Australian Clinical Trials Alliance

Exploring greater partnership between Clinical Trial Networks, Clinical Quality Registries and Trial Coordinating Centres with Industry

Environmental Scan

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2 Acknowledgements

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Document History

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3 Abbreviations

Abbreviation	Meaning
ACTA	Australian Clinical Trials Alliance
ACSQHC	Australian Commission on Safety and Quality in Health Care
AcVA	Australian Cardiovascular Alliance
AHMAC	Australian Health Ministers' Advisory Council
ANZCTR	Australia New Zealand Clinical Trials Registry
CALD	Culturally and linguistically diverse
CAREFOR	Clinical Academic Cancer Research Forum
CTA	Clinical Trial Approval
CTAG	Clinical Trial Action Group
CTD	Clinical Trial Directive
CTJWG	Clinical Trials Jurisdictional Working Group
CTN	Clinical Trial Network (NB the TGA Clinical Trial Notification (CTN) scheme will be written in full to avoid confusion)
CTPRG	Clinical Trials Project Reference Group
CTX	Clinical Trial Exemption
CTJWG	Clinical Trial Jurisdictional Working Group

Abbreviation	Meaning
CTAG	Clinical Trial Action group
EORTC	European Organisation for Research and Treatment of Cancer
HREC	Human Research Ethics Committee
HoMER	Harmonisation of Multicentre Ethical Review
ICMJE	International Committee of Medical Journal Editors
IHPA	Independent Hospital Pricing Authority
IIT	Investigator Initiated Trial
MJA	Medical Journal of Australia
MREA	Medical Research Endowment Account
MRFF	Medical Research Future Fund
MRI	Medical Research Institutes
MTPConnect	MedTech and Pharma Growth Centre
NCTGF	National Clinical Trials Governance Framework
NSW	New South Wales
NGO	Non-Government Organisation
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NIH	National Institute of Health

Abbreviation	Meaning
NIHR	National Institute for Health and Care Research
NMA	National Mutual Acceptance
NOSS	National One Stop Shop
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PIWG	Pharmaceutical Industry Working Group
R & D	Research and Development
RCT	Randomised Controlled Trial
RDTF	Research & Development Taskforce
SA	South Australia
TGA	Therapeutic Goods Administration
UIC	University-Industry Collaboration
UK	United Kingdom
USA	United States of America
VCB	Victorian Cancer Biobank

4 Executive Summary

Clinical trials are conducted by both the academic and industry sectors. Together these two sectors strive to advance health outcomes by bringing new treatments to market and delivering comparative and cost effectiveness information.

The Australian Clinical Trials Alliance (ACTA) is the peak body representing the academic trials sector in Australia. Many of its member organisations work closely with industry to conduct their trials in terms of design, conduct and financial and infrastructure support. ACTA recognises that the pharmaceutical and medical technology sectors are responsible for a large amount of the clinical trial activity in Australia and that this investment underpins a great deal of the clinical trial infrastructure that ACTA member organisations utilise. In light of this, one of the project workstreams (5) of ACTA's current Medical Research Future Fund (MRFF) grant is designed to identify opportunities for academic and industry trial sectors to work more effectively together to capitalise on their shared objectives and investments. This environmental scan is part of that work plan together with a stakeholder engagement exercise delivered through a roundtable. A report from this roundtable has been developed and accompanies this document.

ACTA has several other priority projects that focus on academic and Industry partnerships.

These include:

- The promotion and support of the **national teletrials model** that will enable scaling up of the use of teletrials in rural, remote and regional areas across different disease and discipline areas to provide better access to clinical trials for the broader Australian community.
- Improving trial efficiency through greater implementation and adoption of innovative trials designs. ACTA seeks to disseminate information on **innovative trial designs**, their advantages, and situations in which they can be best applied to enhance their utility.
- Operationalising an **early trial approval model** could result in the implementation of a national model for rapid trial approval processes, with the aim to address the longstanding delays in trial ethics and governance processes that make trials for rare conditions so challenging.

Whilst the environmental scan aimed to identify examples of how the academic and industry-led trials sectors have worked together in Australia in the published and grey literature, there was limited literature available. Instead, a broader assessment of the clinical trial environment was conducted,

and this included a review of industry websites dedicated to facilitating collaboration. In addition, although not originally part of the scope, the scan also examined the international literature and resources related to academic and industry collaborations in clinical trials. There were very few examples relevant to Australia in the international literature, although the centralised resources of the National Institute for Health and Care Research (NIHR) in the UK provided the best illustration of a well-coordinated approach that could potentially be translated at a state and territory level in Australia. The NIHR provides support for the design and conduct of trials with industry partners. There is no similar approach being taken anywhere in Australia at present. The proposed National One Stop Shop (NOSS) in Australia could support such a national approach to bringing industry and academia together through a single point of contact like the NIHR. In the meantime, ACTA has a role in facilitating collaboration and building an environment similar to the NIHR through activities that bring the sectors together across the country.

5 Introduction

Whilst Clinical Trial Networks (CTN) and industry have a shared interest in conducting clinical trials to establish evidence across the spectrum of medicine and healthcare more broadly, the objectives of each sector have some important differences. Industry-sponsored studies are broadly aimed at establishing evidence of the safety and efficacy of investigational products to achieve registration of these products with regulatory authorities. The primary objective of CTN clinical trials is complementary. Whilst CTNs may establish novel indications the typical focus of these trials is to determine comparative effectiveness. CTNs are also involved in the translation of trial results into practice through their engagement or buy-in of a large and broadly distributed group of practicing clinicians.

The landscape for clinical trials has altered dramatically over the last 50 years, moving from predominantly single-site studies to large-scale multicentre, and often multinational, studies. A significant driver of this has been the commercial sector, with the advent of many new therapeutic goods that require validation for safety and efficacy. Alongside these studies, the investigator-initiated sector has also grown, focusing on clinical trials seeking to answer critical questions that optimise care within the health system. In both cases, the effects of the interventions may be relatively small or require long follow-up periods driving the scale, complexity and cost of such studies ever upward. Coupled with ever-tightening regulatory requirements, the cost of trials is more now than ever before, creating a major barrier to their conduct.

