Extension of Encouraging More Clinical Trials in Australia

FEDERATION FUNDING AGREEMENT - HEALTH

Parties	Commonwealth
	New South Wales
	Victoria
	Queensland
	Western Australia
	South Australia
	Tasmania
	Australian Capital Territory
	Northern Territory
Duration	This Schedule is expected to expire on 30 June 2025.
Purpose	This Schedule will encourage more clinical trials in Australia by support for:
Гогрозе	 ongoing implementation of central coordination units to better organise trials sites to improve navigation and access for clinical trial sponsors and participants;
	 ongoing redesign of clinical trials and related research systems and processes to make it easier to participate in safe high quality clinical trials and research, with a focus on streamlining and harmonising approvals, administration and management processes; collaborative development and implementation of the national One Stop Shop for Clinical Trials and Human Research Approvals (the One Stop Shop), and full jurisdictional transition to this single national platform; and collaborating to develop the related National Clinical Trial Front Door (NCTFD);
	 strengthening mutual acceptance of ethical review, through development and implementation of the national accreditation scheme for National Mutual Acceptance (NMA) ethics committees;
	 continued implementation of metrics and ongoing submission of data to the Framework for National Aggregate Statistics (NAS), pending transition to the national One Stop Shop;
	 continuing to embed research as essential health system business;
	 a consistent and cohesive national approaches to the conduct of clinical trials in accordance with the Principles and agreed Priority Actions Areas as endorsed by all Health Ministers in March 2017;
	 ongoing contribution and collaboration on evaluation of the Encouraging More Clinical Trials in Australia measure.

Estimated financial contributions	The Commonwealth will the States of \$6 million i	•			al contributi	on to
	Table 1 (\$ million)	2021-22	2022-23	2023-24	2024-25	Total
	Estimated total budget	1.5	1.5	1.5	1.5	6.0
	Less estimated National Partnership Payments	1.5	1.5	1.5	1.5	6.0
	- NSW	0.225	0.225	0.225	0.225	0.9
	- VIC	0.225	0.225	0.225	0.225	0.9
	- QLD	0.225	0.225	0.225	0.225	0.9
	-WA	0.225	0.225	0.225	0.225	0.9
	- SA	0.15	0.15	0.15	0.15	0.6
	- TAS	0.15	0.15	0.15	0.15	0.6
	- ACT	0.15	0.15	0.15	0.15	0.6
	- NT	0.15	0.15	0.15	0.15	0.6
	Balance of non- Commonwealth contributions	0.00	0.00	0.00	0.00	0.00
Additional terms	NIL					

Output		Performano	ce milestones		Report Due	Payment
	2021-22	2022-23	2023-24	2024-25		
1. Central coordination units	Ongoing operation and support for central , coordination units.	 Ongoing operation and support for central coordination units. 	 Ongoing operation and support for central coordination units. 	 Ongoing operation and support for central coordination units. 		
2. Ongoing redesign of clinical trials and related research systems and processes	 Active engagement with the Clinical Trials Project Refence Group (CTPRG), the Commonwealth, the ACSQHC and the national consultations process to develop the One Stop Shop and the related NCTFD. Active engagement with CTPRG, the Commonwealth, and the ACSQHC to agree crossjurisdictional governance arrangements to underpin the One Stop Shop. Active engagement with CTPRG and the Commonwealth to develop and agree a single set of requirements for Site Specific Authorisations (SSA), to provide a single regulatory experience for users across Australia and for consistent national implementation via the One 	 Active engagement with CTPRG, the Commonwealth, the ACSQHC and the national consultations process to develop and agree the final design for the One Stop Shop, and the related NCTFD. Active engagement in, and full commitment to, agreed and ongoing crossjurisdictional governance of the One Stop Shop and associated systems and processes. Ongoing support and assistance to implement the single set of nationally agreed requirements for SSA, to provide a single regulatory experience for users across Australia and for implementation via the One Stop Shop. 	Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment-to, agreed and ongoing cross- jurisdictional governance of the One Stop Shop and associated systems and processes. Continue to implement agreed communication and education strategy-and continue to actively engage in and advise on change management plans to promote and transition to the national One Stop Shop, as required, noting that further funding would be required for jurisdictional transition,	 Active engagement with CTPRG, the Commonwealth, and other agencies-as required-to support-full implementation and transition to the One Stop Shop, and-its ongoing operations. Active engagement in, and full commitment to, agreed and-ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. Continue to implement agreed communication and education strategy-and continue to actively engage in and advise on change management plans to promote and transition to the national One Stop Shop, as required, noting that further funding would be required for jurisdictional 	2021-22 Reporting due: 14 April 2023	\$225,000

