USC Clinical Trials Centre

Background information for applicants
Manager, USC Clinical Trials Centre (Ref No. 1654)

June 2014
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## Glossary of Terms

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<thead>
<tr>
<th>Acronym</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>AHMAC</td>
<td>Australian Health Ministers’ Advisory Council</td>
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<tr>
<td>ARCS</td>
<td>ARCS Australia Ltd - previously the Association of Regulatory and Clinical Scientists - a professional development association</td>
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<td>ANZCTR</td>
<td>Australia New Zealand Clinical Trials Register</td>
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<td>AuRED</td>
<td>Australian Research Ethics Database</td>
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<td>CTAG</td>
<td>Clinical Trials Action Group</td>
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<td>CTC</td>
<td>Clinical Trials Centre</td>
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<tr>
<td>CTN</td>
<td>Clinical Trials Notification (Scheme)</td>
</tr>
<tr>
<td>DISSR</td>
<td>Department of Innovation, Industry, Science and Research</td>
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<tr>
<td>DoHA</td>
<td>Department of Health and Ageing</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>HoMER</td>
<td>Harmonisation of Multi-Centre Ethical Review Initiative</td>
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<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>ICH-GCP</td>
<td>International Conference of Harmonisation Good Clinical Practice</td>
</tr>
<tr>
<td>KHIP</td>
<td>Kawana Health Innovation Precinct</td>
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<td>NEHTA</td>
<td>National E-Health Transition Authority</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<tr>
<td>NHR</td>
<td>National Health Reform</td>
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<td>QMNI</td>
<td>Queensland Mind and Neuroscience Institute</td>
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<td>PIWG</td>
<td>Pharmaceutical Industry Working Group</td>
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<tr>
<td>PNP</td>
<td>Private Non Profit</td>
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<tr>
<td>PPP</td>
<td>Public Private Partnership</td>
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<tr>
<td>QCTN</td>
<td>Queensland Clinical Trials Network</td>
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<tr>
<td>SCIT</td>
<td>Sunshine Coast Institute of TAFE</td>
</tr>
<tr>
<td>SCPUH</td>
<td>Sunshine Coast Public University Hospital</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<tr>
<td>USC</td>
<td>University of the Sunshine Coast</td>
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1. Executive Summary

This document presents the business case for the development of a ‘world-class’ industry-focused Clinical Trials Centre (CTC) that will be initiated and managed by the University of the Sunshine Coast (USC) to focus on major health issues for people in the region.

It is planned that the USC Clinical Trials Centre will be established in 2014/15, initially located at USC Sippy Downs campus before potentially relocating to a permanent base in the Skills, Academic and Research Centre (SARC) at the Sunshine Coast Public University Hospital (SCPUH) when it opens in late 2016. The CTC will also have a strong relationship with other USC initiatives such as the Inflammation and Healing Research Cluster and Queensland Mind and Neuroscience Institute (QMNI), focused on mental health, currently in planning for the USC Sippy Downs campus.

The $2bn plus investment in the SCPUH presents a major strategic opportunity for USC to strengthen its position in health-related degree programs, to boost graduate employment outcomes, and build research capabilities and outputs. The USC CTC will be a positive asset to USC, the University Hospital, and the healthcare industry and to patients locally, nationally and internationally.

The need for a new industry-focused and globally competitive CTC has been strongly communicated by senior representatives of major pharmaceutical and healthcare companies – including Baxter Healthcare, GlaxoSmithKline Australia Pty Ltd, and Novartis Pharmaceuticals Australia Pty Ltd – who participated in a specially convened discussion forum hosted by USC on 28 June 2011.

Important benefits to USC in establishing a CTC include the opportunity to develop strategic relationships and research partnerships with industry, to increase research funding and output, to help attract world-class staff, provide additional education opportunity for students – including expanding existing undergraduate training in clinical research and regulatory affairs – and to improve access to health care in the local community. The USC CTC will also be a significant asset to the local economy and may support the attraction of healthcare businesses – major graduate employers, to the region.

As well as making early returns to USC, the CTC will also be an additional asset in place should USC ultimately wish to have the option of establishing a full medical school in the longer term, i.e. in 10 to 20 years time.

Globally, the pharmaceuticals and biotechnology sector is the single largest investor in R&D and clinical trials are a central element of the R&D process. In 2004-05, $2.8bn was invested in health R&D in Australia and the clinical trials component of this is worth around $1 billion per annum. Universities play a key role in health R&D and conducting clinical trials. The university sector received 44% of health R&D expenditure in 2004-05.

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1 The 2010 R&D Scorecard, The Top 1,000 UK and Top 1,000 Global Companies by R&D investment, Department for Business Innovation & Skills, UK Government
2 Exceptional Returns, The Value of Investing in Health R&D in Australia II, Prepared for the Australian Society for Medical Research by Access Economics, June 2008
3 Ibid
The business case highlights the steady long-term growth of the clinical trials sector in Australia although notes there has been increased international competition in the last five years. Industry representatives participating in the USC discussion forum highlighted the opportunity for a new CTC that could gain advantages over existing centres by focusing on quality, value, patient recruitment, speed of operations and effective partnerships with industry and others.

The USC CTC can also establish a distinctive competitive position by leveraging its relationship with the SCPUH, set to be one of the world’s largest university hospitals, and a key recruitment source of patients for clinical trials.

The business case highlights that the Sunshine Coast provides an attractive base for clinical trials. The region’s population (335,273 in 2011) is sufficient to support clinical trials has a higher than average proportion of people aged 45 and over – who have higher health care needs – and also has a reasonable proportion of under 17s, representing another potential research base.

The USC CTC will also have the longer term potential to extend its footprint to service a wider region comprising the Local Government Areas of Moreton Bay, Gympie and the Fraser Coast, adding an additional 544,346 people to the catchment area.

The USC CTC will have minimal space requirements in the start up phase and will initially be based on or near the USC campus. The USC CTC will benefit from an Advisory Committee – primarily consisting of senior industry and health sector representatives – and form a wider Stakeholder Group to build understanding of the Centre’s work and boost patient recruitment.

The recruitment of a highly capable and industry focused CTC Manager will be critical to the success of the project. The Centre will also need to fast track the development of professional, fast and efficient systems to support all aspects of the USC CTC operations, including patient recruitment, trial approvals and stakeholder communications.

The USC CTC will require upfront investment to cover the set-up and employment costs for the first 18 to 24 months. Beyond this time the Centre will be expected to reach a break-even position primarily through industry sponsorship of clinical trials and securing other grants.

There are two key risks associated with the project. Firstly, the recruitment of an effective CTC Manager is critical. Industry involvement with the selection process can help reduce the risk of appointing the wrong candidate. Secondly, there is a risk that industry – ‘high expectations, and unforgiving’ – will not be satisfied with the performance of the Centre and will move to work with other national or international centres. This risk can be reduced by close involvement of industry on the Advisory Committee and by the USC CTC implementing effective systems from the outset to deliver results in a professional and timely manner.