Although there is a long tradition of medical research in Australia that has been closely associated with hospitals and health services, initially through teaching hospitals with close ties to universities, funding pressures on hospitals have seen a steady decline in hospital-employee-led and hospital-supported medical research in the last 20 years. Whilst laboratory-based medical research has found a new home in purpose-built Medical Research Institutes (MRIs), clinical trials must be conducted close to patients with staff onsite at health services alongside their colleagues delivering ‘routine’ care. Many hospitals conduct clinical trials, but in most instances, they are treated as a ‘nice-to-have’ rather than an essential service, and it is widely reported that conducting clinical trials is not well supported, with most units having to demonstrate that they can self-support through revenue generation. That is, clinical trials are conducted as a quasi-business in hospitals with the expectation that they will cover their costs or generate a surplus.

5.1 Funding for clinical trials in Australia

Most funding for clinical trials in Australia comes from industry that provides resources to conduct studies directly at hospital sites. The quantum of funding for clinical trials is not easy to identify, and the recent MTPConnect Sector Competitiveness Plan (April 2022) [1] provides two figures for its investment, stating that industry invested about $792 million in 2021 as an R & D spend and separately that $1.4 billion was spent on clinical trials, however more detail is needed to understand both figures. Most funding for trials in Australia by industry goes to the conduct of, for the most part, multinational clinical trials. The current financial management system of clinical trials in hospitals does not permit any ready analysis of clinical trial economic activity across the sector, and it is reported (personal communications) that few sites could give an accurate figure as there is seldom centralised financial management of trial activity. Resolving this is one of the core components of the Australian Commission on Safety and Quality in Health Care (ACSQHC) National Clinical Trials Governance Framework (NCTGF), which requires that health services be able to provide transparent financial accounting of all trial activity. Anecdotally, commercially sponsored clinical trials are responsible for funding approximately 70% - 80% of hospital clinical trial activity.

Most public funding for clinical trials comes from the federal government. In particular, through the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF), which was established in 2015, and has now grown to $20 billion as an endowment account. This fund provides almost $633 million a year compared to $850 million from the NHMRC. Additional funding comes from State governments (e.g. Victoria has committed $1.3 billion since 2014) [2], charities and individual hospital research foundations. Only $74 million of the NHMRC's $850 million Medical Research Endowment Account (MREA) goes to clinical trial and cohort studies (2020 amount), less than 8%. The MRFF has committed $750 million to clinical trials for the 2022-2032 period, which equates to about $75 million per year and essentially matches the NHMRC funding. It is widely recognised that the public funding sources do not provide sufficient funding for clinical trials, especially when the NHMRC Clinical Trials and Cohort Scheme's success rate was just 6.8% (30 funded from 436 applications) in 2020.

5.2 Changes in the regulatory and ethical frameworks

Australia's role in clinical trial activity has increased since the introduction of the Clinical Trial Notification (CTN) scheme in 1992 under the Therapeutic Goods Administration (TGA). In essence, this allows unapproved therapeutic good trials to be mainly managed by institutions, with the Human Research Ethics Committee (HREC) responsible for what regulatory agencies would otherwise do in

other countries. That is, a review of the preclinical safety information and the research protocol is conducted by the HREC, not by the TGA. There are several advantages to this for industry, and it has made Australia more attractive as a less bureaucratically difficult place to conduct trials. In a report prepared for the Australian Health Ministers' Advisory Council (AHMAC) Working Group on a Streamlined National Approach to Ethical and Scientific Review of Multi-centre Health and Medical Research [3] in 2006, the authors noted that the number of CTNs went from 0 in 1990 to 2725 in 2005. In contrast, the number of CTX (Clinical Trial Exemption- reviewed by the TGA before the trial can commence) went from 100 to 2 in the same period. The CTX is now the Clinical Trial Approval (CTA) scheme but is only used for specific high-risk classes of unapproved therapeutic goods such as biologicals.

The immense burden that the CTN scheme created on HRECs became a significant concern in the early 2000s amid concerns that the scheme was at breaking point in the institutions responsible for managing it (primarily hospitals). The Report of the Review of Access to Unapproved Therapeutic Goods [4] 2005- the Bansemer report, named after Alan Bansemer, the author) identified major concerns, particularly with duplication of review of multicentre studies and massive burdens on HRECs in terms of managing safety monitoring. This review brought both the public and private sector clinical trial leaders together to find ways to address the issues, and an immediate focus was on fixing the ethics review model. The AHMAC working group recommended that reforms were made led by the NHMRC to reduce the burden, and this led to the Harmonisation of Multicentre Ethical Review (HoMER) program, which evolved into the National Mutual Acceptance (NMA) scheme. The AHMAC working group further committed to a program of separating the ethical review from research governance processes, which up until the mid-2000s had been largely done together.

5.3 A need for change – industry and academic sectors working together

It was clear that the HoMER reforms were insufficient to fix the inherent problems with conducting clinical trials in Australia. In 2010 the then Labor government, through two ministries (Health and Ageing and Innovation, Industry, Science and Research), created the Clinical Trial Action Group (CTAG) to convene expert panels to advise on ways to make Australia more competitive for attracting clinical trials through structural reform to the conduct and operations of running clinical trials. This CTAG initiative brought together the academic and industry sectors ,over several months, and developed a series of recommendations in a report entitled "Clinically Competitive: boosting the business of clinical trials in Australia" [5] that have influenced clinical trial reform in Australia for the past decade. Notably, the recommendations gave roles to both the public sector and to industry, such

as recommendation K that specifically identified the establishment of the now defunct Pharmaceutical Industry Working Group (PIWG) as taking a leadership role in overseeing many of the reforms.

Recommendation K: That the Pharmaceutical Industry Working Group (PIWG) becomes a mechanism for relevant stakeholders to continue to have input into clinical trials policy and coordinate implementation of improvements by:

- NHMRC regularly reports the progress and success of the HoMER initiative; and periodically reviews the progress of the above recommendations.

However, the focus of the recommendations was very much on commercial clinical trial activity, and in 2012 the Medical Journal of Australia (MJA) convened a Summit led by Profs Steve Webb and John Simes to discuss an equivalent to the PIWG for the non-commercial sector. Picking up on Recommendation I in the CTAG report (NHMRC provide greater support for Clinical Trial Networks through firstly identifying them and secondly facilitating national coordination and collaboration across academia, clinical medicine and industry) the MJA Summit led to the creation of the Australian Clinical Trials Alliance (ACTA) which had its first meetings in 2013 and became a formally incorporated body in 2014.