110000000000000000000000000000000000000	The state of the s	Active engagement	implementation, from a	management and	2022-23	# 1
		with CTPRG and the	source yet to be determined	implementation, from a	Reporting	\$225,000
		Commonwealth to develop,	that is external to this	source yet to be	due:	7223,000
		agree and implement a	Agreement.	determined that is external	14 April	
		communication and	, ig. comment	to this Agreement.	2023	Validation of the Control of the Con
		education strategy to		l to this / ig/cement	2020	
44.00		promote the One Stop			2023-24	
Posterior de la constante de l		Shop.			Reporting	
and the second s		Actively engage			due:	\$225,000
		and participate in high-level			15 April	3223,000
		discussions, as part of the			2024	
		CTPRG, that contribute			2024	
		towards the formulation of		-	2024-25	
		a change management plan			Reporting	
WALLEST CO.		that describes a broadly			due:	\$225,000
		consistent national			15 April	V
		approach for the transition			2025	
		and implementation of the				Ì
W. Carlotte		national One Stop Shop,				
		noting that further funding		The second secon		
		would be required for		THE ADMINISTRAL PROPERTY OF THE PROPERTY OF TH		
		jurisdictional transition,		overent and the second		
		change management and		ANACHRIPATA ANACAR		
		implementation, from a		Children Anna		
		source vet to be				
		determined that is external				
***************************************		to this Agreement.		On.		
3. Strengthening	Ongoing	 Ongoing 	 Ongoing 	 Ongoing 		
mutual acceptance of	participation and	participation and	participation and	participation and		
ethical review	commitment to the NMA	commitment to the NMA	commitment to the NMA	commitment to the NMA		
	Scheme.	Scheme.	Scheme.	Scheme.		
	 Active engagement 	 Active engagement 	 Identify ethics 	Active engagement		
	with CTPRG, the	with CTPRG, the	committees seeking to	with CTPRG, the	}	
	Commonwealth and the	Commonwealth and the	continue participation in the	Commonwealth, the		
	ACSQHC, to develop and	ACSQHC, to develop and	NMA scheme, and work with	ACSQHC, and ethics		
	agree the accreditation	agree the accreditation	CTPRG and the ACSQHC to	committees to promote and	L.	
	scheme for ethics	scheme for ethics	promote and support	support implementation of	- Consistence	

4. Continued implementation of data collection and reporting	committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultations to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design. Contribution of data to the NAS 2021-22, as agreed by the CTPRG; noting that NSW do not contribute revenue data.	committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultation processes to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design. Contribution of data to the NAS 2021-22, as agreed by the CTPRG; noting that NSW do not contribute revenue data.	transition to the new arrangements. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for NMA ethics committees, and implementation in accordance with agreed re-design of the NMA scheme. Contribution of data to the NAS 2023-24, as agreed by the CTPRG; noting that NSW do not contribute revenue data, pending transition of reporting to the One Stop Shop. Develop data and reporting transition plan for implementation of the One Stop Shop.	Contribution of data to the NS 2024-25, as agreed by the CTPRG; noting that NSW do not contribute revenue data, pending transition of reporting to the One Stop Shop	
5. Continuing to embed research as essential health system business	 Active engagement with CTPRG, the Commonwealth and the ACSQHC to further support implementation of the Governance Framework through design and implementation of the One Stop Shop. 		 Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required. 	 Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required. 	
6. Ongoing evaluation	 Active collaboration and contributions to enable 	Active collaboration and contributions to enable	Active collaboration and contributions to enable	Active collaboration and contributions to enable	

ongoing evaluation of the				
ongoing evaluation of the	ongoing evaluation of the	ongoing or and an or an	5656	
measure.	measure.	measure.	measure.	

