HealthConsult

Medical Technology Association of Australia

Enabling Remote Care:

Funding Pathways for Digital Therapeutics and Remote Patient Monitoring

October 2025

Acknowledgments

Project partners for report development:
Medical Technology Association of Australia (MTAA)
MTPConnect
ANDHealth
APACMed

We acknowledge the contributions of the following organisations:
Abbott
Amazon Web Services (AWS)
BIOTRONIK
Cardihab
Elekta
Hydrix Medical
MedTech International
Menzies Institute for Medical Research, University of Tasmania
Vantive
XRHealth

Funding for the development of this report was provided by MTAA and MTPConnect.

Disclaimer

HealthConsult has indicated within this report and all other deliverables the sources of the information provided. All reasonable precautions have been taken by HealthConsult to verify the information referenced in this report. However, the published material is being distributed without warranty of any kind, either expressed or implied. This report has been prepared at the request of the MTAA in accordance with the terms of our contract for this work.

Contents

Tables

Figures

REPORT ON A PAGE

NATIONAL FUNDING PATHWAYS FOR DTX AND RPM

The Problem, the Consequence, the Opportunity

AUSTRALIA LACKS A NATIONAL FUNDING PATHWAY FOR DTX AND RPM

Australians lack equitable and timely access to proven, evidence-based digital health technologies that enable virtual care at home, in aged care facilities, and in the community. Digital therapeutics (DTx) and remote patient monitoring (RPM) solutions are transforming care globally by supporting prevention, early intervention, and guided self-management. In Australia, however, their use is largely limited to pilots and adhoc procurements. Fragmented funding across primary care, hospitals, and private insurance, combined with misaligned procurement and funding decisions, means these technologies must compete with existing services instead of complementing and extending them.

WITHOUT REFORM, INEQUITY DEEPENS AND PROVEN THERAPIES REMAIN OUT OF REACH

Patients continue to face preventable deterioration, hospitalisations and out-of-pocket costs for digital solutions, with rural Australians experiencing the greatest inequity. Clinicians remain unreimbursed for digital monitoring and guided care, adding pressure to a workforce already under strain and limiting the capacity gains that digital solutions could provide. State governments absorb rising emergency presentations and acute care costs that could be avoided with earlier intervention, while private insurers miss the chance to fund digital care models that reduce claims and improve member value. Vendors face commercial risk and investment flight in the absence of predictable reimbursement, putting Australian innovation, jobs and research and development (R&D) at risk.

A PHASED FRAMEWORK PROVIDES THE PATH TO INTEGRATION

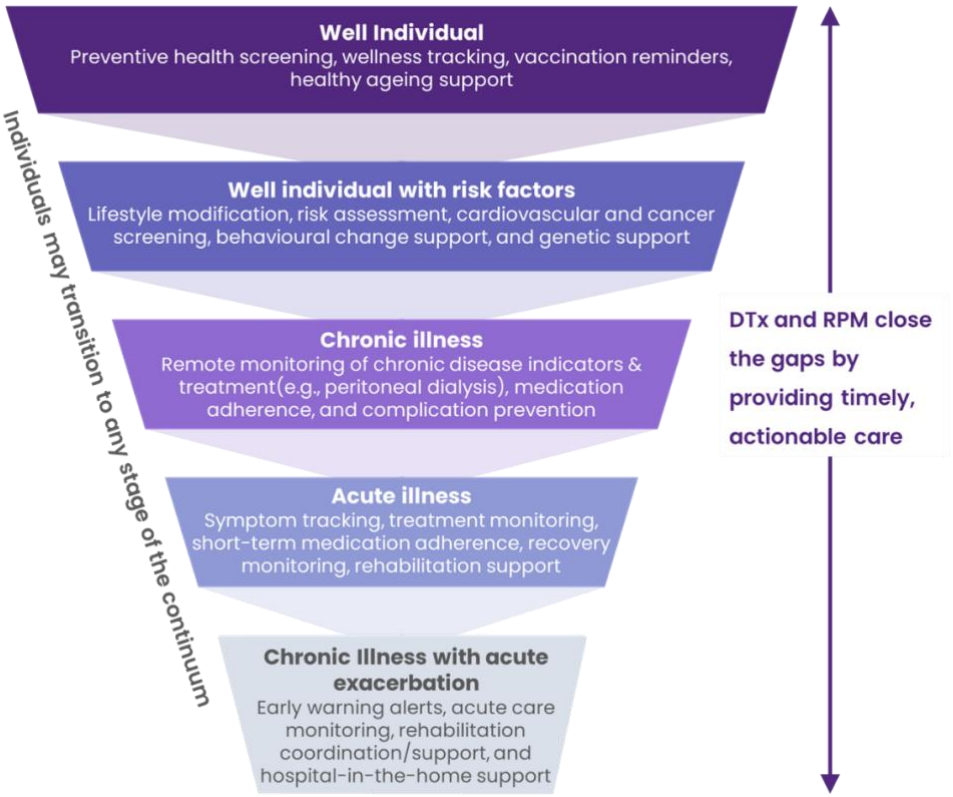
Australia can close the gap by introducing a nationally consistent reimbursement framework for DTx and RPM through a phased approach:

- **Phase 1 - Establish enablers for funding and national coordination:** Create a Commonwealth-led authority National Virtual Care Coordination body, provide targeted grants to bridge pilots into practice, and develop a searchable national library of TGA-approved DTx and RPM
- **Phase 2 – Introduce sector-specific funding pathways:**
  - **Public hospitals:** new IHACPA classifications for bundled service pathways including technology costs
  - **Primary and specialist care:** open access pathway with new HTA framework, MBS funding for additional clinical services, separate technology funding, provisional listing, and expand targeted commissioning
  - **Private sector:** enhanced legislative and policy framework for bundled payments covering services and technology for hospital-substitute care.
- **Phase 3 – Embed permanent reimbursement and system integration:** Establish permanent MBS items and technology funding streams, transition provisional listings to permanent reimbursement, and create joint funding arrangements across all levels of government.

Executive summary

Australians lack equitable and timely access to proven, evidence-based digital health technologies that enable remote care and guided self-management. In contrast, health systems worldwide are shifting from episodic, facility-based care to remote care in the community enabled by digital therapeutics (DTx) and remote patient monitoring (RPM). These technologies support earlier intervention, extend specialist reach and improve treatment adherence across the care continuum. Due to slow take up of DTx and RPM, Australian patients are missing out on faster diagnoses, better treatment outcomes, and more efficient care. Our health system continues to absorb avoidable hospitalisations, administrative duplication and productivity losses while other countries have restructured funding to accelerate digital adoption. This missed opportunity is not only constraining patient access, it is discouraging investment, weakening sovereign capability, and limiting Australia's ability to compete as a global leader in digital health innovation.

Figure 1: The role of DTx and RPM across the care continuum



Source: HealthConsult

This report analyses current funding and adoption barriers, identifies proven international models, and sets out a proposed nationally consistent funding framework to enable equitable, sustainable and evidence-based integration of DTx and RPM into Australian healthcare. The recommended framework adapts successful international design principles to align with Australia's existing funding structures and ensure coordinated national access.

Health Minister Mark Butler at 2025 HIC conference

"Digitisation can help us tackle some of the most significant problems in our health system. Workforce shortages, pressure on our hospitals, fragmentation across different care settings and the need for ongoing coordinated care for those with chronic conditions, just to name a few"

Proven Australian solutions are ready to scale

Australia has demonstrated the capability to integrate remote care and guided self-management into clinical practice, improving access and patient outcomes in several areas. DTx and RPM solutions now deliver evidence-based clinical interventions, as shown in Figure 2.

Figure 2: DTx and RPM Benefits

Clinical evidence examples

Cardihab® Digital Rehabilitation

- 91% completion rates (vs 60-80% traditional)
- 71% reduction in hospital bed days
- Improves uptake: 80% vs 62% and adherence by 26%
- Addresses crisis: 80% of cardiac patients receive no rehabilitation

Vantive® Peritoneal Dialysis

- 45% lower all-cause mortality
- 51% lower cardiovascular mortality
- 77% patients maintained on home dialysis

BIOTRONIK® Cardiac Device Home Monitoring

- 50% mortality reduction in heart failure
- 37% risk reduction in worsening clinical scores
- 84% vs 65% adherence at 12 months
- 50% fewer inappropriate defibrillator shocks

Elekta® Cancer Monitoring

- Clinical calls reduced from 20/month to <5
- Treatment personalisation capabilities

XRHealth® Virtual Reality Therapy

- 91% patient adherence (vs 50% traditional)
- 50+ clinical trials across multiple therapeutic domains

Geographic equity

- **Regional and rural access**: Identical care quality
- **Metropolitan outcomes**: Same clinical results regardless of location
- **Systematic digital deployment**: Nationwide coverage

Multiple pathways to productivity

Hospital utilisation

- Fewer bed days and hospitalisations

Workforce productivity

- More patients per clinical staff member

Prevention focus

- Fewer inappropriate device activations
- Reduced emergency presentations

Infrastructure elimination

- No travel costs
- Reduced facility requirements

Early intervention

- Continuous monitoring identifies issues early
- Prevents serious complications

Improved adherence

- Better completion rates
- Prevents costly disease progression

Service substitution

- Home-based digital alternatives
- Maintains/improves clinical outcomes

Patient Experience Enhancement

- **Healthcare integration**: Into daily life, work & family
- **Convenience**: Care when and where needed
- **Family-centred**: Fits around responsibilities
- **Security** of monitoring and clinical oversight

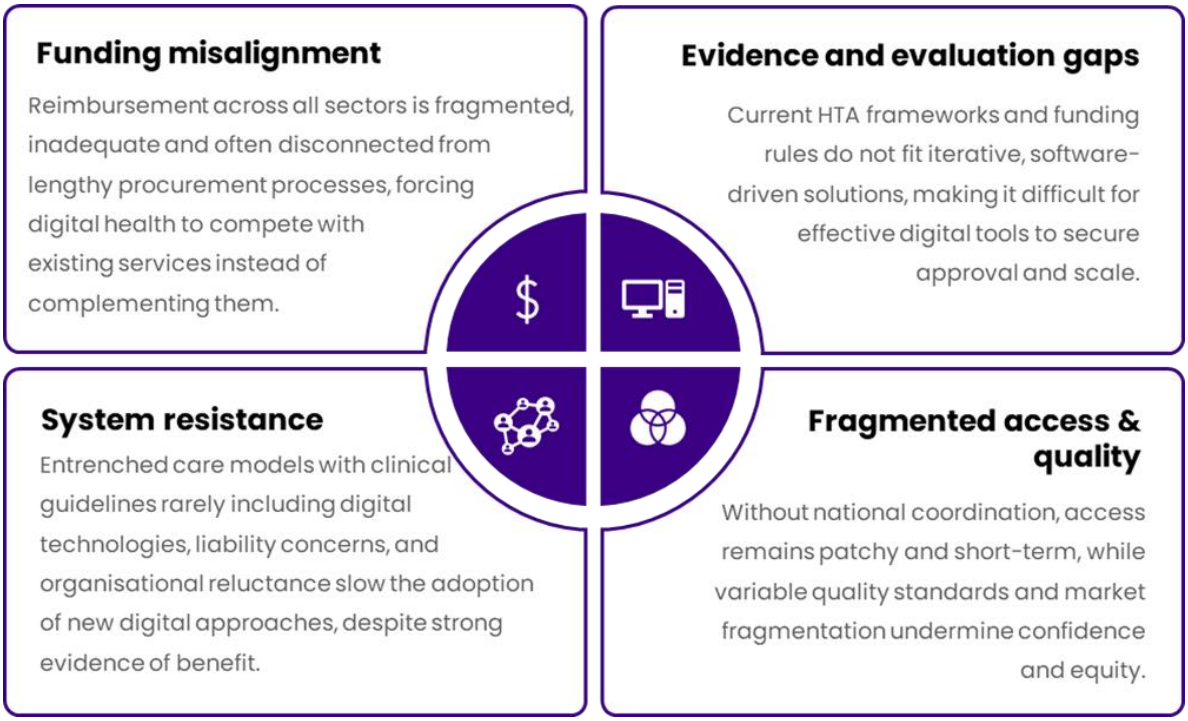
Source: Case studies appendices A-F

These case studies demonstrate that digital health can be successfully adopted in clinical practice, with strong patient engagement and measurable outcome improvements. They also show the potential for remote care models to support vulnerable populations, including aged care residents, people with disability, and those in remote and regional areas. These technologies are not wellness applications, lifestyle tools or consumer health products, they are regulated medical devices that consistently provide measurable therapeutic outcomes and care support that match or exceed conventional hospital-based treatments.

The Australian funding and access gap

Funding for DTx and RPM technologies is fragmented, inconsistent and not designed to support remote care or guided self-management. Products are occasionally indirectly funded by mechanisms such as the Medicare Benefits Schedule (MBS) or hospital Activity-Based Funding (ABF), but these are typically workarounds rather than fit-for-purpose pathways. Access otherwise depends on isolated procurement decisions by the Commwealth, states or local health systems (public and private). This situation creates inequitable patient access, slows adoption and leaves vendors and clinicians navigating an unpredictable funding landscape. Proven technologies, therefore, remain confined to limited deployments, constraining both patient-level and system-wide benefits. Australia faces a consistent set of barriers to adoption, outlined in Figure 3.

Figure 3: Key barriers to the adoption



The challenges vary across care settings, as set out below, but together explain why DTx and RPM have struggled to move beyond application in pilots into routine clinical practice.

- **Primary care and specialist practice**: Current MBS funding is inadequate to cover the full scope of care. Clinician review time, nursing and allied health contributions, and software-based interventions that are not tied to in-person consultations remain largely unfunded. In Australia, there are also no clear incentives for using digital therapeutics, with limited, if any, funding for the technology itself.
- **Public hospitals**: Uptake is constrained by limited relevant Diagnosis Related Group (DRG) and Tier 2 (for non-admitted patients) codes, budget pressures and slow procurement processes. Even where funding mechanisms technically exist, hospitals face practical barriers to using them effectively for virtual home-based/outpatient care.
- **Private hospitals and insurance**: Implementation is fragmented. Despite some positive results from pilots to test the feasibility in their ecosystem, there is no additional benefit coverage by insurers for the DTx or RPM episodes to cover technology costs. This represents a lost opportunity for insurers to differentiate competitively while reducing hospitalisation costs and impacting the implementation of hospital-in-the-home to improve sustainability.
- **Commissioned services (national or regional):** National programs, such as the Digital Mental Health Program, show how commissioning can deliver targeted digital health solutions at scale. However, selective funding can limit diversity by supporting only chosen providers, reinforcing the need for open funding pathways that fund all products meeting agreed evidence and quality thresholds**.** Regional programs also face sustainability, integration and quality assurance challenges. Without a transition to dedicated, long-term pathways, value is often lost once short-term commissioning cycles end.

International evidence and design principles

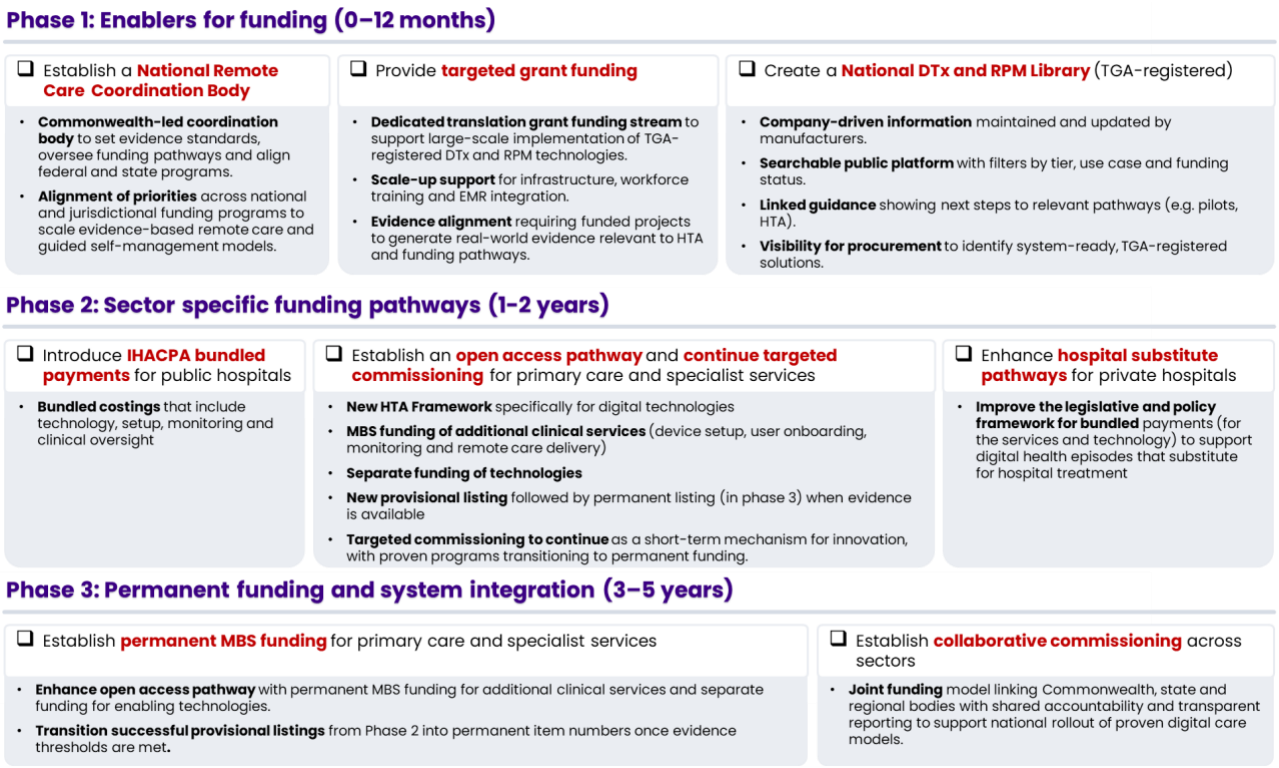
Several countries have established successful funding pathways for DTx and RPM. Germany reimburses over 50 digital therapeutics through its DiGA program, France has created dedicated pathways for both DTx and RPM with dual funding for products and services, and the United States enables comprehensive Medicare billing for remote monitoring. These international models demonstrate common success factors: **nationally coordinated** approaches that avoid fragmentation (Germany, France, South Korea, Belgium), **evidence requirements proportionate to software development cycles** (Germany, France), **dual funding for both technology and clinical services** so adoption is incentivised (France, US, Belgium, the Netherlands), a nationally consistent **funding mechanism open to any accredited provider or developer that meets defined eligibility and safety criteria** with **structured pathways from provisional to permanent listing** (Germany, France, Belgium). Countries have also established **national digital health libraries** (Belgium) to increase visibility and build clinical confidence while using **time-limited national pilot programs** (South Korea, Japan) as transitional mechanisms to bridge the gap between early adoption and permanent funding.

The Australian framework proposed in this report directly incorporates these proven design principles, adapted to align with Australia's existing health system funding structures (MBS, ABF, private insurance) and address the specific barriers identified in Australian implementation.

Funding framework

A framework to enable a nationally coordinated approach to scaling safe, evidence-based remote care and guided self-management models is outlined in Figure 4. The framework combines three core enablers with staged, multiple sector-specific pathways rather than a single approach, recognising that supporting adoption in primary care, public hospitals, private insurance and commissioned services requires tailored mechanisms while maintaining national coordination and consistency.

Figure 4: DTx and RPM solutions funding roadmap



Source: HealthConsult

Summary

Australia already has proven digital health solutions with established clinical efficacy and mature technologies. Implementing a national funding framework for DTx and RPM solutions would provide consistent access, support equity and enable further uptake of remote care and guided self-management across all sectors. Establishing a coordinated national approach would enable the transition from fragmented pilots to sustainable, system-wide adoption and ensure that effective technologies are integrated into routine models of care.

1. Current state and system challenges

Recognising persistent gaps in how Australia assesses and funds digital therapeutics (DTx) and remote patient-monitoring (RPM) technologies, this report examines the barriers preventing evidence-based digital care from scaling beyond pilots and proposes enablers and funding pathways for integration into routine healthcare. DTx and RPM solutions already deliver measurable clinical and economic benefits, enabling remote monitoring, guided self-management and remote models of care that extend clinical reach beyond traditional facilities. However, Australia's current funding and assessment frameworks remain misaligned with these technologies, creating inequitable access, slow adoption and fragmented procurement. Internationally, many countries have resolved similar barriers through coordinated funding reform, but Australia continues to rely on short-term grants and ad hoc commissioning. Without change, proven digital-health innovations will remain trapped in pilot cycles, limiting both patient outcomes and system-wide efficiency.

1.1. Access gaps and mounting system pressures

While digital health technologies such as DTx and RPM are transforming healthcare globally bringing care into homes, aged care facilities, and communities, Australians still face variable access to these evidence-based solutions. Ensuring equitable adoption is key to meeting rising demand for healthcare services and addressing workforce shortages.

Australia's health system faces simultaneous pressures: an ageing population, growing chronic disease burden, rising care expectations, and acute workforce shortages. Allied health services face extensive waiting lists, specialist consultations may involve months of delay, and emergency departments operate under sustained pressure. Traditional, facility-based models can no longer meet demand sustainably. Digital health solutions offer potential to address workforce pressures by enabling clinicians to automate routine monitoring and allow patients to receive guided care at home. International evidence demonstrates that well-implemented programs can enable clinicians to safely manage larger patient cohorts through remote monitoring and predictive alerts, thereby potentially multiplying workforce capacity without proportional increases in staffing.

Without reform, workforce pressures will intensify, inequities will widen, and Australia will continue losing sovereign capability and investment to markets with clearer funding frameworks. DTx and RPM solutions have demonstrated capacity to support prevention, early intervention and guided self-management, yet in Australia, their use remains limited to pilots and ad hoc procurements. Fragmented funding arrangements across primary care, hospitals

and private insurance means these technologies must compete with existing services rather than complement and extend them.

1.2. Proven Australian solutions exist

Digital health technologies are transforming health care delivery across Australia, enabling remote care and guided self-management models that extend specialist expertise, support multidisciplinary collaboration and deliver hospital-quality care in community settings.[1-4] This is vital in a country which faces continuing challenges in delivering equitable healthcare to populations in remote, rural, regional and outer urban settings. While not yet widely implemented across the healthcare system, the evidence base for these new technologies is compelling and the solutions are ready for systematic adoption. These innovations demonstrate how technology can fundamentally reimagine healthcare delivery beyond traditional facility boundaries. Examples of proven care models include:

- Australian DTx solutions that have proven their ability to transform care delivery by enabling remote, personalised therapeutic programs that patients can access anytime, anywhere, while maintaining appropriate clinical supervision (Appendix A, Appendix D, Appendix F).
- Australian RPM technologies that have demonstrated their capacity to replace periodic clinical assessments with health oversight that enables early intervention before acute episodes occur (Appendix B, Appendix C, Appendix E).

Australian DTx and RPM products, together with clinical oversight services, represent proven pathways from traditional healthcare to remote and guided self-managed care delivery that multiplies clinical productivity while improving patient outcomes. This will grow with the expansion of AI and Machine Learning, which is revolutionising diagnostic capabilities and treatment personalisation.[5,6] AI-powered triage systems and symptom checkers are becoming increasingly sophisticated, enabling more accurate self-assessment and appropriate care pathway selection.[7,8]

These remote care and guided self-management models are not theoretical, they are operating successfully across Australia today. Key examples include:

- **Guided self-management rehabilitation with clinical supervision from multidisciplinary teams**: **Cardihab** is delivering cardiac rehabilitation services through private health insurers and hospital programs, enabling patients to complete specialist rehabilitation programs at home with clinical oversight using multidisciplinary teams (case study in Appendix A).
- **Hospital-quality dialysis monitoring in community settings**: **Vantive remote dialysis monitoring** supports patients receiving peritoneal dialysis (PD) at home while maintaining hospital-level clinical oversight using multidisciplinary teams (case study in Appendix B).
- **Continuous monitoring: BIOTRONIK Cardiac Device Home Monitoring** provides continuous cardiac device monitoring for patients across Australia, enabling cardiologists to manage device patients remotely (case study in Appendix C).

- **Coordinated cancer care teams: Elekta ONE Patient Companion** enables cancer care teams to monitor treatment toxicities and adjust protocols remotely, reducing emergency presentations while maintaining treatment safety (case study in Appendix D).
- **Guided self-management coordination: InforMS** enables people with multiple sclerosis to coordinate their care across multiple specialists while self-managing their condition with real-time data sharing (case study in Appendix E).
- **Virtual reality therapy by virtual care team: XRHealth** platform proves that immersive technology can enhance therapeutic outcomes whilst improving healthcare accessibility and efficiency (case study in Appendix F).

These improvements represent fundamental advances in clinical care delivery that are transforming patient outcomes today, as outlined in Table 1.

Table 1: Australian solutions delivering benefits

DTx and RPM Solution	Clinical Evidence	Patient Experience	Economic Analysis
Cardihab *Digital cardiac rehabilitation (CR)* Therapeutic Goods Administration (TGA) Class II	**CR uptake** = lower mortality risk **91% completion rate** vs 20-40% traditional hospital programs drop out **Improves uptake:** 80% vs 62% with face to face CR **Improves adherence** by 26% **Equivalent outcomes** to face-to-face CR with better accessibility **Cardiovascular risk factor improvements,** physical activity, diet, BMI, systolic blood pressure, functional capacity	**High patient satisfaction** across diverse implementation settings **Improved quality of life and patient self-management confidence** **Better access**: Working adults complete around schedules **Geographic equity**: Regional and rural patients have access to the same quality as metropolitan patients **Reduced travel burden**: Eliminates patient travel costs and barriers	**71% reduction** in hospital bed days (30/90 days) **88% reduction** in cardiac bed days (30 days) **40% lower cost** per patient vs traditional **3-4x more patients** per Full-Time Equivalent (FTE) vs face-to-face **Millions in potential savings** from reduced readmissions **Addresses 80% gap** of patients receiving no CR **Return to work productivity** **1.434 Quality-Adjusted Life Year (QALY) gained** vs usual Care **$14,302** Incremental Cost-Effectiveness Ratio per QALY gained **87% of scenarios** Cardihab was the better value choice
Vantive Remote PD Monitoring *Peritoneal dialysis (PD)* TGA-registered devices	**45% lower all-cause mortality** **51% lower cardiovascular mortality** **69% lower hospitalisation** for fluid overload **77% patients remaining** on PD vs non-RPM	**Interface and satisfaction:** 6.8/7 **Ease of use:** 6.6/7 **Usefulness:** 6.1/7 **Reported peace of mind** knowing their clinical team is monitoring and can identify issues before they become serious **Enables dialysis "on country"** for Indigenous communities	**$3,256 annual cost savings** per patient **1-2 fewer hospitalisations** p.a. **2-5 fewer emergency room** visits per patient **32% increase** in proactive care activities

DTx and RPM Solution	Clinical Evidence	Patient Experience	Economic Analysis
BIOTRONIK Cardiac Device Home Monitoring ***Remote Cardiac Device Monitoring*** **TGA-registered since 2005**	**Alert-based monitoring** enhances clinical actionability as part of digital models of care **50% mortality reduction** in heart failure patients **37% risk reduction** in worsening composite clinical scores **84% vs 65% adherence** at 12 months compared to conventional follow-up **50-77% reduction** in inappropriate defibrillator shocks **Non-inferior safety** with superior event detection	**97% patient satisfaction** and wish to continue **Automatic transmission**: Minimal patient interaction required **35% find conventional visits inconvenient** due to travel/age factors **Patients particularly value the convenience and psychological reassurance** provided by continuous monitoring	**Reduced hospitalisation rate** by two-thirds **34% reduction in stay duration** **45-73% reduction** in-clinic follow-up visits Demonstrate **cost-neutral to cost-saving outcomes** across multiple healthcare systems, e.g. €290 savings due to early discharge, €257 outpatient cost savings
Elekta ONE Patient Companion *Cancer Patient Monitoring* TGA Class IIa	**Comparable outcomes** to face-to-face with better accessibility **Improved patient safety** and care quality through symptom monitoring **Treatment personalisation** capabilities **High satisfaction**: Mean ratings 3.2-4.5 (out of 5)	**98% report platform** is easy to use **High adoption** among older users **Self-management** recommendations perceived as "very helpful" **Geographic accessibility**: Eliminates travel barriers	**Phone call reduction**: From 20/month to <5 **5-10 minutes saved** per patient visit **2-hour training**: Minimal infrastructure for rapid deployment **API integration**: Health service analytics and electronic medical record (EMR) integration
XRHealth Virtual Reality (VR) Therapy *Virtual Reality Therapeutics* TGA-registered (3 approvals) + NDIS	**91% patient adherence** vs 50% market standard **93% patient retention,** demonstrating sustained engagement **50+ clinical trials** across multiple therapeutic domains **10+ published studies** demonstrating effectiveness	**81 Net Promoter Score** vs 38 NPS healthcare sector **Peace of mind** through remote monitoring **Immersive environments** creating engaging experiences **Treatment independence** and home flexibility	**Cost-effective alternative** to traditional in-person therapy **Worth up to £341 per patient** from the NHS perspective (UK study) **Eliminated travel costs,** particularly benefiting rural patients **Technology enabling treatment** without proportional staff increases
InforMS Platform *Multiple Sclerosis Management* Co-designed digital health portal pilot National Health and Medical Research Council (NHMRC)/MS Australia partnership grant (Grant ID 1193008)	**Enables shared decision-making** through centralised tracking **Incorporates validated survey tools** and real-time wearable data **Printable health summaries** support clinic visits **Viewed by clinicians** as enhancing appointment efficiency	**No fees** for a person with multiple sclerosis (MS) or their care team **Minimal setup**: Web browser access, no special infrastructure **Reduces duplication** and improves consumer-clinician alignment **Visual dashboards** and goal-setting features	**Cost-per-user model** for service licence **Reduces reactive visits** through enhanced coordination **Long-term potential** to offset care costs **Built on 20+ years** of Australian MS Longitudinal Study (AMSLS) data for evidence-based and validated user needs

Source: Case study data from Appendices A to F, HealthConsult analysis 2025

2. The potential of a DTx and RPM-enabled health system

If Australia establishes a coordinated national funding pathway for DTx and RPM, the health system could expand delivery of technology-enabled care nationwide. Integrated DTx and RPM have the potential to support workforce efficiency, improve chronic disease management and ensure equitable access. These technologies can empower people to manage their health, give clinicians real-time data and predictive insights, and strengthen the sustainability of the health system. This chapter outlines the transformation that systematic adoption could enable and the consequences of inaction.

