AHRA
AUSTRALIAN HEALTH RESEARCH ALLIANCE

Australian Health Research Alliance

Clinical Research Acceleration Platform

Federal Budget Submission

2019

A game changer for Australia's future health and economic advancement

Foreward

As the current Strategy for Medical Research and Innovation states, “The Australian health system must be innovative and respond to future challenges, including new health technologies, communicable diseases, and caring for an ageing population with complex and chronic health problems. Research is the best way to prepare for these challenges. Research can contribute to health system safety and quality, ensure effectiveness of health interventions, and enable Australia to develop better methods of preventing and treating disease”.

With a declining Australian clinical research sector there is rising frustration and disadvantage for:

- the Australian community who deserve and expect improved access to cutting edge new treatments and optimal evidence based quality care
- our Health Professionals who need better and more accessible evidence to guide care and broader access for their patients to innovative new therapies
- our health services in need of better evidence on new treatments and on disinvestment in low value ineffective care
- our governments who seek to promote better health, jobs and wealth

Here the Australian Health Research Alliance (AHRA) as a national collaboration across all nine Health Service led, NHMRC accredited Translation Research Centres encompassing over 90% of funded researchers and 80% of acute health services, with significant jurisdictional, primacy care and private healthcare partnership and regional reach, proposes a solution. We present a compelling case and transformative approach for collective action to create a **National Clinical Research Acceleration Platform**. We seek to integrate all current clinical research activities, government and stakeholders efforts, with a co-designed national approach. We are, firmly focused on partnership with and delivery for the Australian community. This platform proposal is founded on the readily identified barriers and implementation of the recommendations emerging from the National Clinical Research Governance Framework.

We look forward to having the opportunity to work with government, the community and all stakeholders to address this important challenge and deliver health and wealth for Australians.

Co-leads on the AHRA Clinical Research Acceleration Platform on behalf of our national Translation Research Centres:

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A national strategy and implementation plan for a world-leading nationally coordinated clinical research acceleration platform

The need:

Australia's $1.1B annual clinical trial activity is declining with our small, geographically dispersed population, an expensive, fragmented and inefficient clinical research system, rising operational and administrative burden, and challenges around timeliness and capacity to recruit. International competition is now intense with commercial trials offering significant patient and economic benefits worldwide. We now lack competitiveness leaving Australians without access to the latest cutting edge treatments and associated health, jobs and economic benefits (attachment 1).

Despite our world class healthcare system and highly trained health professionals, only half of clinical decisions are evidence-based with rising quality and safety concerns. Investigator-led clinical trials, vital to health system improvement, quality and value-based healthcare face operational and administrative barriers and lack support with adverse health and economic impacts.

This proposal responds directly to calls from the Council of Australian Governments Health Council for clinical trial sector improvement for a nationally coordinated model to overcome fragmentation and inefficiencies. It is addresses gaps and recommendations from the recent National Clinical Research Governance Framework, including the critical need for investment, national coordination and embedding and supporting research within healthcare. It also captures international lessons on the vital role of national leadership, coordination and consistency and the adverse impact of isolated jurisdictional approaches (attachment 1).

It is widely recognised by health, academia, government and industry that we need to leverage jurisdictional efforts, create synergies and coordinate nationally to deliver transformational reform to be competitive in commercial trials, maximise benefit from investigator led trials and deliver for the Australian community (attachment 1 and 2).

The proposers:

The Australian Health Research Alliance (AHRA) is a national collaboration across all nine NHMRC accredited Translation Research Centre's: Monash Partners, Sydney Partnership for Health, Education, Research & Enterprise, Western Australian Health Translation Network, South Australian Translation Research Centre, Sydney Health Partners, NSW Regional Partners, Melbourne Academic Centre for Health, Central Australian Academic Health Science Centre and Brisbane Diamantina Health Partners. We include over 90% of funded researchers and 80% of acute health services nationally, with significant and growing jurisdictional, primacy care and private healthcare partnership (*attachment 2*).

Our **health service led** Translational Research Centre's are designed and funded by the Medical Research Future Fund **to deliver a health system fully informed by quality health and medical research**. Our partnerships between research organisations and healthcare integrate world-class research, clinical care and training to improve health for Australians. Geographical spread and national coordination through these Centre's and AHRA, provides a unique opportunity for rapid development of wide reaching health service led and community accountable research and translation initiatives.

This proposal has been co-developed with and is supported by the Australian Clinical Trial Alliance (ACTA) with a vision for better health through best evidence, for a self-improving healthcare system. ACTA represents the 10,000 clinical researchers within our Clinical Trial Networks (attachment 2). AHRA is ideally placed to engage stakeholders, establish governance, integrate with existing activities and together with ACTA and stakeholders, co-develop and implement a clinical research platform. AHRA will co-design and implement workforce capacity building and embed clinical research and evidence into healthcare. ACTA is ideally placed for a leadership role in platform co-design and will lead the prioritisation, design, initiation and conduct of new clinical trials, whilst both will work to generate and enable translation of evidence into improved healthcare.