In late April 2014 the University Executive approved the establishment of the USC CTC with the immediate recruitment of a suitable manager and establishment of an Advisory Committee to confirm the strategic direction by late 2014. The University will need to carefully manage identified potential risks. The expectation is that the Centre will break even within 18 to 24 months and deliver defined strategic returns to USC including increased research output.
2. Introduction

2.1. Purpose of this Business Case

The purpose of this report is to assist USC and its stakeholders in making decisions on proceeding with the development of a USC CTC. The business case seeks to answer the basic questions:

- Is it feasible for USC to establish a Clinical Trials Centre?
- Is a USC CTC sustainable?
- What are its chances of success?
- What are the risks?

The business case acknowledges that there will be two types of return from this initiative – financial and strategic. From a financial perspective, the Centre needs to reach a break-even position within its first 18 to 24 months of operations. From a strategic perspective, it needs to contribute to USC’s strategic direction and be an attractive option to invest in over other competing priorities.

The development of this business case recognises the place and relevance of the following key events and planning documents:

- Clinical Trial Centre Proposal, Preparation for 28 June 2011
- Discussion Forum: Clinical Trial Centre, 28 June 2011, Background Information
- Meeting Report from the USC CTC Discussion Forum held on 28 June 2011
- USC Clinical Trials Centre Action Plan, 30 June 2011
- Concept Paper, Planning for the Development of a Clinical Trials Centre, Dr Mark Holmes, 25 October 2010

The business case is structured as follows:

1. **Background**: highlighting the $2bn plus investment in the SCPUH and the opportunity this presents to create a CTC as an asset for USC to advance teaching, graduate employment outcomes and boost its research output. Notes plans under consideration by USC to capitalise on the University Hospital development by establishing the QMNI on campus to focus on mental health issues and the potential for the USC CTC to work closely with this Institute.

2. **Describing the need**: explains the clinical trial process, details the investment in R&D by the pharmaceutical and biotechnology industry, summarises the Australian market, the dominant role of Australian universities in conducting clinical trials, growth, current issues, competition, challenges, proposed industry reforms and the opportunity for USC.

3. **Sunshine Coast context**: details the current population of the Sunshine Coast and surrounding region, highlights forecasts of continued population growth, presents the population pyramid with an above average representation of older people (an attractive groups for clinical trials) and a higher than average prevalence in several diseases and risk factors.
4. **Project ambitions and strategic objectives:** includes an ambition statement: ‘To improve health outcomes in rural and remote Australia through the use of clinical trials research, promoting scientific discovery and educating and training future clinical investigators’ and details specific goals to help achieve this, presents a SWOT analysis and concludes that there is a strong opportunity for USC to establish a CTC.

5. **Stakeholder management:** identifies key stakeholder groups and specific partners, including professional bodies, industry, the community, public sector, and other education and research institutes and outlines a communications strategy to increase the chances of success for the USC CTC, particularly with regards to patient recruitment.

6. **Proposed development plan:** detailed solutions for issues raised in the Situational Analysis and SWOT, highlights current staffing capabilities, the opportunity to establish an industry Advisory Committee, and the need to recruit a CTC Manager with industry credibility – this is the number one critical success factor for the project.

7. **Cost-benefit analysis:** provides an estimate of set up and operational costs and expected benefits for USC.

8. **Funding strategy**

9. **Risk analysis and management:** identifies the major issues and risks that could affect the project and suggests mitigating strategies.

2.2. **Background**

In 2006, the Queensland Government announced it would deliver a new tertiary level hospital to meet growing demand for health services on the Sunshine Coast. The Government is investing $2.03bn in the SCPUH, which will open on a 20-hectare green field site at Kawana with 450 beds in 2016 and increasing to 738 beds by 2021. SCPUH will be one of only five university hospitals in the State.

The hospital development will be the largest infrastructure project in Australia and the completed hospital will be the single largest employer in the region with over 3,500 direct staff. It has been cited as the sixth largest teaching hospital in the world.\(^4\)

As a ‘University Hospital’ the SCPUH will work in partnership with tertiary education providers to educate and train the next generations of health professionals and to develop new knowledge through research to contribute to improvements in-patient care.

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The SCPUH will be at the heart of a master planned healthcare precinct at Kawana that will also include:

- A private hospital operated by Ramsay Healthcare, a $150m investment, opening in late 2013 with an initial capacity of 200 beds.
- Skills, Academic and Research Centre (SARC), a $60.8m Centre: will contain the majority of the teaching, learning and research spaces of the SCPUH and will be the focus of education delivery and research by the key stakeholders that include the University of the Sunshine Coast, Griffith University and the Sunshine Coast Institute of TAFE.
- Kawana Health Campus with opportunity for commercial health related developments.

The aim of the precinct is to maximise the benefits that come with locating these services together, including:

- Strengthening public and private health services by promoting the sharing of amenities, staff and expertise.
- Offering hands-on training and education facilities for medical, nursing and allied health students and staff.
- Growing research opportunity by combining expert staff, specialised medical services and technological capacity.
- Integrating infrastructure developments such as public transport with the two hospitals to provide better access and value for money for the public.
- Driving other health related commercial opportunity.

The SCPUH will offer a range of new and expanded services, meaning fewer people having to travel to Brisbane to receive care. It will be the hub of a network of hospitals that includes Nambour General Hospital, Caloundra Health Service, Gympie Hospital, and Maleny Soldiers Memorial Hospital. Once SCPUH opens, there will be a single management structure covering it and the Nambour General Hospital (to be known as the Nambour Campus of the SCPUH).

The new SCPUH development will deliver significant benefits to employment in the region, including:

- Over 3,500 staff in total.
- Recruiting 2,500 new staff to the district.
- Over 2,000 construction workers on site at peak.
- Creating more than 11,000 construction related jobs during the project.
- 15,000 visitors to the health precinct each day generating demand for related services.

USC sees a significant opportunity to commence the development of a USC CTC which will complement clinical trials activities at the new University Hospital.

It is expected that a USC CTC could attract and support ‘world-class’ medical and health research on the Sunshine Coast, thus enabling the University to become integral to the coordination and management of national and international clinical trials.

The development of a CTC will enable USC to expand its undergraduate training in clinical research and regulatory affairs to students in a range of health disciplines, provide an
opportunity to engage with world class healthcare businesses and boost the University’s research output.

As well as making early returns to USC, the CTC could also be an additional asset in place should USC ultimately wish to consider the longer-term option of establishing a medical school. By way of comparison, Griffith University (first students in 1975) established a medical school in 2005, around 30 years into its development; and Bond University (first students 1989) also opened a medical school in 2005 around 16 years into its development. Based on these time scales, USC could potentially seek the option of opening a medical school in the next 15 to 20 year period.

