calming triggers—be it a specific piece of classical music, a video message from a grandchild, or images of a beloved pet. It could then immediately present this media on a nearby smart display or tablet. This provides a powerful, personalized, real-time de-escalation tool. This functionality offers a tangible, evidence-based method to support carers, reduce distress, and align with the national strategic goal of minimizing the use of restrictive practices and psychotropic medications in dementia care.[18]

Section 3: Integrating Social and Quality of Life Metrics for Holistic Assessment

A truly person-centred dementia care model extends beyond the management of cognitive and behavioural symptoms. Australian clinical guidelines emphasize that the ultimate goals of care are to improve quality of life (QoL), maintain function, and maximize comfort for the person with dementia, while also supporting the wellbeing of their carers.[3] The AoI system's 'Social Connection Facilitation'

module [1] provides a strong foundation for measuring these holistic outcomes, which must be systematically integrated into the trial protocol.

3.1 Beyond Social Networking: Measuring What Matters

To demonstrate its value to the Australian healthcare system, AoI must prove its ability to positively impact the outcomes that matter most to individuals and policymakers. This requires integrating validated scales that measure these broader constructs.

The AoI system will be enhanced to capture these metrics longitudinally:

- **Participant Quality of Life:** The 'Circles of Support' and 'Moment Sharing' features [1] will not only facilitate social connection but also track the frequency and nature of these interactions. This objective data will be correlated with subjective QoL scores. The system will be programmed to periodically (e.g., monthly) administer a validated, dementia-specific QoL scale, such as the

DEMQOL or **QUALIDEM**, directly through its user interface.[2] This will provide a robust, longitudinal measure of the intervention's impact on the participant's overall well-being.

- **Carer Wellbeing:** The journey of dementia profoundly impacts carers.[5] The AoI system is designed to alleviate this burden. To measure this effect, the system will periodically prompt the designated primary carer to complete validated scales such as the

Carer Burden Scale [12] and the

Geriatric Depression Scale (GDS).[2] This provides a longitudinal view of the carer's own health outcomes.

This focus on the carer is not an afterthought; it is a strategic necessity. The research plan must frame the primary carer as a co-participant in the trial, whose own outcomes—such as reduced burden, improved mood, and better QoL—are a key measure of the AoI system's success. Australian dementia policy and support services, like Carers Queensland and the National Dementia Helpline, explicitly recognize the immense strain on carers and prioritize their support.[5] By including validated, carer-centric outcome measures in the trial, the research will generate data that speaks directly to a core priority of the Australian health and aged care system. This makes the results far more compelling for policymakers, funding bodies like My Aged Care and the NDIS, and advocacy groups.

3.2 Aligning with Australian Care Principles

The Australian aged care system is increasingly structured around principles of **person-centred care**, **re-enablement**, and **restorative care**.[5] For AoI to be considered for government funding, it must demonstrate its alignment with and support for these principles. The clinical trial protocol will therefore include specific measures to assess this alignment.

- **Person-Centred Care:** The 'Persona Mapping' module is, by its very nature, person-centred.[1] The trial will formally measure this by including user and carer satisfaction surveys that specifically

ask about the degree to which they felt the care and support provided by AoI was tailored to their individual needs, values, and preferences.

- **Re-enablement and Restorative Care:** These principles focus on promoting independence and delaying functional decline.[6] The AoI system's 'Automate Reminders' for medication or daily tasks and its 'Decision Assist' features are designed to do exactly this.[1] The trial will provide concrete evidence of this by using functional scales like the

Direct Assessment of Functional Status (DAFS) or the **DAD scale** as outcome measures.[11] Demonstrating a statistically significant slowing of functional decline in the intervention group compared to the control group would be a powerful testament to AoI's value in promoting independence.

By structuring the clinical framework in this way, the AoI system is transformed from a collection of innovative features into a cohesive, evidence-based platform. It becomes a tool that not only respects the narrative of the individual but also speaks the language of clinical validation, BPSD management, and holistic, person-centred care—the very language required for successful implementation in Queensland and across Australia.

Part II: Regulatory and Ethical Pathway for a Queensland Proof of Concept

Successfully launching a proof-of-concept trial for the 'Aura of Intelligence' system in Queensland requires navigating a complex and rigorous landscape of regulatory and ethical approvals. This is not a secondary administrative task but a critical path that will determine the project's viability. This section provides a detailed, step-by-step guide to securing these mandatory approvals. It will first address the classification of AoI as a Software as a Medical Device (SaMD) and outline the process for achieving compliance with Australia's Therapeutic Goods Administration (TGA). It will then detail the specific requirements for preparing and submitting a comprehensive application to a Queensland-based Human Research Ethics Committee (HREC), with a focus on the unique ethical challenges of dementia research. Finally, it will outline the establishment of a robust clinical and digital governance framework, essential for ensuring patient safety, data integrity, and alignment with national standards.

Section 4: Therapeutic Goods Admin (TGA) for Software as a Medical Device (SaMD)

Any software with a medical purpose intended for supply in Australia is regulated by the Therapeutic Goods Administration (TGA).[20] The AoI system, with its sophisticated monitoring and support functions, unequivocally falls under this purview. Failure to understand and comply with these regulations presents an existential risk to the project.