2.1. The transformation to new care models enabled by technology

Healthcare systems worldwide are experiencing a fundamental evolution from traditional facility-based care to remote care and guided self-management models enabled by digital technologies. This transformation mirrors the productivity revolutions that technology and AI are driving across other sectors. Just as digital innovation has fundamentally reshaped business processes through automation, data analytics and personalised services, digital health technologies are revolutionising how patients seek and receive care, how clinicians practice medicine and how health systems operate.

The COVID-19 pandemic demonstrated that healthcare could rapidly adapt to virtual models when necessary, with telehealth becoming mainstream healthcare almost overnight,[9,10] revealing underlying potential for systematic transformation from time-centric, facility-dependent care to needs-based models driven by objective data and clinical oversight.

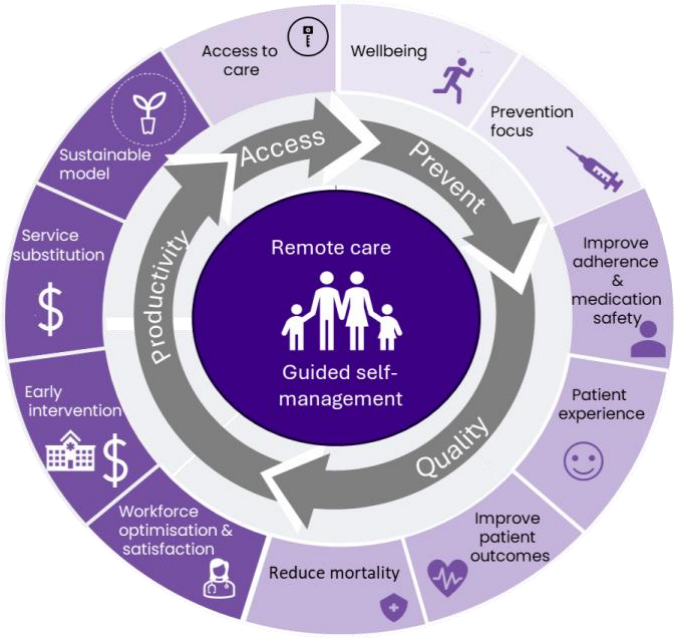
Internationally, this evolution has been characterised by five shifts in care [11-15]:

1. **From episodic to ongoing engagement**: Digital platforms enable ongoing patient monitoring and therapeutic support, augmenting periodic clinic visits with sustained health management and real-time intervention capabilities.
2. **From reactive to predictive healthcare**: Advanced monitoring systems analyse patient data streams to identify health indicators or potential deterioration before symptoms manifest, supporting preventive interventions rather than crisis response.
3. **From facility-centralised to distributed care networks**: Remote care platforms extend specialist expertise to any location with internet connectivity, while digital tools may enable community-based delivery of previously hospital-dependent services.

4. **From provider-directed to guided self-management**: Patients can become active managers of their health conditions through digital self-care programs, with clinical oversight provided through remote monitoring and data analytics rather than solely scheduled appointments.
5. **From manual to technology-enhanced clinical decision-making**: Digital systems can augment clinical expertise by securely analysing monitoring patient data and identifying patterns that may not be visible through manual review, potentially improving decision accuracy, enabling earlier intervention and creating time for direct patient care.

These shifts have shown measurable improvements as outlined in Figure 5. Patients may experience better outcomes through personalised, remote care delivery[12,14] that can improve medication safety, support adherence and help clinicians manage polypharmacy and multimorbidity. Clinicians may practise more effectively with digital decision support, predictive insights and potentially expanded patient reach.[13] This enables them to practise at the top of their licence, spend more time with complex patients and experience greater professional satisfaction. Health systems may achieve better population health outcomes while potentially reducing hospital and emergency utilisation through early intervention and optimised resource allocation,[15] and a more engaged, productive workforce, as earlier intervention and technology-enabled monitoring reduce avoidable demand. As these technologies evolve, particularly with the integration of artificial intelligence, the potential for improved medication safety, clinical accuracy, and workforce sustainability may continue to grow.

Figure 5: Healthcare improvements



Several overseas countries have introduced systematic approaches to digital health integration. Germany reimburses over 50 digital therapeutics via established pathways, with applications routinely providing personalised depression management, diabetes self-care optimisation and chronic pain interventions along with other interventions.[16,17] The United States enables Medicare billing for remote monitoring across multiple specialties, with digital systems optimising care delivery and predicting patient needs.[11,14] These countries have positioned remote care and guided self-management as essential healthcare infrastructure, supporting more consistent adoption patterns.

Countries implementing systematic digital health transformation attract global clinical expertise, research collaboration and technology investment. Their populations benefit from

advanced care models while their health systems achieve improved efficiency and outcomes. Australian companies developing world-leading interventions find a faster path to market in these nations, contributing to a significant loss of early-stage high-value companies offshore.

2.2. Potential care delivery models in Australia

2.2.1. Care in diverse settings

Technology-enabled care models could support safe, high-quality care across homes, workplaces, community centres and traditional facilities. Early evidence suggests remote care programs significantly reduce healthcare costs and deliver equivalent or better clinical outcomes, and are associated with higher patient satisfaction.[18,19] The case study XRHealth's virtual reality therapy platform (Appendix F) eliminated travel costs entirely for rural patients whilst maintaining therapeutic outcomes, with 91% patient adherence compared to 50% for traditional in person therapy.

Workplace health programs integrating DTx platforms could deliver a reduction in employee absenteeism and healthcare-related productivity losses.[20,21] Community pharmacies could evolve into health hubs, extending care access to underserved communities, particularly benefiting culturally and linguistically diverse populations.[22] These hubs could serve as local access points for RPM device distribution, DTx onboarding and technical support.

Emergency care could be revolutionised through virtual triage systems enhanced by RPM data and DTx-guided patient self-assessment tools.[23,24] Ambulance services could incorporate advanced RPM capabilities and DTx platforms, enabling paramedics to deliver evidence-based emergency interventions guided by real-time data analysis and specialist consultation.[25]

2.2.2. Distributed care teams

Multidisciplinary virtual care teams could work across regions, jurisdictions and sectors through secure platforms. This model could multiply workforce capacity by enabling each team member to serve more patients across multiple locations simultaneously, directly addressing workforce shortages whilst improving care coordination efficiency.

Evidence-based DTx interventions could be prescribed and monitored as standard treatment protocols. For example, digital cardiac rehabilitation as demonstrated in the Cardihab case study (Appendix A) could be offered to all eligible patients as an alternative to traditional care, with clinical oversight from new care teams (allied health and nursing) and alternate service providers (Healthdirect), reducing chronic disease management costs and improving clinical outcomes through remote monitoring and early intervention.

New support care teams can visit patients at home to assist with treatment setup, easing the burden on healthcare workers. For example, as noted in the Vantive case study (Appendix B) this could enable assisted peritoneal dialysis (PD) for patients who are clinically suitable but cannot manage treatment independently. Currently, access to remote PD is limited by service

availability, workforce capacity and the absence of a funding mechanism, leaving many patients reliant on in-centre haemodialysis.

Operating on hub-and-spoke models, specialist centres can support distributed care delivery across rural and remote Australia through comprehensive RPM networks, potentially assembling optimal care teams based on patient needs, provider expertise and RPM data trends, with virtual multidisciplinary meetings enhanced by comprehensive RPM dashboards. This could help to address the geographic healthcare disparity where rural Australians experience higher mortality rates due to limited specialist access.[26,27]

2.2.3. Evolution of traditional care models

Clinicians could transition from primarily reactive practice to proactive health management, utilising RPM data and DTx-generated patient insights to identify health risks early. This prevention-focused approach could help address Australia's chronic disease burden, reducing hospitalisation rates whilst improving quality of life.[15,28]

Hospital systems can reimagine their role as integrated health networks offering services across the care continuum. Physical hospitals could focus on complex procedures and acute care, while routine monitoring, medication management and recovery services migrate to DTx-supported remote care settings. RPM devices can enable predictive analytics that anticipate patient deterioration, optimise bed capacity and facilitate proactive discharge planning.[11,15] Post-discharge care can be managed through DTx platforms that guide recovery protocols while RPM devices monitor healing progress and medication adherence.

Remote care models can extend to support diverse settings and vulnerable populations, improving equitable access and reducing healthcare disparities.[3,18]

- **Aged care facilities** could receive hospital-quality medical interventions through virtual specialist consultations and advanced RPM monitoring, potentially enabling residents to receive complex treatments without hospital transfers in some situations.[29]
- **People with disabilities** living independently or in supported accommodation could access specialised care tailored to individual needs, supported by assistive technologies and disability-aware clinical protocols.
- **Home-based aged care recipients** can access hospital-level services, enabling ageing in place whilst receiving comprehensive medical intervention.[29]
- **Virtual clinics** could help address Australia's geographic equity crisis, enabling world-class expertise to reach remote Aboriginal or Torres Strait Islander communities and rural populations who currently travel average distances of 400km for specialist consultations.[30,31]

2.2.4. Preventive care: The foundation of digital health transformation

Preventive care could become a more prominent healthcare focus through broader DTx deployment and community RPM programs. Virtual platforms could deliver personalised

interventions for behaviour modification and chronic disease prevention, while RPM devices enable population health monitoring. Public health initiatives could leverage DTx platforms to deliver health education, vaccination reminders and screening program coordination, supported by RPM data that identifies at-risk populations and measures intervention effectiveness.

Traditional healthcare often operates on a model where patients seek care when symptoms become severe, often requiring expensive emergency interventions. DTx and RPM could support a shift in this paradigm by enabling remote health surveillance that identifies deterioration patterns weeks or months before clinical symptoms manifest. RPM devices capture subtle physiological changes that collectively reveal emerging health risks invisible to conventional periodic assessments.

This approach could potentially transform healthcare by enabling greater investment in preventive measures relative to acute interventions. Rather than primarily treating cardiac events, the system could work to prevent them through remote monitoring. As previously noted, BIOTRONIK Remote Cardiac Device Monitoring has enabled a 37% risk reduction in worsening composite clinical scores, whilst Vantive's remote peritoneal dialysis monitoring demonstrated 69% lower hospitalisation for fluid overload. Digital platforms could enable real-time management that may prevent some complications entirely.

Australia's chronic disease burden represents a significant opportunity for preventive interventions. The economic implications are substantial: preventing cardiac events could generate savings whilst preserving quality of life and workforce productivity. Preventive care through digital platforms could help address geographic inequality, regional and rural communities could potentially access evidence-based prevention programs comparable to metropolitan centres, whilst Indigenous communities could benefit from culturally appropriate programs delivered on country.

Healthcare workforce roles could evolve to include more proactive health coaches interpreting monitoring data streams. This could multiply workforce capacity exponentially; a single specialist can monitor many patients through RPM platforms, whilst DTx interventions could enable allied health professionals to deliver evidence-based prevention programs to previously underserved populations.

2.3. Potential Consequences of Limited Action

Delayed or limited action on digital health funding could have several consequences for Australia's healthcare system, competitiveness and equity:

1. **Commonwealth Government risk.** The Commonwealth Government faces mounting pressures as healthcare costs escalate without the productivity gains that DTx and RPM solutions could provide. Australia risks falling behind in OECD healthcare innovation rankings as comparable countries purposefully implement digital health funding frameworks. Productivity losses from preventable sick leave could continue accumulating, with the

broader productivity benefits from improved workforce health remaining unrealised. A growing consumer expectations gap emerges as Australians increasingly expect digital health coverage, creating dissatisfaction with a healthcare system that appears to lag behind expected standards. Australia's position in health technology innovation may be affected.

2. **State Government challenges.** Emergency departments may continue to experience demand pressure without preventive digital interventions. Rising acute care costs may continue without preventive alternatives. The workforce crisis intensifies as clinical burnout accelerates without digital tools that enable more patients to be monitored per staff member, forcing states to compete for scarce clinical resources rather than multiplying existing capacity through technology. Geographic healthcare disparities may persist or widen. Political liability emerges as regional and rural voters become increasingly frustrated with healthcare accessibility, creating accountability pressures for state governments unable to deliver promised equitable access.

3. **Private Health Insurance under pressure.** Private health insurers face a demographic shift as members increasingly expect digital health coverage as standard, with insurers offering only traditional benefits facing competitive disadvantage and membership attrition. Savings opportunities remain unrealised as insurers cannot reduce claims through preventive digital interventions, forcing cost management through benefit restrictions rather than innovative care models that could enhance member value and control expenses. Market erosion threatens as consumers switch to insurers offering digital benefits. Claims inflation accelerates without prevention alternatives, as expensive acute care costs would continue rising, forcing premium increases that reduce affordability and accessibility for Australian families.

4. **Industry and innovation exodus.** Maintaining the status quo contradicts Australia's own productivity research. The Productivity Commission's May 2024 report found that better integrating digital technology into healthcare could save over five billion dollars annually, yet specifically noted that uptake of remote patient monitoring and digital therapeutics has significantly lagged behind other digital health services. The report noted that innovation diffusion is a primary productivity challenge for Australia's health sector. Without funding pathways, these documented savings would remain unrealised while the DTx and RPM industries face market exodus as companies relocate to countries with established funding pathways, with venture capital following regulatory clarity and market access rather than clinical innovation alone. Investment flight accelerates as venture capital investment in Australian digital health declines, with investors seeking markets with clearer commercialisation pathways, reducing local innovation capacity and creating a "brain drain" of digital health expertise to international markets. R&D decline becomes inevitable as local research and development suffers when companies cannot sustain evidence generation without revenue pathways. Talent drain intensifies as digital health experts move overseas, where funding frameworks support career development and company growth.

Inadequate sovereign capability amplifies this risk. Australia increasingly depends on imported digital health products, data platforms and service infrastructure developed overseas, limiting national control over clinical data, standards, and technology supply chains. This dependency exposes the health system to interoperability, pricing and data-sovereignty vulnerabilities. Collectively, these factors represent a missed economic and strategic opportunity. Australia risks forfeiting an estimated $2+ billion share of the global digital therapeutics market, along with the ability to shape domestic standards, safeguard patient data, and build sustainable digital health industries that support national health priorities.

5. **Healthcare provider strain.** Healthcare providers face clinical burnout as they continue experiencing overwhelming patient loads without easier access to digital tools that multiply workforce capacity and enable proactive rather than reactive care. Workforce shortages intensify as providers struggle to meet growing demand with traditional staffing models, particularly affecting rural and specialist services, where shortages are most acute, unable to extend clinical reach through digital solutions. Quality gaps persist as missing evidence-based digital interventions perpetuate suboptimal outcomes, with providers unable to access internationally proven care enhancement tools. Professional liability risks increase as the delayed adoption of proven care improvements may expose providers to liability concerns when digital standards become established internationally. Revenue pressures mount as providers miss opportunities to access new funding streams for enhanced care delivery models, limiting financial sustainability and service expansion capacity.
6. **Patient and consumer impact.** Patients face the most direct consequences through preventable suffering as avoidable admissions and health deterioration continue without access to monitoring and intervention tools that could prevent serious complications. Financial burden increases through out-of-pocket costs for private digital solutions or travel for specialist care, creating healthcare inequality as those who can afford premium care access better outcomes, whilst others face declining options. Rural inequality persists as geographic healthcare disparities continue, with rural Australians facing significant travel distances for specialist consultations that could be delivered digitally. Safety risks emerge as patients increasingly rely on unvalidated alternatives and internet-based "Dr Google" solutions without clinical oversight and unvalidated consumer self-help apps. A care quality gap develops as missing proven interventions result in suboptimal outcomes, with Australian patients receiving care that lags behind global best practice standards and missing out on access to evidence-based digital therapeutics available overseas or locally developed evidence-based solutions without funding.

3. Key findings

3.1. Key challenges and considerations

Australia's digital health industry faces significant systemic barriers spanning funding, system integration, market dynamics and equitable access that collectively limit patient uptake of evidence-based DTx and RPM technologies.

Table 2: Summary of barriers and priorities for reform

Barrier/Core Issue	Impact
1. Funding	
• Current funding mechanisms (MBS, ABF) are not well suited to digital products and services • Funding decisions are not aligned with procurement or clinical workflows	• Prevents equitable access in routine care • Forces out-of-pocket payment or denial of access • Commercial unsustainability persists
2. Innovation funding and investment	
• Budget pressures across public and private hospitals • Upfront investment required before funding agreements are finalised • Unclear pathways for sustainable funding • Funding cap constraints pit innovation against existing services • Cross-jurisdictional complexity between the Commonwealth and states	• Delays implementation • Reduces availability, especially in regional areas • Technologies are trapped in the pilot phase despite proven clinical and financial benefits
3. Health Technology Assessment (HTA) evidence mismatch	
Traditional HTA: • Not suited to iterative, software-based technologies • Not configured to appraise software-driven value • Is expensive in comparison to the cost of the products	• Delays in listing and funding of proven solutions
4. Adoption and implementation	
• Even with funding, fragmented procurement, slow approvals, and workforce gaps block uptake • Lack of inclusion of digital technologies in clinical guidelines	• Proven technologies fail to reach scale • Patients miss out on benefits
5. Healthcare system barriers	
• Cultural resistance and limited digital literacy • Billing structures tied to in-person care • Professional indemnity concerns about monitoring digital data streams, alert fatigue and clinical response protocol	• Clinician reluctance slows adoption • Underuse of digital tools in everyday care
6. Market and quality issues	
• Lack of quality differentiation and inconsistent product standards	• Confusion among clinicians and payers • Low confidence in digital prescribing
7. Access and equity	
• Localised pilots, advocacy-driven funding, and uneven national coordination	• Patients in rural and underserved areas lack access to proven digital care

Elaborating on the summary in Table 2, the challenges include:

1. **Funding barriers specific to each healthcare sector**

- **Primary care and specialist practice:** The MBS presents fundamental structural barriers to DTx and RPM funding, as it has limited inclusion of digital delivery technologies.[32] Addressing these gaps offers clear system and economic benefits. Continuous RPM and DTx with clinician oversight can reduce unnecessary specialist and emergency visits, improve medication management, and support earlier intervention for chronic and complex conditions. While some digital health technologies may qualify for existing pathways, such as the Medical Services Advisory Committee's (MSAC's) codependent technology assessments, where digital tools are combined with diagnostic tests or therapeutic interventions, most solutions fall outside current frameworks entirely.[33] The traditional barriers include non-physician service delivery and software-based interventions not tied to in-person consultations.[34] The episodic, fee-for-service nature of the MBS also limits reimbursement for ongoing or self-managed digital interventions.[34] From 1 July 2025, the MBS introduced the General Practitioners (GP) Chronic Condition Management Plan (GPCCMP), replacing GP Management Plans and Team Care Arrangements. The reform simplifies processes and allows greater flexibility for care to be delivered by a broader team, including nurses, allied health and other practitioners, whether virtually or in-person.[35] However, while this creates an enabling environment for multidisciplinary digital care, it still lacks a mechanism to fund the DTx or RPM technologies themselves. The Pharmaceutical Benefits Scheme (PBS) listing process presents similar challenges, as DTx and RPM do not align with traditional pharmaceutical product models that the PBS was designed to assess.
- **Public hospital system:** There are limited Australian Refined Diagnosis Related Groups (AR-DRGs) codes and Tier 2 Non-Admitted Services Classification categories for DTx/RPM episodes, limited innovation grant funding and virtual wards operating without systematic funding.[36] Additionally, the disconnect between the available funding streams (Tier 2 Non-Admitted Services Classification codes) and hospitals' budget constraints (operating and capital), coupled with extended procurement timelines, creates a paradoxical barrier where funding mechanisms may exist but remain practically inaccessible. These barriers further delay market entry, with sales cycles extending to 18 months or more, which creates cash flow challenges that particularly impact smaller companies and startups.
- **Private hospitals/insurance:** Private hospitals are developing vendor partnerships with RPM and DTx technology companies, capitalising on patients' willingness to pay for premium digital experiences and the revenue optimisation benefits of earlier discharge and reduced readmissions. However, implementation remains fragmented with individual hospital strategies rather than sector-wide adoption, and many hospitals struggle to provide consistent digital health models of care across their services. Private health insurers possess the legal flexibility to create innovative payment models for services that substitute for hospital services, driven by pressure from members expecting the convenience of digital health coverage and the need to manage claims costs through reduced acute care

utilisation.[37,38] Despite this innovation appetite and potential for competitive differentiation through digital technology benefits, there is currently no hospital benefit coverage for DTx/RPM-integrated episodes, representing a significant missed market opportunity. Additionally, the Prescribed List (PL) focuses primarily on devices implanted into patients, leaving external digital solutions without a clear funding pathway.[39]

- **Commissioned services:** Beyond the big ongoing funding streams like the MBS, services commissioned nationally, by the states and territories or through regional organisations like Primary Health Networks (PHNs), or via collaborative commissioning, offer alternative pathways for digital healthcare innovation. These approaches show promise for chronic disease management, mental health and preventive care. The Australian Government's $135.2 million Digital Mental Health Program[40] exemplifies how commissioned services can deliver targeted digital health solutions at scale, offering flexibility to pilot innovative models, provide wrap-around support for complex populations, and bridge primary-acute care gaps while maintaining national quality standards.

  However, commissioned models face significant challenges. Because they rely on selective procurement, they can unintentionally "pick winners," limiting diversity among solution providers and creating barriers for emerging or niche innovators. This approach contrasts with an open funding pathway, which rewards all products that meet agreed evidence and quality thresholds, encouraging competition, innovation, and sustained market development. The Productivity Commission's Delivering Quality Care More Efficiently interim report strongly endorses transforming preventive health into a national priority, through mechanisms like a National Prevention Investment Framework, collaborative commissioning, and overcoming the limitations of short-term budgeting.[41] Funding sustainability is important as fixed-term contracts create uncertainty when programs conclude. Integration with existing healthcare systems can be complex, particularly ensuring seamless transitions between commissioned services and traditional MBS-covered care. This can lead to service fragmentation, challenging quality assurance across multiple providers, and service discontinuity for patients who develop ongoing therapeutic relationships with digital platforms.

The unpredictable funding landscape and significant gaps across all sectors, especially the exclusion of technology costs from current pathways, pose commercial risks and limit market access. As a result, companies are trapped in enduring pilot cycles and face challenges in developing sustainable business models or scaling their solutions effectively.

2. Funding challenges in digital health innovation

Recent experience from New South Wales (NSW) Health's innovative models of care demonstrates the complexities of funding digital health innovations within existing health system structures. Despite demonstrating both clinical and financial benefits across five innovative models, including the North Sydney Frail Aged program, RPA Virtual Hospital, NSW Telestroke Service, Virtual Clinical Care Centre and Pathways to Community Living Initiative,

funding arrangements have proven problematic and instructive.[42-46] This experience highlights barriers that mirror international challenges in scaling digital health innovations.[47] While not the focus of this report, it is acknowledged that DTx and RPM face pre-market development challenges, including attracting early investment and progressing through development and regulatory pathways compared with traditional biotech and device innovations. Once proven and cleared for clinical use, digital health technologies face a second set of barriers related to post-market funding and integration. NSW Health's experience across multiple virtual care programs demonstrates these persistent issues:

- **Budget pressures and fiscal constraints:** The current budget crisis across public and private hospitals magnifies these challenges. Health services are under financial pressure, facing rising costs, workforce shortages, and limited capacity to invest in innovation. In this environment, even proven digital health models struggle to secure sustained funding, as new programs are often perceived as cost additions rather than efficiency enablers. Without a coordinated funding framework that explicitly links digital innovation to measurable cost savings and productivity gains, health services will continue to prioritise maintaining existing operations over adopting new, evidence-based models of care.
- **Upfront investment requirements**: While implementation varies across programs, new digital and remote models of care often require substantial upfront investment in technology platforms, integration, training, and workforce redesign before funding agreements are finalised. This means health services must carry the initial financial risk and resource burden, frequently diverting funds from other priorities, to launch pilots or sustain operations until Commonwealth or partner funding is secured. These cash-flow pressures can delay or limit implementation, particularly for smaller or regional services with limited financial flexibility.[48]
- **Unclear pathways for sustainable funding**: Many aspects of innovative digital models do not align well with ABF frameworks, leaving unclear pathways for sustainable funding. Remote care services face particular challenges where patient activity occurs in different locations from where costs are incurred, creating misaligned incentives for innovation.[36] In hub-and-spoke models like the NSW Telestroke Service, rural sites receive both ABF and clinical benefits, while metropolitan hubs have limited incentive to incur additional costs and divert resources from their acute services, creating structural disincentives for innovation.[36]
- **Funding cap constraints**: Recent increases in National Efficient Price have consumed most of the national funding cap, meaning innovative models compete with existing services rather than receiving extra funding. This results in reduced Commonwealth contributions towards other in-scope activities rather than genuine new investment in innovation.[36]
- **Cross-jurisdictional complexity**: The division of responsibilities between Commonwealth primary care funding and state acute care funding can serve as a disincentive for states to invest in preventive health and wellbeing initiatives, as these are often viewed as Commonwealth responsibilities.[36] In addition, there is a persistent dissonance between

national funding decisions and state-level procurement processes. Even when funding is available, it does not automatically translate into hospital purchasing or implementation, as state budgets and procurement frameworks operate independently. This disconnect limits the practical uptake of funded digital health technologies within state-run services and constrains system-wide reform.

3. Health technology assessment (HTA) evidence mismatch

The single biggest barrier to HTA keeping pace with emerging digital health technologies lies in the fundamental mismatch between HTA's evidence requirements and the iterative, software-driven nature of DTx and RPM technologies. Companies that are venture-backed startups or mid-stage entities simply cannot afford the extensive 5–10-year evidence generation pathway that HTA bodies typically expect. They are working to prove the clinical utility of software solutions that might cost $50-$200 per patient, not the $50,000 per treatment cycle often seen with pharmaceuticals. Manufacturers themselves frequently report that trial duration and scale are constrained by limited access to research and innovation funding once products reach market readiness. Manufacturers report that these companies can often only finance 3–6-month pilot studies with a limited patient population, which may be insufficient to demonstrate the population health impact needed to justify public funding, especially where technologies derive value from sustained engagement, behavioural modification and integration with care teams over extended periods.

International reviews by agencies such as Germany's BfArM (DiGA evaluation framework) and the UK's NICE Evidence Standards Framework confirm that many digital health submissions provide promising early data but lack the long-term outcomes traditionally required for funding. Even where early evidence of cost effectiveness and real-world efficacy exists, it often falls short of HTA thresholds due to limited duration, sample size or the inability to isolate direct clinical outcomes in complex service environments. This is not a question of lacking value, but of value being expressed in ways that current HTA bodies are not yet configured to appraise.

By the time the HTA evaluation concludes, the product version being assessed may have changed, and the necessary care models may not be widely implemented, making it challenging to generate meaningful real-world evidence. This scenario creates a triple constraint: insufficient funding for robust evidence, inadequate care delivery infrastructure to support the technology, and evolving products that outpace evaluation timelines.

4. Adoption and implementation barriers

Even when digital health technologies meet evidence requirements or achieve funding, adoption remains uneven. Funding alone does not ensure procurement or clinical uptake. Implementation depends on aligned procurement frameworks, workforce readiness, and sustained clinical demand.

Additionally, many of these technologies necessitate care delivery models that are not widely available. Digital health technologies vary in how much clinical oversight they require. Some RPM platforms use automated triage, so clinicians are alerted only when action is needed, while

others rely on nurse or allied health monitoring. Likewise, certain DTx involve specialist input, whereas many can be self-managed or supported by family members. The key is aligning workforce transformation and system processes with each technology's needs — without this, proven solutions may fail to achieve their full impact.

There is also a persistent disconnect between funding and procurement. Even when a funding mechanism exists for the service in which the DTx or RPM is provided, it does not automatically translate into hospital purchasing or implementation, as state budgets and procurement frameworks operate independently. Fragmented procurement processes, limited budget flexibility and lengthy approval cycles prevent even clinically effective technologies from being adopted at scale.

The result is promising innovations dying in one of the many "valleys of death" between pilot success and population-scale implementation, often due to misaligned funding, fragmented procurement and constrained budgets. Addressing these adoption barriers requires coordinated reform that links funding with procurement, workforce readiness and measurable system benefits.

5. Healthcare system barriers

While adoption and implementation challenges relate primarily to system processes, funding mechanisms and procurement alignment, healthcare system barriers reflect the professional, cultural and behavioural dimensions that shape how clinicians and patients engage with digital models of care.

Despite persistent workforce shortages, many clinicians remain cautious about adopting digital health approaches. Some fear that remote care and remote monitoring could reduce the quality or personal nature of face-to-face interactions, while others lack the skills or confidence to deliver care effectively through digital platforms. This cultural hesitation is reinforced by billing structures that continue to reward in-person consultations under the MBS and ABF, offering few incentives to integrate remote or asynchronous care into routine practice.

Medical practitioners express professional indemnity concerns about managing digital health data and assuming liability for remote monitoring decisions. Professional indemnity concerns are less about general liability, as medical practitioners already manage patient data under existing coverage. They are more about uncertainty in interpreting or acting on monitoring data streams, alert fatigue and clinical response protocols, particularly when technologies are unregulated or lack clear clinical governance pathways. Building trust will therefore rely on ensuring that only TGA-approved and clinically validated technologies are deployed, supported by clear practice guidelines and integration within existing medico-legal frameworks.

6. Market and quality issues

The digital health market lacks standardised metrics to help prescribers and healthcare buyers distinguish between high-quality, evidence-based solutions and lower-quality alternatives. This quality differentiation challenge is compounded by competition from free applications

developed by universities, research institutions and advocacy groups, which may lack the rigorous evidence base of commercial solutions but appear more attractive due to cost considerations. The market remains highly fragmented across multiple stakeholders, including patients, clinicians and various payers, each with different priorities and decision-making processes. Low awareness and understanding of the regulation of digital health solutions among software developers further compounds the issues of quality and governance.

7. Access challenges

Current funding allocation often occurs through advocacy-driven processes rather than evidence-based priority setting, resulting in inconsistent availability of digital health solutions across different conditions and patient populations.[49] This ad hoc approach means that some clinical areas receive substantial digital health investment, whilst others with potentially greater evidence base or population health impact remain unfunded.

In the absence of nationally coordinated funding mechanisms, access to digital solutions is often tied to local service capacity, short-term grant funding or time-limited pilots. Even where solutions have demonstrated clinical value, their use may be restricted to specific sites, tied to particular models of care, or discontinued once initial funding concludes.[36]

This fragmented approach limits the potential system-wide benefits of digital solutions. Patients who could benefit may be unable to access them in routine care, and services miss opportunities to support earlier intervention, reduce acute demand or extend care into the community. Without more structured approaches to funding and integration, these technologies will continue to reach only a fraction of those who could benefit.

3.2. International findings on funding models and enablers

This section summarises international findings on a range of funding models and enablers for DTx and RPM products and clinical oversight services, highlighting their key features, strengths, and design considerations and identifying which elements are most relevant for Australia. Full descriptions of each country's model, including detailed processes, governance, and funding structures, are provided in Appendix H. These models are present in order of impact based on our analysis of international experience as summarised in Table 3.

