AUSTRALIAN COMMISSION
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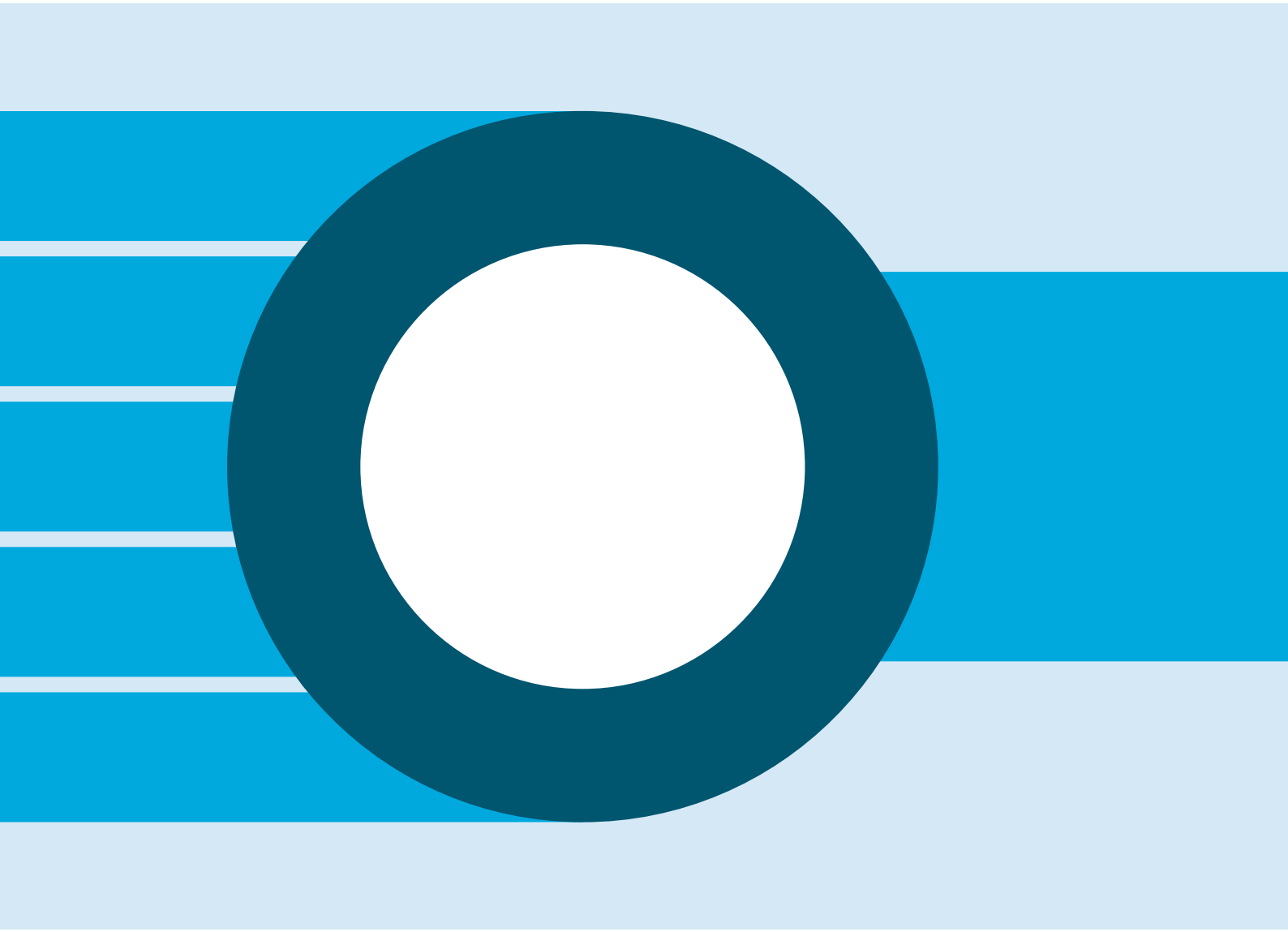

# Consultation Report

## Requirements for the National One Stop Shop, the National Clinical Trials Front Door and core elements of the National Site-Specific Assessment

Australian Government
Department of Health and Aged Care

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# Statement by the Chair

# A process with a purpose: a contribution to better health care for all

**Professor Ian Chubb AC FAA FTS FRSN FACE*
Chair, Health and Medical Research Advisory Group**

## Purpose of this project

The purpose of this project is to inform the development and harness the benefits to Australians of a streamlined, harmonised, effective and predictable operating environment essential for a vibrant health and medical research eco-system: better support, better strategy, better research, better treatments, better health outcomes all conducted within a straightforward connected framework underpinned by the highest standards of integrity.

## Initiation of this project

All Australian Health Ministers agreed on a Revitalised Clinical Trials agenda in March 2017, which provided a level of national agreement on priorities for streamlining processes, building national cohesion, and advancing the clinical trials environment in Australia.†

Stimulus funding has been made available nationally under the Encouraging More Clinical Trials in Australia initiative to assist state and territory governments to achieve system redesign in accordance with the reform agenda. Among other things, this agenda seeks to improve system navigation for researchers, sponsors and participants, streamline trial processes, decrease time to trial start-up, and improve capability to conduct trials across the system.

This project takes those commitments further and was designed to explore ways in which coherence can replace remaining fragmentation.

The concept for the national cross-government One Stop Shop for Clinical Trials and Human Research Approvals (the One Stop Shop) was co-designed by all jurisdictions via the Clinical Trials Project Reference Group (CTPRG).

The proposal to develop a national platform in collaboration with all jurisdictions and key regulatory agencies was announced in 2020.

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* Note from the Chair, Health and Medical Research Advisory Group. These are personal reflections gleaned from attending nearly every formal consultation plus several less formal ones – particularly with jurisdictional representatives.

† ***National Clinical Trials Governance Framework Literature Review***, Australian Commission on Safety and Quality in Health Care, 2022.

## The reason

The world is changing.

Nations large and small, including complex federations like the European Union, are working to coordinate a response to the changing landscape in health care, and positioning to take advantage of opportunities presented by the application of advances flowing from research.

Australia must be willing to lift its game to stay well in the game.

## Why would we care?

In 1891, in the lead up to federation, Henry Parkes toasted 'One people: one destiny'* four words up in lights on Sydney Town Hall on 1 January 1901.

While the noble intention was put into practice imperfectly, it was a profound aspiration for the new nation, and one that we still strive to achieve 121 years on.

A reasonable interpretation of 'the toast' is that a hallmark of a civilised nation is how well it cares for all its people, especially the most vulnerable, all the time: a nation with cultural, social and economic prosperity enjoyed by the maximum number in a secure and safe environment.

One building block is the healthcare system and how it can be equally and equitably accessed by all regardless of their means, and where in Australia they live.

A civilised nation will not just provide access to something, or anything. It will provide access to quality care of the highest order with state-of-the-art treatments available to anybody who needs them.

In health, improvement in care is founded on translating research into practice. It draws on our evolving knowledge to find ways to identify, cure and prevent disease; reduce injury and disability; improve the delivery of health services; and help us to lead healthier lives.†

Clinical trials are one step in the translation pathway. They are essential for evaluating the effectiveness and safety of medicines, devices, services, and clinical interventions.

Over the years, Australia has developed a variety of approaches to managing clinical trials and human-based research. This is predictable in a federation. But it does mean differences between jurisdictions, and even within jurisdictions, can make operations unnecessarily cumbersome. In a world where many nations (and federations) are working to become more attractive trial sites, Australia risks falling behind without considered change.

For Australians to maximise the return to them of their investment in health and medical research, there is a time-critical need to coordinate the way in which research is both strategically supported and translated to care. As emphasised by the Association of Australian Medical Research Institutes in their call for a National Health and Medical Research Strategy‡, while we are good, we can and should be better.

Getting better will require Australia to develop more effective arrangements for ethics and other key approvals with emphasis on integrity, streamlining agreements with sites, monitoring outcomes and ensuring support for all participants.

The best functioning system will ensure Australia is well positioned to respond to future health threats, not only the immediate, with quality and deployable capability. It will empower Australia to coordinate a strategic research effort and inform investments in the whole of the pipeline from early-stage research to treatment.

Any substantial competition is with other countries, not between our jurisdictions.

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* One people, one destiny: speech of the Hon. Sir Henry Parkes, G.C.M.G., to the citizens of Sydney, Gaiety Theatre, 13 June 1891. nla.obj-211987492, National Library of Australia.

† **Australian Health and Medical Research**, Research Australia.

‡ ***Australia's Missing Link: A National Health and Medical Research Strategy***, Association of Australian Medical Research Institutes, November 2021.

## The outcome

A nationally consistent and harmonised operating environment for the approval and management of clinical trials and health-related research: one nation-wide, cross-government, platform.

We have an opportunity to develop an approach that is ethical by design and inculcates integrity at every stage of the research life cycle, consistent with community expectations.

## The benefit of getting it right

Keeping Australians healthy, or effectively treating their illnesses with the best available options, is the goal. It must be our collective aspiration.

There are direct economic benefits as well.

Considerable savings in healthcare costs are derived each year because new and effective treatments result in fewer hospitalisations, and a healthier more productive community.

National and international research investments stimulate the Australian economy. The Medical Technology, Biotechnology and Pharmaceutical (MTP) Sector alone contributed $5.4 billion and $5.5 billion in Gross Value Added (GVA) to the Australian economy in 2020 and 2021.* Of this total, clinical trials are estimated to contribute around $1.4 billion.†

## A brief history of clinical trials

Australia is an attractive place to undertake trials and research. The issue is how to be a priority site in an increasingly complex international environment where nations see trials as one means to strengthen their healthcare systems, and their economies.

The Australian clinical trials policy landscape is complex, and no single government or agency holds all the levers for change.

Human-based research often occurs across multiple jurisdictions and sites, with studies needing several, sometimes time-consuming approvals before they can start. This can result in fragmentation, duplication, significant delays and missed opportunities for patients, researchers, trial sites and sponsors.

In response to these challenges, governments have undertaken initiatives to improve the operating environment for clinical trials and research for well over a decade. For example, a range of initiatives to establish a national approach to scientific and ethical review of multi-centre health and medical research commenced from 2006, following a decision of the then Australian Health Ministers' Advisory Council (AHMAC).

Within the Australian Government, the former Clinical Trials Action Group (CTAG), co-chaired by the then Parliamentary Secretary for Health (now federal Minister for Health) and the Parliamentary Secretary for Innovation and Industry, recognised that greater momentum in key areas of reform were required. The CTAG Report ***Clinically Competitive: Boosting the Business of Clinical Trials in Australia***‡ released in 2011 included 11 recommendations for reform: reiteration of the need to implement harmonisation of multi-site ethical review practices; development of nationally consistent forms and processes; the need to optimise patient recruitment; promotion of e-health practises; and the national coordination of clinical trials networks, amongst others.

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* ***Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan***, MTPConnect, Department of Industry, Science, Energy and Resources, April 2022.

† ***Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth***, MTPConnect, Department of Industry, Science, Energy and Resources, May 2021.

‡ ***Clinically Competitive: Boosting the Business of Clinical Trials in Australia***, Clinical Trials Action Group, Pharmaceuticals Industry Strategy Group, Australian Government, 2011.

While most recommendations have been addressed at least in part, some were beyond the direct influence of the Australian Government.

The cross-jurisdictional Clinical Trials Project Reference Group (CTPRG), formerly the Clinical Trials Jurisdictional Working Group (CTJWG), was established in July 2014. It takes a strategic focus and considers the broad range of issues relevant to enhancing clinical trials and related research and regulatory processes. It seeks to identify and address barriers, including regulatory barriers, to a streamlined and consistent national approach to clinical trials and research that governments can address.

Through this collaboration, all Health Ministers agreed on a Revitalised Clinical Trials Agenda in March 2017.

A further significant reform, the National Clinical Trials Governance Framework is a step towards nationally consistent accreditation of health services undertaking trials. This initiative embeds clinical trials into routine service provision in public and private hospitals and health services, and strengthens clinical and corporate governance arrangements for governments, hospital administrators, health services, private companies, trial sponsors and trial investigators who deliver clinical trials.

There is a chance to build on achievements to date and develop an even better system.

## Why a One Stop Shop?

The most obvious reason is that the work to date has built a momentum for constructive change; an opportunity to make what was described during the consultations as transformational change.

Participants in the consultations saw the need to use a unique opportunity for improvement given the high level of inter-jurisdictional support.

Australia operates in an environment that recognises the sovereignty of jurisdictions with a national regulatory framework that ensures the safety and efficacy of medicines, health treatments and devices. The successes to date, and the complexity, reflect that reality.

The proposal for the One Stop Shop presents a significant opportunity to achieve a nation-wide interconnected, rapidly responsive, streamlined, and intuitive cross-government platform to fast-track trial commencement and patient recruitment – underpinned by integrity of science and of process and concern for all trial participants. When built it will reduce administration and navigation burden for investigators, sponsors, sites, and administrators.

Critical to success will be a genuinely collaborative partnership with Australian jurisdictions and key stakeholders: industry and consumers.

A process with a purpose: more Australians with more options for state-of-the-art treatments.

## Support for a One Stop Shop

I was impressed in the first round of consultations by the breadth of support for the principle of a single national One Stop Shop to cover the research life cycle – including point of first contact with a site, through pre- and post-approval processes to subsequent monitoring; and for a world-leading embedded registry.

There was therefore strong support for incorporation of single national ethics and site-specific approvals, linked to the Good Clinical Practice Inspection Program; and authorisation and notification systems of the Therapeutic Goods Administration (TGA) and the Gene Technology Regulator.

The second round of consultations was also very positive. It was based on a proof of concept: a sample platform that was developed using a micro-services architecture. The concept was used to show how the various pain points (and requirements of the platform) identified in the first round could be managed using that architecture. There was opportunity for participants both to use the concept and to develop further requirements. Again there was substantial support.

More details of the specifications for the platform are in the Report. In particular, I note:

This One Stop Shop platform, when designed, built, tested and implemented would be expected to replace other national and jurisdictional systems – the platform will be specifically built for this purpose:

- Many requirements of the platform have already been collected through the consultation
- Relevant technical expertise should review these collected requirements, and adjust, if necessary, without another round of consultations – we are way past the need for that
- The final agreed list is expected to be put to tender, or a similar test of the market
- That 'builders' will be free to identify the best technological way to meet all the specifications.

Australia cannot afford to let this opportunity pass.

## Governance

Cross-government governance arrangements are essential to success, with representation from all jurisdictional health departments (or equivalent) and key agencies at decision-making and operational/technical levels.

The implementation model that I prefer would be a long-term Inter-Governmental Agreement. It would need to be adapted for purpose, but the underlying principles are shared: balance across jurisdictions; protection from short-term machinery of government changes; hosted by Commonwealth Health (the legal identity with responsibility for securing data, which all governments will collectively own subject to relevant legislative requirements); independent chair; responsible decision making.

Details are in the accompanying Report.

## Conclusion

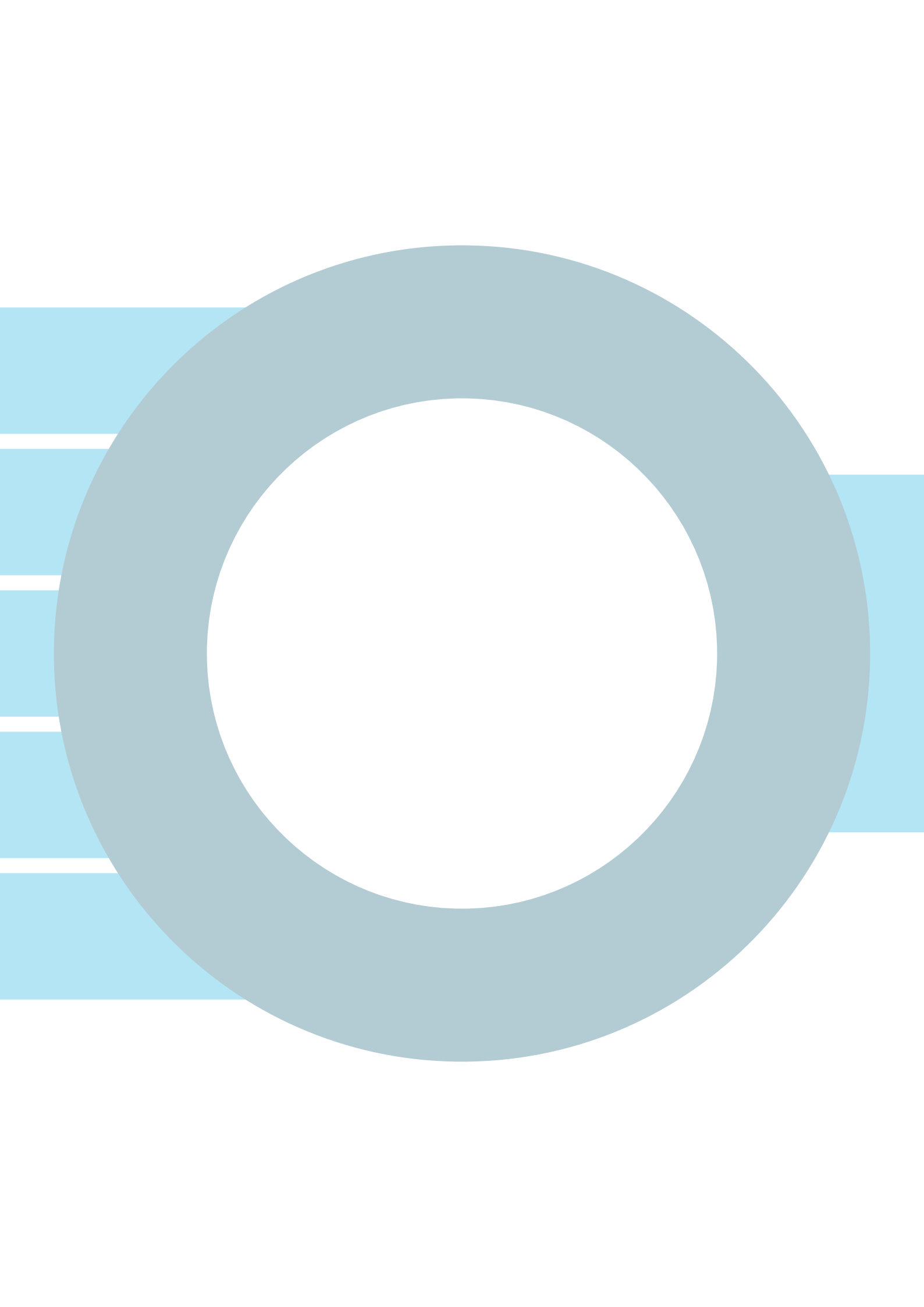
The remarkably deep and wide-ranging consultation leads me to see the clear need for a 'One Stop Shop' as a nation-wide resource with sustainable funding, and with governance arrangements that recognise the Australian reality. Governance should be established in a way that it is free from capricious or idiosyncratic, even when well-meaning, interference.

The initiative should be supported by guaranteed resourcing to support building a high-quality platform and its associated operations, with clearly set out arrangements to sustain it into the future.

A resourced and staffed office within the Australian Government Department of Health and Aged Care will be required to underpin the development and continuous maintenance and refinement of the One Stop Shop, and its evolution, so it remains fit-for-purpose.

The scope should be able to cover all medical and health-related research conducted in Australia. A staged approach to implementation may be appropriate, with an initial focus on public and private hospitals and health services that come within the remit of the National Clinical Trials Governance Framework. The capacity to expand and evolve the platform over time to include all health-related and medical research should be anticipated from the start.

**Professor Ian Chubb AC FAA FTS FRSN FACE**
**Chair, Health and Medical Research Advisory Group**



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# Executive summary

The Australian Commission on Safety and Quality in Health Care (the Commission), in partnership with the Australian Government Department of Health and Aged Care (the Department) and all jurisdictions via the Clinical Trials Project Reference Group (CTPRG), was engaged in 2021 to undertake Australia-wide consultations on a national health-related human research Information and Communication Technology (ICT) platform.

This followed a collaboration in 2020 between all Australian jurisdictional health departments via the CTPRG which developed the concept of a national health-related human research ICT platform to provide a coordinated system of approval and reporting processes for clinical trials and human research in Australia. This platform is called the National One Stop Shop and would be supported by a public facing website (known as the National Clinical Trials Front Door).

In December 2021, the project was expanded to include consultations on the development of the ***National Site-Specific Assessment Core Elements*** for incorporation into the National One Stop Shop.

The consultation project was overseen by the Health and Medical Research Advisory Group chaired by Professor Ian Chubb AC.

The consultation objectives were to gather jurisdictional and sector stakeholder preferences for the National One Stop Shop, capture a detailed understanding of the workflow systems currently in place in the sector, identify future requirements and evaluate the challenges and high-level risks involved in the development and implementation of a National One Stop Shop. An overview of the consultation is provided below. The findings from the consultation also informed the Proof of Concept for the National One Stop Shop and public facing website (the National Clinical Trials Front Door).

Twenty-three findings have been identified which inform five recommendations. Further detail is contained within this Report.

## Overview

The National One Stop Shop initiative has been welcomed by the Australian health research sector as an intuitive, single national approvals, research management and workflow system enabled through digital smart technology to harmonise systems and processes nationally. Industry and the clinical trials sector are strong advocates for a single national cross-jurisdictional platform to address long-standing systemic issues and improve sector productivity.

The breadth of engagement in the national consultation, inclusive of governments, researchers, commercial trial sponsors, health service organisations, universities, individuals, the community and others with an interest in the sector, was exhaustive. There was a sense of genuine enthusiasm and anticipation for the proposed platform as the sector recognised, through demonstration of the Proof of Concept, how improved research and organisational outcomes could be realised through information sharing between components within the platform.

The concept for the National One Stop Shop builds on international evidence that nationalised platforms are critical to building a stronger and more competitive health-research sector, and that jurisdictional collaboration is critical to success in federated health systems.

**Participants throughout the consultation, and views expressed through written submissions, supported a single National One Stop Shop cross-government approvals platform to cover the research life cycle – from point of first contact with a site, through pre- and post-approval processes, to post-research monitoring.**

**Stakeholders agreed the platform should be fit-for-purpose for all jurisdictions, for the conduct of all categories of health and human research that permits users to enter data and upload documents once only and have them automatically shared with all the relevant applications and submissions to various parties.**

The platform would represent significant value for money if delivered via competent service provider(s) and would greatly improve the operating environment for research in Australia. The views expressed confirmed that the risk of not implementing a national approach outweighed the risks associated with implementing national ICT infrastructure.

The platform would deliver more effective and efficient administration of research with greater visibility and transparency of the return on investment for the community. A streamlined, efficient, harmonised, and predictable operating environment is essential for enabling a vibrant, optimal health and medical research ecosystem.

Nationwide reporting on the breadth of research activity would inform policy, regulatory and funding decisions and would assist all governments to respond to areas of need in a rapid, coordinated and strategic manner based on real-time, accurate information.

Ultimately, the National One Stop Shop and the National Clinical Trials Front Door would make it easier for patients, researchers, industry representatives and sponsors to find, conduct, participate and invest in high quality and ethical research in Australia.

This report on the consultation project to develop the requirements and technical mapping of the National One Stop Shop and National Clinical Trials Front Door provides the following:

- An overview of current systems including user experiences and issues to address
- Technical mapping of current system architectures and preferences for the National One Stop Shop and National Clinical Trials Front Door
- Insights from the three national surveys: ***National Systems Survey Report***, ***National Site-Specific Assessment Survey Report*** and ***Community Perspectives Survey Report***
- Themes received through written submissions and consultations
- Outcomes of national consultations to finalise the core elements of the national SSA and, specifications for the final national SSA core data elements
- The features developed in the Proof of Concept
- High-level functional and non-functional requirements for the National One Stop Shop and a public facing website for the community (the National Clinical Trials Front Door)
- Recommendations for implementation.

## Consultation summary

The Commission convened the **Health and Medical Research Advisory Group** chaired by Professor Ian Chubb AC, to advise on the project in line with the requirements of the Secretary of the Department and the expectations of the CTPRG.

Given the complexity of the project and the technical expertise required, eight Expert Reference Groups and ten Subject Matter Expert Panels were also established to inform the consultation approach and test key ideas as they emerged. Membership of these groups is detailed in **Appendix 1**.

The national consultations were conducted in two phases. The objectives of the consultations were three-fold:

### Phase I: 5 October 2021 to 17 December 2021

1. To document, including technical mapping*, current jurisdictional research approval systems and business processes, and those of the Therapeutic Goods Administration (TGA); the Office of the Gene Technology Regulator (OGTR); the National Health and Medical Research Council (NHMRC) and the Australian New Zealand Clinical Trial Registry (ANZCTR) and to:
   a. document current business processes and issues to address
   b. gather high-level functional and non-functional requirements and future business processes for the National One Stop Shop and National Clinical Trials Front Door

* Technical mapping was undertaken by a specialist Business Analysts and System Architecture specialist. Mapping, took into account current system technologies, the flow of data from collection points to general business use and storage, data structures and models.

### Phase II: 12 April 2022 to 29 June 2022

2. To test functional requirements gathered through the first phase of consultation via the Proof of Concept with subject matter experts and refine the sector requirements for the National One Stop Shop and National Clinical Trials Front Door
3. To specify the core elements of the national SSA for public health service organisations for incorporation into the National One Stop Shop ethics and local site approval workflow, via the SSA process.

Consultations involved key Australian Government agencies including the TGA, OGTR and NHMRC, jurisdictional health departments and their research ICT providers, the ANZCTR Executive, representatives from the New Zealand Ministry of Health and Medical Technology and Pharmaceutical (MTP) industry the sector more broadly.

Participants represented jurisdictional health departments, health service organisations, the commercial research sector, universities, medical research institutes, government agencies, Aboriginal and Torres Strait Islander representative groups, consumers and other individuals with an interest in the sector.

The consultation project achieved high engagement with the sector with many of the stakeholders involved numerous times throughout the consultation, including:

- Conservatively, more than 1,400 people attended the consultations
- Fifty-four face-to-face sessions involving more than 870 individuals
- Over 25 jurisdictional, technical and reference group meetings with additional ad hoc meetings upon request
- Ninety-four subject matter experts tested and provided feedback on the National One Stop Shop Proof of Concept
- One thousand and sixty-four individuals reviewed and provided feedback on the Proof of Concept via public webinars
- Eight hundred and twenty-three individuals and groups participating in the targeted consultation to finalise the minimum SSA requirements
- Forty-five written submissions on the needs of the sector for a National One Stop Shop and the minimum SSA requirements were received
- Three surveys were conducted to clarify elements of the design: ***National Systems Survey Report*** (n=599 responses); ***Community Perspectives Survey Report*** (n=477 responses) and ***National Site-Specific Assessment Survey Report*** (n=582 responses).

More than 5,000 stakeholders received periodic updates and emails on the progress of the consultation project through the Commission's comprehensive clinical trials stakeholder contact list.

The consultation schedules and a summary of consultation participation by high-level groupings is provided at **Appendix 2**.

## Findings

A summary of the findings from the extensive consultations on the National One Stop Shop and National Clinical Trials Front Door is provided below. A full discussion of the points raised are included in the report under **Consultation insights**.

### 1 Finding 1: Issues associated with current systems and processes cannot be addressed through maintaining the status-quo

The consultation project identified that existing systems are often supported by local processes and databases as 'work-arounds' due to current system(s) architecture being inflexible, costly to amend and associated with extensive delays when system issues arise and/or enhancements are requested. The application of disparate policies and processes through the various existing systems has also contributed to poor user experience, dissatisfaction of the work force and possibly staff attrition.

Participants supported the intended purpose of the National One Stop Shop, to streamline and harmonise systems and processes nationally and, to build awareness and support for clinical research to make it easier for patients, researchers, industry representatives and sponsors to find, conduct, participate and invest in high quality and ethical research in Australia.

Participants also anticipated that the National One Stop Shop would address issues associated with multiple jurisdictional and private sector ethical and SSA approval systems and processes that research entities and individuals (commercial, academic and clinical) are required

to navigate to conduct research in Australia. A unique national identifier would assist in tracking a project across its lifecycle and clear guidance on data custodianship, approvals and sharing would be welcomed by the sector.

Issues with existing systems are tabulated in **Appendix 3** and in the ***National Systems Survey Report*** (Addendum 1).

### 2 Finding 2: There is jurisdictional and sector wide support for a single, centralised platform that would deliver the core functions of the National One Stop Shop in the first phase of development

Consultation feedback provided a clear and consistent view of the scope and functionality the sector is seeking in a centralised national system '… to be used by all jurisdictions, including universities, for the conduct of all categories of health-related human research'. The sector repeatedly expressed the view that a single information workflow 'enter once, use multiple times' would make it faster and easier for users, minimise duplication and make the research process significantly less burdensome.

Stakeholders preferred a model that would be suitable for the full scale of health-related human research, from single-centre projects to multicentre, multinational randomised controlled clinical trials. The sector called for system capability to enable profile creation for different users and equity in access by the public and private health sectors irrespective of their location to support a robust safety and quality research culture across rural and regional sites, primary care and aged care that would improve access to innovative treatments for the community, wherever they live.

The sector requires a platform developed within a flexible system architecture, that is changeable and adaptable over time, intuitive and provides ease of navigation for end users supported by skip logic. Such logic would enable users to navigate (and be guided through) fields relevant to them.

### 3 Finding 3: Platform enabled reporting on nationally agreed activity/ performance measures would enable compliance reporting and improve the visibility of research operations to inform policy, regulatory and funding decisions

Participants welcomed the functionality of aggregate reporting on already nationally agreed indicators as provided in the National Clinical Trials Governance Framework.* Operational reporting to sites,† sponsors, governments and the community and measures of performance, would be publicly available to demonstrate competitiveness internationally on a cost basis. While reporting against the range of performance measures is required for accreditation, it is therefore important to include relevant capability within the platform. Individual jurisdictions would have the choice as to whether this function is accessible in their state or territory.

Functionality to report on research activity nationally would also enable unique sector analysis, enhance knowledge sharing and greater engagement with local and global networks. It would optimise research efforts across priority areas in health and facilitate the coordination of research effort.

### 4 Finding 4: Cross-jurisdictional governance arrangements would be required for implementation of the platform to ensure ongoing collaboration between state and territory governments

To ensure the achievement of overarching reform objectives, consultation participants strongly supported cross-jurisdictional governance arrangements, with an independent Chair, to oversight the development and management of the national research infrastructure. The platform would be hosted by the Department which would be the legal entity with responsibility for maintaining the platform and securing data, which all governments would collectively own.

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* ***Clinical Trials in Australian Public Health Institutions 2018–19 (NAS reports)*** Framework for National Aggregate Statistics (NAS) – Fourth Activity Report Clinical Trials Project Reference Group (CTPRG).

† Appropriate data governance and data security arrangements under the auspice of a cross jurisdictional governing body would be essential to assuring the community on how research operational data would be held, managed and reported, and would ensure site level data and reporting would be locked down to the site with access by authorised users only.

The data would be held within the Commonwealth secure ICT environment with user permissions defined and user authentication technology built in. This structure would also enable interagency collaborations and capability across national initiatives including but not limited to, the National Collaborative Research Infrastructure Strategy.

There was no support from jurisdictional health departments, the research sector or the community, for the national platform to be outsourced to any other private or public entity.

### 5 Finding 5: The National One Stop Shop platform should be developed within a flexible system architecture enabled through digital smart technology

The sector held that the final platform would be vendor agnostic, intuitive, flexible and adaptable over time. A single national system would be the ideal end-state for the states and territories and the Commonwealth and would provide savings across all jurisdictions. This approach would provide the ability to rapidly advance new standards and process flows, provide close to real-time reporting and enable evaluation of the platform against the needs of sector and the changing international environment.

The application of national standards for data and data exchange to allow system to system-based communication would also be required.

Addressing duplication, fragmentation and challenges associated with unwarranted variation, and ensuring efficient process flows and real time reporting will be difficult to achieve across multiple, distributed systems without massive ongoing investment in integration and standards. Therefore, options for a modular system architecture and recommendations for implementation are provided in the report under **Recommendations for implementation**.