4.1 Classification of 'Aura of Intelligence' as SaMD and CDSS

The first step in the regulatory journey is to formally classify the device. The TGA regulates software as a medical device if its manufacturer intends for it to be used for the "diagnosis, prevention, monitoring, treatment or alleviation of a disease, injury or disability".[20]

- **Analysis of 'Intended Purpose':** The intended purpose of the AoI system, as described in its planning documents, is to "monitor" daily routines and behavioural patterns, "predict" the

likelihood of BPSD, and "alleviate" distress by triggering reminiscence or recommending de-escalation strategies.[1] This falls squarely within the TGA's definition of a medical device under the *Therapeutic Goods Act 1989*.[20]

- **Clinical Decision Support Software (CDSS) Status:** The AoI system functions as a CDSS. It analyzes patient-specific data (persona, behaviour) to provide information and recommendations to a user (a clinician, carer, or the person with dementia) to help them make a health-related decision, such as how to respond to an episode of agitation or what activity to engage in.[22]
- **Risk Classification:** The TGA employs a risk-based classification system for medical devices, ranging from Class I (low risk) to Class III (high risk).[21] The classification determines the regulatory burden. For SaMD, the classification depends on the level of harm that could result from incorrect information or a malfunction.[21]
    - The AoI system is unlikely to be 'excluded' from regulation (as it does more than simply digitize a paper record or manage a healthy lifestyle) or 'exempt' (as its recommendations go beyond simple clinical guideline reminders).[23]
    - If the system's output is intended to **inform a clinician's decision** (e.g., providing a report on behavioural patterns for a GP to review), it would likely be classified as **Class IIa (low-medium risk)**.[21]
    - However, if the system provides a direct recommendation for action to a consumer or carer (e.g., a specific de-escalation technique for severe agitation), and an incorrect recommendation could lead to a negative outcome, it could be classified as **Class IIb (medium-high risk)**.[21]
    - **Conclusion:** A conservative and prudent strategy is to plan for a **Class IIa** submission as a baseline, while being prepared for the requirements of a Class IIb classification. The evidence gathered in the clinical trial will be crucial for justifying the final classification.

4.2 Roadmap for TGA Conformity Assessment

Before a medical device can be legally supplied in Australia, it must be included on the Australian Register of Therapeutic Goods (ARTG).[20] For a Class IIa or higher device, this requires obtaining a TGA conformity assessment certificate, which verifies that the device and its manufacturer meet all regulatory requirements.[27] The process is rigorous and requires meticulous preparation.

The step-by-step process for AoI is as follows:

1. **Appoint an Australian Sponsor:** As a non-Australian manufacturer, it is a legal requirement to appoint an Australian-based sponsor. This entity is responsible for the ARTG inclusion, liaising with the TGA, and post-market obligations.[24]
2. **Engage in a Pre-submission Meeting:** The TGA strongly encourages applicants, especially those with novel technology like AI-driven SaMD, to request a pre-submission meeting.[27] This provides an invaluable opportunity to discuss the proposed device, confirm the likely risk classification, clarify evidence requirements, and resolve potential issues before a formal application is lodged.

3. **Prepare the Technical File:** This is the core of the submission. The technical file is a comprehensive dossier of evidence demonstrating that AoI complies with the TGA's **Essential Principles** for safety and performance.[26] For AoI, this file must include:
    a. **Clinical Evidence:** This is the most critical component. It comprises the full results and analysis from the phased clinical trial outlined in Part III of this plan. The evidence must substantiate all claims made about AoI's performance, such as its ability to reduce BPSD, improve QoL, or enhance carer wellbeing.[25]
    b. **Software Design and Validation:** Detailed documentation of the software development lifecycle, system architecture, algorithms, verification and validation testing, and defect management processes.[27]
    c. **Cybersecurity and Privacy:** A thorough risk assessment and documentation of the measures taken to protect sensitive health data from unauthorized access or breach, including data encryption, secure cloud architecture, and access controls.[27]
    d. **Usability and Human Factors Engineering:** Evidence from the Phase 1 usability trial demonstrating that the intended users (people with mild dementia, carers of varying technical literacy) can use the AoI system safely and effectively to achieve its intended purpose.[27]
4. **Submit the Application and Undergo Assessment:** The application is submitted via the TGA Business Services portal with the requisite fees.[27] The TGA then conducts a detailed assessment of the technical file, a process that can take up to 255 working days.[29] During this time, the TGA may issue requests for further information. Given the novelty of AoI, it is possible the TGA may refer the application to the Advisory Committee on Medical Devices (ACMD) for expert clinical and technical advice.[29]
5. **ARTG Inclusion:** Upon successful completion of the conformity assessment, the TGA issues a certificate, and the Australian sponsor can then apply to have AoI included on the ARTG, permitting its legal supply in Australia.

It is impossible to overstate the interdependence of the clinical trial and the TGA submission. The trial is not an activity to be conducted after the product is built; it is the central pillar of the regulatory submission itself. The trial protocol, including its primary and secondary outcome measures, must be designed from the very beginning with the explicit goal of generating the specific clinical evidence the TGA requires to approve a Class IIa/IIb SaMD. If AoI claims to "reduce carer burden," the trial must use a validated instrument like the Carer Burden Scale as an outcome measure.[12] If it claims to "improve quality of life," it must use a tool like the DEMQOL.[2] This direct, demonstrable link between the product's claims, the trial's methodology, and the regulatory requirements is the most critical strategic element of the entire plan.

Section 5: Human Research Ethics Committee (HREC) Submission for Queensland

Parallel to the TGA process, any research involving human participants in Australia must receive prior approval from a registered Human Research Ethics Committee (HREC).[30] This process ensures the rights, safety, and wellbeing of participants are protected. For a trial involving a vulnerable population such as people with dementia, the ethical scrutiny will be particularly intense.