Table 3: Summary International Funding Models

Model type	Core design features	Evidence & outcomes	Relevance to Australia	Key implication
Technology Funding DE	Direct funding for digital products independent of the service delivery model includes provisional listing followed by permanent listing	• Improved technology adoption • Reduced procurement friction • Measurable clinical improvement	• Technology funding • Provisional pathway to permanent listing	• Foundation for digital health access • Requires a dedicated HTA pathway • Insufficient without clinical service funding
Dual Product & Service Funding FR	Separate funding for clinical service and technology	• Improved clinician adoption • Measurable clinical improvement	• Addresses MBS limitations • Aligns technology and clinical payments	• Highest long-term impact but requires a new HTA stream and ROI alignment.
Bundled Services NL US	Integrated funding for technology, clinical setup, and monitoring within a single payment	• Increased RPM has led to readmission reduction and cost savings	• Works within the existing ABF framework	• High feasibility • Needs cost recognition and address procurement.
Condition-Specific Digital Programs FR	National targeted funding by disease area	• Improved adherence and data collection within defined cohorts	• Builds on the National Diabetes Services Scheme approach • Allows staged entry	• Fragmented access if state-led • Integration gaps across conditions
National Pilot Funding Programs JP KR	Time-limited, evidence-generating funding	• Accelerates access • Provides early revenue for vendors	• Solves "pilot trap" and enables national coordination	• Highly feasible transitional pathway • Needs HTA and sustainable funding linkage
HTA Pathways for Digital Health DE FR UK	Lower upfront evidence thresholds, staged assessment	• Faster access without lowering safety • Strong post-market evidence tracking	• Matches iterative software development cycles and software-driven value	• Essential reform • High feasibility and high system impact
National DTx & RPM Library BE	Searchable registry of DTx and RPM solutions	• Increases visibility and trust • Aids procurement	• Could integrate with ARTG and ADHA mHealth Framework	• Quick win • Needs funding linkage to drive uptake

3.2.1. Technology funding

Direct product funding as a foundation for access

One of the most significant barriers to DTx and RPM adoption is that existing funding models do not recognise the technology component of remote care models. This creates a structural gap where digital health solutions cannot be sustainably implemented, even when clinical pathways exist to support them. The direct funding of the digital product itself addresses this gap by

establishing a dedicated funding stream for the software, devices or platforms that enable remote care and guided self-management.

Strengths aligned with local needs

Germany's DiGA programme[50-55] demonstrates how technology funding can function as a standalone funding pathway. Under DiGA, digital therapeutics are funded directly as products, independent of the clinical service delivery model. This approach removes procurement friction, supports vendor sustainability and enables patients to access validated digital solutions without requiring parallel negotiation of service-level contracts. The German experience demonstrates measurable impact: from 2020 to 2024, the DiGA program generated over 374,000 prescriptions, with real-world evidence showing significant clinical benefits. A multicentre registry study of 191 rheumatology patients found that back pain and weight management DiGAs were most effective, with 50-82% of patients reporting symptom improvements.[56]

An important feature of Germany's model is its **provisional listing mechanism**,[50-55] which enables immediate market access whilst evidence is generated. Digital therapeutics can gain provisional listing for up to 12 months (extendable to 24 months) based on initial evidence of safety and plausibility of benefit. During this period, products are fully funded whilst manufacturers conduct real world studies to demonstrate positive healthcare effects. This staged approach acknowledges that digital solutions evolve rapidly and that requiring full clinical trial evidence before any funding creates insurmountable barriers for smaller developers.

For Australia, technology funding would directly address the structural limitations of the MBS, which does not accommodate software-based interventions or asynchronous care. It would enable separate funding streams for digital products, creating clearer pathways for integrating technology into ongoing patient management. This model is particularly relevant for guided self-management treatments that do not require significant clinical oversight, which, if it is funded, is currently funded by MBS, ensuring access to evidence-based technologies whilst maintaining appropriate safeguards.

Considerations for local adaptation

International experience demonstrates that technology funding alone is insufficient without complementary reforms. Germany's DiGA programme has faced implementation challenges, including low clinician engagement. For Australia, an additional clinical funding streams and aligned service models are essential to ensure that digital health solutions deliver measurable improvements in outcomes, efficiency and system capacity.

3.2.2. Dual product and service funding

The ideal solution, but it may not work in all sectors

While section 3.2.1 established the case for technology funding, dual product and service funding goes further by creating separate funding streams for both the digital product and the

associated clinical service. Currently, existing funding models typically recognise a part of the clinical service component, leaving technology costs unfunded. This creates a structural disincentive for providers to integrate digital health technology into care, particularly when clinical oversight is essential for safe and effective use. Dual funding models address this gap by creating separate funding streams for the product and the service, ensuring both are valued and supported.

Strengths aligned with local needs

France,[57-60], building on the **German DiGA** approach, has RPM and DTx funding frameworks that separate payments for the technology and the associated clinical service. This incentivises both adoption and integration into care pathways. Linking funding for service delivery with the technology itself supports vendors in embedding validated solutions into routine workflows. For providers, it ensures that clinical time spent on DTx and RPM enabled care delivery is recognised and funded, reducing the disincentive to adopt new tools. For vendors, it provides a viable revenue stream during service implementation, making it easier to scale solutions that require close clinical oversight.

France's approach includes staged pathways similar to the provisional listing mechanisms discussed in section 3.2.1. The PECAN pathway provides 12-month provisional funding whilst evidence is generated, followed by potential transition to permanent dual funding through the LATM (List of Products and Services for Remote Monitoring) pathway. Under LATM, funding covers both the technology (device/software costs and patient onboarding) and the clinical service (monitoring, interpretation, and care coordination), creating sustainable implementation models.

In the Australian context, dual funding would enable separate product and service funding streams for multidisciplinary teams, creating clearer pathways for integrating technology into ongoing patient management. It could also extend to guided self-management treatments that do not require continuous clinical oversight, ensuring access to evidence-based technologies while maintaining appropriate safeguards. At the same time, it would help mitigate professional indemnity concerns by ensuring that technology use is clearly linked to a funded clinical oversight role where appropriate. In some cases, only additional funding of the technology would be required if the clinical support is already adequately covered under the MBS.

Considerations for local adaptation

While dual funding streams would create stronger incentives for adoption, they would need to be supported by a dedicated HTA pathway that brings together product and service assessment. Such a pathway should not only define evidence standards and eligibility requirements but also evaluate their combined return on investment, for example, reductions in avoidable hospitalisations, shorter recovery times, and lower infrastructure costs per episode of care. By explicitly linking funding to measurable economic outcomes, governments can build confidence that public spending on digital health delivers net savings and productivity gains. This would provide clarity on evidence standards and eligibility requirements, give vendors and

providers confidence to invest, and establish a foundation for future funding rules and payment mechanisms that keep product and service funding aligned as technologies evolve.

3.2.3. Bundled services

Bundled service pathways offer a mechanism to fund DTx and RPM solutions alongside associated clinical services within a single activity-based or episode payment. International models show that when technology costs are embedded into the funding structure, providers can integrate digital tools more effectively into patient care while maintaining accountability for outcomes and cost efficiency.

Strengths aligned with local needs

In the **United States (US),**[61-70] **dedicated codes for RPM** illustrate how a bundled approach can capture setup, device supply and monitoring costs within the same payment structure as clinical oversight. This model has reduced administrative burden, supported seamless integration of technology and clinical services, and maintained accountability for patient outcomes. Although RPM has existed for decades in the US, it gained unprecedented traction during the COVID-19 pandemic. Today, it is a pivotal tool for managing chronic diseases, reducing hospital readmissions, and enabling hospital-at-home care models. Nearly 50 million Americans use RPM devices, with 80% of the public being favourable towards its use in medical care. Provider adoption has surged dramatically — 81% of clinicians reported using RPM in 2023, a 305% increase since 2021. US RPM programs using these payment models have demonstrated 19-76% reductions in hospital readmissions and up to 38% cost reductions through earlier intervention and better disease management.[71]

Similarly, **Germany's RPM funding**[50-55] and the **Netherlands' integrated care packages**[72-78] demonstrate how bundling can improve patient continuity and enable substitution of lower-cost digital interventions for more resource-intensive services. The case studies, in Appendices A-F, reinforced that bundling supports sustained engagement, better adherence and stronger coordination compared to standalone technology funding. For Australia, similar models could address the current disconnect between service and technology funding, reduce procurement delays and create a viable pathway for both public and private sectors to support comprehensive digital health episodes.

Considerations for local adaptation

International experience shows that if bundling does not cover digital components, providers are forced to absorb platform costs within existing payments or pass on costs to consumers, creating disincentives for adoption. Activity-based models do not always reward adoption of more efficient or cost-saving approaches unless savings are directly recognised in payment structures. Private insurers face additional legal restrictions, limiting funding to hospital substitute services and requiring clear alignment with allowable benefits. Both public and private sectors also face service–product coordination complexity, as vendors must demonstrate how digital tools align with clinical pathways and provider workflows. Across

settings, uptake can be constrained without investment in education, support infrastructure and care navigation. For Australia, any bundled service pathway would need dedicated technology cost recognition, clear eligibility rules for allowable services, and coordinated provider–patient support to ensure adoption and sustainability.

3.2.4. Condition-specific digital programs

Condition-specific programs link funding to defined clinical areas, creating a policy-aligned entry point for digital health while supporting targeted evaluation, such as the recently announced Taiwan "National Health Insurance encourages institutions to strengthen the promotion of peritoneal dialysis and improve the quality of care program".[79] Australia already applies this approach in areas such as the National Diabetes Services Scheme, which provides national, condition-based funding and support infrastructure (although apps to support self-management are not covered). However, for DTx and RPM, condition-specific programs are typically state-led or PHN-driven, leading to fragmented access and inconsistent evaluation. International examples show how applying this model at a national scale for digital health can align adoption with clinical priorities, focus investment where system impact is highest, and enable clearer measurement of value against agreed outcomes.

Strengths aligned with local needs

France's ETAPES program[57-60] demonstrated how targeting a select group of chronic conditions allowed the government to focus resources, tailor implementation requirements and generate condition-specific outcome data that directly informed permanent funding pathways. In the **UK**,[69,70,75,80-86] national programs such as the **NHS Diabetes Prevention Program** have incorporated digital delivery for defined patient groups, showing that condition-based targeting can expand reach while maintaining clear eligibility and performance tracking. In the **US,**[61-70] **Medicare's RPM** funding for chronic conditions creates a sustainable funding stream that is inherently condition-linked, incentivising provider uptake and enabling standardised reporting. Across these examples, condition-based models improved clinical engagement, provided funders with a stronger investment case, and supported more consistent adoption than untargeted or ad hoc funding approaches.

Considerations for local adaptation

In Australia, while condition-specific funding is already used in some areas, it often sits outside national funding schemes, leading to inconsistent access, duplicated infrastructure and variable commissioning standards. Programs designed around specific conditions can face integration and handover gaps, particularly where they must interface with broader health services such as GP records or shared care planning, limiting continuity of care. Models tied to single conditions or delivery channels may also be difficult to replicate across other clinical areas, constraining broader system impact. In addition, managing enrolment, eligibility, reporting, and vendor procurement within each program can create administrative overhead for funders and providers.

3.2.5. National pilot funding programs

One of the most persistent barriers to DTx and RPM adoption in Australia is the absence of a structured, national bridge between early-stage implementation and sustainable funding. Current pilots are typically fragmented across jurisdictions, small in scale, expensive to set up and support, and lack a defined pathway into long-term funding. Without predictable interim support, vendors face significant commercial risk and cash flow challenges while generating the evidence required for HTA, and promising technologies often stall between pilot success and national adoption. Furthermore, pilots are routinely required even for products with published RCT clinical evidence and real-world evidence. Pilots also represent a level of uncertainty to investors who withhold future rounds of investment until pilots scale-up. This creates a void in capital at critical stages in the lifecycle of a startup that, for many, is difficult to survive.

Strengths aligned with local needs

South Korea[87-93] and **France**[57-60] both addressed similar challenges by implementing nationally coordinated pilots with defined timeframes, eligibility criteria and evaluation standards. In **South Korea**, the national pilot program gave vendors a guaranteed period of funding while collecting real world evidence, with central oversight ensuring alignment between trial design, interim reporting and funding decision-making. This avoided the duplication and uneven scale of local initiatives, kept promising technologies moving towards permanent listing, and ensured funders could track usage and performance over time. **France's ETAPES** program applied a similar approach for RPM, replacing region-by-region pilots with a multi-year national framework that funded both implementation and outcome measurement. Clear entry and exit criteria prioritised high-value solutions, and consistent data collection directly informed the design of the permanent LATM pathway. In both cases, governments could manage fiscal exposure while still supporting earlier patient access, and vendors could operate with greater financial certainty during evidence generation in a safe, nationally coordinated environment.

Germany's DiGA provisional listing offered a variation on this concept, providing immediate but time-limited national funding for eligible DTx while further evidence was generated for HTA. This accelerated patient access, maintained vendor viability during evaluation, and gave the government a structured way to assess value before making long-term funding commitments.

Across all three examples, the greatest strengths lay in their national scope, predictable funding windows, interim evidence requirements and clear transition criteria. These features are directly relevant to Australia's need for a coordinated early access mechanism that can reduce commercial risk, avoid the inefficiencies of fragmented ad hoc pilots, and ensure that successful interventions move seamlessly into sustainable funding streams.

Considerations for local adaptation

International experience also highlights design risks to avoid. Pilots can stall if transition mechanisms are unclear, evidence requirements are overly burdensome, or alignment with HTA processes is lacking. Clinicians and health services may experience pilot fatigue if asked to participate without dedicated resourcing or certainty on long-term sustainability, reducing

willingness to engage. Where HTA bodies are not configured for staged reviews, promising evidence from pilots may fail to progress to permanent funding. Even with early access in place, adoption can be limited if provider incentives are weak.

If Australia adopts a similar model, it will be essential to set clear, time-bound transition criteria, maintain transparency in eligibility and evaluation processes, and pair early access with provider incentives and sustainable funding structures. Equally important is embedding planning and commitment for scale-up into pilot design to ensure that successful, evidence-based programs have a defined pathway to national adoption rather than remaining in perpetual pilot status.

3.2.6. HTA Assessment pathways

Australia's current HTA frameworks are calibrated for high-cost medicines or devices, often demanding long-term clinical trials and extensive economic modelling. This creates a mismatch for DTx and RPM, which are software-driven, iterative and often rely on sustained patient engagement and integration with care teams to deliver value. Several countries have adapted their HTA processes to better accommodate the iterative, software-driven nature of DTx and RPM.

Strengths aligned with local needs

Germany's DiGA fast-track[50-55] sets differentiated evidence requirements for digital health, allowing either clinical or patient-reported outcomes as proof of benefit and recognising functional improvements such as therapy adherence. This proportionate approach avoids forcing vendors into multi-year trials before accessing funding, while still requiring alignment with interoperability and data standards. **France's PECAN pathway**[57-60] applies similar principles for provisional assessment, focusing on real world performance and system impact rather than demanding large-scale randomised trials upfront. In the **UK, National Institute for Health and Care Excellence (NICE) Evidence Standards Framework and Early Value Assessment**[69,70,75,80-86] tailors evidence expectations to the product's maturity, cost, and intended use, prioritising feasibility studies and real-world data over long-duration clinical trials.

Across these examples, the common strength is in addressing the structural evidence gap that prevents many DTx and RPM solutions from reaching assessment in Australia. Locally, proportionate evidence thresholds would be particularly valuable for vendors with limited funding horizons, allowing them to enter assessment processes earlier and generate data within the health system. These models also provide HTA bodies with more relevant information on engagement, workflow integration, and system outcomes, areas that current Australian processes often overlook. By embedding post-market evidence generation into the pathway, these countries ensure that assessment remains rigorous without creating prohibitive entry barriers, a balance that aligns closely with Australia's need for more agile and fit-for-purpose HTA processes.

Considerations for local adaptation

International experience also shows that lowering upfront evidence thresholds must be matched with robust post-market monitoring and clear criteria for progression to permanent funding and realistic timeframes for demonstrating value.

In Germany, some DiGA-listed products have faced challenges demonstrating long-term value once in the market, leading to delisting or price renegotiations. While 75% of provisional DiGAs achieved permanent listing, most required 17.5 months for clinical studies—exceeding the one-year timeline.[51] Price negotiations proved contentious: manufacturer-set prices averaging €465 were reduced by over 50% to €221 after negotiation.[51] More concerning, all 14 DiGAs completing negotiations converged around €200 regardless of condition complexity, potentially undermining value-based pricing.[94] At least one top-performing manufacturer filed for insolvency due to cash flow gaps during protracted price negotiations.[94]

France's PECAN pathway has yet to see an app-only solution transition successfully to permanent listing, in part due to structural gaps in legacy funding catalogues. Of the PECAN applications evaluated so far, several have been rejected, and none of those that focused solely on digital therapeutics have achieved permanent listing.[95]

In the UK, while Early Value Assessment provides a defined entry point, it does not guarantee funding, meaning vendors must still navigate fragmented commissioning processes.

For Australia, adopting a similar pathway would require clarity on the types of outcomes HTA will accept, investment in infrastructure to capture real world data, and alignment with funding mechanisms to ensure that positive assessment translates into actual access.

3.2.7. National DTx and RPM Library

Centralised digital health libraries can address the knowledge gap that limits clinical adoption and procurement by providing a comprehensive, nationally coordinated resource of validated DTx and RPM solutions. They allow governments to track, triage and recognise solutions before funding, while giving clinicians access to clear evidence profiles and implementation guidance.

A National DTx and RPM Library would build on Australia's existing regulatory infrastructure to address the critical gap between regulatory approval and clinical adoption. While the Australian Register of Therapeutic Goods (ARTG) provides a listing of TGA-registered medical devices, including DTx, it is currently incredibly difficult to use for clinical or procurement purposes. The ARTG was not designed as a clinical decision-support or procurement tool, and its current interface makes it extremely challenging to identify relevant DTx and RPM solutions by condition or care setting. The ARTG confirms regulatory compliance but does not provide the evidence profiles, implementation guidance, condition-specific filtering, or funding linkage that clinicians and health services need to select and adopt appropriate solutions. Notably, mental health apps, explicitly excluded from ARTG requirements, are also not listed.

Strengths aligned with local needs

International experience demonstrates that regulatory approval alone does not drive uptake.

Belgium's mHealthBelgium[59,96-98] validation pyramid operates as both a national registry and a staged validation process. Products advance through defined levels of recognition, with early stages focused on meeting baseline quality and interoperability standards, and later stages linked to eligibility for public funding. This structure allows solutions to gain visibility and credibility while they build the evidence needed for funding. Stakeholders noted that a similar model in Australia could support systematic clinical uptake by giving clinicians access to a trusted source of validated solutions, each with clear evidence profiles and implementation guidance, reducing reliance on ad hoc adoption.

Considerations for local adaptation

Lessons learned from Belgium show that a library of validated solutions on its own will not drive meaningful clinical uptake. Visibility alone did not guarantee use, with many solutions gaining listing but failing to attract adoption without incentives or integration into funding and procurement pathways. Where libraries lacked advanced search functions or filters by condition, setting or readiness, they were perceived as static directories rather than tools to match solutions to system needs. The absence of consistent impact tracking also made it difficult to assess whether listed products were being adopted or delivering measurable benefits, limiting the case for scale-up. Without active follow-on support, some vendors disengaged after listing, reducing the library's value as a pipeline for future pilots or funded programs. For Australia, a library would need to be fully searchable, track solution status in real time, and provide clear next steps linked to relevant system pathways to convert visibility into sustained use.

Building on Australian foundations

Australia's mHealth Apps Assessment Framework provides a foundation for assessing app quality and safety. A National DTx and RPM Library could be integrated with the mHealth library, creating a unified resource that extends existing work without requiring independent validation of manufacturer claims beyond TGA regulation. The library would rely on:

- TGA regulatory status as the primary quality and safety gate
- Manufacturer-provided information, including evidence summaries, implementation requirements, interoperability specifications, and current funding pathways (MBS items, hospital classifications, private insurance coverage).

4. Funding Framework for DTx and RPM

Australia's healthcare system consists of distinct delivery sectors, each with different funding models impacting DTx and RPM adoption and integration to support remote care and guided self-management:

- **Public hospitals:** ABF and state-based procurement, constrained by budget pressure.
- **Primary and specialist care:** Fee-for-service with MBS reimbursement and includes allied health providers and the delivery of these services in community, home-based and residential aged care settings. Adoption depends on both practitioner and patient engagement. These care environments are increasingly central to remote and guided self-management care models, where DTx and RPM can extend clinical oversight and support continuity of care beyond traditional practice settings.
- **Private insurance:** Allows innovative payment models but requires clear value propositions, scalable solutions and competitive strategies.

Additionally, new initiatives are being recommended to incentivise cross-sector models of care (sometimes enabled through targeted commissioning). These differences mean digital health must follow multiple tailored integration paths rather than a one-size-fits-all approach.

4.1. The Framework

A framework to support a nationally coordinated approach to scaling safe, evidence-based remote care and guided self-management models enabled by DTx and RPM is outlined in Table 4. The framework includes both the enablers necessary to create the foundation for consistent, transparent and scalable adoption and the funding pathways across the health system. The recommended actions directly address the systemic barriers identified in Chapter 3, from funding misalignment to HTA evidence mismatches to healthcare system resistance, through targeted, politically feasible interventions.

Phased implementation is necessary to manage system readiness, build confidence among clinicians and funders, and ensure that reforms are achievable within existing policy and budget settings. Each phase builds on the last, progressing from establishing core enablers to sector-wide reforms and, ultimately, to integrated, sustainable funding pathways. The phases and corresponding actions are detailed in the following sections.

Table 4: Framework Summary

Enablers	Sectors	Funding pathways
• National Remote Care Coordination Body • Grant Funding • National DTx and RPM Library	Public Hospitals	1. New IHACPA classification, costings and bundled service payments that bundle technology costs with clinical oversight, setup, monitoring and remote care delivery 2. Expand remote care and guided self-management models enabled by DTx and RPM with sustainable funding
	Primary Care & Specialist Services	1. New open access pathway, including: • New HTA Framework specifically for digital technologies • MBS funding of additional clinical services (device setup, user onboarding, monitoring and remote care delivery) • Separate funding of technologies • New provisional listing followed by permanent listing when evidence is available 2. Expand the existing targeted commission pathways, but require all successful programs to transition into permanent funding streams when available
	Private Hospitals	1. Enhanced hospital substitute pathways: Improve the legislative and policy framework for bundled payments (for the services and technology) to support digital health episodes that substitute for hospital treatment
	Cross-Sector Care Models	1. Collaborative Commissioning: Joint funding arrangements across Commonwealth, state and regional authorities with shared accountability for outcomes and a single, transparent reporting framework

4.2. Phase 1: Enablers for funding (0-12 months)

Action to establish the foundational enablers that will unlock DTx and RPM adoption across all sectors is required. These interventions directly tackle the funding uncertainty and evidence generation challenges that currently challenge the market.

4.2.1. National Remote Care Coordination Body

Rationale

The absence of national leadership has left Australia with fragmented pilots, variable commissioning and inconsistent funding. State-based procurement cycles and jurisdictional variations in remote care readiness create duplication, slow adoption and inequitable access. Comparable reforms, such as the creation of Genomics Australia in 2025, demonstrate how a national entity can unify governance, evidence standards and funding, and incentivise adoption. Without coordinated leadership, Australia risks continuing down an inefficient patchwork approach where proven DTx and RPM solutions fail to scale beyond local pilots.

Proposed features

- **Commonwealth-led coordination body:** Establish a single national authority to set evidence standards, oversee funding pathways and align federal and state programs and give stakeholders a clear view of available pathways.

- **Alignment of priorities:** Coordinate grant funding, Department of Health, Disability and Ageing, and jurisdictional innovation programs under one strategy to scale evidence-based remote care and guided self-management models enabled by DTx and RPM solutions.

4.2.2. Grant Funding

Rationale

Many Australian digital health companies face the many "valleys of death" between successful pilots and system-wide adoption. Manufacturer anecdotal reports of funding shortfalls and HTA evidence mismatches mean vendors cannot sustain operations while generating the long-term evidence required for funding. Grant funding could bridge this gap by providing translation grants (e.g. the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF)) that directly support the implementation of proven, TGA-registered technologies into routine care. Without this targeted support, high-value solutions risk stalling after early trials, limiting both patient benefit and return on public investment in research.

Proposed features

- **Dedicated translation grant funding stream** for translating TGA-registered digital health technologies into clinical implementation pathways that can be applied at scale.
- **Scale-up support**: Fund infrastructure and workforce transformation activities (e.g., training, integration into EMRs) alongside technology deployment.
- **Evidence alignment**: Require funded projects to generate real world evidence directly relevant to HTA and funding pathways.

4.2.3. National DTx and RPM Library (TGA registered)

Rationale

Clinicians and funders currently face a fragmented marketplace with no reliable way to differentiate evidence-based digital health tools from lower-quality or unproven apps. This situation undermines adoption, creates duplication and limits trust in digital health. International models such as Belgium's *mHealthBelgium* validation pyramid demonstrate the value of a centralised library with staged recognition.

The Library would function as the operational link between regulatory approval (ARTG), evidence standards (digital-specific HTA pathway), and funding mechanisms (MBS items, IHACPA classifications, commissioned services). Rather than duplicating existing registers or creating additional validation/assessment requirements, it would transform regulatory data and manufacturer-provided information into a usable decision-support platform that clinicians, procurement officers, and payers can use to identify, compare, and implement appropriate solutions aligned with their specific needs and available funding pathways. By relying on TGA regulation as the validation standard and allowing manufacturers to update their own funding

and implementation information, the Library remains a low-overhead, high-utility resource that addresses the current accessibility barrier of the ARTG list without creating new bureaucratic processes. While the Library could be integrated with the mHealth Apps Assessment Framework to provide additional quality indicators where available, noting that the mHealth Framework may include a larger scope of products beyond TGA-regulated DTx and RPM, it would not require the framework to be operational to function effectively. This ensures the Library can proceed independently and deliver immediate value to clinicians and health services seeking TGA-registered solutions.

Proposed features

- **Tiered classification:** Tracking maturity and system value through Library tiers. Solutions are grouped into three tiers based on safety and funding status (Table 5).
- **Company-driven information.**
- **Searchable public platform:** Filters by tier, clinical use case, setting and funding status.
- **System-linked guidance:** Each entry includes clear, action-oriented next steps aligned to relevant public pathways (e.g. pilots, HTA, commissioning).
- **Procurement-enabling visibility:** Payers and providers can view system-ready solutions that meet baseline standards.

Table 5: Library tiers for maturity and system value tracking

Tier		Description	Funding status	Typical next step
Tier 3	**Permanently funding**	Solution has successfully passed HTA or equivalent assessment and secured ongoing public funding via MBS, PBS, PL or jurisdiction-wide commissioning.	Yes – Permanent	Implementation support, adoption scaling and post-market monitoring
Tier 2	**Temporarily funded in practice**	Solution is actively used in the health system under a contracted, time-limited, or program-funded arrangement (e.g. PHN, LHD or state-funded pilot). Evaluation may be underway.	Yes – Temporary (e.g. grant, trial, commissioning)	Report outcomes, strengthen evidence and prepare for HTA or broader commissioning
Tier 1	**Safe and compliant**	Solution meets minimum regulatory, safety and privacy requirements (TGA registered). Legally marketable and clinically usable but not yet assessed for system relevance.	No – No public funding or endorsement	Seek pilot funding, evidence generation support

Source: HealthConsult literature review analysis

4.3. Phase 2: Sector specific funding pathways (1-2 years)

Building on Phase 1's evidence, the focus should move to implement sector-specific funding mechanisms that directly address the structural funding barriers across different healthcare sectors, whilst expanding access to DTx and RPM.

4.3.1. Public hospitals

Rationale

Public hospitals face structural barriers to adopting DTx and RPM, as outlined in section 3.1. Although AR-DRG and Tier 2 (for non-admitted patients) codes exist, procurement processes, budget constraints, and the absence of dedicated funding streams render them practically inaccessible. The result is fragmented uptake, inequitable access, and reliance on short-term grants rather than sustainable models. Dedicated, nationally consistent costings and bundled payments that cover technology, clinical oversight, and monitoring are needed to move beyond pilots such as virtual wards and achieve system-wide impact. Furthermore, digital health skills are scarce within the public sector. Significant training and change management to enable digital health workforce capability building and remote care workflows are needed, none of which is currently funded or supported.

Proposed features

- **Create new IHACPA classifications and costings for bundled service pathways** that allow remote care and guided self-management models enabled by DTx and RPM to be funded on a sustainable basis. This includes creating specific IHACPA classifications and codes that bundle technology costs with clinical oversight, setup, monitoring and remote care delivery, similar to US CPT codes for RPM (99453-99458) but adapted for Australian ABF. Include explicit technology cost components within episode payments, following the US CPT model structure, where setup (99453), device supply (99454), and monitoring (99457-99458) are billable components.

4.3.2. Primary care and specialist services

Rationale

The MBS remains the most significant structural barrier to funding for digital health technologies, as outlined in section 3.1. The current system provides insufficient incentives for clinicians to prescribe or utilise remote care enabled by DTx and RPM or prescribe guided self-management, with current MBS funding described as inadequate to cover clinician review time, team support and digital infrastructure. It also relies on patients to self-fund any digital solution that they are directed to use at home.

To address this, an open access pathway is needed where any product that meets the published conditions of listing, such as cost-effectiveness, can be funded (examples include the PBS and the Prescribed List). This should involve specific funding for the digital technology through a new scheme in conjunction with new MBS item codes for clinical support (e.g. device setup, user onboarding, monitoring and remote care delivery) if the existing ones are inadequate.

This should be supported by a new HTA process and provisional listings that provide immediate access while evidence is generated. Currently, there is a mismatch between HTA requirements and the iterative, software-driven nature of DTx and RPM, as discussed in section 3.1. This evidence mismatch prevents effective solutions from being assessed or listed, leaving them trapped between pilot success and mainstream funding. A new HTA pathway, designed

specifically for digital health, is therefore essential to provide proportionate evidence standards, allow earlier market access and embed post-market evidence collection.

At the same time, targeted commissioning has been widely used to fund innovative models of care. While it enables rapid testing, flexibility and wrap-around support for complex populations, targeted commissioning is not ideal as a long-term solution. It is typically fragmented, short-term and limited to specific regions or conditions, meaning patients often lose access once funding cycles end. This creates inequity, duplication and discontinuity of care, particularly when patients build therapeutic relationships with digital platforms that cannot be sustained. Importantly, it typically involves 'picking winners' among technology and service providers, rather than allowing market-driven solutions to compete. It also creates isolated hubs of remote care capability and limits the broader development of essential skills needed system-wide to deliver remote care models. Without clear pathways to permanent funding, commissioning risks becoming a revolving door of pilots that fail to scale and silos of digital health capabilities.