### 6 Finding 6: A national public facing website is the preferred approach for increasing community participation in all health-related human research via the National Clinical Trials Front Door

The single biggest barrier to building awareness and connecting the community to health and medical research, including clinical trials, is the lack of an embedded single national central system that provides real-time reliable information with look-up functionality for the community. The recruitment of participants to clinical trials is largely reliant on specialist clinician referral or admitted patient databases in health service organisations.

Participants supported a public facing website for the community with information flow from the embedded next generation national research registry and other parts of the National One Stop Shop platform that would support the provision of comprehensive information for the community. The website would provide a searchable database, with filters, on clinical trials and health related human research information in plain language(s). A priority for the first iteration of the public facing website would also be a listing or database of rare diseases and treating clinicians, with links to clinical trials.

### 7 Finding 7: National minimum SSA requirements should be incorporated into the single national approval workflow

The SSA was commented on most frequently as the 'thorniest' issue impacting the sector since its implementation in 2009. Information on the process and outcomes of local site risk assessment are fragmented and the necessary approval costs associated with running research are not reported in a uniform manner at the level of health service organisation, network, local health district or jurisdictional health department.

The consultation process confirmed that all elements of the national SSA requirements satisfied the minimum jurisdictional SSA requirements for all health-related human research and that the national SSA requirements, within the National One Stop Shop, would be adaptable to accommodate evolving requirements over time.

The final national SSA core elements incorporating feedback from the sector is provided at Addendum 2b, ***National Site-Specific Assessment Core Elements***.

## 8 Finding 8: Business processes of the TGA associated with the Clinical Trials Notification (CTN) and Clinical Trials Approvals (CTA) Schemes and the Good Clinical Practice Site Inspection Program can be facilitated in the National One Stop Shop

The Proof of Concept demonstrated that it was possible for the technology enabled through the national platform to automate business processes and workflows relating to the CTN and CTA Schemes and integrated with other processes such as Human Research Ethics Application (HREA) and safety notifications. The platform would enable access to authorised users across relevant departments within the TGA. This would include automated payment and invoicing and extractable reporting functionality. The system would also provide a description of the process with clear guidance for all users.

The business requirements for both the TGA and the OGTR have been documented. Work to design and specify all data fields relating to these business processes would be undertaken as a subsequent phase of work (see **Delivery approach** under Recommendations for implementation).

The consultations also heard that adjunct and supportive therapies delivered through clinical trials are usually purchased and managed through existing health service organisations supplier arrangements. While state and territory representatives are generally aware of available stock for their public health services, platform enabled notification functionality could facilitate push notifications to the public and private sectors where they are involved in research (including tele-trial sites), on known shortages of medications and therapies to assist with the management of a critical shortage supply, should it arise. Notifications could include critical information such as the Australian Register of Therapeutic Goods (ARTG) number and pack sizes.

The value of this supportive functionality would increase the visibility of stock locations where they are used for research purposes and, if a particular trial required a particular supportive therapy, manufacturers through a notification process would be able to increase production to ensure supply needs of the sector could be met.

## 9 Finding 9: Platform enabled functions should support the business processes of the OGTR

The OGTR and the sector were supportive of a universal system to support registration and licencing requirements of sites by building on the OGTR's existing business processes. All internal and external users involved in relevant research would be provided with a seamless experience for:

- Laboratory and site registration
- Good manufacturing practice compliance and reporting to the OGTR
- Approval process conducted internally by the OGTR
- Internal OGTR reporting.

## 10 Findings 10: Platform enabled functions should deliver the next generation national research and clinical trial registry

The sector was supportive of the National One Stop Shop platform replacing the current ANZCTR and the Australian Clinical Trials website to provide the single national solution for an embedded national registry and public facing website to increase the utility, reliability and currency of project specific information. The limitations of both the ANZCTR and Australian Clinical Trials website are detailed in the report.

The public facing website of the National One Stop Shop could also incorporate geospatial and disease incidence data to identify geographic patterns of disease, and site profiles (of accredited trial sites) to identify those investigators and sites that could be approached for a study.

The platform would minimise manual workflows and contribute data to the World Health Organization's International Clinical Trials Registry Platform which facilitates publicly accessible prospective registration of all clinical trials.*

Functionality factors to consider in the implementation phase are described in the report under **Consultation insights**. Business requirements for this core platform component have also been developed.

* World Health Organization. **International clinical trials registry platform**. Geneva: WHO.

### 11 Finding 11: There are currently no formal, recognised complaints management and escalation pathways for research participants, nor requirements for sponsors to act should an adverse event occur

Community representatives reflected on a variety of experiences as participants in clinical trials or of supporting someone to participate in a clinical trial. The consultation heard that, while the occurrence of serious adverse events directly related to the investigational product were rare, there is no enforceable requirement for a trial sponsor to act in a timely manner, at no cost to the participant, should serious adverse events occur.

No single entity holds all the levers for the delivery of clinical trials in Australia. Ensuring and oversighting adherence to guidelines is essential for the protection of trial participants. Future governance arrangements for the national platform could give consideration to how the safety and protection of trial participants are best ensured. Past performance of trial sponsor adherence to national guidelines could also be taken into account in their future applications to conduct clinical trials in Australia.

### 12 Finding 12: A research integrity framework should underpin the National One Stop Shop

Research integrity was discussed through the consultations. While most jurisdictions have a Crime and/or Corruption Commission to investigate research fraud, the consultations heard that these events were rare and a greater good could be achieved through the development of the national platform within a research integrity framework.

Participants expected that the National One Stop Shop would be developed in the interest of openness and accountability and would provide assurance to the wider community that there were systems and process in place to support consistently high research standards. There would be with an overarching commitment to continuous improvement, minimising duplication and unnecessary requirements, maximising consistency and the streamlining and harmonising of processes under enduring arrangements with the jurisdictions.

### 13 Finding 13: Implementation of the national platform should have a consumer focus and work efficiently across jurisdictional borders

Consumers and the research community want greater access to innovative trial treatments in a manner that is equitable for all, irrespective of where they live. They were supportive of a streamlined national system that would facilitate an improved clinical trial environment, including capacity to efficiently connect potential participants with appropriate research projects and the provision of each to use publicly available information about clinical trials and health-related human research.

### 14 Finding 14: Further work to improve the timeliness and quality of ethical review nationally would be complimentary to the National One Stop Shop and the harmonisation of systems and processes

The sector supported work underway by the Commission on behalf of the Department and the CTPRG to develop a national quality standard and accreditation scheme for human research ethics committees (HRECs) under the National Mutual Acceptance (NMA) Scheme.

Participants acknowledged that while the NMA Scheme was a key enabler, the accreditation of HRECs would enhance consistency and efficiency in HREC review which would build reciprocal confidence in HRECs review within and between health service organisations and jurisdictions. The sector suggested the quality standards include key HREC functions relating to membership, expertise and training.

The National One Stop Shop would provide the opportunity to refine the information required to support the HREA (and other functions of the platform), so that the minimum information (in addition to that already provided in the study protocol and supporting documents such as the Investigator Brochure) could be developed within the platform. Further work through the design and specification phase would also consider the requirements of providers including Catholic Health Care, the aged care sector, the private hospital sector, ambulance, dental services and the university sector.

### 15 Finding 15: The national platform should be designed in collaboration with Aboriginal and Torres Strait Islander researchers and communities

The consultations were informed by Aboriginal and Torres Strait Islander representative organisations, ethics committees, researchers and networks. These participants recognised that the development of a national platform creates an opportunity to include a genuine review pathway for research projects about, or that seek to recruit Aboriginal and Torres Strait Islander participants.

The platform would facilitate opportunities to build greater collaboration between Aboriginal and Torres Strait Islander researchers and the sector more broadly which would be valuable for sharing lessons learned from Aboriginal and Torres Strait Islander researchers who have developed skills and resources in communicating with remote and metropolitan communities.

### 16 Finding 16: Professional pathways would support research sites to build and maintain a skilled and reliable health research workforce

Developing professional pathways for nurses and other clinical staff to support research sites build and maintain a skilled and reliable research and clinical trial workforce was viewed as critical for the sustainability of the Australian clinical research sector.

### 17 Finding 17: Data migration from existing approval and workflow systems should be via a process that ensures the accuracy of data transferred

Consultation participants, including government agencies, advised on the most pragmatic approach to data migration and broadly agreed that data should be transferred prior to the launch of the new national platform. The sector supported the retirement of existing jurisdictional systems at the point in time when the new national platform would be live. The approach to implementation would be an important priority for jurisdictions and key national agencies participating in the National One Stop Shop.

There was no appetite for any component of the National One Stop Shop to integrate with existing jurisdictional or locally developed systems. An approach to visualising archived research approvals information currently held in jurisdictional systems could be enabled in the national platform.

The preferred approach to data migration and a solution for visualising archived data (currently held by jurisdictional data custodians) is provided in the report. The preferred jurisdictional approach to data migration (as a manual process) is described in **Recommendations for implementation**.

### 18 Finding 18: Jurisdictional health departments would be leaders in the change process in partnership with research networks and the commercial research sector

Setting the approach to managing and communicating the change to move to a new national platform would be the responsibility of jurisdictional health departments under the proposed cross government, governance arrangements.

### 19 Findings 19: Communication and education will be needed to increase community awareness and engagement in the development and enhancement of the National One Stop Shop over time

The importance of communication with the community to improve awareness and build trust in research processes in Australia was repeatedly raised by consultation participants. Meaningful communication and education for the community should be cross-cultural and aim to build health literacy not only in relation to health-related research, but health care and the Australian health system more broadly.

In the report, under recommendations for implementation, the delivery approach proposes a specific workstream for providing a comprehensive communication and education strategy for the community.

### 20 Finding 20: Potential risks for implementation of the National One Stop Shop and mitigating strategies

The risks most frequently identified by consultation participants related to both 'doing nothing' and 'a lack of ambition' in delivering all components of the National One Stop Shop. The opportunity is now, to harness Australia's capacity to deliver quality human-related research as the technologies are available to deliver the solution. A lack of ambition would lead to the delivery of a partial solution that would not meet the needs of governments, the research sector and the community and would not improve the operating environment for the research.

Sector representatives also raised the risks related to ensuring appropriate governance arrangements in place prior to undertaking further work to develop the platform. Implementing appropriate governance arrangements would ensure sufficient resourcing of the platform and oversight of the platform operations. This would include responsibilities for achieving ongoing agreement on the scope of the platform, time to implementation and, the prioritisation of enhancements based on the changing needs of the states and territories and the sector over time.

### 21 Finding 21: The preferred delivery timeline is less than three years

Given the scope of the National One Stop Shop and public facing website, the project estimate for a complete solution should be delivered within two to three years.

A detailed discussion is provided in the report under Recommendations for implementation.

### 22 Finding 22: Guidelines for the review and escalation of very serious adverse events (that may require a research participant to undergo additional medical treatment) are applied invariably by trial sponsors

Sponsors should adhere to national guidelines relating to on-going medical care of trial participants that experience a very severe and/or rare adverse event following participation in a clinical trial. Mechanisms to ensure the safety and protection of trial participants in any health-related human research undertaken in Australia need to be articulated in national guidelines. Past performance of trial sponsor adherence to national guidelines should be taken into account in future applications to conduct clinical trials in Australia.

### 23 Finding 23: Use of the platform should encourage and uphold research integrity

The national platform would be developed in the interest of openness, fairness and accountability and should provide assurance to the wider community that there are systems and processes in place to support consistently high research standards.

The Australian Code for the Responsible Conduct of Research (2018) applies to all research. The platform must therefore support the universal principles of research integrity (honesty, rigour, respect, accountability and transparency) throughout the lifecycle of each project, from concept to design, conduct and also the dissemination of results would also cover systems and processes that enhance good research practice rather than hinder it.

## Recommendations

Based on the detailed analysis of the consultation feedback and the findings above, the following recommendations support the Department and the CTPRG to implement the National One Stop Shop and public facing website as a nationally consistent approach to realising a harmonised operating environment for the approval and management of clinical trials and health-related research: one nation-wide, cross-government, platform.

The Health and Medical Research Advisory Group make the following recommendations to inform the implementation of the National One Stop Shop and public facing website for the community.

### 1 Recommendation 1: Implement a high-quality, fit-for-purpose National One Stop Shop and public facing website for the community by December 2025

Development and implementation of the national platform, the National One Stop Shop and a public facing website for the community (the National Clinical Trials Front Door) should be expedited. This is to minimise further duplication of local system development and further investment in existing systems enhancement by the states and territories. It also capitalises on the existing engagement and willingness of stakeholders to be involved in the national platform demonstrated through the extensive consultations.

The business case must be developed expeditiously and include the full cost, including (but not limited to) building the platform, education and training, the transfer of data from existing systems and ongoing operational costs. This investment will strengthen the capacity of the Australian research sector to deliver high quality research outcomes which will attract further investment, business opportunities and growth in the Australian economy more broadly over time.

The scope and requirements of the platform were thoroughly tested with all stakeholders who agreed that the platform should be fit-for-purpose for all jurisdictions, for the conduct of all categories of health-related human research.

The first phase of development should deliver a single national platform that provides all components of a national cross-government central platform within a single national digital workflow. Non-functional (system security) requirements should be strategically aligned with whole-of-government policies.

The national research ICT infrastructure should be hosted in the Commonwealth secure ICT environment (the legal identity with responsibility for securing and holding data which all governments collectively own. There was no appetite through the consultations for the platform to be hosted by a private entity.

### 2 Recommendation 2: Enduring cross-jurisdictional governance arrangements for the management and implementation of the national platform must be established. The governing body would be responsible for the implementation and management of the platform

The national platform should be implemented and managed by cross-government, governance arrangements with an independent Chair and advisory subcommittees from the commercial research sector, research networks and the community. It is anticipated that participation in the governance arrangements would be enabled by jurisdictions committing to relevant intergovernmental agreements, including the *Encouraging More Clinical Trials in Australia Agreement*. The underlying principles of the inter-governmental agreement would ensure balance across jurisdictions, protection from short-term machinery of government changes and responsible decision making.

There would be an overarching commitment to continuous improvement, minimising duplication and unnecessary requirements, maximising consistency, streamlining and harmonising of processes under enduring arrangements with the jurisdictions is essential.

The platform would be built to meet the needs of jurisdictions and the Commonwealth, reflecting the outcomes of national consultations. All have agreed that they will retire their existing systems. This would ensure all public sector research would be managed through the national platform. The platform would be available for use by the private health care sector, the aged care sector and others to ensure a seamless and truly national approach.

Detail supporting this recommendation is provided in the report under Consultation insights, the ***Community Perspectives Survey Report*** and key findings.

### 3 Recommendation 3: The platform architecture should deliver as a minimum, all requirements gathered and tested through the consultation process

The national consultation has identified the requirements which can inform a technically agnostic platform including robust governance arrangements, secure hosting environment, and requirements for the appropriate management of privacy and confidentiality of data. A single national system would be the ideal end-state and would provide savings across all jurisdictions. This approach provides the ability to rapidly advance new standards and process flows and provide real-time reporting.

Based on expert advice and sector feedback there is no support for the integration of the national platform with existing approval systems currently operating within the jurisdictions. Engaging with multiple proprietary providers is high-risk and costly and is not supported. Instead, a single vendor or single consortia should be engaged, following an open approach to market.

An overview of the potential architecture solutions considered for the platform is detailed in the report under System gap analysis. Recommendations for implementation and the proposed approach to implementation are also provided.

### 4 Recommendation 4: The National One Stop Shop should provide a public interface so the community and their carers can easily identify trial and research options (previously referred to as the National Clinical Trials Front Door)

In the first phase of development, information flowing though the platform should provide a publicly accessible, searchable database of all health-related human research with filters for clinicians and members of the community to search for a trial or health-related human research projects with information in plain language(s).

The website should provide all registered clinical trials in Australia, and their recruitment status, site location and site contact details. An online directory with matching capability, linking researchers, clinicians, and participants should also be enabled. The website would also provide a prospectus for potential research partners and the commercial research sector to search for trial sites and obtain information on site capability, capacity and status of accreditation. The community supports functionality to enable individuals to provide 'consent to be contacted' and the website could also enable links to proprietary recruitment providers. A priority for the first iteration of the public facing website would also be a listing or database of rare diseases and treating clinicians, with links to clinical trials.

### 5 Recommendation 5: The development of the platform should be accompanied by a targeted communication strategy and education campaign tailored to meet the needs of the community

The strength of the Australian health research sector relies on the support of the community. A communication strategy and education campaign which targets community awareness and assists in building trust in health related-human research processes in Australia, is essential. Meaningful communication should be cross-cultural and aim to build health literacy not only in relation to health-related human research, but health care and the Australian health system more broadly.

# Consultation report

## Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) in partnership with the the Australian Government Department of Health and Aged Care (the Department) and all jurisdictions via the Clinical Trials Project Reference Group (CTPRG) has delivered national consultations and a Proof of Concept for a national health-related human research platform known as the National One Stop Shop and the National Clinical Trials Front Door, which would provide a public facing website for the community.

The concept for the National One Stop Shop builds on international evidence that nationalised platforms are critical to building a stronger and a more competitive health-related human research sector, including clinical trials, and that jurisdictional collaboration is critical to success in federated systems. The National One Stop Shop initiative has been welcomed by the health and human research sectors, including universities. Industry and the clinical trials sector are strong advocates for this functionality to address long-standing systemic issues and sector productivity.

The Commission convened the **Health and Medical Research Advisory Group** chaired by Professor Ian Chubb AC, to advise on the project in line with the requirements of the Secretary of the Department and the expectations of the CTPRG. Subject Matter Expert Panels and Reference Groups were also established to inform the consultation approach and to test key ideas as they emerged.

## The Commission

The Commission works in partnership with patients, consumers, health professionals, managers, policy makers and healthcare organisations to achieve a sustainable, safe, and high-quality health system. The Commission's strategic intent 2020–2025 has four priority areas:

1. Safe delivery of health care
2. Partnering with consumers
3. Partnering with healthcare professionals
4. Quality, value, and outcomes.

A key role of the Commission is to lead and coordinate improvements in safety and quality in health care in Australia by identifying issues and policy directions and recommending priorities for action.*

The Commission's work is informed by Australian and international research and evidence, external advisory committees, working groups, public consultation and workshops. Proposals are referred to the Commission's Inter-Jurisdictional Committee and Private Hospital Sector Committee for review and input before consideration by the Commission's Board. Major Commission proposals are then provided to the Health Chief Executives Forum and Health Council.

The Commission is jointly funded by all Australian governments on a cost sharing basis. The Commission is situated in Sydney and is managed on a day-to-day basis by its Chief Executive Officer. More information can be found on the **Commission's website**.

* 2019, Addendum to the National Health Reform Agreement 2011.

## Background to the project

A vibrant health and medical research sector serves to attract and retain high quality clinicians in Australia and builds the knowledge, capability and capacity of clinical staff and our health systems. Substantial national and international research investments stimulate the Australian economy, are a source of significant commercial gain, and provide important research infrastructure support.

A streamlined, efficient, harmonised, and predictable operating environment is essential for enabling a vibrant, optimal health and medical research ecosystem. With this, Australia will be better placed to effectively coordinate research effort, better inform medical research investments at all levels of the system, rapidly deploy and coordinate research capability, and ensure we are well positioned to rapidly respond to future health threats with high-quality evidence supported by research of the highest integrity.

Broad consultations with the sector over the last decade* identified key barriers to conducting clinical trials and research in Australia that include long-standing fragmentation and variation between health services and jurisdictions, difficulties with patient recruitment, and lengthy start-up times due to duplication, red-tape and inconsistency in approvals and related processes.

In response to these issues, plans to develop a national platform in collaboration with all jurisdictions and key regulatory agencies were announced in 2020. The concept for the National One Stop Shop and the National Clinical Trials Front Door was co-designed by all jurisdictions via the CTPRG, prior to the consultation process.

The Commission's review of the national and international **literature** in 2018† and updated in 2021, revealed that governments investing in their local research and development environments had realised increased productivity. The Commission drew on work undertaken to update the literature review with evidence for nationalised ICT infrastructure, as well as research registration, regulatory notifications and other systems that facilitate participant recruitment and accurate and real-time reporting on research activity.

Several countries have implemented initiatives to streamline the ethical review and clinical trials regulatory processes to improve the clinical trials operating environment. The most notable changes in infrastructure are occurring in the European Union (EU) with the implementation of new regulation, Regulation EU 536/2014, and the launch of the Clinical Trial Information System (CTIS) in January 2022. All European member states are required to adhere to the Regulation to achieve research approvals via the multi-national CTIS within four weeks. In the United Kingdom (UK), the bi-national Integrated Research Application System (IRAS) manages all permissions and approvals for research in the UK.

South Korea continues to be a leader in the Asia Pacific region and internationally with the national eCommerce platform the KoNECT (Korea National Enterprise for Clinical Trials) comprising a One Stop Shop; Business Centre; Interactive Gallery and the KoNECT Integrated Clinical Trial Information System (KIIS). KIIS aims to provide all stakeholders with the information required to plan and conduct clinical trials in South Korea. It provides access to pharmaceutical, health care and clinical trial data sets, and information about South Korea's clinical trials over the last five years. Research approvals are routinely achieved within four weeks.

International research approval systems have various levels of integration with other systems, such as: look-up functionality via linked databases of member countries (in the EU and the UK); jurisdictional data bases; trial sites; clinical conditions; sponsors and affiliate organisations and to the regulator for product information. In the EU and the UK, ethics and local site authorisation is achieved through a single workflow system and process.

* ***Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth***, MTPConnect, Department of Industry, Science, Energy and Resources, May 2021.

† ***Evidence Check on national human research approvals infrastructure. Addendum to the National Clinical Trials Governance Framework Literature Review*** (2018). Australian Commission on Safety and Quality in Health Care, 2022.

## The current Australian research technical environment

In Australia, stakeholders both public and private are required to enter similar information into multiple systems, multiple times to comply with regulatory and ethical guidelines for the conduct of health and medical research. For example, researchers and sponsors are required to enter information relating to the Human Research Ethics Application (HREA) and SSA into various research management systems as well as the Australian, ANZCTR and the TGA trial management systems.

Australia has implemented several initiatives to improve the clinical trials operating environment and clinical trials approval processes such as the National Mutual Acceptance (NMA) scheme and the development of the HREA by the NHMRC. Australia has recently published the National Teletrials Compendium which consists of two publications addressing the principles and the standard operating procedures for clinical trials and teletrials. Australia has also developed an accreditation scheme for health service organisations conducting clinical trials.

However, there is no centralised national research workflow or system. New South Wales (NSW) and the Australian Capital Territory (ACT) have implemented the Research Ethics and Governance Information System (REGIS). The Ethical Review Manager (ERM) is used in Queensland (Qld), Victoria and Mater Research. The Western Australia (WA) Government Department of Health has implemented the Research Governance Service (RGS) and more recently, Research GEM has been implemented in South Australia (SA).

These various, disparate systems and processes implemented across Australia have created a fragmented and complex operating environment, without visibility and transparency of the research process.

## National One Stop Shop for all health-related human research approvals

All Australian jurisdictional health departments collaborated to develop the concept for the national ICT approvals platform that, at its core, would provide a national system for key approval and reporting processes for clinical trials and human research within a single national ICT portal. The portal would include a sophisticated national ethics, governance and research management system; incorporate the Clinical Trials Notification (CTN) and Clinical Trials Approvals (CTA) schemes; include requirements of the Office of the Gene Technology Regulator (OGTR) in addition to an embedded next-generation national clinical trials registry and other modules to enable accurate and real-time information on clinical trials activity to enable appropriate monitoring of performance and to seek to reduce research waste.

The key strength of the National One Stop Shop is that it would be founded on, and seek to effectively join up and replace, individual and divergent jurisdictional health trial and research management systems, ideally achieving a single consistent national system. Jurisdictional sovereignty of clinical trials workflows within the portal will be maintained. Most jurisdictions have indicated a preference to move directly to a single national platform provided it meets the jurisdictional requirements.

The National One Stop Shop would facilitate rapid and streamlined approvals and address long-standing challenges with duplication, delays and fragmentation that would be unlikely to be otherwise overcome. It would reduce investigator and sponsor administrative and navigation burden and expedite time to trial commencement. The National One Stop Shop would enable and underpin a new nationally consistent approach to accreditation for trials sites in public and private hospitals, and it would provide reporting functionality that will serve to maintain Australia's reputation for safety and quality in research, and drive quality improvement and strategic positioning.

The delivery of a National One Stop Shop would progress Australia's agenda to position itself as a global leading destination for research and clinical trials and assist all governments to respond to areas of need in a rapid, coordinated and strategic manner. This will ensure better health for Australians while increasing investment in the sector and contributing to economic recovery following the COVID-19 pandemic environment.

## National Clinical Trials Front Door

Complementary to the National One Stop Shop is a proposal to develop a cutting-edge National Clinical Trials Front Door website. The functionality would include a national volunteer register and portal with artificial intelligence (AI) capability, interfacing with and drawing on key functionality of the National One Stop Shop to help match prospective participants to trials. Specific functionality for the National Clinical Trials Front Door website was refined through the second phase of the national consultation, with technical specifications for a public facing website for the community included in the Proof of Concept.

## Accreditation scheme for ethics committees participating in the National Mutual Acceptance (NMA) scheme

The NMA Scheme currently operates via a Memorandum of Understanding (MOU) that recognises each jurisdiction's existing ethical review processes. This includes multicentre ethics review in public health service organisations for any form of human research as defined in the *National Statement on Ethical Conduct in Human Research* (National Health and Medical Research Council, 2018).* In order that Human Research Ethics Committees (HREC) reviews of human research are accepted under the NMA scheme, the HREC conducting the review must be certified under the NHMRC National Certification Scheme.

The authorising environment for the ethical review of human research already minimises regulation. However, site level lack of confidence in other stakeholders and HRECs have created a barrier to achieving greater efficiencies that are possible through mutual acceptance of ethical review. The NMA scheme has sought to address these system complexities and challenges and has been consistently identified as a key enabler of Australian clinical trials.

While there is an agreed national HREA, and therefore agreed data fields, these fields are not mandatory and implementation varies. Differences in standard data fields and definitions reflect the variation between most jurisdictions and their research management systems. Additionally, it is not possible for HRECs to meet their responsibilities to monitor the research in the post-approval phase due to issues that could potentially be resolved through a single national platform.

Jurisdictions agreed in late 2019 to expand the NMA scheme through development of an accreditation scheme via the CTPRG and the Commission to enable a single ethical and scientific review by public and private ethics committee providers that have been accredited in Australia. The accreditation of HRECs aims to enhance consistency and efficiency and build reciprocal confidence in HRECs review to support the expansion of the NMA scheme across the public, private and not-for-profit health care sectors.

The Commission is undertaking a concurrent project on behalf of all jurisdictions via the CTPRG to develop a national quality standard and accreditation scheme for national HRECs under the NMA scheme.

* National Health and Medical Research Council ***National Statement on Ethical Conduct in Human Research*** (2007) – Updated 2018.

### Minimum requirements for the national SSA and authorisation process

In 2018, the national core SSA elements were drafted by ACT Health on behalf of the CTPRG. In 2019, the core elements of the national SSA were refined through a formative evaluation process lead by the Commission.

In 2019, the CTPRG acknowledged the lack of a single SSA continues to be a major barrier to timely research site authorisation in Australia. The CTPRG then agreed that the development of a single national process for local site risk assessment and the authorisation of health and human research is essential to the successful implementation of the National One Stop Shop. Further to this, there was a decision under the Overlapping Regulations agenda to expedite development of the single national SSA requirements for jurisdictional agreement by the end of March 2022.

## Policy context

The Australian Government is the most significant investor in the health and medical research sector to improve health outcomes and develop Australia as a global destination for medical sector jobs, research and clinical trials. National and international research investments stimulate the Australian economy. The Medical Technology, Biotechnology and Pharmaceutical (MTP) sector alone contributed $5.4 and $5.5 billion in Gross Value Added (GVA) to the Australian economy in 2020 and 2021.* Of this total, clinical trials are estimated to contribute around $1.4 billion.† The health and medical research sector employs approximately 32,000 people and contributes a further 78,000 jobs in the medical technologies and pharmaceutical sector.† Several policy initiatives have underpinned recent improvements in the sector.

### Encouraging More Clinical Trials in Australia

In 2016, through the CTPRG, the $7 million Encouraging More Clinical Trials in Australia initiative under the Revitalised Clinical Trials Agenda, was implemented. This initiative was the key overarching national initiative driving reform and efficiency in the conduct of clinical trials to assist state and territory governments achieve system redesign. Among other things, this agenda sought to establish central points of contact to reshape locally operating clinical trial processes and systems, improve system navigation for sponsors and participants, streamline trial processes and time to trial start-up, and improve workforce capacity. The federal Budget 2021–2022 allocated a further $6 million to enhance Australia's status as a leading option to conduct clinical trials by continuing the Encouraging More Clinical Trials in Australia program.

### National Mutual Acceptance Scheme

The NMA of ethical and scientific review of clinical trials scheme was established in 2013 and in December 2015, the scope of NMA Scheme was expanded beyond clinical trials to include all human research. As noted above, this initiative has been valuable in reducing HREC review timelines, however, further work is now underway to streamline the acceptance of the NMA across the public and private health care sectors.

* ***Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth***, MTPConnect, Department of Industry, Science, Energy and Resources, May 2021.

† ***Clinically Competitive: Boosting the Business of Clinical Trials in Australia***, 2011, Clinical Trials Action Group, Pharmaceuticals Industry Strategy Group, Australian Government.

## National Clinical Trials Governance Framework

The ***National Clinical Trials Governance Framework and User Guide**** is a key element of the Revitalised Clinical Trials Agenda and was endorsed by all jurisdictions in February 2022. The outcome will be the integration of clinical trials into health service corporate and clinical governance systems and nationally consistent accreditation of clinical trial services under the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme from early 2023.

Building on these initiatives, the proposal for an interconnected and sustainable national platform for all health and medical human research, combined with other initiatives underway, represents transformative change for the sector. At a minimum, the components of the proposed national platform have jurisdictional and industry support to reduce duplication, expedite trial commencement and enable the first real-time national picture of health and medical human research activity.

# Consultation method

A targeted consultation and stakeholder engagement approach was developed and endorsed by the Department and the CTPRG. Advice on the approach was provided the **Health and Medical Research Advisory Group** (Advisory Group) chaired by Professor Ian Chubb AC and oversighted by the Commission's governance committees and Board. Subject Matter Expert Panels and Reference Groups were also established to inform the consultation approach and to test key ideas as they emerged (**Appendix 1**).

The consultation and engagement strategy approach identified key stakeholders with whom to consult and opportunities for early engagement. It also outlined the strategy for the most efficient and meaningful way to build awareness and engage the various key stakeholder groups.

The approach outlined below ensured all stakeholders had the opportunity to participate in the consultations, receive information on the evidence for change and the opportunity to share their preferences for the national platform. In this way, the approach provided confidence and reassurance to the sector on the transparency of the process and ensured their views on the national platform for all health-related human research, were reflected in the final recommendations.

## Objectives

The objectives of the consultation were three-fold:

1. To document, including technical mapping†, current jurisdictional research approval systems and business processes, and those of the TGA; OGTR; NHMRC and ANZCTR Executive to
   a. document current issues
   b. gather high-level functional and non-functional requirements and future business processes for the National One Stop Shop and National Clinical Trials Front Door.
2. To test functional requirements gathered through the first phase of consultation via a Proof of Concept with subject matter experts and refine the sector requirements for National One Stop Shop and National Clinical Trials Front Door.
3. To specify the core elements of national SSA for public health service organisations for incorporation into the National One Stop Shop ethics and local site approval workflow, via the SSA process.

This third objective was added following a decision in December 2021 by the CTPRG to expedite the development of the minimum SSA requirements. An additional consultation process was conducted concurrently to the already planned Phase II consultation to address this.