It is beyond the scope of this review to catalogue the myriad of activities of both industry and ACTA since the CTAG report. However, there has been a positive and open dialogue. Both camps primarily operated on their areas of interest and worked together largely around streamlining governance and ethics. ACTA was awarded a Medical Research Future Fund (MRFF) grant [6] in 2017 to grow, strengthen and support Australia's investigator-led and registry data-informed clinical trials sector. The focus of that grant was directed toward supporting the Clinical Trial Networks; however, two activities were more broadly relevant to the academic and industry sectors. These were strengthening Consumer Engagement and Embedding Clinical Trials in health care. Whilst these activities showed strong outcomes, better engagement between industry and the academic sectors would have added further value to these activity areas.

Recognising the need to work more closely with industry, the MRFF 2020 Enhancing Clinical Trials Network Capabilities Grant includes an activity under workstream 5 'Facilitating Industry Funded/Sponsored Trials'. This workstream aims to facilitate opportunities for greater collaboration between ACTA members that include Clinical Trial Networks, Clinical Quality Registries, and Trial

Coordinating Centres (Academic) with the commercial (Industry) sector. There are two sub-components to workstream 5, namely:

5.1-Promote partnership between CTNs, CQRs and CCs with Industry.

5.2-Leverage expertise with CTNs and CCs by partnering with industry to assist with one or more trial designs, site-identification, and trial conduct for industry trials.

This work moves well beyond the original areas of mutual interest in the CTAG work, which focused on the barriers created by inefficient and often duplicative ethics and governance processes. Whilst these matters have not been entirely resolved, the scope of this ACTA work program is to explore opportunities for the academic and commercial sectors to work more closely together to derive mutual benefit for each other, but more importantly, for patients.

5.4 Aim/Scope of this report

The specific objective defined by ACTA for this report was to “Undertake an environmental scan including a detailed literature review of published and grey literature related to the conduct of clinical trials led by ACTA members and Industry in Australia with a focus on ways in which the two sectors are currently working together." As there is scant information in the literature, published or grey, this report has been extended to a high-level review of existing public-private collaborations in clinical trials in Australia and around the world. Environmental Scan: Current environment for industry and academic trial collaboration

5.5 Methodology

The environmental scan that we have conducted is aligned specifically with the objective set out in the ACTA work plan, namely to “Review existing approaches to building synergies and partnerships between investigator-led and industry clinical trials sectors and explore ways to improve partnerships and advance activities of mutual interest.” This review is not a systematic review of the literature but instead seeks to report on published and ‘grey’ literature that can provide contextual information that will inform the work plan for ACTA to build greater collaborative opportunities.

We used standard search engine approaches for the terms “Academic and industry trials collaborations” using PubMed, Google Scholar, Scopus and Web of Science and through a web search using google as the primary search engine. The source documents (journal articles, book chapters, web pages, government, Non-Government Organisation (NGO) and industry reports identified and used in the environmental scan are detailed in Appendix A.

5.6 Academic Literature

This environmental scan sought to identify academic publications providing examples where the two sectors have demonstrated effective collaboration or where there are programs aimed at achieving greater collaboration. Unfortunately, there is scant literature published in the academic world about this topic, and the papers that are published in academic journals have been essentially opinions and news items only. Some articles have critically examined the nature of industry sponsorship in academic-led clinical trials from the perspective of influence on the analysis and reporting of data. For instance, Rasmussen et al. (2018) [7] identified that whilst academic investigators may be involved in reports about clinical trials published in well-recognised medical journals, they reported that the data analysis was often conducted without their input and that whilst the collaboration was regarded as beneficial, they reported some loss of academic freedom. Similarly, in a recent review Gazendum, et al. (2022) [8] reported that "Industry-funded trials investigating biologic therapies are more likely to yield statistically significant positive outcomes and use placebo comparators when compared to non-industry-funded biologic therapy trials in high-impact medical journals." This review contrasts with a paper published earlier by Linker et al. (2017) [9] that did not find such an association in Randomised Controlled Trials (RCTs) in oncology in terms of reporting positive outcomes. However, they found that industry-funded trials were more likely to use placebo controls but used higher-quality methodologies overall. The authors identified enhanced scrutiny of possible bias as a reason for this and by the mandating registration of all trials on public registries since 2005 by the International Committee of Medical Journal Editors (ICMJE) on behalf of its participating journals.

In an opinion piece in the Journal of Oncology Practice in 2008, Bressler and Shilsky [10] from the Cancer and Leukemia Group B in the USA identified the barriers and enablers as well as the potential pitfalls of greater collaboration between investigator-led academic groups and industry. The Bressler opinion cited a prior opinion piece by Martine Piccart, a medical oncologist and former President of the European Organisation for Research and Treatment of Cancer (EORTC), that was published in Nature (2007) [11]. The Piccart paper described the potential concerns for industry-led clinical trials leading to biased outcomes and proposed that an arm's length approach be adopted and that academic trial groups should lead registration trials of unapproved therapeutic goods. Bressler and Shilsky endorsed this model and further outlined how it might be achieved. Since these were published, there have been only a handful of reviews of such academic-industry collaborations in Europe and the USA in the last decade.

A report on a workshop in 2010 led by the Institute of Medicine, one of the National Academies established by the National Academy of Sciences in the USA, identified some important challenges

facing the sector in bringing novel therapeutics through from development to market and beyond. The report "Extending the Spectrum of Precompetitive Collaboration in Oncology Research: Workshop Summary" [12] identified several important initiatives that had fostered greater collaboration between industry and academia with a focus mostly on drug discovery and preclinical testing. Specifically, they identified some key barriers such as differing standards in approach between the sectors with a risk that academic approaches would not meet regulatory standards and the work would need to be repeated. In addition, there was a clear culture of 'them and us' and some mutual distrust that needed to be overcome. The report noted several factors contributing to issues in bringing new drugs to market, and these included declining investment in R&D by industry and increased complexity in running trials that increased costs significantly. However, it was also noted that this drove efficiency, collaboration and increases in public data sharing, including initiatives such as the data sharing platform Clinical Study Data Request (CDSR) [13]. In a review paper, Kochhar et al. [14] noted that whilst this data sharing platform was valuable it was under-utilised and expensive to run. More than 50% of studies in the resource have never been accessed and it is unclear whether this is due to a lack of knowledge about them or lack of interest. Data sharing is a requirement of the NHMRC [15] and clinical research organisations in Australia have policies related to this, such as those of the VCCC [16]. An additional resource is Vivli [17], and a search reveals that there are over 600 Australian studies in this.