Two complementary funding pathways are needed: targeted commissioning as a transitional mechanism for innovation and evaluation that can be used without the necessity for full HTA processes, and open access pathways (including a payment scheme for the technology component) to allow proven models to be adopted into routine care, enabling sustainability, equity and system-wide access. This approach also incentivises innovation in all areas when it may be beneficial, not just those that may be the subject of targeted commissioning.

Proposed features

- **Open access pathway**: This includes:
  - **New HTA Framework:** Create a staged, digital technologies-specific evaluation pathway with proportionate evidence requirements that accepts local and international data and recognises behavioural outcomes like adherence and self-management. The pathway should also include provisional listing mechanisms to generate real-world Australian evidence while technologies demonstrate clinical and economic value. In addition to iterative data collection, the framework should allow for alternative evidence sources, including simulation, modelling and predictive studies, particularly where they can reliably estimate long-term clinical or economic outcomes that would otherwise take years to observe.
  - **Provisional listing** before permanent listing in Phase 3, including:
    i. Create MBS provisional item pathways (18-36 months) to enable immediate clinical access through temporary Medicare rebates while generating Australian-specific evidence for permanent integration. These should only be created where existing codes do not cover the setup and monitoring required. The codes should be for:
       - remote care delivery including patient onboarding and setup, ongoing remote monitoring and data review with multidisciplinary team coordination that enable GPs, nurses, allied health professionals, and care coordinators to be appropriately funding for their roles in delivering comprehensive remote care programs (e.g., a variation of the Chronic Condition Management Plans to suit remote care with a remote monitoring aspect MBS Item 11725), or
       - guided self-management Medicare item numbers for patient onboarding and setup by multidisciplinary teams to enable safe self-management, with ongoing oversight through existing consultation items.

ii. New provisional funding model for digital technologies (software licences, device provision as required) **prior to permanent listing in Phase 3**

- **Targeted commissioning (transition to permanent funding)**: Continue short-term commissioning to support innovation but require all successful programs to transition into permanent funding streams when available. Support implementation via national or state-run platforms for enrolment, procurement and reporting to reduce duplicated overheads across funders and settings.

  To safeguard translation and avoid "reinventing the wheel," commissioning frameworks should include mechanisms to identify and prioritise proven, commercially available, TGA-registered digital health solutions before funding new pilots. This ensures public investment accelerates scale-up rather than duplication, and that research-led innovations transition efficiently into practice.

  Focus commissioning on conditions where digital models can support broader reform goals (e.g. out-of-hospital care, guided self-management) and can be extended across geographies or populations. Ensure impact assessments go beyond clinical endpoints such as avoided utilisation, patient activation and workforce efficiency. Develop minimum standards for eligibility, service model requirements and evaluation metrics to ensure consistency and scalability.

4.3.3. Private hospitals

Rationale

Section 3.1 highlights that private hospitals and insurers face fragmented adoption of DTx and RPM. The Prescribed List excludes standalone digital solutions, and private insurers have been slow to offer enhanced benefit coverage, despite opportunities for competitive differentiation and improved sustainability. Without reform, access will continue to depend on isolated pilots and advocacy-driven arrangements. A key pathway to long-term sustainability is embedding DTx and RPM within hospital-in-the-home programs or as hospital-substitutable services delivered in the community. These models substitute inpatient care with clinically supervised digitally enabled services delivered in the home. Evidence shows they reduce readmissions, shorten length of stay and improve patient experience while also lowering claims costs. If other approaches are inadequate to facilitate funding by insurers, an approach similar to the Prescribed List or an extension of the eligibility of the Prescribed List could be considered. Digital health should be explicitly considered as part of private health reforms.

Proposed features

- **Enhance hospital substitute pathways**: Improve the legislative and policy framework for bundled payments (for the services and technology) to support digital health episodes that substitute for hospital treatment (e.g., virtual cardiac rehabilitation, remote post-surgical monitoring).

4.4. Phase 3: Permanent funding and system integration (3–5 years)

By Phase 3, the enabling foundations and sector specific pathways are in place, with new HTA processes established and provisional MBS items providing access to early adopters. The next step is to embed permanent funding mechanisms that provide certainty for clinicians, patients and vendors. This ensures that proven DTx and RPM solutions are no longer dependent on

temporary funding but are fully integrated into Australia's funding system with equity and long-term sustainability.

4.4.1. Primary care and specialist services

Rationale

As outlined in section 4.3.2, primary and specialist care reforms such as a digital-specific HTA pathway, provisional item numbers and targeted commissioning provide important early access but are not sufficient to sustain long-term adoption. These mechanisms are temporary by design and cannot deliver the certainty needed for clinicians, patients and vendors. To move beyond this, Phase 3 establishes permanent MBS items with funding streams that explicitly recognise both the clinical services required to deliver remote care and the enabling digital technologies. Without this dual recognition, proven solutions risk remaining confined to short-term pilots or provisional codes. Permanent arrangements ensure that once evidence thresholds are met, DTx and RPM can transition seamlessly into routine practice, supporting national scale-up with equity and sustainability.

Proposed features

- **Enhance open access pathway**: Establish permanent funding for:
  i. MBS funding of additional clinical services (device setup, user onboarding, monitoring and remote care delivery)
  ii. Separate funding of technologies
- **Transition successful provisional listings:** Progress listings from Phase 2 into permanent item numbers once evidence thresholds are met.

4.4.2. Cross-sector care models

Rationale

Australia's split funding responsibilities create structural disincentives for the prevention of chronic disease. The Commonwealth funds primary care and out-of-hospital services, while states fund public hospitals. When digital health solutions reduce hospital admissions, the savings largely benefit states, but the costs often fall to the Commonwealth. This misalignment discourages either level from investing fully in prevention. To overcome these barriers, collaborative cross-sector funding models are needed to align incentives, pool resources, reduce duplication and provide clear transition pathways from pilots to permanent funding. Collaborative commissioning supports equitable national rollout of proven digital care models by linking Commonwealth funding, state service delivery and regional commissioning within one consistent accountability framework.

Proposed features

- **Collaborative commissioning:** In addition to Phase 2 targeted commissioning, **establish joint funding across Commonwealth, state and regional bodies with shared accountability for outcomes** and a single, transparent reporting framework. This approach aligns with recommendations in the *Productivity Commission's Delivering Quality Care More Efficiently*,[99] which calls for cross-jurisdictional funding models to drive national consistency in preventive and digitally enabled care.

  How it would function:

  - **Commonwealth** contributes to technology, primary care, and out-of-hospital service costs through dedicated funding envelopes (e.g. MBS, or a new digital health innovation stream).
  - **States and Territories** co-fund implementation and workforce components through activity-based or block grants, ensuring integration with public hospital and community services.
  - **Regional bodies (PHNs and LHDs)** coordinate commissioning at the local level, tailoring implementation to population needs, maintaining provider networks, and ensuring data flows for performance monitoring.
  - **Governance and operation:** A joint governance board — comprising representatives from all three levels — would set outcome targets (e.g. reduced hospitalisations, improved patient activation, workforce efficiency), oversee evaluation, and ensure reinvestment of savings into further digital enablement. Funding could be pooled or matched based on jurisdictional responsibility, with clear attribution of benefits and costs.

4.5. Conclusions

As health systems globally transition towards digital-enabled care models, the evidence demonstrates that Australia possesses proven solutions, established clinical efficacy and mature technologies ready for systematic deployment. This report demonstrates that implementing a national funding framework for DTx and RPM technologies would enhance patient access, promote healthcare equity, build sovereign capability and position Australia competitively within the evolving international digital health landscape**.**

Australia can close the funding and access gap for proven digital health solutions by refining a range of existing funding pathways so that they are better suited to considering digital health technologies. These changes would allow the health system to move from fragmented, short-term pilots to consistent, sustainable access for DTx and RPM to enable remote care and guided self-management models across all delivery sectors.

5. References

1. Sturgiss E, Desborough J, Hall Dykgraaf S, et al. Digital Health to Support Primary Care Provision During a Global Pandemic. *Aust Health Rev*. 2022;46(3):269-272. doi:10.1071/ah21263

2. Mathew S, Fitts MS, Liddle Z, et al. Telehealth in Remote Australia: A Supplementary Tool or an Alternative Model of Care Replacing Face-to-Face Consultations? *BMC Health Services Research*. 2023;23(1):341. doi:10.1186/s12913-023-09265-2

3. Moore G, Du Toit A, Jameson B, Liu A. *The Effectiveness of Virtual Hospital Models of Care*. 2020.

4. Krahe MA, Larkins SL, Adams N. Digital Health Implementation in Australia: A Scientometric Review of the Research. *DIGITAL HEALTH*. 2024;10:20552076241297729. doi:10.1177/20552076241297729

5. Paul JK, Azmal M, Talukder OF, Haque ANMSNB, Meem M, Ghosh A. Harnessing Machine Learning for Improved Diagnosis, Drug Discovery, and Patient Care. *Computational and Structural Biotechnology Reports*. 2025;2:100051. doi:https://doi.org/10.1016/j.csbr.2025.100051

6. Sadr H, Nazari M, Khodaverdian Z, et al. Unveiling the Potential of Artificial Intelligence in Revolutionizing Disease Diagnosis and Prediction: A Comprehensive Review of Machine Learning and Deep Learning Approaches. *European Journal of Medical Research*. 2025;30(1):418. doi:10.1186/s40001-025-02680-7

7. Da'Costa A, Teke J, Origbo JE, Osonuga A, Egbon E, Olawade DB. Ai-Driven Triage in Emergency Departments: A Review of Benefits, Challenges, and Future Directions. *International Journal of Medical Informatics*. 2025;197:105838. doi:https://doi.org/10.1016/j.ijmedinf.2025.105838

8. Wallace W, Chan C, Chidambaram S, et al. The Diagnostic and Triage Accuracy of Digital and Online Symptom Checker Tools: A Systematic Review. *NPJ Digit Med*. 2022;5(1):118. doi:10.1038/s41746-022-00667-w

9. Valdes D, Alqazlan L, Procter R, Dale J. Global Evidence on the Rapid Adoption of Telemedicine in Primary Care During the First 2 Years of the Covid-19 Pandemic: A Scoping Review Protocol. *Systematic Reviews*. 2022;11(1):124. doi:10.1186/s13643-022-01934-3

10. Australian National Audit Office. The Auditor-General Auditor-General Report No.10 2022–23 Performance Audit: Expansion of Telehealth Services. Department of Health and Aged Care; 2023.

11. Tan SY, Sumner J, Wang Y, Wenjun Yip A. A Systematic Review of the Impacts of Remote Patient Monitoring (Rpm) Interventions on Safety, Adherence, Quality-of-Life and Cost-Related Outcomes. *npj Digital Medicine*. 2024;7(1):192. doi:10.1038/s41746-024-01182-w

12. Hallberg S, Harrison D. Telemedicine Via Continuous Remote Care: A Proactive, Patient-Centered Approach to Improve Clinical Outcomes. *JMIR Diabetes*. 2021;6(4)doi:10.2196/23646

13. Agarwal P, Fletcher GG, Ramamoorthi K, Yao X, Bhattacharyya O. Uses of Virtual Care in Primary Care: Scoping Review. Review. *J Med Internet Res*. 2025;27:e55007. doi:10.2196/55007

14. Wartenberg C, Elden H, Frerichs M, et al. Clinical Benefits and Risks of Remote Patient Monitoring: An Overview and Assessment of Methodological Rigour of Systematic Reviews for Selected Patient Groups. *BMC Health Services Research*. 2025;25(1):133. doi:10.1186/s12913-025-12292-w

15. Taylor ML, Thomas EE, Snoswell CL, Smith AC, Caffery LJ. Does Remote Patient Monitoring Reduce Acute Care Use? A Systematic Review. *BMJ open*. 2021;11(3):e040232.

16. Schmidt L, Pawlitzki M, Renard BY, Meuth SG, Masanneck L. The Three-Year Evolution of Germany's Digital Therapeutics Reimbursement Program and Its Path Forward. *npj Digital Medicine*. 2024;7(1):139. doi:10.1038/s41746-024-01137-1

17. Lewkowicz D, Wohlbrandt AM, Bottinger E. Digital Therapeutic Care Apps with Decision-Support Interventions for People with Low Back Pain in Germany: Cost-Effectiveness Analysis. *JMIR Mhealth Uhealth*. 2022;10(2):e35042. doi:10.2196/35042

18. Arsenault-Lapierre G, Henein M, Gaid D, Le Berre M, Gore G, Vedel I. Hospital-at-Home Interventions Vs in-Hospital Stay for Patients with Chronic Disease Who Present to the Emergency Department: A Systematic Review and Meta-Analysis. *JAMA Network Open*. 2021;4(6):e2111568-e2111568. doi:10.1001/jamanetworkopen.2021.11568

19. Caplan GA, Sulaiman NS, Mangin DA, Aimonino Ricauda N, Wilson AD, Barclay L. A Meta-Analysis of "Hospital in the Home". *Med J Aust*. 2012;197(9):512-9. doi:10.5694/mja12.10480

20. Amirabdolahian S, Pare G, Tams S. Digital Wellness Programs in the Workplace: Meta-Review. Review. *J Med Internet Res*. 2025;27:e70982. doi:10.2196/70982

21. Kechagias EP, Papadopoulos GA, Rokai I. Evaluating the Impact of Digital Health Interventions on Workplace Health Outcomes: A Systematic Review. *Administrative Sciences*. 2024;14(6):131.

22. Mohammad A, Saini B, Chaar BB. Pharmacists' Experiences Serving Culturally and Linguistically Diverse Patients in the Australian Community Pharmacy Setting. *International Journal of Clinical Pharmacy*. 2021;43(6):1563-1573. doi:10.1007/s11096-021-01284-5

23. Morlotti C, Cattaneo M, Paleari S, Manelli F, Locati F. The Digitalization of Emergency Department Triage: The Perspectives of Health Professionals and Patients. *BMC Health Services Research*. 2024;24(1):1406. doi:10.1186/s12913-024-11862-8

24. Cotte F, Mueller T, Gilbert S, et al. Safety of Triage Self-Assessment Using a Symptom Assessment App for Walk-in Patients in the Emergency Care Setting: Observational Prospective Cross-Sectional Study. Original Paper. *JMIR Mhealth Uhealth*. 2022;10(3):e32340. doi:10.2196/32340

25. Al Badawi AK, Nashwan AJ. The Future of Prehospital Emergency Care: Embracing Ai Applications in Ambulance Services. *International Emergency Nursing*. 2024;72:101385. doi:https://doi.org/10.1016/j.ienj.2023.101385

26. Morrissette K, Siket M. Hub and Spoke 2.0: A Narrative Review of Digital Strategies in Rural Healthcare Delivery Models. *Medical Research Archives*. 2025;13(6)doi:10.18103/mra.v13i6.6656

27. NSW Ministry of Health. Rural Nurse Practitioners - a Framework for Service and Training in Nsw Health. 2023;

28. Thomas EE, Taylor ML, Banbury A, et al. Factors Influencing the Effectiveness of Remote Patient Monitoring Interventions: A Realist Review. *BMJ Open*. 2021;11(8):e051844. doi:10.1136/bmjopen-2021-051844

29. Trankle SA, Reath J. Afterhours Telehealth in Australian Residential Aged Care Facilities: A Mixed Methods Evaluation. *BMC Health Services Research*. 2023;23(1):1263. doi:10.1186/s12913-023-10257-5

30. Australian Institute of Health Welfare. *Survey of Health Care: Selected Findings for Rural and Remote Australians*. 2018. https://www.aihw.gov.au/reports/rural-remote-australians/survey-health-care-selected-findings-rural-remote

31. The Senior. Rural Patients Waiting Weeks and Travelling 150km for Medical Care. Updated 20/01/2023. Accessed 27/06/2025, https://www.theland.com.au/story/8019968/rural-patients-waiting-weeks-and-travelling-150km-for-medical-care/

32. Medicare Benefits Schedule Review Taskforce. An Mbs for the 21st Century Recommendations, Learnings and Ideas for the Future. *Final Report to the Minister for Health*. 2020. https://www.health.gov.au/sites/default/files/documents/2020/12/medicare-benefits-schedule-review-taskforce-final-report.pdf

33. Department of Health Disability and Ageing. Msac Codependent Details. Department of Health, Disability and Ageing. Updated 21/11/2024. Accessed 27/06/2025, https://hpp.health.gov.au/article-details/?id=5c386c11-ae01-4ee2-a919-3063b9b284ec

34. MBS Review Advisory Committee. Telehealth Post-Implementation Review - Final Report. 2024. https://www.health.gov.au/sites/default/files/2024-06/mbs-review-advisory-committee-telehealth-post-implementation-review-final-report.pdf

35. Department of Health Disability and Ageing. Upcoming Changes to Chronic Disease Management Framework – Mbs Items for Gp Chronic Condition Management Plans. Australian Government. Updated 22/05/2025. https://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/650f3eec0dfb990fca25692100069854/35bc9280594efa33ca258c9200126149/$FILE/PDF%20Version%20-%20Upcoming%20Changes%20to%20Chronic%20Disease%20Management%20Framework%20-%20GPCCMPs.pdf

36. Independent Health and Aged Care Pricing Authority. Virtual Care Project – Final Report. 2025. https://www.ihacpa.gov.au/sites/default/files/2025-02/virtual_care_project-final_report.pdf

37. Lynch J. Bupa Unleashes $20m Fund to Change Private Healthcare. The Australian,; 2025. https://www.theaustralian.com.au/business/technology/bupa-unleashes-20m-fund-to-

change-australias-crisisplagued-private-healthcare/news-story/962560b0ffa6647231e7dc08d78b464d#:~:text=Technology-,Bupa%20unleashes%20%2420m%20fund%20to%20change%20Australia's%20crisis%2Dplagued,risk%20factors%20affect%20their%20health

38. Long D. Nib Targets Growth through Membership Benefits. The Australian,; 2024. https://www.theaustralian.com.au/business/growth-agenda/nib-targets-growth-through-membership-benefits/news-story/dad3630ffe6767d8f19c88ade329320f

39. Department of Health Disability and Ageing. Medical Devices and Human Tissue Products Covered under Private Health Insurance. Australian Government. Updated 13/03/2025. Accessed 23/07/2025, https://www.health.gov.au/topics/private-health-insurance/what-private-health-insurance-covers/medical-devices-and-human-tissue-products-covered-under-private-health-insurance

40. The Hon Mark Butler MP. Delivering High-Quality Free Digital Mental Health Supports. Australian Government. Updated 19 February 2025. Accessed 25/06/2025, https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/delivering-high-quality-free-digital-mental-health-supports

41. Productivity Commission. Delivering Quality Care More Efficiently: Interim Report. Australian Government. Updated 13/08/2025. Accessed 01/09/2025, https://www.pc.gov.au/inquiries/current/quality-care/interim

42. Shaw M. Sustaining a Virtual Hospital Model with Miranda Shaw, Rpa Virtual Hospital. Updated 21/11/2023. Accessed 21/06/2025, https://www.hfma.org.au/news-item/14690/sustaining-a-virtual-hospital-model-with-miranda-shaw-rpa-virtual-hospital

43. NSW Health. Small Hospitals Funding Model Review. NSW Government; 2024. https://www.health.nsw.gov.au/regional/Publications/nsw-health-small-hospitals-funding-review-2024.pdf

44. Williams K, Kobel C, Westera A, et al. Pathways to Community Living Initiative: Final Evaluation Report. 2021. Accessed 18/06/2025. https://ro.uow.edu.au/articles/report/Pathways_to_Community_Living_Initiative_Final_Evaluation_Report/27844056?file=50601873

45. eHealth NSW. Telestroke Provides Life-Saving Care to 1,000 Regional Nsw Residents. NSW Government. Updated 20/10/2021. Accessed 23/06/2025, https://www.ehealth.nsw.gov.au/news/2021/telestroke-regional

46. Agency for Clinical Innovation. Benefits of Virtual Care. NSW Government. Accessed 23/06/2025, https://aci.health.nsw.gov.au/virtual-care-in-practice/about/benefits

47. Swannell C. Collaborate or Risk Death of Innovation, Commonwealth Told. Health Services DAily. Updated 06/08/2025. Accessed 08/08/2025, https://www.healthservicesdaily.com.au/collaborate-or-risk-death-of-innovation-commonwealth-told/32405

48. Agency for Clinical Innovation. Service Funding, Budgets and Reporting. NSW Government. Accessed 07/07/2025, https://aci.health.nsw.gov.au/virtual-care-in-practice/implementation/budgets-funding-and-reporting

49. Khanal S, Nghiem S, Miller M, Scuffham P, Byrnes J. Development of a Prioritization Framework to Aid Healthcare Funding Decision Making in Health Technology Assessment in Australia: Application of Multicriteria Decision Analysis. *Value in Health*. 2024;27(11):1585-1593. doi:10.1016/j.jval.2024.07.003

50. Schmidt L, Pawlitzki M, Renard BY, Meuth SG, Masanneck L. The Three-Year Evolution of Germany's Digital Therapeutics Reimbursement Program and Its Path Forward. *NPJ Digit Med*. 2024;7(1):139. doi:10.1038/s41746-024-01137-1

51. Goeldner M, Gehder S. Digital Health Applications (Digas) on a Fast Track: Insights from a Data-Driven Analysis of Prescribable Digital Therapeutics in Germany from 2020 to Mid-2024. Original Paper. *J Med Internet Res*. 2024;26:e59013. doi:10.2196/59013

52. Schliess F, Affini Dicenzo T, Gaus N, et al. The German Fast Track toward Reimbursement of Digital Health Applications: Opportunities and Challenges for Manufacturers, Healthcare Providers, and People with Diabetes. *J Diabetes Sci Technol*. 2024;18(2):470-476. doi:10.1177/19322968221121660

53. Gensorowsky D, Witte J, Batram M, Greiner W. Market Access and Value-Based Pricing of Digital Health Applications in Germany. *Cost Effectiveness and Resource Allocation*. 2022;20(1):25. doi:10.1186/s12962-022-00359-y

54. Dittrich F, Mielitz A, Pustozerov E, Lawin D, von Jan U, Albrecht UV. Digital Health Applications from a Government-Regulated Directory of Reimbursable Health Apps in Germany-a Systematic Review for Evidence and Bias. *Mhealth*. 2023;9:35. doi:10.21037/mhealth-23-17

55. Spethmann S, Hindricks G, Koehler K, et al. Telemonitoring for Chronic Heart Failure: Narrative Review of the 20-Year Journey from Concept to Standard Care in Germany. Review. *J Med Internet Res*. 2024;26:e63391. doi:10.2196/63391

56. Albrecht A, Taubmann J, Minopoulou I, et al. Real-World-Evidence of Digital Health Applications (Digas) in Rheumatology: Insights from the Digareal Registry. *Rheumatol Ther*. 2025;12(2):267-282. doi:10.1007/s40744-025-00744-y

57. QuickBird Meidcal. Pecan Dmd – Guide to Diga in France. Updated 10/07/2025. Accessed 05/06/2025, https://quickbirdmedical.com/en/pecan-france-diga-dmd/

58. European Med Tech and IVD Reimbursement Consulting (MTRC). General Market Access Landscape for Health Apps in Europe. 2025;

59. Tokarska J, Foxon G, Zakrzewska K, Craddy P. Pt21 Evaluation and Reimbursement of Digital Therapeutics in Germany, France, Belgium and England. *Value in Health*. 2023;26(12):S292. doi:10.1016/j.jval.2023.09.1543

60. Olesch A. Pecan: France's Fast-Track Scheme for Digital Health Applications. ICT&health. Updated 10/09/2024. Accessed 05/06/2025, https://icthealth.org/news/pecan-frances-fast-track-scheme-for-digital-health-applications

61. Centers for Medicare & Medicaid Services (CMS). Telehealth & Remote Patient Monitoring. Accessed 05/06/2025, https://www.cms.gov/files/document/mln901705-telehealth-remote-patient-monitoring.pdf

62. Digital Therapeutics Alliance. United States Dtx Regulatory & Reimbursement Pathways. Updated 01/2022. Accessed 05/06/2025, https://dtxalliance.org/wp-content/uploads/2022/01/US-Regulatory-and-Reimbursement-Pathways.pdf

63. Health Recovery Solutions. 2024 Remote Therapeutic Monitoring Cpt Codes: Cheat Sheet. Accessed 05/06/2025, https://www.healthrecoverysolutions.com/blog/2024-remote-therapeutic-monitoring-cpt-codes-cheat-sheet

64. Health Resources and Services Administration (HRSA). Billing for Remote Patient Monitoring. Updated 17/01/2025. Accessed 05/06/2025, https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-and-remote-patient-monitoring/billing-remote-patient

65. Green O, Acosta S, Alonso A, et al. Reimbursement of Digital Therapeutics in the U.S. What Is the Outlook? Triny Life Sciences; 2022. https://trinitylifesciences.com/wp-content/uploads/2022/10/Trinity-White-Paper-Reimbursement-of-Digital-Therapeutics-in-the-U.S.pdf

66. The Peterson Center on Healthcare. Evolving Remote Monitoring: An Evidence-Based Approach to Coverage and Payment. Updated 16/04/2025. Accessed 05/06/2025, https://petersonhealthcare.org/news/evolving-remote-monitoring-report/

67. Software as a Medical Device Working Group. Software as a Medical Device (Samd): Clinical Evaluation. International Medical Device Regulators Forum; 2017. https://www.fda.gov/media/100714/download

69. Medical Technology Association of Australia. Digital Health: Breaking Barriers to Deliver Better Patient Outcomes. 2023. https://www.mtaa.org.au/digital-health-report#:~:text=MTAA%E2%80%99s%20Digital%20Health%3A%20Breaking%20Barriers%20to%20Deliver%20Better,with%20an%20emphasis%20on%20current%20and%20emerging%20technologies.

70. Asia Pacific Medical Technology Association (APACMed). Digital Health Reimbursement Policy Forum 2024. 2024. https://apacmed.org/digital-health-reimbursement-policy-forum-2024/

71. InstuitionLabs. Remote Patient Monitoring in the United States: 2025 Landscape Report. Updated 27/04/2025. Accessed 6/10/2025, https://intuitionlabs.ai/articles/remote-patient-monitoring-united-states-2025-landscape

72. van Kessel R, Srivastava D, Kyriopoulos I, et al. Digital Health Reimbursement Strategies of 8 European Countries and Israel: Scoping Review and Policy Mapping. Review. *JMIR Mhealth Uhealth*. 2023;11:e49003. doi:10.2196/49003

73. CMS Legal. Key Legal Aspects of Implementing Digital Therapeutics (Dtx) in Netherlands. 2023. Accessed 09/07/2025. https://cms.law/en/int/publication/cms-dtx-legal-navigator/the-netherlands?format=pdf&v=60

74. Netherlands Got. Government Encouraging the Use of Ehealth (Telehealth). Accessed 03/07/2025, https://www.government.nl/topics/ehealth/government-encouraging-use-of-ehealth

75. European Med Tech and IVD Reimbursement Consulting (MTRC). A General Overview of the Market Access Landscape for Remote Patient Monitoring in European Countries.

. Accessed 03/07/2025, https://mtrconsult.com/remote-patient-monitoring

76. European Med Tech and IVD Reimbursement Consulting (MTRC). Dutch Healthcare Authority Published the Second Release of the 2023 Drg Package. Updated 26/10/2022. Accessed 05/07/2025, https://mtrconsult.com/news/dutch-healthcare-authority-published-second-release-2023-drg-package

77. van Steenkiste J, Verberk I, Versmissen J, Dohmen D, Jainandunsing S. Home Blood Pressure Telemonitoring in the Netherlands: A Pilot Study in Gp Practices. *BMC Digital Health*. 2024;2(1):16. doi:10.1186/s44247-024-00072-1

78. European Med Tech and IVD Reimbursement Consulting (MTRC). General Market Access Landscape for Health Apps in Europe. Updated 03/2025. https://mtrconsult.com/market-access-landscape-health-apps-europe

79. National Health Insurance Administration. Announcement "National Health Insurance Encourages Institutions to Strengthen Promotion of Peritoneal Dialysis and Improve Care Quality Plan". Ministry of Health and Welfare. Updated 22/05/2025. https://www.nhi.gov.tw/ch/cp-18268-9f400-3258-1.html

80. National Institute for Health and Care Excellence (NICE). Early Value Assessment (Eva) for Medtech. Accessed 05/06/2025, https://www.nice.org.uk/what-nice-does/our-guidance/about-medical-technologies-guidance/early-value-assessment-eva-for-medtech

81. Digital Therapeutics Alliance. England Dtx Regulatory & Reimbursement Pathways. Updated 09/2024. Accessed 05/06/2025

https://dtxalliance.org/wp-content/uploads/2022/01/UK-Regulatory-and-Reimbursement-Pathways.pdf

82. Medicines & Healthcare products Regulatory Agency. Implementation of the Future Regulations. Updated 26/02/2025. Accessed 05/06/2025, https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices/implementation-of-the-future-regulations

83. National Institute for Health and Care Excellence (NICE). Evidence Standards Framework for Digital Health Technologies. Accessed 05/06/2025, https://www.nice.org.uk/what-nice-does/digital-health/evidence-standards-framework-esf-for-digital-health-technologies

84. NHS England. Digital Technology Assessment Criteria (Dtac): Transformation Directorate. Accessed 05/06/2025, https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

85. Williams MG, Stott R, Bromwich N, Oblak SK, Espie CA, Rose JB. Determinants of and Barriers to Adoption of Digital Therapeutics for Mental Health at Scale in the Nhs. *BMJ Innovations*. 2020;6(3):92-98. doi:10.1136/bmjinnov-2019-000384

86. Carr D, Moran V. Hta17 Nice Early Value Assessment: A New Avenue for Evidence Generation and Early Market Access in the Digital Therapeutics Space in the United Kingdom. *Value in Health*. 2024;27(12):S356. doi:10.1016/j.jval.2024.10.1842

87. Digital Medicine Society. South Korea National Companion Guide: Pursue Dht Market Access in South Korea. Accessed 05/06/2025, https://dimesociety.org/international-digital-health-regulatory-pathways/south-korea/

88. Qualtech. Qt Analysis: World's First Digial Medical Product Act Enforcement Rules Established in Korea - March/April 2025. Updated 25/03/2025. Accessed 05/06/2025, https://www.qualtechs.com/en-gb/article/korea-digital-medical-products-act-march-2025

89. MDREX Newsletter. Hira Completes Research on Development of Guidelines for Generating Economic Evidence Concerning Digital Therapeutics. Updated 11/03/2025. Accessed 05/06/2025, https://mdrex.stibee.com/p/46

90. Shin HJ, Cho IT, Choi WS, Kim HR, Kang MB, Yang WJ. Digital Therapeutics in Korea: Current Status, Challenges, and Future Directions - a Narrative Review. *J Yeungnam Med Sci*. 2025;42:8. doi:10.12701/jyms.2024.01004

91. Yoon S, Jung S. Current Healthcare Policy and Environmental Status of Digital Health Medical Devices in South Korea. Accessed 05/06/2025, https://www.ispor.org/docs/default-source/intl2023/ispor23yoonposter127681-pdf.pdf?sfvrsn=c616c64f_0

92. Aranca. Healthcare Reimbursement Outlook in Korea: Pricing and out-of-Pocket Spending for Healthcare Services. Accessed 05/06/2025, https://www.aranca.com/assets/images/pra/pdf/Therapy-Insights-Healthcare-Reimbursement-Outlook-in-Korea.pdf

93. Kwon S, Han SJ, Kim K-H. Pp26 Critical Review of the Reimbursement Process for Software as a Medical Device and Challenges in South Korea. *International Journal of Technology Assessment in Health Care*. 2023;39(S1):S59-S59. doi:10.1017/S0266462323001812

94. Nicol-Schwarz K. Diga Promised German Digital Health Startups Access to 73m Patients — but Slow Insurers and Poor Adoption Hold It Back. Sifted. Updated 7/07/2023. Accessed 6/10/2025, https://sifted.eu/articles/diga-promised-german-healthtechs-access-to-73m-patients-but-insurer-roadblocks-and-slow-adoption-are-limiting-its-potential

95. Meditech Access. The Road to Dtx Reimbursement: Lessons from Pecan & Lppr. Updated 4/03/2025. Accessed 06/10/2025, https://mtac.iges.com/news/2025/digital_therapeutics_dtx_france_2025/index_eng.html

96. Gerkens S, Roberfroid D, Miguel L, Thiry N, De Laet C, Pouppez C. *Remote Monitoring of Patients with Cardiovascular Implantable Electronic Devices: A Health Technology Assessment*. 2021.