Signed for and on behalf of the Commonwealth of Australia by

The Honourable Mark Butler MP Minister for Health and Aged Care

[Day] [Month] [Year]

Signed for and on behalf of the New South Wales by

The Honourable David Harris MP Minister for Medical Research

[Day] [Month] [Year]

15 June 2023

Output		Performan	ce milestones		Report Due	Payment
	2021-22	2022-23	2023-24	2024-25		
1. Central coordination units	 Ongoing operation and support for central coordination units. 	Ongoing operation and support for central coordination units.	Ongoing operation and support for central coordination units.	Ongoing operation and support for central coordination units.		
2. Ongoing redesign of clinical trials and related research systems and processes	 Active engagement with Clinical Trials Project Reference Group (CTPRG), the Commonwealth, the ACSQHC and the national consultations process to develop the One Stop Shop and the related NCTFD. Active engagement with CTPRG, the Commonwealth, and the ACSQHC to agree cross-jurisdictional governance arrangements to 	 Active engagement with CTPRG, the Commonwealth, the ACSQHC and the national consultations process to develop and agree the final design for the One Stop Shop, and the related NCTFD. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing crossjurisdictional governance of the One Stop Shop and associated systems and processes. Continue to implement agreed 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 		

underpin the One Stop Shop. • Active engagement with CTPRG and the Commonwealth to develop and agree a single set of requirements for	Ongoing support and assistance to implement the single set of nationally agreed requirements for SSA, to provide a single regulatory experience for users	communication and education strategy and change management plans to promote and support full transition to the One Stop Shop, as required.	Continue to implement agreed communication and education strategy and change management plans to promote and support full	14 April 2022 14 April 2023	\$225,000 \$225,000
Site Specific Authorisations (SSA),	across Australia and for implementation		transition to the One Stop Shop, as	15 April 2024	\$225,000
to provide a single regulatory experience for users across Australia and for consistent national implementation via the One Stop Shop.	via the One Stop Shop. Active engagement with CTPRG and the Commonwealth to develop, agree and implement a communication and education strategy to promote the One Stop Shop. Complete and implement a state- wide change management plan to promote and support implementation and transition to the national One Stop		required.	15 April 2025	\$225,000

		Shop, in collaboration with CTPRG and the Commonwealth.			
3. Strengthening mutual acceptance of ethical review	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultations to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design. 	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultation processes to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, 	 Ongoing participation and commitment to the NMA Scheme. Identify ethics committees seeking to continue participation in the NMA scheme, and work with CTPRG and the ACSQHC to promote and support transition to the new arrangements. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for NMA ethics committees, and implementation in accordance with agreed re-design of the NMA scheme. 	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. 	

4. Continued implementation of data collection and reporting	Full contribution of data to the NAS 2021-22, as agreed by the CTPRG.	and NMA scheme re-design. • Full contribution of data to the NAS 2022-23, as agreed by the CTPRG.	 Full contribution of data to the NAS 2023-24, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop. Develop data and reporting transition plan for implementation of the One Stop Shop. 	Full contribution of data to the NAS 2024-25, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop	
5. Continuing to embed research as essential health system business	Active engagement with CTPRG, the Commonwealth and the ACSQHC to further support implementation of the Governance Framework through design and implementation of the One Stop Shop.		Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	
6. Ongoing evaluation	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	Active collaboration and contributions to enable ongoing evaluation of the measure.	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	Active collaboration and contributions to enable ongoing evaluation of the measure.	*

Signed for and on behalf of the Commonwealth of Australia by

The Honourable Greg Hunt MP Minister for Health and Aged Care

> [Day] February 2022

Signed for and on behalf of the State of Victoria by

The Honourable Jaala Pulford MP Minister for Employment

Minister for Innovation, Medical Research and the Digital Economy

17 May 2022

Output		Performand	ce milestones		Report Due	Payment
	2021-22	2022-23	2023-24	2024-25		
1. Central coordination units	 Ongoing operation and support for central coordination units. 	 Ongoing operation and support for central coordination units. 	 Ongoing operation and support for central coordination units. 	 Ongoing operation and support for central coordination units. 		
2. Ongoing redesign of clinical trials and related research systems and processes	 Active engagement with Clinical Trials Project Reference Group (CTPRG), the Commonwealth, the ACSQHC and the national consultations process to develop the One Stop Shop and the related NCTFD. Active engagement with CTPRG, the Commonwealth, and the ACSQHC to agree cross-jurisdictional governance arrangements to 	 Active engagement with CTPRG, the Commonwealth, the ACSQHC and the national consultations process to develop and agree the final design for the One Stop Shop, and the related NCTFD. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing crossjurisdictional governance of the One Stop Shop and associated systems and processes. Continue to implement agreed 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 		