**Inflammation and Healing Research Cluster (Inflame)**

In October 2013 the University launched the Inflammation and Healing Research Cluster (Inflame) established to contribute to sustainable improvements in individual health outcomes related to dysfunctional inflammatory processes. Discipline areas currently include, but are not restricted to: immunology, pharmacology, microbiology, virology, clinical medicine, sports medicine, health communication, molecular biology and physiology. The Inflame development program will include education and training functions focusing on the wide range of career pathway approaches needed to develop an effective health research workforce on the Sunshine Coast. This research cluster, along with the Cluster for Health Improvement and the USC CTC will create the opportunity for collaborative cross discipline opportunities for innovative medical health research, particularly for students and early career researchers, among partner researchers, clinicians, universities and institutions.

**Queensland Mind and Neuroscience Institute (QMNI)**

USC is currently developing plans for the QMNI as an on-campus facility that will be a major innovative research environment for studying issues relating to mental health and age-related neurological disorders, and the best approaches for ameliorating and supporting those suffering from these diseases. QMNI will have strong links to the Brain and Mind Research Institute at the University of Sydney and the Orygen Youth Health Research Centre in Victoria.

When funding proposals for the QMNI are successful, the Institute will be a massive asset for the USC CTC and present an opportunity for the USC CTC to build a competitive position in clinical trials related to mental health and neurological disorders.

**KEY POINTS**

- $2bn plus investment in new University Hospital creates major opportunities to advance USC’s growth and strategies to grow allied health teaching, boost graduate employment and significantly increase research outputs.
- SARC is a $60.8m centre at the SCPUH site to include shared teaching and research space for USC, Griffith University, and the Sunshine Coast Institute of TAFE.
- SCPUH will be the region’s single biggest employer with 3,500 staff.
- The proposed QMNI and SARC facility located at the SCPUH will give the USC CTC the opportunity to build a competitive position in conducting clinical trials related to mental health and neurological disorders.
2.3. Describing the Need

This section aims to:

- Define what a clinical trial is, explain the clinical trial process and how it fits as a central element in the research and development process.
- Detail the massive investment in R&D by the pharmaceutical and biotechnology industry – dominated by global players – and provide an overview of the Australian market and identify competitive opportunity for the new USC CTC.
- Highlight the key recommendations of an important recent report by the Australian Government on ‘Boosting the Business of Clinical Trials in Australia’ and identify opportunity for the USC CTC to gain a competitive advantage by implementing best practice recommendations and meeting industry needs and expectations.

Clinical Trials Explained

A clinical trial is a scientific study, or an organised test of medicines and new treatment options involving patient and non-patient human volunteers. Clinical trials confirm whether medicines are safe and effective to introduce as new treatments for a particular disease or condition. Clinical trials may also be used to determine whether an existing medicine can be safely and effectively used for other diseases and/or conditions.\(^5\) Figure 1, below, illustrates the three main clinical trial phases as part of the overall R&D process for new medicines.

Figure 1: The Clinical Trials Process

![Clinical Trials Process Diagram]

Source: Adapted from The Australian Medicines Industry, www.ausmedindustry.com.au viewed 12 April 2012; and presentation on Global Drug Development: Keeping Australia Competitive by Mitch Kirkman, Novartis; April 2011

Clinical trials are one of the proven methods of clinical practice improvement and innovation. They represent a major research activity in Australia and a major investment nationally and internationally, with $2.8 billion spent on health R&D in Australia in 2004-05, where clinical trials were a major component.\(^6\)

The majority of health R&D since 1992-3 has been undertaken in clinical R&D, which increased at an annual growth rate of 12% from $413m to $1.43bn.\(^7\) The conduct of clinical trials in Australia involves not only the pharmaceutical and biotechnology industries, but also many different research institutions and hospitals, and governments and other organisations concerned with healthcare, research, education, training and commercialisation. Collaboration among these elements is an important factor influencing the success of clinical research.

**Figure 2: Health R&D (SEO) Performed by Sector, 2004-05**

<table>
<thead>
<tr>
<th>Sector</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Commonwealth</td>
<td>11%</td>
</tr>
<tr>
<td>State / Territory</td>
<td>3%</td>
</tr>
<tr>
<td>Higher Education</td>
<td>26%</td>
</tr>
<tr>
<td>Private Non Profit</td>
<td>3%</td>
</tr>
<tr>
<td>Business</td>
<td>44%</td>
</tr>
</tbody>
</table>

Private: 42%  
Public: 58%

Source: Access Economics, based on ABS data

Universities play a key role in the health innovation ecosystem – universities performed 44% of health R&D, businesses 26%, private non-profit (PNP) organisations 16%, and government organisations 14%.

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\(^6\) Access Economics, June 2008, Exceptional Returns: the value of investing in health R&D in Australia II, prepared for the Australian Society of Medical Research  
\(^7\) Ibid
In a global context, Australia has historically been seen as a reasonably attractive place to undertake high quality clinical trials with competitive advantages including:

1. Quality of academic clinical leaders
2. Good healthcare infrastructure
3. Ethnically diverse and informed population
4. Reliable recruitment
5. Reasonable time frames
6. Reasonable costs

The pharmaceutical industry operates on a global basis and Australia faces increasing competition as a destination for conducting clinical trials, particularly from emerging markets in Asia (China, India and Korea), Latin America and Central and Eastern Europe. These emerging markets are becoming increasingly attractive to drug developers as they improve their capacity to run later stage trials and because of lower costs, their larger patient populations and growing commercial importance.

Figure 3: Level of Clinical Trial Activity in Australia, 2008

![Bar chart showing clinical trial activity in Australia by phase and company type in 2008.](chart)

Figure 3 shows a sample of 1,192 trials in Australia in 2008 with 92% of these commissioned by global companies. It also highlights the dominance of Phase 3 trials with global companies.
Overall, Australian companies have a relatively minor role in the market with the exception of the preclinical stage where they account for 21% of clinical trial activity.

Figure 4 below highlights the number of Clinical Trial Notifications in Australia over a six-year period.

**Figure 4: Clinical Trial Notifications: 2003-2009**

<table>
<thead>
<tr>
<th>Financial Year</th>
<th>Total number of notifications</th>
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</thead>
<tbody>
<tr>
<td>2003-04</td>
<td>2,378</td>
</tr>
<tr>
<td>2004-05</td>
<td>2,776</td>
</tr>
<tr>
<td>2005-06</td>
<td>2,576</td>
</tr>
<tr>
<td>2006-07</td>
<td>3,182</td>
</tr>
<tr>
<td>2007-08</td>
<td>2,792</td>
</tr>
<tr>
<td>2008-09</td>
<td>2,986</td>
</tr>
</tbody>
</table>

The number of new clinical trials commencements peaked in 2006/07 but has since fallen by 6% as global competition intensifies.

In an effort to boost Australia’s competitiveness as a location for clinical trials, the Australian Government commissioned the Clinical Trials Action Group (CTAG) to review the industry and to make recommendations for change. The Government has endorsed the group’s recommendations – these include measures to improve the timeliness of clinical trial approvals and to improve patient recruitment – and sustained collaboration between industry, education and government is now needed to fully implement these reforms to maintain and boost Australia’s international competitiveness in clinical trials.