* National Clinical Trials Governance Framework and User Guide. Australian Commission on Safety and Quality in Health Care, 2022. **www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide**

† Technical mapping was undertaken by a specialist Business Analyst and System Architecture specialist who took into account current system technologies, the flow of data from collection points to general business use and storage, data structures and models.

## Initial scope for the National One Stop Shop for discussion through consultations

Gathering jurisdictional preferences was a key outcome of the consultations in addition to developing a detailed understanding of the workflow systems currently in place in the jurisdictions and their future requirements for the National One Stop Shop and National Clinical Trials Front Door. The capabilities considered by the sector included:

1. The integration of research applications, notifications, approvals and reporting processes for clinical trials and all human research within a single national digital resource. Information is to be shared across multiple systems to expedite the research review and approval process and increase the currency and reliability of information across the life cycle of the clinical trial or research project.
   - Key functionality: complete essential forms within a single ICT platform to reduce the burden and confusion caused by navigating multiple systems, forms and platforms and repeat entry of the same information.
2. Compatibility with existing jurisdictional ethics and local SSA systems and processes, which over the longer term enables jurisdictions to de-commission their systems in favour of the single national integrated platform. Notably, a single national platform would also assist smaller jurisdictions that have not yet invested in web-based research workflow systems.
   - Key functionality: interoperability with existing workflow systems within the public health sector. Integration with other sectors including the private health service sector, universities and private and public research institutes may also be considered.
3. Incorporation of the Clinical Trials Notification (CTN)/Clinical Trial Approval (CTA) schemes and Adverse Event Management System (AEMS) managed by the TGA.
   - Key functionality: information related to the CTN/CTA submissions, variations and AEMS may be drawn from a single approvals process embedded in the national platform and provide real-time information on the status of trials and emerging safety and quality issues.
4. The embedding and integration of a next generation clinical trials registry (building on the current ANZCTR) to provide the next World Health Organization (WHO) Australian primary registry and provide a complete register of all clinical trials conducted in Australia. The registration of clinical trials will be automated through integration with the national platform and data may be provided and accessed by third parties seeking to recruit sites, investigators, and participants to clinical trials.
   - Key functionality: The registry will enable the publication of current information on trial status; trial protocols and the outcomes of all trials to minimise duplication and reduce research waste.
5. The capacity to explore other clinical trial and research approvals to be incorporated into the National One Stop Shop over time, such as relevant approvals for the Gene Technology Regulator.
6. Provision of sophisticated reporting functionalities for multiple users including but not limited to site level reporting dashboard for trial coordinators, trial investigators, trial sponsors, funders, and consumers.
7. Technical support for future potential enhancements through integration with national health data collections, including national health registries to support health, welfare and care options for the community and government policy development.

Non-functional requirements underpinning the National One Stop Shop platform would be strategically aligned with whole-of-government policies (WoG) including but not limited to:

- ICT Customisation and Bespoke Development Policy
- ICT Skills Policy
- Australian Government Architecture
- Cyber Security Policy
- Cloud Computing Strategy
- Open Source Software Policy
- WoG Common Operating Environment
- Environmental Sustainability of ICT
- Gov2.0
- Data Centre Strategy
- Digital Service Standard.

## Consultation approach

A targeted consultation and stakeholder engagement strategy was developed to ensure high impact stakeholders participated in the national consultation process, received information on the evidence for a national platform and had the opportunity to share their information and preferences for the National One Stop Shop and the National Clinical Trials Front Door.

The consultation was undertaken in two phases, with an additional consultation to finalise the minimum SSA requirements undertaken concurrently with Phase II.

The Consultation and Stakeholder Engagement Strategy provides the consultation purpose and objectives and identifies key stakeholders with whom the Commission consulted (**Appendix 2**). **Figure 1** illustrates the consultation approach to meeting the overall consultation objectives. **Figure 2** provides the consultation roadmap.

### Phase I consultation: 5 October 2021 to 17 December 2021.

The literature review of 2018* with evidence for national research infrastructure was updated and three surveys were developed to maximise the breadth of stakeholder engagement through the first and second phases of consultation.

The first survey conducted in 2021, the ***National Systems Survey Report*** focussed on the user experience of current systems, businesses processes and requirements for a national health-related human research workflow system, inclusive of ethics and local site approvals, with functionality for a national health-related human research registry; notifications to the TGA and reporting to support implementation of the National Clinical Trials Governance Framework (Addendum 1).

The second survey focused on the minimum national SSA requirements, the ***National Site-Specific Assessment Survey Report*** (Addendum 2a) and the ***Community Perspectives Survey Report*** (Addendum 3) focussed on the experience of the community in accessing clinical trial and research information and/or, of participating in, or supporting someone to participate in, a clinical trial or research project.

Consultation sessions were recorded and the feedback mapped against identified stakeholder groups using Enterprise Architecture software. Composite diagrams were created. Specification Manager Software was used to enable viewing of the diagram in text with a traceability window to show the relationships between entities and individuals (Relationship Matrix) and the feedback received including future state business requirements. Multiple additional meetings between the Commission's Business Analyst and System Architecture Design Specialist were conducted with the custodians of the existing jurisdictional and other systems.

### Phase II consultation: 12 April 2022 to 29 June 2022

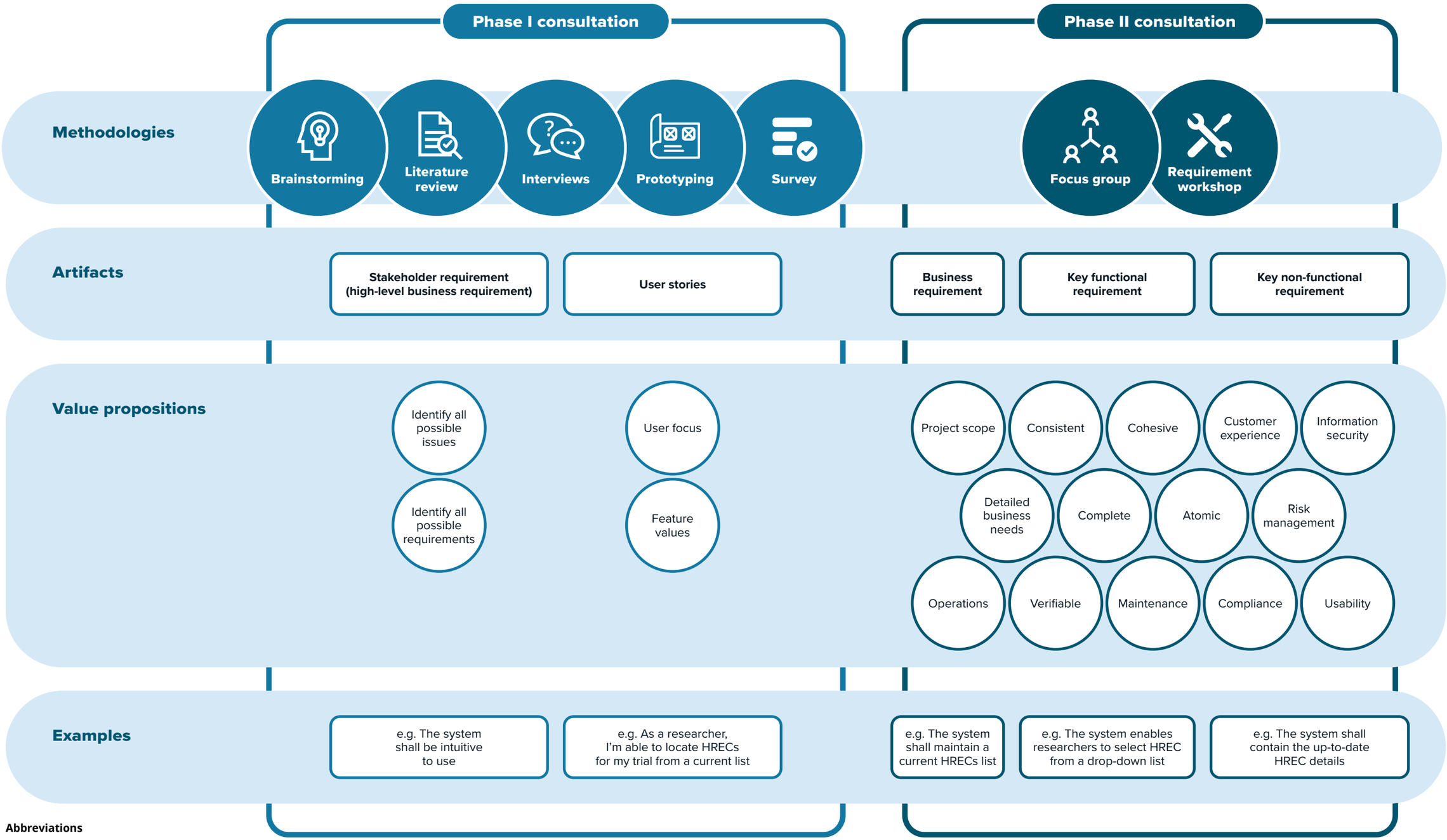
Beginning in April 2022, the second phase of the consultation involved testing the requirements developed in the Proof of Concept and gathered through the first phase of the consultation. As a first step, the Proof of Concept was tested with the CTPRG, jurisdictional health departments and Commonwealth agencies.

The consultation was then extended to the Subject Matter Expert Panel members representing the sector who worked through the various Proof of Concept workflows. This allowed them to interact with the services developed within the Proof of Concept and to provide feedback on the potential design, navigation and logic of the national platform. A feedback feature was also developed within the Proof of Concept to enable the generation of a report of stakeholder feedback received during each session.

In addition to seeking participant feedback on the Proof of Concept and to further refine the functional and non-functional requirements for the national platform, all participants were asked to reflect on their past experience with new system implementation; to provide their views and advice on approaches to managing change; their preferred options for data migration and potential risks that should be considered for implementing the platform.

* ***Evidence Check on national human research approvals infrastructure. Addendum to the National Clinical Trials Governance Framework Literature Review*** (2018). Australian Commission on Safety and Quality in Health Care, 2022.

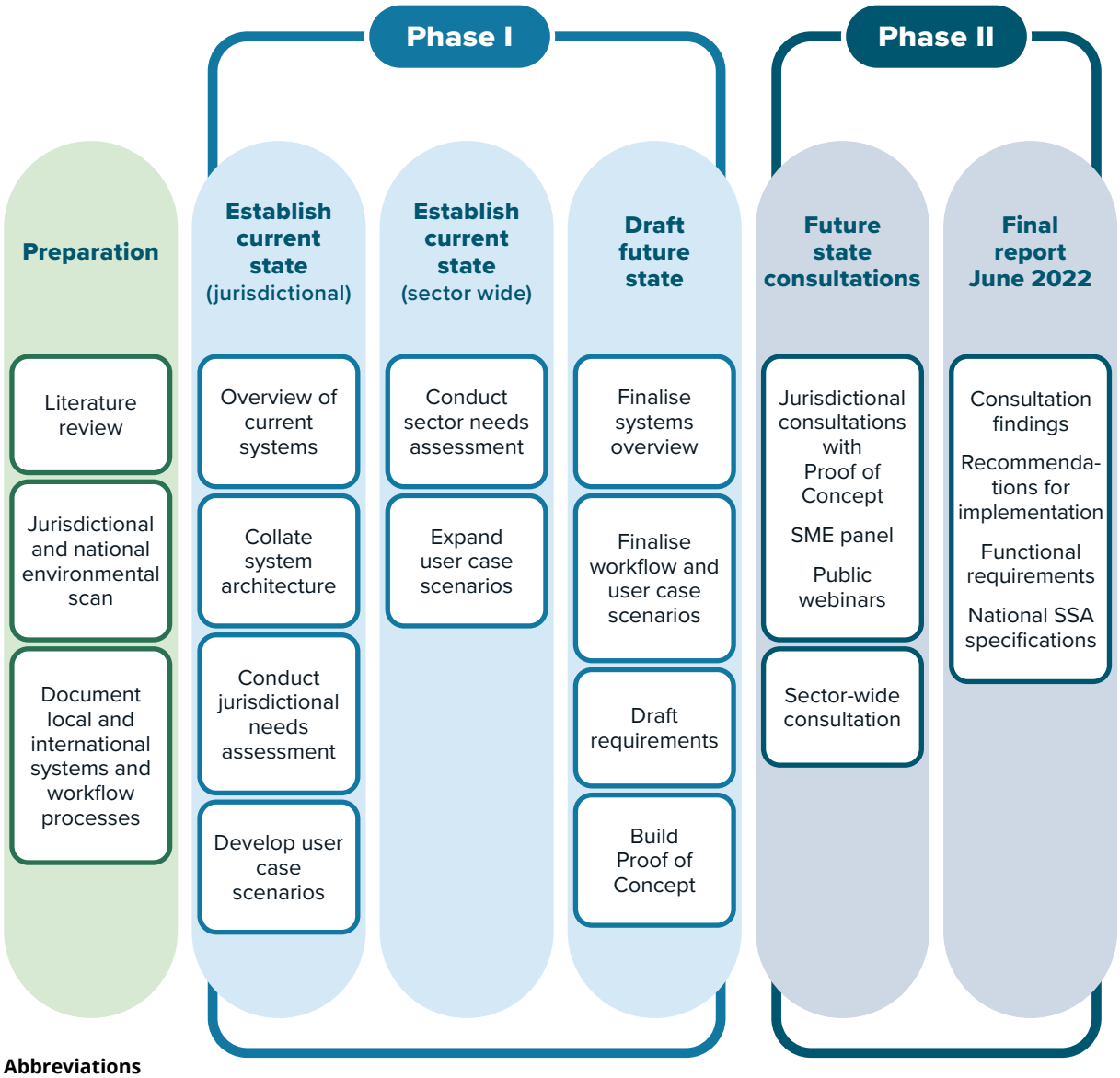
**Figure 1:** Consultation approach




**Abbreviations**

HREC – Human Research Ethics Committee

**Figure 2:** Consultation roadmap to June 2022




**Abbreviations**

SME – Subject Matter Expert
SSA – Site-Specific Assessment

## Approach to finalising the national minimum SSA requirements

Concurrent, targeted and public consultations on the minimum SSA requirements were undertaken through February and March 2022, oversighted by an Expert Reference Group with membership nominated by the CTPRG.

The CTPRG agreed that development of a single national SSA was critical to the successful development of the National One Stop Shop platform. The aim of the single national SSA is to ensure a single process and minimum information requirements for local site (risk) assessment and authorisation of research in health service organisations.

Work to finalise the national core SSA elements was expedited under the Overlapping Regulations Agenda in December 2021, which led to the CTRPG nominating jurisdictional experts to form an Expert Reference Group in February 2022 under the project governance arrangements of the National One Stop Shop project.

The core principles underpinning the national SSA, agreed by CTPRG, are:

- Streamline the SSA process, minimising duplication and unnecessary requirements, and maximising consistency
- Include common national (above the line) requirements
- Include jurisdictional specific, legislated (below the line) requirements
- Consistent with minimum requirements specified in the National Clinical Trials Governance Framework and all relevant legal or regulatory requirements, as well as being sufficient to provide decision-makers with confidence that patient safety and clinical standards are being maintained
- Collect sufficient quality data to strengthen the oversight provided by governing bodies
- Adaptable, and enable periodic planned updates and modifications, to accommodate evolving requirements over time.

The SSA process is described in the **National Clinical Trials Governance Framework***, including pre- and post-authorisation activities. The National Clinical Trials Governance Framework also describes the roles and functions of individuals responsible for undertaking local research site risk-assessment and recommending authorisation to the Chief Executive Officer or their delegate.†

The SSA process assesses the following:

- The capacity for the site to support the project, including the availability of potential trial participants at the site
- Financial arrangements for the project
- Insurance and indemnity arrangements
- The availability of appropriately certified and trained staff to meet the requirements of the project
- Local approvals relevant to the conduct of the project including appropriate approvals for data access.

Pre-authorisation activities:

- Liaising with the research investigators, their teams, and sponsors regarding the preparation of applications for site authorisation
- Managing the process of site authorisation, reviewing the SSA and recommending authorisation of the project to the Chief Executive Officer or their delegate
- Ensuring a copy of the HREC approval, indemnity and insurance documents have been received, agreements applicable to the project have been signed
- Ensuring collection of the appropriate fees for site authorisation
- Documenting all SSA decisions and maintaining a current record on the appropriate database
- Reviewing and managing amendment documentation related to projects
- Collecting and providing data on operational metrics to the governing body.

* National Clinical Trials Governance Framework and User Guide. Australian Commission on Safety and Quality in Health Care, 2022. **www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide**

† Several jurisdictions have implemented SSA Modules, check-lists and guidance material such as Vic, Qld and WA.

Post-authorisation activities:

- Managing and reviewing amendments of authorised research projects
- Having visibility of authorised projects through review of annual and final site progress reports submitted by the Principal Investigator
- Receiving project related safety reports
- Receiving complaints related to the conduct of a project and escalating these to the appropriate officer within the health service organisation.

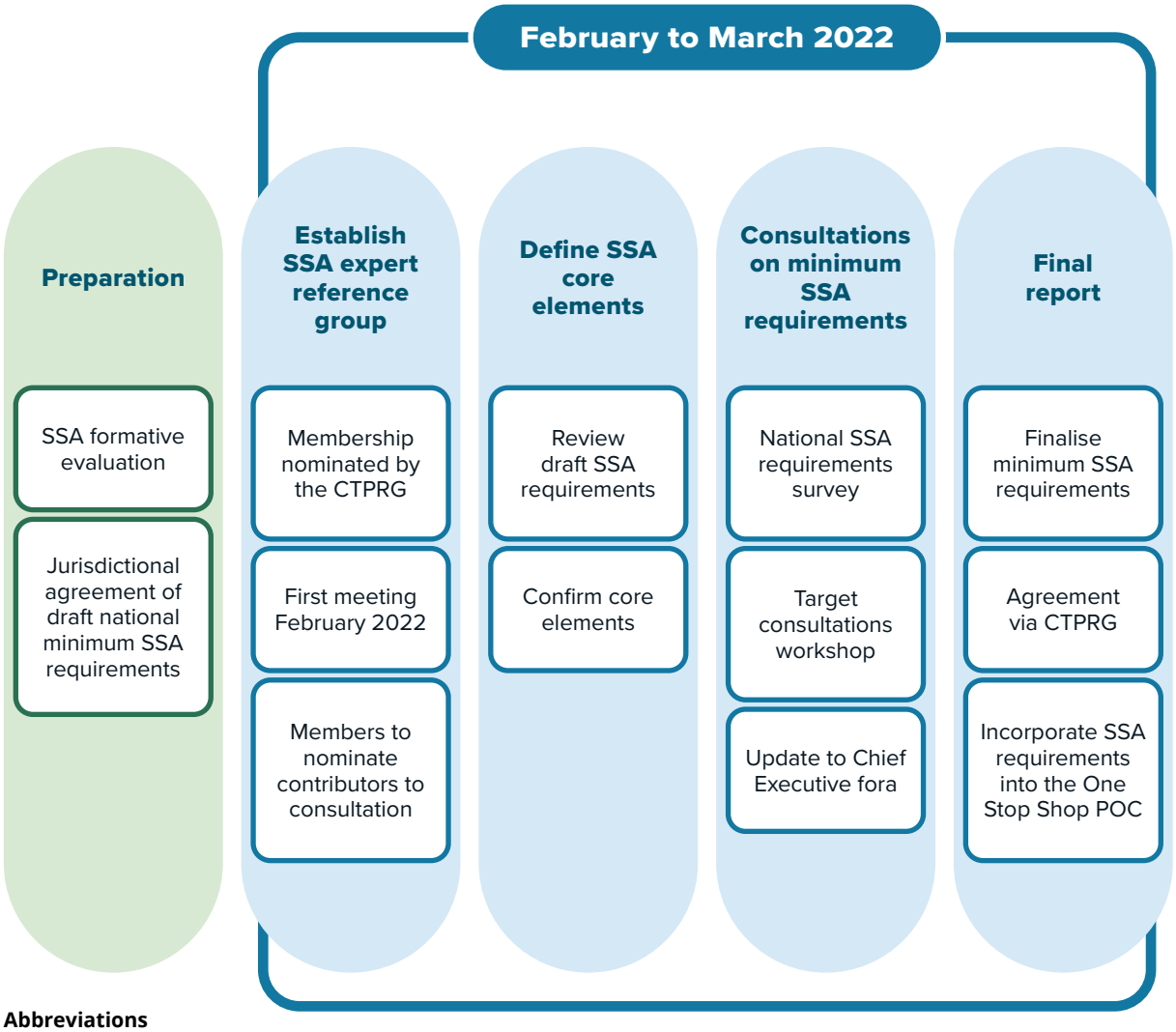
### Method of engagement

The draft national SSA core elements, agreed by the CTPRG, were provided to the Expert Reference Group for review and refinement prior to targeted consultation with research officers and research governance officers in each jurisdiction. Table 1 provides the summary of consultation activities. **Figure 3** provides the SSA consultation roadmap.

**Table 1:** National SSA consultation activities

| Date | Activity |
|---|---|
| **15 February 2022** | Expert Reference Group convened:<br>▪ Review the draft ***National Site-Specific Assessment Core Elements***<br>▪ Review of the ***National Site-Specific Assessment Survey Report*** |
| **28 February 2022** | ▪ ***National Site-Specific Assessment Survey Report*** distributed to members and published on the Commission's website<br>▪ Electronic survey distribution to all stakeholders |
| **28 February 2022** | Targeted SSA consultation meeting 1 |
| **2 March 2022** | Targeted SSA consultation meeting 2 |
| **3 March 2022** | Targeted SSA consultation 3 |
| **8 March 2022** | Targeted SSA consultation 4 |
| **9 March 2022** | SSA consultation public webinar 1 |
| **11 March 2022** | ***National Site-Specific Assessment Survey Report*** closed |
| **18 March 2022** | SSA consultation public webinar 2 |
| **24 March 2022** | Report to CTPRG on consultation outcomes |

**Figure 3:** SSA consultation roadmap February to March 2022




**Abbreviations**

CTPRG – Clinical Trials Project Reference Group
POC – Proof of Concept
SSA – Site-Specific Assessment

# Consultation insights

## Highlights

- Over 1,400 stakeholders engaged in the consultations
- A detailed analysis of current jurisdictional system architecture was conducted and preferences for the National One Stop Shop were gathered
- Consultations identified significant systems issues and pragmatic solutions
- Consultation identified strong support for the integration of workflows to deliver a seamless, adaptive, and responsive national system for the management of the full lifecycle of health-related human research activities.

## Participation

Initial consultation on the National One Stop Shop and the National Clinical Trials Front Door commenced in October 2021. Prior to, and throughout the consultation period, more than 5,000 stakeholders received periodic updates and emails on the consultation progress via the Commission's extensive stakeholder database.

### Phase I consultation

More than 870 of the 1,000 people registered, attended at least one or more than one of the 54 sessions during the first phase of consultation and more than 25 reference group meetings and jurisdictional and technical meetings were held upon request.

Participants represented jurisdictional health departments, health service organisations, industry, universities, medical research institutes, government agencies, Aboriginal and Torres Strait Islander representative groups, consumers and other individuals with an interest in the sector. More than 350 individuals attended the first phase public webinar series.

### Phase II consultation

Focus groups to consider the interactive Proof of Concept were conducted with the CTRPG, the TGA, OGTR and NHMRC; jurisdictional health departments; ANZCTR Executive, before being reviewed by the Subject Matter Expert Panel members (n=94) (**Appendix 2**).

Over 1,064 individuals attended the second series of public webinars.

Forty-five written submissions on the needs of the sector (n=36) and/or the national SSA core elements (n=9) were received. The ***National Systems Survey Report*** received 599 responses; the ***Community Perspectives Survey Report*** received 477 responses and the ***National Site-Specific Assessment Survey Report*** received 582 responses.

### Consultation on minimum SSA requirements

Consultation on the minimum SSA requirements resulted in detailed mapping of the current ethics and SSA approvals workflows (**Appendix 3**). Relevant national and jurisdictional meeting note diagrams and relationship matrices have also been developed.

Overall, 824 individuals and groups (inclusive of survey respondents) participated in consultations to finalise the national core SSA requirements. See Addendum 2a, ***National Site-Specific Assessment Survey Report*** and Addendum 2b, ***National Site-Specific Assessment Core Elements***.

## Current state systems, issues, and future preferences

**Table 2** provides a summary of the systems and workflows reviewed and documented through the consultation process.* For those jurisdictional systems developed for the purpose of an approvals workflow the majority of the HREA data fields, as provided in the NHMRC HREA, were similar. However, there was no similarity in the SSA data fields between jurisdictional systems.

Consultation discussions were documented in meeting notes and recorded as meeting note diagrams using Enterprise Architecture Software to illustrate the relationships between individuals, entities and their views on current issues and preferences for a future national platform. A summary of current issues and high-level future requirements are provided in **Appendix 3**.

* There were some additional local health service and other provider systems, developed for a purpose which the Commission team became aware of during the consultations, which were unable to be mapped.

**Table 2:** Current jurisdictional health research management systems reviewed

| Jurisdiction or entity | System (Vendor) | Workflow |
|---|---|---|
| **ACT Department of Health** | REGIS (F1 Solutions) | Ethics approval |
| **Alfred Health** | Internal bespoke | Research management |
| **ANZCTR** | ANZCTR (name of system) | Clinical trial registration |
| **Bellberry** | eProtocol | Ethics approval |
| **Macquarie University Hospital** | Clinical Trial Management System | Research project management |
| **Mater Research Queensland** | Ethics RM (Infonetica) | Ethics and SSA approvals |
| **NHMRC** | HREA workflow (F1 Solutions) | Ethics approval |
| **Northern Territory Department of Health** | No system | Paper based/email-based ethics triage and workflow |
| **NSW Health** | Advarra Clinical Trial Management System (high-level overview) | Research project management |
| **NSW Health** | REGIS (F1 Solutions) | Ethics and SSA approvals |
| **Office of the Gene Technology Regulator** | No system | Registration applications |
| **Public Health Research Network – Western Australia** | Bespoke system | Data linkage HREC approval process |
| **Queensland Department of Health** | Ethics Research Management-(Ethics R) (Infonetica) | Ethics and SSA approvals |
| **South Australia** | GEMS | Ethics and SSA approvals |
| **Tasmania** | Moving to implementation of F1 solution (REGIS) | Previously paper based/email based/ethics workflow |
| **Therapeutic Goods Administration** | eBusiness portal, IBM Notes and integrated with a reporting software – Cogno Analytics. | CTN and CTA process and reporting |
| **Victoria** | Ethics RM (Infonetica) | Ethics and SSA approvals |
| **Western Australia** | Research Governance System | Ethics and SSA approvals |
| **Western Australian Department of Health – Public Health Research Unit** | Bespoke system | Ethics approval for data linkage studies |
| **Western Australia Public Health Research Application System** | Bespoke system | Ethics and SSA approvals |

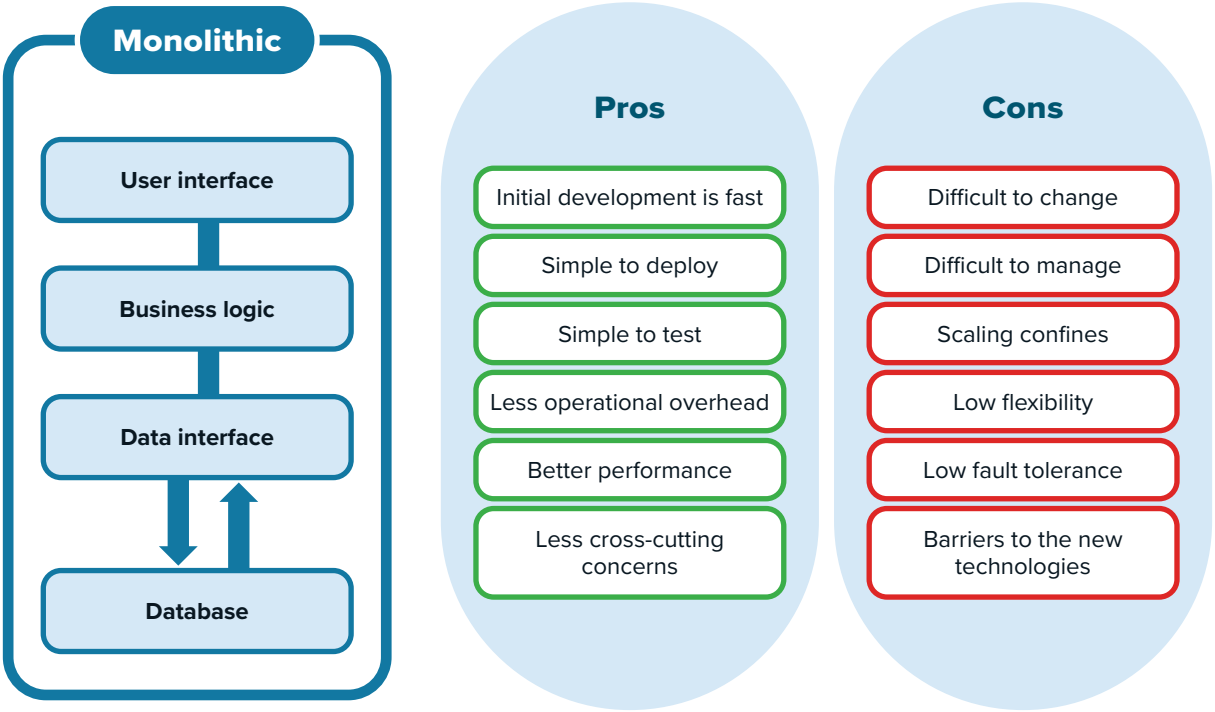
## Overview of current jurisdictional system architecture

Technical mapping and user experiences shared through the consultations revealed issues associated with poor user experience navigating current jurisdictional research workflow systems were in part due to the nature of the system architecture. Jurisdictional systems have been developed for a single purpose using a particular form of system architecture that limits capacity to change and facilitate additional system requirements overtime. This is called monolithic architecture. Each application consists of one system where parts, such as the code-base and business logic, are modular and the modules are interconnected and dependent on one another – a monolith. This is the simplest form of ICT system architecture usually implemented as a single purpose solution, in this case the purpose is for ethics and research approval workflow (Figure 4).

Systems developed using monolithic architecture are developed as a simple technical 'stack' which can be developed rapidly and is relatively simple to deploy and test. For example, a developer can implement end-to-end testing by simply launching the application and testing the user interface. It is also simple to deploy once the package is copied to the application server and it is simple to scale horizontally by running multiple copies behind a load balancer.

However, monolithic applications can also be difficult to scale when different modules have conflicting resource requirements. The entire application needs to be updated and with each update, continuous deployment becomes difficult.

**Figure 4:** Monolithic system architecture



Perspectives of the sector regarding issues with current systems and preferences for improved functionality through the National One Stop Shop were aligned with the responses received to the ***National Systems Survey Report***. This survey focussed on the evaluation of current systems; ethics approval workflow and processes; SSA systems enabled workflow; information and resource needs; reporting requirements and options for the next generation national research registry. The survey findings are provided at Addendum 1, ***National Systems Survey Report***.

The survey was in the field for 14 weeks, closing 31 January 2022. The average time spent completing the survey was 17 minutes and, noting that respondents were not required to answer every question, the completion rate was 66%. A total of 599 survey responses were received. Of these, 590 respondents identified as belonging to one of 27 stakeholder groups and of these, 389 (66%) respondents reported having been involved in the sector for more than 10 years.

### HREC approval workflow in current systems

On average, respondents had experience with at least two research workflow systems. Among these, the systems most used by the 542 respondents were:

- ERM Queensland, Mater Research Queensland, and Victoria (289; 53%)
- REGIS in NSW and ACT (276; 51%)
- NHMRC (261; 40%).

When asked which system the respondents used most regularly, ERM and REGIS were again the top responses of the 477 responses received.

Issues identified by 555 respondents in relation to the current systems included:

- Navigating the various approval processes and systems (390; 70%)
- Duplicative manual data entry into multiple systems (344; 62%)
- Ethical review and approval process and systems (336; 61%)
- Comparative timeliness of research start-up (279; 50%)
- Local site research authorisation (278; 50%).

