

Queensland

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 Queensland 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 Queensland have agreed a Project Plan that sets out Queensland's strategy for delivering on the outputs of the Agreement.
4. Consistent with the agreed Project Plan, 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.
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 QCTCU including website and placement/identification of four liaison points within existing or emerging Queensland Academic Health Translation Centres.</p> <p>Initiate workforce support including education and training of research ethics and governance officers, and clinical research coordinators to build workforce competency and capability.</p> <p>Public launch of the QCTCU, associated website and liaison points.</p>	<p>Delivery of the Clinical Trial Capability Project, including publication of at least 100 clinical trial site profiles on the QCTCU website to demonstrate the impact of the QCTCU on reducing the administrative load on clinical trial sites and approval timeframes.</p>	<p>Delivery of a Clinical Research Coordinator Workforce Strategy to increase the clinical trial research capacity of regional and rural sites and junior staff, and integrate and support the state-wide coordination of trials.</p> <p>Publication on the QCTCU website of a new state-wide Clinical Research Coordinator Workforce Strategy including SOPs and guidelines</p>	<p>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.</p> <p>Completion of forward planning based on outcomes of analysis and business case.</p>	<p>30 April 2018</p> <p>30 April 2019</p> <p>30 April 2020</p> <p>30 April 2021</p>	<p>\$428,520</p> <p>\$257,160</p> <p>\$257,160</p> <p>\$257,160</p>

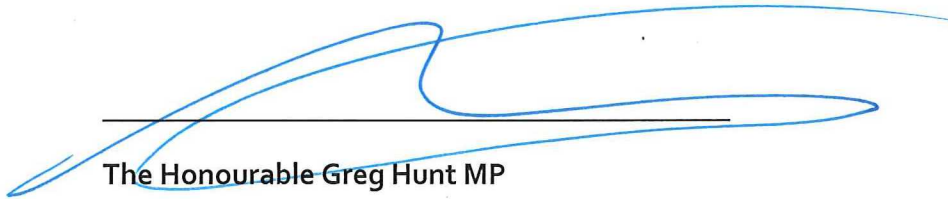
Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
Implement new and enhanced clinical trial data collection and reporting, in accordance with clause 8(b) of the Agreement.	Full contribution of data to the National Aggregate Statistics (NAS) 2017-18, as agreed by the Clinical Trials Project Reference Group (CTPRG)	Full contribution of data to the expanded NAS 2018-19, as agreed by the CTPRG.	Full contribution of data to the expanded NAS 2019-20, as agreed by the CTPRG.	Full 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.	<p>Delivery of pilot oncology tele-trials / satellite site model across Queensland.</p> <p>Publication and mandating of revised Standard Operating Procedures (SOPs) that include the tele-trials model.</p>	Review, and publication of analysis, of pilot oncology tele-trials model and revised SOPs based on outcomes.	<p>Delivery of expanded tele-trials model to disciplines other than oncology across Queensland and other partners.</p> <p>Tele-trials model integrated within regional health system arrangements, and impact analysis based on increased number of tele-trials compared to baseline (provided in annual performance report).</p>	Ongoing delivery of tele-trials model.		
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		

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
		Framework.	Framework.	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, written over a horizontal line.

The Honourable Greg Hunt MP

Minister for Health

12 / 4 / 2018

Signed for and on behalf of the State of Queensland by



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

The Hon Steven Miles MP

Minister for Health and

Minister for Ambulance Services

12 / 6 / 2018