Australia continues to be an attractive location for Phase 1 clinical trials due to several factors including fast approval processes, academic clinical trial centres and high quality clinical practice. Although a smaller sector than later stage trials, Phase 1 clinical trials are well placed for further growth and present the opportunity to translate discoveries from Australia’s first class biomedical research sector into clinical practice.

Later stage trials with large numbers of participants are more expensive to conduct and overseas locations will be significant competitors as industry can be more sensitive to these costs and may prefer to conduct later stage trials in key commercial markets with larger populations.

The National Health and Medical Research Council (NHMRC) lists 86 existing clinical trial networks in Australia. The vast majority of these are focused on specific health issues and diseases. Cancer and oncology is the largest grouping by far, being the focus for 28 networks with other conditions being researched by just one to four networks.

Industry representatives’ participating in a USC Clinical Trials Centre workshop has strongly suggested there are opportunities for additional CTCs in Australia.

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The USC CTC could also boost its competitive position by:

- Recruiting a business-like and effective manager with industry credibility – a critical success factor.
- Adopting best practice systems and principles from the outset, including addressing the issues raised by the CTAG.
- Learning from leading national and international centres and from a high level Advisory Committee.

Clinical trials are one of the proven methods of clinical practice improvement and innovation. There have been over 3,300 clinical trials registered on the Australian New Zealand Clinical Trials Registry since it was established in 2005, and approximately 18,000 people now participate in clinical trials each year throughout Australia. They represent a major research activity in Australia and a major investment nationally and internationally, as illuminated in the following statistics:

- According to Medicines Australia, the Australian medicines Industry contributes $18 billion a year to the Australian economy and makes a significant contribution to the health of all Australians. Its member companies employ 14,000 Australians in high-value jobs and export goods worth $4.12 billion a year.
- $2.8 billion was spent on health R&D in Australia in 2004-05 and clinical trials were a major component.\(^9\)
- Around $100 million is saved each year in the health care costs of people on trials where standard treatments are subsidised by clinical research funding.
- The clinical trials sector is worth around $1 billion per annum to Australia with direct foreign investment of over $450 million per annum. The pharmaceuticals industry has estimated that pharmaceuticals clinical trials alone are worth $450 million each year in Australia.
- The therapeutics industry invests $540 million dollars in clinical trials in Australia each year.

However, significant investment is necessary due to the high costs of administering clinical trials. Australia is facing increased competition for investment in clinical trials from international locations in the Asia-Pacific and Central-Eastern European regions. These newer locations have a larger population from which to select trial participants, and can offer lower trial costs and shorter trial start-up times.

Measures to increase the attractiveness of conducting clinical trials in Australia need to support both strong and independent clinical research capacity as well as increased pharmaceutical and biotechnology industry investment, as these sectors enhance and complement each other.

In recognition of the need to remain competitive in clinical research, the Australian Government established the CTAG at the end of 2009. CTAG was given the task of developing strategies to improve the operating environment for clinical trials in the country. The final report submitted by CTAG in June 2011 made recommendations in key areas that included: key performance

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\(^{9}\) Access Economics. June 2008, Exceptional Returns: the value of investing in health R&D in Australia II. Australian Society for Medical Research
measures that need to be considered when conducting clinical trials; ways to streamline review processes, including human research ethics; and improvements to patient recruitment. Implementation of these recommendations has significant benefits for patients, the industry, the health system and researchers.

CTAG confirmed the need for additional investigation centres for the conduct of clinical research in Australia, and that these centres of medical expertise should focus on providing solutions to important health issues such as chronic diseases (such as cardiovascular disease, diabetes mellitus and cancer), mental health and indigenous health. There is also a need to enhance clinical practice in Australia, both in the hospital and ‘out-of-hospital’ environments.

The Sunshine Coast is one of Australia’s most popular tourist destinations and fastest growing residential regions – the 2006 Census indicates that the catchment population in the District’s Southern Cluster (Gympie and Sunshine Coast Council’s combined population) is expected to increase by 8,600 to 9,900 people annually. This growth, combined with an aging population and the changing nature of disease and injury within the community, specifically increases in chronic disease across all age groups, is driving unprecedented demand for services and social infrastructure.

Addressing health issues for people living in rural and remote Australia could become an important focus for the USC CTC. The National Rural Health Alliance Inc. reported recently on the metropolitan-rural inequity that is occurring in key areas such as health. For instance, there is now clear evidence of lower overall life expectancies for both indigenous and non-indigenous people living in rural and remote Australia. Several reports have highlighted higher rates of smoking, alcohol consumption, obesity, perinatal death, injury and disability, and mortality from cancer in rural and remote areas. Also, there has been a noticeable reduction in the number of health professionals and services in rural and remote Australia, making access to Medicare-funded services very difficult.

**KEY POINTS**

- Clinical trials represent a major research activity globally and in Australia, clinical R&D in Australia was valued at $1.43bn in 2004-05.
- Universities play a key role in performing 44% of health R&D.
- Clinical trial activity in Australia is dominated by global companies and by Phase 3 trials.
- Clinical trial activity in Australia grew significantly up until 2006-07 and has reduced by 6% (2008-09) partly as a result of increased international competition.
- Australia is still seen as an attractive location for early stage trials due to fast approval processes, academic clinical trials centres and high quality clinical practice.
- The CTAG report confirmed a need for additional investigation centres in Australia.
- Industry representatives have highlighted the need for a new CTC that adopts best practice and is professionally run with an industry credible manager.
3. Sunshine Coast – a suitable location for conducting clinical trials

Located 100km north of Brisbane, the Sunshine Coast is one of Australia’s fastest growing regions with a population of 335,273 (2011) forecast to grow by over 50% to over 500,000 by 2031, a substantial catchment area to support patient recruitment to clinical trials.

Whilst the core focus of the CTC will be on the Sunshine Coast, beyond the establishment phase there will also be an opportunity to build connections with health professionals and referral sources to boost patient recruitment from the wider region – from Moreton Bay in the south; north to Gympie and the Fraser Coast. This aligns with USC’s strategic direction of broadening its geographic footprint as demonstrated by the planned investment in a new teaching facility at Gympie with an initial focus on nursing and allied health.¹⁰

Figure 5: Population Growth: Sunshine Coast and Surrounding Regions

<table>
<thead>
<tr>
<th>Local Government Area</th>
<th>Median Age</th>
<th>Population</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2011</td>
<td>2011</td>
<td>2021</td>
<td>2031</td>
</tr>
<tr>
<td>Sunshine Coast</td>
<td>41</td>
<td>335,273</td>
<td>420,439</td>
<td>508,177</td>
</tr>
<tr>
<td>Moreton Bay</td>
<td>36.6</td>
<td>390,204</td>
<td>467,860</td>
<td>533,170</td>
</tr>
<tr>
<td>Gympie</td>
<td>41.6</td>
<td>49,287</td>
<td>57,669</td>
<td>67,373</td>
</tr>
<tr>
<td>Fraser Coast</td>
<td>42.9</td>
<td>104,855</td>
<td>130,005</td>
<td>164,143</td>
</tr>
<tr>
<td>Total region</td>
<td>40.5</td>
<td>879,619</td>
<td>1,075,973</td>
<td>1,272,863</td>
</tr>
</tbody>
</table>

Population figures source: Queensland Government, Office of Economic and Statistical Research, viewed online 2 May 2012 at www.oesr.qld.gov.au

The region’s population pyramid (see Figure 6) is skewed towards older people making it a particularly suitable region for conducting clinical trials for treatments for chronic diseases affecting the elderly.