The opportunity:

In Australia, industry trials generate $1.1B annually and support 7000 tertiary qualified jobs. Our clinical trial networks conducted over 1000 trials from 2004-14, with actionable evidence to improve health and health system and returns of $5.83 per dollar invested. Together AHRA and ACTA as peak bodies in research, bring leadership, expansive national reach and unique and complementary capabilities to deliver on opportunities. Integrating jurisdictional and Federal government efforts, building on international learnings and leveraging our reach, collaboration and healthcare and research leadership, we aim to develop and implement a nationally coordinated and integrated clinical research acceleration platform for Australians.

The pathway:

We propose a co-designed two stage approach to accelerating clinical research (Figure 1).

Figure 1: Proposed process for a nationally coordinated clinical research acceleration platform.

Proposed Process

Engage | Co-Design road-map | Coordinate and Integrate | Implement road-map |Evaluate | Sustain

Stage One: Leadership, governance, road map codesign and workforce development

1a) Establish national leadership, governance and coordination:
- engage of all stakeholders
- integrate existing clinical research activities at all levels of the system
- partner and align with Federal and State governments policies and activities
- establish of a national collaborative governance and coordination system

1b) Co-develop a road map for a nationally coordinated, integrated clinical research platform with agreed partnerships, roles, objectives and milestones

2) Co-design and implement a national research workforce capacity and research culture and quality building program supporting:
   - consumer and community
   - health professional and clinical research delivery workforce
   - policy makers, health service managers and organisations delivering clinical research.

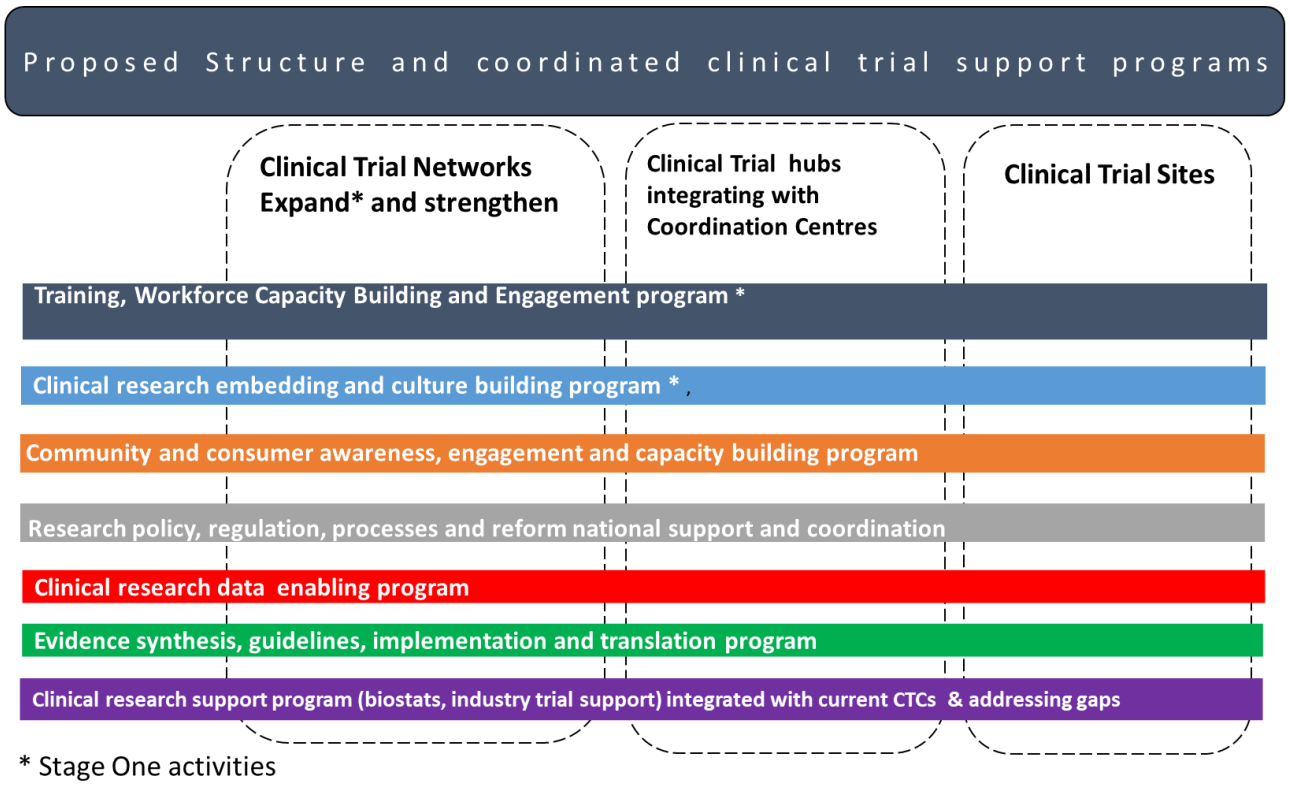
   This work will support and enable the work of the ACSQHA and research accreditation processes

3) Clinical Trial Network expansion to new prioritised networks through ACTA.