underpin the One Stop Shop. Active engagement with CTPRG and the Commonwealth to develop and agree a single set of requirements for Site Specific Authorisations (SSA), to provide a single regulatory	assistance to education implement the single and character set of nationally manage agreed requirements for SSA, to provide a education and character set of nationally agreed for set of nationally promotes a full training and character set of national se	gement plans to ote and support onsition to the top Shop, as education strategy and change management plans to promote and	14 April 2022 14 April 2023 15 April 2024	\$225,000 \$225,000 \$225,000 \$225,000
the One Stop Shop.	communication and education strategy to promote the One Stop Shop. Complete and implement a state-wide change management plan to promote and support implementation and transition to the national One Stop			

3. Strengthening mutual acceptance of ethical review	 Ongoing participation and commitment to the NMA Scheme. Active engagement 	Shop, in collaboration with CTPRG and the Commonwealth. Ongoing participation and commitment to the NMA Scheme. Active engagement	 Ongoing participation and commitment to the NMA Scheme. Identify ethics committees seeking to 	 Ongoing participation and commitment to the NMA Scheme. Active engagement
	with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. • Engagement in consultations to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design.	with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. • Engagement in consultation processes to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees,	continue participation in the NMA scheme, and work with CTPRG and the ACSQHC to promote and support transition to the new arrangements. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for NMA ethics committees, and implementation in accordance with agreed re-design of the NMA scheme.	with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector.

4. Continued implementation of data collection and reporting	 Full contribution of data to the NAS 2021-22, as agreed by the CTPRG. Full contribution of data to the NAS 2022-23, as agreed by the CTPRG. 	 Full contribution of data to the NAS 2023-24, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop. Develop data and reporting transition of plan for implementation of the Full contribution of data to the NAS 2024-25, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop
5. Continuing to embed research as essential health system business	 Active engagement with CTPRG, the Commonwealth and the ACSQHC to further support implementation of the Governance Framework through design and implementation of the One Stop Shop. 	One Stop Shop. Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required. Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.
6. Ongoing evaluation	 Active collaboration and contributions to enable ongoing evaluation of the measure. Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. Active collaboration and contributions to enable ongoing evaluation of the measure.

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Signed for and on behalf of the Commonwealth of Australia by

The Honourable Greg Hunt MP Minister for Health and Aged Care

13 February 2022

Signed for and on behalf of the Queensland by

The Honourable Yvette D'Ath MP

Minister for Health and Ambulance Services

[Day] [Month] 2022

4/4/2022

Output		Performan	ce milestones	,	Report Due	Payment
	2021-22	2022-23	2023-24	2024-25		
1. Central coordination units	 Ongoing operation and support for central coordination units. 	 Ongoing operation and support for central coordination units. 	Ongoing operation and support for central coordination units.	 Ongoing operation and support for central coordination units. 		
2. Ongoing redesign of clinical trials and related research systems and processes	 Active engagement with Clinical Trials Project Reference Group (CTPRG), the Commonwealth, the ACSQHC and the national consultations process to develop the One Stop Shop and the related NCTFD. Active engagement with CTPRG, the Commonwealth, and the ACSQHC to agree cross-jurisdictional governance arrangements to 	 Active engagement with CTPRG, the Commonwealth, the ACSQHC and the national consultations process to develop and agree the final design for the One Stop Shop, and the related NCTFD. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing crossjurisdictional governance of the One Stop Shop and associated systems and processes. Continue to implement agreed 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 		

