

# Western Australia

## 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 Western Australia 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 Western Australia have agreed a Project Plan that sets out Western Australia's strategy for delivering on the outputs of the Agreement.
4. Consistent with the agreed Project Plan, 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 Services and liaise with the state-wide CTDMC; and
  - (c) expand functionality of the Western Australian Research Governance Service that will facilitate first-time participation in national streamlining and data collection and reporting efforts.
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.

Table 1: Milestones, reporting and payment summary

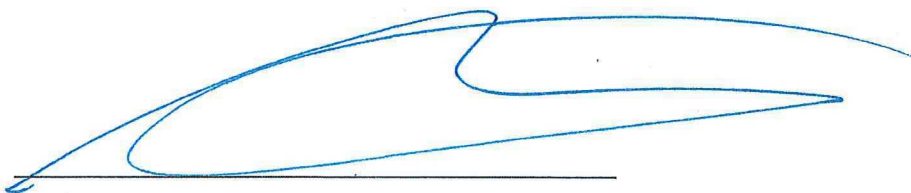
Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
Establish new and enhanced central coordination unit in accordance with clause 8(a) of the Agreement.	<p>Establish the state-wide Clinical Trials Data Systems Manager (CTDSM) role within CTDMC.</p> <p>Finalise agreements with HSPs on establishment of CTLO roles.</p>	Finalise CTDSM and CTLO roles and deliver expert guidance to WA research sector (as detailed in annual performance report).	Delivery of preliminary analysis of the benefits of Clinical Trials and Data Management Centre (CTDMC) model, including CTDMC and CTLO roles, as part of initial business case planning to substantiate continuation.	<p>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.</p> <p>Agreements finalised by HSPs on continuation of CTLO roles.</p>	<p>31 May 2018</p> <p>30 April 2019</p> <p>30 April 2020</p> <p>30 April 2021</p>	<p>\$357,100</p> <p>\$214,300</p> <p>\$214,300</p> <p>\$214,300</p>
Implement new and enhanced clinical trial data collection and reporting, in accordance with clause 8(b) of the Agreement.	<p>Full contribution of data to the National Aggregate Statistics (NAS) 2017-18, as agreed by the Clinical Trials Project Reference Group (CTPRG).</p> <p>Enhanced WA Research Governance Service (RGS) IT data functionality and reporting capability, and</p>	<p>Full contribution of data to the expanded NAS 2018-19, as agreed by the CTPRG.</p> <p>Clinical trials data collection processes embedded in RGS, and improved reporting capability.</p>	<p>Full contribution of data to the expanded NAS 2019-20, as agreed by the CTPRG.</p> <p>Delivery of ad hoc reporting functionality for researchers and administrators.</p>	<p>Full contribution of data to the expanded NAS 2020-21, as agreed by the CTPRG.</p> <p>Delivery of public searching capability for clinical trials in WA.</p>		

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
	data migration from local systems commenced.					
Embed research and clinical trials processes in accordance with clause 8(d) of the Agreement.	Active engagement with the Clinical Trials Project Reference Group (CTPRG), Commonwealth and ACSQHC to develop the Clinical Trials Governance Framework.	Active engagement with CTPRG, Commonwealth and ACSQHC to develop the Clinical Trials Governance Framework.	Active engagement with CTPRG, Commonwealth and ACSQHC to implement the Clinical Trials Governance Framework.	Active engagement with CTPRG, Commonwealth and ACSQHC to implement the Clinical Trials Governance Framework.		

**SIGN OFF**

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

*Signed for and on behalf of the Commonwealth of Australia by*

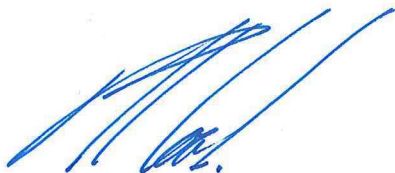
A large, stylized handwritten signature in blue ink, consisting of several sweeping, connected strokes.

**The Honourable Greg Hunt MP**

Minister for Health

12/6/2018

*Signed for and on behalf of the State of Western Australia by*

A handwritten signature in blue ink, featuring a series of sharp, diagonal strokes.

**The Honourable Roger Hugh Cook MP**

Minister for Health

14/6/2018