97. Lievevrouw E, Marelli L, Van Hoyweghen I. Weaving Eu Digital Health Policy into National Healthcare Practices. The Making of a Reimbursement Standard for Digital Health Technologies in Belgium. *Soc Sci Med*. 2024;346:116620. doi:10.1016/j.socscimed.2024.116620

98. Chalmers M, Hughes J, Samavedam S, Kanade P. Mt59 Overview of Approved Digital Therapeutics in Belgium. *Value in Health*. 2023;26(12, Supplement):S437. doi:https://doi.org/10.1016/j.jval.2023.09.2285

99. Productivity Commission. Delivering Quality Care More Efficiently - Interim Report. Australian Government. Updated 13/08/2025. https://www.pc.gov.au/inquiries-and-research/quality-care/interim/

100. Asia Pacific Medical Technology Association (APACMed). Landscape of Digital Health Reimbursement Policies in Japan. Accessed 05/06/2025, https://apacmed.org/wp-content/uploads/2022/06/Masterdeck-Landscape-of-digital-health-reimbursement-policies-in-Japan.pdf

101. Digital Therapeutics Alliance. Japan Dtx Regulatory & Reimbursement Pathways. Updated 01/2022. Accessed 05/06/2025, https://dtxalliance.org/wp-content/uploads/2022/01/Japan-Regulatory-and-Reimbursement-Pathways.pdf

102. Nomura A. Digital Health, Digital Medicine, and Digital Therapeutics in Cardiology: Current Evidence and Future Perspective in Japan. *Hypertens Res*. 2023;46(9):2126-2134. doi:10.1038/s41440-023-01317-8

103. Nomura A. Digital Therapeutics in Japan: Present and Future Directions. *Journal of Cardiology*. 2025;85(5):360-365. doi:https://doi.org/10.1016/j.jjcc.2024.11.005

104. Pharmaceuticals and Medical Devices Agency. Regulations and Approval/Certification of Medical Devices. Accessed 05/06/2025, https://www.pmda.go.jp/english/review-services/reviews/0004.html

105. Pharmaceuticals and Medical Devices Agency. Japanese Regulatory Considerations for Digital Health Technology. Accessed 05/06/2025, https://www.pmda.go.jp/files/000266816.pdf

106. (APACMed) APMTA. Hta for Medical Devices in Japan. Updated 29/02/2024. Accessed 05/06/2025, https://apacmed.org/wp-content/uploads/2024/03/HTA_for_Medical_Devices_Practices_Overview_Japan.pdf

107. Digital Therapeutics Alliance. Singapore Dtx Regulatory & Reimbursement Pathways. Updated 09/2024. Accessed 10/06/2025, https://dtxalliance.org/wp-content/uploads/2024/12/Singapore-Regulatory-and-Reimbursement-Pathways_2024_r2.pdf

108. ICLG. Digital Health Laws and Regulations Singapore 2025. Updated 04/03/2025. Accessed 10/06/2025, https://iclg.com/practice-areas/digital-health-laws-and-regulations/singapore

109. L.E.K. Consulting. Navigating the Digital Health Reimbursement Landscape in Asia-Pacific. Accessed 10/06/2025, https://www.lek.com/sites/default/files/insights/pdf-attachments/LEK-APACMed_Digital-Health-EI.pdf

110. Low L, Lim H. An Mhealth Application (Drbuddy) to Improve Remote Patient Monitoring in a Hospital at Home Program in Singapore. *International Journal of Integrated Care*. 2025;25:75. doi:10.5334/ijic.ICIC24037

Appendix A Cardihab case study

Cardihab Platform Overview

- **Australia's only TGA-registered digital therapeutic** for cardiac rehabilitation (CR)
- **SmartCR mobile app** + care program + structured nurse telehealth consultations
- **TGA Class I → Class II** (November 2024 regulatory transition)
- **Evidence-based CR** following CSANZ and National Heart Foundation guidelines
- **Comprehensive coverage:** Acute coronary syndrome, MI, unstable angina, atrial fibrillation, device implantation, valvular disease
- **Specialised programs:** Cardiac Rehabilitation, Primary Prevention, Heart failure
- Better access, completion rates, efficiency and scalability, with equivalent outcomes to face-to-face

The challenge in CR

- **568,000 cardiac hospitalisations p.a** (2021-22)[6]
- **~80%** received NO cardiac rehabilitation[1]
- **Less than 10%** completed cardiac rehabilitation[1]
- **Women 75% less likely** to be referred[1]
- **CVD** was the underlying cause of 45,000 Australian deaths in 2022 (24% of all deaths)[6]
- est 24 % CVD emergency readmissions[8,9]

CR Proven clinical outcomes

- **CR uptake** = lower mortality risk[5]
- Each cardiac rehab session attended cuts readmission and death risk by 2%[7]
- Digital cardiac rehabilitation was associated with significant reductions in
  - all-cause hospitalisations
  - cardiac-related hospitalisations
  - Emergency department visits[5]

Cardihab Clinical Evidence -"Proven Outcomes"

- **Equivalent outcomes to face-to-face CR**[3]
- **Improves uptake:** 80% vs 62%
- **91% completion rate**[4] vs 20-40% face-to-face dropout[4]
- **Cardiovascular risk factor improvements**, physical activity, diet, BMI, systolic blood pressure, functional capacity[2,4]
- **Improved quality of life and patient self-management confidence** [2,4]
- 1.434 yrs QALY Gained
- $14,302 per quality year gained. Significantly lower than the $50k value threshold
- 87% of scenarios DeCR was the better value choice

Cardihab Economic Impact

- **Hospital bed days reduced:** 71% (30/90day), 51% (12-month)[4]
- **Cardiac bed days reduced:** 88% (30day), 74% (90day)[4]
- Significantly improves access to care [2,4]
- **Lower readmission burden**[5]
- Millions in **potential savings**
- reduced **patient travel burden** [2]
- improved efficiency by 3-4x **more patients per FTE** vs face-to-face CR
- **Addresses gap 80% receiving no CR**[1]
- **Commonwealth benefits**: return to work productivity, reduced healthcare utilisation, quality of life

Current Funding Pathways

- **Public Hospitals:** Use NEP codes but lack budget clarity & implementation guidance
- **Private Insurance:** Direct licensing works but limits access to 45% with private cover
- **Primary Care:** No specific MBS codes, especially for nursing and allied health
- **Critical Gap**: No funding for hospital-to-community transition care
- **Quality Crisis:** Inconsistent CR delivery methods & low compliance to quality indicators

Key Learnings - "Cardihab-Specific Success Factors"

- **Hospital substitute positioning:** Access existing codes without new approvals
- **Evidence foundation:** RCT non-inferiority enabled substitute classification
- **Private insurance innovation:** Direct licensing created sustainable partnerships
- **Implementation guidance needed:** Code availability insufficient without budget clarity
- **Quality differentiation required:** Distinguish digital therapeutics and SaMD from telehealth consultation.

Source: (Beleigoli A, 2024) SA DataLink Study (Varnfield M, 2014) (Rivers JT, 2022) (Braver J M. T., 2025) (Braver J M. T., 2023) (Australin Institute of Health and Welfare, 12 Dec 2024) (Duscha BD, 2024). (Australian Institue of Health and Welfare) (Dang T, 2024), Cardihab website accessed June 2025.

A.1. Introduction

Cardihab stands as Australia's only TGA-registered digital therapeutic for cardiac rehabilitation (CR), representing a pioneering example of how digital health innovations can navigate the complex Australian funding and regulatory landscape whilst addressing critical gaps in cardiovascular care delivery. Currently classified as a TGA Class I device, the platform is transitioning to Class II following legislative changes implemented in November 2024.

This solution combines synchronous and asynchronous care, enabled by mobile application technology, guideline aligned care programs and structured telehealth consultations to deliver evidence-based CR that has demonstrated equivalent outcomes to traditional face-to-face programs, superior access and completion rates and significant reductions in hospital bed days and healthcare utilisation.

The solution can provide care programs for patients discharged following a broad spectrum of cardiovascular events and procedures. The therapeutic scope aligns with National Heart Foundation guidelines, encompassing acute coronary syndrome, myocardial infarction, as well as unstable angina. The platform accommodates a personalised approach to the specific requirements of cardiovascular disease management and secondary prevention CR.

Post-cardiac procedure and/or event patients can access the program with appropriate clinical clearance from their healthcare provider. In addition, people with a high risk of cardiac events or heart failure can benefit from specialised attention through program modules that address the unique clinical needs of these populations.

A.2. The challenge in cardiac rehabilitation

Despite the highest levels of evidence on CR effectiveness, its translation into practice is compromised by low participation. A recent South **Australia Data Linkage Study** (Beleigoli A, 2024) **reviewed** 84,064 eligible patients over 5 years, with <10% completing CR.

This study reveals the magnitude of the healthcare crisis that digital therapeutics could address:

- 84,064 CR eligible individuals identified over 5 years
- 88% did not receive any CR (74,189 people)
- Less than 10% completed CR (7,681 people)
- Women are 75% less likely to be referred to CR
- 5,767 cardiovascular deaths within 12 months after hospital admission
- 14,628 cardiovascular-related readmissions within 12 months after index hospitalisation.

A.3. The evidence and outcomes

A.3.1. Clinical evidence and outcomes

The platform's digital therapeutic's evidence base encompasses multiple peer-reviewed studies demonstrating clinical effectiveness, including **Varnfield et al. 2014** (Varnfield M, 2014)**:**

Randomised controlled trial showing non-inferiority to face-to-face cardiac rehabilitation, **Rivers et al. 2022** (Rivers JT, 2022)**:** Demonstrated improved uptake among patients declining conventional rehabilitation. **Braver et al. 2025** (Braver J M. T., 2025)**:** European Heart Journal study showing 12-month outcomes with sustained benefits and significantly reduced healthcare utilisation and bed days, demonstrating survival benefits, quality life year gains and cost effectiveness vs usual care.

CR body of evidence

- Any CR access was associated with lower mortality risk compared with not receiving CR (Braver J M. T., 2023)
- CR benefits extend up to 36 months after the index cardiac event (Braver J M. T., 2023)
- Each cardiac rehab session attended cuts readmission and death risk by 2% (Duscha BD, 2024)
- Digital cardiac rehabilitation was associated with significant reductions in all-cause hospitalisations, cardiac-related hospitalisations and emergency department visits (Braver J M. T., 2023)

Cardihab specific outcomes

- Improves survival with +1.434 QALY gained vs usual care (Braver J M. T., 2025)
- More cost-effective than usual care in 87% of scenarios (Braver **J M. T., 2025**)
- Readmission bed day reductions 71% (Braver J M. T., 2025)
- Improves uptake by 28% [80% vs 62%] (Varnfield M, 2014) and by 42% [63% vs 21%] (Rivers JT, 2022) particularly useful for those patients who find conventional CR impractical, inconvenient or unappealing
- Improves adherence by 26% [94% vs 68%] (Varnfield M, 2014)
- Improves completion rate 37% [80% vs 47%] (Varnfield M, 2014) and 91% versus historical 20-40% dropout rates for face-to-face programs (Braver J M. T., 2025)
- Significant improvements across cardiovascular risk factors including significant improvements in blood pressure, BMI, diet quality, and medication adherence (Braver J M. T., 2025), emotional state (anxiety and psychological distress) and improved health related quality of life (Varnfield M, 2014), physical activity levels doubled from baseline with sustained benefits at 12 months (Braver J M. T., 2025)

A.3.2. Patient experience and digital equity considerations

Cardihab demonstrates consistently high patient satisfaction across diverse implementation settings, with patients particularly valuing the convenience and accessibility of home-based delivery. The platform successfully reduces traditional barriers, including travel requirements that disproportionately affect older patients, regional and rural communities and individuals with limited transportation access. Many of these populations (such as those from lower socioeconomic status groups and non-urban areas) have higher rates of cardiovascular disease and less access to cardiac services, thus compounding health disparities. (Braver J M. T., 2025) Patients express strong appreciation for the therapeutic relationships maintained through nurse interactions, with medication management support proving especially valuable for those navigating complex post-cardiac event medication regimens.

The digital therapeutic addresses a gap by providing validated alternatives for patients who decline traditional face-to-face programs or cannot access programs due to extensive wait lists, ensuring these individuals receive essential secondary prevention care rather than no CR.. (Rivers JT, 2022)

Implementation shows a digital divide affecting equitable access. Technical literacy and personal preference for how to give/receive healthcare can hinder initial engagement with

digital health tools. This is observed through clinician reluctance to adopt digital solutions and the subsequent reluctance to offer these solutions to patients, as well as patients' preferences.

Language and cultural barriers can add to equity challenges in similar ways to conventional care. Barriers for Indigenous communities also exist and are further constrained by access to technology and infrastructure which may take years to overcome.

A.3.3. Cost effectiveness and efficiency gains

Healthcare system value emerges through documented reductions in hospital resource utilisation that translate directly into cost savings for health services managing constrained budgets and capacity limitations.

Cardihab demonstrates economic value through operational efficiency rather than simple cost reduction:

Implementation Costs:

- Annual licensing model
- Minimal patient costs (smartphone/internet connectivity, blood pressure cuff for hypertensive patients)
- No facility, equipment or space requirements compared to traditional programs

Implementation Efficiency:

- 2-hour training program for clinical staff
- No additional infrastructure requirements (utilises existing computers/phones)
- API integration available for health service analytics platforms

Healthcare System Benefits:

- 3-4 times more patients per FTE compared to conventional rehabilitation.
- Hospital bed day reductions compared with the usual care group: 71% (30-day), 71% (90-day), 51% (12-month) (Braver J M. T., 2025)
- Cardiac-related bed day reductions compared with the usual care group: 88% (30-day), 74% (90-day) (Braver J M. T., 2025)

System-Wide Impact:

- Reduced patient travel costs and geographic access barriers (Braver J M. T., 2025)
- Addresses eligible patients currently receiving no CR (approx. 80% did not receive CR) (Braver J M. T., 2023)
- Commonwealth benefits through improved productivity, reduced healthcare utilisation and enhanced quality of life

Cost-Effectiveness:

- 1.434 yrs QALY Gained (Braver J M. August 2025)
- $14,302 per quality year gained. Significantly lower than the $50k value threshold (Braver J M. August 2025)
- 87% of scenarios DeCR was the better value choice (Braver J M. August 2025)

In a scenario where conventional rehab was provided at reported 20% capacity, plus an additional 4000 patients per annum were provided Cardihab, we estimate:

- Net readmission savings of **$7.9m p.a. and**
- **16,000 bed days saved p.a.**

Workforce efficiency improvements through remote monitoring capabilities enable clinical staff to provide oversight for larger patient populations without proportional increases in clinical time investment or access to scarce facilities and gym equipment. This efficiency gain becomes particularly important in addressing the fundamental workforce constraints that limit traditional CR delivery across Australian. Health services across all settings, but in particular in regional, remote and rural settings, struggle to recruit and retain sufficient clinical staff to meet current demand.

The digital therapeutic addresses the fundamental economic challenge where approximately 80 per cent of eligible patients receive no CR, resulting in preventable readmissions and downstream healthcare utilisation costs that far exceed the investment required for appropriate secondary prevention interventions. Commonwealth benefits through improved workforce productivity, reduced healthcare utilisation, enhanced quality of life outcomes, and prevention of secondary cardiac events create system-wide value that extends beyond health service budgets to encompass broader economic and social benefits.

A.4. Current funding mechanisms and challenges

A.4.1. Public hospital

The public hospital funding landscape demonstrates both the opportunities and challenges facing digital therapeutics seeking sustainable funding within existing healthcare frameworks. Cardihab's utilisation of the hospital substitution Tier 2 Non-Admitted Services Classification code 40.21 for CR delivery provides a practical example of how validated digital therapeutics that demonstrate clinical equivalence, can leverage existing funding mechanisms without requiring entirely new funding structures.

Cardihab's digital therapeutic meets the hospital substitution criteria based on randomised controlled trial and real world study evidence demonstrating equivalence to face-to-face CR and therefore has access to the same funding mechanisms as traditional face-to-face programs for clinical services but not the software. This approach recognises that digital delivery represents an alternative rather than an additional service, supporting services funding through established healthcare funding frameworks that already acknowledge the clinical and economic value of CR.

However, implementation barriers reveal the complexity of translating funding code availability into practical funding access. Confusion regarding code usage and eligibility affects health service adoption, with many potential implementers unaware of available funding mechanisms or uncertain about appropriate application processes. The absence of accompanying funding guidance with code publication creates implementation challenges that require individual health services to develop their understanding of funding mechanisms.

Budget allocation ambiguity at the health service level represents perhaps the most significant barrier to broader adoption. Health services report having access to appropriate funding codes for services but not for the DTx and are lacking budget allocation clarity that would enable program implementation. This disconnect between funding mechanism availability and budget planning creates a situation where some funding exists in theory but remains inaccessible in practice.

A.4.2. Private healthcare networks

Private health insurance integration provides an alternative funding pathway that leverages existing CR benefits while demonstrating how digital therapeutics can extend coverage access without requiring benefit redesign. Direct licensing agreements with private health insurers create sustainable funding relationships that support national implementation through major insurers, whilst maintaining clinical oversight through qualified healthcare providers.

The Medibank case study demonstrates how private health insurers can expand member access to CR through digital delivery whilst maintaining cost effectiveness through improved completion rates and reduced healthcare utilisation. (Braver J M. T., 2025) Coverage through existing CR benefits ensures that digital delivery integrates seamlessly with established benefit structures rather than requiring new benefit categories that might face resistance or implementation delays.

Provider-based procurement and payment models enable health insurers to leverage their existing provider networks while expanding service delivery capability through digital platforms. This approach maintains clinical accountability through established provider relationships whilst enabling geographic service expansion that would be difficult or impossible to achieve through traditional face-to-face delivery models.

National implementation capability through major insurers demonstrates the scalability potential of digital therapeutics when appropriate funding mechanisms support broad adoption. However, this model's limitation to approximately forty-five per cent of Australians with private health insurance highlights the equity challenges that emerge when digital therapeutic access depends on insurance coverage rather than clinical need.

A.5. Other challenges

A.5.1. Transition from hospital to primary care

The gap between hospital and primary care in Australian healthcare funding impacts various interventions beyond CR. Limited funding for this "virtual healthcare space" hinders digital therapeutics during patient transitions from acute to community care.

New clinical pathways could be explored, including:

- MBS code development for nurses and allied health professionals is important for effective CR delivery
- Integrating Healthdirect to leverage existing Commonwealth-funded infrastructure for national digital therapeutic services.

A.5.2. Quality assurance and clinical governance challenges

The significant variability in conventional CR program quality across Australia necessitated the recent introduction of quality indicators and standards for CR implementation. Furthermore,

telehealth & phone-call-based programs often lack clinical governance and alignment with these quality indicators and guidelines.

These challenges in program variability are more easily overcome through standardised digital therapeutic solutions but successful integration into routine clinical implementation requires clinical workflow redesign, upskilling clinical workforce and change management to embrace efficient use of digital solutions.

A.6. Success factors and implementation learnings

A.6.1. Critical success factors

- **Robust clinical evidence and real world data:** Multiple peer-reviewed studies and platform dashboards demonstrating clinical and economic benefits
- **Crisis-driven adoption:** Health services facing capacity or outcome pressures are more receptive to innovation
- **Virtual care team integration and leadership:** Greater success via virtual care integration and enthusiastic leadership vs adding onto traditional CR workflows without service redesign
- **Clear value proposition:** nuanced yet clear value proposition by stakeholder type.

A.6.2. Key implementation insights

- **Evidence foundation essential:** TGA registration and clinical trials provide credibility for funding discussions
- **Multiple access pathways required:** Accommodating diverse healthcare system entry points and patient preferences
- **Patient centred and efficiency focus:** Digital therapeutics provide value through better patient engagement, operational efficiency and improved outcomes
- **Quality governance is important:** Distinguishing clinically validated and governed digital therapeutics from unvalidated approaches.

A.7. Conclusion

Cardihab's experience navigating Australian funding pathways demonstrates both the immense potential of digital therapeutics to transform healthcare delivery and the urgent need for purpose-built funding frameworks that recognise their unique value proposition.

A.8. References

1. Clinical effectiveness and utilisation of cardiac rehabilitation after hospital discharge: data linkage analysis of 84,064 eligible discharged patients (2016–2021). Beleigoli A, Foote J,

Gebremichael LG, Bulamu NB, Astley C, Keech W, et al. s.l. : Heart Lung Circ., 2024, Vols. 33(8):1036-45.

2. Smartphone-based home care model improved use of cardiac rehabilitation in postmyocardial infarction patients: results from a randomised controlled trial. Varnfield M, Karunanithi M, Lee CK, Honeyman E, Arnold D, Ding H, et al. 2014, Heart, pp. 100(22):1770-9.

3. The Impact of a Mobile App on Participation in Cardiac Rehabilitation and Understanding Barriers to Success: Comparative Cohort Study. Rivers JT, Smith C, Smith I, Cameron J. s.l. : JMIR Cardio, 2022, Vol. 6(1):e24174.

4. Effects of a digitally enabled cardiac rehabilitation intervention on risk factors, recurrent hospitalization and mortality. Braver J, Marwick TH, Salim A, Hakamuwalekamlage D, Keating C, Yiallourou SR, et al. s.l. : Eur Heart J Digit Health., 2025, Vols. 6(1):1-16.

5. Digital Health Programs to Reduce Readmissions in Coronary Artery Disease: A Systematic Review and Meta-Analysis. Braver J, Marwick TH, Oldenburg B, Issaka A, Carrington MJ. s.l. : JACC Adv., 2023, Vol. Sep 7;2(8):100591.

6. Australin Institute of Health and Welfare. Heart, stroke and vascular disease: Australian facts. [Online] 12 Dec 2024. https://www.aihw.gov.au/getmedia/61010c29-cd66-46c7-9d7d-de590c0c7788/heart-stroke-and-vascular-disease-australian-facts.pdf?v=20250619134216&inline=true.

7. A Detailed Analysis of Cardiac Rehabilitation on 180-Day All-Cause Hospital Readmission and Mortality. Duscha BD, Ross LM, Hoselton AL, Piner LW, Pieper CF, Kraus WE. s.l. : J Cardiopulm Rehabil Prev., 2024, Vols. Mar 1;44(2):99-106. doi: 10.1097/HCR.0000000000000835. Epub 2023 Dec 19. PMID: 38113355; PMCID: PMC10913862.

8. Australian Institute of Health and Welfare. Transition between hospital and community care for patients with coronary heart disease: key results 2013. [Online]

9. Hospital costs for unplanned readmissions within 30 days of hospitalisations with heart failure, Australia, 2013-2017: a retrospective cohort study. Dang T, Chan W, Khawaja S, Fryar J, Gannon B, Kularatna S, Parsonage W, Ranasinghe I. s.l. : Med J Aust, 2024, Vols. Sep 16;221(6):317-323. doi: 10.5694/mja2.52424. Epub 2024 Aug 27. PMID: 39188208.

10. Cost-effectiveness of a digitally enabled cardiac rehabilitation programme for patients with coronary heart disease, Justin Braver, Thomas H Marwick, Melinda J Carrington, Catherine Keating, Brian Oldenburg, Paul Scuffham, *European Journal of Preventive Cardiology*, 2025;, zwaf512, https://doi.org/10.1093/eurjpc/zwaf512

Appendix B Vantive case study

Vantive Remote Patient Management Solution Overview

- Comprehensive solution with three components: Homechoice Claria cyclers + Sharesource connectivity platform + MyPD patient mobile app
- Sharesource is the world's most evidenced remote PD patient monitoring technology with 100+ million treatments delivered globally
- TGA-registered medical device (Sharesource and Homechoice Claria cycler) with pilot electronic medical record (EMR) integration underway
- Evidence-based monitoring following Four Therapy Pillars: adherence, catheter function, fluid management, adequacy assessment
- Enables complete PD coverage: APD (automated) and CAPD (continuous ambulatory) enabled by MyPD with near real time/daily data transmission of therapy data, vitals, catheter photos
- Comprehensive care: Sharesource features a visual dashboard with colour-coded flags, remote prescription changes, photo review capability.

The Challenge -"The Reliance on Haemodialysis"

- 76% of patients receive in-centre haemodialysis (HD)vs only 24% home therapies[1]
- 6:1 patient: HD chair ratios in some centres running three shifts daily[1]
- 27% of HD units have non-operational chairs, many due to staffing shortages or funding[1]
- In-centre HD locations often force Indigenous patients to relocate from communities[1]
- Workforce constraints limiting HD chair capacity expansion[1]

Proven clinical outcomes of APD Patients With RPM"

- 45% lower all-cause mortality (p=0.006) in Mexican RCT[2]
- 51% lower cardiovascular mortality (p=0.04)[2]
- 69% lower hospitalisation for fluid overload/insufficient dialysis (p=0.03)[2]
- 3.2 months longer technique survival on PD therapy[2]
- 77% increase in technique survival for APD with RPM[2]
- 10% improvement in blood pressure control[2]
- 50% reduction in daily antihypertensives[2]

Economic Impact of APD Patients With RPM

- $23,000 annual cost savings per patient (US simulation study)[2]
- 1-2 fewer hospitalisations per patient annually[2]
- 2-5 fewer emergency room visits per patient[2]
- 1-4 fewer home visits per patient[2]
- 4-8 fewer unplanned clinic visits per patient[2]
- 32% increase in proactive care activities[2]
- 17% decrease in reactive tasks[2]
- Eliminates patient travel costs and geographic barriers
- Enables dialysis "on country" for Indigenous communities

Current Funding Pathways

- Public Hospitals: Single PD funding code covers all costs - technology, consumables, nursing - no RPM recognition
- No separate recognition or funding for remote monitoring activities, regardless of care quality
- No mechanism to capture or reward improved patient outcomes
- Budget allocation decisions left entirely to individual hospital discretion
- Competitive disadvantage: Identical funding regardless of RPM provision vs non-RPM competitors.

Key Learnings - "Vantive-Specific Success Factors"

- **Strong commercial relationships:** Built on established company trust since 2017
- **Robust evidence foundation:** International RCT data demonstrating clinical and economic benefits
- **Equipment loan model:** Cyclers and modems provided on loan, reducing capital expenditure barriers
- **Clinical champion development:** Early adopter sites became advocates through peer influence
- **Comprehensive training:** Competency-based programs with ongoing optimisation support

Source: (Sabanayagam D, 2025) (Vantive), Vantive website accessed June 2025, Vantive Sharesource Global Treatment Data. Accessed August 2025.

B.1. Introduction

The Vantive Remote Patient Management system provides visibility into peritoneal dialysis (PD) patients' at-home treatments, enabling clinicians to identify problems sooner and take actions to maximise the potential of PD with timely, accurate data and the ability to enter and adjust device programs remotely. It is a digital health solution that can help address Australia's dialysis capacity crisis while delivering superior clinical outcomes. With over 100+ million treatments delivered globally, the solution demonstrates how remote monitoring can support home dialysis care delivery.

The Vantive remote patient monitoring solution integrates three core components: Homechoice Claria automated peritoneal dialysis (APD) cyclers with connectivity, the Sharesource web-based clinical platform providing real time patient management, and the MyPD patient mobile app that enables continuous ambulatory peritoneal dialysis (CAPD) patients to enter therapy data, and collection of vitals for APD and CAPD patients via Bluetooth-connected devices or manual entry. The information visible in Sharesource is transmitted from the Claria via a modem and shared from MyPD. Both the cycler and Sharesource platform hold TGA registration as medical devices, with pilot electronic medical record (EMR) integration currently underway with NSW Health as part of their single digital patient record initiative. The Sharesource platform integrates four key pillars—adherence monitoring, catheter function assessment, fluid management oversight and adequacy assessment—to ensure comprehensive patient monitoring and optimal dialysis treatment. Remote monitoring transforms nursing workflow from reactive to proactive care delivery. The visual dashboard employs colour-coded flags (red, yellow, green), enabling nurses to triage 20-100 patients at a glance and identify priority cases requiring immediate attention. This approach allows clinical teams to intervene early when trending data suggests potential issues, potentially even before patients experience symptoms.

B.2. The challenge of dialysis access

Australia faces a significant dialysis capacity crisis characterised by overwhelming reliance on resource-intensive in-centre haemodialysis and inadequate utilisation of home-based therapies. Current statistics reveal that 76% of patients receive in-centre haemodialysis while only 24% access (Sabanayagam D, 2025) home dialysis options, creating pressure on healthcare infrastructure and limiting patient access to optimal care.