Respondents were asked to identify the positive aspects of the ethics workflow systems they use most regularly. More than half of the respondents offered a response (n=338; 56%). Responses included system features such as:

- Ease of use (74; 22%)
- A centralised platform for approvals (52; 15%)
- Online and minimised paperwork (36; 11%).

Other system features viewed positively included:

- Having an overview of application status/ progress (30; 9%)
- Ability to share with multiple users (27; 8%)
- Access to support/helpdesk (21; 6%)
- Pre-populated text (16; 5%).

Verbatim responses received regarding likes and dislikes of current systems are provided in the ***National Systems Survey Report*** at Addendum 1. Preferences for overcoming functionality limitations of current systems included:

- Having to upload documents one by one
- Confusing instructions
- Having to duplicate text responses
- Difficulties/complications in amending or editing submissions
- Slow page-loading speeds
- Problems storing and archiving documents within the system
- No oversight on the progress of their submission.

Survey respondents and consultation participants agreed their preference for a national centralised system that integrates and supports the requirements of all jurisdictions and therefore supports multi-site submissions. Sector requirements include, but are not limited to:

- Standardising systems to improve consistency across all jurisdictions for definitions, requirements, processes, and policies relating to ethics approvals
- Communicating requirements clearly, in plain language, simplifying and scaling down complexity of the business processes
- A clear view of the status of the application as it progresses through the workflow, with timely communication regarding deadlines, next steps, and anticipated approval timeframes to improve transparency of the process

- Reducing data-entry duplication by enabling text to be carried across to relevant sections (where information is common to the applications required for multiple sites)
- Further work to ensure that the HREC workforce has the skills and qualifications necessary to assess applications and oversee their approval in a timely and consistent manner.

## Support for the integration of workflows of the HREC and SSA

Within this section of the survey respondents were asked in which jurisdictions they had sought site-specific assessments (SSA). On average, 440 respondents had obtained SSA in at least two different jurisdictions. Of these, the jurisdictions most cited were New South Wales (55%), Victoria (42%) and Queensland (40%). More detailed information on the respondents experience of the current SSA process is provided in the ***National Site-Specific Assessment Survey Report*** at Addendum 2a.

Respondents of the Systems and Processes Survey were asked to offer their suggestions on functionality that could improve SSA workflows in the future. Suggestions included:

Respondents were asked to offer their suggestions on how to support the integration of ethics approvals, regulatory approvals and SSA authorisations into a single platform. Responses from 298 respondents are illustrated below with representative verbatims:

> 'HREC approval letters to be visible in the "system" so that new sites have access to previous approvals.'
>
> 'Allowing the system to add new sites and new site will be able to see previous approved documents and letters.'
>
> 'Only require documents to be uploaded once, but accessible through all forms. Auto-complete forms, to remove duplicate data entry.'
>
> **Consistent and standardised requirements**
>
> 'It is so hard when you do cross-jurisdictional research and have to spend hours working out exactly how each jurisdiction wants the forms completed.'
>
> 'Clear understanding of the site authorisation workflow, seems to be different at every site and not transparent.'
>
> **A national portal**
>
> 'One central system used across Australia and the ability to perhaps just submit to one authorisation office per organisation.'
>
> **Ethics and local site-specific assessment governance integration**
>
> 'A truly integrated application process that would incorporate ethics and "governance" for all sites in one step.'
>
> **Visibility of timelines**
>
> 'Timeline of SSA submission relative to ethics submission if both at the same site can be unclear.'

## Minimising data-entry duplication

Duplicative data entry was identified as a significant barrier to the conduct of efficient and effective research. Respondents identified those fields that required repeat input on applications for multi-site research. These are included in the ***National Site-Specific Assessment Core Elements*** at Addendum 2b.

When asked for suggestions on how to minimise data duplication, respondents cited a variety of solutions, all of which support the development of a fit-for-purpose, fully integrated platform featuring a seamless single workflow which would provide an intuitive user experience across all agencies, institutions, and business processes. Below are some representative verbatims from respondents.

> **Develop a single, centralised hub for all reviews, approvals, and authorisations**
>
> 'One system should be used throughout Australia and the next steps should be automatic.'
>
> 'A truly national system which includes site-specific assessments – it all pre-populates from the one entry'
>
> 'A single application that goes to all relevant sites.'
>
> **Apply the research protocol to other workflow-specific requirements**
>
> 'I have NEVER understood why it needs to be broken down and sliced up both for ethics, then again for governance, then again for the Clinical Trials Research Agreements (CTRA) and then again for the Risk Assessment Office, then again for the multi-institutional agreements. It is one endless process after another which is just driving researchers away from doing valuable work. There's the protocol and there is the budget. All the information is in there.'
>
> 'Allow references to page and sections of protocol.'

'Reduce the overlap between the protocol and the platform data entry – for example, allowing "See protocol section XX" in the platform data entry. [Alternatively] using a shorter protocol that simply describes the study methods, and [then] including project background, risks, risk management, etc. in the platform.'

**Enable pre-population/auto-population of text across relevant fields**

'Have a cohort of information, such as "title", "PIs", "sponsor", that is automatically pre-populated in all future documents.'

'Allow the system to migrate data over from one form to another for instance "title", "recruitment process", "documents", etc.'

**Enable document and data sharing across workflows**

'HREC approval letters within the system should be visible by governance without site submission.'

'Having one upload option for documents to be sent to ethics and research governance officers (RGOs) for site-specific assessments (SSA). The ability to copy, for example, "investigator details" and/or "contact details" would be helpful.'

'If you could upload all your study documents on to the platform ONCE. If you absolutely need something very specific for only one site, there could be a site-specific folder for uploading a new document [for that] one site.'

**Co-design and test the platform with representative users**

'More user acceptance testing (UAT). Have actual study coordinators or ethics submission people try out the systems first, and give users an opportunity to point out areas that don't work/ are repetitive/could be improved, etc.'

'Can we please have genuine co-design between users (ethics, regulatory and researchers/ coordinators) in the design rather than having ethics and regulators design things that work for their purpose.'

'Conduct data-mapping exercises for a range of different types of research; co-design new systems with users.'

## Next generation national clinical trials and research registry

### Current arrangements

The World Health Organization's International Clinical Trials Registry Platform (ICTRP) is a 'network of international clinical trial registers to ensure a single point of access and the unambiguous identification of trials'. Its main aim is to facilitate publicly accessible prospective registration of all clinical trials.*

Registration on a WHO Primary Registry is required by the International Committee of Medical Journal Editors as a condition of publication of research results generated by a clinical trial.

At this time, Australian and New Zealand clinical trials can be registered in two leading web-based clinical trial registry platforms which are both WHO Primary Registries: ClinicalTrials.gov or ANZCTR. Registration is free and the registries provide the full spectrum of trials: pharmaceutical drugs, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies. Trial information is publicly available and provides information such as: the trial objectives, research design and recruitment status, treatment under investigation, outcomes, investigator details and contact details.

The ClinicalTrials.gov registry is a United States-based site that lists clinical trials undertaken in any country.

The ANZCTR is a separate system that users need to navigate to register their trial and the consultation heard, that it is not widely used as sponsors and researchers prefer to register on ClinicalTrials.gov (which provides a 'feed' of information to update ANZCTR). A limiting feature of the ANZCTR is that data and information are manually updated. Data are not updated regularly, limiting its utility for researchers, sponsors, and the community more broadly.

Participants in the consultation on the National One Stop Shop agreed that the ANZCTR is under-utilised by researchers and members of the community more broadly when searching for a trial and in its current form, would not support a national public facing website.

* World Health Organization. **International clinical trials registry platform**. Geneva: WHO.

While the enhanced Australian Clinical Trials website, launched by the Australian Government in 2018 as a 'joint initiative between the National Health and Medical Research Council and the Department of Industry, Innovation and Science to provide information and resources to consumers, healthcare providers, researchers and industry about clinical trials' aims to provide information on clinical trials underway and connect the community to research of interest, consultation participants reported that the website was not well known to the sector and was not connected to any other system to support currency of the information. There is now an opportunity, through the One Stop Shop, to provide an interconnected, redeveloped system to support currency of the information and utilise most recent technologies.

The sector was supportive of the National One Stop Shop platform replacing the current ANZCTR and the Australian Clinical Trials website. The National One Stop Shop would provide the single national work-flow of core services that would support an embedded national registry and public facing website. This single national solution would ensure currency of information with search and filter functionality that would increase the utility and reliability and of the public facing website.

### Future arrangements

The current process for curation of the submitted information is largely manual. To support the search functionality by trial, site and participant characteristics, the embedded registry would need to include agreed core data items, agreed definitions with other agencies stakeholders whose business processes would be incorporated in the platform (which as the TGA and the OGTR). Internal system data audit trails and automated query processes would be implemented as agreed by various groups to provide a streamlined curation pathway, including but not limited to a process for handling duplicate submissions and procedures to ensure the protection of confidential information. Functionality would also be specified to support reporting, and information sharing (such as protocols in camera or the final protocol, analysis plans and publications) in a standardised format.

Other factors to consider in the implementation phase include:

- The registrant: currently the person authorised to register a clinical trial is the trial sponsor. The platform should define the authorised person and provide guidance on the process (this should not be delegated to a satellite or secondary site)
- Requirements for updating a trial name or protocol ID following curation and/or HREC approval
- The approach to the administration of the platform. Support should be provided by a team of qualified individuals to mitigate delays in trial registration and/or the progress of an application within the system
- The potential for a two-step process to trial confirmation and registration. That is, platform enabled system automated queries and editing/query/by personal oversighting the process to ensure the registry continues to meet the requirements of a WHO Registry
- System enabled notification to the HREC and other parties as changes are requested an/or implemented
- Common fields to be curated and additional checks importing information from ClinicalTrials.gov
- Flexibility in the order of process that is, a non-linear workflow for registration. For example, registration prior to ethics review and flexibility to accommodate the different types of studies/relationships
- Functionality to protect the confidential information terms and condition for sharing information between nominated parties within the systems based on user authorised access requirements
- Responsiveness to incorporating new WHO requirements as they are released rolls out new requirements regularly and expects registries to take it up
- How summary results will be entered, curated and published on the public facing website.

As far as possible, feedback received, supported a national platform that would remove manual interactions to minimise duplication through interconnectivity with other business workflows to enable automatic updates through internal service messaging. The next generation national registry would also provide a catalogue of all research as required by the Australian Research Data Commons to build awareness of primary data sources that may be used for secondary research purposes which is the focus of the

Health Studies Australia National Data Asset (HeSANDA project) and provide a searchable database, with filters, on clinical trial, health and human research information in plain language(s).

The next phase of work to design and specify the functions of the National One Stop Shop platform would be undertaken with the WHO registry experts oversighting the implementation of features to ensure quality assurance procedures for manual checking of data accuracy (curation), processes to address proprietary concerns regarding registering new trials and entering information and roles and responsibilities of individuals for these functions.

An approach to data migration is provided ahead in the report.

## Incorporation of business processes of the TGA to enable the CTN and CTA business processes and those of the OGTR

Currently the TGA have separate internal systems and processes to manage the CTN and CTA Schemes and separate internal systems reporting capability and, the OGTR does not currently have any systems in place for use by external stakeholders when registering with the OGTR. Both agencies were supportive of the opportunity for these business processes to be included in the National One Stop Shop which they viewed as a unique opportunity for a truly national joined-up approach. Enabling the business processes of the TGA and the OGTR, including but not limited to the GCP site inspection program, safety and adverse event reporting and advising the sector on shortages of medicines or adjunct therapies delivered through a clinical trial, were supported by both agencies. Meeting Note Diagrams and relationships as well as future business processes and functional requirements have been developed in consultation with both agencies.

## The National Clinical Trials Front Door – a recruitment portal for the community

In Australia there are a number of initiatives to improve research participant recruitment including but not limited to:

- Australianclinicaltrials.gov.au
- Clintrial Refer for healthcare professionals
- The George Institute Join Us Registry
- Opyl
- Clinical Trials Recruitment and Social Media Insight
- Health Match
- Step-Up for dementia research
- Cancer Institute NSW.

Nonetheless, recruitment to clinical trials is largely reliant on specialist clinician referral or admitted patient databases in health service organisations. No national central system provides real-time reliable information with look-up functionality for the community. This is the single greatest barrier in Australia in connecting the community to health and medical research including clinical trials.

Consultation discussions explored options for improving participant recruitment, including a national volunteer participant registry enabled by AI technologies to inform concept development of the National Clinical Trials Front Door. This would draw on the intended capability of the proposed National One Stop Shop which at a minimum would enable the 'profile service' to link researchers, clinicians and participants as well as a service directory with links to third party recruitment providers.

Representatives of organisations providing recruitment services participated in the consultations. While several are proprietary businesses, others rely on publicly available information regarding where clinical trials are occurring to promote their services. Some charge licencing fees to recipients of their services. A range of views and options in relation to the national recruitment portal were put forward through the consultation discussions.

In the first instance there was little support for participant screening technologies that would link to the electronic medical record to functions in the national platform. However, participants supported a public facing website for the community with information flow from the next generation national research registry and other parts of the platform to support the provision of comprehensive information for the community. The website would provide a searchable database, with filters, on clinical trials and health related human research information in plain language(s). A priority for the first iteration of the public facing website would also be a listing or database of rare diseases and treating clinicians, with links to clinical trials.

Members of the community responding to the ***Community Perspectives Survey Report*** stated they supported the proposition of having their data stored via a 'consent to be contacted data-base' for the purpose of making themselves available for clinical trials or research projects, if they could retain the right to determine how their information was shared with third parties. Consultation participants agreed with the sentiment that, it is essential to build engagement and public trust through transparency and the provision of information to the community. Respondents were less supportive of their information being held by a private entity.

Future phases of work need to be undertaken to explore options for matching capability, and/or a volunteer participant database such as exploring the potential for links to the Pharmaceutical Benefits Scheme and the Medical Benefits Scheme and mechanisms for enabling different providers or services to feed-into and support the plethora of health apps currently operating in the health-related research environment.

Additionally, due to the many recruitment providers already successfully operating across Australia further work would be required to understand innovative approaches to participant recruitment. While there was no support for any single provider to deliver this functionality there was broad support from consultation participants for the next generation registry to provide a central public access point and facilitate connectivity for the community.

## Community perspectives

The ***Community Perspectives Survey Report*** collected input from community members on their experience of participating in or, supporting someone else to participate in a clinical trial or other health related research project. The survey was developed using an exploratory design to capture the experience of research participants and/or a participant's carer to generate ideas and recommendations to inform the development of the proposed National Clinical Trials Front Door.

Two pathways were built into the survey: one for those who participated directly in a trial, and one for those who had supported others to participate a trial, such as a child. The survey received 477 responses. The completion rate was 62%, respondents were not required to answer every question.

The full ***Community Perspectives Survey Report*** is provided at Addendum 3.

The exploratory design supported unforced responses across 11 open-ended questions on topics including the pathways by which individual respondents became involved in clinical trials, the consent processes they experienced, their information needs, and their personal feelings about the experience. A set of quantitative questions captured baseline data regarding past participation in clinical trials, willingness to participate in clinical trials in the future, and likelihood to recommend clinical trials to others.

This approach captured a high-level view of the community experience and generated ideas and recommendations to inform the development of the proposed National Clinical Trials Front Door.

Of the 477 people who responded to the survey, just over half (54%; 255 of 475) had previously participated in a clinical trial or in some other form of health-related human research. Approximately one third of respondents (34%; 160 of 473) said they had supported someone else, such as a child to participate in a clinical trial or health-related human research.

Two main motivators for research participation emerged:

1. A person was contributing to a broader social good
2. The hope that, as a participant, they received a better treatment (with the investigational product) and/or may have a better personal outcome.

These motivators were evident among those who had not yet participated in a trial or research, as well as those that had. A sample of verbatim responses are provided below:

> 'I like to contribute to research, also I work in social science research so know how hard it can be to get participants.'
>
> 'So that I could do my bit in making the treatment process easier and better for anyone else who may unfortunately need the same treatment I underwent. To help improve in any possible way.'
>
> 'Because I had a condition that at the time was not well understood and the research looked like it would contribute to the body of knowledge about the condition.'
>
> 'Best chance of surviving leukaemia.'
>
> 'I've always felt giving back a little is a very little inconvenience for the benefit of all. Like pay it forward. Some trials and studies may have offered me personally an opportunity to access new types of care currently not mainstream so while potential for negative overall benefit did offer a chance at greater than standard.'

Of those that had participated in research project, 97% (166 of 172) indicated that they would recommend participation in a trial or research to others, suggesting an overall positive experience.

Of the 477 people who responded to the survey, almost half (46%; 220 of 477) had not previously participated in a clinical trial or some other form of health-related human research. When prompted, explanations included: being healthy and therefore not having any need to participate; not been invited to participate or had not been aware of any opportunities to participate. Only four of 220 respondents mentioned they had not met the eligibility criteria for a clinical trial or health-related human research project.

Respondents who had not participated in a clinical trial or health-related human research in the past were then asked if they would be prepared to do so in the future. Of those who chose to respond. Seventy-seven per cent (120 of 157) indicated they would be prepared to participate in a clinical trial or in health-related human research in the future.

### Experience of trial participation

Respondents expressed appreciation for enrolment processes that were simple and comprehensive in the information they provided. Community members highlighted experiences where there was a notable absence of pressure, and sufficient time for them to ask questions about the trial and consider options for their care.

Large volumes of information, particularly information that was dense with medical jargon and terminology were regarded as disincentives to participation.

Characteristics of the team and the engagement process that were associated with positive experiences of participating in a trial or research project included friendly, respectful relationships with members of the research team, ongoing communication and updates throughout the trial or research project, and the sharing of trial results at the end of the project. The inverse characteristics – unfriendly, impersonal staff, poor communication and lack of follow-up – were associated with a negative experience.

Among those who responded regarding what they liked about the experience (n=171) commonly cited points included:

- A quick, easy and simple enrolment process, typically online
- Contact with attentive, helpful staff who were able to explain and answer questions
- Comprehensive information about aims, processes, risks and benefits of trial/research
- A respectful approach with no pressure to join.

Verbatim responses are provided below:

'Clear communication and explanation. Listing of contacts for questions about the research.'

'Easy, friendly staff who understood what the study was about and were able to clearly explain everything and knew the answers to my questions.'

'Factual pitch with a clear purpose. Easy to register and answer questions, that is, no time-wasting.'

'The people explaining what would happen clearly in everyday language.'

'No pressure to participate.'

'Via email and you just registered if interested. No pressure.'

'Someone to contact if I had questions.'

Among those who responded regarding what they did not like about the experience (n=156), commonly cited points included:

- Overly complicated information and processes
- Sub-standard information that did not answer all questions
- Inconvenience of having to appear in person for enrolment
- Perception of disrespectful attitude or questions.

A sample of verbatim responses are provided below:

'There was a lot of paperwork to read, I understood it, but others may have struggled.'

'Long consent document, which I know put another person off participating in the trial.'

'I had to attend the site to receive the information rather than it being provided to me in advance by email.'

'I don't think the people delivering the message realised the importance of allowing time for consideration.'

'Insufficient information about how data would be handled, including naïve assumptions about "deidentification" of data.'

'The PICF used such simple language that it treated me like an idiot.'

'Invasive questions from the questionnaire.'

'Onerous and time-consuming.'

'They tried to get me to sign that they could use my DNA for other research. I said no. I was quite offended by this and wonder if other people may have been misled.'

'We were not advised that we could say we didn't want to take part.'

## Considerations for a national volunteer registry

Respondents who had previously participated in a clinical trial or research project were asked how they found out about the opportunity to participate. They were asked to select from options which included: social media, google/ internet search, website, healthcare professional, friend or family member, support group, direct contact from researcher(s), or a trial recruitment app (such as HealthMatch, ClinTrial Refer or Join Us). Respondents were also offered the option of 'other'.

Over 50% (87 of 173) of those who had previously participated in a trial or research indicated that they had found out about it through a healthcare professional.

Approximately 24% (41 of 173) were actively approached by researchers.

Other common sources included social media (13%; 23 of 173), support group (11%; 19 of 173), friend or family member (10%; 18 of 173) or website (10%; 17 of 173).

Twenty-five per cent (43 of 173) selected the 'other' option and cited triggers which included print materials (such as posters or flyers in health settings) and newsletters, either from health organisations or special interest groups.

Respondents were asked if they would be comfortable having their data stored securely in a national volunteer registry for the purpose of being contacted about future opportunities to participate in clinical trials or health-related human research. Seventy-six per cent (239 of 314) of those who responded to the community perspectives survey, indicated that they would feel comfortable having their data stored in this way, for this purpose

When asked whether they would prefer to have control over how their information was shared within the national volunteer registry, and what sort of contact requests they received, 90% (274 of 304) agreed that they would prefer that level of control.

Respondents were then presented with a list of potential organisations/groups and asked if they would feel comfortable with any or all of these groups having access to their information within a national volunteer registry.

Approximately 70% (216 of 307) felt comfortable with medical research institutes/organisations having access to their contact information. This was closely followed by clinicians (66%; 202 of 307), government funded organisations (61%; 188 of 307), public hospitals (58%; 179 of 307) and universities (56%; 173 of 307).

There was less support for private hospitals (40%; 122 of 307) and private research organisations (35%; 106 of 307) to hold their data than for the groups described above.

Approximately 16% (50 of 307) were not comfortable with any of these groups having access to their information within a national volunteer registry.

## Finalisation of the SSA core elements

The description of the SSA process, including pre- and post-authorisation activities, is already agreed by all Australian jurisdictions as provided the National Clinical Trials Governance Framework. There are also jurisdictional policies in place that provide detailed guidance on the approach to undertake the local site risk assessment.*

The core SSA elements cover four areas of information that health services require to conduct a risk assessment for the conduct of research on their premises:

- Project Registration
- Evidence of HREC Approvals
- Recruitment and Financial Information
- Departmental and Executive approval.

Across all elements consultation participants and survey respondents indicated these elements satisfied the minimum jurisdictional requirements for all health-related human research.

Approximately 812 individuals contributed to the consultation process (including the CTPRG, the SSA Reference Group and consultation participants). Five hundred and eighty-two completed surveys were received. The survey was open for 12 days from 28 February 2022 to 11 March 2022. The average time spent to complete the survey was 13 minutes and the overall completion rate was 67% (noting respondents were not required to answer every question).

The survey was primarily designed to collect feedback on the CTPRG approved draft national SSA core elements. The survey also sought to capture insights related to respondents' levels of satisfaction with existing SSA processes, with an open-ended question prompting a more detailed response. The full ***National Systems Survey Report*** and ***National Site-Specific Assessment Core Elements*** are provided at Addenda 2a and 2b.

Respondents were asked to give their overall assessment of the length, complexity, and suitability of the draft national SSA, in a set of close-ended questions at the end of the survey. A sub-analysis of key questions was undertaken, to provide a more detailed review of responses by both stakeholder group, and jurisdiction. Respondents were permitted to assign themselves to more than one stakeholder type as relevant. As a result, the total sample sizes of the sub-analyses differ from those of the core analysis for the relevant questions and respondents may belong to more than one grouping.

Within each of the four sections, Registration, HREC Approvals, Recruitment and Financial Information, and Departmental Approvals, most survey respondents indicated that the questions provided satisfied the minimum requirements within their jurisdiction for research Registration (71%; 308 of 431) HREC Approvals (70%; 292 of 419) Recruitment and Financial Information (74%; 297 of 402) and Departmental Approvals (69%; 276 of 398). This was consistent with the advice received from the Expert Reference Group, expert targeted SSA consultation participants and participants attending the public webinars.

Overall, consultation participants and survey respondents felt that the draft national SSA was 'just right', being neither too long nor too short. Similarly, the majority felt that it was suitably comprehensive.

The survey revealed that for each of the core SSA elements between 69–74% of respondents were satisfied with the core elements provided. Between 16–21% were not satisfied and the other 9–12% didn't know.

Further analysis indicated differences between stakeholder groups with researchers and investigators slightly more likely to view the draft core elements as 'too long' and 'overly

* Research governance and site-specific assessment process and practice.

complicated', and research governance officers and research officers slightly more likely to view it as 'too short' and 'not detailed enough.'

Those individuals responding to the question relating to 'overall perception' (68%; 396 of 582) who identified as 'research investigators' and 'researchers' were the groups most likely to say that the draft national SSA was too long (approximately 37% and 36% respectively). Support for this statement was similarly high among 'directors of research', 'clinician investigators as sponsors', and 'research sponsors', although the sample sizes of these groups were small (n<30).

There were also notable differences between stakeholder groups regarding the length, complexity, and suitability of the draft National SSA. Twenty five per cent (96 of 398) of responses received to the question relating to 'overall perception' who identified as 'research governance officers', indicated the draft national SSA was too short. A summary of these findings is provided in the survey report section titled 'Overall Perceptions'.

Survey respondents indicating that the core SSA elements did not meet their requirements (16–21%; 90–122 of 582) were prompted to elaborate on their response. Their insights, concerns and recommendations have been considered in addition to the feedback received from experts through the targeted consultations and broader consultation process.

Where additional feedback was received, responses were provided to assist members of the Expert Reference Group and CTPRG in their review. It is important to note that:

- In developing and refining the proposed SSA elements feedback from consultation participants and the survey respondents was balanced against feedback from the Reference Group and their nominated experts to ensure compliance with relevant minimum national/jurisdictional requirements.
- Several issues raised would effectively be addressed via the introduction of the proposed National One Stop Shop platform. Where it is considered that this potential capability would resolve issues or simplify requirements, this has been incorporated into the proposed logic/rationale underpinning the proposed SSA requirements. For example, the National One Stop Shop platform could provide an intuitive digital smart form with skip logic; enable digital Chief Executive Officer sign-off and configurable delegations according to structures/requirements in each jurisdiction; SSA core elements built into the single national approval workflow; the use of standard definitions; in-built guidance and explanatory notes on the process and requirements for all users.
- Where there were variations between jurisdictions (these were minimal), they could be easily accommodated via configurable functionality anticipated for the National One Stop Shop platform (that is, additional approvals by public health officials following HREC approval such as required by the Queensland Civil and Administrative Tribunal).

On the 24 March 2022, the CTPRG endorsed in principle the single national SSA core elements with agreed amendments for implementation via the proposed National One Stop Shop, subject to further feedback through the second phase of consultations. The minimum national core SSA elements were publicly available throughout the second phase of consultations and the sector contributed further advice on the final core elements as provided at Addendum 2b.

It is intended that in accordance with key principles previously agreed by CTPRG, the SSA requirements will be adaptable, and periodic planned updates and modifications will be possible through the proposed National One Stop Shop platform and with the agreement of all CTPRG members, to accommodate evolving requirements over time.

Through the second phase of consultation a subset of the core elements were included in the Proof of Concept for further testing with the sector. Additionally, the national core SSA elements were broadcast and pushed via email to the Expert SSA Reference Group and the sector (over 5,000 stakeholders) and, were publicly available on the Commissions website. Feedback on the core elements were received through the subject matter expert panels, the public webinars and written submissions. Nine written submissions were received. The requested changes include:

Question-specific changes:

- Q4 – Include option to select more than one type of 'Research Type' which may be important for multi-disciplinary research.
- Q4 – Option of 'Other' should be available as per the HREA
- Remove 'Is this a low/negligible risk research' and 'is this greater than low risk research'.

This is not relevant for RGOs as it relates to research risk for the Human Research Ethics Committee and not institutional risk.

- Q10.a and Q11.a – Clarify the CV upload and GCP upload function
- Q11.a – Enable addition of multiple 'Site Coordinator/Contact Person'
- Suggest making GCP upload mandatory for all types of research
- Q13.g – Allow for upload of multiple HREC amendment approval letters
- Q13.g and Q13.i – Remove N/A option
- Q15 – Recruitment strategy question added to include details about how participants are identified and how initial contact with participants is made. This is valuable to understand the time and resources required to recruit participants, and other factors for example, whether the site is introducing the study and referring patients to the lead site or recruiting/consenting the patients themselves. This could be completely pre-filled from the HREC application.
- Q4 – Research Type, the option of 'Other' should be available as per the Human Research Ethics Application (HREA)
- Remove Q6a – that is, Is this a low/negligible risk research? Yes/No
- Remove Q6b – that is, Is this greater than low risk research? Yes/No.

General changes:

- Potentially, two questions are not relevant for RGOs as they relate to research related risk which the HREC assesses not the RGOs. These are not related to institutional risk
- There remain opportunities to shorten the length of the SSA, particularly if the RGO will see information provided in the HREA in the One-Stop-Shop platform
- Consider cases where a teletrial model is used, that the parallel review and authorisations of multiple satellite site (cluster) research governance applications can be supported in the SSA.
- Conflict of interest may not be adequately covered and could be strengthened to avoid risk of conflict of interest.

The ***National Site-Specific Assessment Survey Report*** and ***National Site-Specific Assessment Core Elements*** are at Addenda 2a and 2b.

## Consultation summary

Consultation and survey findings indicated sector wide support for an intuitive, single national approvals and research management and workflow system enabled through digital smart technology. The system would enable accurate and real-time information on clinical trials and research activity, enable appropriate monitoring of performance to effectively join up and replace individual and divergent jurisdictional health trial and research management systems, and ideally achieve a single consistent national system.

At a minimum the sector supported a National One Stop Shop that:

- Provides all components of a national cross-government research workflow and associated management system and approvals platform housed within a central platform (including ethics, local SSA and authorisation with full research management functionality for any user (that is, public health system or private, not-for-profit and industry)
- Embeds the next generation WHO Australian primary national clinical trials registry with automated registration to facilitate best-practice access to trials for patients and strategic capability for governments and stakeholders. This, together with a capability to fulfil requirements of the Australian and New Zealand Primary WHO Registry Network associated with the ICTRP
- Incorporates national clinical trials systems such as the CTN and CTA schemes as well as aspects of Good Clinical Practice Site Inspection Program managed by the TGA, together with the capacity to incorporate other relevant approvals systems (such as those required by the Gene Technology Regulator)
- Provides sophisticated reporting functionalities for different users – from financial reconciliation to key performance indicators that can continue to benchmark and drive improvements across the sector, to site-level reporting and dashboards for trial coordinators, sites, and sponsors
- Provides project management functionality for all research projects not only clinical trials, with sophisticated monitoring and reporting for different users (including but not limited to, project and participant visit management, financial reconciliation, safety, and adverse event reporting, annual HREC reporting)

- Embeds the National Clinical Trials Governance Framework accreditation obligations and automates data/ reports/processes to support the accreditation process
- Assists all governments to respond to areas of need in a rapid, coordinated, and strategic manner based on real-time, accurate information regarding research activity and site capability.

Stakeholders agreed the platform should be fit-for-purpose for all Australian jurisdictions, including universities, for the conduct of all categories of health and human research that permits users to enter data and upload documents once only and have them automatically shared with all the relevant applications and submissions to various parties.

The platform should enable researchers and sponsors to create an application and for individuals to review and authorise/progress approvals throughout the lifecycle of the project. Transparency of the process to track the status of an application as it moves through various stages of review and approval, with various agencies and/or stakeholders is essential. Reporting capabilities would be built to meet the needs of various users that are aligned with relevant legal, safety and regulatory requirements and enable publication of nationally agreed performance measures.

The platform should be supported by instructions that are clear, simple, and easy to understand, backed by a reliable technical support system or 'helpdesk'.

In relation to the national SSA, essential core elements for the platform to enable the SSA process include the auto-population of information between the HREC workflow and the SSA workflow using digital smart technology with skip logic and, the provision of clear guidance and practical support materials for applicants and individuals undertaking the assessment process.

During the first phase of consultations, the nature of the platform was frequently raised. Consultation participants sought a potential system solution to enable interaction with a possible system architecture solution and features of a potential future national platform. The interactive tool would assist in the refinement of user case scenarios and draft functional and non-functional requirements of the national platform through the second phase of consultations. This view was supported by technical experts participating in the discussions, the Health and Medical Research Advisory Group and the CTRPG. The Proof of Concept was developed to assist in the second phase of consultations.

