

**South Australian Productivity Commission  
2020 Health and Medical Research Inquiry**

**Submission from the  
Adelaide BioMed City Clinical Trials Expert Taskforce**

**Committee Members**

<b>Chair:</b>	Prof John Beltrame
<b>Adelaide BioMed City:</b>	Yvette Van Eenennaam Dr Tamara Leclercq
<b>CALHN:</b>	Prof Guy Ludbrook (PARC) Bernadette Swart Dr Elena Voss
<b>SAHMRI:</b>	Prof Tim Hughes Liddy Griffith
<b>University of Adelaide:</b>	Prof Paul Rolan
<b>University of SA:</b>	Prof Susan Hillier Prof Alan Boddy Greg Sharplin

## Background

- Clinical Trials are the foundation of evidence-based medicine, improving our understanding of clinical disorders and the source of therapeutic medical advances.
- The World Health Organisation definition of ‘clinical trials’ includes ‘*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes*’. These health-related interventions may include medications, biological products, vaccines, medical devices, surgical procedures, psychotherapeutic/behavioural therapies, health service modification, preventative care strategies and educational plan.
- From an administrative perspective, clinical trials are best considered in relation to their funding source, i.e. industry-sponsored or investigator-initiated clinical trials. The features of these clinical trial types are summarised below.

Industry Sponsored Clinical Trials	Investigator-initiated Clinical Trials
<b>Financial Implications</b> <ul style="list-style-type: none"> <li>• Funding Source - For-profit company</li> <li>• IP belongs to industry sponsor</li> <li>• Milestone-based funding</li> </ul>	<ul style="list-style-type: none"> <li>• For-profit, non-profit, or govt grant agency</li> <li>• IP for investigator institution/granting body</li> <li>• Grant funds as per award schedule</li> </ul>
<b>Clinical Trial Design</b> <ul style="list-style-type: none"> <li>• Phase I-IV studies, mainly multicentre</li> <li>• Monitor – Contract Research Organisation (CRO), HREC</li> </ul>	<ul style="list-style-type: none"> <li>• Phase I-IV studies, multicentre, often 1 site</li> <li>• Monitor – HREC annual review</li> </ul>
<b>Implications for Researcher</b> <ul style="list-style-type: none"> <li>• Study aims/design by sponsor</li> <li>• Funding source for research staff</li> <li>• Funds managed via hospital SPF /Uni</li> <li>• Often employ hospital staff</li> </ul>	<ul style="list-style-type: none"> <li>• Study aims/design by researcher</li> <li>• Grant funds often insufficient for project</li> <li>• Funds managed by grant admin (ie Uni)</li> <li>• Barriers if employ Uni/SAHMRI staff</li> </ul>
<b>Implications for Health Service</b> <ul style="list-style-type: none"> <li>• Patient access to new therapies at no cost</li> <li>• Randomised ‘Usual Care’ often subsidised</li> <li>• Kudos – limited, as one of many centres</li> <li>• IP – no access</li> <li>• Governance fees support Research Office</li> </ul>	<ul style="list-style-type: none"> <li>• Patient access new/repurposed therapies</li> <li>• Randomised ‘Usual care’ not subsidised</li> <li>• Kudos – original research</li> <li>• IP – possible partner</li> <li>• Facilitate Staff Attraction &amp; Retention</li> </ul>
<b>Research Training</b> <ul style="list-style-type: none"> <li>• Good Clinical Practice – mandatory</li> <li>• Limited training. Potentially involve registrars</li> </ul>	<ul style="list-style-type: none"> <li>• Good Clinical Practice – mandatory in 2021</li> <li>• Important opportunity for MD/PhD students</li> </ul>