5.1 The Queensland HREC Process

In Queensland, research conducted within public health services is managed through a centralized system. For a multi-site trial, the National Mutual Acceptance (NMA) scheme allows for a single ethical review by one lead HREC to be accepted by other participating sites, streamlining the process.[31]

Applications for HREC review in Queensland are prepared and submitted using the **Ethical Review Manager (ERM)** online portal.[31] A complete and successful submission requires a package of meticulously prepared documents.

Table 4: HREC Submission Document Checklist for Queensland (ERM)

Document Name	ERM Requirement	Key Content for AoI Trial	Status/Owner
Human Research Ethics Application (HREA) Form	Required	The main online application form completed within ERM, detailing all aspects of the research.	To be completed
Research Protocol	Required	The comprehensive trial protocol as detailed in Part III of this plan, including rationale, design, methodology, participants, interventions, and outcome measures.	To be developed

			loped
Participant Information and Consent Form (PICF)	Required	Separate forms for the person with dementia and their carer/substitute decision-maker. Must use simple language and clearly explain risks, benefits, data handling, and the voluntary nature of participation. Must include a section on assessing capacity to consent.	To be drafted
Data Management Plan	Required	A detailed plan for the secure collection, storage, de-identification, and eventual destruction of highly sensitive personal and health data, compliant with the *Privacy Act 1988*.	To be developed
Curricula Vitae (CVs) of Investigators	Required	CVs for the Principal Investigator and all key research staff to demonstrate requisite expertise.	To be collated
Recruitment Materials	Required	Copies of any flyers, advertisements, emails, or scripts that will be used to recruit participants.	To be

			drafted
Questionnaires & Scales	Required	Copies of all clinical assessment tools and surveys to be used in the trial (e.g., RUDAS, NPI, DEMQOL, Carer Burden Scale).	To be collated
Investigator's Brochure / Device Manual	Required (if applicable)	A manual for the AoI system, explaining its function for the HREC's review.	To be developed
Peer Review Correspondence	Recommended	Evidence of independent scientific peer review of the research protocol, which strengthens the application.	To be sought

5.2 Addressing Key Ethical Considerations for Dementia Research

The HREC's primary concern will be the protection of a vulnerable participant group. The application must proactively and comprehensively address several key ethical challenges.

- **Informed Consent:** This is the most complex ethical issue. The protocol must detail a robust process for managing consent.[5]
    - *Assessing Capacity:* A clear, validated method for assessing a potential participant's capacity to provide informed consent must be included. This will likely be performed by the Principal Investigator or a qualified clinician on the team.
    - *Substitute Decision-Making:* For participants who are determined to lack capacity, the protocol must adhere strictly to Queensland's guardianship and administration laws. Consent must be obtained from a legally authorized substitute decision-maker, such as a person with an Enduring Power of Attorney for health matters.[5] The PICF must be designed to be understood by this person, often a family member.
    - *Process of Consent:* Consent must be treated as an ongoing process, not a one-time event. The protocol must describe how researchers will continually check for and respect a participant's assent or dissent throughout the study, even after initial consent has been given by a substitute.
- **Privacy and Confidentiality:** The AoI system is designed to collect an unprecedented amount of personal and health information.[1] The HREC submission must therefore include an exceptionally strong data management plan. This plan must detail technical safeguards (e.g., end-to-end encryption, secure Australian-based cloud storage, role-based access controls) and procedural safeguards (e.g., data de-identification protocols). The plan must demonstrate full compliance with the

Privacy Act 1988 and the Australian Privacy Principles (APPs).[34]

- **Minimising Risk and Participant Burden:** The HREC will carefully scrutinize the potential for the trial to cause burden or distress.[36] The trial design should highlight how AoI's passive data collection can

reduce burden by minimizing the need for frequent and potentially stressful in-person testing. The protocol must also have a clear plan for managing any distress caused by the intervention (e.g., an upsetting memory prompt) and a formal process for identifying, managing, and reporting adverse events to the HREC and other relevant bodies.

A powerful argument can be made in the HREC submission by framing the AoI system as a tool that enhances the safety and quality of telehealth, a now-permanent feature of the Australian healthcare system. The Australian Health Practitioner Regulation Agency (AHPRA) and the Medical Board of Australia have established clear guidelines for telehealth, emphasizing that the standard of care must be safe and, where possible, meet the same standards as an in-person consultation.[37] A key challenge in telehealth is the clinician's lack of a pre-existing relationship with the patient and the inability to gather rich contextual data.[40] The AoI system directly addresses this gap. Its 'Persona Mapping' provides a deep, longitudinal patient history and its 'Behavior Modeling' offers objective data on function and behavior that a simple video call cannot capture. Therefore, the ethical submission can argue that AoI does not just

use telehealth; it *improves* it for this specific population by providing the consulting clinician with a richer, more objective dataset, thereby enhancing the safety and quality of the remote consultation. This positions AoI as a responsible innovation that strengthens a recognized mode of care delivery.

Section 6: Establishing a Clinical and Digital Governance Framework

To ensure patient safety, data integrity, and regulatory compliance, the AoI trial must operate within a robust governance structure. This framework is not merely a bureaucratic requirement; it is a fundamental component of responsible research and a prerequisite for partnership with Australian health services. Proactively establishing this framework demonstrates a mature understanding of the healthcare environment and builds critical trust with partners and regulators.