Stage Two: Implementing the road map and national coordinated clinical research platform. The proposed structure will be refined through co-design (figure 2). It includes;

- *Clinical Trial Networks* will be supported and strengthened
- *Clinical Trial Coordinating hubs* within Translation Research Centre's with core programs, supported and if needed expanded Clinical Trial Coordination Units
- *Clinical Research delivery sites* networked and supported in diverse health settings

Figure 2: Nationally Coordinated Clinical Research Acceleration Platform structure and programs.



* Stage One activities

Proposed core programs will support the ACSQHA, National Reforms and Jurisdictions by:

- embedding and sustaining stage one workforce and community capacity building
- embedding and sustaining a strong research culture
- driving consistent and efficient ethics, governance, quality and trial delivery processes with wide geographical and public and private and primary healthcare reach
- harnessing data and IT opportunities to optimise clinical research
- supporting ACTA and others in design, planning and innovation in clinical trials
- evidence synthesis, guideline, implementation of evidence and translation program

- providing simple and pilot investigator study and commercial trial support
- supporting specialised expertise in biostatistics, health economics and design
- monitoring activities and delivering progress against milestones
- co-designing and implementing strategies for co-funding and sustainability

Policy Alignment:

This proposal is founded on State and Federal government priorities and the National Clinical Trials Governance Framework developed under COAG Health Council, endorsed by all Health Ministers in 2017. It aligns with MTPConnect recommendations and the Australian Medical Research and Innovation Strategy.

It is founded on the principles of broad stakeholder engagement and co-design, is led by the health sector and encompasses the academic sectors, community, State and Federal government agencies, philanthropy and industry. It builds on prior substantive government efforts and addresses fragmentation and inefficiency. It leverages international learnings on the fundamental importance of national coordination and consistency and brings together peak bodies and all stakeholders to deliver innovation, transformation and impact.

Cost:

This two-stage proposal requires an overall national investment of $50M (table 1). Stage One investment is $9.8M (2019-2020) and Stage Two $40.2M (2021-2023) to implement, evaluate, refine and establish a sustainable national clinical research platform. A more detailed budget is provided in attachment 3.

Table 1: Budget overview

	2019 ($)	2020 ($)	2021 ($)	2022 ($)	2023 ($)
Component Detail - Stage 1	**4356773**	**5474755**			
Component Detail - Stage 2			**12632540**	**13686945**	**13848986**
Total Cost					**50000000**

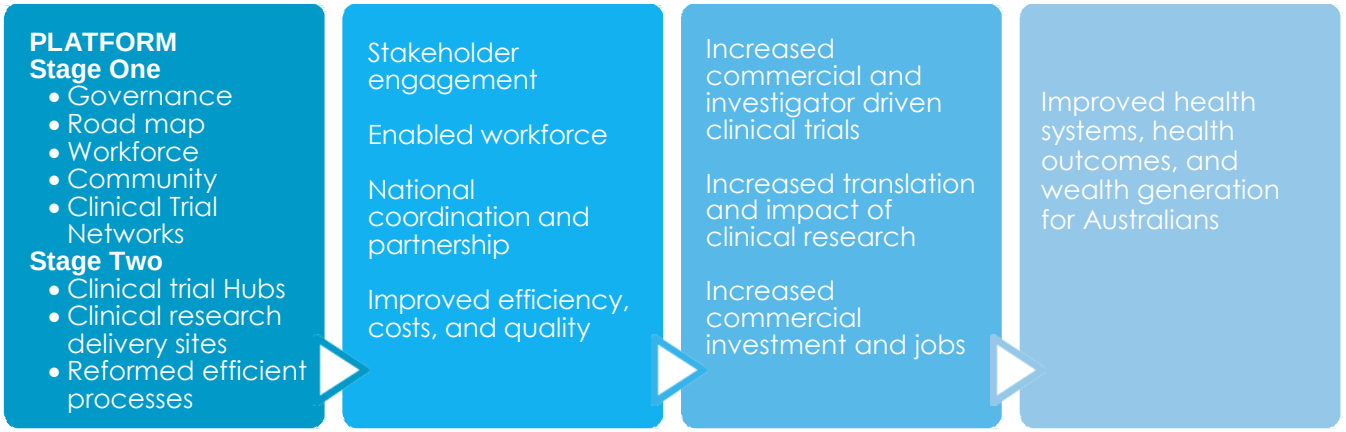
Impact:

Here we will address identified barriers and jointly deliver National Clinical Research Governance Framework, MTPConnect and other government and industry body recommendations to accelerate clinical research (attachment 1, fig 3). Specifically we will:

- Engage all relevant stakeholders, governments and community
- Integrate and streamline existing activities
- Deliver a national governance, leadership and coordination structure and processes
- Generate an engaged, skilled and supported workforce
- Deliver an accredited and capable health sector with an embedded research culture
- Engage and build capacity in our community with greater research partnership and participation
- Create new clinical trial networks (e.g Indigenous, mental health and primary care)
- Streamline and accelerate ethics and governance and generate efficiencies
- Increase clinical trial participation numbers and access across organisations and geography
- Increase investigator led trials to deliver evidence informed direct and tangible health benefit including through disinvestment, with a 5.8:1 return on investment
- Increase commercial trials and revenue over 5 years, creating 600 tertiary qualified jobs and generating $98M annually with a 9.6:1 return on investment

Ultimately we will improve health and wellbeing, providing access for Australian children, adolescents, families, adults and the elderly to the best cutting edge treatments, whilst delivering greater prosperity, jobs and wealth for Australia.

Figure 3: Logic Model for investment in a National Clinical Research Acceleration Platform



Attachment 1: Evidence supporting a coordinated national approach to clinical research

Australian reports and reviews into clinical trials and medical health research extracted from the National Clinical Research Framework literature review 2019

Organisation	Report title	Issues identified	Recommendations
MTP Connect 2017	*Clinical Trials in Australia: The economic profile and competitive advantage of the sector*	Lengthy and highly variable site-to-site and study-to-study governance approval processes which results in: – Variability in start-up times – Some sites being reluctant to take the lead role in a clinical trial and hence responsibility for providing ethics approval – Some sites not processing ethics reviews in parallel with governance applications resulting in lengthy trial start-ups. – Complex and variable clinical trial costing resulting in high per-patient costs, adversely affects Australia's outlook as a trial destination. Limited capabilities and tolerance for high risk or innovative trials leading to difficulties in establishing a sustainable competitive advantage Education and training and development of competency frameworks for research governance officers Patient recruitment Collaboration across clinical trials networks Metrics Supporting infrastructure and capability for clinical trials	Two priority areas identified for improvement: • Improve the attractiveness of Australia as a clinical trials destination – what activities are key to building a sustainable competitive edge in targeted areas? • Progress towards a national, single whole-of-sector system for ethics approval Improve recruitment through public education about the role and benefits of clinical trials. Educate clinicians about clinical trials in their area or field of expertise. Leverage the rollout and potential of electronic medical records. Link EMRs across districts and states making patient records available to trial sites looking to recruit. Establish sufficient capabilities and expert capacity in trials involving novel design types, components, translational medicine and proof of concepts Enhance transparency and visibility of the clinical trials sector How can the sector track activity and performance more consistently to accurately assess the state and improvements of initiatives over time and national clinical trial metric tracking? Achieve complete coverage and improved data quality in activity tracking. Options include expanding national reporting of statistics across jurisdictions, sponsor types and trial sites or alternatively, a general ethics mandate for all trials to register and update entries on ANZCTR. Challenges to be resolved in any implementation design are: the mandate for complete entries and incentives for updating should be the same throughout a trial, and data linkages and IT system differences between jurisdictions. Clinical trial coordination units and cross-jurisdictional working groups may have an important role to play in specialised data collection, linkage and analysis. Specific steps also needed to address instances where data gaps or lack of data fields are limiting the ability to describe or track trial activity for the rapidly growing medical device sector. Implement the systematic collection of key performance indicators and metrics measuring the level of benefits flowing to the sector. Priority metrics cover performance (trial activity, trial start-up time (including ethics and site approval), number of participants, actual vs targeted recruitment, recruitment timeline – time from first patient in to last patient treated Also, economic activity (expenditure – industry, non- industry/NHMRC funding). Employment (trial sponsors/ site/clinical). Potential future sources/data-collection methods include NAS via public and private HRECs and standardised approvals; ANZCTR – expanded HREC requirements for registration and improvements in data cleaning. NAS and extension to private sites.