Another report from a 2010 workshop (Transforming Clinical Research in the United States Challenges and Opportunities: Workshop Summary) [18] summarised the outcomes from a meeting of clinical trial experts from academic research centres, pharmaceutical companies, contract research organisations, government, clinical research networks, and patient advocacy groups. These stakeholders came together to discuss their clinical trial successes and failures, the challenges they face in conducting clinical research, and strategies for improving the efficiency of clinical trials while maintaining the highest standards for the data generated. The workshop was focused on four disease areas: cardiovascular disease, depression, cancer, and diabetes and was limited to large, multisite Phase III trials, NIH trials that were not aimed at regulatory approval and on post-registration studies. The workshop examined the activities of the Clinical and Translational Science Awards (CTSA) Program, [19] the Clinical Trials Transformation Initiative (CTTI), [20] the National Institutes of Health's (NIH's) Roadmap for Medical Research [21] and international efforts aimed at enhancing clinical trials. The CTSA program has been running since 2006 and provides grants to consortium members to accelerate bench-to-bedside activities. Australia has no comparable activity as it is a national approach to improving clinical trial capability across 46 institutions in 26 states. The closest related activity would be the CTPRG and the proposed National One Stop Shop. CTTI is a public-private

partnership with an ambitious program described in the Transforming Trials 2030 [22] vision that aligns with many of ACTAs programs and those of CT:IQ. Critically, Janet Woodcock, the current FDA Principal Deputy Commissioner, identified the need for a national infrastructure to support clinical trial activities that would be like a highway system or electricity grid. Episodic and ad-hoc funding from individual trial activity does not enable a sustainable clinical trial environment. Interestingly, it was noted that unlike the UK, where the NIHR was made possible through a national universal healthcare system, the US had no underlying framework to implement such a vision. Australia does have a universal system and could build a national infrastructure.

In Europe, Stahel et al. (2020) [23] reported on the work of the Clinical Academic Cancer Research Forum (CAREFOR), that had formed an Industry Working Group to bring together industry and academia. They identified three tiers of capability for CTN based on their size and recognised that how they interact with industry will depend on their capabilities to conduct trials on their own. This variability in capability was seen as an issue because the lack of standardised practices meant that the industry had to negotiate independently using multiple operating frameworks, which is very inefficient. They also identified that academics do not 'consider concepts such as return on investment or the issue of 'sustainability' of the business in choosing how to invest but prioritise merely by scientific/patient merit.' They also identified the need to streamline trial start-up processes and that centralisation and eliminating duplicative processes were essential. They also noted that the EU Clinical Trial Directive (CTD), by creating distinctions between commercial and non-commercial sponsorship of trials, has created a barrier that hinders academic-industry partnerships. Chrysalis is aware of this occurring in Australia, where sites have incorrectly attributed industry sponsorship to industry supported CTN trials. The authors proposed four principles to guide interactions between academia and industry:

1. Clarify the roles and responsibilities of all partners involved in the study to generate a strong sense of belonging to a team.

2. Involve legal teams from an early stage to draft a contract with a clear vision of the study reflecting the needs of both parties.

3. Acknowledge that data is an important output of the study, and the creator of the data is its custodian bearing the responsibility concerning sharing it in the ultimate interest of the patient.

4. Agree on the intent of the trial before its start. If trial results indicate a societal/patient benefit bringing the study to registration, an agreement needs to be envisaged that meets

both the requirements of industry and academic cooperative groups noting that some issues (e.g., Informed Consent Form language) may not be able to be obtained from 100% of the patients retrospectively, while other contract areas (e.g. cost of data transfer) may be negotiated in later agreements subject to fair market value and other applicable regulations.

5.7 Non-Academic Literature

5.7.1 Australia

The Federal Government has created a series of websites after the CTAG report that relate to clinical trials and provide valuable resources. In particular, the Australian Clinical Trials [24] website, which is now operated by the Commonwealth Department of Health (noting that the NHMRC ceased all involvement in clinical trial improvement activities as of 30th June 2017). However, it does not provide any details about how industry and the academic sectors might work together and is more aimed at attracting overseas investors/industry to come to Australia to do clinical trials. The researcher section is focused on ethics and governance and whilst it contains comprehensive links to other websites provides no mechanisms or information to help create trials.

The Commonwealth Department of Health commissioned a report published in 2015 entitled "Analysis of recently conducted clinical trials" [25]. The purpose of the review was to:

"Conduct an in-depth analysis of recently conducted clinical trials in Australia to determine the critical success factors and/or reasons for the failure of clinical trials in Australia. The focus of the research was on pharmaceutical and medical device clinical trials conducted within (sic) the last five years that were commercially funded and conducted in more than one jurisdiction. "

The key barriers that industry reported in the reviewed documents were related to ongoing issues with single ethical review and governance approval. A significant contributor to failure was inaccurate feasibility assessments related to recruitment. Australia was seen as attractive because of the reputation of investigators and their ability to achieve recruitment, which appeared to contradict the finding that this was not always true. Australia was seen as very costly in conducting trials and the slow start-up times that were still prevalent caused concerns about attracting trials in this context. Despite the recommendation in the CTAG report to undertake a national pricing for clinical trial conduct, this was done through the Independent Hospital Pricing Authority (IHPA) (Determination of standardised costs associated with conducting clinical trials in Australia) [26] such standardised costs have yet to be achieved and it is widely reported that no one currently uses this guideline or indeed did so when it was published in 2015.

5.7.1.1 State and Territory Clinical Trial Initiatives

Although there is no published literature on State or Territory funded initiatives, a variety of websites can be found that mention clinical trial initiatives. Not one of the websites visited outlined how industry and academic sectors may work together and provide details not dissimilar to a 'tourist brochure', giving information about potential clinical trial services that investors may wish to use. A summary of these sites with their links is provided in table 1.

Table 1: Stand territory clinical trial initiatives.