underpin the One Stop Shop. • Active engagement with CTPRG and the Commonwealth to develop and agree a single set of requirements for	Ongoing support and assistance to implement the single set of nationally agreed requirements for SSA, to provide a single regulatory experience for users	communication and education strategy and change management plans to promote and support full transition to the One Stop Shop, as required.	Continue to implement agreed communication and education strategy and change management plans to promote and support full	14 April 2022 14 April 2023	\$225,000 \$225,000
Site Specific Authorisations (SSA), to provide a single	across Australia and for implementation via the One Stop	•	transition to the One Stop Shop, as required.	15 April 2024	\$225,000
regulatory experience for users across Australia and for consistent national implementation via the One Stop Shop.	 Shop. Active engagement with CTPRG and the Commonwealth to develop, agree and implement a communication and education strategy to promote the One Stop Shop. Complete and implement a state- 		requirea.	15 April 2025	\$225,000
	wide change management plan to promote and support				
	implementation and transition to the national One Stop				

-		Shop, in collaboration with CTPRG and the Commonwealth.			9
3. Strengthening mutual acceptance of ethical review	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultations to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design. 	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultation processes to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, 	 Ongoing participation and commitment to the NMA Scheme. Identify ethics committees seeking to continue participation in the NMA scheme, and work with CTPRG and the ACSQHC to promote and support transition to the new arrangements. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for NMA ethics committees, and implementation in accordance with agreed re-design of the NMA scheme. 	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. 	

		and NMA scheme re-design.			
4. Continued implementation of data collection and reporting	 Full contribution of data to the NAS 2021-22, as agreed by the CTPRG. 	Full contribution of data to the NAS 2022-23, as agreed by the CTPRG.	 Full contribution of data to the NAS 2023-24, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop. Develop data and reporting transition plan for implementation of the One Stop Shop. 	Full contribution of data to the NAS 2024-25, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop	
5. Continuing to embed research as essential health system business	 Active engagement with CTPRG, the Commonwealth and the ACSQHC to further support implementation of the Governance Framework through design and implementation of the One Stop Shop. 		 Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required. 	Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	
6. Ongoing evaluation	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	Active collaboration and contributions to enable ongoing evaluation of the measure.	

Signed for and on behalf of the Commonwealth of Australia by

The Honourable Greg Hunt MP Minister for Health and Aged Care

[Day] February 2022

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

The Honourable Stephen Dawson MLC Minister for Emergency Services; Innovation and ICT; Medical Research and Volunteering

[Day] [Month] [Year]

31 March 2022

Output		Performan	ce milestones		Report Due	Payment
	2021-22	2022-23	2023-24	2024-25		
1. Central coordination units	Ongoing operation and support for central coordination units.	Ongoing operation and support for central coordination units.	Ongoing operation and support for central coordination units.	Ongoing operation and support for central coordination units.	- - - - - - -	
2. Ongoing redesign of clinical trials and related research systems and processes	 Active engagement with Clinical Trials Project Reference Group (CTPRG), the Commonwealth, the ACSQHC and the national consultations process to develop the One Stop Shop and the related NCTFD. Active engagement with CTPRG, the Commonwealth, and the ACSQHC to agree cross-jurisdictional governance arrangements to 	 Active engagement with CTPRG, the Commonwealth, the ACSQHC and the national consultations process to develop and agree the final design for the One Stop Shop, and the related NCTFD. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing crossjurisdictional governance of the One Stop Shop and associated systems and processes. Continue to implement agreed 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 		

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underpin the One Stop Shop. • Active engagement with CTPRG and the Commonwealth to develop and agree a single set of requirements for	Ongoing support and assistance to implement the single set of nationally agreed requirements for SSA, to provide a single regulatory experience for users communication and education strategy and change management plans to promote and support full transition to the One Stop Shop, as required.	Continue to implement agreed communication and education strategy and change management plans to promote and support full	14 April 2022 14 April 2023	\$150,000 \$150,000
Site Specific Authorisations (SSA), to provide a single regulatory experience for users across Australia and for consistent national implementation via the One Stop Shop.	across Australia and for implementation via the One Stop Shop. • Active engagement with CTPRG and the Commonwealth to develop, agree and implement a communication and education strategy to promote the One Stop Shop. • Complete and implement a state-wide change management plan to promote and support implementation and transition to the national One Stop	transition to the One Stop Shop, as required.	15 April 2024 15 April 2025	\$150,000

3. Strengthening	Ongoing	Shop, in collaboration with CTPRG and the Commonwealth. Ongoing	Ongoing participation	• Ongoing
mutual acceptance of ethical review	participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultations to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design.	participation and commitment to the NMA Scheme. • Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. • Engagement in consultation processes to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees,	and commitment to the NMA Scheme. Identify ethics committees seeking to continue participation in the NMA scheme, and work with CTPRG and the ACSQHC to promote and support transition to the new arrangements. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for NMA ethics committees, and implementation in accordance with agreed re-design of the NMA scheme.	participation and commitment to the NMA Scheme.