6.1 Adopting the National Model Clinical Governance Framework

The Australian Commission on Safety and Quality in Health Care (ACSQHC) has published the National Model Clinical Governance Framework, which is the benchmark for all health service organisations, including those hosting clinical trials.[41] The AoI trial's governance structure must be built upon its five core components:

1. **Governance, Leadership, and Culture:** A formal Trial Steering Committee will be established. This committee will include the Principal Investigator (providing clinical leadership), a technical lead from the AoI development team, the trial coordinator, and, crucially, at least two consumer representatives (a person with lived experience of dementia and a carer). This aligns with the 'Partnering with Consumers' standard and formalizes the commitment to co-design mentioned in AoI's planning documents.[1]
2. **Patient Safety and Quality Improvement Systems:** The trial will implement clear, documented procedures for incident management (e.g., responding to a data breach or a participant adverse event), open disclosure with participants if something goes wrong, and a formal system for managing and responding to participant feedback and complaints.[42]
3. **Clinical Performance and Effectiveness:** All research staff will be required to provide evidence of their qualifications and complete formal Good Clinical Practice (GCP) training. The Principal Investigator will be responsible for the supervision and performance management of the research team.[30]
4. **Safe Environment for the Delivery of Care:** In this context, the "environment" is primarily the digital platform. This involves ensuring the AoI system is secure, reliable, and fit for its clinical purpose, with risks managed through the TGA conformity assessment process.[42]
5. **Partnering with Consumers:** As noted, consumer partnership will be embedded at the highest level of governance through representation on the Trial Steering Committee, ensuring the trial remains grounded in the needs and preferences of those it aims to serve.[41]

6.2 Compliance with Digital Health and Privacy Legislation

As a digital health solution, AoI is subject to a specific layer of governance beyond general clinical practice. The governance framework must explicitly address these requirements.

- **National Safety and Quality Digital Mental Health (NSQDMH) Standards:** While AoI is a broader dementia support tool, its features for managing BPSD (which includes depression and anxiety) bring it into the realm of digital mental health. The NSQDMH Standards, particularly the 'Clinical and Technical Governance Standard' and the 'Model of Care Standard', provide an essential best-practice benchmark for ensuring the safety and quality of the service.[43] Adhering to these standards will be a key objective of the governance framework.
- **Privacy and Data Security Legislation:** The framework must ensure strict compliance with the Commonwealth *Privacy Act 1988* and its Australian Privacy Principles (APPs).[34] It will also need to align with Queensland Health's own information governance policies. This includes policies on data sovereignty (ensuring data is stored in Australia), secure data transfer, and audit logging.
- **Future Interoperability:** While initial deployment may be standalone, the governance framework must be forward-looking. It should anticipate future integration with national digital health infrastructure like My Health Record and the use of Healthcare Identifiers. This means designing the system and its governance in a way that is compliant with the *My Health Records Act 2012* and the *Healthcare Identifiers Act 2010* from the outset, to avoid costly re-engineering later.[44]

Establishing this comprehensive governance framework from the proof-of-concept stage is a critical strategic decision. It is not just a compliance exercise but the creation of a significant commercial asset. When approaching a Queensland Hospital and Health Service (HHS) as a potential trial partner [45], presenting a pre-existing, robust governance plan that mirrors their own internal structures and aligns with national standards [46] will dramatically increase their confidence and willingness to engage. It de-risks the project in their eyes and in the eyes of regulators, demonstrating that the AoI team understands the complex, safety-critical environment of Australian healthcare. This trust is invaluable and can significantly accelerate partnership, ethics, and regulatory approval timelines.

Part III: A Strategic Plan for Proof-of-Concept Implementation in Queensland

This part of the report transitions from foundational frameworks to a practical, actionable plan for the execution of the 'Aura of Intelligence' proof-of-concept trial in Queensland. It details a phased clinical trial protocol designed to systematically build the necessary evidence for clinical and regulatory acceptance. It then identifies the key clinical roles and strategic partners within Queensland required to bring this trial to fruition. Finally, it outlines the commercialisation pathways within the Australian health system, explaining how the evidence generated by the trial can be leveraged to secure long-term funding and market access.

Section 7: A Phased Clinical Trial Protocol

A well-designed clinical trial is the engine that will generate the evidence needed to prove AoI's value. The protocol must be pragmatic, starting with fundamental questions of usability and feasibility before moving to more complex and expensive efficacy testing. This phased approach minimizes risk and ensures that resources are deployed efficiently. The design is informed by successful Australian digital health trials, such as the large-scale "Maintain Your Brain" intervention [48] and the user-centric design of Dementia Australia's "BrainTrack" app.[50]

7.1 Overall Trial Design: A Hybrid Implementation-Effectiveness Study

The trial will follow a prospective, multi-phase, hybrid implementation-effectiveness design. This modern trial design is pragmatic, allowing for the evaluation of clinical effectiveness while simultaneously gathering data on how the intervention can be best implemented in a real-world setting. The initial phases will focus on implementation outcomes (e.g., feasibility, usability, acceptability) to ensure the technology is robust and user-friendly, before progressing to a larger trial focused on effectiveness outcomes (e.g., clinical efficacy, cost-effectiveness).