The system gap analysis, the system architecture and business requirements included in the Proof of Concept and the future platform business requirements gathered through the consultation process and recommendations for implementation are provided in this part of this report.

# System gap analysis and development of the Proof of Concept

## System gap analysis

Various system architectures were reviewed as potential system architecture solutions to demonstrate platform functionality through the Proof of Concept. A key requirement was that the system can enable multiple functions and is 'agile, intuitive; easy to navigate; has capacity to grow, is flexible and future proof'.

A microservices application approach involves building application infrastructure with individual services that function independently. These services have their own logic and database while also working together as a distributed system with inter-process communication. **Table 3** provides a comparison of monolithic system architecture and microservices system architecture.

The microservices architecture can provide:

- Optimised scaling – scaling decisions can be made at a more granular level
- Better fault isolation – one microservice fails, all others will continue to work
- Increased business agility – microservices are relatively small and simple, and provide the freedom to experiment and fail fast
- Increased developer productivity – developer only needs to understand a small, isolated piece of functionality.

**Table 3:** Monolithic versus microservices architecture

| Feature | Monolithic | Microservices |
|---|---|---|
| **Deployment** | Deploy as it is | Deploy services individually |
| **Maintenance** | Programming language | DevOps, Docker, Kubernetes, etc. |
| **Reliability** | One failure causes the whole system down | One failure doesn't affect other services |
| **Scalability** | Scale up/out as a whole | Scale up/out on individual service |
| **Agility** | Fixed on certain technology | Different technologies for different business needs |
| **Development** | Tight coupling | Loose coupling |
| **Upgrade** | Slow release | Fast release |
| **Testing** | End to end testing | Each service needs to be tested |

## The Proof of Concept

As outlined in **Appendix 3** (current issues and future requirements) and Addendum 1 (***National Systems Survey Report***) issues with the current systems and disparate business processes and poor user experience were frequently raised.

The Proof of Concept was developed based on the stakeholder requirements gathered through the first phase of consultations and documented as Meeting Note Diagrams to finalise the high-level functional and non-functional requirements for the national platform. The purpose of the Proof of Concept was to demonstrate:

- That it is technically possible to build the National One Stop Shop platform using a flexible ICT system architecture
- How pain points and limitations of current systems and workflows can be addressed through the national platform
- How an enhanced workflow can make business processes more efficient
- That it is possible to design an intuitive system that enables the research application review and process; facilitates transparency of the review and approval process through a visible and date stamped timeline; user dashboards; notification and communication capability; project management functionality and other business processes.

Testing the subset of user case scenarios through the Proof of Concept with the jurisdictions, Commonwealth agencies and the sector more broadly was undertaken using multi-media approaches including, videos and real-time interactive sessions, targeted meetings, written submissions and open forums. Subject Matter Expert review and testing was undertaken with user feedback enabled within the tool. Experts and public consultation participants were asked to advise on considerations for the potential future system architecture and platform functionality. Is this way, feedback was collated to refine the requirements.

The Proof of Concept (which could have ongoing utility through the design and specification phase) enabled the review of, and interaction with, a possible system architecture and features of a single information stream that addressed the pain points associated with current systems and processes.

Individuals were encouraged to navigate through a subset of functions, to further refine their requirements and consider additional functionality for the proposed National One Stop Shop. **Table 4** provides the summary of pain points and issues to be addressed through the interactive tool. **Proof of Concept subset of functions** provides the subset of functions included in the interactive tool for demonstration to the sector.

> **The Proof of Concept is not the final platform, it is a high-level interactive workflow with a subset of core functions for demonstration and further testing with the sector.**

The Proof of Concept was developed within the Commission's secure Commonwealth Azure environment and is compliant with:

- ICT Customisation and Bespoke Development Policy
- ICT Skills Policy
- Australian Government Architecture
- Cyber Security Policy
- Cloud Computing Strategy
- Open Source Software Policy
- WoG Common Operating Environment
- Environment sustainability of ICT
- Gov2.0
- Data Centre Strategy
- Digital Service Standard.

**Table 4:** Current pain points and technical solutions developed in the Proof of Concept

| Pain point | Explanation | Solutions |
|---|---|---|
| **Lack of transparency** | ▪ No visibility on the application review process<br>▪ No visibility on the workload of the committees and committee members | ▪ Enable notifications<br>▪ Provide a timeline<br>▪ Enable communication within the system<br>▪ Enable workload visibility |
| **Difficult communication process between different users** | Applicants and reviewers communicate with each other via external emails | ▪ Enable comments on the application<br>▪ Comment review process |
| **Complicated and difficult to navigate** | ▪ The user must navigate back and forth between questions to find the section they need to address<br>▪ Functions are unclear and cluttered | ▪ Table of contents panel<br>▪ Project space |
| **Lack of guidance for users** | ▪ Questions require further or prior knowledge<br>▪ Lack of understanding of the questions and workflow | ▪ Information box<br>▪ Knowledge sharing |
| **Inefficient review process** | ▪ Sponsors cannot submit an application<br>▪ Application goes back and forth between the applicant and reviewers due to lack of preliminary review | ▪ The 'applicant' can be a sponsor or researcher<br>▪ Pre-HREC submission review process (or triage by the HREC Secretariat) |
| **ANZCTR does not display up to date data** | ▪ The Registry needs to be manually updated (usually by the sponsor)<br>▪ There is integration between the HREA and SSA, Research Management Systems(s) and clinical trials registry | Single integrated workflow inclusive of Research Management System, HREA and SSA integration |
| **Sign off process takes longer time due to lack of e-signature capability** | Manual sign off process | Digital signature |

| Pain point | Explanation | Solutions |
|---|---|---|
| **Duplicate data entry and duplicate review process** | Same data fields get reviewed by ethics committees and research office | ▪ Combine into a single workflow<br>▪ HREC reviews ethics data<br>▪ Governance reviews SSA data |
| **No LNR pathway** | No review pathway for LNR in the current system | Pre-screening questions |

## Proof of Concept subset of functions

Proof of Concept inclusions:

- Subset of HREA workflow
- Subset of the HREA amendment workflow
- Subset of SSA workflow
- Subset of amendment workflow
- Subset of CTN workflow
- Subset of ANZCTR data fields
- Subset of research project types
- Subset of project management functionalities
- Subset of all user types
- Communication capability internally, with various users
- In-apps notifications
- Guidance for all users
- User dashboard
- Application approval timeline for all users
- E-signature
- CTN generation automation
- CTN payment
- National registry creation and update automation
- Subset of KPI reporting
- Role-based authorisation.

## Proof of Concept assumptions

Key assumptions underpinned the development of the Proof of Concept. For example, the demonstration system assumes a single digital workflow for submission of the HREA and the SSA, and:

- Parallel review of the HREA and SSA
- A pre-submission review process (performed by the HREC Secretariat in the current state, or a triage team in the potential future state)
- Both sponsor and researcher can be an applicant
- The application undergoes a pre-ethics committee submission review (by either a HREC Secretariat by a main committee or a subcommittee)
- There are accredited, non-accredited, certified and specialist HRECs
- All ethics committees will host review meetings
- The application would be reviewed by a single ethics committee
- The committee members can only exchange comments with other committee members from the same committee
- Only HREC Secretariat/Chair can exchange comments with the applicant on behalf of the committee
- Only HREC Chair can approve the application on behalf of the committee
- All data fields in the CTN form come from the HREA and SSA application
- All data fields required by the national research registry come from the single national workflow including the research project management functions.

Figure 5 illustrates the conceptual diagram of the Proof of Concept. The concept design demonstrates the subset of users and all requests moving through an Application Programming Interface (API) gateway where their requests will be authenticated and authorised. This determines which services the user has access to.

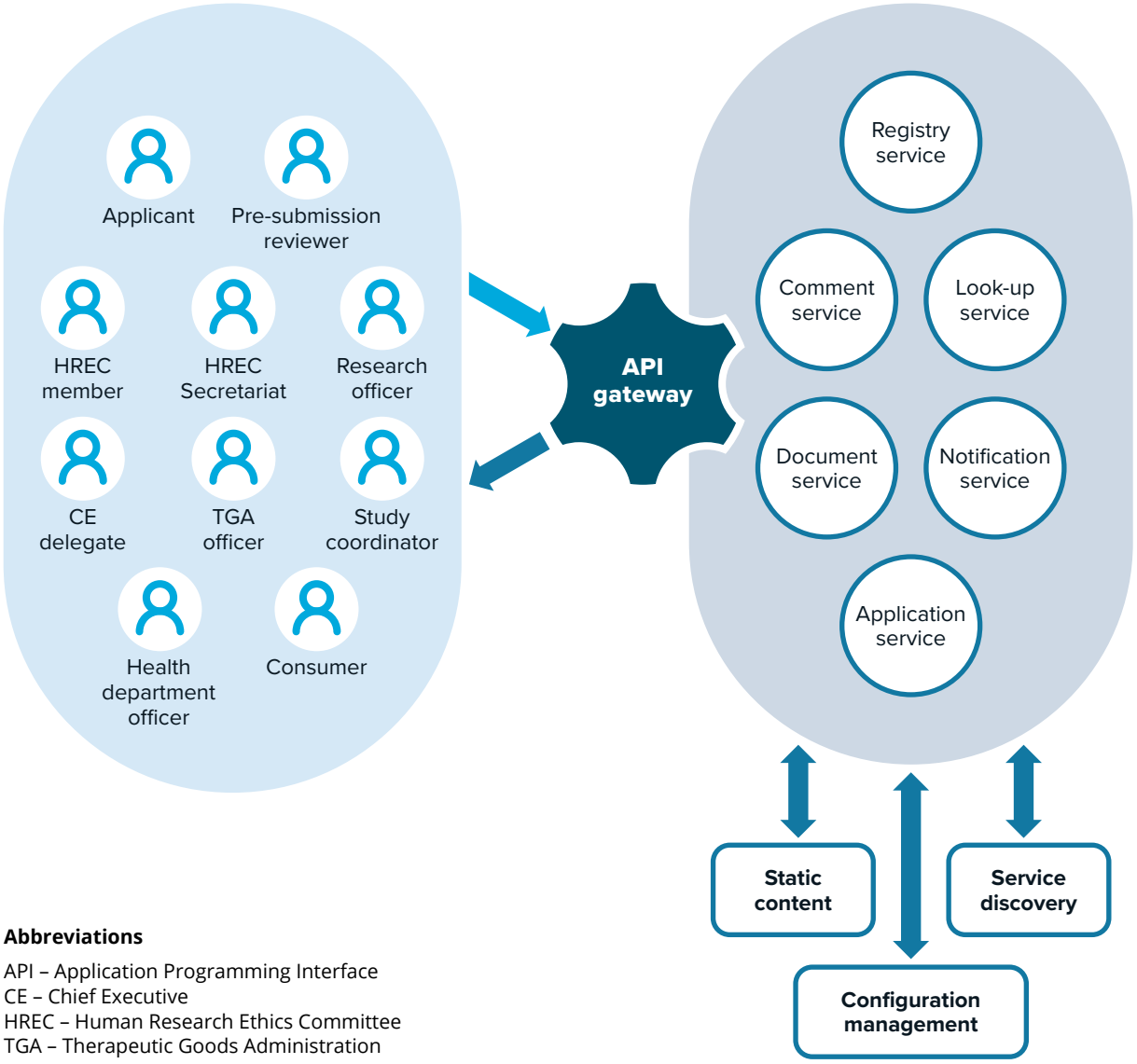
In the backend, each service is running independently on a dedicated port, so that it will not bring down the whole system if it stops running.

All services and their locations and configurations are registered under a service registry component. This component provides a service discovery service which allows services to communicate with each other. For example, when an application is submitted, it triggers several notifications to both applicants and

reviewers. In this case, the application service will first check the availability of the notification service via the service discovery component.

In addition to this, the system has a configuration management component which holds and provides runtime configuration to all services. The system can also manage static content files which hold all the study documents securely, such as study protocols.

**Figure 5:** Conceptual diagram

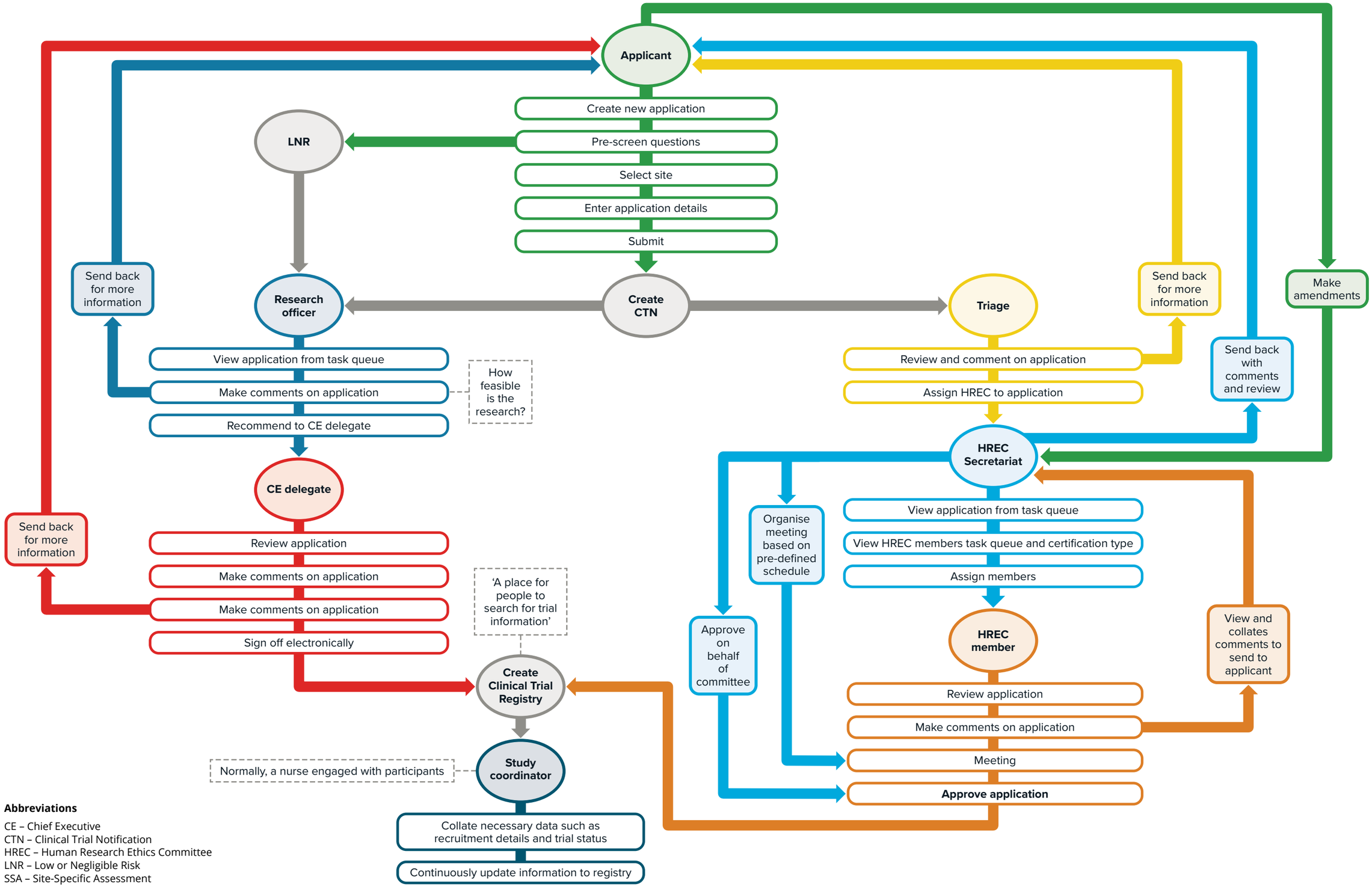



**Abbreviations**

API – Application Programming Interface
CE – Chief Executive
HREC – Human Research Ethics Committee
TGA – Therapeutic Goods Administration

Figure 6 describes the high-level workflows developed in the Proof of Concept.

**Figure 6:** High level of Proof of Concept components

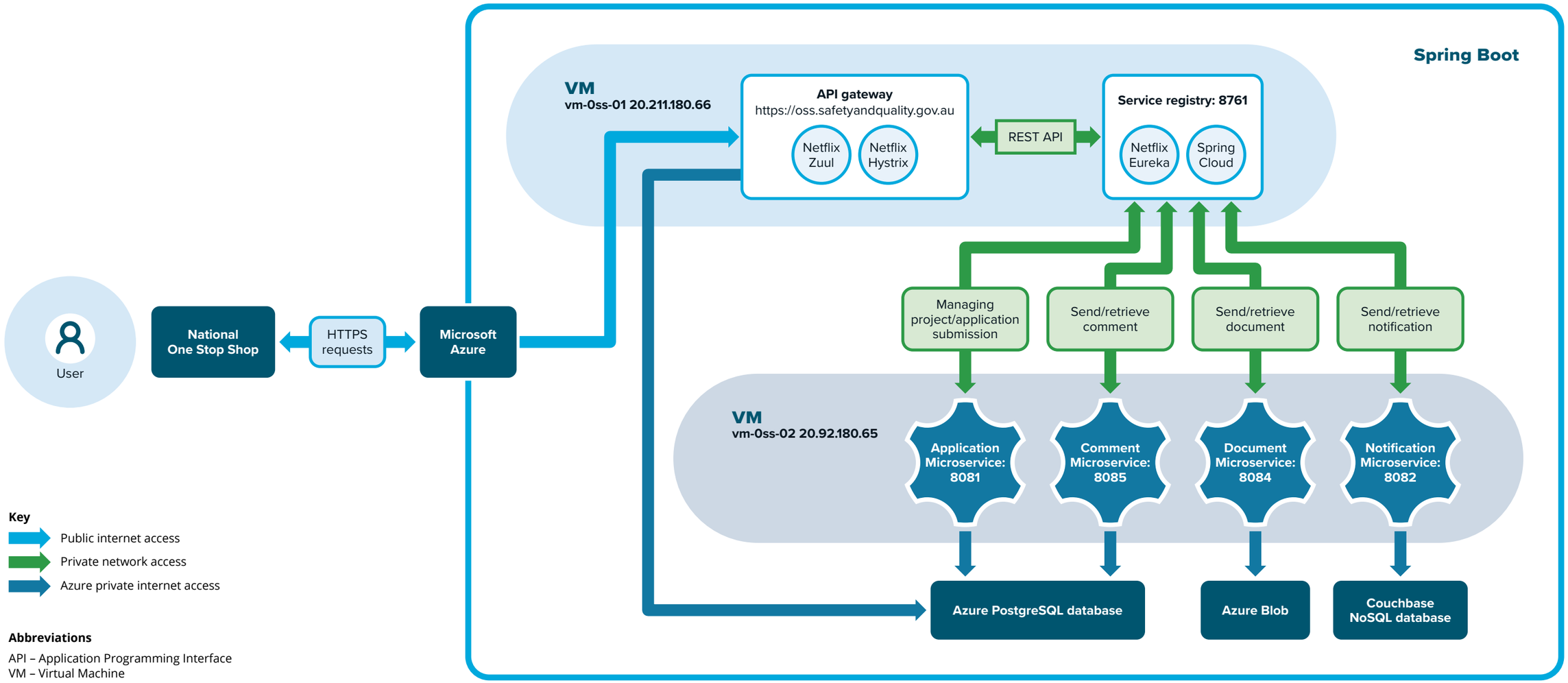



**Abbreviations**

CE – Chief Executive
CTN – Clinical Trial Notification
HREC – Human Research Ethics Committee
LNR – Low or Negligible Risk
SSA – Site-Specific Assessment

Figure 7 describes the high-level infrastructure, applications, and technology components.

**Figure 7:** Interactive tool architecture design




**Key**

- Public internet access
- Private network access
- Azure private internet access

**Abbreviations**

API – Application Programming Interface
VM – Virtual Machine

From the infrastructure perspective, the entire Proof of Concept solution is hosted under the secured Commonwealth Azure environment, which provisioned two virtual machines to host different microservices running on dedicated ports. From the application and technology perspective, the API gateway services act as an entry point to receive, authenticate, and authorize all the HTTPS requests from the client and allow them to access all the running services. It integrates Netflix Zuul and Hystrix to provide routing, filtering, security, and circuit-breaking capabilities. The registry service is hosted on the same virtual machine as the gateway service. It is made up of Netflix Eureka and Spring cloud Configuration, which provides load balancing, service registration, service discovery, and configuration management capabilities.

All the other microservices are running from another virtual machine. Application service (application submission and project management), comment service (send/receive comments), and the API gateway service all leverage Azure PostgreSQL database, a SQL database. At the same time, the notification service is running on a Non-SQL database – Couchbase. Document service is responsible for sending and retrieving uploaded documents from Azure Blob. The backend services are developed under the SpringBoot framework, which can provide a comprehensive programming and configuration model for modern Java-based enterprise applications on any deployment platform. The client-facing user interface was developed using Angular, an open source, JavaScript front-end framework capable of building large-scale, robust web applications.

## Proof of Concept user stories

### Applicant

As an applicant, I want to:

- Create a user profile for myself
- Create an application for my trial study
- Upload supporting documents to my application
- Address the comments from the reviewers
- View all my trial studies from a dashboard
- Receive notifications when my application has been submitted, reviewed and approved
- View the timelines for my applications
- Make the payments for my CTN applications.

### HREC Secretariat

As a HREC Secretariat, I want to be able to:

- Create a user profile for myself
- View all the ethics applications that are assigned to my committee from a dashboard
- Triage the applications and assign them to different committees based on their workload if I am from a main committee
- Review and comment on the ethics data fields in an application and assign it back to the applicant on behalf of my committee
- Assign the application to the committee members from my committee if I am from a subcommittee
- Receive notifications when an application is assigned to my committee
- Approve an ethics application on behalf of the chair and committee.

### Committee member

As a committee member, I want to be able to:

- Create a user profile for myself
- View all the ethics applications that are assigned to me by the committee secretariat from a dashboard
- Review and comment on the ethics data fields in an application
- See and reply the comments made my other committee members who is also reviewing the same application
- Receive notification when an application is assigned to me.

### Research officer

As a research officer, I want to be able to:

- Create a user profile for myself
- View the applications that are assigned to me from a dashboard
- Review and comment on the SSA data fields in an application
- Receive a notification when an application is assigned to me
- Receive a notification when the application is authorised by the Chief Executive (CE) delegate
- Assign the application to a CE delegate.

### Chief Executive delegate

As a CE delegate, I want to be able to:

- Receive an email notification when an application is assigned to me by a research officer
- Open the application via a secured temporary link
- Digitally sign off the application.

### Study coordinator

As a study coordinator, I want to be able to:

- Create a user profile for myself
- Receive a notification when the study is authorised by a CE delegate
- Update the trial status
- Set the trial start date from my site
- Set staff FTE to a trial study
- Add participants to a trial study
- Add visit details to a participant from a trial study.

### Consumer

As a consumer, I want to be able to:

- Access to the portal without login
- Search any trial details from a registry.

### Health department user

As a health department user, I want to be able to:

- View the FTE by project by site
- View total and mean number of days from ethics application submission to approval by each committee.

## Summary of business requirements

The high-level functional and non-functional requirements gathered through the consultation on the National One Stop Shop and National Clinical Trials Front Door have been developed for provision to the Department.

### State and territory requirements

In the future solution, an applicant can be a sponsor, a researcher, a trial coordinator, or an investigator. A profile can be created for either a user or an institution (for example, site, committee).

Once a profile is created, it can be maintained in several ways. For example, from a local site, the study coordinator can create a profile which includes the person's details and any certificates and CV that need to be attached. At the same time, a manager from the site can invite the study coordinator to an authorised study. When this user's certificate is about to expire, both user and the manager can also be notified. This way, there is no need to enter the same user's details in multiple places or forms. The user's profile details can be maintained efficiently and retrieved from a user profile registry service whenever and wherever it needs to be loaded. In addition, the site can create and maintain its profile, and the profile registry service will ensure the site information will appear the same across all types of workflows and application forms.

Ethics and SSA applications can be combined and submitted as a single national application but reviewed in parallel by the HREC and the research officers from the local sites. Ethics data elements can be migrated from the existing ethics application from NHMRC while SSA core elements are finalised across all the jurisdictions. Below the line data fields will also be considered in the SSA design for each jurisdiction.

Comprehensive pre-screening questions and business logic can also be programmed into the system to ensure applications can be assigned to the correct review pathway. For example, a Low or Negligible Risk (LNR) application can be assigned to a local site for a review without being mistakenly assigned and reviewed by an ethics committee. Another good example to demonstrate the intelligence of the pre-screening process is the data linkage study.

The future system could also incorporate mechanisms for all types of studies. For example, adaptive trials. The system could also forward any data linkage studies to the Public Health Research Network (PHRN) approvals system to seek approval from the data custodian. As PHRN has already developed this process, there is no need to duplicate this process in the National One Stop Shop platform.

As national consultations revealed that some jurisdictional ethics committees and several sites have implemented a triage process, this process was also developed in the Proof of Concept as part of the existing (and potential future) ethical review process. In developing the triage process the principles as provided in the *Standard Principles for Operation National Mutual Acceptance of Single Ethical and Scientific Review of Multi-centre Human Research Projects* were considered such as Principle 1 National Mutual Acceptance of single scientific and ethical review of multi-centre clinical trials and Appendix 1 Multi-Centre Research – Research conducted at more than one site within the authority of more than one HREC. While the consultations heard from jurisdictions such as Victoria that a streamlining Framework was not implemented because research applicants preferred to choose an HREC, in other jurisdictions and in some health service organisations, a triage process has been implemented.

Building the triage process into the Proof of Concept demonstrated that this process could be accommodated, if required, in the final platform. The goal of the triage process is to allow the main ethics committee (either a national ethics committee or the main committee of a health service organisation or at the jurisdictional level) to make a preliminary review of a submitted application to ensure it has been completed appropriately prior to submission to the HREC Secretariat. In the current state, a triage process could also serve to minimise the number of ethics reviews of multi-centre research.

From a system features perspective, feedback received through the Subject Matter Expert panels and public webinars, indicated the features developed in the Proof of Concept were well received.

Commentary from panel members largely reiterated the needs of the sector for:

- Configurable dashboards that would allow all types of users to customise their dashboards for different purposes (examples such as Kanban Boards were provided by participants)
- Push notification capability would allow users to receive emails and SMS when the system triggers a task
- Document storage capability, of sufficient size, that would allow users to manage all uploaded supporting documents (including video and other multimedia material). This feature should also ensure the most recently approved documents are at the top of the document list and documents can be archived
- The timeline feature (transparency of the review process) to be enabled and visible to all parties
- The application review comments would also enable tracked changes to be captured in pdf documents within the system.

## Therapeutic Goods Administration

In the future platform a CTN or CTA application can be triggered by a sponsor, an investigator, a health organisation, an ethics committee, a TGA officer, or even as a system event. For example, a CTN can be automatically generated and assigned to a sponsor when an ethics application is submitted or under-review by an ethics committee. The CTA could also be triggered manually after being reviewed by an ethics committee.

From a data specification perspective, in the current state, many data fields are currently repetitively entered via different application forms and in different systems. For example, the researcher (or applicant) needs to fill in the site details in an SSA application multiple times, and the sponsor repeats this process when making a notification to the TGA. Duplicate data entry increases the risk of the data discrepancy issues arising through the application and approval process.

After assessing all the current CTN and CTA data fields, technical mapping identified that CTNs could be submitted during the HREA or SSA application process as some of the data fields could be retrieved from the future profile registry service. For example, sponsor details, site details and HREC details could be retrieved from the profile service, and study details will come from the submitted ethics application. Sponsors could manually fill in additional data fields like device or medicine details. These features were demonstrated in the Proof of Concept.

From a functionality perspective, features such as online payments, push notifications and in-system review capability could also be enabled to allow a more streamlined process for different stakeholders.

### Adverse event reporting and the TGA Good Clinical Practice (GCP) Inspection Program

Repeatedly throughout the consultations, the process for reporting adverse events to sponsors, an HREC and if required the TGA was unclear to researchers and participating sites. Despite guidance being provided within the *National Statement on Ethical Conduct in Human Research*, participants sought clarity on how the national platform could facilitate an efficient and effective reporting process for all parties. The Proof of Concept demonstrated that the communication and notification features in addition to the provision of clear guidance on the reporting process could be provided by the system.

The future platform using technologies demonstrated via the Proof of Concept would also support the GCP Inspection Program. In addition, a mobile application could also be developed to facilitate all GCP inspection activities from the site. For example, the user could export communications received via an HREC review, amendment or annual reporting process as evidence and attach it to the GCP plan, created by the TGA. The review features would enable communication with a site and sponsor and ultimately the outcome of the GCP Inspection to be attached to a study and/or a site.

## Office of the Gene Technology Regulator (OGTR)

Currently, the OGTR does not have any systems in place for use by external stakeholders when registering with the OGTR. The future platform could support the DIR (Dealings Involving the intentional Release) and DNIR (Dealings Not Involving the intentional Release) licensing processes of OGTR where the sponsor can create a DIR or DNIR application under a study. The profile registry service could prepopulate the details of the organisation and the applicant contact details into both application forms to reduce duplicate data entry. Both applications could then be submitted to an IBC (Institutional Biosafety Committee) for a review, where the committee members can leverage all the review features enabled by the OSS platform. Furthermore, the IBC members can assign the application forms to any verified experts or agencies for review, and the external group can also assign them to the OGTR team for a final decision. A Risk Assessment Risk Management Plan can also be pre-configured on the future platform to facilitate the OGTR team's decision. Ultimately, the future platform will notify the sponsor of the decision and publish the outcome to the OGTR website via an API.

## Australian New Zealand Clinical Trials Registry

While the requirements of the business processes of the ANZCTR can be built into the National One Stop Shop platform, further work through the design and specification phase will be needed to ensure the next generation national research registry meets the WHO requirements for a national clinical trials registry.

Currently users are required to be verified prior to submitting a trial on ANZCTR. This could be facilitated through the platform and the applicant could be onboarded to the platform as part of the profile creation process. The system could also enable the sponsor to register a new trial or amend an existing one. In addition, the system could also allow the sponsor to transfer the ownership of an existing record.

If required, a two-step verification process could be enabled, for the system and ANZCTR validation, for maximum data integrity and accuracy. Furthermore, the future solution could integrate with existing registries (ClinicalTrials.gov, Australian Cancer Registry, Australian Clinical Trials Registry) for record linkage and updates.

From a data specification perspective, all data fields shared between any existing ANZCTR forms and ethics and SSA forms could be prepopulated. Other additional information could also be provided by the sponsor and/or applicant manually.

From a system functionality perspective, the push notification functionality could be enabled for sponsors and the ANZCTR team. Internal communication could then facilitate a more streamlined and timely review and approval process.

Ultimately, the final solution would allow a consumer to access the registry by providing an option to browse the trial information in plain language(s) using multiple languages translator system functionality. Members of the community can even register their interests via the public facing website for a particular trial or research into a particular clinical area, alternatively, if a trial was actively recruiting the site would receive a notification automatically. This component would be the true 'front door' for participant recruitment.

## Research management and reporting

During the consultations, jurisdictional health department participants and research sites requested the platform provide the breadth of research management capability including operational and financial reporting. This aligns with local strategic action plans* and would enable sites without exception and at a minimum, report against the requirements of the National Clinical Trials Governance Framework.

Opinion on the need for site level research management functionality was mixed. Most jurisdictions and some stakeholders insisted that research management capability is a required and indispensable feature of the platform. One jurisdiction suggested inclusion of this functionality ought to be optional and not contingent on participating in the other platform components.