Organisation	Report title	Issues identified	Recommendations
Australian Government, Department of Education and Training 2016	*2016 National Research Infrastructure Roadmap*	Regulatory environment – the fast tracking of clinical trials, medical device development and access to government data were identified as being hampered by the regulatory environment. Standards and accreditation – National research infrastructure facilities need to be encouraged to undertake accreditation or certification. This should be included as part of the planning and identified in annual business plans.	Improve efficiency of clinical trials Formal, national or international, accreditation and certification for facilities and services is critical to fostering greater engagement with industry and other end users of research. Certification and accreditation recognises the standard provided by the research infrastructure facility and demonstrates that the products or service meets specific standards. For some industries, such as health and medical research and development, certification is a legal or contractual requirement.
NHMRC 2015	*Clinical trials ready*	What would signal that Australia is clinical trials ready?	– Governance and ethics-approval procedures are efficient, reliable, timely and predictable, including: accepting single ethical review Internal and external communication is effective, accurate and responsive Standards and quality assurance/quality control processes are clearly defined Participant recruitment is effective, efficient and predictable Staffing levels are adequate, and staff have appropriate expertise, qualifications and experience IT systems and software are efficient and effective Site uses a standard set of template documents that are agreed between sites and sponsors Sites publish information on capability, performance and activity Research is seen as core business A demonstrable clinical trials track record (in both quantity and quality) Clinical trials costs and overheads are transparent and clearly stated.
Roche 2015	*Clinical Trials in Australia*	Inconsistent trial costs Fragmented and variable ethics and governance process Patient recruitment Fragmented IT systems and paperwork requirements – inefficient, inconsistent and manual, variability and incompatibility between states and sites	Establish a national clinical trials office – a statutory body with buy-in and involvement from health and industry portfolios at both state and federal levels Standardisation of templates, systems and processes, and governance officer job descriptions to ensure that ethics and governance approvals are fit for purpose and efficient Site accreditation to promote adherence to best practice and timelines National clinical trials portal to increase awareness among patients of the existence of clinical trials and provide the opportunity for earlier access to new treatments.

Organisation	Report title	Issues identified	Recommendations
NHMRC 2015	Report of a national consultation. *Clinical Trials Ready: An NHMRC concept to recognise clinical trial sites that are 'ready' 'willing and able' to conduct clinical trials*	The NHMRC had identified the need to: Streamline research ethics and governance approval Improve training and education of clinical trial proponents Increase recruitment into clinical trials An NHMRC initiative called 'clinical trials ready' was developed in response. The initiative involves the recognition of clinical trial sites, including public and private hospitals and other organisations that are 'ready, willing and able' to carry out high-quality clinical trials in a timely, transparent and efficient manner. The proposed potential benefits of the clinical trials ready initiative were: Improved awareness, transparency and clarity Less duplication of ethics and governance review processes More clinical trials would be attracted to Australia, due to faster approval processes, transparency in costs and timeframes and the high quality of the research. A consultation was subsequently held to obtain the views of stakeholders, which are summarised in this report.	The following is a summary of the responses: The majority of respondents considered the proposed Clinical Trials Ready initiative to be viable and likely to make clinical trial sites more attractive to potential sponsors Most respondents were in favour of there being no restriction on which type of clinical trial should be included The key desired characteristics of the initiative were identified as: efficient, reliable, timely and predictable governance/ethics- approval procedures; transparency of sites, costs and participant recruitment mechanisms; and that research needed to be seen as core business and embedded in the culture of the clinical trial site Recognition as a clinical trials ready site would follow a 2-phase assessment process and would last for a fixed period of time. Recognised sites would be required to report annually to the oversight committee and publish performance metrics There was strong support for a web-based, searchable registry of recognised sites. Similar, existing overseas schemes were cited e.g. UK Clinical Research Collaboration Registered Clinical Trials Unit Network (UK-CRC), and the US-based Alliance for Clinical Research Excellence and Safety (ACRES) Site Accreditation and Standards Initiative (SASI). The majority view was that the initiative should be a transparent process, managed by the NHMRC, with an expert oversight Several respondents also proposed that research be included as one of the National Safety and Quality Health Service (NSQHS) Standards General consensus that institutional support for the scheme would be essential for its success. Activities proposed as a means to demonstrate institutional support included: management support for clinical trials; education for institutional executives on clinical trial requirements; a dedicated research office/clinical trials unit; secure employment for site staff with proper classifications; funding of clinical trials initiatives; support from state/territory health departments; and a person/team at each site responsible for monitoring conformance to the Clinical Trials Ready criteria. Respondents agreed that the Clinical Trials Ready initiative should be monitored to determine its effect on clinical trials start- up costs and times, to ensure an appropriate return on investment. body to advise on the development, training and quality standards improvement.
Australian Government Department of Health 2015	*Analysis of recently conducted clinical trials – final report*	Costs of conducting clinical trials in Australia and lack of standardised clinical trial costs Patient recruitment Lengthy ethics and governance approval processes – no national system of ethics and governance processes Poor research infrastructure and accountability	National system of ethics and governance processes Standardised format and templates Parallel ethics and governance process Standardised trial costs