7.2 Phase 1: Feasibility and Usability Testing

- **Objective:** To test and refine the AoI prototype with end-users to ensure it is acceptable, easy to use, and fit for purpose before wider deployment.
- **Participants:** A small cohort of 10-15 dyads, each comprising a person with mild dementia and their primary carer. Participants will be recruited through community-based partners in the Brisbane area, such as a Dementia Australia support group or a residential aged care facility associated with Alzheimer's Queensland.[52]
- **Intervention:** Participants will be provided with the AoI system (e.g., on a supplied tablet) and trained on its use. They will use the system in their own homes for a period of 4 to 6 weeks.
- **Outcome Measures:**
    - **Primary Outcomes:** The primary focus will be on qualitative data and usability metrics. This will include semi-structured interviews and focus groups with participants and carers to explore their experience, perceived benefits, challenges, and suggestions for improvement. These sessions will be recorded, transcribed, and analyzed thematically. Standardized usability questionnaires, such as the System Usability Scale (SUS), will also be administered.
    - **Secondary Outcomes:** The system will collect quantitative data on adherence and engagement, such as the frequency of logins, duration of use, and which features are most and least accessed.
- **Justification:** This initial phase is a critical de-risking step. It ensures that the technology is functional and acceptable to its target audience before significant resources are committed to a larger efficacy study. The data gathered directly provides the 'human factors' and usability evidence required for the TGA conformity assessment submission.[27]

7.3 Phase 2: Single-Site Pilot Study

- **Objective:** To gather preliminary data on the efficacy of the AoI system on key clinical outcomes and to test and refine the full trial procedures (recruitment, assessment, data collection) in a controlled environment.
- **Design:** This phase will be a single-group, pre-post intervention study. A more robust design, if resources permit, would be a small-scale randomised controlled trial (RCT) with a wait-list control group.

- **Participants:** A cohort of 40-50 dyads will be recruited through a specialist dementia clinical trial unit in Brisbane, such as the University of Queensland Centre for Clinical Research (UQCCR) or The Prince Charles Hospital's Dementia Research Unit.[53]
- **Intervention:** Participants in the intervention group will use the AoI system in their homes for a period of 3 to 6 months. The control group will receive standard care.
- **Outcome Measures:** This phase introduces quantitative clinical measures.
    - **Primary Outcome:** The primary measure will be the change from baseline to the end of the intervention period in a validated measure of BPSD, such as the **Neuropsychiatric Inventory (NPI)**, which is considered a gold standard in clinical trials.[2]
    - **Secondary Outcomes:** Change from baseline in a suite of validated scales covering the key domains identified in Part I:
        - **Cognition:** Rowland Universal Dementia Assessment Scale (RUDAS) or GPCOG.[7]
        - **Function:** Disability Assessment for Dementia (DAD) scale.[11]
        - **Participant Quality of Life:** DEMQOL.[2]
        - **Carer Outcomes:** Carer Burden Scale and Geriatric Depression Scale (GDS).[2]
- **Justification:** This pilot study will generate the first quantitative data on AoI's clinical efficacy. This data is essential for powering the sample size calculations for the larger Phase 3 trial, strengthening grant applications, and providing the initial clinical evidence required for the TGA submission.

7.4 Phase 3: Multi-Site Efficacy Trial (RCT)

- **Objective:** To definitively determine the effectiveness and cost-effectiveness of the AoI system in a larger, more diverse population, providing the high-quality evidence needed for widespread adoption.
- **Design:** A multi-site, pragmatic randomised controlled trial. Participants will be randomly allocated to either the AoI intervention group or a control group receiving standard care. An attention-control group (e.g., using a simple health information app) could also be considered to control for the effects of technology engagement.
- **Participants:** A larger cohort of 150-200+ dyads, with the final number determined by power calculations from the Phase 2 data. To enhance the generalisability of the findings, recruitment will occur across multiple sites in Queensland, ideally including metropolitan (Brisbane), regional, and remote locations, mirroring the successful approach of the "Maintain Your Brain" trial.[48]
- **Intervention:** Use of the AoI system for a longer duration, typically 12 months, to assess sustained effects.
- **Outcome Measures:** The outcome measures will be the same as in Phase 2, but the longer follow-up will allow for assessment of the intervention's long-term impact. A formal health economic analysis will also be incorporated, collecting data on hospital admissions, medication use, and use of other health services to determine the cost-effectiveness of the AoI system.
- **Justification:** This pivotal trial is designed to produce Level 1 evidence (the highest level) of efficacy. The results of this trial will form the cornerstone of the final TGA submission for market

approval, provide the definitive evidence required by funding bodies like My Aged Care for inclusion in their programs, and be suitable for publication in high-impact, peer-reviewed medical journals.

The design of this trial protocol can draw significant strength from existing Australian digital health precedents. The "Maintain Your Brain" trial, led by UNSW's Centre for Healthy Brain Ageing, demonstrated that a large-scale, multi-component, personalized online lifestyle intervention could significantly improve cognition in older adults over a three-year period.[48] This provides a powerful precedent for AoI's multi-faceted approach. The "Maintain Your Brain" trial's use of online cognitive tests and its ability to recruit from metropolitan, rural, and remote areas proves the feasibility of the proposed Phase 3 design.

Similarly, the strategy employed by Dementia Australia for its "BrainTrack" app is highly instructive.[50] BrainTrack uses engaging, travel-themed games to encourage regular (monthly) user interaction. Crucially, it allows users to generate a PDF report of their results over time, which they can then take to their GP as a conversation starter. This is a real-world, successful implementation of the "clinical wrapper" strategy. The AoI trial protocol should adopt this proven model: use the engaging, personalized "Aura" interface to drive long-term participant adherence, and design the system to generate simple, actionable reports that are easily integrated into existing clinical workflows. By citing these successful, government-funded Australian projects in HREC and grant applications, AoI can be positioned not as a high-risk, unknown entity, but as the next logical and innovative evolution in a proven digital health strategy for dementia care.