State/Territory	Website	Comment
Australian Capital Territory	https://www.health.act.gov.au/research/research-ethics-and-governance/clinical-trials [27]	High level information about ethics and governance processes and sites.
New South Wales	NSW Health & Medical Research | clinicaltrialsNSW [28]	High level information about ethics and governance processes and sites.
Northern Territory	https://nt.gov.au/wellbeing/cancer-services/cancer-clinical-trials [29]	Very little relevant information other than they are involved in Cancer trials.
Queensland	https://clinicaltrialsqld.com/ [30]	High level information about ethics and governance processes and sites.
South Australia	https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/health+and+medical+research/clinical+trials/clinical+trials [31] and https://adelaidebiomedcity.com/clinical-trials/ [32]	High level information about processes and sites. Adelaide Biomed city has more detail on using them-mostly advertising to be used.
Tasmania	https://www.health.tas.gov.au/about/research/clinical-trials [33]	High level information about ethics and governance processes and sites.

Victoria	https://www.clinicaltrialsandresearch.vic.gov.au/ [34] and https://victrials.com.au/ [35]	High level information about ethics and governance processes and sites. VCT Gateway is directed at attracting industry trials but provides no resources about collaboration.
Western Australia	No specific trial information	No information.

None of these websites provides resources that illustrate how industry can work with academia, and all sites are focused on bringing ready-to-go industry trials to a state or territory site. In the Health and Medical Industries report [36] for South Australia, a key enabler identified was the SA Health Clinical Trial Portal, and a tender has gone out recently (April 2022). Detail in this report on how this portal will work to attract more trials or any detail about promoting greater collaboration between academic and industry-led trials sectors would be valuable.

5.7.1.2 The National One-Stop-Shop

A consultation about this initiative is being led by the ACSQHC and all the jurisdictions (under the Clinical Trials Jurisdictional Working Group (CTJWG)). The aim of the National One-Stop-Shop (NOSS) [37] is to facilitate clinical research, and in particular clinical trials. It is envisaged that the NOSS will provide a single national platform to manage ethics and governance approvals and enable greater integration with TGA resources, the Office of the Gene Technology Regulator (OGTR) and the Australia New Zealand Clinical Trials Registry (ANZCTR). It will also provide a means to generate reports about clinical trial activity that are hard to obtain. In addition, consideration is being given to a 'National Clinical Trials Front Door' to facilitate connecting the community to researchers. The Medicine Australia Research & Development Taskforce (RDTF) strongly supports the initiative and recognises the opportunities it may deliver. It is important to balance the enthusiasm for this concept with the practical reality that, to date, there has been very slow progress made on initiatives such as the harmonisation of multicentre ethics, and there remain many areas of inconsistency between jurisdictions despite the best intentions of the National Mutual Acceptance (NMA). If the NOSS could solve this, it would be of enormous benefit to the sector broadly, but the timeline for implementation is uncertain, and will require a significant investment to make it a reality.

5.7.1.3 ACTA trial resources

ACTA has worked to develop a range of online trial resources, and some of its main products from the first round of MRFF funding include the Consumer Involvement and Engagement Toolkit [38], which it co-developed with CT:IQ. The toolkit is relevant to academic and industry sectors and

provides practical tools to assist both sectors separately and as collaborators. Similarly, the Embedding clinical trial resources [39] are useful to all clinical trial activities regardless of the sector, although there is an emphasis on comparative effectiveness trials. Additional activities that would provide value to industry include the health and economic return on investment work and innovative trial design and data activities.

5.7.1.4 CT:IQ

The Clinical Trials: Impact and Quality (CT:IQ) [40] initiative was established "to develop and implement recommendations that will improve the impact, quality and efficiency of clinical trials, leading to more rapid, lower cost and higher quality evaluation of healthcare interventions in Australia". It is an excellent example of public and private partnership and brings together industry, academia, government and regulators and provides consumer engagement opportunities. The aim of CT:IQ is not to develop specific clinical trials or be involved in their conduct but instead to undertake joint projects that will be relevant to the sector, such as developing resources for the use of eConsent, the Consumer Involvement and Engagement Toolkit (which it produced jointly with ACTA) and ways to optimise clinical trial site recruitment.

5.7.1.5 Academic-University led initiatives

We were only able to identify one article that proposed greater industry-academic partnership for clinical trials, and this was a report on the Australian Cardiovascular Alliance (ACvA) [41] - roundtable discussions in 2019 entitled "Building an Academic—Industry Partnership to Tackle Australia's Biggest Health Burden" [42]. In many respects, they proposed a National Front Door for cardiovascular research covering all aspects, including but not limited to clinical trials. The consortium is working toward a Coronary Artery Disease (CAD) Frontiers grant which will include an Industry Roundtable.

5.7.1.6 Industry reports

In Australia, there is a long history of Clinical Trial Networks (CTNs) working with industry on joint ventures, but this has been related to the industry providing investigational products and/or financial support for specific trials. The relationships built have yet to be coordinated by a central body and depend on leaders of the CTN to foster links. No publicly available guidance documents exist on any CTN website or publications about how such collaborations have been conducted.

Several reports have been published about the clinical trial sector in the last ten years, but they have yet to specifically address elements of direct collaboration between industry and academic trial activities. Instead, they describe the operations and challenges they face separately, even though many of the challenges, primarily related to research governance and site processes, are common to

both. For instance, a report [43] on recruitment and retention in clinical trials by Ernst and Young in 2016, commissioned by the CTJWG (Now the CTPRG) was focused on patient recruitment into clinical trials. It made 14 recommendations to address the issue of recruitment and retention. Several of the recommendations are pertinent to both academic and industry clinical trials sectors, e.g.:

Recommendation 7: The CTJWG is to work with jurisdictions to progress ongoing and long-term roles for research nurses, support the inclusion of clinical research into job descriptions for clinicians, and embed the need for ongoing site training and mentorship in running clinical trials.

A skilled workforce to conduct clinical trials at sites is in the interests of the entire sector. However, the CTJWG needs more influence to make this happen at sites, and certainly not without any dedicated budget to support it. As a result, this has not happened.

Recommendation 8: The CTJWG, the NHMRC and research entities focus on clinical trial recruitment and retention strategies in special groups such as culturally and linguistically diverse (CALD) communities, youth, Indigenous Australians, rural and remote communities, and people with a mental illness. Focused strategies to be developed for cognitively impaired potential trial participants, supported by advice to jurisdictions on guardianship legislation as an enabler of recruitment.

