# Encouraging More Clinical Trials in Australia NATIONAL PARTNERSHIP FOR STREAMLINED AGREEMENTS

Formalities and	d operation of schedule
Parties	Commonwealth
	New South Wales
	Victoria
	Queensland
	Western Australia
	South Australia
	Tasmania
	Australian Capital Territory
	Northern Territory
Effect on other agreements	The Project Agreement on Encouraging More Clinical Trials in Australia that commenced on 13 March 2018 is replaced by this Agreement and Schedule. This Schedule is expected to expire on 20 June 2021.
Purpose	This Schedule will encourage more clinical trials in Australia by supporting:
	<ul> <li>(a) the redesign of clinical trials systems, with a focus on the establishment of central coordination units to better organise clinical trials sites, streamline clinical trials processes and make it easier to conduct and participate in safe, high quality clinical trials; and new networks and partnerships;</li> </ul>
	(b) new and enhanced clinical trial data collection and reporting;
	(c) improvements to core hospital governance arrangements; and
	(d) a consistent and cohesive national approach to the conduct of clinical trials in accordance with the Principles and agreed Priority Action Areas and the Revitalised Clinical Trials Agenda as endorsed by the Council of Australian Governments Health Council in March 2017.

Estimated
financial
contributions

The Commonwealth will provide an estimated total financial contribution to the States of \$1,500,000 in respect of this Schedule, noting this does not include payments made prior to 1 July 2020 under the previous agreement.

Table 1 (\$ million)	2020-21	Total
Estimated total budget	1.5	1.5
Less estimated National Partnership Payments	1.5	1.5
- New South Wales	0.30	0.30
- Victoria	0.214	0.214
- Queensland	0.257	0.257
- Western Australia	0.214	0.214
- South Australia	0.145	0.145
- Tasmania	0.072	0.072
- Australian Capital Territory	0.153	0.153
- Northern Territory	0.145	0.145
Balance of non-Commonwealth contributions <sup>(a)</sup>	0.0	0.0

<sup>(</sup>a) States are not required to provide financial and in-kind contributions under the terms of this Agreement. However, as States are responsible for the provision of public hospital services, they allocate their own source funding and provide in-kind contributions accordingly, including in support of activities funded

# Additional terms

The Commonwealth and the states have agreed project plans that set out each party's strategy for delivering on the outputs of the agreement.

Output	Performance milestones	Report due	Payment	
	2020-21			
Establishing new and enhanced central coordination units or equivalent in accordance with the Council of Australian Governments Health Council Revitalised Clinical Trials Agenda.	Continue to implement three AHRTC CTCSPs and deliver consolidated priority expertise and/or programs as identified in CTCSP Activity Plans and NSW Progress Report, and agreed with the Commonwealth.  Complete formal analysis of trial activity compared to baseline (to be provided in 17-18 performance report and agreed with the Commonwealth) to demonstrate the impact of CTCSPs and support the business case for ongoing delivery as an effective and sustainable model  Complete formal analysis of number of trials and trial sites with access to prioritised expertise and support services compared to baseline (to be provided in 17-18 performance report and agreed with the Commonwealth) to demonstrate the impact of CTCSPs and support the business case for ongoing delivery as an effective and sustainable model	15 May 2021	W Progress Report, and  ne (to be provided in 17-18 of demonstrate the impact of so an effective and sustainable  with access to prioritised provided in 17-18 performance the impact of CTCSPs and the and sustainable model  tatistics (NAS) 2020-21, as	\$300,020
Implementing new and enhanced clinical trial data collection and reporting to inform systems improvement with interoperability and data flow capability, and contribute to better sector knowledge, recruitment and overall sector performance, including through continued implementation and expansion of metrics and ongoing submission of data to the national data collection under the Framework for National Aggregate Statistics (NAS).	Contribution of data to the expanded National Aggregate Statistics (NAS) 2020-21, as agreed by the Clinical Trials Project Reference Group (CTPRG).			
Establishing and maintaining new networks and partnerships within and between jurisdictions, clinical trial networks, communities of practice (eg. oncology, working with ATSI groups) and registries.	Continue to implement a shared clinical trial platform across the three AHRTCs, and complete overarching activities across AHRTCs that demonstrate improvement in clinical trial finance management, awareness and acceptance, availability and sharing of quality systems, as identified in CTCSP Activity Plans and NSW Progress Report, and agreed with the Commonwealth.			