The region has a slightly lower than normal percentage base of younger people (aged 0-19) and is significantly under represented in the 20-34 age range with people leaving the region to seek improved employment opportunity.

A presentation by Professor John Lowe, Head of USC’s School of Health and Sport Sciences to the clinical trial industry discussion forum\textsuperscript{11} firmly corrected any perception that Coast residents were ‘healthier than normal’ and highlighted that the Sunshine Coast had an equal or higher prevalence of the following diseases or risk factors compared with the Australian average:

- Mental health and behavioural problems
- Circulatory system diseases
- Respiratory system diseases
- Musculoskeletal diseases
- Smoking
- High alcohol consumption
- Physical inactivity and obesity

\textsuperscript{11} USC Clinical Trial Centre Discussion Forum, 28 June 2011.
KEY POINTS

- Sunshine Coast population - 335,273 (2011) – is sufficient to support clinical trials. Sunshine Coast is one of Australia’s fastest growing regions and is forecast to grow to 508,177 by 2031.
- Taking a wider view of the region – including neighbouring Local Government Areas – increases the population base to 879,619 (2011), forecast to grow to almost 1.3 million in 2031.
- The Sunshine Coast population pyramid is ‘top heavy’ with an over representation of older people making it a particularly suitable region for conducting clinical trials for treatments for chronic diseases affecting the elderly.
- Sunshine Coast is not ‘healthier than normal’ but in fact has a higher than average prevalence of several diseases or risk factors including mental health, circulatory and respiratory system diseases and higher than average rates of smoking and alcohol consumption.

4. Project Ambitions and Strategic Objectives

4.1. Project Ambitions, Objectives and Goals

<table>
<thead>
<tr>
<th>Ambition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through the use of clinical trials research, promoting scientific discovery and educating and training future clinical investigators.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>To develop a ‘world-class’ industry-sponsored Clinical Trials Centre that will be managed by USC and will focus on major health issues for people in the region.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Goal 1:</td>
</tr>
<tr>
<td>To enhance and develop new pathways to confront chronic health issues in regional Australia, ensuring that USC’s research addresses community concerns and that the community benefits from the findings.</td>
</tr>
</tbody>
</table>
Specific Goal 2:
To make significant gains on health issues such as mental health, lifestyle diseases (e.g. cardiovascular disease, diabetes, gastrointestinal disorders, renal disease, cancer), and indigenous health.

Specific Goal 3:
To enhance existing educational pathways and develop new methods to educate and excite the next generation of specialists, GPs and clinical trial coordinators, including linking into international networks.

Alignment with Strategic Objectives
The project objectives fit with and contribute to the strategic objectives of USC and its real and potential partners.

USC’s strategic objectives include:
1. Enable access to the USC experience
2. Deliver high quality teaching, learning and graduate outcomes
3. Build research productivity and output significantly
4. Develop USC for a sustainable future.

The strategic objectives of the SCPUH include:
1. To provide excellent care through collaboration, enquiry and education.
2. To achieve the vision as a fully functioning University Hospital, the Queensland Government will:
   - Provide excellent patient care
   - Develop new knowledge through research to contribute to national and international improvements in patient care
   - Educate and train the next generations of staff to perform all components.

5. Situation Analysis – Defining Reality

SWOT Analysis
This section provides an analysis of the internal strengths and weaknesses of USC and the external opportunity and threats associated with the current external environment. While it is not an exhaustive list, it provides a high level view of the breadth and depth of issues that need to be considered in progressing this significant project.

Strengths
- Australia has an international reputation for conducting clinical trials to a very high standard.
Australia has a high quality of clinical research facilities and medical researchers and investigators.

Committed State Government – SCPUH is part of a $7 billion program of works to deliver new and expanded health services across the State.

USC is well positioned to develop and manage a CTC:
- USC is regionally relevant and recognised nationally and internationally for excellence in teaching, research and engagement.
- USC has a rapidly growing School of Health and Sport Sciences, which is currently seeking Clinical Trial Notification (CTN) with the Therapeutic Goods Administration (TGA) on a growing number of projects.
- USC has a relationship with ARCS Australia – building on a partnership established in 2010 to offer a new introductory course in clinical trial management for biomedical science students.
- Initial base of skilled staff immediately available.
- Biomedical staff are eager to run clinical trials.
- Rapid growth of University overall – expected to have 15,000 students by 2020 with many studying health, science and education.
- Access to well organised patient support groups in the local community.
- Less competition on the Sunshine Coast from other CTCs for recruitment of patients.
- Strong referral networks and excellent links to regional groups who have systems to access patient records.
- Ready access to the Innovation Centre Sunshine Coast and network of businesses to develop e-health infrastructure and software.

The project is a good fit with the SARC so there is high potential for co-location – the USC SARC management committee has been established to facilitate development of collaborative arrangements between the SARC’s foundation partners.

**Weaknesses**
- As it is ‘early days’, performance metrics are not available to promote to industry.
- Limited experience by USC staff in conducting clinical trials.
- USC does not have a medical school.

**Opportunity**
- Sufficient population base on the Sunshine Coast – and neighbouring regions – to support patient recruitment for clinical trials.
- Demographic and disease profile of the Sunshine Coast – high proportion of older people and over representation in several chronic diseases and health issues that will be highly appropriate to administer clinical trials on at the USC CTC.
• Capitalise on the high profile and the $2bn plus investment in the SCPUH.

• A critical asset to attract and support world-class medical and health research on the Sunshine Coast.

• Address significant health issues for people living in rural and remote Australia.

• For USC to connect with and provide value to the Sunshine Coast community.

• For USC to become integral to the coordination and management of national and international trials.

• USC will be able to expand its undergraduate training in clinical research and regulatory affairs to students in a range of health disciplines.

• Supply graduates to the pharmaceutical industry with knowledge and skills in the principle disciplines of clinical research and regulatory affairs, as regulated by local and international standards – the demand for clinical research professionals has outstripped supply for several years.

• Provide the potential to allocate research funds to address local health issues and improve the quality of health services.

• To build on existing experiences and best practice to avoid typical start-up delays, expenses and frustrations – for instance, whenever possible, use Medicines Australia’s standard forms and the standard costs established by the NHMRC.

**Threats**

• Increasing global competition for clinical trials with a lower cost base and access to larger markets.

• Potential delay in hospital opening date.

• Competition – or non-cooperation – from other educational institutes for clinical trials.

• Not meeting industry expectations – low tolerance for any delays, unprofessional staff or operations.

• If not industry-focused, could prove difficult to attract high calibre researchers to the regional area.

• Not gaining approval – or satisfying clinical trials site criteria – from professional bodies.