Organisation	Report title	Issues identified	Recommendations
Health Consult for NHMRC 2014	*National consultation on a good practice process for the governance authorisation of clinical trials*	Need for improved efficiency in ethics and governance processes Inter-jurisdictional variation in standards, protocols and requirements regarding governance Identification of legislative barriers to full implementation of National Mutual Acceptance scheme. Clarification and agreement on the roles and activities for individuals and entities involved in Need to improve the understanding of why clinical trial research is important – to workforce, patients, health system Need a skilled competent and sustainable research management workforce to support a timely, efficient and high-quality process. Lack of funding for research governance officers leading to under-resourcing Public hospital revenue stream from clinical trials to fund RGO positions has been decreasing as the number of trials has decreased. Public hospital budget for research infrastructure eroded due to budgetary constraints, clinical trial planning and preparation process.	National ethics and governance processes but with enough flexibility to accommodate the specific nature of some trials (e.g. low-risk non-drug trials; high risk paediatric studies) Nationally agreed or standard frameworks, systems, training, education, documentation Ethics and governance processed concurrently National accreditation scheme for sites to be accredited as 'research mature' and able to perform clinical trials Communication plan/map – who communicates what and when? Plus timeframes and/or benchmarks for key steps in the site- governance process. Build a research culture in the healthcare sector by behavioural and organisational change – 'Research is core business'.
Australian Clinical Trials Alliance 2014	*Report on the 2014 National Summit of Investigator-Initiated Clinical Trials Networks*	Landscape of clinical trials in Australia Clinical trials and the health system Key role and potential of investigator networks and public-good trials Supporting a highly skilled clinical trials workforce Strategies for increasing our capacity to Incorporate trials within clinical quality registries Link networks to conduct more cross-discipline trials	Make research outputs a key performance indicator for hospitals Improve the quality of routinely collected data and facilitate linkages to research databases Expand risk-adjusted clinical registries to collect outcomes data across a broad range of high-cost, high-significance areas of medicine Advance local expertise in trial methodology Liaise with the Independent Hospital Pricing Authority to develop an appropriate costing framework for investigator-initiated clinical trials Develop models of partnership with international investigators and funding agencies to conduct large-scale pragmatic trials

Organisation	Report title	Issues identified	Recommendations
Australian Government, Department of Health and Ageing 2013	*Strategic Review of Health and Medical Research* (The McKeon Review)	Research generally undervalued and poorly managed in the hospital system Resources provided to hospitals predominantly focus on immediate consumer needs Research viewed as an added cost Funding originally earmarked for research in hospitals typically used to cross-subsidise other services Sector leadership and governance is required to direct, focus, oversee and coordinate activity, drive the strategic HMR vision Lack of evaluation of research performance and outcomes within research institutions and LHNs Greater integration and embedding of research in the health system is required Decline in Australia's international clinical trial competitiveness due to: – Increasing costs due to the rising relative value of the Australian dollar – Rapid increase in clinical trial capacity of low-cost countries – Complex, time-consuming and costly approvals processes for ethics and governance review – Lack of standardised costs for clinical trial activities across Australia – Lack of access to appropriate clinical trial support infrastructure – Difficulty in recruiting participants driven by limited access to patients by healthcare providers and lack of national patient-data infrastructure to identify participants. Non-commercial trials are underfunded despite their significant potential benefits Coordinate and share resources and expertise between clinical trials networks (e.g. outcome measurements, data safety monitoring boards, education for researchers) Abolish the need to gain approval from multiple ethics and governance committees	Embed research in the health system and drive research activity Establish sector leadership and governance Manage and refocus LHN research, implement key performance indicators (KPIs) and monitor performance. Accreditation and funding of hospitals and LHN research should be determined in part on an acceptable level of participation in clinical research, as an integral part of high-quality healthcare delivery. This should require hospitals and LHNs to report on a range of research KPIs in annual reports, including research budget and actual spending, number of staff active in research, number of clinical trials undertaken, number of consumers recruited to trials and outputs from clinical research, including outcomes for patient care. Facilitate research activity undertaken by health professionals by dedicated research time alongside other health services duties Introduce a set of competitive practitioner fellowships that provide protected time (50% of work time) for the most promising health professional researchers Provide health professionals with the opportunity to be trained and participate in research should they wish Establish integrated health research Centres, Build health professional research capacity Enhance public health research and health services research Support non-commercial clinical trials Inform policy with evidence The current level of expenditure on teaching, training and research (TTR) be understood and tracked in terms of an accounting-based system of separate reporting of each TTR item (i) so that the research component can be clearly identified and benchmarked against healthcare outcomes in individual LHNs Accompanying this, the panel recommends a 10-year goal of 3%–4% of government expenditure on health research and development be adopted Establish and resource a leadership body to facilitate translation of research into evidence-based healthcare and policy; provide policy advice and drive sector reforms; track and monitor HMR investment and outcomes; and work with key organisations charged with delivering better health services. Establish and encourage research organisations to evaluate performance and research outcomes of investment. Performance to be evaluated across a mix of knowledge-based outputs, research inputs, and commercial, clinical and public health outcomes. Establish funded integrated health research centres (IHRCs) to integrate research excellence with healthcare service delivery and facilitate best-practice translation of researchy into healthcare delivery. Reform clinical trials processes to address major constraints of approval times, infrastructure, lack of uniform costing, funding and patient access. Accelerate clinical trial reforms: – Build on CTAG Report recommendations – Develop an online approval workflow system for trials – Enhance the consumer recruitment portal – Establish 8–10 national ethics committees – Establish a national clinical trials liability insurance scheme Drive a national approach to implementation of clinical trials reforms through the establishment of a national clinical trials office within the HMR leadership body