## Adelaide BioMed City Precinct Clinical Trial Facilities

- The precinct is uniquely constituted of a range of clinical trial facilities providing a variety of services. These are located within the precinct with the largest quaternary institution in South Australia (RAH), extensive basic laboratory facilities (SAHMRI, University of Adelaide and University of South Australia), accessibility to University research students, and adjacent to a large independent Phase I-II clinical trial facility (CMAX). The key facilities are detailed below.
- PARC. This 12-bed multi-user facility has an international reputation and is located within the RAH intensive Care Unit. It is particularly adept to undertaking high acuity clinical trials requiring invasive monitoring or interventions. The PARC team has been established for over 10 years and has recently transitioned from the University of Adelaide to CALHN.
- RAH Clinical Trials Centre. This purpose-built 10 room facility is ideally located to provide an outpatient clinical trial service. Indeed, its location is so ideal that it is current been commandeered as the Hospital COVID-19 clinic.
- SAHMRI Clinical Trials Unit. This 6-room facility is well located for outpatient clinical trials and close to research laboratory & imaging facilities.
- University of Adelaide Health & Medical School. This 14-bed facility is located in the Adelaide Health & Medical School Building and has gamma camera facilities and a gait laboratory. It has specialised skills, equipment and facilities for assessing brain function, electrophysiology, gastrointestinal manometry and studies in pain. It has a self-contained laboratory for sample processing. It is well suited to undertaking studies on healthy individuals as well as ambulatory patient studies. It is suitable for clinical projects to be led by students under supervision.
- UniSA Clinical Trials. UniSA's multi-purpose Facility supports industry funded and investigator-led trials in healthy volunteers and patients across the Adelaide BioMed City precinct. Located at UniSA's City East Campus the Facility provides purpose-built, dedicated clinical research spaces and expertise including: 10 clinic rooms; neurophysiology and exercise physiology suites; open multi-purpose space; volunteer kitchen; analytical laboratory; and monitored ultra-cold storage facility.

## Adelaide BioMed City Clinical Trials Expert Taskforce

- The Adelaide BioMed City (ABMC) Partners established the ABMC Clinical Trials Expert Taskforce in 2018 with the objective to *'facilitate a collaborative and coordinated approach in attracting and undertaking clinical research studies in the clinical trial facilities of Adelaide BioMed City Partners'*.
- The Taskforce committee has representatives from the Partner institutions including CALHN, SAHMRI, University of Adelaide and University of South Australia. The representatives have expertise in both industry & investigator-initiated clinical trials, as well as research governance.
- Achievements of the group to date include:
  - Identifying the clinical trial facilities available within the biomedical research precinct
  - Listing of senior clinical trial researchers within precinct
  - Internal sharing of clinical trial cost templates
  - Providing a forum for national & international research organisations and research support organisations to discuss their activities/products with senior precinct clinical researchers.
  - Clinical Trial Management System options & variability amongst precinct organisations
  - Establish the ABMC Clinical Trials website (<https://adelaidebiomedcity.com/clinical-trials/>)
  - Utilising the ABMC Clinical Trials website as a contact portal for research organisations

- Ongoing focus areas for the committee include:
  - 1. Improving Awareness of ABMC Clinical Trials**
    - Promoting/Marketing the Website
    - Updating the list of Investigators on the Website
  - 2. Promoting Collaboration Amongst ABMC Clinical Trialists.**
    - Sharing template of clinical trial costs
    - Establish Central Pool of Clinical Trial Co-ordinators
  - 3. Strengthening the ‘Competitive Edge’ of ABMC Clinical Trials**
    - Clinical Trial Staff Credentialing
    - High Profile Investigators
    - Database of Healthy Volunteers
    - Disease-focussed Database of Potential Patient Participants
    - Research Student Participation (PhD, medical, nursing)
- *Value of the ABMC Clinical Trials Website.* This has attracted significant attention, with enquiries both from research organisations and patients eager to participate in clinical trials. The website also provides information on the available facilities and governance processes. It requires more marketing so that organisations are aware of its availability.