The crisis manifests through multiple interconnected challenges (Sabanayagam D, 2025):

- Capacity constraints force some centres to accommodate up to six patients per haemodialysis chair, with centres in Western Sydney operating three dialysis shifts daily to manage patient demand
- Workforce limitations compound capacity issues, with 27% of dialysis units reporting non-operational chairs, many due to staffing shortages or funding limitations that prevent full facility utilisation
- Treatment failure rates exceed 50% for Australian PD patients after five years, forcing transitions to in-centre haemodialysis and further straining system capacity

- Geographic inequities particularly affect Indigenous communities, where patients must relocate from remote areas to access dialysis services in major centres like Darwin, Alice Springs or Cairns, disrupting cultural connections and family support systems.

B.3. The evidence and outcomes

B.3.1. Clinical evidence and outcomes

The effectiveness of the Sharesource platform is supported by evidence from a randomised controlled trial and observational studies across diverse healthcare systems, including a Mexican cluster-randomised trial (Paniagua R, 2025) Paniagua et al. involving 21 hospitals with 403 remote monitoring patients versus 398 conventional patients, and a Spanish prospective multicentre cohort study (Centellas-Pérez FJ, 2024) Centellas-Pérez et al. using propensity-matched analysis of 232 patients recruited at 16 Spanish Hospitals.

The key clinical outcomes include:

- 45% lower incidence of all-cause mortality (p=0.006) (Paniagua R, 2025)
- 51% lower incidence of cardiovascular-specific mortality (p=0.04) (Paniagua R, 2025)
- 69% lower incidence of hospitalisations due to fluid overload and/or insufficient dialysis efficiency (p=0.03) (Paniagua R, 2025)
- lower mortality rate with RPM versus without RPM (Centellas-Pérez FJ, 2024)
- Significantly better technique survival outcomes (Centellas-Pérez FJ, 2024)
- Lower rates of adverse cardiovascular events (Centellas-Pérez FJ, 2024)

Technique survival benefits across multiple studies demonstrate:

- 3.2 months longer technique survival for APD patients with RPM
- 77% increase in technique survival for APD with RPM

Additional clinical outcomes include:

- 10% increase in ultrafiltration
- 10% improvement in blood pressure control
- 50% reduction in daily antihypertensive medications
- Enhanced adherence through objective monitoring versus patient self-reporting

Source: (Vantive) Vantive Sharesource evidence

B.3.2. Patient experience and digital equity considerations

Patient satisfaction data (Vantive) reveals consistently high usability ratings for the MyPD mobile application:

- Interface and satisfaction: 6.8/7
- Ease of use: 6.6/7
- Usefulness: 6.1/7

Patients consistently report "incredible comfort" knowing their clinical team monitors treatment data and can identify issues before they become serious. This peace of mind proves particularly valuable during the initial months when patients feel nervous about performing dialysis correctly at home. The platform's photo sharing capability enables secure transmission of exit site and drainage bag images, allowing efficient clinical review of evidence, which could allow

earlier diagnosis of infectious complications. Geographic access to dialysis reduces patient travel costs, crucial for those in remote areas, allows Indigenous patients to receive treatment "on country," preserving cultural and family ties, and lessens carer burden as well as productivity losses for families.

B.3.3. Cost effectiveness and efficiency gains

Multiple international studies demonstrate significant healthcare resource savings from PD and remotely monitored PD that translate directly into system-wide economic benefits and operational efficiency gains.

Direct cost reductions:

- $23,000 annual cost savings per patient (US simulation study) (Vantive)
- $121,233 savings per 100 patients annually (Colombian study) (Ariza JG, 2020)
- $3,256 annual savings per patient (Australian health economics extrapolation) (Baxter, 2023)

Resource utilisation improvements:

- 1-2 fewer hospitalisations per patient annually (Vantive)
- 2-5 fewer emergency room visits per patient (Vantive)
- 1-4 fewer home visits per patient (Vantive)
- 4-8 fewer unplanned clinic visits per patient (Vantive)

Workflow optimisation:

- 32% increase in proactive activities versus 17% decrease in reactive tasks (Vantive)
- Automated data collection eliminates manual record-keeping for APD patients
- Visual dashboard enables rapid patient triage and clinical decision-making

Quality assurance:

- Standardised monitoring protocols across all patients, regardless of location
- Objective data replaces subjective patient reporting with measurable treatment parameters
- Consistent clinical responses through customisable flag-based alerts

System-wide economic impact

The economic value proposition extends beyond direct healthcare savings to encompass broader productivity and social benefits:

Commonwealth benefits:

- Workforce productivity improvements through reduced patient disability and earlier return to employment
- Infrastructure savings through reduced demand on dialysis chair capacity
- Quality improvement through consistent monitoring standards across diverse geographic locations

Patient and family benefits:

- Eliminated travel costs, creating particular value for remote and rural patients
- Reduced productivity losses through fewer clinic visits and hospitalisations
- Enhanced quality of life through home-based treatment and maintained community connections

B.4. Current funding mechanisms and challenges

B.4.1. Public hospital

The public hospital funding landscape for Vantive Sharesource and MyPD reveals significant structural challenges within existing healthcare funding frameworks. The current funding structure operates through a single PD code that provides hospitals with a predetermined allocation based on national efficient pricing, regardless of whether remote patient monitoring is utilised. Hospitals then distribute this funding internally to cover all PD-related costs, including

consumables, nursing staff, equipment and any additional services such as remote monitoring. This creates a fundamental inequity where hospitals using the Vantive remote patient monitoring solution receive identical funding to those providing conventional PD without any remote monitoring capabilities.

According to the National Hospital Cost Data Collection, the average monthly cost of delivering PD is reflected across multiple cost buckets, including nursing staff, consumables, equipment and overhead costs. However, there is no mechanism within this system for hospitals to separately report or claim funding for remote patient activities. Hospital administrators must absorb all Sharesource subscription costs from their existing PD allocation, despite the platform delivering demonstrable improvements in patient outcomes and system efficiency.

The current funding model creates a situation where hospitals investing in superior technology and achieving better patient outcomes—including reduced hospitalisation rates and improved treatment adherence—receive no additional revenue recognition. This misalignment fundamentally undermines incentives for innovation adoption and fails to capture the broader system benefits that remote monitoring delivers.

Health services report varying levels of awareness regarding funding mechanisms, with significant confusion about how to allocate budgets for remote patient monitoring implementation within existing cost structures. The absence of specific guidance accompanying funding codes creates implementation barriers even where theoretical funding pathways exist.

Despite funding limitations, widespread adoption among Vantive customers demonstrates that clinical value can override pure cost considerations in healthcare decision-making. This is despite the fact that public hospitals acquire remote patient monitoring through competitive tender processes, which can often be focused on costs rather than additional clinical benefits and operational efficiency.

The National Benchmarking Portal data shows substantial variation in reported PD costs across hospitals, ranging from as low as $37 per month (likely reflects a reporting or coding anomaly rather than true PD delivery costs) to significantly higher amounts, reflecting inconsistencies in cost reporting and coding practices that further complicate funding clarity.

B.4.2. Private healthcare networks

Private health insurance presents limited opportunities within the current Australian healthcare structure, as PD is exclusively provided through the public hospital system. Unlike in-centre haemodialysis, which operates in both public and private settings, PD remains solely within public health service delivery models.

However, private health insurers do offer assisted home haemodialysis services, recognising that home-based dialysis with nursing support costs less than in-centre treatments. This model demonstrates the private sector's willingness to fund alternative care delivery approaches when cost benefits are established.

B.5. Other challenges

B.5.1. Implementation challenges and solutions

- **Security Assessment Complexity Underestimated**: Privacy and security evaluations required significantly more time and resources than initially anticipated. Some health services conduct annual security reassessments, creating an ongoing administrative burden and costs that were not fully anticipated during initial planning.
- **Clinical Adoption Variability:** Limited adoption among some nephrologists who prefer printed reports, with generational differences affecting technology engagement. The MyPD app is expected to drive increased clinician engagement through patient initiative.
- **Connectivity Limitations:** Remote area internet limitations affected some implementations, though improving satellite technology is expanding access possibilities.
- **Quality assurance and clinical governance.** Variability in PD delivery quality across Australia creates challenges for establishing appropriate funding frameworks. Current funding mechanisms do not differentiate between comprehensive remote monitoring programs and minimal "phone call-only" consultations, despite significant differences in clinical value and resource requirements. This lack of quality differentiation potentially undermines incentives for investing in comprehensive platforms like Sharesource, as hospitals receive identical funding regardless of the sophistication and effectiveness of their monitoring approaches.

B.5.2. Assisted PD innovation

Perhaps the most significant funding barrier identified relates to assisted PD—a service model that would allow consideration of PD by patients who are physiologically suitable for PD but cannot perform the treatment independently due to physical limitations such as reduced dexterity, visual impairment, or inability to manage the physical demands of treatment setup or are not confident to perform therapy at home without supervision. Currently, many patients who could benefit from home-based PD must receive in-centre haemodialysis because they cannot independently manage treatment requirements. An assisted PD model would involve trained support workers visiting patients' homes one or two times daily to help with treatment setup and disconnection, while patients perform the actual dialysis independently. This model:

- **is a cost-effective alternative:** Lower cost than assisted home haemodialysis while maintaining PD benefits and remote monitoring capabilities.
- **could expand eligibility:** Enable PD access for patients currently requiring in-centre haemodialysis due to physical limitations rather than clinical contraindications, or who are lacking confidence to undertake therapy at home.
- **but has no funding model to support this innovative model.**

B.6. Success factors and implementation learnings

B.6.1. Critical success factors

- **Strong commercial relationships and trust**: The successful rollout of Sharesource was built upon existing relationships and trust established over many years of equipment, consumable and service provision.
- **Clinical evidence foundation**: The availability of evidence from randomised controlled trials and real world studies proved important for overcoming institutional resistance, even though the data was not Australian-specific.
- **Operational efficiency value proposition**: The ability to manage 3-4 times more patients per full-time equivalent staff member through remote monitoring resonated strongly with resource-constrained hospitals.
- **Integrated workflow design**: Success required positioning remote monitoring management as a workflow enhancement rather than an additional burden. The visual dashboard approach, enabling rapid patient triage and prioritisation, proved essential for clinical adoption. Equally important was the app's role in keeping patients and clinicians connected — enabling secure, real-time sharing of data that supported proactive intervention, early issue identification and more continuous, coordinated care.

B.6.2. Key implementation insights

- **Evidence Foundation Critical:** International clinical trial data proved essential for clinical acceptance, demonstrating that Australian-specific data is not required for adoption when robust global evidence exists.
- **Commercial Model Innovation:** Monthly subscription scaled to unit size provided a predictable cost structure while loan-based equipment reduced capital barriers.
- ➢ **Clinical Champion Development:** Early adopter sites became advocates for broader implementation, with peer-to-peer influence proving more effective than vendor promotion.
- **Case Study Reinforcement:** Ongoing research and outcomes data strengthened adoption decisions and provided confidence in clinical value delivery.

B.7. Conclusion

The Vantive Sharesource experience demonstrates both the transformative potential of remote patient monitoring coupled with digital health tools (like patient mobile application) and the urgent need for funding frameworks that recognise digital health innovation value.

The Vantive Sharesource experience demonstrates both the transformative potential of remote patient monitoring and the urgent need for funding frameworks that recognise digital health innovation value.

B.8. References

1. Dialysis care in Australia: a call for reform and innovation. Sabanayagam D, Makris A, Sciberras F, Scholes-Robertson NJ, Wong G. s.l. : Med J Aust, 2025, Vols. 202(1):1-3. doi: 10.5694/mja2.52672.

2. Vantive. Enhance your PD program with the Sharesource connectivity platform.

3. Remote monitoring of automated peritoneal dialysis reduces mortality, adverse events and hospitalizations: a cluster-randomized controlled trial. Paniagua R, Ramos A, Ávila M, Ventura MJ, Nevarez-Sida A, Qureshi AR, et al. s.l. : Nephrol Dial Transplant, 2025, Vols. 40(3):588-597.

4. Impact of remote monitoring on standardized outcomes in nephrology-peritoneal dialysis. Centellas-Pérez FJ, Ortega-Cerrato A, Vera M, Devesa-Buch RJ, Muñoz-de-Bustillo E, Prats M, et al. s.l. : Kidney Int Rep., 2024, Vols. 9(2):266-276.

5. Evaluating a remote patient monitoring program for automated peritoneal dialysis. Ariza JG, Walton SM, Sanabria M, Bunch A, Vesga J, Rivera A. s.l. : Perit Dial Int., 2020, Vols. 40(4):377-383.

6. Baxter. PD Academy. 2023.

Appendix C BIOTRONIK HMcase study

BIOTRONIK Cardiac Device Home Monitoring (HM) Platform Overview

- World's pioneering remote cardiac monitoring technology - TGA-registered since 2005
- Cardiovascular implantable electronic devices + Berlin-based Home Monitoring Service Centre
- Global reach: Over 160 countries worldwide
- Evidence-based: 7 randomised controlled trials with 3,800+ patients
- Comprehensive coverage: Pacemakers, ICDs, CRT devices and insertable cardiac monitors

The Challenge - "Remote Monitoring Access Opportunity"

- **Resource-intensive** requiring multiple healthcare personnel[1]
- **71-93%** of conventional in-clinic follow-up visits are "non-actionable" requiring no intervention[1]
- **98% of days unmonitored** with conventional calendar-based follow-ups[1]
- **35-145 days delay** in cardiac event detection with conventional care[1]
- **26% decline** in patient adherence over 12 months with conventional care[1]
- **Technical failures undetected** for 1.9-4.9 months visits[1]
- **Patient inconvenience:** 35% find in-clinic visits inconvenient due to travel/age factors[1]

Clinical Evidence -"Proven clinical outcomes"

- **50% mortality reduction** in heart failure patients[1]
- **37% risk reduction in worsening composite clinical score with worsening heart failure[1]**
- **84% vs 65% adherence** at 12 months compared to conventional follow-up[1]
- **Non-inferior safety** with superior cardiac event detection across all studies[1]
- **Superior technical event detection** - nearly twice the rate vs conventional care[1]
- **Inappropriate shock reduction**: 50-77% reduction in inappropriate shock[1]
- **High patient satisfaction:** 97% satisfied and wish to continue using technology[1]

Economic Impact -"Healthcare and System Value"

- **Reduced hospitalisation:** Two-thirds reduction in arrhythmia/stroke admissions[1]
- **Shortened hospital stays:** 34% reduction in stay duration without safety compromise[1]
- **Cost-neutral to cost-saving** across multiple healthcare systems[1]
- **45-73% reduction** in in-clinic follow-up[1]
- **Extended device longevity:** 7.9-11 months additional battery life[1]

Current Funding Pathways

- **MBS codes approved:** Current fees $75-$216 annually for monitoring
- **Prescribed List:** $1,450 for CardioMessenger (reduced from $1,960)
- **Funding gaps:** Technical service support affected by PL benefit reductions across all CIED pricing, impacting comprehensive service delivery
- **Provider incentive misalignment:** barrier of episode-based payment outside the hospital
- **Public sector implementation barriers:** Budget allocation clarity needed in public sector

MSAC Challenges

- Traditional prostheses frameworks do not fit digital
- Difficulty recognising digital therapeutic value
- Protracted evidence development timelines 8-year assessment vs immediate international clinical benefits

Key Learnings - "BIOTRONIK HM-Specific Success Factors"

- **Robust evidence foundation:** 7 RCTs and MSAC approval provided regulatory credibility
- **Proven clinical superiority:** Only remote monitoring system demonstrating mortality reduction
- **Global infrastructure advantage:** Berlin-based service centre supporting 160+ countries
- **Automatic transmission:** Minimal patient interaction required, improving data integrity
- **Funding challenges:** PL benefit reductions threaten service sustainability, PL narrow device definitions, inpatient coverage only slow and limit innovation
- **Clinical Engagement:** extensive timelines in guideline directed therapy/diagnostic adaptation and adoption to fast evolving digital solutions.

C.1. Introduction

BIOTRONIK Cardiac Device Home Monitoring represents a pioneering remote cardiac monitoring technology, standing as Australia's first TGA-registered system since 2005[3]. The platform combines automatic transmission of cardiovascular implantable electronic device (CIED) data through the patients CardioMessenger® with data management at the Berlin-based Home Monitoring Service Centre. This platform not only allows physicians to safely and securely review patient cardiac rhythm information but also sends alerts in response to clinician determined relevant changes in cardiac and device status, thereby facilitating near continuous surveillance of both the patient's condition and the device. Today, Home Monitoring reaches more than 160 countries worldwide, supported by a comprehensive evidence base in remote cardiac monitoring.

The model of care for remote monitoring is currently in flux due to convergence of several macro drivers including increased burden of chronic diseases, broader digitalisation and data deluge trends in healthcare, technologies that can shape care models and bring patients into the care loop, shortage of skilled healthcare workforce, and the need to do more with fewer resources. These macro drivers are driving capital investments towards virtual and hybrid models of care (such as hospital-in-the-home, virtual hospitals, remote clinics), which will require suitable funding design and structure to incentivise ongoing investment and innovation. This larger trend sits above the current models of care for remote monitoring of CIEDs in cardiac patients and will inevitably impact how these services develop and are delivered and funded.

The BIOTRONIK system provides monitoring for patients with various CIEDs including pacemakers, implantable cardioverter defibrillators, cardiac resynchronisation therapy devices and insertable cardiac monitors. The platform's evidence foundation encompasses seven randomised controlled trials enrolling more than 3,800 patients with CIEDs, demonstrating the ability to safely replace in-office follow-up visits whilst detecting clinical and technical events earlier than conventional care.

C.2. The challenge: conventional calendar-based follow-up limitations

Current CIED management requires patients to attend regular, calendar-based, in-clinic follow-up visits to monitor device function and assess patient health status. This approach places considerable burden on healthcare infrastructure whilst lacking continuous monitoring. Multiple studies demonstrate the significant limitations of this traditional care model, highlighting the urgent need for more efficient monitoring solutions.

The key challenges with conventional follow-up include:

- Resource-intensive requirements: CIED management requires specialised input from cardiologists, nurses and technicians with visits every three to six months
- Inefficient resource utilisation: RCTs and observational studies report that 62% to 100% of event-triggered follow-up visits are actionable, compared with just 7% to 29% of conventional calendar-based follow-up visits

- Limited monitoring coverage: Even the most frequent calendar-based follow-up schedules leave 98% of days unmonitored
- Significant event detection delays: Median time from symptomatic event onset to physician evaluation of 35.5 days, and asymptomatic events 41.5 days (TRUST trial, n=1,339)
- Extended cardiac event delays: Average time from cardiac event onset to physician evaluation of 145 days in pacemaker patients (COMPAS trial, n=494)
- Declining patient adherence: Patient adherence to scheduled in-clinic follow-up visits declined by 26% over 12 months (TRUST study)
- Patient inconvenience factors: Advanced age, need for accompaniment, and travel time contribute to 35% of patients describing in-clinic follow-up as inconvenient
- Technical event detection failures: an observational study of 69 patients with ICDs and CRTs found the average time from device failure to follow-up visit of 1.9 months (3-monthly visits) and 4.9 months (6-monthly visits)
- End-of-device-life management issues: Results of a study of 218 postmortal explanted IPGs found 20% of explanted devices had surpassed recommended replacement time, with 8% being non-functional

C.3. The evidence and outcomes

C.3.1. Clinical evidence and outcomes

BIOTRONIK Home Monitoring is supported by a comprehensive evidence base in remote cardiac monitoring, encompassing multiple peer-reviewed studies demonstrating clinical effectiveness including: **TRUST (2010):** Landmark randomised controlled trial (n=1,339) demonstrating safety and superior event detection in ICD patients; **COMPAS (2012):** Randomised trial (n=494) showing reduced hospitalisation and earlier event detection in pacemaker patients; **IN-TIME (2014):** Pivotal heart failure study (n=667) demonstrating >50% mortality reduction; **ECOST (2013):** Economic and safety trial (n=433) showing reduced inappropriate shocks and extended device longevity; **EuroEco (2015):** Health economic trial (n=303) demonstrating cost-neutral implementation across five European countries; **REFORM (2014):** Follow-up optimisation study (n=155) validating reduced clinic visits; **OEDIPE (2008):** Early discharge safety study (n=379) showing reduced hospitalisation duration. These seven randomised controlled trials, enrolling more than 3,800 patients, all demonstrate National Health and Medical Research Council (NHMRC) evidence level II ranking.

The key clinical outcomes include:

- **Significant mortality reduction:** >50% reduction in cardiovascular mortality (3.4% vs 8.7%, HR 0.36 [0.17-0.74], p=0.004) in heart failure patients (IN-TIME study, n=667)
- **Superior clinical outcomes with worsening heart failure:** 37% risk reduction in worsening composite clinical score (18.9% vs 27.2%, p=0.013) in IN-TIME study
- **Maintained patient adherence:** 84% adherence at 12 months vs 65% with conventional follow-up (p<0.001) in TRUST study[15]
- **Inappropriate shock reduction:** 50% reduction in patients receiving inappropriate shocks (ECOST trial)[42] and 77% reduction in single-centre study (p=0.0001)
- **Superior event detection:** Time from event onset to physician evaluation reduced from up to 40 days to < 6 days (p < 0.001)
- **Technical event detection improvement:** Nearly twice the number of technical events detected compared to conventional care (0.055 vs 0.027 events per patient year, p=0.005)

C.3.2. Patient experience and digital equity considerations

BIOTRONIK Home Monitoring demonstrates consistently high patient satisfaction across diverse implementation settings, with 97% of patients reporting satisfaction with the technology and wishing to continue using it for their CIED management[27]. Patients particularly value the convenience and psychological reassurance provided by continuous monitoring, knowing they are connected to a network that monitors their condition. The automatic transmission feature of Home Monitoring addresses digital literacy concerns by requiring minimal patient engagement in network operation. However, implementation does reveal digital equity challenges, including technical issues that can hinder initial engagement and differences between device platforms that may affect access. Language and cultural barriers present additional equity considerations, increasing development costs for translating medical device instructions and requiring tailored solutions for diverse populations. Despite these challenges, patients consistently report health related quality of life equivalent to those receiving conventional care, with no increased fear, anxiety, or depression demonstrated across multiple randomised controlled trials (COMPAS, REFORM, OEDIPE, EuroEco), while benefiting from the therapeutic relationships maintained through structured clinical oversight and medication management support.

C.3.3. Cost effectiveness and efficiency gains

Healthcare System Value (1)

- Reduced hospitalisation rates: Total hospitalisations due to atrial arrhythmia and stroke reduced by two-thirds ($p<0.05$) compared to conventional care (COMPAS trial)
- Shortened hospital stays: Protocol-driven hospitalisation in IPG duration 34% shorter ($p<0.001$) without compromising safety (OEDIPE trial)
- Extended device longevity: 7.9 months additional ICD battery life (95% CI: 2.6-13.2 months, $p=0.005$) through 76% reduction in capacitor charges and 11 months extra pacemaker longevity

Economic evaluations demonstrate cost-neutral to cost-saving outcomes across multiple healthcare systems:

- OEDIPE trial: €290 per patient savings through safe early discharge following pacemaker implantation/replacement
- ECOST trial: €257 per ICD patient annual outpatient cost savings
- EuroEco trial: €574 per patient savings over two years
- UK long-term model: Cost-neutral implementation with £11,500 per average patient over ten years

Efficiency Gains - Home Monitoring enables healthcare systems to manage more patients per FTE compared to conventional programs through:

- Elimination of unnecessary in-clinic visits (71-93% are non-actionable)
- Automated data transmission requiring minimal patient interaction
- Task redistribution allowing physicians to focus on clinical decision-making

C.4. Current funding mechanisms and challenges

C.4.1. Public hospital

Public hospital implementation of Home Monitoring faces complex funding challenges despite the availability of established funding mechanisms. While MSAC approved remote monitoring in 2014 following comprehensive health technology assessment, establishing the clinical and

economic evidence base for public funding consideration, the actual implementation relies primarily on state-based hospital budgets and tendering processes rather than direct federal funding. Most large Local Health Districts include remote monitoring in their tender requirements, but implementation is constrained by limited budgets and infrastructure capacity, with hospitals typically unable to provide coverage to all eligible patients due to resource limitations. The system is further complicated by the absence of dedicated funding for technical service support, as public hospitals must rely on employed cardiac physiologists or contracted services to provide the technical oversight previously supported through industry arrangements in the private sector. Consequently, coverage rates in public hospitals average 60-70% compared to over 90-95% in the private sector, with many hospitals restricting access to high-priority patients such as ICD recipients while excluding other patients. This creates a two-tiered system where access to evidence-based remote monitoring technology is determined by hospital capacity and budget allocation rather than clinical need, despite the demonstrated clinical and economic benefits that support open access.

C.4.2. Private healthcare networks

Private healthcare integration represents the most successful funding pathway for Home Monitoring, combining MSAC approved MBS codes for clinical services with Prescribed List coverage for device funding to create comprehensive funding mechanisms. MSAC's 2014 approval established specific MBS codes that enable private cardiologists to claim annual monitoring fees ranging from $75-$216 depending on device type, reflecting the clinical complexity and resource requirements of different cardiac devices. These codes are regularly updated through cardiac service reviews and include both annual monitoring services and event-triggered consultation fees equivalent to face-to-face consultations, ensuring appropriate remuneration for clinical oversight. However, cardiologists report that the MBS fees are insufficient to cover the workload generated by continuous monitoring data, which can lead to out-of-pocket charges of up to $400 annually for comprehensive remote monitoring services discouraging patients from staying on remote monitoring. Another concern is that it creates significantly more work for doctors, who now have continuous access to patient data around the clock. Device funding is provided through the Prescribed List, with the CardioMessenger covered at $1,450 (reduced from the original $1,960), including the transmitter device, network connectivity and industry technical service support, though progressive benefit reductions have affected service sustainability. This multi-layered funding approach - combining MBS professional fees and Prescribed List device funding, and direct industry technical support - enables comprehensive coverage for private patients, resulting in over 90% adoption rates among eligible private patients. However, the model's limitation to approximately 55% of Australians with private health insurance, combined with inadequate MBS fee levels that necessitate patient co-payments, highlights ongoing challenges in achieving truly equitable access to this evidence-based technology across all patient populations.

C.5. Other challenges

C.5.1. Provider incentive misalignment

A key barrier against wider adoption of remote monitoring is the current design of provider incentives and how payments are structured around episodes of care (such as a hospitalisation episode which requires inpatient treatment for a defined period that creates revenue for providers). This creates significant limitations around widespread use of continuous remote monitoring technology as it fragments care between in patient and community settings with multiple friction points between them, making it difficult for providers to justify. The current funding structure inadequately recognises the continuous nature of remote monitoring services. While conventional follow-up visits generate discrete billing opportunities, the ongoing surveillance and data analysis required for effective remote monitoring creates sustained clinical workload without proportional funding recognition. This structural challenge requires funding reform to align provider incentives with the continuous care model that remote monitoring enables.

C.5.2. MSAC/Prescribed List process challenges

The MSAC assessment process, while ultimately successful, revealed significant challenges in evaluating digital health technologies within frameworks designed for traditional medical interventions. BIOTRONIK's journey through MSAC spanned eight years from initial submission to final approval (2007-2015), with an earlier 2008 application being rejected when MSAC found the procedure safe but could not demonstrate clinical effectiveness, preventing formal economic assessment. The protracted timeline created substantial lost opportunities for patient access to remote monitoring during a period when the technology was already demonstrating clinical benefits internationally.

In establishing a fee-for-service model for remote monitoring, alignment with pre-remote monitoring practices was sought to demonstrate the delivered value, but as a result the MBS construct for clinical support of remote monitoring had a restricted lens.

Further the PL process when considering the device/digital architecture components struggled with fundamental definitional challenges, as digital platforms like remote monitoring do not meet traditional definitions of prostheses or implants, requiring navigation through Part C of the Prescribed List at ministerial discretion rather than established pathways. MSAC's 2014 deferral highlighted specific concerns about transmitter costs, questioning the suitability of the technology for Prescribed List funding and requiring additional economic modelling to account for device costs - issues that reflected the committee's uncertainty about how to evaluate integrated digital health solutions. The evidence requirements proved particularly challenging for digital technologies, with MSAC expressing concerns about cost utility when survival benefits were achieved with the same number of office visits, demonstrating difficulty in recognising the value proposition of digital therapeutic platforms that fundamentally change care delivery models rather than simply substituting existing services.

C.5.3. Technical Service Support

Technical service support (TSS) is generally a requirement to maintain the information ecosystem and all the architecture outside the medical device specific issues. This has been provided in the privately insured population by cardiac device companies. The TSS component is supported by Prescribed List benefits embedded in the pricing of both the CardioMessenger and the broader CIED configurations, both of which have experienced progressive erosion over time. This dual impact significantly affects the sustainability of comprehensive technical support services by cardiac device companies that are important to successful remote monitoring implementation.

C.5.4. Quality assurance and clinical governance challenges

Quality assurance challenges emerge from variable service delivery models that allow inadequate approaches to claim equivalence with comprehensive platforms demonstrated in clinical trials. The current framework requires stronger clinical governance to distinguish legitimate therapeutic interventions from minimal consultation approaches, ensuring patients receive full clinical benefits. This necessitates standardised training and accreditation programs for technical staff across all provider models, maintaining the clinical oversight and technical expertise that enabled superior outcomes in the evidence base whilst developing sustainable funding mechanisms for comprehensive rather than fragmented service delivery.

C.5.5. Limits to further innovation

Australia has invested in a digital platform that enables the remote monitoring of a patient's CIED. This platform has the capabilities to innovate and expand, delivering improved quality of life and productivity efficiencies in managing this high acuity chronic patient cohort. Remote Monitoring is the start of the journey, as the digital journey grows, we see the development of smart algorithms, alignment with other technologies in managing comorbidities, patient behavioural engagement etc. that will inform and enrich patients' lives.

The PL does currently not incentivise this potential expanded capability in developing the digital journey.

C.6. Success factors and implementation learnings

C.6.1. Critical success factors

- **Evidence Foundation.** Multiple peer-reviewed studies demonstrating clinical and economic benefits provided credibility for funding discussions and regulatory approval through both TGA registration and MSAC assessment.
- **Infrastructure Advantage.** Berlin-based global service centre provides 24/7 monitoring capability, global mobile network coverage with minimal local infrastructure requirements, enabling rapid implementation across diverse healthcare settings.

- **Automatic Operation.** Unlike competitor systems requiring patient interaction, BIOTRONIK's Home Monitoring's automatic transmission ensures superior data integrity and patient adherence whilst minimising training requirements.

C.7. Conclusion

BIOTRONIK's Home Monitoring demonstrate the potential for remote monitoring to transform cardiovascular care delivery whilst navigating complex funding landscapes. The platform's success in achieving both clinical and economic benefits, supported by the most comprehensive evidence base in remote cardiac monitoring, provides a model for digital health innovation implementation.