	Complete analysis of increased interaction, collaboration and sharing of best practice and expertise across the Office for Health and Medical Research and the three AHRTCs compared to baseline (to be provided in 17-18 performance report) to demonstrate impact.
Embedding research and clinical trials processes into core hospital governance arrangements.	Active engagement with CTPRG, Commonwealth and Australian Commission on Safety and Quality in Health Care (ACSQHC) to implement the national Clinical Trials Governance Framework.

This schedule was agreed by the Commonwealth and New South Wales when the overarching National Partnership was signed.

#### **NSW Project Plan summary**

New South Wales will seed fund the New South Wales Australian Health Research Translation Centres (AHRTCs) to:

- (a) develop Clinical Trial Coordination and Support Platforms (CTCSPs) aligned with the Sydney Health Partners, the Sydney Partnership for Health, Education, Research and Enterprise (SPHERE) and NSW Regional Health Partners, and including metropolitan Local Health Districts (NHDs) and Specialty Health Networks (SHN);
- (b) provide facilitation services, via the CTCSPs, for sponsors, investigators, referrers, administrators and participants accessing and navigating trials;
- (c) provide an overarching framework for research governance;
- (d) partner with investigators and their teams to ensure timely and efficient activation and execution of trials;
- (e) develop shared infrastructure; and
- (f) drive complementary improvement initiatives via LHDs in the areas of clinical trials start-up; costings; clinical trials management; and quality management to deliver specialist advice and support in key areas such as trial feasibility, financial and contractual arrangements, recruitment strategies and performance monitoring.

Table 2B: Victoria — Perform	Table 2B: Victoria – Performance requirements, reporting and payment summary				
Output	Performance milestones	Report due	Payment		
	2020-21				
Establishing new and enhanced central coordination units or equivalent in accordance with the Council of Australian Governments Health Council Revitalised Clinical Trials Agenda.	Delivery of report on professional evaluation of the pilot studies, including proposed refinements to the model and planning for ongoing implementation.	15 May 2021	\$214,300		
Implementing new and enhanced clinical trial data collection and reporting to inform systems improvement with interoperability and data flow capability, and contribute to better sector knowledge, recruitment and overall sector performance, including through continued implementation and expansion of metrics and ongoing submission of data to the national data collection under the Framework for National Aggregate Statistics (NAS).	Full contribution of data to the expanded National Aggregate Statistics (NAS) 2020-21, as agreed by the Clinical Trials Project Reference Group (CTPRG)				
Establishing and maintaining new networks and partnerships within and between jurisdictions, clinical trial networks, communities of practice (eg. oncology, working with ATSI groups) and registries.	Active engagement of regional buddies in planning for ongoing implementation.				
Embedding research and clinical trials processes into core hospital governance arrangements.	Active engagement with CTPRG, Commonwealth and the Australian Commission on Safety and Quality in Health Care (ACSQHC) to implement the national Clinical Trials Governance Framework.				

This schedule was agreed by the Commonwealth and Victoria when the overarching National Partnership was signed.

#### **Victoria Project Plan summary**

Victoria will expand the functions of its state-wide Coordinating Office for Clinical Trial Research (Coordinating Office (DHHS) that will:

- (a) provide a centralised 'front door' for trial sites and clinical trial units in 11 leading teaching hospitals and provide information and referral;
- (b) work with a professional consulting service to develop a 'model' for central clinical trial units at the hospital level to serve as primary points of contact and centres of excellence in trial conduct, planning and support;
- (c) establish a buddy system to partner primary points of contact with secondary hospitals in regional settings to ensure full geographic coverage, working collaboratively with the Department of Health and Human Services clinical and other networks, Safer Care Victoria, Monash Partners and Melbourne Partners;
- (d) test two pilot sites and undertake a consultation process to inform final model development and a strategy for implementation and full state-wide establishment once additional funding sources become available; and
- (e) continue to enhance and expand clinical trials data capture and reporting capability at the central point of contact and state-wide levels, which will support continued participation in national data improvement efforts.