• People recruited to key positions do not meet industry expectations.

• Low level of community understanding of role of clinical trials.

• Reputation threat from negative community reaction to clinical trials.
6. Stakeholder Management

6.1. Stakeholder Identification

Figure 7: USC Clinical Trials Centre, key influences on business model

SWOT CONCLUSIONS AND KEY POINTS

- Australia has a strong international reputation as a location to conduct clinical trials. USC well positioned to manage a CTC.
- Main weaknesses relate to USC’s early stage of development but this also presents a ‘green field’ opportunity to establish a Centre following best practice principles, listening to industry’s needs and growing with the new University Hospital.
- Development of the SCPUH presents an outstanding opportunity for USC to establish a CTC as an asset to boost teaching, graduate employment opportunities, attract high quality staff and boost research output.
- Main threats are with maintaining industry relationships and the quality of key staff not meeting expectations.
**Stakeholders**

The following overview identifies the key stakeholders in the development of the USC CTC, issues for each stakeholder (including potential stakeholder interests, objectives, conflicts, positive or negative potential impacts and opportunity for synergies) and the action planned to resolve conflicts or maximise opportunity.

**Figure 8: Key Stakeholders List by Category**

<table>
<thead>
<tr>
<th>Category</th>
<th>Stakeholder</th>
<th>Issues or Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional bodies</td>
<td>ARCS Australia Ltd</td>
<td>Previously the Association of Regulatory and Clinical Scientists, a professional development association for people working in the development of therapeutic goods. USC entered into a partnership with ARCS Australia in 2010 to offer a new introductory course in clinical trial management for biomedical science students.</td>
</tr>
<tr>
<td></td>
<td>Medicines Australia</td>
<td>Represents the discovery-driven pharmaceutical industry in Australia. Member companies supply 86% of the medicines that are available to Australian patients through the Pharmaceutical Benefits Scheme.</td>
</tr>
<tr>
<td></td>
<td>Queensland Clinical Trials Network</td>
<td>A peak industry body for preclinical and clinical trials and related service providers aims to position itself as the primary point of contact for domestic and international organisations seeking to undertake preclinical and clinical research in Australia.</td>
</tr>
<tr>
<td>Industry</td>
<td>Baxter Healthcare</td>
<td>Potential Sponsor. $13.9bn USD revenue in 2011; 48,500 staff. Develops, manufactures and markets products that save and sustain the lives of people with a variety of conditions including chronic and acute medical conditions.</td>
</tr>
<tr>
<td></td>
<td>GlaxoSmithKline Australia Pty Ltd</td>
<td>Potential Sponsor. $27.4bn USD revenue in 2011; 97,000 staff. Three primary areas of business: pharmaceuticals, vaccines and consumer healthcare. Invested $56m in Australian R&amp;D in 2010. GSK Medicines Research Centre conducts early stage clinical trials.</td>
</tr>
<tr>
<td></td>
<td>Novartis Pharmaceuticals Australia Pty Ltd</td>
<td>Potential Sponsor. $58.5bn USD revenue in 2011; 124,000 staff. Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care products, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. In Australia, employs over 700 people and invests $24m annually in local research.</td>
</tr>
<tr>
<td><strong>Industry</strong></td>
<td>Proscribe Medical Communications</td>
<td>Provides medical communication services to many of the leading international names in pharmaceuticals, biotechnology and academia. Based in Noosa Heads with staff located in Sydney, Melbourne, Adelaide, Brisbane, China, and Japan.</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Community</strong></td>
<td>Current and future patients</td>
<td>As key users of the intended services, have specific medical conditions, needs and requirements. Research needed to fully understand needs and priorities.</td>
</tr>
<tr>
<td><strong>Public Sector</strong></td>
<td>Queensland Health</td>
<td>Effectively manages the scientific and ethical review of human research, through the implementation of a research governance framework and other relevant processes.</td>
</tr>
<tr>
<td></td>
<td>Sunshine Coast Public University Hospital</td>
<td>Key partner, need to understand their key medical specialties, gaining cooperation and written agreements, processes, insurance and risk management issues, and build relationships with key staff.</td>
</tr>
<tr>
<td></td>
<td>Clinical Trials Action Group (CTAG)</td>
<td>Established by the Commonwealth Government to identify and progress necessary reforms to secure Australia’s competitiveness in the clinical trials sector. Opportunity for USC CTC to implement best practice recommendations.</td>
</tr>
<tr>
<td></td>
<td>Australian Government</td>
<td>Endorsed the CTAG report recommendations and will work with all States and Territories through the Australian Health Ministers’ Advisory Council to implement them, and with the universities and private hospital sector through Universities Australia and Australian Private Hospitals Association. The USC CTC project brief intends to align with the recommendations.</td>
</tr>
<tr>
<td></td>
<td>Sunshine Coast Council</td>
<td>Health and wellbeing identified as a key economic sector. Council can promote the USC CTC as an asset supporting industry attraction and engagement.</td>
</tr>
<tr>
<td></td>
<td>Therapeutic Goods Administration (TGA) and Human Research Ethics Committee (HREC)</td>
<td>TGA is the government regulatory body that oversees closely the conduct of clinical trials in Australia. HREC approves all clinical trials to ensure that the privacy, safety and well being of clinical trial participants are protected.</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td>University of the Sunshine Coast</td>
<td>Strong support for the project from USC leadership. Business case and funding approval has been endorsed by University Executive. USC will take lead role in implementing and running CTC, managing facility, processes and partnerships.</td>
</tr>
<tr>
<td>Education</td>
<td>Griffith University</td>
<td>Partner in SARC, clarify any specific partnering opportunities.</td>
</tr>
<tr>
<td>--------------------</td>
<td>---------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Sunshine Coast</td>
<td>Partner in SARC, clarify any specific partnering opportunities.</td>
</tr>
<tr>
<td></td>
<td>Institute of TAFE</td>
<td></td>
</tr>
</tbody>
</table>
| Research Institutes, Networks and Registers | George Clinical | Potential Sponsor, the contract research arm of The George Institute, an independent, global scientific research institute based in Australia, China and India. The Institute has a team of world-renowned opinion leaders in a range of major therapeutic areas contributing to the planning, design, research, analysis and reporting of trials in six main clinical areas:  
  - Cardiovascular disease and diabetes  
  - Renal disease  
  - Neurological and mental health  
  - Lifestyle and nutrition, including obesity  
  - Critical care and trauma  
  - Injury  
  - Musculoskeletal conditions. |
|                    | BioPharmaceuticals Australia (BPA) | Tailored contract manufacturing, able to produce small quantities needed for early stage clinical trials. |
|                    | Pharmaceutical Industry Working Group (PIWG) | CTAG recommendation that PIWG become a mechanism for relevant stakeholders to continue to input into clinical trials policy and coordinate improvements. |
|                    | Local primary care services (GPs, referring medical specialists) | Need to build referral base from GPs and specialists to assist recruitment. |
|                    | Australian and New Zealand Clinical Trials Registry | An online register of clinical trials being undertaken in Australia, New Zealand and elsewhere. Studies need to be registered in advance – before first subject is recruited – in a publically accessible database to meet Declaration of Helsinki requirements and to be considered for publication in key medical journals. |
|                    | International Clinical Trials Registry | Run by the World Health Organisation. A voluntary platform to link clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials with a view to enhancing access to information by patients, families, patient groups and others. |
6.2. Communications Strategy

Target Markets

Develop and implement a consultation strategy to engage with all target market stakeholder groups listed in Figure 8 above.