The direct opportunity in developing the digital health funding landscape is to build on BIOTRONIK's investment and encourage further innovation on the back of the existing cardiac Home Monitoring platform technology which connects to tens of thousands of actively monitored patients throughout remote/rural/regional/metropolitan Australia.

C.8. References

1. BIOTRONIK. Home Monitoring: The Value of Continuous Remote Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs).

2. MSAC Australian Government. Application 1197.1 - Remote monitoring for patients with implanted cardiac devices. [Online] https://www.msac.gov.au/sites/default/files/documents/1197-FinalDAP.docx.

Appendix D Elekta ONE case study

Elekta ONE Patient Companion Platform Overview

- **Australia's TGA Class IIa registered digital therapeutic** for cancer patient monitoring
- **Patient Companion mobile app + machine learning symptom tracking + structured clinical team management**
- **Evidence-based monitoring** using validated National Cancer Institute's Common Terminology Criteria for Adverse Events questionnaires (4)
- **Comprehensive coverage:** All cancer types, immunotherapy, radiation therapy, systemic treatments
- **Specialised programs:** Immune checkpoint inhibitor module, survivorship support

The challenge in cancer care

- **Traditional follow-up gaps between scheduled healthcare visits**
- **Delayed detection of treatment toxicities**
- **Inadequate symptom capture with paper-based systems**
- **Increased emergency presentations due to unmanaged symptoms**
- **Geographic and accessibility barriers:** Patients travel significant distances for specialist care, making additional visits impractical
- **Workflow inefficiencies:** time on manual documentation and telephone triage
- **Reactive rather than proactive care:**

Clinical Evidence and patient experience

- **Comparable outcomes to face-to-face with better accessibility**[3]
- Symptom monitoring = **improved patient safety and care quality**[1,2,3,4]
- **Treatment personalisation**[1]
- **Supports patient self-management** of treatment-related symptoms[1]
- **Self-management recommendations perceived by patients as "very helpful"**[1]
- **98%** of patients report the platform **is easy to use**[1]
- **High adoption rate among older users**[1]
- **High satisfaction** with patients, nurses and doctors with mean ratings ranging from 3.2 to 4.5 (out of 5)[2]

Economic Impact - "Healthcare and System Value"

- **Implementation Costs:** Annual subscription model, minimal patient costs
- **Implementation Efficiency:** 2-hour training and no additional infrastructure enables rapid deployment[2]
- API **Integration:** Health service analytics and electronic medical record (EMR) integration
- **Phone call reductions**: From 20 per month to less than 5[1]
- **Consultation efficiency:** 5-10 minutes saved per patient visit[1]
- **System-Wide Impact**: Eliminates patient travel costs and geographic barriers[1]

Current Funding Pathways

- **Direct clinic sales:** Annual subscription model for public and private clinics
- **No MBS funding:** Doctors not funded for digital monitoring work
- **Critical Gap:** No funding for clinical team monitoring time
- **Quality opportunity:** TGA registration distinguishes from free alternatives
- **Implementation Barrier:** Cost burden falls entirely on healthcare providers despite proven benefits
- **Current funding models** do not reward preventive interventions and efficiency gains

Key Learnings - "Elekta-Specific Success Factors"

- **Evidence foundation:** Multiple peer-reviewed studies enabled TGA registration
- **Clinical champion essential:** Doctor support is critical for implementation
- **Patient Centred** Design: The platform's intuitive user interface and minimal time burden
- **Integration critical:** Workflow integration with electronic medical record (EMR) systems essential for adoption

Source Elekta Patient Companion marketing materials accessed July 2025 Schmalz et al. 2020 Iivanainen et al. 2019 Elekta brochure TGA Public Summary ARTG 431690

D.1. Introduction

Elekta ONE Patient Companion powered by Kaiku Health stands as Australia's TGA-registered Class IIa digital therapeutic for comprehensive cancer patient monitoring and management. The platform combines sophisticated patient-reported outcome monitoring with machine learning algorithms to deliver evidence-based symptom monitoring and support tools to deliver personalised care. The system enables remote patient monitoring between scheduled appointments, facilitating early detection of treatment-related toxicities and supporting personalised care delivery. The platform integrates seamlessly with existing clinical workflows through its comprehensive suite of features including automated symptom questionnaires, real time alert systems, patient education modules and clinical dashboards.

The platform can provide monitoring for patients across all cancer types and treatment modalities. The therapeutic scope aligns comprehensively with evidence-based cancer care guidelines, encompassing medical oncology, radiation therapy and systemic treatments. The platform extends its therapeutic reach to patients receiving immune checkpoint inhibitor therapy, those undergoing radiation treatment and patients requiring long-term survivorship monitoring. Specialised program modules offer dedicated management programs that address the unique clinical needs of different cancer populations and stages of care.

D.2. The challenge in cancer care

Cancer patients experience a complex array of symptoms arising from both their underlying malignancy and the various treatment modalities employed. Traditional healthcare delivery models rely heavily on scheduled appointments and patient-initiated contact for symptom reporting, creating significant gaps in continuous monitoring that can compromise patient safety and treatment outcomes.

This includes:

- Limited visibility between appointments: Patients may experience significant symptoms or treatment-related toxicities in the days or weeks between scheduled visits, with no systematic mechanism for early detection or intervention.
- Inadequate symptom documentation: Traditional paper-based systems and episodic reporting fail to capture the full spectrum of patient experiences, particularly lower-grade symptoms that may indicate emerging toxicities.
- Geographic and accessibility barriers: Many patients travel significant distances for specialist cancer care, making additional visits for symptom management impractical and costly.
- Workflow inefficiencies: Clinical staff spend considerable time on manual documentation, telephone triage and administrative tasks that could be automated through digital solutions.
- Reactive rather than proactive care: Current systems primarily respond to symptoms after they become severe enough to prompt patient-initiated contact, missing opportunities for early intervention and symptom prevention.

D.3. The evidence and outcomes

D.3.1. Clinical evidence and outcomes

The platform's evidence base encompasses multiple peer-reviewed studies demonstrating clinical effectiveness and safety improvements across diverse cancer populations, including Iivanainen et al. 2019 (4) Retrospective study showing good adherence with median 11 questionnaires per patient and symptom patterns consistent with clinical trials. Schmalz et al. (2020) evaluated the platform in a multi-country pilot study involving 45 patients with advanced non-small cell lung cancer receiving cancer immunotherapy. The study demonstrated high user satisfaction across all stakeholder groups.

The key clinical outcomes include:

- Comparable outcomes to face-to-face with better accessibility
- Treatment personalisation: Machine learning capabilities enabled personalised questioning algorithms that reduced patient burden while maintaining comprehensive symptom capture
- Supports patient self-management of treatment-related symptoms
- Self-management recommendations perceived by patients as "very helpful"
- Demonstrated high satisfaction with patients, nurses and doctors with mean ratings ranging from 3.2 to 4.5 (out of 5) across seven key attributes including onboarding, usefulness, communication, ease of use, communication, efficiency, empowerment and quality of care. (2)
- Enhanced decision-making through real time access to patient-reported data and longitudinal symptom tracking

D.3.2. Patient experience and digital equity considerations

Patient Companion demonstrates consistently high patient satisfaction across diverse implementation settings. Iivanainen et al. 2020 Prospective feasibility cohort study demonstrating high patient satisfaction with 95% of patients said they would recommend using it in the follow-up of cancer patients and some correlations between symptoms and treatment benefit. Age is not a factor in limiting platform usage, with research showing that older patients achieve comparable engagement rates to younger demographics. The platform includes proxy reporting capabilities, enabling family members or caregivers to assist with questionnaire completion when needed.

Patients particularly value the educational components of the platform, with 80% of patients engaging with disease- and treatment-specific educational materials. The median time to complete symptom questionnaires ranges from 2-10 minutes, making the platform practical for regular use without creating excessive burden. However, digital equity considerations remain important. Language and cultural barriers present additional challenges, though the platform supports multiple languages including European and Asian languages, with ongoing development for additional linguistic support.

The key outcomes include:

- Patients believe following self-management instructions can delay or prevent the need to see a doctor
- 98% of patients report the platform is easy to use
- High adoption rate among older users

D.3.3. Cost effectiveness and efficiency gains

Healthcare system value emerges through documented operational efficiencies and workflow optimisations that translate into tangible benefits for healthcare providers managing resource constraints.

Elekta demonstrates economic value through operational efficiency:

Implementation costs:

- Annual subscription model with unlimited patient usage per licence
- Minimal or no patient costs (smartphone/internet connectivity)

Implementation efficiency:

- 2-hour training program for clinical staff enables rapid deployment (2)
- No additional infrastructure requirements (utilises existing computers/phones) (2)
- API integration available for health service analytics platforms and electronic medical record

Healthcare system benefits:

- Phone call reductions: from 20 per month to less than 5 minutes (1)
- Consultation efficiency: 5-10 minutes saving per patient visit as clinicians are no longer burdened with manual data collection

System-wide impact:

- Elimination of patient travel costs and geographic access barriers (1)

Workforce efficiency improvements enable clinical staff to provide oversight for larger patient populations without proportional increases in clinical time investment. This efficiency gain becomes particularly important in addressing the fundamental workforce constraints that limit traditional cancer monitoring delivery across Australian health services.

The platform addresses the fundamental challenge where many cancer patients receive inadequate symptom monitoring between scheduled visits, resulting in preventable complications and downstream healthcare costs that far exceed the investment required for appropriate digital monitoring interventions.

Evidence Gap: While operational benefits are well-documented, **comprehensive economic analysis including return on investment calculations remains limited**. This represents a significant opportunity for future research to quantify the full economic value proposition of digital patient monitoring in oncology.

D.4. Current funding mechanisms and challenges

D.4.1. Public hospital

Oncology clinics access the product via direct clinic sales. This landscape demonstrates both the opportunities and challenges facing digital therapeutics seeking sustainable funding within existing healthcare frameworks. Elekta's utilisation of annual subscription models provides a practical example of how digital therapeutics can leverage direct procurement without requiring entirely new funding structures.

The evidence-based classification supported by TGA registration enables digital therapeutics to access direct procurement through healthcare budgets. This approach recognises that digital

delivery represents an operational enhancement rather than an additional service, supporting implementation through established healthcare funding frameworks.

D.4.2. Private healthcare networks

The funding landscape is the same in the private Oncology Clinic area.

D.5. Other challenges

D.5.1. Transition from hospital to primary care

The divide between hospital-based and community-based care within Australian healthcare funding affects a range of interventions beyond cancer monitoring. Physicians are compensated for direct patient interactions, such as in-person or telephone consultations, but not for reviewing information on dashboards—even when such reviews may lead to improved outcomes. So, there is a hesitancy for them to do work in an application like this, even if it makes their work more efficient because they do not get funding for it. At present, there is no funding mechanism for nursing staff to undertake this task on behalf of physicians, creating a disincentive to utilise these tools.

Other challenges include:

- **Technology Infrastructure Costs:** While the platform itself requires minimal infrastructure, healthcare providers must ensure adequate technology infrastructure and staff training **without financial support** from existing funding mechanisms.
- **Outcome Measurement Complexity:** Current funding models struggle to recognise and reward **preventive interventions, and efficiency gains** that digital monitoring provides, focusing instead on episode-based care delivery.

D.5.2. Quality assurance and clinical governance challenges

The variability in cancer monitoring quality across Australia challenges digital therapeutic integration but provides opportunities for improvement with standardised platforms. Current variations in monitoring approaches suggest digital therapeutics can offer more consistent solutions than traditional programs. The TGA registration requirement provides strong clinical governance to distinguish comprehensive digital therapeutics from minimal consultation approaches this is as opposed to ad hoc patient survey creation used by some clinics to monitor patients.

D.6. Success factors and implementation learnings

D.6.1. Critical success factors

- Implementation success requires strong clinical leadership and champion support throughout the organisation. Healthcare providers report that physician buy-in is essential for successful platform adoption and sustained usage.
- The platform's seamless integration with existing clinical workflows ranks as the most important factor for successful implementation, enabling healthcare providers to incorporate digital monitoring without disrupting established care delivery patterns.
- The platform's intuitive user interface and minimal time burden (2-10 minutes per questionnaire) ensures high patient engagement and sustained usage over extended treatment periods.
- Cloud-based architecture and minimal technical requirements enable rapid deployment without significant infrastructure investment or ongoing maintenance burden.
- Evidence-based outcomes and peer-reviewed research provide credibility for implementation discussions and support business case development for healthcare executives.

D.6.2. Key implementation insights

- **Evidence foundation essential:** TGA registration and clinical trials provide credibility for implementation discussions
- **Efficiency focus over cost reduction:** Digital therapeutics provide value through operational efficiency and improved outcomes
- **Integration Complexity:** While standard HL7 messaging integration is straightforward, healthcare providers using non-standard systems may require additional technical support for seamless integration.
- **Quality Assurance Requirements:** Healthcare providers must establish clinical governance frameworks for digital monitoring that ensure appropriate response to patient alerts and maintenance of clinical oversight responsibilities.

D.7. Conclusion

Elekta ONE Patient Companion's platform addresses fundamental challenges in cancer care whilst providing measurable improvements in patient safety, clinical workflow efficiency and healthcare resource utilisation. Success factors centre on clinical champion engagement, seamless workflow integration and demonstrated clinical value supported by robust evidence rather than complex technology features.

D.8. References

1. Elekta. ONE Patient Companion product materials and clinical documentation. July 2025.

2. ePROs in the follow-up of cancer patients treated with immune checkpoint inhibitors: a retrospective study. Schmalz O, Jacob C, Ammann J, Liss B, Iivanainen S, Kammermann M, Koivunen J, Klein A, Popescu RA. s.l. : Journal of Cancer Research and Clinical Oncology, 2020, Vols. 145(3), 765-774.

3. Follow-Up of Cancer Patients Receiving Anti-PD-(L)1 Therapy Using an Electronic Patient-Reported Outcomes Tool (KISS): Prospective Feasibility Cohort Study. Iivanainen S, Alanko T, Vihinen P, Konkola T, Ekstrom J, Virtanen H, Koivunen J. s.l. : JMIR Form Res, 2020, Vol. 4(10):e17898.

4. ePROs in the follow-up of cancer patients treated with immune checkpoint inhibitors: a retrospective study. Iivanainen S, Alanko T, Peltola K, Konkola T, Ekström J, Virtanen H, Koivunen JP. s.l. : Cancer Res Clin Oncol, 2019, Vols. 145:765–774.

5. Elekta. ONE Patient Companion powered by Kaiku Health product brochure. July 2025.

6. TGA. Public Summary for ARTG Entry 431690 - Clinical data collection/management information application software.

Appendix E InforMS case study

InforMS platform overview

- Co-designed, multiple sclerosis (MS)-specific digital health portal aggregating data across consumer, clinician, wearable and research sources
- Integrated web platform + wearable connectivity + symptom tracking via MySymptoMS app
- Designed for self-management, shared decision-making and precision care in MS
- Visual dashboards, goal-setting features, trusted resources and printable summaries
- Planned integration with My Health Record, and current integration with MSBase and the Australian MS Longitudinal Study (AMSLS)

The challenge – "The MS management gap"

- People with MS often face fragmented health data across multiple providers and tools
- Memory burden and complexity in tracking symptoms, appointments and care plans
- Limited structured communication between consumers and clinicians
- Inaccessible or non-specific tools like My Health Record, not tailored to MS needs
- Inadequate tools for integrating real world symptom and wearable data into clinical care
- Difficulty in capturing longitudinal insights needed for personalised MS management

Clinical evidence and consumer experience

- Enables shared decision-making and personalised care through centralised health tracking
- Incorporates validated survey tools and real time data from wearable devices
- Printable health summaries support clinic visits and care transitions
- Viewed by clinicians as enhancing appointment efficiency, reducing data gaps

Economic impact - "Healthcare and system value"

- No fees for the person with MS or their care team; cost-per-user model for service licence
- Minimal setup: No special infrastructure or integration required – runs through web browser.
- Reduces duplication and improves consumer-clinician alignment in complex care settings
- Ongoing evaluation of health behaviour, outcomes and system value as part of trial
- Long-term potential to offset care costs by reducing reactive visits and enhancing coordination

Current funding pathways

- Development and evaluation funded through NHMRC/MS Australia partnership grant (Grant ID 1193008)
- Not currently available for public rollout or covered by health services
- MS Australia supports further development and exploration of funding models
- Lack of defined funding for consumer self-management tools outside clinical workflow
- Avenues for future funding will be based on the results and evaluation of the current research project.

Key learnings - "InforMS-specific success factors"

- Evidence-led design: Built on 20+ years of AMSLS data and validated user needs
- Co-design excellence: Developed with and for people with MS to ensure usability and relevance
- Flexible integration: Links with symptom apps (e.g., MySymptoMS) and wearables
- Tailored utility: Dashboard, notebook, and goal tracking help people with MS manage a lifelong condition
- Future-ready: My Health Record integration and real world evaluation underway

Source: InforMS case study consultation, (Multiple Sclerosis Australia, 2025)

E.1. Introduction

InforMS is a purpose-built, co-designed digital health platform developed to improve care for people living with multiple sclerosis (MS). The system integrates self-reported health data, wearable inputs, clinical data linkages and research survey findings into a single consumer-centred portal. Optimised for web and mobile use, InforMS supports self-management and shared decision-making by offering visual dashboards, symptom and goal tracking and personalised care summaries. Developed in close collaboration with the MS community, clinicians and researchers, the platform aims to streamline disease management, reduce burden, and enable more responsive, precision-oriented MS care. It links to companion tools including the MySymptoMS app (msresearchflagship.org.au/community/my-symptoms) and MSBase registry (an international online registry for neurologists studying MS and other neuro-immunological diseases). and draws from over 20 years of data from the Australian MS Longitudinal Study (AMSLS; www.msaustralia.org.au/amsls/).

The vision for InforMS emerged from a national consultation in 2018, where MS Research Australia (now part of MS Australia) convened key stakeholders to identify high-priority strategies to stop and reverse MS. One of the resulting pillars was the creation of a consumer-centred health data portal. Development of InforMS began in 2020, coordinated by the Menzies Institute for Medical Research at the University of Tasmania (www.utas.edu.au/menzies) in partnership with MS Australia, HealthCare Software Pty Ltd, and MSBase with funding from NHMRC and MS Australia (Grant ID 1193008[1]). It was developed in close collaboration with people with MS, and representatives from MS Australia and their member organisations, the MS Neurology Group of the Australian and New Zealand Association of Neurologists and MS Nurses Australasia. The platform is currently in a 2-year research evaluation phase and is designed to serve as a lifelong digital health companion and resource for people with MS.

E.2. The challenges in MS care

MS is the most common acquired chronic neurological disease affecting young adults, often diagnosed between the ages of 20 to 40 and, in Australia, affects three times more women than men. As yet, there is no cure. There is no known single cause of MS, but many genetic and environmental factors have been shown to contribute to its development. In MS, the body's own immune system mistakenly attacks and damages the fatty material – called myelin – around the nerves. This results in a range of symptoms, but no two people experience MS in the same way[2]. Symptoms can include fatigue, mobility challenges, pain and cognitive difficulties. Ongoing management requires individualised tracking of symptoms, functional changes,

[1] Note: the contents of any published material developed as part of the grant are the responsibility of the authors and do not necessarily reflect the views of NHMRC

[2] https://www.msaustralia.org.au/what-is-multiple-sclerosis-ms/

medication effects, review of new and active lesions via MRI, and quality of life impacts over time.

Despite the complexity of MS, traditional healthcare delivery relies on periodic neurologist visits and disconnected health records, placing the burden of coordination and symptom recall on the person with MS – many of whom experience memory, processing or attention difficulties.

The key challenges to MS healthcare include:

- Limited continuity between appointments: Most people with MS see their neurologist just once or twice a year, with no structured mechanism for monitoring in between.
- Fragmented and inaccessible health information: Clinical records, research data (e.g. AMSLS), wearable data and patient observations remain siloed, with no integrated system tailored to MS.
- Cognitive burden and memory challenges: MS can impair cognition, making it difficult for people with MS to recall events, symptoms or medication responses, especially in the absence of tools to track this over time.
- Underutilisation of real world data: Longstanding research efforts like the AMSLS have captured vital insights on symptom burden, economic impact and lived experience, yet this data has not been available to people with MS or clinicians during everyday care.
- Lack of proactive, personalised support: Current care remains reactive, with interventions based on snapshots taken during infrequent clinic visits rather than ongoing trends or patient-reported outcomes.

E.3. The evidence and outcomes

E.3.1. Clinical evidence and outcomes

InforMS is currently undergoing a two-year national research evaluation supported by the NHMRC and MS Australia grant. The platform is underpinned by over two decades of data from the AMSLS, which collects real world evidence from more than 2,500 participants annually and has informed numerous national policy and service reforms. This foundational dataset has been embedded into the InforMS design, supporting personalised care planning, disease tracking and patient-led reporting.

While formal outcome data from the platform is forthcoming, early feedback from both clinicians and people with MS during its development points to significant expected benefits:

- Integration of validated MS-specific measures from AMSLS and companion tools such as the MySymptoMS app
- Longitudinal data capture, allowing symptom trend analysis across fatigue, cognition, pain and function
- Printable care summaries to support neurology consultations and multidisciplinary care planning
- Clinicians anticipate improved efficiency and focus during appointments when InforMS summaries are brought in by people with MS.

E.3.2. Consumer experience and digital equity considerations

Initial user feedback during development highlights high accessibility and satisfaction with the platform:

- Designed with MS-specific accessibility needs in mind, including low cognitive load and compliance with the current high standards for visual, auditory and motor accessibility online.
- Feedback suggests that people with MS feel InforMS will better equip them for clinical appointments when using the summary and tracking tools. The platform is designed to work on any device (phone, tablet, or computer), includes online accessibility features and optional paper-based AMSLS surveys. This ensures that everyone can participate regardless of their technology access or individual needs.

E.3.3. Cost effectiveness and efficiency gains

Cost effectiveness modelling will be undertaken as part of the platform's formal evaluation. However, based on thorough consultation with stakeholders during its development, InforMS expects potential efficiency benefits through:

- Reduced duplication and more focused consultations
- Decreased burden through streamlined symptom and care documentation
- Low technical burden—centrally hosted with no local setup required
- Free to users during research phase; long-term funding and licensing models under development with a vision for it to remain free to users long-term
- Contextual economic impact: MS costs Australia approximately $2.45 billion annually, with average per-person costs of $73,457 in 2021. The paper also noted the prevalence of MS is rising, and costs rise sharply for those who have higher levels of disability. Solutions like InforMS may contribute to reducing avoidable care costs through better symptom management, earlier intervention and informed decision-making.

E.4. Current funding mechanisms

Currently, InforMS is being piloted as part of a research initiative to first determine whether it is useful and improves health outcomes for people with MS, before being rolled out further. Consequently, there is currently no defined commissioning structure within Local Health Districts or state-funded neurology programs to support the clinical implementation of digital self-management tools like InforMS. Future funding mechanisms are being explored as InforMS is evaluated.

E.4.1. Further considerations

InforMS is primarily focused on facilitating self-management of health by people with MS and shared decision-making with their care team. However, while the platform enables people with MS to consolidate and communicate their health information, there is currently no digital mechanism for interoperability with clinical care teams – people with MS must bring their InforMS information to their healthcare practitioner. As a result, InforMS relies heavily on the person with MS acting as the central coordinator across their care settings, which may limit its utility in more complex care transitions or for users with cognitive impairments. However, future developments are planned to include such features.

As a research platform, InforMS has been developed with strong ethical oversight and governance through its Steering Committee, which includes neurologists, MS nurses, researchers, state-based MS organisations, IT experts and people with MS. The platform does not require TGA regulation or assessment with the current functionality available. Future scaling of the platform would require clarification of its clinical governance model, data custodianship and long-term hosting and support arrangements.

E.5. Success factors and implementation learnings

E.5.1. Critical success factors

The success of InforMS to date is largely attributed to its strong foundation in longitudinal research, its MS-specific design and its commitment to co-design with the MS community. Drawing on over 20 years of AMSLS data, the platform has been able to integrate validated and meaningful metrics into a user-friendly tool. The involvement of people with MS at all stages of development has ensured the tool addresses real world needs, particularly cognitive load, accessibility and care coordination. The use of structured data inputs and consumer-controlled summaries has also enabled a scalable approach to personalised MS care without increasing clinician burden.

E.5.2. Key implementation insights

Development efforts have revealed the importance of flexibility and low barriers to use. The platform supports web-based access on any device, incorporates visual dashboards, goal-setting features and science-backed resources. Print-friendly summaries allow integration into in-person clinical workflows even in the absence of EMR integration. However, findings from the research study will inform broader system adoption when rolling InforMS out beyond the research phase, including sources of ongoing funding, additional data sharing methods with the care teams, and governance. Additionally, uptake may depend on ongoing consumer engagement to maximise benefit in self-management.

E.6. Conclusion

InforMS represents a best practice example of user-centred digital health for chronic neurological care. While not yet rolled out at scale or funded through health service channels, its strategic alignment with MS-specific needs, strong co-design, and longitudinal data capabilities position it as a high-potential candidate for future adoption under a self-management or coordinated care funding model.

E.7. References

1. Multiple Sclerosis Australia. 2025 Multiple Sclerosis Australia, [Online] July 2025. https://www.msaustralia.org.au/.

2. Campbell, J., van der Mei, I., Taylor, B., & Palmer, A. [Online] February 2023. https://www.msaustralia.org.au/wp-content/uploads/2023/02/health-economic-impact-of-multiple-sclerosis-in-australia-in-2021_final.pdf.

Appendix F XRHealth case study

XRHealth Platform Overview

- VR therapy platform with 50,000+ patients treated globally, and 1+ million VR sessions completed (1)
- Complete therapeutic ecosystem: VR headset + 150+ therapeutic environments + clinician control platform + service delivery from AHPRA registered clinicians.
- ARTG-registered medical device (3 approvals: cognitive function, biomechanical rehabilitation, mindfulness) with NDIS provider registration (in 4 support classes 0103, 0123, 0124,0128)
- Evidence-based therapy - mental health, chronic pain, cognitive training, physical rehabilitation, mindfulness
- Complete coverage: Telehealth service delivery and home-based therapy with real-time remote therapeutic monitoring (RTM)
- Clinician portal with remote VR control, patient mirroring, real-time adjustments, and full analytics dashboard

The Challenge - "Access Challenge"

- Geographic barriers prevent rural and remote patients accessing consistent therapy
- Traditional therapy faces capacity constraints with long waiting lists
- Workforce shortages limiting expansion of allied health services

Clinical Evidence - "Proven Therapeutic Outcomes"

- 91% patient adherence vs 50% market standard (1)
- 93% patient retention demonstrating sustained engagement (1)
- 50+ clinical trials completed across multiple therapeutic domains (1)
- 10+ published clinical studies demonstrating platform effectiveness (1)

Patient Experience

- 81 Net Promoter Score vs 38 NPS in healthcare sector (1)
- Peace of mind through continuous monitoring and support
- Immersive therapeutic environments creating engaging experiences
- Treatment independence and flexibility at home
- Gamified therapy approaches improving engagement and outcomes
- Supports "therapy on country" for Indigenous communities

Economic Impact

- Cost-effective alternative to traditional in-person therapy reducing system burden (2)
- Economic analysis demonstrated cost-effectiveness (gameChange), worth up to £341 per patient from NHS perspective or £1,967 from societal perspective (2)
- Eliminated travel costs particularly benefiting rural and remote patients
- Reduced clinic appointment pressure through home-based therapy delivery (2)
- Technology enabling treatment delivery without proportional staff increases (2)

Current Funding Pathways

- NDIS Funding: Registered as assisted technology provider across 4 categories with evidence-based justification
- No specific Medicare recognition: Allied health telehealth codes available without headset
- Private health insurance gap: Limited coverage for innovative digital therapeutics
- Funding inconsistency: NDIS funding approval variability creates unpredictable access plan to plan

Key Learnings - "XRHealth-Specific Success Factors"

- Robust evidence base is proving essential for clinical acceptance and funding justification. This includes a major 346-patient multicentre RCT significant clinical efficacy (4)), and studies demonstrating economic validation (2)
- Flexible commercial model: Monthly application and treatment plan access with headset provision reducing capital expenditure barriers for healthcare providers
- Technology integration sophistication: Platform architecture enabling seamless clinical workflow integration, remote monitoring capabilities, and comprehensive analytics supporting both clinical decision-making and administrative requirements.

F.1. Introduction

XRHealth represents a paradigm shift in digital therapeutics, delivering evidence-based virtual reality (VR) therapy solutions that address Australia's allied health access challenges. With over 50,000 patients treated globally and 1+ million VR sessions completed (1), the platform exemplifies how immersive technology can transform healthcare delivery.

The platform integrates three core components: VR headsets preloaded with evidence- based therapeutic applications, a comprehensive web-based clinician platform providing remote control and real-time monitoring, and an extensive library of 150+ therapeutic environments spanning mental health, chronic pain, cognitive training, and physical rehabilitation. The platform is listed on the Australian Register of Therapeutic Goods (ARTG) for three medical device categories (cognitive function, biomechanical rehabilitation, and mindfulness applications) (3) and maintains 4 National Disability Insurance Scheme (NDIS) registration classes as a service and assisted technology provider.

The XRHealth platform transforms clinical workflow from traditional appointment-based delivery to continuous, data-driven therapeutic monitoring. The clinician control centre enables real-time oversight of patient sessions, remote VR environment control, and comprehensive analytics tracking progress across multiple therapeutic domains. This approach allows clinical teams to personalise treatment plans dynamically and intervene proactively when data trends indicate treatment optimisation opportunities.

F.2. The challenge of access

Australia confronts significant challenges in allied health service delivery characterised by capacity constraints, geographic inequities, and workforce shortages limiting access to evidence-based therapeutic interventions. Current statistics reveal substantial unmet need across diverse population groups, creating pressure on healthcare infrastructure and limiting patient access to timely, appropriate care.

This includes:

- Capacity and access constraints: Traditional therapy delivery models face significant capacity limitations with extensive waiting lists preventing timely intervention during critical periods of mental health need.
- Geographic inequities: Rural and remote communities experience disproportionate barriers accessing specialist mental health services, forcing patients to travel significant distances or relocate to receive appropriate care, disrupting community connections and support systems.
- Workforce limitations: Allied health professional shortages compound access issues, with insufficient clinicians to meet growing demand particularly in regional areas and specialised therapeutic domains.
- Treatment engagement challenges: Traditional therapy models often struggle with patient adherence and engagement, particularly among younger demographics seeking more interactive, technology-enabled healthcare experiences.