		to conduct multi-centre trials Standardise common trial documentation Move to a regulatory framework that is proportionate to the additional risk for people participating in public-good clinical trials Develop an appropriate model of consent for comparative effectiveness studies when these involve widely used and approved therapies	Provide Develop models of partnership with industry to both conduct clinical trials and improve the competitive environment for conducting trials in Australia Increase public awareness of the purpose and importance of clinical trials and increase public support through major educational campaigns Conduct 'research on research' to demonstrate and understand what it is we do currently and how it can be done better, and how it affects healthcare outcomes Develop effective models of consumer engagement in clinical trials Advocate widely for the health and economic benefits of clinical trials and clinical quality registries to support a self-improving health system.additional funding of $50–$100m p.a. for non-commercial clinical trials
Biotext 2012	*Review of the literature on participation in clinical trials: barriers and incentives for healthcare practitioners and consumers.*	Patient recruitment is one of the biggest barriers to clinical trials Reasons for patients not participating in clinical trials include a lack of knowledge about clinical trials, practical barriers such as time constraints, costs, transport access Health professionals cited strict clinical trial inclusion and exclusion criteria.	Improve awareness of clinical trials by providing information and avenues for access, for example websites.
Medicines Australia 2011	*Keeping Clinical Trials in Australia: Why Action is Needed Now*	Clinical trials in Australia has been declining by an average of 13% per year. The aims of this paper were to: explain how clinical trials work; why trials are declining in Australia; why to reverse this trend, and strategies to restore Australia's international reputation for clinical trials. Weaknesses were identified including: small and geographically dispersed population; comparatively higher costs, inefficiencies in approval processes, increasing competition from emerging markets such as Eastern Europe, India and China due to cost advantages, skilled labour, larger populations and increasingly sophisticated healthcare systems to produce quality trial data.	For all political parties to work constructively and collaboratively to ensure that the recommendations arising from the 2011 Clinical Trials Action Group Report are implemented as a matter of priority. The recommendations include: – Improving the timeliness of ethics and governance review – Providing for cost recovery of efficient clinical trials – Ensuring clinical trials can take advantage of the developing e- health system – Improving patient recruitment – Facilitating better national coordination and greater collaboration across trial networks Improving reporting and monitoring of the value and performance of clinical trials and reviewing the progress and effects of implementing the recommendations.