4.	Continued implementation of data collection and reporting	Full contribution of data to the NAS 2021-22, as agreed by the CTPRG.	and NMA scheme re-design. • Full contribution of data to the NAS 2022-23, as agreed by the CTPRG.	 Full contribution of data to the NAS 2023-24, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop. Develop data and reporting transition plan for implementation of the One Stop Shop. 	Full contribution of data to the NAS 2024-25, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop	
5.	Continuing to embed research as essential health system business	 Active engagement with CTPRG, the Commonwealth and the ACSQHC to further support implementation of the Governance Framework through design and implementation of the One Stop Shop. 		Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	
6.	Ongoing evaluation	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	Active collaboration and contributions to enable ongoing evaluation of the measure.	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	Active collaboration and contributions to enable ongoing evaluation of the measure.	

Signed for and on behalf of the Commonwealth of Australia by

The Honourable Greg Hunt-MP Minister for Health and Aged Care

[Day] [Month] 2022

30/3/2022

Signed for and on behalf of the State of South Australia by

The Honourable Christopher Picton MP Minister for Health and Wellbeing

[Day] [Month] 2022

10/6/22.

Output		Performan	ce milestones		Report Due	Payment
	2021-22	2022-23	2023-24	2024-25		
1. Central coordination units	 Ongoing operation and support for central coordination units. 	Ongoing operation and support for central coordination units.	 Ongoing operation and support for central coordination units. 	Ongoing operation and support for central coordination units.		
2. Ongoing redesign of clinical trials and related research systems and processes	 Active engagement with Clinical Trials Project Reference Group (CTPRG), the Commonwealth, the ACSQHC and the national consultations process to develop the One Stop Shop and the related NCTFD. Active engagement with CTPRG, the Commonwealth, and the ACSQHC to agree cross-jurisdictional governance arrangements to 	 Active engagement with CTPRG, the Commonwealth, the ACSQHC and the national consultations process to develop and agree the final design for the One Stop Shop, and the related NCTFD. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing crossjurisdictional governance of the One Stop Shop and associated systems and processes. Continue to implement agreed 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 		

underpin the One Stop Shop. • Active engagement with CTPRG and the Commonwealth to develop and agree a single set of requirements for	Ongoing support and assistance to implement the single set of nationally agreed requirements for SSA, to provide a single regulatory experience for users communication and education strategy and change management plans to promote and support full transition to the One Stop Shop, as required.	Continue to implement agreed communication and education strategy and change management plans to promote and support full Continue to implement agreed 24 April \$150,00 \$150	
requirements for Site Specific Authorisations (SSA) to provide a single regulatory experience for users across Australia and for consistent national implementation via the One Stop Shop.	experience for users required. across Australia and	support full transition to the One Stop Shop, as required. 15 April 2024 15 April 2025 \$150,00	
	promote and support implementation and transition to the national One Stop		

		Shop, in collaboration with CTPRG and the Commonwealth.		
3. Strengthening mutual acceptance of ethical review	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultations to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design. 	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultation processes to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, 	 Ongoing participation and commitment to the NMA Scheme. Identify ethics committees seeking to continue participation in the NMA scheme, and work with CTPRG and the ACSQHC to promote and support transition to the new arrangements. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for NMA ethics committees, and implementation in accordance with agreed re-design of the NMA scheme. 	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector.

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_		and NMA scheme re-design.			
4. Continued implementation of data collection and reporting	Full contribution of data to the NAS 2021-22, as agreed by the CTPRG.	Full contribution of data to the NAS 2022-23, as agreed by the CTPRG.	 Full contribution of data to the NAS 2023-24, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop. Develop data and reporting transition plan for implementation of the One Stop Shop. 	Full contribution of data to the NAS 2024-25, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop	
5. Continuing to embed research as essential health system business	Active engagement with CTPRG, the Commonwealth and the ACSQHC to further support implementation of the Governance Framework through design and implementation of the One Stop Shop.		 Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required. 	Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	
6. Ongoing evaluation	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	Active collaboration and contributions to enable ongoing evaluation of the measure.	