F.3. The evidence and outcomes

F.3.1. Clinical evidence and outcomes

The platform's therapeutic effectiveness is supported by clinical data from XRHealth's implementation globally and 50+ clinical trials with 10+ published studies (1) including a major randomised controlled trial published in The Lancet Psychiatry (4).

The key clinical outcomes include:

- Superior adherence and retention: 91% patient adherence compared to 50% market standard for traditional therapeutic interventions with 93% patient retention indicating sustained therapeutic engagement (1).
- Treatment duration and engagement: Patients typically access telehealth services with the VR headset for 18-19 months, demonstrating sustained therapeutic engagement and platform utilisation.
- Healthcare system adoption: Platform implemented across major health systems including VA (United States), NHS (England), and various international health networks demonstrating institutional confidence and clinical acceptance (1).
- Large-scale RCT evidence: A 346-patient multicentre randomised controlled trial published in The Lancet Psychiatry demonstrated significant clinical efficacy (4). The gameChange VR therapy showed a 47% reduction in agoraphobic avoidance (adjusted mean difference −0.47, 95% CI −0.88 to −0.06; Cohen's d −0.18; p=0.026) and significant distress reduction (−4.33, −7.78 to −0.87; Cohen's d −0.26; p=0.014) at 6 weeks compared to usual care alone.
- Virtual Reality Exposure Therapy (VRET) evidence: Extensive research portfolio demonstrating VRET effectiveness across multiple conditions. Studies show VRET as effective as traditional exposure therapy with meta-analysis by Carl et al. (2019) finding significant reductions in anxiety and PTSD symptoms comparable to traditional approaches (5).
- Targeted treatment benefits: The trial demonstrated that VR therapy particularly benefited patients with severe agoraphobic avoidance, showing moderate-to-large improvements that persisted for 6 months (4). Patients with severe avoidance at baseline were able to complete two more activities (such as walking down the street or going to a shopping centre independently) 26 weeks after VR therapy.
- Cross-condition efficacy: Research using XRHealth platform demonstrates effectiveness across diverse populations: children social anxiety disorders including fear of darkness (66.6% satisfactory improvement), adults with agoraphobia (98% session completion, 87% adherence, 72% satisfaction), aviophobia treatment (>50% anxiety reduction), and public speaking anxiety (significant physiological improvements measured via electrodermal activity) (5).

F.3.2. Patient experience and digital equity considerations

Patient feedback consistently demonstrates high satisfaction with VR therapy delivery across diverse demographic groups and clinical conditions.

- **Patient satisfaction excellence:** Net Promoter Score of 81 compared to 38 NPS benchmark in healthcare sector, reflecting exceptional patient satisfaction (1)
- **User experience excellence:** High interface satisfaction ratings across therapeutic applications, with particular strength in immersive environment design and therapeutic engagement.
- **Accessibility and inclusion:** Platform design accommodates diverse patient needs including sensory considerations, motor limitations, and cognitive variations through customisable interfaces and progressive therapeutic approaches.

- **Digital literacy support:** Comprehensive onboarding and technical support ensuring successful platform adoption regardless of baseline technology experience, with particular attention to older adult users and culturally diverse communities.
- **Geographic access enhancement:** Home-based therapy delivery eliminates travel requirements, crucial for rural and remote patients, whilst maintaining clinical oversight through remote monitoring capabilities.
- **Cultural responsiveness:** Platform capability supporting "therapy on country" approaches for Indigenous communities whilst maintaining connection to cultural practices and community support systems.
- **Family and carer** integration: Therapeutic approaches incorporating family involvement and carer support where appropriate, recognising the importance of holistic care delivery approaches.

F.3.3. Cost-effectiveness and efficiency gains

Implementation data demonstrates healthcare resource optimisation through VR-enabled care delivery based on documented platform usage, provider feedback, and published economic analysis.

Clinical Efficiency Improvements:

- Automated progress tracking through VR session data collection (1)
- Technology costs managed through monthly application access model ($150/month per headset)
- Equipment costs (~$1,050 per headset) managed by XRHealth rather than healthcare providers

Healthcare System Benefits:

- Reduced clinic capacity pressure through home-based therapy options (2).
- Technology enabling treatment delivery without proportional staff increases (2).

Demonstrated Economic Value:

- Comprehensive economic analysis published in Journal of Medical Internet Research demonstrated gameChange is cost-effective, worth up to £341 per patient from NHS perspective or £1,967 from societal perspective. For patients with severe agoraphobia, economic value increases to £877 (NHS) or £3,073 (societal perspective) per patient (2).
- Implementation costs estimated at £184 per patient using NHS Band 4 staff delivery model (2).

Patient and Family Benefits:

- Eliminated travel costs creating particular value for rural and remote patients
- Flexible home-based treatment scheduling
- Access maintained for patients without home internet through clinic-based models
- Reduced societal costs through decreased informal caregiving burden (-£1,576, 95% CI -£3,432 to £280) (2).

F.4. Current funding mechanisms and challenges

XRHealth platform achieves full insurance coverage under HCPCS code E1905 “Virtual reality cognitive behavioural therapy device (cbt), including pre-programmed therapy software” in the United States, demonstrating international precedent for VR cognitive behavioural therapy device funding and establishing pathway for similar Australian recognition.

F.4.1. NDIS funding pathway

XRHealth has achieved NDIS registration as an assisted technology and services provider across four categories, establishing a viable funding pathway for eligible participants whilst highlighting broader funding challenges.

NDIS Success Framework:

- **Evidence-based justification:** Platform meets NDIS criteria for assisted technology requiring clinical letters explaining how VR headset will help participants, with applications processed through the National Disability Insurance Agency.
- **Clinical integration requirements:** NDIS funding requires clinical assessment and recommendation letters from treating clinicians explaining therapeutic necessity.
- **Implementation challenges:** NDIS approval demonstrates significant variability across plan managers despite consistent evidence requirements, with participants reporting different responses to identical queries.

F.4.2. Funding structure challenges

Current funding challenges include:

- **NDIS variability and inconsistency**: Approval processes demonstrate significant variability across plan managers and coordinators, creating unpredictable access for eligible participants despite consistent clinical evidence and platform capabilities.
- **Mainstream population gap:** Non-NDIS patients lack specific funding pathways, creating access barriers for broader population groups who could benefit from VR therapeutic interventions.
- **Medicare integration limitations:** Current Medicare structure lacks recognition for innovative digital therapeutics, despite telehealth codes providing partial coverage for clinical consultation components without headset provision.
- **Private health insurance coverage:** Limited recognition within private health insurance frameworks for digital therapeutic devices, requiring out-of-pocket payment for technology components despite clinical service coverage.

F.5. Other challenges

F.5.1. Implementation challenges and solutions

- **Clinical workflow integration:** Successful implementation requires significant change management support transitioning clinicians from traditional face-to-face delivery to hybrid models incorporating VR technology and remote monitoring capabilities.

- **Technical infrastructure requirements:** Platform implementation necessitates reliable internet connectivity and technical support infrastructure, creating particular challenges for rural and remote service delivery locations.
- **Digital literacy considerations**: Patient onboarding requires tailored approaches accommodating diverse technology experience levels, with particular attention to older adults and culturally diverse communities requiring additional support.
- **EHR integration complexity:** Healthcare system integration requires custom development and workflow modification to achieve seamless clinical record management and billing process alignment.

F.5.2. Cultural and clinical acceptance

- **Clinician engagement variability:** Adoption rates vary significantly across healthcare provider demographics, with technology-savvy clinicians demonstrating higher engagement and advocacy for platform capabilities.
- **Patient population preferences:** Therapeutic approach preferences vary across demographic groups, requiring flexible implementation strategies accommodating traditional therapy preferences alongside innovative VR modalities.
- **Evidence communication:** Clinical acceptance requires ongoing education regarding research evidence and therapeutic efficacy, particularly among healthcare providers with limited digital health experience.

F.6. Success factors and implementation learnings

F.6.1. Critical success factors

- **Regulatory foundation excellence:** Comprehensive regulatory approvals including ARTG registration, and NDIS registrations providing legitimacy and funding pathway access essential for healthcare system adoption and clinical confidence.
- **Evidence-based clinical foundation:** Comprehensive research portfolio including 50+ clinical trials and peer-reviewed publications proving essential for clinical acceptance and funding justification. This includes a major 346-patient multicentre RCT published in The Lancet Psychiatry demonstrating significant clinical efficacy (4), economic validation published in Journal of Medical Internet Research showing cost-effectiveness worth up to £877-£3,073 per patient for severe cases (2), and extensive VRET research across multiple international institutions demonstrating effectiveness across diverse conditions and age groups, without requiring local evidence replication studies.
- **Technology integration sophistication:** Platform architecture enabling seamless clinical workflow integration, remote monitoring capabilities, and comprehensive analytics supporting both clinical decision-making and administrative requirements.

- **Commercial model flexibility:** Monthly application access with headset provision reducing capital barriers whilst providing upgrade pathways and equipment replacement without additional healthcare provider investment requirements.
- **Comprehensive support infrastructure:** Clinical training programs, ongoing technical support, and change management assistance enabling successful platform adoption regardless of baseline technology sophistication.

F.6.2. Key implementation insights

- **Evidence translation:** International clinical trial data including a major multicentre RCT published in The Lancet Psychiatry with economic validation in Journal of Medical Internet Research, plus extensive VRET research across multiple universities and clinical settings (University of Balearic Islands, Hospital del Mar, Universitat Pompeu Fabra, University of Central Florida, Hofstra University) providing comprehensive foundation for Australian adoption decisions without requiring local evidence replication, enabling faster implementation timelines.
- **Technology acceptance factors**: Clinician technology comfort levels significantly influencing implementation success, with technology-savvy providers demonstrating superior patient engagement and therapeutic outcomes.
- **Patient demographic considerations:** Younger patient populations and neurodivergent individuals showing particular affinity for VR therapeutic approaches, whilst older adults requiring additional onboarding support but achieving excellent outcomes with appropriate assistance.
- **Scalability requirements:** Successful implementation requiring minimum critical mass of patients and clinicians to justify infrastructure investment and achieve sustainable service delivery models.

F.7. Conclusion

The XRHealth experience demonstrates both the transformative potential of virtual reality therapeutics and the significant importance of funding frameworks that recognise innovative digital health solutions. With demonstrated clinical efficacy across multiple therapeutic domains and successful implementation across major international health systems, the platform proves that immersive technology can enhance therapeutic outcomes whilst improving healthcare accessibility and efficiency.

F.8. Bibliography

1. **XRHealth.** *Revolutionising therapy with AI-powered Extended Reality (VR/MR) solutions for healthcare. Platform presentation, .* 2025.

2. *Estimating the Economic Value of Automated Virtual Reality Cognitive Therapy for Treating Agoraphobic Avoidance in Patients With Psychosis: Findings From the gameChange Randomized Controlled Clinical Trial.* **Altunkaya J, Craven M, Lambe S, et al.** s.l. : J Med Internet Res, 2022, Vol. 24(11): e39248.

3. **TGA Medical Device Registrations.** *Cognitive Function Interactive Software (ARTG 335031), Biomechanical Function Analysis/Interactive Rehabilitation System (ARTG 335032), Cognitive Function Interactive Software (ARTG 335033).* 2020.

4. *Automated virtual reality therapy to treat agoraphobic avoidance and distress in patients with psychosis (gameChange): a multicentre, parallel-group, single-blind, randomised, controlled trial in England with mediation and moderation analyses.* **Freeman D, Lambe S, Kabir T, et al.** s.l. : Lancet Psychiatry, 2022, Vols. 9: 375–88.

5. **XRHealth.** *Cognitive Behavioral Therapy (CBT) and Virtual Reality (VR) for Enhanced Therapeutic Outcomes: Exposure Therapy. Research and clinical evidence compilation,.* 2025.

6. *Virtual reality exposure therapy for anxiety and related disorders: A meta-analysis of randomized controlled trials.* **Carl E, Stein AT, Levihn-Coon A, et al.** s.l. : Journal of Anxiety Disorders, 2019, Vols. 61: 27-36.

Appendix G Project methodology

This project aimed to identify feasible funding pathways for DTx and RPM technologies in the Australian health system, with a focus on options that are tailored to the funding and delivery structures of primary and specialist care, public hospitals and private insurance.

The scope of the work included a structured review of international models, in-depth consultations with Australian stakeholders, development of local case studies, and analysis of sector-specific options to support policy and design decisions. The project examined structural features and policy levers that could improve access to evidence-based DTx and RPM solutions across the Australian health system.

The methodology employed a mixed-methods approach comprising four core components:

- **International evidence review**

  A structured literature review and jurisdictional scan were conducted across nine countries: Germany, France, the United States, South Korea, Japan, the United Kingdom, Singapore, the Netherlands and Belgium. The review examined funding models, evidence requirements, assessment processes and implementation experiences relevant to DTx and RPM technologies.

- **Stakeholder consultations**

  Twelve in-depth consultations were undertaken with federal, state and private funders, clinicians, advocacy groups and policy experts. These interviews were guided by a tailored protocol covering system enablers, current challenges, policy and implementation considerations and views on proposed reform directions. Notes were thematically analysed to identify cross-cutting issues and sector-specific insights.

- **Case study development**

  Six case studies were selected to reflect a diversity of digital health applications and solutions, business models and regulatory classifications. Each case study was developed through interviews with vendors, review of supporting documentation (e.g. regulatory approvals, published studies), and verification of evidence claims. The case studies were used to illustrate real world implementation pathways, funding challenges and value propositions.

- **Options development and analysis**

  Drawing on the findings above, a set of sector-specific funding options was developed and tested through an internal workshop. These options explored the applicability of product-based, service based and hybrid funding approaches and considered policy levers such as the MBS, ABF, block funding and commissioning models. Each option was assessed in terms of funding flow, eligibility, evidence requirements and alignment with sector objectives.

This mixed-methods approach allowed triangulation of policy, implementation and operational considerations across both international and local contexts. The methodology and consultation themes were informed by the Project Plan and Investigation Framework developed in collaboration with MTAA.

Appendix H International evidence

Internationally, health systems have begun to respond to the funding gap for digital health technologies by developing targeted policy mechanisms. Countries have introduced a range of approaches to support the funding and adoption of DTx and RPM, including new product listing frameworks, service-linked payments, bundled care models and hybrid funding arrangements. While these models vary based on system structure and policy priorities, they reflect a shared recognition that funding is essential for enabling patient access. This chapter outlines how other countries have approached the challenge, highlighting lessons and design elements that may be relevant to Australia.

H.1. Germany

Germany uses two distinct approaches for DTx and RPM reimbursement: the DiGA fast-track pathway enables provisional reimbursement of low-risk DTx under statutory insurance, and RPM solutions are reimbursed through standard HTA processes, with coverage granted for select conditions like heart failure.[50-55]

Model strengths aligned with local needs

DiGA's fast-track model was widely recognised as one of the most mature and structured approaches internationally, and several features were seen as promising for the Australian context. The ability to access reimbursement while generating real world evidence was viewed as particularly relevant, given the limited local funding for early-stage trials. Stakeholders also noted the advantages of reimbursing the product directly, rather than tying access to a clinical service or provider. This design was seen as supportive of smaller digital health companies, many of whom operate independently of traditional care settings.

Limitations and challenges for local adaptation

At the same time, DiGA's success relies on infrastructure and policy settings that are not yet in place in Australia. The evidentiary thresholds — including demonstration of positive healthcare effects and alignment with national data and interoperability standards — would be difficult to meet without additional investment in infrastructure and evaluation support. The model has also seen limited prescribing uptake in Germany due to a lack of incentives for clinicians to engage with digital tools. In contrast to DTx, RPM reimbursement remains confined to specific conditions with strong clinical trial evidence, with no dedicated framework to support broader service delivery or integration.

H.2. France

France has a national reimbursement framework for both DTx and RPM based on a two-step process.[57-60] The PECAN pathway enables 12-month provisional funding for CE-marked digital

solutions while real world evidence is generated. DTx permanent reimbursement may follow via inclusion on the LPPR (List of Reimbursable Products and Services), though no app-only digital solution has yet achieved this. For RPM, the LATM pathway provides permanent hybrid funding through predefined lump-sum payments covering both the product and associated clinical service.

Model strengths aligned with local needs

The French approach was seen as highly relevant to Australia, particularly in its use of provisional funding to enable early access. Stakeholders welcomed PECAN's structured entry point for digital solutions that may not yet meet full HTA thresholds, with lower initial evidence requirements and the ability to test real world performance before progressing to permanent listing. LATM was also recognised for its hybrid structure, offering product reimbursement alongside clinical onboarding or service payments — an approach seen as essential for sustainable RPM models. The direct payment to vendors, including onboarding costs, was identified as a strong design feature that better reflects the operational realities of implementing digital care.

Limitations and challenges for local adaptation

Despite its strengths, the model also revealed implementation issues that stakeholders felt would be relevant in Australia. No standalone digital solution has successfully transitioned from PECAN to LPPR due to the absence of a defined reimbursement category for app-only products. This was seen as a major structural barrier, highlighting how legacy benefits lists can prevent digital solutions from achieving long-term funding, even after initial success. The LATM pathway, while progressive, was seen as difficult to align with existing MBS-based billing systems, particularly given the lump-sum payment design and parallel funding for clinical care. These elements would require significant changes to provider payment models and system-level funding flows if adapted locally.

H.3. United States

The United States does not have a national product-based funding pathway for DTx or RPM. Coverage is decentralised and varies by payer. Funding is typically service based, flowing through clinicians, providers or platform arrangements. Medicare permits billing for certain digital mental health services and remote therapeutic monitoring (RTM) through G-codes and CPT codes.[61-70]

Model strengths aligned with local needs

The US model shows how digital solutions can be used to support funded clinical services under existing service based billing structures. Medicare (US) permits providers to bill for RTM using CPT codes that cover patient-reported outcomes such as pain, functional status and medication adherence. While the funding flows to clinicians rather than vendors, the model offers one of the few formal mechanisms for recognising the clinical value of behavioural

outcomes — a gap often noted in Australian HTA processes. Stakeholders viewed this as relevant to the Australian context, where provider billing may form the entry point for digital health solutions, but broader reform is needed to reflect the types of outcomes digital solutions are designed to improve.

Limitations and challenges for local adaptation

While RTM and CPT billing enable some digital solutions to enter the health system, the US model remains highly fragmented and difficult to scale. Coverage varies across payers, with inconsistent policies and contractual terms that create uncertainty for developers and uneven access for patients. CPT billing typically requires clinician involvement and is limited to defined conditions under Medicare. Although the model recognises behavioural outcomes such as medication adherence or functional status as part of the value generated by the digital solution, funding is still routed through provider billing rather than directed to the product developer. In contrast, Australia's HTA and funding processes do not consistently account for these types of outcomes, which limits support for digital solutions focused on engagement, self-management or therapy adherence. Without complementary reforms to both funding models and assessment frameworks, service based mechanisms alone, like the US model, are unlikely to provide a scalable path forward.

H.4. South Korea

South Korea is in the early stages of formalising national funding for digital health solutions. Since 2023, DTx products approved by the Ministry of Food and Drug Safety may receive temporary funding through a formal three-year pilot program managed by the Ministry of Health and Welfare (MOHW) and the Health Insurance Review and Assessment Service (HIRA). Permanent funding depends on a full HTA review, although no DTx has yet been listed on the National Health Insurance benefits catalogue. For RPM, funding occurs through standard service fees embedded in condition-specific care, with no dedicated pathway or direct product funding.[87-93]

Model strengths aligned with local needs

Korea's structured use of a formal pilot program was seen as a practical solution to the challenges faced by digital health developers operating under tight funding and rapid product iteration. The model addresses a key gap in the Australian system by offering a nationally administered, time-limited pathway for evidence generation prior to full HTA submission. This was seen as particularly relevant for venture-backed or mid-stage companies that are unable to sustain the multi-year evidence generation timelines typically required for funding. It also reflects the realities of digital solutions, which evolve quickly and often target behavioural or engagement outcomes that sit outside traditional HTA criteria. Central coordination by MOHW and HIRA provides policy coherence and avoids the fragmentation often seen in local pilot programs.

Limitations and challenges for local adaptation

While Korea's pilot model provides a clear structure, its impact to date has been limited. Clinical uptake has been slow, with high dropout rates and long assessment timelines contributing to delays in progression from pilot to full funding. Access to the pilot is not automatic and may be perceived as ad hoc or selective, with little transparency around eligibility or review processes. For RPM, funding remains confined to existing condition-specific service fees, with no dedicated support for broader remote care models. Telemedicine is still not funded under Korea's national insurance scheme, and even well-established technologies such as implantable cardiac monitors have struggled to gain coverage. These constraints highlight the importance of pairing provisional funding with investment in clinical pathways, infrastructure and policy settings that enable scalable adoption.

H.5. Japan

Japan uses a bundled, service based approach to digital health funding. DTx solutions must first be approved by the Pharmaceuticals and Medical Devices Agency and then assessed by the Ministry of Health, Labour and Welfare for inclusion in the National Health Insurance. Funding flows to providers via existing technical fee structures, and while pathways exist for both software and associated clinical services, there is no dedicated funding category for digital solutions. RPM is funded similarly, embedded into physician-led service tariffs through condition-specific inclusion.[70,100-106]

Model strengths aligned with local needs

Japan's model illustrates how digital health solutions can be incorporated into existing funding structures through a combination of regulatory and medical society endorsement. Despite the absence of a dedicated product listing framework, pathways now exist for both the clinical service component and the software itself, creating opportunities for selective inclusion. This may be relevant to Australia's current system, where existing MBS item structures could accommodate certain digital interventions with appropriate endorsement and pricing advice. The use of technical fees to support bundled care delivery was also seen as compatible with clinical workflows.

Limitations and challenges for local adaptation

Access to funding in Japan remains highly dependent on case-by-case negotiations, requiring medical society endorsement before submission and significant effort to establish technical fee categories. These barriers can delay or prevent market entry, especially for smaller developers. While a handful of digital applications, such as a smoking cessation app, have been funded, overall uptake remains limited. The model lacks a formal, centralised assessment or listing process, which may affect transparency and scalability. Stakeholders noted that although these features mirror some aspects of Australia's MBS processes, Japan's reliance on society-led petitions and fragmented evaluation pathways would not resolve local challenges around consistent access, product recognition or long-term adoption.

H.6. United Kingdom

The UK does not operate a unified national funding scheme for DTx or RPM. Coverage decisions are made at the devolved nation or local trust level, with digital health solutions entering the system through service level commissioning, procurement frameworks, or evaluation processes such as NICE's Evidence Standards Framework or Early Value Assessment (EVA). Funding remains service based, with digital tools often funded indirectly as part of broader care models or transformation initiatives like virtual wards. There is no dedicated national funding stream or registry for digital health products.[69,70,75,80-86]

Model strengths aligned with local needs

The UK's use of structured evaluation mechanisms offers a clear model for enabling early engagement with promising digital solutions. Tools like NICE's EVA help identify technologies with system potential before full evidence generation is complete, providing a credible entry point that bridges innovation and procurement. While they do not guarantee funding, these mechanisms create a defined front door for assessment, support more consistent triage and give developers early clarity on alignment with national priorities. Australia currently lacks such a pathway, and adopting a similar intake and evaluation function could strengthen market coordination, reduce duplication and better guide investment across jurisdictions.

Limitations and challenges for local adaptation

Despite these enablers, the UK model remains fragmented and resource-intensive to navigate. NICE evaluation or Digital Technology Assessment Criteria (DTAC) compliance does not confer funding, and digital health vendors must still negotiate access with individual NHS trusts or commissioning bodies. This localised procurement process creates uncertainty and slows uptake, even for evaluated products. These issues closely mirror challenges in Australia, where assessment alone does not translate into funding or commissioning. The UK experience highlights the need to pair evaluation with centralised investment, procurement levers or funding models to ensure impact at scale.

H.7. Singapore

Singapore does not operate a formal funding framework for DTx or RPM. Digital health technologies are typically adopted through a combination of government-backed pilots, research grants and institutional funding from public health clusters or private providers. There is no centralised HTA process, listing pathway or national funding mechanism specific to digital solutions. Singapore's health financing model is built around co-payment, with subsidies supporting but not fully covering most health services, including digital health. Digital health policy remains under active development, with a dedicated unit within the Ministry of Health and Technology overseeing future directions.[107-110]

Model strengths aligned with local needs

Singapore's approach reflects a pragmatic early implementation model that may offer lessons for Australia's initial phases. While not a funding framework in the traditional sense, Singapore facilitates access through short term grants, institutional pilots and co-payment policies that reflect shared responsibility for health costs. This model supports early adoption by allowing public health clusters to test digital solutions within operational budgets, without needing major structural reform. For Australia, where full-scale reforms may be politically or structurally difficult in the short term, similar use of transitional funding and phased adoption could serve as a bridge between innovation and longer-term funding pathways.

Limitations and challenges for local adaptation

Singapore's model is not designed to support scale or guarantee access. In the absence of formal assessment, listing or pricing pathways, digital products rely on variable institutional interest and temporary grant funding, creating limited certainty for developers. There are no mechanisms to transition from pilot funding to mainstream adoption, and the co-payment model may not align with Australia's public expectations of Medicare-funded care. Singapore's experience offers useful insights only at the early implementation stage; without a formal pathway for long-term funding, its approach is unlikely to translate directly to broader system-wide adoption in Australia.

H.8. Netherlands

The Netherlands does not operate a centralised funding model for DTx. Digital solutions are typically funded through care contracts negotiated between health insurers and providers or through time-limited innovation grants. Decisions are decentralised and made on a case-by-case basis, with no formal HTA or listing mechanism for DTx. In contrast, RPM services can be funded nationally via an add-on DRG code (OZP 039133), paid every 120 days on top of routine service fees. This requires RPM to be embedded within existing care delivery.[72-77]

Model strengths aligned with local needs

The RPM pathway in the Netherlands demonstrates a model of condition-agnostic funding that supports clinical integration without requiring product-level listing. By linking payment to ongoing care delivery and enabling long-cycle billing, the approach reduces administrative burden and incentivises long-term engagement. This may offer relevant insights for Australia's hospital or PHN-led RPM programs, where continuity of care and outcome tracking are critical. The use of innovation grants also shows how early pilots can be supported flexibly in a decentralised funding environment.

Limitations and challenges for local adaptation

The absence of a national assessment or funding process for DTx creates significant uncertainty for developers. funding relies on individual negotiations with payers and providers, limiting consistency and scalability. While the RPM add-on tariff supports integration within hospital

services, it does not support standalone solutions or outpatient-led models, which are key to many Australian use cases.

H.9. Belgium

Belgium provides a structured product-based funding model for DTx and RPM, coordinated through the mHealthBelgium validation pyramid. Only Level 3 validated products, which demonstrate clinical benefit, socioeconomic value, and integration into an approved care pathway, are eligible for public funding through the National Institute for Health and Disability Insurance.[59,96-98] The same validation structure underpins RPM funding through condition-specific care bundles.

Model strengths aligned with local needs

The pyramid model offers a transparent, nationally coordinated pathway for validation and recognition, even before funding is achieved. This structure enables clearer navigation for developers, more consistent expectations for funders and providers, and a scalable intake process for emerging technologies. By supporting early-stage recognition through Level 1 and 2, the model enables structured engagement and pipeline visibility without requiring immediate HTA submission. These features are highly relevant to the Australian context, where many digital health products remain at pre-commercial or pre-evidence stages. The centralised validation library also provides a potential solution to Australia's fragmented intake landscape.

Limitations and challenges for local adaptation

Despite its appeal, the model has achieved limited throughput. Very few DTx products have successfully progressed to Level 3 due to the high evidentiary thresholds and requirement for integration with an approved care pathway. The model does not include dedicated funding mechanisms for pilot studies or real world evidence generation, which may limit participation by smaller developers. While Belgium's use of bundled payments and procurement conventions may be less relevant to Australia, the validation library itself provides a promising system enabler. It demonstrates how digital health intake, and triage can be managed centrally, while maintaining high evidence standards and alignment with broader system goals.

Appendix I Glossary

Term	Definition
Activity-based funding (ABF)	A hospital funding model where services are funded based on the type and volume of activity delivered (e.g., Diagnosis-Related Groups), rather than block grants.
Bundled payment models	Funding arrangements that provide a single payment for an entire episode of care (e.g., a surgical procedure plus rehabilitation), which may include both digital and in-person components.
Commissioning	The process of planning, contracting and monitoring health services to achieve defined outcomes. Commissioning may support pilots or targeted programs but can also underpin long-term national or regional programs. Unlike dedicated funding, it often relies on time-limited contracts and variable integration into the broader health system.
Digital therapeutics (DTx)	Evidence-based software applications that deliver medical interventions directly to patients to prevent, manage or treat a disease or disorder. Unlike wellness apps, DTx are regulated as medical devices. Note: Under the changes introduced in February 2021 digital mental health tools are excluded from regulation if they are intended for the management of any aspect of mental health, as long as the following conditions are met: the software follows established clinical practice guidelines; and the guidelines are referenced and the reference to them is displayed in the tool; and the user can clearly view the guidelines. If the digital mental health software is a medical device and does not meet ALL these conditions, it is regulated by the TGA.
Dual product and service funding	A funding approach that separately recognises both the digital product (e.g., software, device) and the associated clinical service (e.g., clinician time, care coordination), ensuring adoption is both safe and incentivised.
Guided self-management	A model of healthcare delivery where patients use digital tools, apps or monitoring devices to manage aspects of their own care, with varying levels of clinical support. This approach enables greater autonomy, convenience, and engagement and is a key feature of many DTx solutions
Health technology assessment (HTA)	A structured evaluation of the safety, clinical effectiveness and cost effectiveness of health technologies to inform funding and policy decisions.
Medicare Benefits Schedule (MBS)	Australia's schedule of government-subsidised health services, primarily fee-for-service payments for medical practitioners. Current MBS design limits funding for digital products.
Pharmaceutical Benefits Scheme (PBS)	Australia's national program subsidising prescription medicines. PBS processes do not accommodate digital-only therapeutics, as they are not medicines.
Prescribed List (PL)	A list of medical devices and prostheses eligible for funding by private health insurers. Current definitions limit coverage for digital and remote monitoring devices.
Remote care	The use of digital technologies to deliver healthcare remotely, encompassing telehealth, remote monitoring and digital therapeutics.
Remote patient monitoring (RPM)	The use of digital technologies (e.g., connected devices, wearables) to monitor patient health status outside traditional care settings, enabling timely needs based clinical intervention.

Term	Definition
Service-linked payments	Funding mechanisms tied to clinical services delivered by providers (e.g., monitoring, consultations), which may include digital inputs but do not directly pay for the digital product itself.
Open access pathway	A nationally consistent, transparent funding framework that any accredited provider or developer can access if they meet defined eligibility, evidence and safety criteria. It guarantees sustainability beyond pilots and ensures equity nationwide.