**Adelaide BioMed City** HOME ABOUT PARTNERS **CLINICAL TRIALS** RESEARCH GOVERNANCE RESEARCH PLATFORMS

Adelaide BioMed City is an integrated multi-facility campus for undertaking clinical trials to the highest international standards

**Why conduct clinical trials at Adelaide BioMed City?**

- World-class facilities, expertise and support
- Outstanding researchers delivering innovation and integrity
- Robust pipeline of research activities – basic research, clinical studies, health services and public health research
- Expert community of medical staff and life scientists
- Specialist capabilities – including medical imaging and high acuity
- Integrated partnership between the new Royal Adelaide Hospital, SAHMRJ, the University of Adelaide and the University of South Australia
- Key industry relationships including CMAX and national and international Clinical Research Organizations

Adelaide BioMed City Clinical Trials Website (<https://adelaidebiomedcity.com/clinical-trials/>)

## 1. Policy Environment

- Have recent reforms to ethics approvals processes (eg mutual acceptance), been successful?

The National Mutual Acceptance (NMA) was an initiative to expedite ethics approval of industry-sponsored clinical trials. This has been achieved, with many of these trials now being approved by Eastern States ethics committees, with recognition in SA via NMA.

This has several ramifications for South Australia. Firstly, these trials are being centrally administered by key (Eastern State) investigators, who have obtained the ethics approval. Accordingly, those sites are well supported and remunerated by the industry sponsor. Secondly, prior to NMA, each institutional ethics committee would invoice for its services but that revenue pathway has been curtailed. Thus, alternative support for the LHN research office must be found. Thirdly, the ethics committee chair frequently reviews these decisions and has on occasions disagreed with the original ethics committee decision. This then is managed via LHN governance approval process, which remains specific to the hospital.

## 2. Workforce.

- What connections are there between SA Health and university workforces?

As implied in the table above, industry-sponsored trials are generally conducted within the auspices of the hospital, whereas grant-sponsored clinical trials relate to both the hospital and university. The Clinical Academics are also an important link between hospital & university, typically supervising both industry-sponsored & investigator-initiated trials.

There is an opportunity for the Universities and hospital to collaborate on clinical trial training standards. In 2021, all clinical trial staff will be required to have completed Good Clinical Practice (GCP) training. The Universities, as our major education establishments, are well placed to provide this training both to undergraduate (eg BHealth Science) and post-graduate students (eg PhD training), as well as providing dedicated courses for hospital staff.

## 3. Infrastructure

- How well is existing SA public and private HMR infrastructure being utilised?

CMAX is a large private clinical trial centre, located across the road from the RAH. This very successful and productive organisation has its roots in the old-RAH. Thus, it has a close collaboration with RAH staff, with hospital staff involved in its operation. As a consequence, there is cross-referral of projects between the organisations. This is particularly relevant for PARC, given that this facility is well suited to undertaking invasive studies.

## 4. Collaboration

- Are current levels of collaboration by SA researchers/institutions optimal?

Although the ABMC precinct institutions are centrally located, they could collaborate better. Barriers to collaboration include competitive rather than collaborative administrations and limited awareness of research activities within the precinct.

- What steps could be taken to enhance collaboration amongst research institutions?

Some of the innovation being initiated by the ABMC Clinical Trials Expert Taskforce include:

1. The *ABMC Clinical Trials website* is a conduit for facilitating collaboration since all the precinct researchers are listed on a common site, with readily available biosketches. This information is not only of value to external research organisations but also provides local researchers with information on the available skillsets in the precinct.
2. A *stocktake of research equipment* available within the precinct has been previously undertaken but should be updated. This will facilitate sharing of specialised resources.

3. *Recruitment databases* for healthy volunteers and potential clinical trial patients.
4. *Study Coordinator Database*, which will communicate to investigators, details of potential available study coordinators and will also provide a portal for investigators to advertise potential available positions.

## 5. Translation of Research

- What are the opportunities & barriers to commercialisation of HMR?

The ABMC precinct has world class research facilities, esteemed clinical researchers, a large cohort of hospitalised patients, PARC, dedicated clinical trials centres, and a wide-spectrum of clinical activity including some whole of State services (eg Burns unit). These facilities and staff provide a tremendous environment for clinical research and thus the opportunity to develop novel IP and thus commercialisation.