Signed for and on behalf of the Commonwealth of Australia by

The Honourable Greg Hunt MP Minister for Health and Aged Care

[Day] February 2022

Signed for and on behalf of the State of Tasmania by

The Honourable Jeremy Rockliff MP Minister for Health and Wellbeing

[Day] [Month] 2022

Output		Performand	ce milestones		Report Due	Payment
	2021-22	2022-23	2023-24	2024-25		
1. Central coordination units	Ongoing operation and support for central coordination units.	Ongoing operation and support for central coordination units.	Ongoing operation and support for central coordination units.	 Ongoing operation and support for central coordination units. 		
2. Ongoing redesign of clinical trials and related research systems and processes	 Active engagement with Clinical Trials Project Reference Group (CTPRG), the Commonwealth, the ACSQHC and the national consultations process to develop the One Stop Shop and the related NCTFD. Active engagement with CTPRG, the Commonwealth, and the ACSQHC to agree cross-jurisdictional governance arrangements to 	 Active engagement with CTPRG, the Commonwealth, the ACSQHC and the national consultations process to develop and agree the final design for the One Stop Shop, and the related NCTFD. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing crossjurisdictional governance of the One Stop Shop and associated systems and processes. Continue to implement agreed 	 Active engagement with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 		

underpin the Stop Shop. Active engage with CTPRG a Commonwead develop and single set of requirements Site Specific Authorisation to provide a single set of regulatory experience for across Austrafor consistent national implementat the One Stop	assistance to implement the single set of nationally agreed requirements for SSA, to provide a single regulatory experience for users across Australia and for implementation via the One Stop Shop. To users of the commonwealth to develop, agree and implement a	communication and education strategy and change management plans to promote and support full transition to the One Stop Shop, as required.	Continue to implement agreed communication and education strategy and change management plans to promote and support full transition to the One Stop Shop, as required.	14 April 2022 14 April 2023 15 April 2024 15 April 2025	\$150,000 \$150,000 \$150,000
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3. Strengthening	Ongoing	Shop, in collaboration with CTPRG and the Commonwealth. • Ongoing	Ongoing participation	Ongoing
mutual acceptance of ethical review	participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultations to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design.	participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultation processes to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees,	and commitment to the NMA Scheme. Identify ethics committees seeking to continue participation in the NMA scheme, and work with CTPRG and the ACSQHC to promote and support transition to the new arrangements. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for NMA ethics committees, and implementation in accordance with agreed re-design of the NMA scheme.	participation and commitment to the NMA Scheme.

4. Continued implementation of data collection and reporting	Full contribution of data to the NAS 2021-22, as agreed by the CTPRG.	and NMA scheme re-design. • Full contribution of data to the NAS 2022-23, as agreed by the CTPRG.	 Full contribution of data to the NAS 2023-24, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop. Develop data and reporting transition plan for implementation of the One Stop Shop. 	Full contribution of data to the NAS 2024-25, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop	
5. Continuing to embed research as essential health system business	Active engagement with CTPRG, the Commonwealth and the ACSQHC to further support implementation of the Governance Framework through design and implementation of the One Stop Shop.		Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	 Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required. 	
6. Ongoing evaluation	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	