Organisation	Report title	Issues identified	Recommendations
Clinical Trials Action Group 2011	*Clinically competitive: Boosting the business of clinical trials in Australia.*	Timeliness of ethics and research governance clinical trial approvals Benefits of e-health for clinical trials Improving patient recruitment Level of support for clinical trials networks	Single ethical review for multi-centre human health and medical research and: Adoption of in-common policies, procedures and forms Introduce policy on clinical trials to ensure efficiency through national consistency of processes adequate support structures for conducting clinical trials and provides an incentive to reach a 30-day calendar timeframe for both ethics and governance review, which sponsors would pay a defined additional amount efficiency supports a 60-day maximum timeframe for governance and ethics review The compliance with which would be a condition of certification of ethical review processes under HoMER initiative Allows concurrent review of the ethics and governance components of a clinical trial Allows a 'stop clock' during efficient ethics and research governance review when additional input is required before consideration can continue Monitor progress of these initiatives through jurisdictions publicly reporting annual data on a timeliness of ethics and governance review – types and numbers of clinical trials in a consistent format Include clinical trials activity and timeliness of approvals for clinical trials as a key performance indicator (KPI) when jurisdictions negotiate new agreements with public hospital CEOs A table of standard costs associated with conducting clinical trials be developed for all trial sponsors in alignment with Australian Government health reform initiatives as they are introduced. The table should include a reasonable additional payment to support the 30-day timeframe for efficient ethics and governance review. Introduce policy and/or systems that allow access (both on- site and remote) by clinical trial monitors and auditors to the electronic health records of clinical trial participants Request NEHTA and state and territory governments maketo support increased the clinical research system a key consideration when designing, developing and implementing e-health standards, specifications, strategies, frameworks, systems and programs The NHMRC develop a consumer-friendly web portal that includes information on current clinical trials in Australia The NHMRC and Department of Innovation, Industry, Science and Research (DIISR) investigate the feasibility of creating a comprehensive and searchable web portal similar to the US- based clinicaltrials.gov that would include patient recruitment, monitoring trial outcomes, registration and reporting of trial activity and to: Identify the clinical trial networks in Australia Facilitate national coordination and encourage collaboration across academia, clinical medicine and industry Measure performance of clinical trials Report patient data for epidemiological and clinical trial feasibility studies Hospital performance data around clinical trials would include (e.g. timeliness, costs of trials, participation rates, comparisons with overseas counterparts, phases of trials covered, number of patients per trial, number of employees involved in trials and their field of expertise, and the clinics engaged in clinical trials and their area of expertise). Hospital KPIs related to clinical trials activity and timeliness could be introduced to ensure that clinical research is a priority in the healthcare system and is supported. Once KPIs have been established in the public system, these indicators will set the accepted performance benchmarks for Australia that will influence placement of trials in the university and private hospital sectors

Attachment 2: Overarching stakeholders and partners: a Clinical Research Acceleration Platform

Attachment 3: Proposed Budget

Component Detail -	Stage 1		Component Detail - Stage 1		Component Detail - Stage 2		
			2019 ($)	2020 ($)	2021 ($)	2022 ($)	2023 ($)
1a) AHRA National leadership, governance and coordination Centre 1b) Co-develop road map for a nationally coordinated, integrated clinical research platform with agreed partnerships, roles, objectives and milestones	Activities: engage of all stakeholders integrate existing clinical research activities at all levels of the system partner and align with Federal and State governments policies and activities establish of a national collaborative governance and coordination system	*Clinical Academic Director*	210000	216300	222789	229473	236357
		National Manager based at Monash	168000	173040	178231	183578	189085
		National governance, quality and audit coordinator	132000	135960	140039	144240	148567
		Admin Officer	80600	83018	85509	88074	90716
		Communications officer	96000	98880	101846	104902	108049
		National coordinating Office expenses, consumable and travel	50000	50000	50000	50000	50000
		National Launch Event and co-design symposium, annual meetings	25000	15000	15000	15000	15000
		Graphic design, Banding, Website, IT and resources	25000	5000	5000	5000	5000
		Monash and Sphere - Government and Industry Liaison Officers	172800	177984	183324	188823	194488
		Translation research centre - Network coordinating team	1080000	1112400			
		Office expenses, consumable and travel/accommodation in the hubs	157373	157373			
2) Co-design and implement a national research workforce capacity and research culture and quality building program	*1-Consumer and community* *2-Health professional and research delivery workforce* *3- Policy makers, health service managers delivering clinical research*	*Community Engagement Team*	540000	556200			
		National workforce and community Online training Platform		225000			
		Workforce development team	1080000	1112400			
		Health service accreditation support, research culture building team	540000	556200			
3)CTN expansion- new networks via ACTA	Prioritise and support new clinical trial networks			800000	800000	800000	800000
Component Detail -	**Stage 2**						
Clinical Trial Networks; support/ strengthened	Continued ACTA support					1000000	1000000
Clinical Trial Coordinating hubs within Translation Research Centres		*Translation research centre - Network coordinating team*			1145772	1180145	1215550
		Office expenses, consumable and travel/accommodation in hubs			157373	157373	157376
		Community Engagement Team			572886	590073	607775
		Workforce development team			1145772	1180145	1215550
		National Promotion and Marketing Campaign			200000	200000	100000
		Clinical trial support hub experts [Biostatistics, Design, Health Eco]			2016000	2076480	2138774
		Embedding, evidence synthesis, guideline and implementation team			1680000	1730400	1782312
		Data Coordinator Team			1008000	1038240	1069387
		Research data management system			400000	200000	200000
		National workforce and community Online training Platform			225000	225000	225000
		Artificial Intelligence and clinical trial management system/Software			300000	300000	300000
Clinical Research delivery sites	In diverse healthcare settings networked and coordinated	*Site based coordinators*			2000000	2000000	2000000
			4356773	5474755	8850803	9877856	10011723
	Total Budget						50,000,000