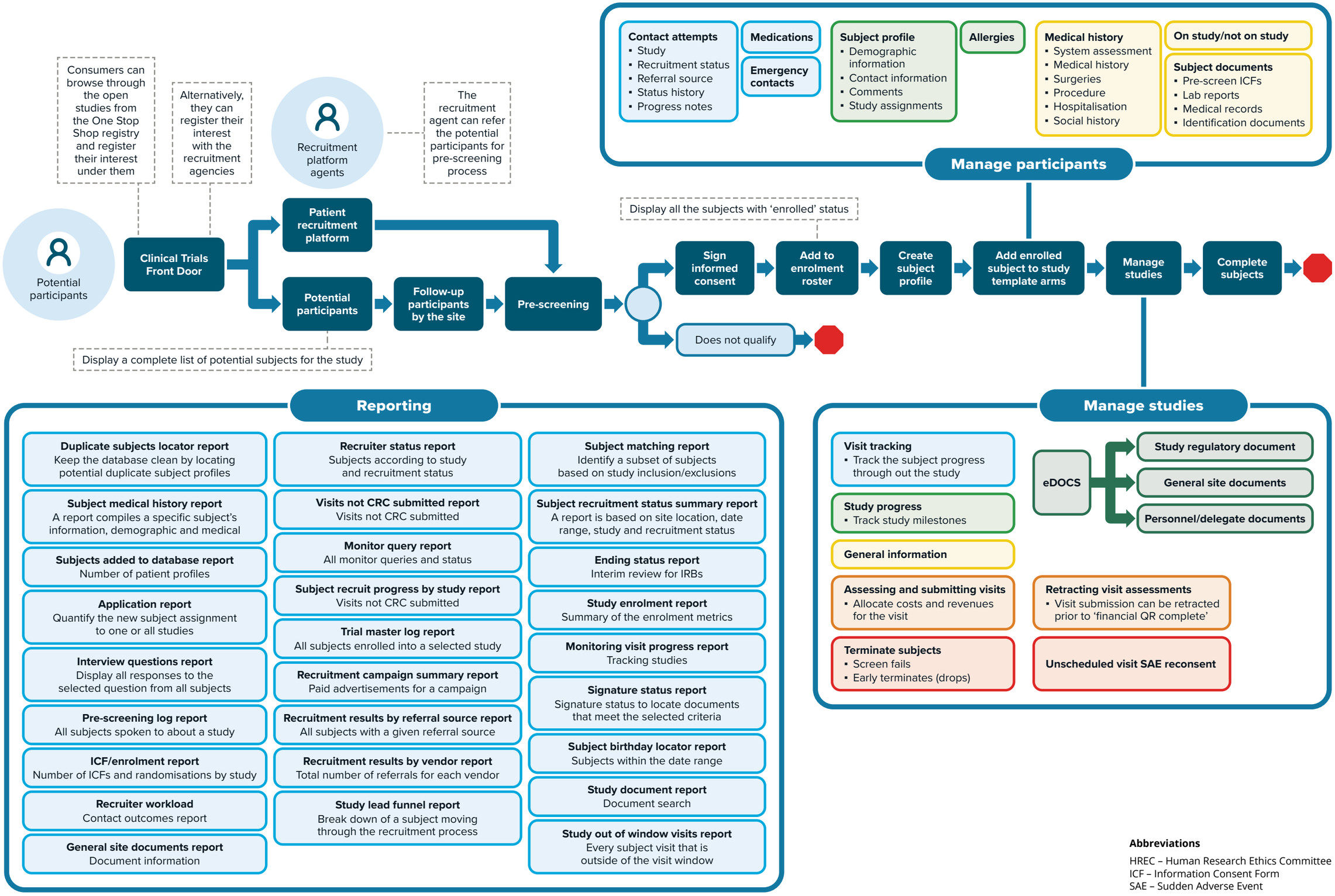
The Business Analyst worked with organisations to review and map their current research management solutions. The vendor of one jurisdictional research management product was also consulted (Advarra).

At a high level, stakeholders agreed research management and reporting components should include the following features:

- **Configurable user dashboard** – Following local SSA authorisation, the project would automatically appear in the research coordinator's dashboard who can then add or manage existing projects via the dashboard (site details are uploaded from the SSA data fields)
- **Participant recruitment management capability** – If a member of the public registers their interest in a trial via the public facing website (the National Front Door) the coordinator could receive a system automated push notification and contact the potential participant to undertake screening for the research project
- **Participant management** – When a potential candidate is recruited to the research project, the system enables the study coordinator to create a participant profile which contains information such as, number of contact attempts, participants demographic details, medical history, medical records and other information relevant to project participation
- **Study management** – The coordinator would be able to create a profile for an authorised study including participant visit tracking, study progress notes, and any electronic documents that should be attached to the project
- **Finance and payments** – The study management capability would also enable financial tracking and workforce management including but not limited to, calculation of oncosts for services provided by the site (for example, pathology and pharmacy dispensing), invoicing for site study visits and financial reconciliation capability
- **Reporting** – The reporting functionality is automated across the platform so that no additional manual data entry is required in order to generate operational and financial reporting against the agreed KPIs provided in the National Clinical Trials Governance Framework (such as total number of trials by trial phase and sponsor type and expected vs actual recruitment). Calculated reports would be automatically generated alternatively sites could download information as a CSV or Excel spreadsheet to develop their own reports.

* Queensland Department of Health Clinical Trial Strategic Action Plan for increasing clinical trial activity 2022–2025.

**Figure 8:** Research management system features




**Abbreviations**

HREC – Human Research Ethics Committee
ICF – Information Consent Form
SAE – Sudden Adverse Event

## Subject Matter Expert (SME) Panel Feedback

Through ten SME panel sessions (n=94 participants) 156 comments and/or new requirements were collated through the Proof of Concept.

SMEs representing the sector worked through the various Proof of Concept workflows which allowed them to interact with the services developed within the Proof of Concept and to provide feedback on the potential design, navigation and logic of the national platform. A feedback feature was also developed within the Proof of Concept and a report following each session was then generated.

Feedback on features development in the Proof of Concept related to the following platform components:

- **Comment feature** – The comment feature enabled in-system communication between the applicant and various reviewers following the submission process. This feature was well received, and additional suggestions were provided. For example, during a HREC review meeting, the HREC secretariat should be able to collate the member's comments by selecting the comments using a check-box additionally, feedback on a document should also be enabled, including feedback on documents provided as PDFs with changes tracked. Overall, participants agreed the comment feature was essential for traceability and transparency of the review process.
- **Dashboard feature** – The dashboard feature was also well received by the SME panel members. It was designed differently for different type of users in the Proof of Concept. For example, in the Proof of Concept the applicant can create a new study, view notifications, and manage all the submitted applications and associated documents while a HREC secretariate can view the skill sets and workload of all their committee members. SME panel members also suggested that the dashboard should be configurable (like a Kanban Board*) for various parties working within the platform, such as research officers, and allow users to better manage their tasks.
- **Document upload** – The Proof of Concept demonstrated that documents can be uploaded to an application without limitations on the format or size. SME panel members noted that this feature represented a vast improvement on similar features within existing systems. This feature could also enable the applicant to upload documents by categories and date of recency (such as the most recent and current version of the patient information sheet and consent form) and upload multiple documents at once.
- **HREC review meeting** – In the Proof of Concept, the HREC Secretariat can review/discuss the application with members of HREC, collate HREC member comments and assign the application back to the applicant. This feature inspired the SME panel participants, who suggested additional services (features) within the system to better facilitate the review meeting. For example, the system should allow the HREC Secretariat to create meeting agendas, including a listing of all applications to review, and generate meeting minutes.
- **Timeline** – All SME panel participants applauded the timeline feature in the Proof of Concept. Participants recognised this feature as one of the most important features of the platform. For the first time, this feature provides transparency of the review and amendment process and will be a game change. This feature would underpin the future reporting capability of the platform so that benchmarks for each part of the process can be provided.
- **CTN** – The component of the CTN process developed in the Proof of Concept demonstrated how this business process could be streamlined in the national platform. Currently this process requires three different internal TGA systems and several internal teams. The future platform would enable a CTN to be triggered automatically whenever a minimum of system enabled criteria are met and/or, it could be triggered by a sponsor or site (such as a commercial trial sponsor or investigator researcher located in a health service organisation). The final platform would enable all the requisite business processes and reporting requirements of the TGA.
- **Pre-screening questions** – The Proof of Concept demonstrated that is possible to build intelligence into the system via a series of pre-screening questions to enable an applicant to follow an appropriate approval pathway. This feature is not present in existing approval systems. One frequently

* Project management software tool.

raised issue during the first phase of consultations highlighted the number of applications submitted to HRECs seeking a low or negligible risk (or similar) pathway because the researcher is seeking a pathway of 'least resistance' or a pathway that will deliver the fastest review or avoid an HREC review. This has increased the workload of the HREC secretariat and the research office. SME panel participants supported this feature noting that, the pre-screening questions should be judiciously curated so as not to misguide users.

- **User guidance** – In-system guidance was a feature enabled in the Proof of Concept as textual explanations for each question during the application process. Guidance could be provided in various formats including hover notes and videos. SME panel participants acknowledged the value of this function and suggested expanding this feature to provide detailed guidance on all business processes within the system as well as training materials for all users.
- **Other features** – SME panel members suggested additional features such as, the system should enable an application to be saved as draft so the user doesn't have to complete the whole application at once and, the future platform should support multiple types of browsers to ensure the platform can function well in in all circumstances. A mobile application could also be developed to facilitated and push notifications would ensure all users are updated in real-time on any device. Panel members also suggested the delivery of the platform should be supported by concurrent work to improve technology literacy and ensure ongoing user feedback and system evaluation ensures the future platform continues to meet the needs of the sector.

## Public webinar feedback

The Proof of Concept was well received by the sector, with some degree of relief that it is technically possible to overcome existing system issues. Through the online discussions, the sector focussed on features such: the process to authenticate users; data management and data security; timeline for implementation; costs; enabling multiple user profiles to reflect an individuals' appointments at various organisation (such as universities, medical research institute and health service organisations).

All participants firmly supported the move away from separate jurisdictional processes and systems. The views expressed confirmed that the risk of not implementing a national approach outweighed the risks associated with implementing national ICT infrastructure. Few participants could identify a positive experience of data migration when moving from one system to another, and many agreed that actively recruiting trials or projects and information relating to compounds in development, should be manually transferred across into the new system. All other information could be enabled through view access (see **Data migration strategy**).

Consumer representatives sought assurance that the outcomes of research would be made publicly available (positive, negative and indeterminate findings) in plain language(s), and that the platform would enable a comprehensive public facing website, supported through a community education and communication strategy. Such an approach would also facilitate communication on the change to a national approach.

In response to the questions raised during the public webinars responses to frequently asked questions were developed (**Appendix 4**).

## Recommendations for implementation

Strategic planning to implement the National One Stop Shop platform and associated National Clinical Trials Front Door in Australia would be a consideration for the jurisdictions via the CTPRG, delivered under the cross-jurisdictional governance arrangements and operationalised under the auspice of the governance committee once established.

A potential operational approach was developed in discussion with the technical expert engaged by the Commission and on reflection of the insights received through the consultation process. Specifically, insights relating to user experience of building and implementing new systems; the architecture of current systems and the level of user engagement in the design process.

The approach outline below, describes a co-design with users across the sector that would deliver the National One Stop Shop in a way that is continually informed by user needs and would deliver the platform in a timely manner.

In project management terms, the governing body would be the 'sponsor' of the platform, responsible for setting the strategic direction for implementation and maintenance of the national infrastructure. Strategic planning would consider the structure of the operational committee and resource management and would appoint an operations committee or similar 'business owner' to implement the plan (**Figure 9**).

Under this structure the project director would be responsible for managing different workstreams and reporting to the project sponsor:

- A change lead
- Operations lead
- Technical owner
- ICT project manager
- Project manager oversighting overall project delivery.

Under the project director, the change lead would lead a team to design training materials, make training plans, communicate with various stakeholders, and manage project changes.

Under the project director, business analysts and domain experts* would work closely with the technical team to define detailed requirements and report to the operational lead.

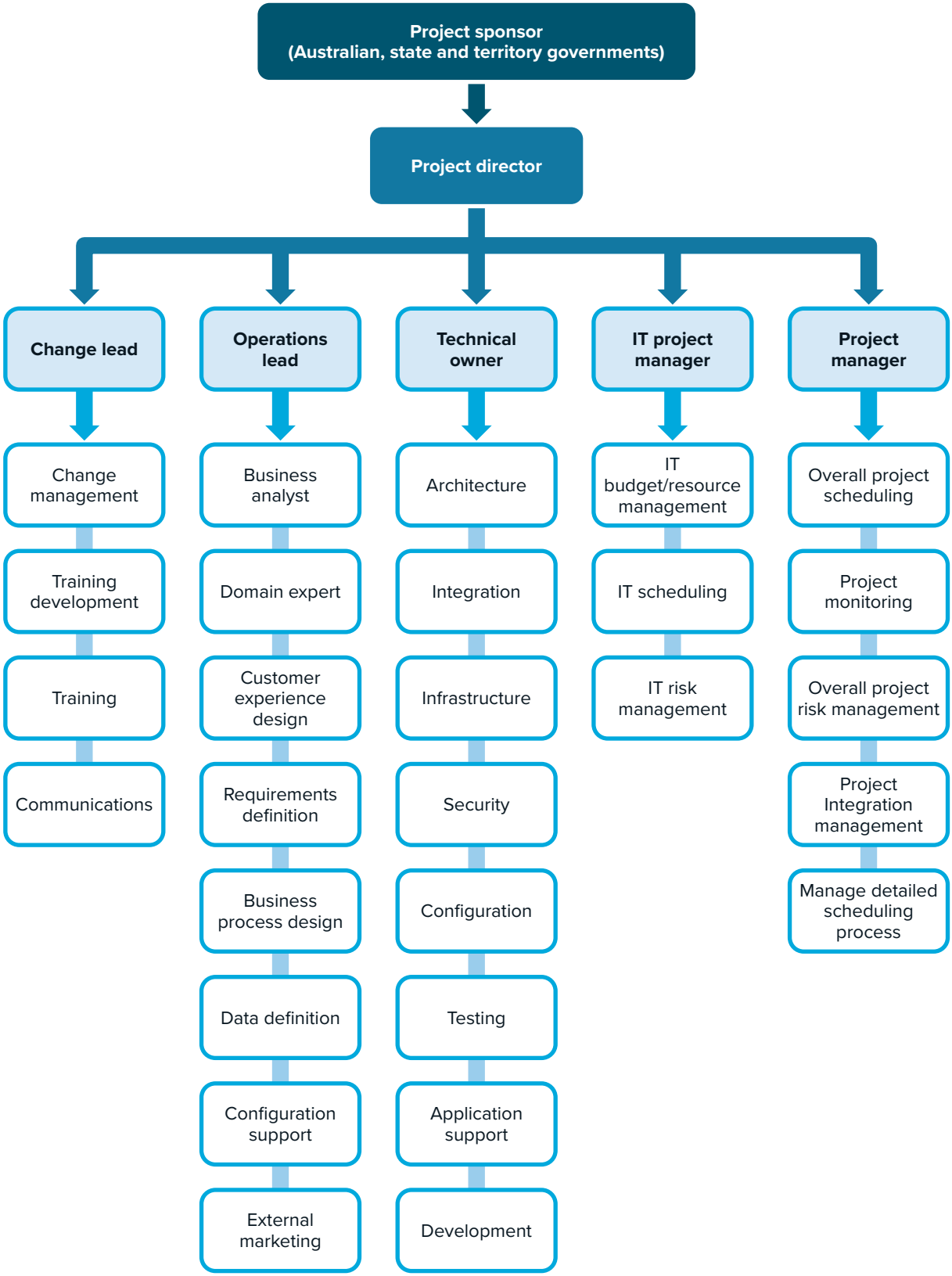
The operation team would be responsible for marketing and consumer engagement.

Under the technical stream, there would be a solution architect who is responsible for defining the entire platform solution, a security architect to guide security controls and compliance, an infrastructure architect (a cloud architect) to design and implement infrastructure setup, and several development teams, and testing teams for the implementation of different business domains. A technical lead would be responsible for managing this team and reporting back to the project director.

Given the scale and complexity of the project, there would be two project managers. One project manager to work closely with the technical lead to manage all the technical activities and the other to oversee the entire project's progress.

* 'Domain experts' are system users in the field including but not limited to: researchers, sponsors, HREC officers and research officers and representatives of the TGA, OGTR and ANZCTR.

**Figure 9:** Resource management recommendation



## Dependencies

Following establishment of the governing body for the implementation of the National One Stop Shop and National Clinical Trials Front Door, the development of the strategic and operational plans would consider the following dependencies related to the (next) design and specification phases:

1. All jurisdictions must agree on the HREA workflow (note: work to gain agreement on the SSA core elements and workflow has been completed as part of this consultation process). For example, the review and triage process (or no triage process), who can submit the application, who can delegate the application to other parties and delegations for approvals, etc.
2. All jurisdictions must agree on the data elements of HREA and SSA application and amendment data fields including nuances for each jurisdiction (if required) and the rationale for nuances.
3. Jurisdictions should nominate domain experts to advise on the design, specification, build and release of each component of the platform. These domain experts would not only advise on the design and specification but would remain engaged for iterative testing throughout the phases of product development.
4. Data sharing arrangements must be agreed upon by all jurisdictions and key national agencies.
5. All jurisdictions (informed by their jurisdictional ICT departments) and key national agencies via the governing body would monitor progress and agree on decision changing and scope updates.
6. The proposed design methodologies and system architectures must be assessed, discussed and agreed upon by all jurisdictions and key national agencies via the governing body prior to the commencement of development work.

## Delivery approach

An agile approach for the implementation of the National One Stop Shop and National Clinical Trials Front Door is proposed as illustrated in **Figure 10** to streamline the delivery timeline (Note: this figure is not the entire project plan). This approach would facilitate product features to be released through multiple concurrent phases of release with project team members being allocated more efficiently across multiple work streams.

In general, with sufficient resources and agreements in place, all product features would be delivered in three years across six release cycles with a contingency of six to twelve months built into the schedule.*

The core business domains having already been broadly supported by the sector for implementation would comprise the first phase of work for the development of the platform. During the Phase I Release cycle, one team would focus on the ethics and SSA application development as this is the core business functionality. Concurrently, another dedicated team should engage with TGA on the CTN and CTA design and development and another team would work with the OGTR on developing their core business processes.

The third team would work with ANZCTR Executive on its core business requirements and data migration from the existing registry. In this way, by the end of the first year, most data fields will be finalised and built, which will forge a solid foundation for developing other product features. From a resource allocation perspective, the solution architect, project manager, and business analysts could always be allocated between the three teams. The security and infrastructure architect could join the project team during the design phase. But each team must have different domain experts who are able to contribute to the analysis and design phase for each distinct deliverable.

* Traditional design and development processes usually take longer than 12 months.

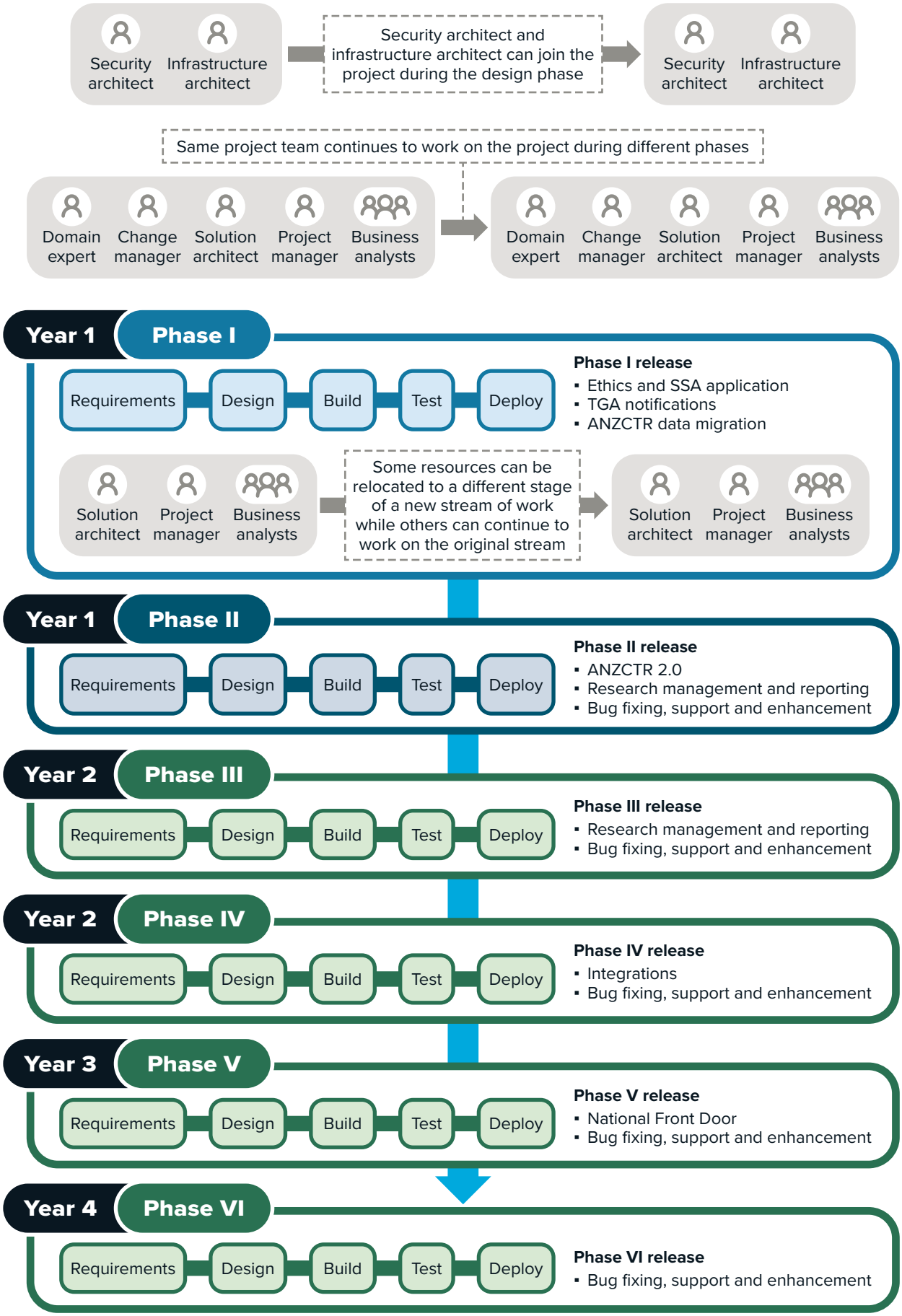
Once Phase I Release enters the build phase, the business analysts can start to work on requirement gathering and analysis for research management and reporting for the Phase II Release cycle. The same team who worked on ANZCTR data migration can continue working on the next generation registry because they should have the best knowledge. This way, the following release cycle can always start without waiting for the previous cycle to end, maximising resource utilisation and shortening the delivery timeline. The research management and reporting component would be undertaken concurrently with the design and delivery phase with a dedicated developer.

One team would be allocated to provide technical support, and a service desk team must be available to answer the calls from end users and triage the issues if they are product bugs. Enabling private providers to link to the public facing website would be undertaken in subsequent releases because these system relationships would be built upon the foundation of the other core business components.

For change management and education, given the complexity of this project, these components are core to success. The work force, representative of researchers, investigators, ethics committee secretariats and committee members, research coordinators and sponsors, would test and verify (pilot) the process from end to end.

The extensive consultation for the National One Stop Shop and National Clinical Trials Front Door revealed that, the importance of education and change management must not be underestimated. To allow early engagement, the change manager and education team could leverage the Proof of Concept and engage with the domain expert testing groups without waiting for the entire product release.

**Figure 10:** Recommendations for delivery



## Domain-driven design

The domain-driven design was implemented in the Proof of Concept based on insights from the literature review, international and domestic systems mapping, and the national consultation process regarding the National One Stop Shop and National Clinical Trials Front Door. The benefits of domain driven design in the national platform would:

- Enable multiple user journeys- that is, all types of users will use the same platform to undertake different workflows and business processes
- Include multiple business domains – this includes, HREA and SSA approvals, trial registration, TGA notifications, registration with the OGTR, research management functions and the public facing website for the community
- Be flexible enough to adopt additional changes to the existing workflow and enable improvements overtime.

The future system would be underpinned by complex business logic to enable the multiple business domains to operate. This software design approach is called domain-driven design because it is based on the business domain, and its strength is to solve complex problems. In general, domain-driven design is a software design approach focused on modelling software to match a domain according to input from that domain's experts.*

Domain driven design focuses on three principles:

1. The primary focus of the project provides the core domain and domain logic
2. Complex designs are based on models of the domain
3. Collaboration between technical and domain experts is crucial to creating an application model to solve domain problems.

Therefore, during the design phase, domain expert groups would be formed to work closely with the project team, including the developers, to achieve:

- **Good engagement** – This has already been demonstrated during the second phase of national consultations with SME panel members who applauded the level of detail included in the Proof of Concept based on the first phase of consultation
- **Thorough testing** – Thorough testing of the requirements through the design phase with the domain experts and end users
- **Better communication** – This is particularly important to ensure a clear understanding of the requirements between the technical team and the domain experts. Domain-driven design focus ensures understanding of each core domain and domain logic by all parties.

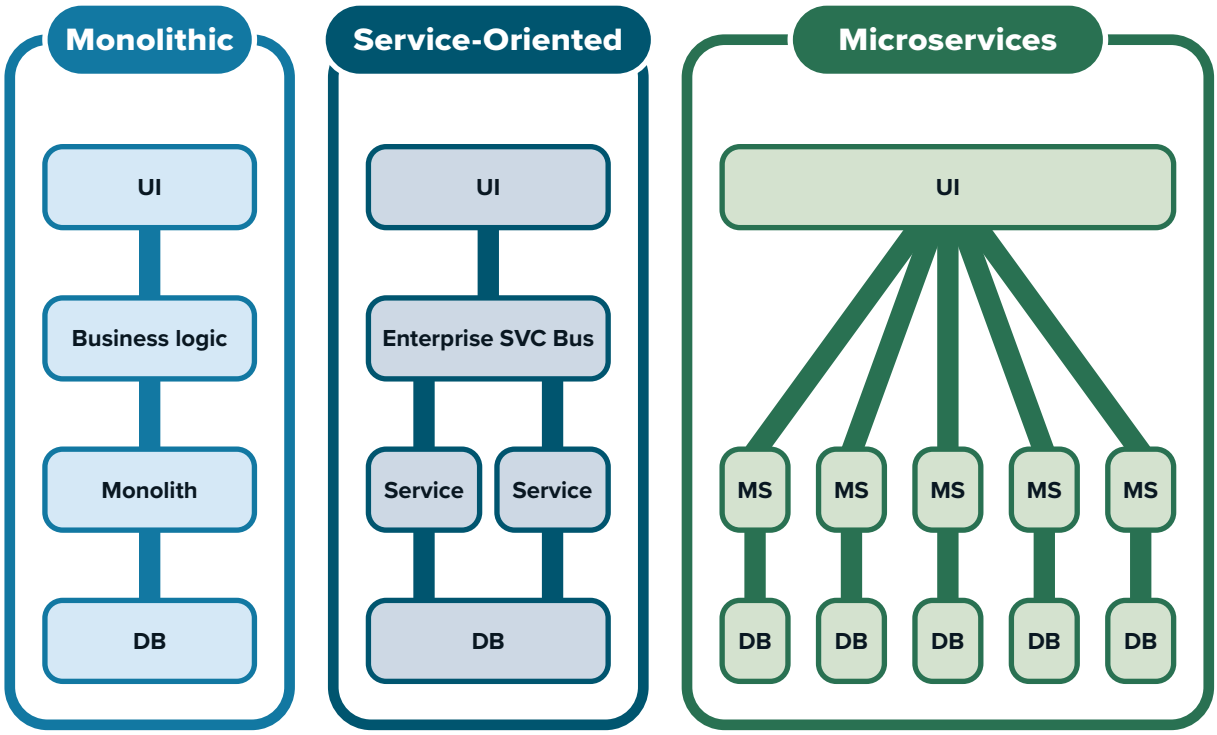
The Proof of Concept has enormous utility in a domain-driven design approach because it can be used by the development team to test and confirm design and build related activities. For example, once a domain expert raises an essential requirement, the change can be developed in the Proof of Concept, and in weeks or even days, the domain expert can be invited to test this feature. This iterative approach ensures the requirements are right and flushes out potential risks and issues in the build phase. For example, a feature that the domain expert initially raised could create a. usability issue, which could be flushed out in the Proof of Concept and brought back to the domain expert for further requirement updates.

* Eric Evans introduced the concept of Domain-Driven Design in 2003, in his book *Domain-Driven Design: Tackling Complexity in the Heart of Software*.

## Microservices or Service-Oriented Architecture (SOA)

Monoliths start small, but as requirements grow, development teams bolt new functions on top of each existing function. This happens until the monolith becomes interdependent, complex, and challenging to untangle. This interdependence is problematic when making upgrades or changes. The code from different development teams working on different areas of the application invariably conflicts and collides. Ultimately, this happens until it is impossible to manage application improvements.

**Figure 11:** Monolithic versus Service-Oriented and Microservices architecture




**Abbreviations**

DB – Database
MS – Microservices
UI – User interface

Modern software development increasingly relies on a distributed, service-based architectural pattern to achieve scalability, reliability, and rapid build, test, and release cycles. Two of the most popular service-based approaches are service-oriented architecture (SOA) and microservices.

SOA is an approach to breaking up the components required for applications into separate service modules that communicate with each other over a shared enterprise event bus to meet specific business objectives. Each module is considerably smaller than a monolithic application and can be deployed to serve different purposes in an enterprise.

Microservice architecture is generally considered as an evolution of SOA as its services are more fine-grained and function independently of each other. Therefore, if one of the services fails within an application, the application will continue to function since each service has a distinct purpose. The services in microservices communicate via APIs and are organised around a particular business domain. Together, these services combine to make up complex applications.

Many of the significant characteristics of SOA and microservice are similar. Both are designed to effectively break up large, complicated applications into smaller pieces that are more flexible to arrange and deploy. However, there are some key differences between the two:

- **Architecture** – Microservice architecture is based on smaller, finely granular services that are focused on a single purpose and can function independently of one another. Consequently, it is architected to share as few service resources as possible. Since SOA has larger, more modular services that are not independent of one another, it is architected to share resources as much as possible.
- **Data storage** – With microservices, the individual services generally have their own data storage. With SOA, almost all services share the same data storage units. Sharing the same data storage enables SOA services to reuse shared data but also results in tight coupling and interdependence between services.
- **Communication** – SOA communication is traditionally handled by an ESB (Enterprise Service Bus), which provides the medium by which services talk to each other. However, using an ESB can slow the communication of services and compromise the entire application if a failure occurs. In contrast, microservices rely on simpler messaging systems, like APIs, which are language agnostic and enable quicker communication.
- **Coupling and cohesion** – SOA is based on sharing components, making its systems slower and more prone to failure. In contrast, microservice does not involve any component sharing, allowing any failure points in a particular service to be quickly isolated before compromising application performance.
- **Deployment** – Since microservice services are smaller and largely independent of one another, they are deployed much more quickly and easily than those in SOA. In SOA, adding a service involves recreating and redeploying the whole application.

The Proof of Concept has successfully demonstrated how microservices can be used to develop a system that addresses the main issues and pain points through the Phase I consultation. Four independent services were created to allow the following tasks:

1. Submit and load applications
2. Trigger notifications
3. Upload and download supporting document
4. Make and load comments.

The services are loosely coupled to allow failure to be isolated, which makes the system more resilient. For example, if the notification service is failed, the failure will not shut down the entire platform. Both architectures offer significant advantages over monolithic architecture, and detailed assessments must be carried out by the ICT panel and agreed upon by all jurisdictions' IT department representatives.

In conclusion, both SOA and microservices architectures are routinely run in the cloud, which increases the flexibility for building and deploying application. Ultimately, the best approach depends on the business needs and use cases.

