

New South Wales

PROJECT AGREEMENT FOR ENCOURAGING MORE CLINICAL TRIALS IN AUSTRALIA

PART 1: PRELIMINARIES

1. This Schedule has been developed in accordance with clause 12(a) of the Project Agreement for Encouraging More Clinical Trials in Australia and should be read in conjunction with that Agreement.
2. This Schedule will commence as soon as it is agreed between the Commonwealth and New South Wales and expire on 30 June 2021 or on completion of the project whichever is earlier, including final performance reporting and processing of final payments against milestones.

PART 2: PROJECT MILESTONES, REPORTING AND PAYMENTS

3. In accordance with clause 12 of the Agreement, the Commonwealth and New South Wales have agreed a Project Plan that sets out the New South Wales strategy for delivering on the outputs of the Agreement.
4. Consistent with the agreed Project Plan, 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.
5. In accordance with clause 8 and 15 of the Agreement, milestones, their relationship to outputs, expected completion dates, relevant reporting dates and expected payments are set out in Table 1.

6. In relation to the delivery of its Outputs and Milestones set out in Table 1, New South Wales will deliver its obligations in accordance with clauses 8(a) and 8(c) of the Agreement through its use of the financial contribution provided under this Agreement and will deliver its obligations in accordance with 8(b) and 8(d) of the Agreement through its ongoing participation and engagement with the Clinical Trials Project Reference Group (CTPRG).

Table 1: Milestones, reporting and payment summary

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
Establish new and enhanced central coordination unit in accordance with clause 8(a) of the Agreement.	Complete three Consultation Frameworks (one per AHRTC) to guide consultations to identify strengths, barriers, needs, and opportunities to facilitate and enable trial activity.	Implement three AHRTC CTCSPs (one per AHRTC) and delivery of consolidated priority expertise and/or programs to be identified in CTCSP Activity Plans and NSW Progress Report, and agreed with the Commonwealth.	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.	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 three environmental scans (one per AHRTC) that maps current infrastructure and support services against current (and projected) clinical trial activity.	Implement and publically launch of three Clinical Trial Program Manager/ Project Officer roles to progress AHRTC CTCSP Activity Plans.		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	15 May 2018	\$500,240
	Establish three AHRTC-level CTCSPs to provide facilitation services, an overarching framework for research governance, partnerships, and shared infrastructure.				15 May 2019	\$300,020
	Complete three 2017-21 CTCSP Activity Plans (one per AHRTC) detailing planned priority				15 May 2020	\$300,020
				15 May 2021	\$300,020	

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
	<p>posts/activities/projects to improve performance of AHRTCs in initiating and delivering clinical trials, by addressing inefficient governance processes, unpredictable recruitment, difficulties managing trial finance and trial awareness and engagement.</p> <p>Finalise agreements with AHRTCs on establishment of Clinical Trial Program Manager/ Project Officer roles.</p>				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	
Implement new and enhanced clinical trial data collection and reporting, in accordance with clause 8(b) of the Agreement.	Contribution of data to the National Aggregate Statistics (NAS) 2017-18, as agreed by the Clinical Trials Project Reference Group (CTPRG)	Contribution of data to the expanded NAS 2018-19, as agreed by the CTPRG.	Contribution of data to the expanded NAS 2019-20, as agreed by the CTPRG.	Contribution of data to the expanded NAS 2020-21, as agreed by the CTPRG.		
Establish and maintain new networks and partnerships in accordance with clause 8(c) of the Agreement.	Nil.	Establish a shared clinical trial platform across the three AHRTCs (coordinated by SPHERE), including conduct of two	Continue to implement a shared clinical trial platform across the three AHRTCs, and complete overarching	Continue to implement a shared clinical trial platform across the three AHRTCs, and complete		

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
		steering groups (Project and Design Research) and workshops to align CTCSP and LHD clinical trial improvement processes	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.	<p>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.</p> <p>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</p>		

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
				performance report) to demonstrate impact.		
Embed research and clinical trials processes in accordance with clause 8(d) of the Agreement.	Active engagement with CTPRG, Commonwealth and ACSQHC to develop a draft Clinical Trials Governance Framework.	Active engagement with CTPRG, Commonwealth and ACSQHC to develop a draft Clinical Trials Governance.	Active engagement with CTPRG, Commonwealth and ACSQHC to implement the national Clinical Trials Governance.	Active engagement with CTPRG, Commonwealth and ACSQHC to implement the national Clinical Trials Governance.		

SIGN OFF

The Parties have confirmed their commitment to this Schedule as follows:

Signed for and on behalf of the Commonwealth of Australia by

A large, stylized handwritten signature in blue ink, written over a horizontal line.

The Honourable Greg Hunt MP

Minister for Health

~~1/2017~~
24/4/2018

Signed for and on behalf of the State of New South Wales by

A large, stylized handwritten signature in blue ink, written over a horizontal line.

The Hon Brad Hazzard MP

Minister for Health

12/JUN/2018