In contrast, the following barriers limit the capacity to undertake clinical trials, thereby reducing research productivity and the potential to develop novel innovations.

1. Lengthy institutional IP entitlement negotiations, thereby delaying project starts.
  2. Slow patient recruitment
  3. Limited availability of study coordinators
  4. Ambivalent hospital commitment to research
- What steps can be taken to remove or reduce these barriers?
    1. Standard contracts between institutions for IP agreements
    2. Facilitate Patient Recruitment
    3. Develop research coordinator workforce
    4. Research KPI's for hospitals

## 6. Competitive Advantage

- What type of clinical trials are being undertaken in South Australia?

Unaware of data for the whole State but within Central Adelaide Local Health Network (CALHN), given a total number of almost 1,000 clinical trials per annum, 55% are industry-sponsored trials and the remainder investigator-initiated. Thus, with a total annual revenue from clinical trials of over \$24.5 million, 57% of funds are from industry-sponsored trials.

Also based on the CALHN Research Office data, the types of clinical trials undertaken include Phase-I (13%), Phase II (21%), Phase-III (65%), and Phase-IV (1%).

- What are South Australia's competitive strengths and weaknesses in clinical trials?

South Australia has a very good reputation for clinical trials; our *strengths* include:

- Favourable Australian (applicable for all States vs international) R & D tax-incentives
- Moderate-sized State, with 90% of the population located in Adelaide (centralised)
- Lower cost-of-living and office space costs
- New biomedical precinct (see above)
- Internationally-renowned clinical researchers in academia

Weaknesses in South Australian clinical trial environment include:

- Limited administrative collaboration between research institutions – 'red tape' delays
- Limited awareness of SA clinical researchers by industry
- Poor success in Australian Government grants (NHMRC & MRFF)
- Hospital & University administrative instability with constant change in senior executives.
- Few multinational Pharma companies with head office in Adelaide
- Limited experienced study coordinator availability (fail to attract since job insecurity)

## ABMC Clinical Trials Expert Taskforce Recommendations.

Future directions for the ABMC Clinical Trials Expert Taskforce to facilitate conducting clinical trials within the precinct, include the following initiatives:

1. Develop a policy environment promoting research within the hospitals by initiating KPI's for hospital executives. These should include targets in research project initiations and research office administrative metrics.
2. Facilitate connectivity by establishing the following databases on the ABMC website:
  - a. *Study Coordinator Database* – providing contact details of study co-ordinators available to assist in clinical trials.
  - b. *Clinical Trial Employment Database* – listing of available clinical trial positions including project managers, project administrators and study co-ordinators
  - c. *Healthy Volunteer Database* – contact details of healthy volunteers available for clinical trials.
  - d. *Clinical Trial Patient Database* – contact details of patients available for clinical trials, with their particular preference for clinical trial participation.
3. Improve collaboration by expanding the *Clinical Trial Investigator Database* on the ABMC website, which details senior research investigators and their research interests. This will function to increase awareness of research expertise both externally to potential industry partners and also internally to other South Australian clinical researchers.
4. Increase awareness of specialised research equipment and facilities by updating the ABMC equipment stocktake.
5. Increase public/private infrastructure, by increasing interaction and collaboration with CMAX, providing cross-referral of appropriate patients.
6. Develop standard research agreements between precinct research institutions to enhanced administrative efficiency.
7. Facilitating clinical trial patient recruitment by (a) routinely inviting hospital patients (invitation included in hospital admission information) to register in the Clinical Trial Patient Database, so they can be contacted for any relevant clinical trials, (b) public media campaign either by SA Health or ABMC, as to the importance of clinical trials and need for patients to participate, and (c) partnering with a commercial clinical trial recruitment organisation (eg Trialfacts).

By undertaking the above initiatives, the ABMC Clinical Trials Expert Taskforce expects to improve clinical trial productivity within South Australia. Support from State Government in achieving these objectives would be of great value.