## Other considerations for implementation

Compared to on-premises solutions, cloud computing offers many benefits, including quick deployment, efficiency and cost reduction, scalability, unlimited storage capacity, and disaster recovery, to name a few. On top of that, famous public cloud providers (for example, Amazon, Azure GCP) have already provided many certifications that meet global compliance requirements, such as ISO 27001, Payment Card Industry Data Security Standards (PCI DSS), *American Health Insurance Portability and Accountability Act* (HIPPA), and more. The future solution should be hosted in a secured cloud space governed jointly by the Australian Government and the jurisdictions.

Capacity planning is the process of degerming the production capacity needed by a solution. In this context, current storage requirements and the incremental percentage per year will be needed to estimate space in the cloud and anticipate the future traffic volume so the capability of the future platform will not become the bottleneck for performance. Jurisdictions should provide their current and monthly incremental storage usage and the estimated total number of users.

The National One Stop Shop and National Clinical Trials Front Door consultation participants held that the final platform would be vendor agnostic, intuitive, flexible and adaptable over time. The chosen architecture should ensure the future platform can:

- Enable multiple user journeys across different sectors and business domains
- Enable and support a common workflow to support streamlining and harmonisation of approvals processes, and accommodate legislated jurisdictional variations to this process, and related functions
- Offer high fault tolerance where a single point of failure will not bring down the entire system
- Allow a specific service to be scaled. For example, consumer visits could result in high volume traffic compared to sponsor visits.
- Ensure the platform is flexible enough to adopt any changes to the existing workflows and any new workflows to facilitate regular updates, ongoing improvements

A single national system, the National One Stop Shop, would be the ideal end state and would provide savings across all jurisdictions. This approach would provide the ability to rapidly advance new standards and process flows, provide close to real-time reporting and enable evaluation of the platform against the needs of sector and the changing international environment.

In accordance with stated requirements of the Digital Transformation Agency, including with respect to interoperability capability and a single touch, 'tell us once principle', any modern system should provide services to accept and send standards-based data. This requires the development of national standards for data and data exchange to allow system to system-based communication.

National standards for data and data exchange alone however, would not be sufficient to address key challenges of duplication, fragmentation and variation across the sector, or to adequately support common process flows or real time reporting across all jurisdictions and key agencies. This would be difficult to achieve across multiple, distributed systems without massive ongoing investment in integration and standards.

Complexity, cost and risk become significantly compounded to the point of being prohibitive if multiple proprietary systems are contemplated as part of the distributed system. This is an important factor to take into account when determining appropriate system architecture to support the platform.

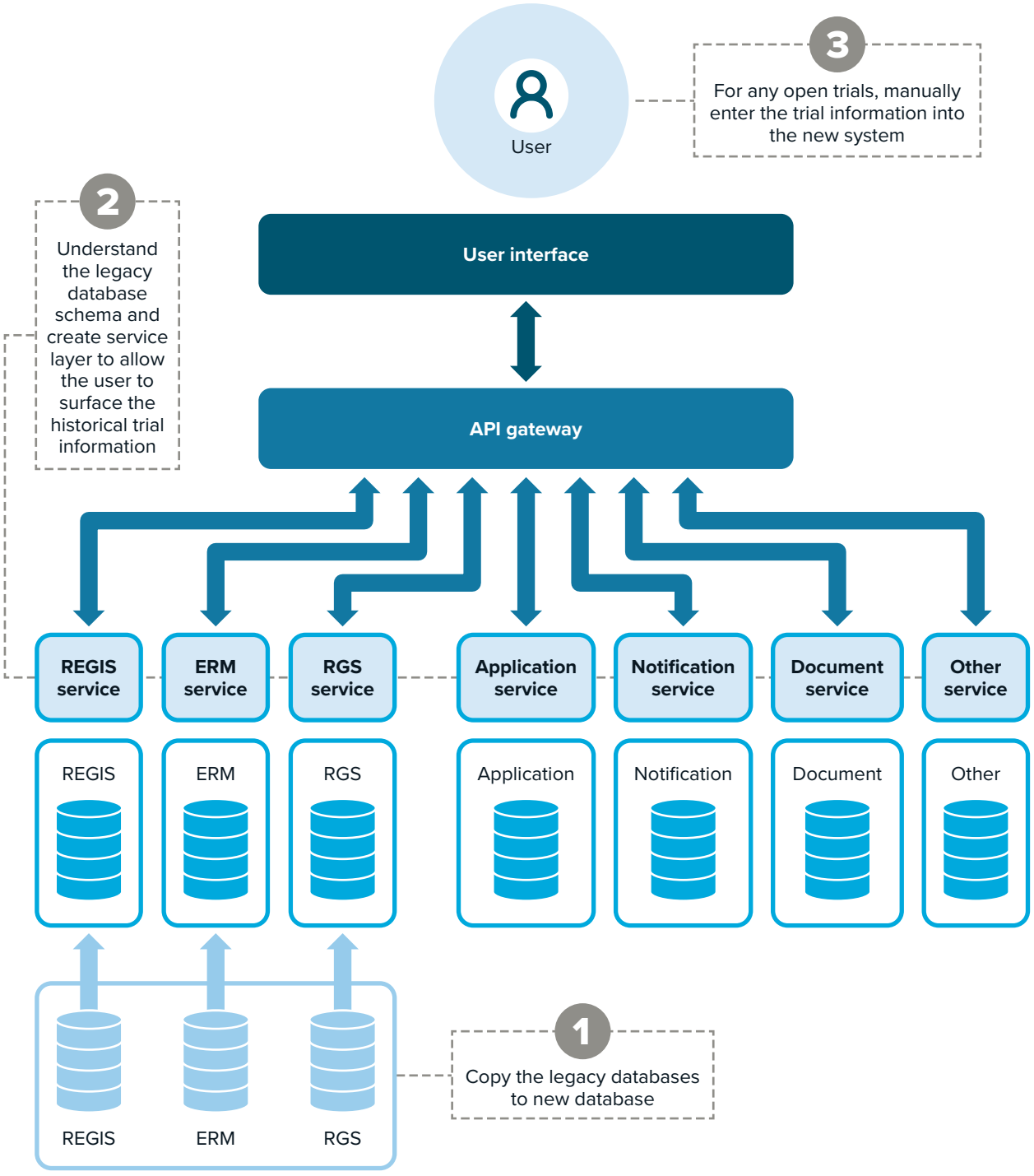
A further risk identified in multiple systems would be losing the benefit of cross jurisdictional reporting and consistency to common processes and data standards.

## Data migration strategy

Jurisdictional health department representatives and consultation participant's past experience with data migration has not been seamless. Most expressed concern for how the process would be undertaken. Some jurisdictions did not want to repeat this experience due to the complexity and challenges associated with previous experiences. However, other jurisdictions believe that historical data must be migrated across because some studies will carry out over decades, and the sector cannot lose visibility on those studies.

To solve this problem, the project must understand how the historical data will continue to be used in the new system. A more practical solution can be introduced if users only need to read but not continue to operate the historical data (**Figure 12**). For REGIS and ERM, the jurisdictions can work with the vendor to access a copy of their current database. After that, a service layer can be created to allow the National One Stop Shop to retrieve the data from those databases. A user could still use their existing project ID to search the historical record. However, if the user needs to update their historical record, a complete data migration is required. Alternatively, specific funding could be provided for jurisdictions operational activities, with dedicated resources to undertake data-entry into new system.

**Figure 12:** Data migration solution



Migrating data from RGS into the National One Stop Shop will be straightforward given WA Health owns the data. Jurisdictions that do not hold their current data will be more challenged in this regard. The data migration activity will need to be coordinated by each jurisdiction system administrator.

The only database that would be migrated into the National One Stop Shop is the ANZCTR database. A planning session would be carried out at the beginning of the design phase, and a dedicated team and resources would be assigned to achieve this.

The goal of the data migration is to migrate the existing records into the new infrastructure so the ANZCTR team can continue to operate the registry with minimal disruptions. This would include the following steps:

1. **Explore and assess the source** – Understand what data needs to be migrated and what new data fields need to be added to the new national research registry
2. **Define and design the migration** – Minimise the complexity of the data transformation process given the intention is to migrate data to a new infrastructure rather than to an entirely new application
3. **Build the migration solution** – Develop the ETL (extract, transform, load) pipeline
4. **Conduct a live test** – A rehearsal of the migration process from a UAT environment with actual production data to ensure the accuracy of the implementation and completeness of the new application. This process will identify exactly how long all the data will take to migrate and determine which migration approach is most suitable – 'Big Bang' or 'Trickled'.
5. **Flipping the switch** – Coordinate with all the upstream and downstream systems of the migration. Then execute the migration as planned.
6. **Audit** – Once the migration is done, audit the data to ensure the accuracy of the migration.

Additionally, work to assess the user access will be undertaken during the application design phase to ensure the correct data access privileges are applied to each user.

# Appendices

## Appendix 1: Project Governance

### Health and Medical Research Advisory Group

| Committee member name | Committee contribution | Role title and organisation |
|---|---|---|
| **Professor Ian Chubb AC** | Chair | Chair |
| **Professor Chris Brook PSM** | Special advisor | CTPRG Chair and independent expert |
| **Dr Megan Campbell** | First Nations Peoples; health and medical research organisation | Medical Advisor, National Aboriginal Community Controlled Health Organisation |
| **Professor David Currow** | Clinical trials | Deputy Vice-Chancellor (Health and Sustainable Futures), University of Wollongong |
| **Ms Elizabeth DeSomer** | Medicines Australia – expertise in research and governance operations | CEO, Medicines Australia |
| **Dr Philip Gould and Ms Allyson Essex** | Australian Government Department of Health and Aged Care Executive representatives | Australian Government Department of Health and Aged Care |
| **Ms Melissa Hagan** | Jurisdictional representative | Director, Queensland Clinical Trials Coordination Unit and co-Chair, Clinical Trials Collaborative Forum |
| **Ms Erica Kneipp** | Universities Australia/ university sector – expertise in strategic research and operations | Head of Research Strategy and Transformation Lead at the Australian National University College of Health and Medicine |
| **Ms Robyn Kruk AO** | Executive national level state public, regulation and service delivery | Chair, Mental Health Australia |
| **Ms Anne McKenzie AM** | Consumer representative | Consumer Advocate |
| **Ms Terrie O'Brien** | Australian Government Department of Health and Aged Care representative | Director, Clinical Trials Section Health and Medical Research Office, Health Economics and Research Division, Department of Health and Aged Care |
| **Dr Antonio Penna** | Jurisdictional representative | Executive Director, NSW Office for Health and Medical Research |

| Committee member name | Committee contribution | Role title and organisation |
|---|---|---|
| **Dr Ian Pieper** | Expert HREC and research governance | Chair Human Research Ethics Committee, University of Canberra University |
| **Professor John Simes** | Australian and New Zealand Clinical Trials Registry (ANZCTR) – expertise in clinical trials research | Senior Associate Director, National Health and Medical Research Council (NHMRC) Clinical Trials Centre; Director, ANZCTR |

## Reference groups

### Research and Development (R&D) Taskforce

A collaboration between Medicines Australia, AusBiotek and the Medical Technology Association of Australia (MTAA):

- Abbott
- ARCS
- Biotronik
- Bristol Myers Squibb
- CMAX
- Johnson and Johnson
- Lilly
- Medicines Australia
- Medpace
- Merck Sharp and Dohme
- MTAA
- Novartis
- Paradigm Pharma
- Roche
- Southern Star
- Stryker.

### Clinical Trial Collaborative Forum

- Abbott
- ACTA/CTC
- AusBioteck
- CEO ACTA
- CEO ARCS
- CEO Bellberry HREC
- CTPRG members
- Interim CEO MPT Connect
- Medical Technology Association of Australia (MTAA)
- Medicines Australia
- PRAXIS

### ANZCTR Executive

- A/Director Data and Informatics
- Director of Evidence Integration
- Executive Lead ANZCTR
- Manager
- Senior Analyst Programmer
- Senior Evidence Analyst

### MTPConnect and small to medium enterprises (SMEs)

- Abbott Medical, Director
- Bayer, Head of Clinical Operations
- Bayer, Manager of Monitoring
- Bayer, Manager of Start Up Specialist
- Biogen Australia, Clinical Country and Site Lead
- Biotronik Australia, Director Clinical and Regulatory Affairs
- Boehringer Ingelheim, Clinical Research Manager
- Boehringer Ingelheim, Head of Clinical Operations
- Bristol Myers Squibb, Associate Director Government Affairs, Policy and Advocacy Access
- Bristol Myers Squibb, Senior Director Clinical Operations
- ICON, CRA II
- ICON/Bayer, Manager of Monitoring
- Medical Technology Association of Australia, Code of Practice and Project Manager
- Medicines Australia, Head Strategic Policy Implementation
- Medicines Australia, Manager Industry Regulatory Policy
- MTPConnect, Senior Director Stakeholder Engagement

- Novo Nordisk, Senior Director CMRQ
- Pfizer Australia, Country Trials Manager
- Pfizer Australia, Director Start Up Project Management
- Pfizer Australia, Senior Director, Clinical Site Operations
- Pfizer Australia, Site Activation Partner
- Pfizer Australia, Site Relationship Partner
- Pfizer Australia, Site Relationship Partner
- Stryker, Senior Manager Clinical Research

### Health service research sector (Australian Institute of Health Innovation [AIHI])

- Australian Alliance for Artificial Intelligence in Healthcare
  - Precision Health Care Flagship
  - Consumer Health Flagship
  - Safety, Quality and Ethics Flagship
  - Workforce Program
- Centre for Health Informatics (CHI)
- Director, Centre for Healthcare Resilience and Implementation Science (CHRIS)
- Health services researcher
- NHMRC Centre for Research Excellence in Digital Health Care
- Program Manager, Health services researcher

### Aboriginal and Torres Strait Islander Health Advisory Group

- Aboriginal Health Policy Officer, Public Health Services Tasmania
- Chair – Director, Aboriginal Health Policy Directorate, Public and Aboriginal Health Division, Western Australian Department of Health
- Chief Aboriginal Health Adviser, Aboriginal Strategy Oversight – Victorian Department of Health
- Chief Executive Officer, Australian Indigenous Doctors' Association (AIDA)
- Chief Executive Officer, Congress of Aboriginal and Torres Strait Islander Nurses and Midwives (CATSINaM)
- Cultural Capability Advisor – Aboriginal and Torres Strait Islander Cultural Capability, Queensland Health, Aboriginal and Torres Strait Islander Health Branch, Strategy, Policy and Planning Division
- Director Aboriginal Health Flinders and Upper North Local Health Network, SA Department for Health and Wellbeing, Aboriginal Health
- Director Aboriginal Health Limestone Coast Local Health Network Inc – SA Health, SA Department for Health and Wellbeing, Aboriginal Health
- Director, Aboriginal Health, South Western Sydney Local Health District
- Director, Medical Advisor, National Aboriginal Community Controlled Health Organisation
- Executive Director, Aboriginal and Torres Strait Islander Health, Cairns and Hinterland Hospital and Health Service AHHA Representative
- Manager of the Aboriginal and Torres Strait Islander Liaison Service, Policy Partnerships and Programs, ACT Health Directorate
- Principal Advisor, NSW Department of Health
- Principal Policy Officer, Aboriginal Health Policy, NT Department of Health, Aboriginal Health Policy, Health System Policy and Strategy

### Consumer advocates, organisations and their members

- Clinical Trials Advocate, AccessCR (conduit for communication through the AccessCR wide-membership base)
- Health and Medical Research Advisory Group consumer representative and supporting organisations

### SSA Expert Reference Group members

- A/Director, Research and Innovation Office, Western Australian Department of Health
- A/Manager, Research Data, Ethics and Governance Services, Research and Innovation Office, Western Australian Department of Health
- Clinical Trials Manager, Western Sydney Local Health District
- Clinical Trials Project Reference Group representatives
- Co-Chair CTCF
- Director of Research, St Vincent's Hospital
- Director of the Queensland Clinical Trials Coordination Unit (QCTCU) in Queensland Department of Health
- Experienced Trial Coordinator
- Expert Human Research Ethics Committees
- Individual with expertise participating in national consultations
- Research Governance Officer, SA Health
- Principal Policy Officer, Queensland Health

- Project Manager (Embedding Quality Research), Sydney Research Ethics and Governance
- Project Officer, Department of Jobs Precincts and Regions
- Research Governance Officer, Tasmanian Department of Health
- Research Governance Project Coordinator, Tasmanian Department of Health
- Senior Director, Research Ethics and Governance, Centre for Health and Medical Research, ACT Department of Health
- Staff Specialist Intensive Care Unit, Darwin Hospital

## Expert panels

### Panel 1 – ICT technical experts

- Computer Scientist and Artificial Intelligence Specialist, University of Adelaide
- Ethical and Compliance Specialist (Data61)
- Healthcare System Integration Specialist, Xtramile Solution
- Managing Director, Accenture
- Security Specialist
- Solution Architect, Xtramile Solutions

### Panel 2 – SME panel (three groups)

#### Group 1

- Australian Institute of Health Innovation (Human Factors) representatives (two)
- Centre for Healthcare Resilience and Implementation Science, Faculty of Medicine, Health and Human Sciences
- Pharmacist, TGA representatives (two)
- Pharmacovigilance Inspector, TGA
- Technical Lead, Clinical Trials, Risk Management Section, Therapeutic Goods Administration (TGA)

#### Group 2

- ANZCTR Manager, NHMRC Clinical Trials Centre, University of Sydney
- CEO, Cancer Trials Australia
- IT Business Partner, Bellberry Limited
- Principal Policy Officer, Office of Precision Medicine and Research, Queensland Department of Health
- REGIS Technical SME, eHealth NSW (covers F1 Solutions)
- ThinkPlace, Digital Transformation Manager

#### Group 3

- A/Manager, Research Data, Ethics and Governance Services, Research and Innovation Office, Western Australian Department of Health
- A/Senior Policy Officer at Western Australian Department of Health
- Executive Director Medicines Management, NT Health
- Manager, Research Governance, Telethon Kids Institute
- President of the Australian Dental Council
- Project Coordinator, Research Governance, Tasmanian Department of Health
- Senior Manager, Ethics and Research Governance Office, Alfred Health

# Appendix 2: Stakeholder engagement strategy and consultation schedule

## Stakeholder engagement strategy (February 2021)

The Commission collated a comprehensive stakeholder contact list of more than 5,000 individuals and groups. Individual stakeholders and groups were invited to participate in the initial consultations and all stakeholders were kept informed on the progress of the work via receive regular email updates on the project (push communication). The Commission website was also be updated regularly with information on the consultation process (pull communication).

The following provides an overview of the key stakeholder groups and individuals identified to date, their **level of interest and influence on the project**, the **type of engagement**, **goals of engagement** and **methods of engagement**. The consultation plan was updated throughout the project in partnership with the Department, the Chair and the CTPRG.

### High level of interest and high level of influence on the project

#### Type of engagement

Build awareness and knowledge and enable them to act as champions.

#### Goals of engagement

These stakeholders are engaged and equipped to actively contribute to the development of options for the national ICT infrastructure.

#### Methods of engagement

This group should be the 'first to know' and champions of the consultation. The Commission will work with these stakeholders to ensure they support the consultations and the national ICT portal via the provision of information and participation in meetings and 'show cases.' These stakeholders will understand the risks of not implementing national research infrastructure and engage with their counterparts in the consultations. As these stakeholders hold authority and credibility, they need to support senior executives and managers to engage with relevant areas and staff to create awareness and provide messaging on how the proposal is aligned with the national agenda. They also need to act as a conduit back to the Commission and/or the Department about matters of significance.

- Government Health Ministers
- The Australian Government Department of Health and Aged Care
- Directors General and/or Secretaries of health departments
- Officers of Health and Medical Research (where these roles are in place)
- CTPRG
- Chief Scientists (State/Territory and Australian Government)
- Therapeutic Goods Administration
- National Health and Medical Research Council (NHMRC)
- Inter-Jurisdictional Committee
- Private Hospital Sector Committee
- Commission Board
- Jurisdictional eHealth agencies (suggest as an expert panel)
- Clinical Trials Collaborative Forum
- Research & Development Taskforce
- Universities/Universities Australia (as a conduit to Medical Research Institutes)
  - medical research institutes (for example, the George Institute, ANZAC Research Institute, The Garvan, Heart Research Institute)
- Research Australia
- MTPConnect (Collaboration of Medicines Australia, Medical Technology Association of Australia and Ausbiotech – conduit to SMEs)

- ANZCTR
- F1 Solutions
- ERM (Infonetica)
- Aboriginal and Torres Strait Islander Health Advisory Group – conduit to AHMRC (NSW). Commission advisory group. Members represent the following organisations
  - National Aboriginal and Torres Strait Islander Health Standing Committee
  - State and Territory Aboriginal and Torres Strait Islander branches of health departments
  - National Aboriginal Community Controlled Health Organisation
  - Congress of Aboriginal and Torres Strait Islander Nurses and Midwives
  - Australian Indigenous Doctors' Association
  - Aboriginal and Torres Strait Islander units from a health service organisation
  - University centres with focus on Aboriginal and Torres Strait Islander health, such as the Wardliparingga Aboriginal Research Unit, South Australian Health and Medical Research Institute
  - Australian Healthcare and Hospitals Association

### High level of interest and medium level of influence on the project

#### Type of engagement

Involve and collaborate.

#### Goals of engagement

Work directly with these stakeholders throughout the consultations to ensure their views and concerns are heard and considered in the development of options for a preferred solution.

#### Methods of engagement

Workshops at conferences, forums, expert panels, face-to-face meetings and meetings via remote technology.

These stakeholders have detailed knowledge of the various health and human research systems and need to engage in the consultations. It is important that they are fully across the 'why this', 'why now', risks of not changing and the anticipated future benefits. Awareness messaging and risk management/resistance management strategies will be focused on this group. They also need to understand what this will mean for their stakeholders, organisations and staff. Knowledge of the consultation approach and activities, opportunities and reference material is key to this group to provide support and advice to their stakeholders. Feedback from this group is important.

- Australian Clinical Trials Alliance
- Australian Health Research Alliance and Australian Health Research Translation Centres
- Cancer Australia
- Cancer Council Australia
- Cancer Trials Australia
- Clinical Oncology Society of Australia
- Commonwealth and Scientific Research Organisation
- Australian Research Data Commons and National Research Infrastructure
- Data and IT Infrastructure groups (AIHI, Digital Health Agency, AIHW, Digital CRC, Google, Accenture)
- Public Health Association of Australia
- Sydney University
- eHealth Agencies in jurisdictional health departments
- Commercial trial sponsors
- Cooperative group trial sponsors
- Health department representatives/local health districts/networks
- Non-profit agencies including Therapeutic Innovations Australia
- NHMRC Australian Health Ethics Committee
- Medical Research Future Fund
- Medical Services Advisory Committee
- ARCS Australia (as a conduit to Clinical Research Organisations)
- Bellberry Human Research Ethics Committee
- Privacy Commission
- Pharmaceutical Benefits Advisory Committee
- Catholic Healthcare Australia
- Consumer organisations
- Endpoint IQ

### High level of interest and low level of influence on the project (highly impacted)

#### Type of engagement

Inform and consult.

#### Goals of engagement

To provide these stakeholders with balanced and objective information to assist their understanding of the current issues, alternatives and potential future opportunities. Obtain their feedback on the international evidence and options for future ICT requirements.

Methods of engagement: These stakeholders will need to receive personalised messaging seeking information on their needs and future requirements including email distribution, website updates, and attendance at conferences and sector meetings. High impacted stakeholders will need to participate in the consultations and provide detailed information on their expectations for the One Stop Shop and the National Clinical Trials Front Door. These organisations will be using the platform on a daily basis and will need detailed information about what this means (from an operational perspective) for them.

- Contract Research Organisations (managed through Medicines Australia)
- Clinical trial/health and medical research investigators
- Hospital clinical trial coordinators and managers
- Directors of clinical governance
- Ethics and research governance officers
- Hospital Boards
- Clinical and non-clinical managers
- Quality managers
- Consumer representatives
- Hospital accreditation bodies
- Health administrators
- Health service research organisations

### High level of interest and low level of influence on the project (low impact)

#### Type of engagement

Inform and consult.

#### Goals of engagement

To provide these stakeholders with balanced and objective information to assist their understanding of the current issues, alternatives and potential future opportunities. Obtain their feedback on the international evidence and options for future ICT requirements.

#### Methods of engagement

These stakeholders will need to receive messaging seeking information on their needs and future requirements including email distribution, website updates, and attendance at conferences and sector meetings. Low impacted stakeholders can participate in the consultations and provide information on their expectations for the One Stop Shop and the National Clinical Trials Front Door, and should be kept informed of the outcomes of the work. Some members of these organisations may use the ICT Portal, so they will need to understand what it means for them.

- Insurance groups that underwrite the of conduct clinical trials in universities, public and private health facilitates
- Australian Medical Association
- Australian Digital Health Agency
- MyGov
- The Health Technology Assessment Team
- The Australian Research Management Society
- Aged care sector
- Primary Health Networks
- Council of Deans of Medicine and Science
- Australian Academy of Health and Medical Sciences
- Nuclear Medicine industry group
- Radiology and Pathology peak bodies
- Society of Clinical Research Organisations
- Clinical Trials: Impact & Quality (CT:IQ) consortium

## Consultation schedule

### Phase I consultation sessions – 5 October 2021 to 17 December 2021

| Week | Date | Organisation |
|---|---|---|
| 1 | **Tuesday 5 October** | Therapeutic Goods Administration; Accenture |
| | **Wednesday 6 October** | ACTA |
| | **Friday 8 October** | Clinical trials collaborative group forum (meeting organised externally) |
| 2 | **Monday 11 October** | Queensland Department of Health |
| | **Tuesday 12 October** | Victoria; ERM Infonetica |
| | **Wednesday 13 October** | NSW Department of Health |
| | **Thursday 14 October** | Inter-Jurisdictional Committee (IJC) |
| | **Friday 15 October** | F1 Solutions |
| 3 | **Monday 18 October** | Western Australian Department of Health |
| | **Tuesday 19 October** | NHMRC; Primary Care Committee (PCC) |
| | **Wednesday 20 October** | ACT Department of Health; Private Hospital Sector Committee (PHSC) |
| | **Thursday 21 October** | Commission Board |
| 4 | **Monday 25 October** | South Australia Department of Health |
| | **Tuesday 26 October** | ERM (Infonetica); Tasmanian Department of Health |
| | **Thursday 28 October** | Northern Territory Department of Health |
| | **Friday 29 October** | ANZCTR |
| 5 | **Monday 1 November** | Chair unavailable (AM); AIHI – reference group |
| | **Tuesday 2 November** | ARHA; AHRTCs |
| | **Wednesday 3 November** | Research Australia; Clinical societies |
| | **Thursday 4 November** | BAC unavailable – Stroke workshop |
| | **Friday 5 November** | MTPConnect; Medicines Australia; Medical Technology Association of Australia; Ausbiotech |
| 6 | **Monday 8 November** | Data and IT Infrastructure groups (AIHI, AIHW, Digital CRC, Google, Accenture) |
| | **Tuesday 9 November** | ARDC; NCRIS; CSIRO |
| | **Wednesday 10 November** | ACTA Presentation |
| | **Thursday 11 November** | Clinical registries |
| | **Friday 12 November** | Universities Australia – Deans of Medicine and Nursing; OGTR |

| Week | Date | Organisation |
|---|---|---|
| 7 | **Monday 15 November** | Public Health organisation – reference group |
| | **Tuesday 16 November** | MRIs; ARCS; CROs |
| | **Wednesday 17 November** | Industry; Professor Villis Marshall; ARCS; Cooperative group trial sponsors |
| | **Thursday 18 November** | Public Health Organisations |
| 8 | **Monday 22 November** | ACTA |
| | **Tuesday 23 November** | Consultation briefing meeting; CTPRG meeting |
| | **Wednesday 24 November** | Cancer Australia; Cancer Council Australia; Cancer Trials Australia; COSA |
| | **Thursday 25 November** | Aboriginal and Torres Strait Islander representative organisations |
| | **Friday 26 November** | Consumer groups (two sessions to be confirmed) |
| 9 | **Monday 29 November** | Bellberry Human Research Ethics Committee, NHMRC research Committees |
| | **Tuesday 30 November** | Queensland Department of Health, Directors of Research quarterly meeting |
| | **Friday 3 December** | Hospital Boards |
| 10 | **Tuesday 7 December** | Hospital clinical trial coordinators and managers; University clinical trial coordinators and managers |
| | **Wednesday 8 December** | CQR Framework review AG Meeting |
| | **Thursday 9 December** | Ethics and research governance officers HSOs; Ethics and research governance officer's universities |
| | **Friday 10 December** | Directors of research and Directors of clinical governance |
| 11 | **Monday 13 December** | AIHI; Quality Managers; Trial investigators (session #2) |
| | **Tuesday 14 December** | Clinical and non-clinical managers; Health administrators; health department representatives/local health districts/ networks, directors, research nurses, pharmacists; Hospital accreditation bodies; Industry (session #2) |
| | **Wednesday 15 December** | HMRAG meeting 2 |
| | **Thursday 16 December** | CROs and commercial companies; Clinical Trials Collaborative Forum |
| | **Friday 17 December** | Foundations; CROs (session #2) |

### Phase II consultations – 12 April 2022 to 29 June 2022

| Week | Date | Organisation |
|---|---|---|
| 1 | Tuesday 12 April | Pre-CTPRG meeting |
| | Wednesday 13 April | CTPRG meeting |
| 2 | Monday 18 April | Easter Monday |
| | Tuesday 19 April | Easter Tuesday |
| | Friday 22 April | R&D Taskforce (reference group) |
| 3 | Wednesday 27 April | HREC coordinators (OSS update) |
| 4 | Monday 2 May | WA – initial discussion – Phase II; SA – initial discussion – Phase II; ACT – initial discussion – Phase II |
| | Wednesday 4 May | Qld – initial discussion – Phase II |
| | Thursday 5 May | Medicines Australia |
| 5 | Wednesday 11 May | ALLG presentation |
| | Thursday 12 May | Aboriginal and Torres Strait Islander Health Advisory Group meeting (reference group); TAS – initial discussion – Phase II |
| 6 | Monday 16 May | Briefing NHS Health; Patricia Bradd; NT – initial discussion – Phase II |
| | Thursday 19 May | Jurisdictional meeting; Jurisdictional meeting |
| | Friday 20 May | NSW (Tony Penna) – matters related to the OSS |
| 7 | Monday 23 May | ARCS conference |
| | Tuesday 24 May | ARCS conference |
| | Wednesday 25 May | ARCS conference |
| | Friday 27 May | NSW SEF meeting; NT SEF meeting; Department meeting; Tony Penna meeting |
| 8 | Tuesday 31 May | Department meeting |
| 9 | Monday 6 June | SME panel 1 |
| | Tuesday 7 June | SME panel 3 |
| | Wednesday 8 June | SME panel 10; Consumer reference group |
| | Thursday 9 June | SME panel 4 |
| | Friday 10 June | SME panel 5 |
| 10 | Tuesday 14 June | Jurisdictional meeting |
| | Wednesday 15 June | SME panel 6 |
| | Thursday 16 June | SME panel 7 |
| | Friday 17 June | Public webinar; SME panel 2 |

| Week | Date | Organisation |
|---|---|---|
| 11 | Wednesday 22 June | SME panel 8 |
| | Thursday 23 June | SME panel 9 |
| | Friday 24 June | Public webinar; R&D meeting |
| 12 | Monday 27 June | ANZCTR follow up panel meeting |
| | Tuesday 28 June | SCHN meeting |
| | Wednesday 29 June | Public webinar |

## Consultation participation

### Summary of National One Stop Shop and National Clinical Trials Front Door consultation participation

Note: Participants attended at least two to three sessions each. Additional ad hoc meetings were held and multiple meetings with the jurisdictions via the CTPRG were undertaken directly with the Chair and the Department. Additional meetings to technically map existing systems and test the requirements developed in the Proof of Concept were also conducted with the Commission technical team and jurisdictional representatives and the private sector (approximately 30 meetings).