Table 2C: Queensland – Pe	Table 2C: Queensland – Performance requirements, reporting and payment summary			
Output	Performance milestones	Report due	Payment	
	2020-21			
Establishing new and enhanced central coordination units or equivalent in accordance with the Council of Australian Governments Health Council Revitalised Clinical Trials Agenda.	Completion of formal analysis of clinical trial activity compared to baseline (to be provided in 2017-18 performance report and agreed with the Commonwealth) to demonstrate the impact of the QCTCU on reducing the administrative load on trial sites and approval timeframes, to support the business case for, and delivery of, the QCTCU as an effective and sustainable model.  Completion of forward planning based on outcomes of analysis and business case.	30 April 2021	\$257,160	
Implementing new and enhanced clinical trial data collection and reporting to inform systems improvement with interoperability and data flow capability, and contribute to better sector knowledge, recruitment and overall sector performance, including through continued implementation and expansion of metrics and ongoing submission of data to the national data collection under the Framework for National Aggregate Statistics (NAS).	Full contribution of data to the expanded National Aggregate Statistics (NAS) 2020-21, as agreed by the Clinical Trials Project Reference Group (CTPRG).			
Establishing and maintaining new networks and partnerships within and between jurisdictions, clinical trial networks, communities of practice (eg. oncology, working with ATSI groups) and registries.	Ongoing delivery of tele-trials model.			
Embedding research and clinical trials processes into core hospital governance arrangements.	Active engagement with CTPRG, Commonwealth and Australian Commission on Safety and Quality in Health Care (ACSQHC) to implement the national Clinical Trials Governance Framework.			

This schedule was agreed by the Commonwealth and Queensland when the overarching National Partnership was signed.

#### **Queensland Project Plan summary**

Queensland will establish a state-wide Queensland Clinical Trials Coordination Unit (the QCTCU) that will:

- (a) act as a central point of contact for sponsors, investigators, referrers and patients;
- (b) include liaison points within Queensland Academic Health Translation Centres to develop networked clinical trial hubs across multiple Hospital and Health Services (HSS);
- (c) include a Clinical Trial Capability Project to measure Queensland's baseline clinical trials capability, including identification of under-represented clinical areas and current public-private partnerships, and achievements and improvements as a result of introducing new clinical trials models in Queensland;
- (d) deliver a Clinical Research Coordinator Workforce Strategy;
- (e) support the application of common, streamlined clinical trial processes;
- (f) facilitate a coordinated and networked approach that also maximises clinical trials resource utilisation and participation; and
- (g) implement a tele-trials model with satellite regional sites across Queensland, New South Wales and the Northern Territory to improve regional patient access to trials, with an initial focus on oncology.

Table 2D: Western Australia – Performance requirements, reporting and payment summary			
Output	Performance milestones	Report due	Payment
	2020-21		
Establishing new and enhanced central coordination units or equivalent in accordance with the Council of Australian Governments Health Council Revitalised Clinical Trials Agenda.	Delivery of final reports on effectiveness and sustainability of Clinical Trials and Data Management Centre (CTDMC) model, including CTDSM and CTLO roles as part of business case to substantiate continuation.  Agreements finalised by HSPs on continuation of CTLO roles.	30 April 2021	\$214,300
Implementing new and enhanced clinical trial data collection and reporting to inform systems improvement with interoperability and data flow capability, and contribute to better sector knowledge, recruitment and overall sector performance, including through continued implementation and expansion of metrics and ongoing submission of data to the national data collection under the Framework for National Aggregate Statistics (NAS).	Full contribution of data to the expanded National Aggregate Statistics (NAS) 2020-21, as agreed by the Clinical Trials Project Reference Group (CTPRG).  Delivery of public searching capability for clinical trials in WA.		
Embedding research and clinical trials processes into core hospital governance arrangements.	Active engagement with CTPRG, Commonwealth and Australian Commission on Safety and Quality in Health Care (ACSQHC) to implement the Clinical Trials Governance Framework.		

This schedule was agreed by the Commonwealth and Western Australia when the overarching National Partnership was signed.

#### Western Australia Project Plan summary

Western Australia will enhance its state-wide Clinical Trials and Data Management Centre (CTDMC) that will:

- (a) act as a central contact point and node for the conduct of national and international clinical trials, and provide new clinical trials patient data systems capability;
- (b) establish Clinical Trial Liaison Officers (CTLOs) within each of the four metropolitan public Health Service Providers (HSPs) to:
  - i. provide expert guidance and centralise support to individual hospitals to streamline processes;
  - ii. guide financial and contractual management and patient recruitment; and
  - iii. support the efficient conduct, monitoring and reporting of trials; and
  - iv. identify linkages across Health Service Providers and liaise with the state-wide CTDMC; and
  - v. expand functionality of the Western Australian Research Governance Service that will facilitate first-time participation in national streamlining and data collection and reporting efforts.