Signed for and on behalf of the Commonwealth of Australia by

The Honourable Greg Hunt MP Minister for Health and Aged Care

[Day] February 2022

Signed for and on behalf of the State of Australian Capital Territory by

Ms Rachel Stephen-Smith MLA

Minister for Health

[Day] [Month] 2022

14 April

Table 2H: Northern	Territory – Performance	requirements, reporting a	nd payment summary		
Output		Performan	ce milestones	Report Due	Payment
	2021-22	2022-23	2023-24	2024-25	
1. Central coordination units	Ongoing operation and support for central coordination units.	Ongoing operation and support for central coordination units.	and support for and	going operation I support for tral coordination ts.	
2. Ongoing redesign of clinical trials and related research systems and processes	 Active engagement with Clinical Trials Project Reference Group (CTPRG), the Commonwealth, the ACSQHC and the national consultations process to develop the One Stop Shop and the related NCTFD. Active engagement with CTPRG, the Commonwealth, and the ACSQHC to agree cross-jurisdictional governance arrangements to 	 Active engagement with CTPRG, the Commonwealth, the ACSQHC and the national consultations process to develop and agree the final design for the One Stop Shop, and the related NCTFD. Active engagement in, and full commitment to, agreed and ongoing cross-jurisdictional governance of the One Stop Shop and associated systems and processes. 	with CTPRG, the Commonwealth, and other agencies as required to support full implementation and transition to the One Stop Shop, and its ongoing operations. Active engagement in, and full commitment to, agreed and ongoing cross- jurisdictional governance of the One Stop Shop and associated systems and processes.	ive engagement in CTPRG, the immonwealth, and er agencies as uired to support implementation transition to the e Stop Shop, and ongoing erations. ive engagement and full imitment to, eed and ongoing ers-jurisdictional ernance of the e Stop Shop and ociated systems processes.	

underpin the One Stop Shop. Active engagement with CTPRG and the Commonwealth to develop and agree a single set of requirements for Site Specific Authorisations (SSA),	Ongoing support and assistance to implement the single set of nationally agreed requirements for SSA, to provide a single regulatory experience for users across Australia and for implementation	communication and education strategy and change management plans to promote and support full transition to the One Stop Shop, as required.	Continue to implement agreed communication and education strategy and change management plans to promote and support full transition to the One Stop Shop, as	14 April 2022 14 April 2023 15 April 2024	\$150,000 \$150,000 \$150,000
to provide a single regulatory experience for users across Australia and for consistent national implementation via the One Stop Shop.	via the One Stop Shop. Active engagement with CTPRG and the Commonwealth to develop, agree and implement a communication and education strategy to promote the One Stop Shop. Complete and implement a state- wide change management plan to promote and support implementation and transition to the national One Stop		required.	15 April 2025	\$150,000

3. Strengthening	Ongoing	Shop, in collaboration with CTPRG and the Commonwealth. • Ongoing	Ongoing participation	. Ongoing	
mutual acceptance of ethical review	participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultations to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, and NMA scheme re-design.	 Origoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth and the ACSQHC, to develop and agree the accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. Engagement in consultation processes to inform development of a national quality standard to underpin the accreditation scheme for NMA ethics committees, 	 Ongoing participation and commitment to the NMA Scheme. Identify ethics committees seeking to continue participation in the NMA scheme, and work with CTPRG and the ACSQHC to promote and support transition to the new arrangements. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for NMA ethics committees, and implementation in accordance with agreed re-design of the NMA scheme. 	 Ongoing participation and commitment to the NMA Scheme. Active engagement with CTPRG, the Commonwealth, the ACSQHC, and ethics committees to promote and support implementation of the agreed accreditation scheme for ethics committees to strengthen the NMA scheme and support its expansion beyond the public sector. 	

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4. Continued implementation of data collection and reporting	by the CTPRG.	and NMA scheme re-design. • Full contribution of data to the NAS 2022-23, as agreed by the CTPRG.	 Full contribution of data to the NAS 2023-24, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop. Develop data and reporting transition plan for implementation of the One Stop Shop. 	Full contribution of data to the NAS 2024-25, as agreed by the CTPRG, pending transition of reporting to the One Stop Shop	
5. Continuing to embed research as essential health system business	Active engagement with CTPRG, the Commonwealth and the ACSQHC to further support implementation of the Governance Framework through design and implementation of the One Stop Shop.		Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	Active engagement with CTPRG, and the ACSQHC to support evaluation of the Governance Framework, as required.	
6. Ongoing evaluation	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	 Active collaboration and contributions to enable ongoing evaluation of the measure. 	Active collaboration and contributions to enable ongoing evaluation of the measure.	

Signed for and on behalf of the Commonwealth of Australia by

The Honourable Greg Hunt MP Minister for Health and Aged Care

[Day] February 2022

Signed for and on behalf of the State of Northern Territory by

The Honourable Natasha Fyles MLA Minister for Health

[Day] [Month] 2022

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