Effective communications will be a critical success factor for the USC CTC, particularly to support patient recruitment. This is a very important issue in Australia where 90% of industry-sponsored trials experience patient recruitment delays.12

The USC CTC can gain a competitive advantage by acting immediately on the recommendations by the CTAG on how to improve patient recruitment, including:

- Development of a consumer friendly portal to include information on all clinical trials in Australia – this is a national initiative but USC could use its own and other relevant regional websites to promote awareness of trials and build participation.
- Maximising communication and involvement of GPs – and other medical specialists – in referrals and clinical trial process, linking trials with GP software to prompt patient identification and referrals; encourage doctors to talk to their patients about suitable clinical trial options.
- Building awareness and understanding of clinical trials with general public; this is another national initiative that could be supported through existing USC communications channels such as the USC website, Community Magazine, media releases, community engagement activities and by using explanatory material such as the recently produced Consumers Guide to Clinical Trials13.

Other key recommended communications actions:

- Establishment of a Stakeholder Group is established to build understanding of the USC CTC’s work, progress and plans.
- Build understanding across key staff at USC.
- Initiate discussions with key stakeholder groups, including Specialists, Sunshine Coast Hospital and Health Service and Private Hospitals.
- Development of a USC CTC website and marketing materials – targeted at consumers, local health professionals, and industry sponsors.

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7. Proposed Development Plan

The University as the initiator of the USC Clinical Trials Centre

The University opened in 1996 with 500 students. Today, with about 10,000 enrolled students, USC is on track to reach projected student enrolments of 12,000 by 2015. USC is well positioned to develop and manage a CTC. USC is one of Australia’s fastest growing universities, serving the Sunshine Coast and extended region from north Brisbane to the Fraser Coast.

Health is one of the fastest growing program areas within the University, led by the School of Health and Sport Sciences and the School of Nursing and Midwifery in the Faculty of Science, Health, Education and Engineering.

The establishment of the SCPUH – which will employ over 3,500 health professionals – as well as the 2013 opening of the Ramsay Healthcare Private Hospital and continued population growth in the wider region will all continue to fuel the growth of health education and research at USC.

In 2010, USC signaled its interest in clinical trial management by entering into a partnership with ARCS Australia to offer a new introductory course in clinical trial management for biomedical science students. This was the first undergraduate course in Australia to be linked to training provided by ARCS Australia. Demand for clinical research professionals has outstripped supply for several years and this training and education initiative will help to supply workforce ready graduates for the health sector and industry. The course has also enabled USC and ARCS Australia to build a productive working relationship which will assist in planning for the new CTC.

Organisational positioning and structure

The USC CTC will become an internal research centre at USC and will be positioned as an asset to gain research grants, industry funding and support the administration of clinical trials research. Initially the Manager, USC CTC will report to the Executive Dean, Faculty of Science, Health,
Education and Engineering. The USC CTC will need internal structures and strong communication channels to involve:

- Key teaching and research staff
- Executive Dean, Faculty of Health, Science, Education and Engineering
- Head of School – School of Health and Sport Sciences
- Head of School – School of Nursing and Midwifery
- Pro Vice-Chancellor (Research)
- Director, Marketing and Communications
- Director, Development Office
- Chief Executive Officer, Innovation Centre Sunshine Coast

Beyond this internal structure, two other groups will be needed:

- USC CTC Advisory Committee: core membership will be representatives from industry and the health sector.
- USC CTC Stakeholder Group: a wider consultative group to meet 2 to 3 times per year as well as being part of an ongoing communications program.

**Location**

Initially, the USC CTC will initially have minimal space requirements, essentially basic office and meeting space for the Centre Manager and a small support staff.

Details of any additional clinical space to accommodate visiting clinical trial patients are to be determined but are likely to include:

- Reception desk and seating area for trial participants
- Offices (manager, coordinator/s, administrator)
- Hot desk office for visiting industry staff
- Meeting room/tea room
- Participant treatment room with phlebotomy chair and fold-out examination table
- Toilet/bathroom
- Small laboratory PC1 for specimen handling and preparation
- Small pharmacy room for investigational product preparation

Initially, the USC CTC will be located on the main USC campus with the potential to relocate to premises nearby when the University Hospital opens in late 2016. The USC CTC will essentially be a service and systems based organisation rather than simply a facility in a fixed location. The USC CTC will also have a strong strategic relationship – and even a physical presence – in the new QMNI facility proposed for development within the health and medical precinct at USC Sippy Downs campus.

**Partnerships (Research, business, community)**

Senior professionals from the international therapeutics industry.
Experience and Capabilities

Dr Karen Woolley, Proscribe Pty Ltd, Noosa Heads
Karen is a former President of ARCS and is currently an Adjunct Professor to USC and member of the Sunshine Coast Hospital and Health Service Board. Karen is highly respected by professionals in the Australian and international clinical research and regulatory industries, which will be highly beneficial to the development of the proposed USC CTC. Karen also has extensive networks, including senior professionals from the international therapeutics industry who live on the Sunshine Coast and who may be interested in assisting USC with the development of the proposed USC CTC.

Assets

Small-Scale Clinical Trials at USC

Leading up to the establishment of the USC CTC, it is recommended that USC encourage small-scale clinical trials to be conducted on campus to enable staff to both develop capacity in medical and health research, and gain experience in managing and monitoring clinical trials. There has already been one approved clinical trial completed at USC. Details are as follows:

- **Effects of omega-3 fatty acids on cardiovascular biomarkers in patients with essential hypertension** (CTN Trial Number 2010/0436; ACTRN1261000713099) – This double-blind randomised clinical trial has been funded by USC internal grants and with in-kind support from Blackmores Australia. It commenced in 2009 and was completed in 2011. The research team included Dr Fraser Russell, Dr Chris Askew, Dr Mark Holmes and Dr Peter Brooks. Several research students were involved with this clinical trial.

Recruitment

1. Establish a USC CTC Advisory Committee

It is recommended that an advisory committee be formed that will have the responsibility of developing a long-term strategic plan for the development of the USC CTC.