This has become a major focus of the funding agencies and is a key criterion for assessment for funding clinical trials. However, there is no specific incentive for industry trials to address this in Australia, and the current frameworks and resources available at sites mitigate such inclusion.

Recommendation 9: Over the short term, the CTJWG to work with the NHMRC and the Australian Government Department of Health to devise an online leading practice guide to the successful design, management, administration and conduct of clinical trials, starting with the creation of a culture that embeds clinical trials within leading practice clinical care and reflecting the primary consideration of safety for clinical trial participants. This resource should be continuously reviewed and updated and could include a set of tools for practical implementation.

The CTJWG or NHMRC are in a position to create such a resource; no work besides that done by ACTA has addressed this.

The MedTech and Pharma Growth Centre (MTPConnect) have published a report each year called the "Medical Technology, Biotechnology and Pharmaceutical Competitiveness Plan" [1], the most recently published in April 2022. From its inception in 2015, MTPConnect, as an independent Not-for-

Profit Growth Centre, has worked to build Australian competitiveness and investment across the sectors they represent. Importantly, MTPConnect has provided a model of how the academic and industry sectors may be brought together to work toward common goals. Although their priorities are more diverse than just clinical trials, this is Priority 4 of 7 sector priorities that they identify. The MTPConnect report needs to touch on how the academic and industry trials sectors might work more together and only identifies delays in governance as a matter of importance.

The MTPConnect report provides a high-level summary of R&D expenditure across the sector, but it is impossible to derive how much is dedicated to clinical trials. In the 2022 report, it is stated that Australia's clinical trial industry contributes $1.4 billion to Australia's economy annually (2019 figure), although it is not clear how this figure is derived. The 2021 report states that clinical trials offset the cost of care at sites when this is not an accurate representation of how trials are costed and operated in the real world. Sponsors will only pay for activities and procedures that are in addition to Standard of Care (SoC) and sites will often take extra time in negotiating budgets due to this issue. There have been reports of hospitals, Medicare and health funds not wishing to pay for standard of care (SoC) procedures on a trial and this arises where there is no clear definition of SoC. Indeed, it is a major cause of trial start-up delay. The additional costs of trial activity in academic-led trials are often not fully costed, and there is limited funding to pay for them.

5.7.2 International Activities

It is challenging to find country-specific information related to academic/industry clinical trial collaborations unless individual countries have a dedicated national clinical trial resource like the UK. A great deal of the collaborations found related to industry working with academics to take their discoveries into early phase trials and beyond. This is therefore collaboration between life science technology researchers and industry rather than between academic and industry clinical trial teams.

5.7.2.1 United Kingdom

In the UK, the National Institute for Health and Care Research (NIHR) has established a national resource to support the life science industry to partner and collaborate with the National Health Service (NHS) and social care services. A dedicated web portal [44] functions as a 'front door' or 'One Stop Shop' that is user-friendly and directed toward fostering engagement. The major services are:

- Assistance in running commercial studies in the NHS
- A service to assist the MedTech sector in translating their innovations into the clinical setting
- Interactive costing tool for transparent budget negotiation
- Single point of contact and Industry Engagement Managers across each local network
- Access to expertise within the NHS as well as for patient engagement.

This support is underpinned by dedicated funding, including access to grant funding provided by the NIHR to support collaboration. There is also a dedicated resource to foster collaboration that includes joint funding for researcher career development (NIHR Academy, [45] established in 2018) and tools to assist industry in accessing facilities and infrastructure such as data, analytical support and biospecimens. A specific feature of the NIHR resource is the Translational Research Collaborations [46] network of universities, NHS Trusts and research centres that industry can reach out to for early-phase translational research. The eight collaborations/partnerships span the major disease conditions such as oncology, cardiovascular and respiratory diseases. A statistical service is embedded into this overall resource to facilitate clinical research design.

The NIHR-BioResource [47] infrastructure is a single database of patients who have given consent to access their data and specimens. The website includes a dedicated page for Industry researchers [48]; however, the cost to access this is relatively high by Australian standards (12,000 GBP just to set up an account and then 3,630 GBP for each site to be accessed. A saliva sample is 285 GBP. Comparable Australian costs for saliva from state-run biobanks have historically been under $50).

None of the Australian biobanks currently publish their fees for access to samples. No comparable Australian service provides a national coordination service to access patient data or samples for industry or academia. The State-wide Victorian Cancer Biobank (VCB) [49] only manages specimens and data from people diagnosed with cancer and only from select collection sites. The NSW Health Statewide Biobank [50] provides services to researchers to assist with biospecimen collection, processing and storage but is not responsible for the collections but provides resources to support both biobankers and researchers to facilitate biospecimen access and use.

5.7.2.2 United States of America

We were unable to identify a central website or resources, but from the academic reports reviewed in this report, it was clear that there is an extensive discussion between industry and academic trial groups. Moreover, the National Institute of Health (NIH) has dedicated funding activity for Academic-Industrial Partnerships where clinical trials may be considered.

Name	Website	Comments
Clinical Trials Transformation Initiative (CTTI)	https://ctti-clinicaltrials.org/who_we_are/transforming-trials-2030/ [22]	A public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration is a dedicated group of individuals and organisations who want to change and improve clinical trials. Representation/Collaboration from public and private sectors (members) [51].

		Vision BY 2030: Clinical trials are patient-centred and easily accessible. Clinical trials are fully integrated into health processes. Clinical trials are designed with a quality approach. Clinical trials maximally leverage available clinical and non-clinical data, including data collected via digital technologies, to minimise collection of necessary trial specific data. Clinical trials contribute knowledge about how to prevent, diagnose, and treat disease, and clinical trials are one of many sources of information that can be acted upon to improve population health. CTTI has issued more than 30 sets of evidence-based recommendations and associated frameworks and tools to inform and drive change across the research community in areas including: • Quality by Design https://ctti-clinicaltrials.org/our-work/quality/quality-by-design/ [52] • Novel Clinical Trial Designs https://ctti-clinicaltrials.org/our-work/novel-clinical-trial-designs/ [53] • Patient Engagement https://ctti-clinicaltrials.org/our-work/patient-engagement/ [54] • Strengthening Investigator Site community https://ctti-clinicaltrials.org/wp-content/uploads/2020/01/investigator_community_recommendations_final_1.pdf [55] • Ethics and Human Research Protection https://ctti-clinicaltrials.org/our-work/ethics-and-human-research-protection/ [56]

5.7.2.3 Canada

There is a robust clinical trials environment in Canada. According to the association of the British Pharmaceutical Industry Canada ranks 9th in terms of the number of Phase I trials globally, and 8th in terms of the number of trials in Phase II and Phase III. Canada is the G7 leader in clinic trials productivity. Details can be found on a dedicated government website [57] outlining their support for clinical trials.