Table 2: Phased Clinical Trial Protocol Summary

Trial Phase	Primary Objective	Design	Key Outcome Measures (Primary & Secondary)	Target n (dyads)	Duration
Phase 1: Feasibility & Usability	Refine prototype and assess user acceptability.	Single-group, mixed-methods feasibility study.	Primary: Qualitative feedback (thematic analysis), System Usability Scale (SUS). Secondary: Adherence/engagement data.	10-15	4-6 weeks

Phase 2: Single-Site Pilot	Assess preliminary efficacy and test trial procedures.	Single-group pre-post or small RCT with wait-list control.	Primary: Change in Neuropsychiatric Inventory (NPI) score. Secondary: Changes in RUDAS, DAD, DEMQOL, Carer Burden Scale.	40-50	3-6 months
Phase 3: Multi-Site Efficacy	Determine definitive effectiveness and cost-effectiveness.	Multi-site, pragmatic Randomised Controlled Trial (RCT).	Primary: Change in NPI score. Secondary: Changes in RUDAS, DAD, DEMQOL, Carer Burden Scale; Health Economic Analysis.	150-200+	12 months

Section 8: Assembling the Queensland Clinical Team and Strategic Partnerships

No clinical trial can succeed without a skilled team and strong local partnerships. This section identifies the essential personnel and key organizations within Queensland's dementia care ecosystem that are critical for the successful execution of the AoI proof-of-concept trial.

8.1 Essential Clinical Trial Roles and Responsibilities

A successful trial requires a dedicated, multidisciplinary team with clearly defined roles, reflecting the collaborative nature of modern healthcare.[55] The following key roles must be recruited locally in Queensland:

- **Principal Investigator (PI):** This is the most critical role. The PI must be a senior, respected clinician—typically a geriatrician, neurologist, or old-age psychiatrist—with a strong track record in clinical research and an affiliation with a major Queensland university or hospital. The PI provides essential clinical oversight, lends credibility to the study, and is ultimately responsible for the ethical conduct of the trial and the safety of the participants. Potential PIs can be identified through professional networks such as the Queensland Dementia, Ageing and Frailty Clinical Network.[45]
- **Clinical Trial Coordinator:** This individual is the operational manager of the trial. They are responsible for the day-to-day execution of the protocol, including managing the HREC and governance submissions, overseeing participant recruitment and scheduling, ensuring data quality, and acting as the primary point of contact for participants.
- **Allied Health Assessors:** The involvement of allied health professionals is crucial for conducting the trial's assessments and aligning with best-practice multidisciplinary care models.[55] An

Occupational Therapist (OT) or a **Registered Nurse** with experience in aged care will be required to administer the cognitive, functional, and quality of life assessments at baseline and follow-up points. Their clinical expertise is vital for interpreting the data and supporting participants.

- **Technical Liaison:** A member of the AoI development team must be designated as the technical liaison for the trial. This person will be responsible for deploying the technology, training participants and staff, providing real-time troubleshooting and technical support, and gathering direct feedback to inform iterative improvements to the system.

8.2 Targeted Strategic Partners in Queensland

Building a network of strategic partners is essential for recruitment, clinical execution, and ensuring the trial's relevance to the local healthcare system. A phased partnership strategy should be employed, engaging different partners as the trial progresses from feasibility to efficacy testing.

This approach builds momentum and de-risks the project for larger, more resource-intensive partners. The initial focus should be on community-based organizations for the Phase 1 feasibility study, as they are closer to the end-user and can facilitate recruitment for a small-scale study more rapidly than large academic institutions. The positive results and refined prototype from this initial phase can then be used to build a much more compelling case for partnership with major clinical trial units for the larger Phase 2 and 3 efficacy trials.

Table 3: Key Queensland Stakeholder and Partner Matrix

Partner Name	Partner Type	Relevance to AoI	Recommended Engagement Phase	Key Contact (if available)
Alzheimer's Queensland	Service Provider & Advocacy	Direct access to people with dementia and carers for recruitment. Deep understanding of user needs. Potential site for usability testing.[52]	**Phase 1** (Feasibility/Usability)	Via general inquiries or professional networks.
Dementia Australia (Qld)	Advocacy & Support	Crucial for consumer engagement, participant recruitment through support programs, and disseminating findings. Lends significant credibility to the project.[13]	**Phase 1, 2, 3** (Ongoing)	National Dementia Helpline (1800 100 500) for initial contact.
University of Queensland	Clinical	Leading research centre with a specific Dementia & Neuro Mental Health	**Phase 2, 3**	Dr. Nadeeka Dissanayaka

Centre for Clinical Research (UQCCR)	Trial Site	Research Unit. Actively involved in technology-based intervention trials.[53] Prime partner for efficacy trials.	(Pilot & Efficacy)	(Dissanayaka Group).
The Prince Charles Hospital	Clinical Trial Site	Major teaching hospital with an established Internal Medicine and Dementia Research Unit. HREC is part of the NMA scheme.[54]	**Phase 2, 3** (Pilot & Efficacy)	TPCH-IMSresearch@health.qld.gov.au
Mater Research	Clinical Trial Site	Has a dedicated Neuroscience Clinical Trials Team that includes dementia research. Part of the NMA scheme.[60]	**Phase 2, 3** (Pilot & Efficacy)	Via general inquiries to Mater Clinical Trials.
Qld Dementia, Ageing and Frailty Clinical Network	Government/Strategic	Key advisory body within Queensland Health. Engagement provides system-level insights, support, and potential pathways for broader implementation.[45]	**Phase 2, 3** (Ongoing)	Dr. Fiona Baker (Chair).
Dementia Behaviour Management Advisory Service (DBMAS)	Specialist Service	Partnership could validate AoI's BPSD management features and provide a pathway for integration with existing specialist services in Queensland.[13]	**Phase 3** (Implementation)	Via DBMAS Qld contacts.