Table 2E: South Australia – Performance requirements, reporting and payment summary				
Output	Performance milestones	Report due	Payment	
	2020-21			
Establish new and enhanced central coordination unit in accordance with clause 8(a) of the Agreement.	Completion of monitoring and evaluation activities to identify effectiveness of, and revisions to, the CTCU.	30 April 2021	\$144,653	
Implement new and enhanced clinical trial data collection and reporting in	Full contribution of data to the expanded National Aggregate Statistics (NAS) 2020-21, as agreed by the Clinical Trials Project Reference Group (CTPRG).			
accordance with clause 8(b) of the Agreement.	Delivery of monitoring and evaluation activities to identify user and stakeholder satisfaction with the new IT system			
	Establishment of the new system by all SA Human Research Ethics Committees (HRECs) and Research Governance Offices (RGOs) at all identified sites.			
	Delivery and distribution of approved and standardised clinical trial collection and reporting tools for the new system.			
	Delivery of monitoring and evaluation activities to identify user and stakeholder satisfaction with the new IT system.			
Establish and maintain new networks and partnerships in accordance with clause 8(c) of the Agreement.	Delivery of monitoring and evaluation activities to identify continued implementation of the Research Focus Implementation Plan.			
Embed research and clinical trials processes in accordance with clause 8(d) of the Agreement.	Active engagement with CTPRG, Commonwealth and Australian Commission on Safety and Quality in Health Care (ACSQHC) to implement the national Clinical Trials Governance Framework.			

This schedule was updated by agreement between the Commonwealth and South Australia in March 2020.

## **South Australia Project Plan summary**

South Australia will establish a state-wide Clinical Trials Coordination Unit (the CTCU) that will:

- (a) serve as a central point of contact for sponsors, researchers, coordinators and participants;
- (b) provide specialised support and advice services in key areas to improve efficiencies across sites;
- (c) develop a central web portal of key clinical trials information and activities in South Australia;
- (d) implement a new research ethics and governance management system, with enhanced data collection and reporting capability that will support expanded metrics collection and ongoing participation in national improvement efforts; and
- (e) work with key stakeholders including the South Australian Health and Medical Research Institute, the South Australian Academic Health Science and Translation Centre, the Clinical Research Committee, universities and Local Health Networks to embed a strategic, whole-of-system, consistent and streamlined approach to clinical trials in South Australia.

Table 2F: Tasmania – Performance requirements, reporting and payment summary				
Output	Performance milestones	Report due	Payment	
	2020-21			
Establishing new and enhanced central coordination units or equivalent in accordance with the Council of Australian Governments Health Council Revitalised Clinical Trials Agenda.	Complete public (external) reporting against the Research Strategy.	15 May 2021	\$71,791	
Implementing new and enhanced clinical trial data collection and reporting to inform systems improvement with interoperability and data flow capability, and contribute to better sector knowledge, recruitment and overall sector performance, including through continued implementation and expansion of metrics and ongoing submission of data to the national data collection under the Framework for National Aggregate Statistics (NAS).	Full contribution of data to the expanded National Aggregate Statistics (NAS) 2020-21, as agreed by the Clinical Trials Project Reference Group (CTPRG).			
Establishing and maintaining new networks and partnerships within and between jurisdictions, clinical trial networks, communities of practice (eg. oncology, working with ATSI groups) and registries.	Nil.			
Embedding research and clinical trials processes into core hospital governance arrangements.	Active engagement with CTPRG, Commonwealth and Australian Commission on Safety and Quality in Health Care (ACSQHC) to implement the national Clinical Trials Governance Framework.			

This schedule was agreed by the Commonwealth and Tasmania when the overarching National Partnership was signed.

#### **Tasmania Project Plan summary**

Tasmania will establish and embed a state-wide Research Governance Office (RGO) within the Department of Health and Human Services (DHHS) that will:

- (a) function as a central point of contact for sponsors, researchers, participants, research institutes and other stakeholders supported by a Research Governance Framework and communication strategy;
- (b) build on Tasmania's existing single ethical review process, and leverage off work that other jurisdictions have already undertaken, to develop a single system-wide Research Strategy and introduce unified processes across the state to improve system navigation, cohesion, streamlining and capacity;
- (c) develop and implement a state-wide Information and Communication Technology (ICT) platform that will enhance clinical trial data, provide research governance management and external reporting, and support efficient translation of research outcomes into practice improvement; and
- (d) establish strategic linkages with Ambulance Tasmania, the Tasmania Health Service (THS), the University of Tasmania (UTAS), the Menzies Institute for Medical Research, the Clifford Craig Research Foundation and the Royal Hobart Hospital Research Foundation.