Canadian Clinical Trials Coordinating Centre (CCTCC) - government-funded, central coordinating agency created to improve clinical trial landscape and implement recommendations summarised here [58].

The Canadian Cancer Trials Group states on their website [59], to have industry partnerships with pharmaceutical and drug manufacturers where they have access to their investigational new drugs.

5.7.2.4 New Zealand

There is a low level of university-industry collaboration (UIC) in New Zealand, according to a report released by Universities New Zealand and Deloitte Access Economics [60]. Based on a 2017 Organisation for Economic Co-operation and Development (OECD) survey of small and medium enterprises, only about 5% of NZ firms collaborate with higher education or research institutes, putting New Zealand at 29th out of 33 OECD countries.

The article also describes the five key success factors that are required for building successful collaborations:

- **Developing long-term strategic relationships with ongoing interaction**—collaboration is aligned with the strategic interests of firms while giving universities research funding, improved curriculum relevancy and experience for students
- **Making a two-way exchange**—going beyond funding to share infrastructure and equipment
- **Encouraging new avenues for innovation**—using individual industry managers to forge links across the university to develop new areas for innovation for their companies
- **Building strong communication links between university and industry**—regular site visits, and maintaining university-industry contact during and after projects increases the likelihood of future collaboration
- Establishing clear guidelines around intellectual property ownership early.

The University of Auckland is one of the members of the EpiGen Global Research Consortium [61],

which was established in 2006 with the Human Development and Health Academic Unit, University of Southampton, the MRC Lifecourse Epidemiology Unit, University of Southampton, Singapore Institute for Clinical Sciences and the National University of Singapore. Among its many roles is promoting commercial partnerships to support academic research.

5.7.2.5 Europe

The European Commission (EU), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have recently launched an initiative to transform clinical trials within Europe: Accelerating Clinical Trials in the EU (ACT EU) [62].

The ACT EU will build on the Clinical Trials Regulation and the recently launched (31 Jan 2022) Clinical Trials Information System (CTIS).

In Europe, about 40% of clinical trials are sponsored by academia, while the other 60% are by the pharmaceutical industry. The paper acknowledges that both groups 'need greater support and enablement for Europe to flourish as a global focus for clinical research', but does not emphasise the need for collaboration between academia and industry.

The Pharmaceutical Strategy for Europe 2020 [63] acknowledges the need to enable collaboration amongst various stakeholders, including academia, to meet the needs of patients and health systems.

5.7.2.6 Japan

Department of Industrial-Academic Collaboration [64] – is part of the Japan Agency for Medical Research and Development. Little information is shared on the website about how this department facilitates this collaboration or where to go next. The focus of the support is both on the early pre-clinical phases of Research and Development, and on Proof of concept in human subjects, through to clinical efficacy trials. They provide one example of such a collaboration in a news article but no other information.

Centre for Clinical and Translational Research (CCTR) [65] has set up the West Japan Academia Translational Research Network (WAT-NeW) and the Asia-Pacific Research and Development Network (ARDENT) to facilitate industry -academia collaboration.

5.7.2.7 Singapore

Singapore's Ministry of Health established the Consortium for Clinical Research and Innovation, Singapore (CRIS) [66], on the 6th of April 2022. It brings together five national R&D, clinical translation and service initiatives that are under the stewardship of the Ministry of Health: Singapore Clinical

Research Institute (SCRI), National Health Innovation Centre, Singapore (NHIC), Advanced Cell Therapy and Research Institute, Singapore (ACTRIS), Precision Health Research, Singapore (PRECISE), Singapore Translational Cancer Consortium (STCC).

One of the objectives of CRIS is to foster industry engagement and build networks and collaborations for clinical trials in the region.

5.7.3 Industry-led Initiatives

Table 2 summarises industry websites supporting the academic sector to undertake research, including clinical trials. The type of support is primarily funding or provision of therapeutic products (in a strategic area of interest) or both. A few offer collaboration arrangement, although details are not provided on the websites.

Table 2 Summary of Industry support for investigator-led clinical trials

Company	Website	Comment
AbbVie	https://www.abbvie.com/partnerships/additional-collaboration-opportunities/investigator-initiated-studies-iis.html [67]	The AbbVie IIS Program – is for academic and community-based physicians and researchers worldwide interested in conducting their research with AbbVie-associated products. Does not specify clinical trials Applications via the IIS Study Submission Portal.
Astellas	https://www.astellas.com/en/partnering/for-academics [68]	Provides an online form to apply to partner with them in research. Aimed at drug discovery. Not specific to clinical trials.
AstraZeneca	https://www.astrazeneca.com/partnering/externally-sponsored-scientific-research.html [69]	Provides an online form to request funding for interventional clinical research (Phase I-IV) involving authorised, unauthorised or discontinued AstraZeneca compounds no longer being developed.
Bayer	https://www.bayer.com/en/innovation/research-and-development [70]	Details of their Driving Open innovation programs and partnering are not accessible to the public.