Section 9: Funding and Commercialization Pathways in Australia's Health System

The ultimate goal of the proof-of-concept trial is not only to achieve clinical validation but also to pave the way for the long-term commercial viability of the 'Aura of Intelligence' system in Australia. This requires a clear understanding of the primary funding streams for aged and disability care—the National Disability Insurance Scheme (NDIS) and My Aged Care—and a strategy for positioning AoI within these complex systems.

9.1 Positioning AoI as Assistive Technology (AT) for NDIS and My Aged Care

The most viable commercial pathway for AoI in Australia is to have it classified and funded as **Assistive Technology (AT)**.

- **NDIS Pathway (for Younger-Onset Dementia):** The NDIS provides funding for Australians under the age of 65 with a permanent and significant disability, which explicitly includes younger-onset dementia.[61] The NDIS defines AT as equipment or devices that help a person do things they cannot do because of their disability, or help them do things more easily or safely.[62] The AoI

system—with its reminders, safety features, and communication aids—fits this definition perfectly. Funding for AT is typically allocated under a participant's 'Capital Support' budget.[63]

- **My Aged Care Pathway (for people over 65):** The Australian government provides subsidized aged care services through My Aged Care. For individuals living at home, this is primarily delivered through **Home Care Packages (HCPs)**.[64] These packages have a flexible budget that can be used for goods, equipment, and assistive technology that are linked to the person's assessed care needs and goals.[64] The government is also moving towards a new 'Support at Home' program, which is planned to include a dedicated Assistive Technology and Home Modifications (AT-HM) scheme, further solidifying this funding pathway.[66]

9.2 Evidence Requirements for AT Justification

Access to these government funding streams is not automatic. For an item of AT to be funded, particularly a mid-to-high cost item (the NDIS defines mid-cost as $1,500-$15,000 and high-cost as over $15,000), it must be deemed 'reasonable and necessary'.[62] This determination is made by an assessor—such as an Aged Care Assessment Service (ACAS) assessor for My Aged Care, or an Occupational Therapist (OT) or NDIS planner for the NDIS—based on evidence that the technology will help the person achieve their goals.[55]

The entire clinical trial protocol outlined in this plan is designed to generate precisely the portfolio of evidence required for these assessors to write a strong, successful funding application. The trial outcomes will provide objective proof of AoI's benefits across multiple domains:

- **Improved Safety:** Data from the trial on reduced falls (which can be monitored via integrated wearables), fewer instances of wandering (from location tracking features), or better medication adherence (from the reminder system) provides concrete evidence of risk reduction.
- **Increased Independence and Function:** Demonstrating through validated scales like the DAD or IADL that participants using AoI maintained their ability to perform daily tasks for longer provides a powerful justification for funding.[11]
- **Reduced Behavioural and Psychological Symptoms:** Evidence of a reduction in BPSD, as measured by the NPI, demonstrates that AoI can reduce distress and improve the home environment, often a key goal in a care plan.[2]
- **Reduced Carer Burden:** Showing a statistically significant reduction in carer stress and depression, as measured by the Carer Burden Scale and GDS, is a compelling outcome for funding bodies who recognize the need to support informal carers.[12]
- **Improved Quality of Life:** Positive changes in QoL, measured by the DEMQOL, directly address the ultimate goal of person-centred care.[2]

9.3 The 'Prescription' Model for Commercialisation

Given that access to NDIS and My Aged Care funding is mediated by professional assessors, the most effective go-to-market strategy in Australia is a 'prescription' model. The primary commercial goal is not to market AoI directly to consumers, but to convince the clinical gatekeepers—the OTs, nurses,

geriatricians, and NDIS planners—that recommending or 'prescribing' AoI is an evidence-based, clinically sound decision that will lead to better outcomes for their clients.

The clinical trial is the engine of this strategy. The evidence portfolio generated from the three trial phases becomes the core of the commercialisation toolkit. This evidence will be used to:

1. Develop training materials and presentations for allied health professionals, demonstrating how AoI can help them achieve their clients' goals.
2. Create template justification reports that OTs and other assessors can adapt for NDIS and My Aged Care funding applications, pre-populated with the clinical evidence from the trial.
3. Publish the results in peer-reviewed journals to build credibility and drive awareness within the clinical community.

This model shifts the focus from consumer marketing to professional education and evidence dissemination. The commercial success of 'Aura of Intelligence' in the Australian market will be a direct function of the successful execution of this research plan, creating an undeniable evidence base that empowers clinicians to make it an integral part of modern dementia care.

Part IV: Synthesis and Strategic Recommendations

This final part of the report consolidates the detailed analysis from the preceding sections into a cohesive, high-level strategic roadmap. It provides a synthesized timeline of key activities, identifies the project's critical path, and concludes with a set of clear, actionable recommendations to guide executive decision-making and ensure the successful transition of the 'Aura of Intelligence' system from concept to a clinically validated and commercially viable reality in Queensland.

Section 10: Integrated Roadmap and Critical Path Analysis

The journey from a conceptual technology to a regulated, evidence-based medical device is a multi-stage process with significant interdependencies. A clear, integrated roadmap is essential for managing this complexity, allocating resources effectively, and tracking progress against key milestones.

10.1 A Synthesized, Time-lined Roadmap

The following visual timeline presents a high-level overview of the key activities and milestones required to execute the Queensland proof-of-concept plan. It integrates the parallel streams of clinical development, regulatory submission, ethical approval, and partnership engagement.

(Note: The following is a descriptive representation of a Gantt chart timeline.)

Project Year 1: Foundation and Feasibility

- **Quarters 1-2:**
    - **Clinical/Technical:** Finalize the "Clinical Wrapper" prototype of the AoI system, embedding the data collection architecture for the mapped clinical scales.