**Table 5:** Consultation participation

| Activity | Attendees/respondents (aggregated) |
|---|---|
| Phase I consultation session attendees (including CTPRG members) | 850 |
| SSA expert consultations (attendees) | 346 |
| *National Systems Survey Report* (responses) | 599 |
| *National Site-Specific Assessment Core Elements* (responses) | 477 |
| *Community Perspectives Survey Report* (responses) | 582 |
| Phase II consultation session attendees (including CTPRG members) | 1,064 |
| Subject Matter Expert Panels (attendees) | 94 |
| Consultation participation | 4,012 |

**Table 6:** Consultation participation

| Category (broad participant categories) | Attendance (each group of attendees attended between one to three sessions each) |
|---|---|
| ACT Department of Health | 9 |
| Australian New Zealand Clinical Trials Registry (ANZCTR) | 8 |
| Clinical registry | 39 |
| Clinical Trials Project Reference Group (CTPRG) | 10 |
| Clinical trials workforce – other | 68 |
| Consumer representatives | 37 |
| Data and Infrastructure including system developers and jurisdictional eHealth representatives | 24 |
| Health administrators | 147 |
| HRECs officers | 66 |
| Industry representatives including contract research organisations | 168 |
| Medical research institute | 88 |
| National Health and Medical Research Council (NHMRC) | 3 |
| New Zealand Ministry of Health | 3 |
| NSW Department of Health | 9 |
| NT Department of Health | 3 |
| Office of the Gene Technology Regulator (OGTR) | 8 |
| Other Australian Government Agencies (CSIRO, NCRIS, etc.) | 10 |
| Queensland Department of Health | 5 |
| Research coordinators | 121 |
| Research managers | 167 |
| Research governance officers | 112 |
| Research investigators | 165 |
| SA Department of Health | 7 |
| Tasmanian Department of Health | 6 |
| Therapeutic Goods Administration (TGA) | 8 |
| University sector | 116 |
| Victorian Department of Health | 4 |
| Western Australian Department of Health | 14 |
| **Total** | **1,425** |

# Appendix 3: Phase I consultation insights – Current system issues and future sector requirements by platform components

| Platform component | Current system issues | Future sector requirements |
|---|---|---|
| **Systems and processes** | ▪ Monolithic system structures; hierarchical; inflexible; costly to amend and associated with delays in addressing system issues<br>▪ Limited capacity<br>▪ States and territories have different processes which slows things down<br>▪ No ability to build a profile (user; health service; clinician; researcher)<br>▪ Communication between users (for example, applicant and HREC) are undertaken outside of the workflow system usually via email<br>▪ No internal notification functionality that links to external systems such as email<br>▪ No data and information from current systems on research phases (that is, the project is open, closed, in follow-up, paused or abandoned) | ▪ The system needs to be agile and intuitive; easy to navigate; has capacity to grow (microservices structure), flexible and future proof<br>▪ 'End to end' for the research workflow and pipeline<br>▪ Enable a single notification, approvals and reporting platform that hold confidential information securely (user access and permissions) and enables notification and communication with sponsors, researchers, approving authorities, approving HREC and HREC members and research sites<br>▪ Ensures predictability and efficiency in research operations<br>▪ Education and training for systems users – include 'bubble notes' for data fields to guide the user<br>▪ Data extraction capability<br>▪ User authorisation and permissions defined<br>▪ System generated unique national identifier for each project, that is the same for all parts of the process across all states and territories (including the next generation national research registry)<br>▪ System enabled communication and notifications<br>▪ Enable a user profile to be created: upload CV/insurance certificate etc and notification to the user when the documents are due to be updated (for example, NHRMC SAPHIRE system). The platform could also enable profiles for health service organisations; clinicians; researchers<br>▪ Embedded single national workflow. Work towards 4–6-week approval process (incorporating ethics and local site risk assessment)<br>▪ Timeline for transparency<br>▪ Consider a pre-submission feasibility assessment prior to SSA submission<br>▪ System enabled guidance for the user<br>▪ Ability to extract data<br>▪ A well-designed reporting system will be critical for success<br>▪ Supports internal communication between researchers, HREC secretariat, sponsors, and reviewers<br>▪ Passport or register of researchers, to avoid providing qualifications, publications etc multiple times (for example, like a procurement panel)<br>▪ National reporting on trial activity<br>▪ Searchable table and reporting using NHMRC descriptions for study type<br>▪ A system that functions like a 'mortgage application'<br>▪ When logging a new project or searching for projects use the NHMRC research categories<br>▪ Greater technical integration with the eMR (currently restricted by privacy restrictions and cyber security protections) |
| **Document management** | ▪ No central document management repository<br>▪ No visibility of research operations or trial management functionality (cost calculations and reporting are absent from current public sector systems) | ▪ Contract and Conflicts of Interest (COI) – document management functionality<br>▪ Reporting and transparency in the approvals process<br>▪ Visibility of the breadth of research activity nationally<br>▪ Feasibility assessment (prior to HREC review) for health services and sponsors<br>▪ Inbuilt research management system for all research not only clinical trials. Trial management functionality should include cost calculations and reporting<br>▪ System enabled document digital sign-off<br>▪ Data storage |

| Platform component | Current system issues | Future sector requirements |
|---|---|---|
| **Data integrity and security compliance** | ▪ Data entry and data integrity issues – data outputs are only as good as the data entered | ▪ Data security and integrity<br>▪ Cyber security and impact assessment related to how data are shared<br>▪ Inbuilt quality assurance functionality and processes for checking (curation) of data accuracy (regarding next generation research registry)<br>▪ Enable data access and data sharing with permissions<br>▪ Enable two-factor authentication |
| **HREC workflow** | ▪ Nationally agreed workflow and data fields (data items in jurisdictional systems match the NHMRC HREA) but no single national system<br>▪ Single HREC review not widely accepted under NMA<br>▪ Duplication of data fields for the HREC and SSA process<br>▪ Variation in the quality of the HREA review which directly impacts the acceptability of ethics approvals under the NMA scheme<br>▪ NMA doesn't apply to universities. Universities have a separate, parallel process. Universities will accept an HREC approval by a public sector HREC (and do not re-prosecute the review process) | ▪ Enable direct sponsor submission<br>▪ Should ensure minimal duplication of review and decisions<br>▪ Describe the role and function of the HREC and the roles of individuals undertaking these functions<br>▪ Provide more guidance on the review of tele-trials<br>▪ Concurrent HREA and scientific review process<br>▪ Enable the HREC workflow for the Population Health Research Network (PHRN) and pathway for data linkage projects approvals and requests to data custodians<br>▪ Enable a clearing house 'triage' to check the application (like a mortgage application) before submission to the HREC secretariat. This includes a 'queue' of applications and notifications of the next available meeting via a HREC with expertise to conduct the review and the accreditation status of the HREC<br>▪ Guidance on the principles of the National Statement and how they should be applied to various types of research (such as Health service research) for example, threshold for a waiver of consent; research reviewing medical records<br>▪ Incorporate workflow relevant to obtaining additional jurisdictional legislation such as the *Queensland Public Health Act 2005*<br>▪ Enable annual reporting to NHMRC |
| **SSA workflow** | ▪ No nationally agreed workflow or data fields ('thorniest' issue raised)<br>▪ Fragmented data and reporting<br>▪ The cost of running a trial at a site is not visible and able to be accurately estimated (fragmented data collection regarding financial information)<br>▪ No visibility of research operations and financial reconciliation within the site | ▪ Nationally agreed SSA checklist (rather than a site-specific form) and national site-specific 'envelope' where information is uploaded once for example, insurance certificates, budgets, and other information<br>▪ Internal communication and notifications for improved efficiency of the local site authorisation process<br>▪ Electronic signature with two-factor authentication (for example, rather than a Head of Department needing an account)<br>▪ Visibility of the SSA authorisation process and timeline<br>▪ Visibility of financial reconciliation research processes via research management functionality within the platform |

| Platform component | Current system issues | Future sector requirements |
|---|---|---|
| **Therapeutic Goods Administration notifications and approvals** | ▪ Current TGA system limitations which impact the reliability and consistency of their data assets<br>▪ The Clinical Trials Notification (CTN) and Clinical Trials Approvals (CTA) databases are not fit for purpose, limiting connectivity and the accuracy of notification and incoming safety information<br>▪ The current database has been developed in IBM Notes and integrated with a reporting software – COGNO. Within the current system it is hard to integrate and create dynamic files<br>▪ The CTN and CTA processes and system do not align (or integrate with) with the electronic HREA or the Bellberry submission system<br>▪ Australia plan to implement the TGA Good Clinical Practice (GCP) Inspection Program (piloted in 2019/20)<br>▪ There is no clear pathway for managing the safety reporting and notification pathways<br>**Safety reporting**<br>▪ There are no clear lines of responsibility for safety reporting. Individuals and trial sites default to processes they are familiar with and that may have been superseded<br>▪ There is confusion regarding safety and quality reporting. For example, Adverse Event (AE) reports are often submitted via email, Severe AE reports (SARs) are also submitted manually. There is confusion regarding individual (researcher, sponsor, clinician, regulator) compliance obligations and responsibilities for safety reporting<br>▪ There is confusion regarding how information is reported, updated, and acted upon. There is no clear path for understanding safety and the notification pathway. Currently GMP under the CTN Scheme is at the discretion of the sponsor and the HREC, no evidence of trial phase is required. This impacts a risk-based approach to evaluating safety<br>▪ The TGA has also heard the rising levels of public concerns around the accessibility of public health information. These concerns have occurred because of the limitations with current quality management systems to meet public demands for more detailed information. There is a known need for people to access more information not less | ▪ Functionality to enable an agile approach to system development as needed with extractable reporting relating to the CTN and CTA processes that are aligned and integrated with other processes such as HREC and safety notification across all levels within the TGA<br>▪ The system should provide the process and the guidance for users to enable streamlined and timely safety and adverse event reporting<br>▪ Facilitate reporting to enable the GCP Site Inspection Program<br>▪ Facilitating therapeutic AE reporting<br>▪ Reporting for authorised prescriber practice and Special Access Schemes could be included in the platform as a second phase of work |
| **Office of the Gene Technology Regulator (OGTR)** | ▪ The OGTR has processes but no universal system to support registration and licencing requirements | ▪ System enabled laboratory and site registration<br>▪ System enabled GMP compliance and reporting to the GTR<br>▪ Approvals process for the GTR<br>▪ Gene Technology Regulator<br>▪ Enable workflow for GTR approvals<br>▪ Enable GTR reporting |
| **Reporting and project management** | ▪ Currently multiple different systems (IRM, redcap, excel) – minimal reporting functionality – unsure about the integrity of the data<br>▪ ERM and REGIS/GEM have little reporting functionality that is reliable and relevant to various users including research investigators, research coordinators and health service organisations<br>▪ No research management system functionality to facilitate reporting on research activities, staffing and financial management as required under the National Clinical Trials Governance Framework | ▪ Comprehensive research management functionality should be enabled through the national system, including: operational reporting, financial management, workforce management, project and trial visit management and, reporting as required under the National Clinical Trials Governance Framework<br>▪ Enable role-based research management functionality<br>▪ Enable safety and quality reporting. Include functionality that supports Adverse Event (AE) reporting and Severe AE reports (SARs) and provide guidance for individual (researcher, sponsor, clinician, regulator) compliance obligations and responsibilities for safety reporting<br>▪ Update KPIs (currently provided in the Governance Framework) to include<br>– the timeliness of COI process (at the time of site selection and review of the initial protocol)<br>– measure of time-lost<br>– number of tele-trials<br>– measure of feasibility assessment for example, time from first approach to first patient recruited<br>▪ Support reporting and information for the GCP Inspection Program<br>▪ Support annual reporting<br>▪ Enable OGTR reporting and TGA reporting at all levels<br>▪ Enable Certified HREC to report to the NHMRC on number of reviews annually |

| Platform component | Current system issues | Future sector requirements |
|---|---|---|
| **Australian and New Zealand Clinical Trials Register** | ▪ Not widely used. Sponsors and researchers prefer to register on ClinicalTrials.gov (which provides a 'feed' of information to update ANZCTR)<br>▪ Data are not updated regularly, limiting its utility for researchers, sponsors, and community more broadly<br>▪ Not-fit-for-purpose to provide a national public facing website<br>▪ Multiple versions of the same trial on the site | ▪ Automated registration through approvals and ongoing monitoring and reporting processes<br>▪ Retain sovereignty of our national registry<br>▪ Ensure it meets the World Health Organization (WHO) compliance requirements<br>▪ Addresses proprietary concerns regarding registering new trials and entering information (roles and responsibilities of individuals for accurate data entry)<br>▪ Support linking to other registries (ClinicalTrials.gov) and removing the manual entry to minimise duplicate trial registration<br>▪ Inbuilt quality assurance functionality and, processes for checking (curation) of data accuracy (regarding next generation national research registry)<br>▪ Underpin a cutting-edge website for use by the community<br>▪ Provide a look up a database of trials for GPs<br>▪ Enable functionality to provide a catalogue of all research to enable the approvals to access the primary data source for a secondary research purpose (HaSanda)<br>▪ Decentralised technology and putting power in the hands of the user through smart apps<br>▪ Interconnectivity for example, when study closes, that information feeds into the registry<br>▪ Capacity to 'lodge your protocol' (or register in camera) as well as submit an HREA. This is to ensure the study conducted was the same as the study intended as provided in the protocol<br>▪ Capacity to provide summary results<br>▪ Link to publications DORA, ORCHID |
| **National Clinical Trials Front Door – Recruitment** | ▪ Recruitment is largely based on referral to a clinical trial by a specialist clinician referral<br>▪ No national system with look-up functionality for the community<br>▪ Ongoing barriers with connecting to community to health and medical research including clinical trials | **Initial**<br>▪ Platform enabled access to a searchable database, with filters, on clinical trial information in plain English<br>▪ Plain language(s) statements for all health-related human research<br>▪ Consent to be contacted registry<br>**Potential future additions**<br>▪ Platform enabled service directory that links to third party providers<br>▪ Online directory and matching capability, linking researchers, clinicians, and participants<br>▪ Need an ability for all the different providers to feed-in and support the plethora of health apps<br>▪ Volunteer participant data-base that links to the PBS and MBS<br>▪ Consent to contact database<br>▪ Database of rare diseases and treating clinicians<br>▪ AI enabled technology participant recruitment registry |

## Other additions and integrations

| Platform component | Future sector requirements |
|---|---|
| **Site feasibility assessment** | ▪ The future platform should enable the capture of standard site feasibility sponsor requirements in one place information requirements for sponsors. Information could be captured and stored by field, condition, patient group and population spread and site levels resources (for example, pharmacy, pathology, imaging, clinical space)<br>▪ Health services also need to know if the trial is worth running within their organisations prior to the HREC and SSA process being conducted. The national platform could also enable a pre-submission feasibility assessment |
| **Education and communication community (research, clinical and consumers)** | ▪ Provide a guide for researchers to ensure an application follows the correct process including bubble guidance, YouTube videos and process descriptions<br>▪ Increasing health literacy through delivering education for the community on what research is and the benefits of research for the community<br>▪ In-built system navigation guidance and resources |
| **Other considerations** | ▪ Suitable for a full range of clinical trial designs, including pilot trials, cluster randomisation, comparative effectiveness designs, adaptive designs, trials using e-consent, registry-randomised trials, trials using remote follow-up and projects that evaluate non-pharmacological interventions, including trials of devices, surgical procedures, diagnostic methods, process of care (including health service research), physical therapy and psychological therapy<br>▪ Centralised resources for consumers (point of contact and support for the community)<br>▪ Comply with the *Data Availability and Transparency Act 2022*<br>▪ Workflows to accommodate access to various data bases via the data custodians such as the AIHW<br>▪ Embed the workflow for Public Health Research Ethics Committees<br>▪ Epidemiology – links to the AIHW disease data<br>▪ Biobanking – look at the UK Biobanking model<br>▪ Enable links to Clinical quality registries<br>▪ Capacity to hold 'research data' (facilitate the ARDC – Hasanda project)<br>▪ Integration with other systems (for example, the tax system integrates with multiple other systems)<br>▪ Health services should enable the clinical research recruitment component within their eMR or patient flow systems (CITRIX). Focus eMR on accessibility – an easy first step (enables pre-screening and feasibility assessment)<br>▪ Link investment to research outcomes and link research outcomes to the translation of evidence into practice<br>▪ Opportunities to link to approvals within the education sector such as schools – social science research<br>▪ Complexity of the consent form impacts the Re-think the national PICF form – perhaps have a standard pamphlet on participating in research and then a two to four-page consent form on the research<br>▪ Sponsors agree to use the new national platform and the functionality it provides |

# Appendix 4: Frequently asked questions

### 1. What will be the benefit of the National One Stop Shop?

The proposal for the National One Stop Shop was co-designed with all jurisdictions and builds on key reforms and initiatives driven through the Clinical Trials Project Reference Group to strengthen Australia's clinical trials and research sector and make it easier for patients, researchers, sponsors, sites and all governments to participate in clinical trials and research and access cutting-edge treatments.

The National One Stop Shop would facilitate rapid and streamlined approvals and address long-standing challenges with duplication, delays and fragmentation that would be unlikely to be otherwise overcome. It would reduce investigator and sponsor administrative and navigation burden and expedite time to trial commencement.

### 2. What is the anticipated timeline for implementation of the One Stop Shop?

The Commission is finalising the consultation report including high-level requirements and recommendations for consideration by jurisdictions.

Following agreement, the platform will go through a tender process. Further work is required to finalise the data elements of agreed features and functionalities.

### 3. Will the National One Stop Shop be applicable to both public and private health service organisations and universities?

It was heard through the consultations that the National One Stop Shop should extend beyond the public and private hospital sector to incorporate the university, primary care and independent medical research sectors.

Stakeholders preferred a model for the national platform that is suitable for the full scale of health-related human research, from single-centre projects to multicentre, multinational randomised controlled clinical trials including:

- The full range of clinical trial designs; pilot studies; cluster randomisation, comparative effectiveness designs; adaptive designs; trials using e-consent; registry-randomised trials; trials using remote follow-up and projects that evaluate non-pharmacological interventions and trials of devices; surgical procedures; diagnostic methods and process of care (including health service research), physical therapy and psychological therapy
- The full range of observational study designs, including studies using de-identified administrative data either with or without linkage of multiple datasets.

### 4. What is the purpose of the Proof of Concept?

The Proof of Concept (POC) was developed based on the stakeholder requirements gathered through the first phase of consultations. The purpose of the POC is to:

- Demonstrate that it is technically possible to build the National One Stop Shop platform using a flexible ICT system architecture
- Demonstrate how pain points and limitations of current systems and workflows can be addressed through the national platform
- Demonstrate how an enhanced workflow can make business processes more efficient
- Demonstrate that it is possible to design an intuitive system that enables the research application review and process; facilitates transparency of the review and approval process through a visible and date stamped timeline; user dashboards; notification and communication capability; project management functionality and many other features.

The POC is not the final platform, it is a high-level interactive workflow with a subset of core functions for demonstration and further testing with the sector through the second phase of consultations.

### 5. How will the One Stop Shop integrate with the National Clinical Trials Governance Framework requirements?

An issue raised during the consultations was the need to facilitate reporting requirements of the National Clinical Trials Governance Framework (Governance Framework).

It is proposed that the National One Stop Shop would underpin the Governance Framework and the accreditation of health services for the conduct of clinical trials. The research functionality that includes operational and financial reporting would enable health services meet the requirements within the Governance Framework.

### 6. What governance arrangements are being considered for the National One Stop Shop?

Consultation participants expressed preferences for how the National One Stop Shop should be supported long-term. To achieve the desired outcomes, cross-jurisdictional governance arrangements with representation from all jurisdictional health departments, or their equivalent, and the Therapeutic Goods Administration, the Office of the Gene Technology Regulator, the National Health and Medical Research Council and the Australian Commission on Safety and Quality in Health Care, would be needed to harmonise the approvals processes nationally.

### 7. What are the benefits of microservices?

Microservices system architecture is a collection of small, independently deployable services that contain their own business logic and database with a specific goal. These services are not multiple monolithic systems which are integrated into a single platform.

Microservices offers several advantages over monolithic architecture:

- **Agility** – Promote agile ways of working with small teams that deploy frequently
- **Flexible scaling** – If a microservice reaches its load capacity, new instances of that service can rapidly be deployed to the accompanying cluster to help relieve pressure
- **Continuous deployment** – It offers more frequent and faster release cycles
- **Highly maintainable and testable** – Teams can experiment with new features and roll back if something doesn't work, making it easier to update code and accelerating time-to-market for new features
- **Technology flexibility** – Freedom to select fit-for-need technologies to program different services
- **High reliability** – Deploying changes for a specific service without the threat of bringing down the entire application.

### 8. What is the concept of triage? (pre-submission review)

One of the pain points raised through the consultations was the inefficient review processes: application go back and forth between applicants and reviewers due to a lack of preliminary review.

A triage process (or pre-submission review) could be introduced as part of the existing review process to reduce the number of reviews by an ethics committee. The goal of such a process is to allow the main ethics committee (either a national ethics committee or a main committee at the jurisdiction level) to make a preliminary review of a submitted application so that an ethics committee will further review only quality applications.

### 9. What happens if a study gets registered on a different public registry such as ClinicalTrials.gov?

The Commission is working closely with the Australian New Zealand Clinical Trials Registry to ensure all existing and business processes future business workflows are included into the National One Stop Shop. The future solution could integrate with existing clinical trials registries such as ClinicalTrials.gov, Australian Cancer Registry, Australian Clinical Trials Registry) for record linkage and updates.

Support linking to other registries (ClinicalTrials.gov) and removing the manual entry to minimise duplicate trial registration.

### 10. Is there a plan to create more alignment between ethics committees?

The Commission is undertaking a concurrent project on behalf of all jurisdictions via the Clinical Trials Project Reference Group to further strengthen standards for human research ethics committees (HRECs) and expand the National Mutual Acceptance (NMA) Scheme.

The accreditation of HRECs aims to enhance consistency and efficiency in human research ethical review and build reciprocal confidence in HRECs to support the expansion of the NMA Scheme. It is anticipated that a limited number of HRECs will be accredited across the public, private and, potentially in the future, university sectors nationally.

The Commission has established the Ethics Committee Advisory Group, chaired by Dr Conor Brophy, with membership comprising **eminent experts** in human research ethics processes and representatives from current NMA institutions and jurisdictions. A targeted and national consultation strategy has been developed to foster appropriate engagement of the research sector and consumers across Australia.

### 11. Will all project data from current systems be migrated to the National One Stop Shop?

Various options for data migration were discussed through the second phase of consultations. Some jurisdictions had negative experiences with data migration and would prefer not to repeat the process. Other jurisdictions believe that historical data must be migrated to the National One Stop Shop to ensure visibility over long-term continuing projects. Additional work is required to understand how historical data would be used in the National One Stop Shop.

The Australian New Zealand Clinical Trials Registry database will need to be migrated to the National One Stop Shop.

### 12. What kind of support will be available to users?

It was frequently heard through the consultations that ongoing support will be essential for the successful implementation of the National One Stop Shop including:

- A technical helpdesk made available to users
- Guidance for researchers to ensure an application follows the correct process including bubble guidance, YouTube videos and process descriptions
- In-built system navigation guidance and resources
- Education campaign for the community to increase health literacy on what research is and the benefits of research for the community.

### 13. Will a feasibility process be included in the National One Stop Shop?

The national One Stop Shop could enable a pre-submission feasibility assessment.

Health services would need to know if a trial is worth running within their organisations prior to ethics and SSA review process being conducted.

It was heard throughout the consultations that the National One Stop Shop should enable the capture of standard site feasibility requirements. Information could be captured and stored by field, condition, patient group and population spread and site levels resources.

### 14. How will the National Clinical Trials Front Door coordinate activities and effort and integrate with existing third-party recruitment providers?

Consultations have revealed strong support for a National Clinical Trials Front Door using information from the national research registry and other parts of the national platform, that acts as a central access point to facilitate connectivity: a point where consumers, clinicians and researchers can readily identify up-to-date information about trials of relevance to them, and about each other. A National Clinical Trials Front Door with this focus could provide a directory and link to third party recruitment (and other) providers and be valuable in navigating across the sector.

The National Clinical Trials Front Door would be an information sharing platform as opposed to a recruitment platform. Patient recruitment capability is core to the business models of many existing individual clinical trial research organisations and operators. Investment in a volunteer patient registry as a core part of the National Clinical Trials Front Door is seen by many as an unnecessary disruptor that could threaten established business models of multiple existing operators, without obvious or substantial improvement.

### 15. How will low and negligible risk research or non-interventional research (across multiple states) be managed?

It was heard throughout the consultations that a low and negligible risk pathway would be required. This workflow was demonstrated through the Proof of Concept. Similarly, approval pathways for adaptive trial designs could be enabled through the National One Stop Shop.

Comprehensive pre-screening questions and business logic could be programmed into the system to ensure applications can be assigned to the correct review pathway.

### 16. Could users have multiple roles within the system?

Users could be assigned multiple roles with the National One Stop Shop. There would be administrator functions to ensure roles are verified and ensure data are retained when people move on.

# Acronyms and abbreviations

| Acronym/ abbreviation | Definition |
|---|---|
| **ACT** | Australian Capital Territory |
| **AEMS** | Adverse event management system |
| **AHMAC** | Australian Health Ministers' Advisory Council |
| **AI** | Artificial intelligence |
| **ANZCTR** | Australian New Zealand Clinical Trial Registry |
| **API** | Application Programming Interface |
| **ARGT** | Australian Register of Therapeutic Goods |
| **CE** | Chief Executive |
| **Commission** | Australian Commission on Safety and Quality in Health Care |
| **CTA** | Clinical Trials Approvals |
| **CTAG** | Clinical Trials Action Group |
| **CTIS** | Clinical Trial Information System |
| **CTJWG** | Clinical Trials Jurisdictional Working Group |
| **CTN** | Clinical Trials Notification |
| **CTPRG** | Clinical Trials Project Reference Group |
| **Department** | Australian Government Department of Health and Aged Care |
| **DIR** | Dealings Involving the intentional Release |
| **DNIR** | Dealings Not Involving the intentional Release |

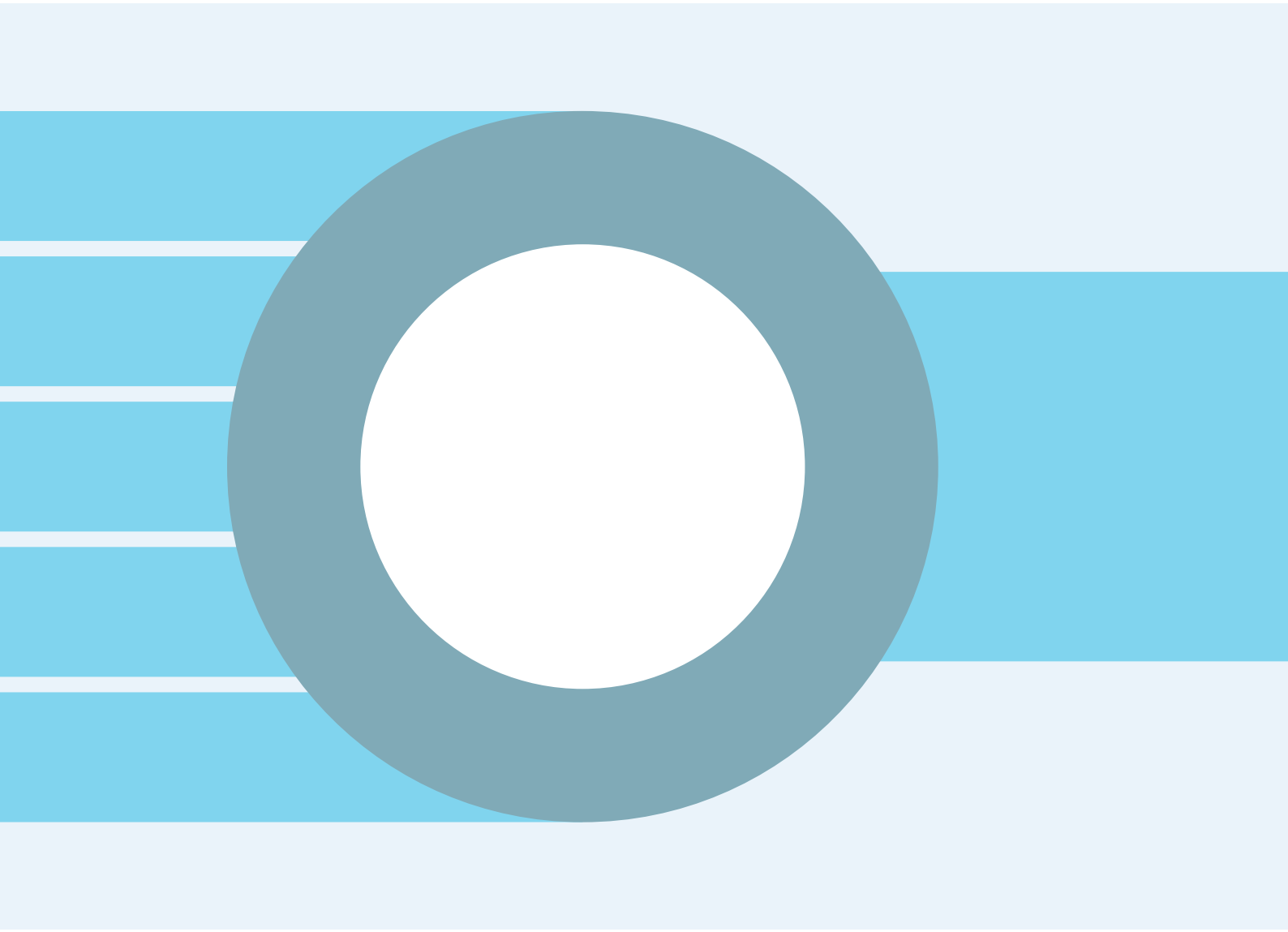
| Acronym/ abbreviation | Definition |
|---|---|
| **ERM** | Ethical Review Manager |
| **ESB** | Enterprise Service Bus |
| **ETL** | Extract, transform, load |
| **EU** | European Union |
| **GCP** | Good Clinical Practice |
| **GVA** | Gross Value Added |
| **HIPPA** | *American Health Insurance Portability and Accountability Act* |
| **HREA** | Human Research Ethics Application |
| **HREC** | Human Research Ethics Committee |
| **IBC** | Institutional Biosafety Committee |
| **ICT** | Information and Communication Technology |
| **ICTRP** | International Clinical Trials Registry Platform |
| **IRAS** | Integrated Research Application System |
| **ISO** | International Standards Organization |
| **KoNECT** | Korea National Enterprise for Clinical Trials |
| **KIIS** | KoNECT Integrated Clinical Trial Information System |
| **LNR** | Low or Negligible Risk |
| **MOU** | Memorandum of Understanding |

| Acronym/ abbreviation | Definition |
|---|---|
| MTP | Medical Technology, Biotechnology and Pharmaceutical |
| NHMRC | National Health and Medical Research Council |
| NMA | National Mutual Acceptance Scheme |
| NSW | New South Wales |
| NT | Northern Territory |
| OGTR | Office of the Gene Technology Regulator |
| PCI DSS | Payment Card Industry Data Security Standards |
| PHRN | Public Health Research Network |
| Qld | Queensland |
| REGIS | Research Ethics and Governance Information System |
| RGS | Research Governance Service |
| SA | South Australia |
| SME | Subject Matter Expert |
| SOA | Service-Oriented Architecture |
| SQL | Structured Query Language |
| SSA | Site-Specific Assessment |
| TGA | Therapeutic Goods Administration |
| UAT | User acceptance testing |
| UK | United Kingdom |
| WA | Western Australia |
| WHO | World Health Organization |
| WoG | Whole-of-government |

# List of addenda

Please see the separately attached documents:

- Addendum 1: ***National Systems Survey Report***
- Addendum 2a: ***National Site-Specific Assessment Survey Report***
- Addendum 2b: ***National Site-Specific Assessment Core Elements***
- Addendum 3: ***Community Perspectives Survey Report***.

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