Output	Performance milestones	Report due	Payment
	2020-21		
Establishing new and enhanced central coordination units or equivalent in accordance with the Council of Australian Governments Health Council Revitalised Clinical Trials Agenda.	Delivery of survey and review of Standard Operating Procedures (SOPs) for all ACT clinical trials, and update and publication of revised SOPs informed by review outcomes.  Signed agreements with all ACT CCT partners to enable centralised management and coordination of clinical trials within ACT.	30 April 2021	\$153,225
Implementing new and enhanced clinical trial data collection and reporting to inform systems improvement with interoperability and data flow capability, and contribute to better sector knowledge, recruitment and overall sector performance, including through continued implementation and expansion of metrics and ongoing submission of data to the national data collection under the Framework for National Aggregate Statistics (NAS).	Full contribution of data to the expanded National Aggregate Statistics (NAS) 2020-21, as agreed by the Clinical Trials Project Reference Group (CTPRG).  NAS data requirements and automated reporting capability incorporated into innovative ICT system.		
Establishing and maintaining new networks and partnerships within and between jurisdictions, clinical trial networks, communities of practice (eg. oncology, working with ATSI groups) and registries.	Nil.		
Embedding research and clinical trials processes into core hospital governance arrangements.	Active engagement with CTPRG, Commonwealth and Australian Commission on Safety and Quality in Health Care (ACSQHC) to implement the national Clinical Trials Governance Framework.	1	

This schedule was agreed by the Commonwealth and the ACT when the overarching National Partnership was signed.

## **Australian Capital Territory Project Plan summary**

The Australian Capital Territory will expand its recently established state-wide Centre for Clinical Trials (CCT) that will:

- (a) act as a central point of contact for sponsors, researchers, coordinators and participants;
- (b) provide centralised support and coordination of all public sector clinical trials within ACT, including development of streamlined mechanisms to enable New South Wales (NSW) residents to participate in ACT based trials;
- (c) develop and implement an innovative Information and Communication Technology (ICT) platform that will enhance clinical trial data and recruitment capability, and support efficient translation of research outcomes into practice improvement; and
- (d) introduce a research mentorship program for new and early career researchers to enhance capability and research activity within ACT.

Table 2H: Northern Territory – Performance requirements, reporting and payment summary				
Output	Performance milestones	Report due	Payment	
	2020-21			
Establishing new and enhanced central coordination units or equivalent in accordance with the Council of Australian Governments Health Council Revitalised Clinical Trials Agenda.	Complete a NT research needs assessment (including translational research), aligned with strategic priorities of the NT Department of Health and two Health Services.  Complete monitoring and evaluation activities to identify impact, effectiveness of, and revisions to, the Northern Territory Clinical Trials Coordination Unit (NTCTCU), including coordination of the clinical trial pathway.	30 April 2021	\$144,553	
Implementing new and enhanced clinical trial data collection and reporting to inform systems improvement with interoperability and data flow capability, and contribute to better sector knowledge, recruitment and overall sector performance, including through continued implementation and expansion of metrics and ongoing submission of data to the national data collection under the Framework for National Aggregate Statistics (NAS).	Full contribution of data to the expanded NAS 2020-21, as agreed by the Clinical Trials Project Reference Group (CTPRG).  Capture data on recruitment as a proportion of all eligible patients.			
Establishing and maintaining new networks and partnerships within and between jurisdictions, clinical trial networks, communities of practice (eg. oncology, working with ATSI groups) and registries.	Finalise agreement between NT, Queensland and Western Australia to attract and support Northern Australian clinical trials that seek to address public health priorities and areas of significant disease burden that contribute to the continuing gap in life expectancy between non-Indigenous and Indigenous Australians.  Completion of NTCTCU's NT research needs assessment and evaluation, with recommendations for sustainable research structures that meet population needs.			
Embedding research and clinical trials processes into core hospital governance arrangements.	Active engagement with CTPRG, Commonwealth and Australian Commission on Safety and Quality in Health Care (ACSQHC) to implement the national Clinical Trials Governance Framework.	-		

This schedule was agreed by the Commonwealth and the NT when the overarching National Partnership was signed.

#### The Northern Territory Project Plan summary

Northern Territory will consolidate and expand existing functions to establish a central point of contact (unit) for clinical trial sponsors, researchers, coordinators and participants that will:

- (a) provide a single point of application for research ethics and site specific approvals;
- (b) provide a centralised source of advice and facilitate the introduction of standard operating procedures across all Northern Territory Department of Health sites, informed by strong Indigenous leadership, to support and encourage best practice and culturally appropriate research and recruitment, including for vulnerable populations;
- (c) enhance clinical information systems and Information and Communication Technology (ICT) capability to assist clinical trial recruitment, and to facilitate NT participation in ongoing national reporting and streamlining activities; and
- (d) work with comparable units in Queensland and Western Australia to establish a formal partnership arrangement to attract and support Northern Australia clinical trials, drawing on existing expertise in key research institutions and national clinical trials networks to inform and encourage high-quality national and international trials.