Baxter	https://www.baxterhealthcare.com.au/our-story/fueling-collaborative-innovation/research-continuing-education-grants [71]	Provide funding and/or product support, as well as potential specialised services. Support for clinical and pre-clinical studies FAQs are also available.
Boehringer Ingelheim	https://www.boehringer-ingelheim.com.au/innovation/innovation/funding-opportunities [72]	Provides two types of funding support for organisation and research studies: Investigator-Initiated Studies (IIS) & Medical Education Grants.
Bristol Myers Squibb (BMS) (Celgene) (Australia)	https://www.celgene.com.au/research-development/clinical-trials/investigator-initiated-trials/ [73]	Investigator-initiated trials - Supports clinical and translational research in diseases related to the company's current and future areas of interest. Types of support not described on the website.
CSL Behring (US link)	https://www.cslbehring.com/r-and-d/awards-and-grants/investigator-initiated-studies [74]	Provide funding/drug supply for Investigator-Initiated Studies (IIS) that advance medical and scientific knowledge of CSL Behring products and the diseases they are designed to treat.
Eli Lilly	https://www.lillyinvestigatorresearch.com/ [75]	Programs financial support for external researchers for projects that strategically fit with Lilly's area of research interest.
Gilead (US link)	https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research#ISR [76]	Provide support through Investigator-Sponsored Research (ISR) Grant Program. Gilead provides ISR grants primarily in their therapeutic areas of expertise. Types of support are not described on the page.
GlaxoSmithKline (GSK)	https://www.gsk.com/en-gb/research-and-development/partnerships/supported-studies/	Investigator-Sponsored Studies/Trials - GSK provides support in the form of funding, products (including GSK products, adjuvants for vaccines, placebo, or other

	[77]	medicinal products necessary for the research) or both. **Collaborative Studies** (research sponsored and conducted by an external sponsor) - GSK provided support by contributing to study design and deliverables add the provision of funds and /or products. Under specific circumstances, GSK may also provide specialised capabilities or activities.
Johnson & Johnson (US link)	https://jnjmd-iis-portal.idea-point.com/Home.aspx [78]	J & J medical device companies - research funding and/or product support for investigator-initiated research (clinical and scientific).
Merck	https://www.merckgroup.com/company/responsibility/en/ISS-Principle-EN.pdf [79] https://www.merckgroup.com/en/partnering/collaboration/collaboration-in-healthcare.html [80]	Investigator Sponsored Studies (ISS) Committed to the principle of "smarter together," Merck welcomes the opportunity to work with and support external investigators. In principle document (dated 2018) is only accessible - link to further information broken. Partnering with healthcare is focused on early-stage licensing opportunities, new technology or strategic research alliance. No mention of clinical trials.
Moderna	https://trials.modernatx.com/for-researchers/ [81]	Partner and sponsor Healthcare Professionals in clinical trials. Not much detail but it has a Site Registry Form.
Novartis	https://www.novartis.com/sites/novartis_com/files/novartis-investigator-initiated-trials.pdf [82]	Provides funding, drug product or both. Investigator Initiated Trials (IITs) and Investigator Initiated Research (IIRs). Support clinical and non-clinical research in strategic areas of interest. Online applications for unsolicited IIT requests.
Novo Nordisk	https://www.novonordisk.com/partnering-and-open-innovation/our-approach-to-partnering.html [83]	States that they partner with universities, biotech companies, individual scientists and entrepreneurs but does not indicate if there are funding or grant programs.

Otsuka	https://otsuka.com.au/research/ [84]	No information available on investigator-initiated support programs.
Pfizer	https://www.pfizer.com/about/programs-policies/grants/investigator-sponsored-research [85] https://www.cybergrants.com/pfizer/Research/GMG_ResearchApplication_ExternalPreview.pdf [86]	Provides financial and/or non-financial support through Investigator Sponsored Research (ISR) grants. Grant is for pre-clinical and clinical studies (including interventional and non-interventional), that involve a Pfizer asset (e.g., commercial drug, investigational drug, pure compound). Types of non-financial support are not described on the page. The grant requester is responsible for the independent initiative's design, implementation, sponsorship, and conduct.
Roche	https://www.roche.com/innovation/process/clinical-trials/investigator-initiated-studies [87]	Support for investigator-initiated studies (IIS) includes drug supply, funding, material and/or information, provided they align with the company defined areas of strategic interest. The sponsor/investigator has to fulfil (or agree to) requirements, including: • Having the scientific, technical and operational capabilities to conduct a study as a sponsor, including adequately trained staff to execute a study (GCP, GMP, etc.) • Have expert statistical support submit a scientifically well- designed and well-written study proposal.
Sanofi	https://www.sanofi.com/en/science-and-innovation/clinical-trials-and-results/investigator-sponsored-studies [88]	Accepts and reviews unsolicited proposals from health care professionals (HCPs), scientists, and researchers or institutions (i.e., external sponsor) for research support. Two types of proposals: 1. Investigator Sponsored Studies/Trials (ISS)/(IST) 2. Externally Sponsored Collaborations (ESC) conducted in collaboration with an institution or

		organisation (the external sponsor must not be a pharmaceutical company nor a vendor. Individual investigators are not eligible to enter into an ESC with Sanofi). Support includes funding, and drug supply (collaboration - protocol development). Support provided is not defined on the website.
Takeda (Global, Japan based)	https://www.takeda.com/en-au/what-we-do/research--development/Supporting-Scientific-Community/investigator-initiated-research/ [89]	Investigator Initiated Research (IIR) program supports innovative interventional, non-interventional, and basic science studies that address important medical and scientific questions related to our compounds and IIR areas of interest. Takeda provides supports such as funding, study product, safety information and/or authorisation to reference Takeda's NDA or other regulatory submissions (e.g., IND). Takeda reviews completed proposals both within and outside of the areas of interest. Decisions are based upon scientific merit, alignment with research areas of interest and availability of resources.

6 Summary

Overall, there is a minimal amount of literature regarding public-private partnerships for clinical trial activities and none specific to Australia. Most of the literature identified was obtained from government reports or websites. The academic literature has been either opinion or policy statements about the role of industry in clinical trials or has explored how industry sponsorship has influenced reporting of trials. This latter commentary is somewhat controversial as it has implied that direct or indirect sponsorship may influence reporting of trial outcomes. However, on balance no negative allegations have been substantiated and the checks and balances imposed by regulators, review boards and institutions make this very unlikely.

There is, therefore, a great deal of opportunity to explore ways to enhance academic and industry partnerships and the roundtable held by ACTA as part of this project has identified some areas to work on together. The activities that Australia chooses to work on will differ from those of other jurisdictions due to how health services are delivered here (public vs private, state and territory versus commonwealth management and policies). That is, models in other countries may provide some guidance but are not necessarily translatable to the Australian context. Nevertheless, some key findings are relevant to ACTA's work, in particular, understanding the needs of industry and how their existing pathways for collaboration work. As part of this program of work, ACTA should ensure that it produces accessible outputs describing the initiatives, including clear examples of how to foster greater collaboration.

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