    - **Regulatory:** Appoint an Australian Sponsor. Prepare documentation and initiate a pre-submission meeting with the TGA to confirm the regulatory pathway and risk classification.
    - **Partnerships:** Secure a partnership with a community-based organization in Queensland (e.g., Alzheimer's Queensland) for the Phase 1 trial.
    - **Ethics:** Prepare and submit the HREC application for the Phase 1 Feasibility and Usability Trial.
    - **Milestone 1:** TGA pre-submission meeting completed.
    - **Milestone 2:** HREC approval for Phase 1 received.
- **Quarters 3-4:**
    - **Clinical/Technical:** Execute the Phase 1 trial (n=10-15 dyads). Analyze qualitative and usability data. Refine the AoI prototype based on feedback.
    - **Regulatory:** Begin compiling the TGA Technical File with initial usability data.
    - **Partnerships:** Initiate discussions with major clinical trial units in Brisbane (e.g., UQCCR, Prince Charles Hospital) for the Phase 2 pilot study, presenting the positive results from Phase 1.
    - **Milestone 3:** Phase 1 Feasibility and Usability Trial completed.

Project Year 2: Pilot and Submission

- **Quarters 5-6:**
    - **Clinical/Technical:** Prepare the protocol and materials for the Phase 2 Pilot Study.
    - **Regulatory:** Continue development of the TGA Technical File.
    - **Partnerships:** Finalize agreement with a clinical trial site for Phase 2.
    - **Ethics:** Prepare and submit the HREC application for the Phase 2 Pilot Study.
    - **Milestone 4:** HREC approval for Phase 2 received.
- **Quarters 7-8:**
    - **Clinical/Technical:** Execute the Phase 2 Pilot Study (n=40-50 dyads) over a 6-month period. Collect and analyze preliminary efficacy data.
    - **Regulatory:** Finalize the TGA Technical File with the complete clinical evidence package from Phase 1 and Phase 2. Submit the formal TGA Conformity Assessment application.
    - **Milestone 5:** Phase 2 Pilot Study completed.
    - **Milestone 6:** TGA Conformity Assessment application submitted.

Project Year 3 and Beyond: Pivotal Trial and Market Entry

- **Quarters 9-12 (and ongoing):**
    - **Clinical/Technical:** Based on TGA feedback and Phase 2 results, design and seek funding for the larger, multi-site Phase 3 Efficacy Trial (RCT).
    - **Regulatory:** Respond to any TGA requests for information during their assessment period (up to 255 working days).
    - **Ethics:** Prepare and submit the HREC application for the Phase 3 RCT.
    - **Milestone 7:** TGA Conformity Assessment Certificate received and ARTG listing achieved.
    - **Milestone 8:** Phase 3 RCT commences.

- **Milestone 9:** Commercialisation activities begin, leveraging the TGA approval and trial evidence to engage with NDIS and My Aged Care providers.

10.2 Critical Path and Strategic Recommendations

Analysis of this integrated roadmap reveals that the project's overall timeline is dictated by two parallel, interdependent streams that form the **critical path**: **(1) the phased generation of clinical evidence through the trials**, and **(2) the TGA conformity assessment process**. The TGA submission cannot be completed without the clinical data, and the project cannot proceed to commercialisation without TGA approval. Delays in either of these streams will directly delay the entire project.

Based on this analysis, the following strategic recommendations are provided to guide the project's execution:

1. **Prioritise Early and Proactive Regulatory Engagement:** The uncertainties of the regulatory pathway represent the single greatest risk to the project timeline and budget. An immediate priority must be to engage with the TGA for a pre-submission meeting. Confirming the likely risk classification (Class IIa vs. IIb) and specific clinical evidence requirements upfront will de-risk the entire project and allow for the clinical trial protocol to be designed with precision from day one.
2. **Adopt the Phased Partnership Strategy:** Resist the temptation to immediately approach large, prestigious academic centres. Begin the journey in Queensland by partnering with smaller, more agile community-based organizations like Alzheimer's Queensland or a local aged care provider for the Phase 1 usability trial. This will build momentum, generate crucial early data, and refine the product quickly. A successful, user-validated prototype is a far more compelling proposition to present to major clinical trial units like UQCCR for the subsequent efficacy trials.
3. **Appoint a Dedicated Regulatory and Governance Lead:** The complexity of the TGA and HREC submission processes, combined with the need to establish and maintain a robust clinical governance framework, cannot be managed as an ancillary task. A dedicated individual or expert consultant with experience in Australian medical device regulation and clinical trials must be appointed. This role is essential for navigating the bureaucracy, ensuring compliance, and keeping the project on its critical path.
4. **Mandate an Integrated "Design for Evidence" Approach:** The technical development team and the clinical trial team must work in a deeply integrated fashion. The specific data points required to measure the trial's clinical outcomes (e.g., NPI scores, DAD scale items) must be embedded into the AoI software architecture from the very beginning. Treating clinical data collection as an add-on at a later stage will lead to costly and time-consuming redevelopment. The trial's evidence requirements must drive the product's technical design.
5. **Centre the Carer in the Value Proposition:** In all communications—with partners, ethics committees, regulators, and funding bodies—consistently emphasize the benefits of the AoI system for the carer. The Australian health and aged care system places a high priority on supporting informal carers. By designing the trial to explicitly measure outcomes like carer burden and wellbeing, and by highlighting these results, AoI can position itself as a holistic solution that

supports the entire "Circle of Support," making it a far more attractive and fundable proposition within the Australian context.