The membership of the Advisory Committee could include:

- Senior USC academic staff.
- Chair of the USC HREC.
- CEO of ARCS Australia.
- Senior professionals from the therapeutics industry. Dr Woolley has agreed to recommend professionals with extensive research and development experience in the therapeutics industry who may be interested in becoming members of the Advisory Committee. Some of these professionals are located in South-East Queensland, including the Sunshine Coast, while others are located interstate.
- Representative(s) from Sunshine Coast Hospital and Health Service. Governance issues for conducting clinical trials at the USC CTC will need to be worked through; hence it is recommended that a representative be invited on the Advisory Committee.
- Sunshine Coast medical specialists and health professionals currently involved with clinical trials being conducted in the local region.
• Representative from the Sunshine Coast Division of General Practice.
• Representative from the Griffith University Medical School or other Griffith University medical research centre. Since the SCPUH will include the Griffith University medical school, it is anticipated that Griffith University medical researchers and investigators may require a CTC to conduct trials on new therapeutics agents.

2. **Appoint a CTC Manager (Full-time)**

A CTC Manager with extensive industry experience will be appointed at USC to oversee the development of the USC CTC. The CTC Manager will have the responsibility of:

• Interacting with the USC SARC management committee.
• Establishing ICH-GCP protocols for clinical trial management.
• Establishing suitable investigators (specialists, physicians) for clinical trials to be conducted at the USC CTC.
• Attracting companies (national and international) to conduct clinical trials at the USC CTC.
• Staffing the USC CTC.
• Interacting with medical researchers to be located at the SCPUH.
• Organising student placements for USC undergraduate training programs.

The CTC Manager will be expected to report about the CTC development to the Advisory Committee on a regular basis, thus ensuring that target deadlines are being met.

3. **Appoint a Clinical Trials Coordinator**

It is recommended that a Clinical Trials Coordinator be appointed to provide key management support for the staff conducting small-scale clinical trials at USC. The Clinical Trials Coordinator will have the responsibility of:

• Assisting with the recruitment of study participants.
• Managing appointment times for participants with researchers.
• Collecting and processing of specimens (e.g. blood, urine, saliva).
• Ensuring adherence of each clinical trial with ICH-GCP and approved study protocols.
• Reporting adverse events to the HREC and TGA (if required).
• Assisting with the preparation of human ethics applications and clinical trial data analysis.

4. **Specialist Training in Clinical Trials Management for USC Staff**

Specialist training in clinical trials will be offered for USC staff identified as being likely to be involved in clinical trials research. ARCS Australia offers a comprehensive training program including Post Graduate Certificate programs offered in collaboration with the University of Melbourne, such as Specialist Certificate in Clinical Research (Clinical Trials Monitoring), and Specialist Certificate in Clinical Research (Clinical Trials Coordination).
8. Cost-benefit Analysis

The Rationale

Benefits for USC

- Opportunity to establish a ‘world-class’ CTC with a focus on priority areas for rural and remote health such as mental health, lifestyle diseases (e.g. cardiovascular disease, diabetes, gastrointestinal disorders, renal disease, cancer), indigenous health, and clinical practice in the hospital and ‘out-of-hospital’ (ambulance, industry) environments.
- Opportunity to manage national and international clinical trials being conducted in the local region, thus supporting medical and health research being conducted by USC staff.
- Strengthen links with regional medical and health services.
- Expand undergraduate coursework at the University for students in biomedical science and allied health (e.g. nursing, paramedics) to provide industry ready graduates. The USC CTC will provide ‘work placement’ opportunity for the USC students.
- An asset to help attract world class staff.
- Beyond start-up phase, self funding with industry support.
- A key asset to improve research productivity and output.
- A key piece of infrastructure toward a long term option of bidding for a medical school.

Benefits for the SCPUH

- Raise the profile and rapidly increase the reputation of the SCPUH.
- Access a new source of revenue for the SCPUH that could function as a profit centre, without detracting from patient care.
- Facilitate professional development opportunity for specialists, GPs and clinical trial coordinators (USC graduates), providing a change from routine patient care and the ability to link into international clinical trial networks.
- Enable these health-care professionals to gain early experience, in a controlled setting, with new therapeutic agents for inadequately treated diseases.
- Provide the potential to allocate research funds to address local health issues and improve the quality of health services.
- Enhance the efficiency of conducting non-industry funded clinical trials by leveraging the infrastructure and procedures established for the CTC.
- Attract high-calibre health-care professionals to the Sunshine Coast, based on the opportunity to conduct ‘world-class’ research at the USC CTC (world class = participating in international clinical trials of new medicines and medical devices, led by world-leading experts).

Benefits for the Sunshine Coast Community

- The potential to improve health outcomes for patients participating in clinical trials.
- The ability to gain early access to new therapeutic agents and devices being developed to treat the type of diseases that affect the local community.
- The possibility of enhancing continuity of care by retaining specialists and GPs who are motivated by continued opportunity to be investigators in clinical trials.
• The potential to attract and retain experienced, talented, research-focused specialists and GPs to the Sunshine Coast.

Start up

The medium term plan is for the USC CTC to be self-financing with funding by sponsor companies and external research grants. The aim is for the USC CTC to be self-financing within 18 to 24 months of start-date. Key activities and associated timing are provided as follows:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business case presented to University Executive</td>
<td>April 2014</td>
</tr>
<tr>
<td>Business case approved and budget allocated by USC</td>
<td>May 2014</td>
</tr>
<tr>
<td>Recruitment process for USC CTC Manager</td>
<td>June to August 2014</td>
</tr>
<tr>
<td>USC CTC Manager commences employment</td>
<td>October to December 2014</td>
</tr>
<tr>
<td>USC CTC Advisory Committee appointed</td>
<td>By late 2014</td>
</tr>
<tr>
<td>First clinical trial commences</td>
<td>By end 2015</td>
</tr>
</tbody>
</table>

9. Funding Strategy

The University will provide sufficient funding to support the first 18 to 24 months of operations for the CTC. Beyond this, the principal funding strategy will be to build relationships with key industry partners who are the major funder of clinical trials in Australia.

Grant funding will also be sought from funding sources such as CRE in Clinical Research Scheme\(^\text{14}\) operated by the Australian Government’s National Health and Medical Research Council.

A study of the funding of clinical trial research in Australia\(^\text{15}\) found that on average, 65% of funds came from Biotechnology, Pharmaceutical and Medical Device companies, 10% from NHMRC grants, 7% from State Governments, 4% from other Federal Government sources and 14% from other sources (e.g. charitable organisations, societies, foundations, collaborative groups).

Many universities conduct fundraising campaigns to raise money to support their CTCs and the Development Office will be well placed to assist as USC and the University Foundation Board regard this as a strategic priority.

10. Risk Analysis and Management

A risk analysis has been conducted to identify the major issues and risks that could affect the project, particularly in the initial stages of the project. Subsequently, each risk has been quantified in terms of the likelihood of an event occurring and the possible impact or consequences should it occur, and management strategies suggested. See Appendix 1.

Twelve specific risks were identified and all of these were regarded as having ‘unlikely’ or ‘possible’ likelihoods of occurring. None were regarded as having a ‘likely’ or ‘almost certain’


\(^{15}\) Value of industry sponsored clinical trials in Australia, Clinical Trials NSW, 2009
chance of occurring. If the risk event did occur, there could be a major consequence in eight of the cases and risk mitigation strategies are listed to reduce the chances of this occurring.

The table below lists the key risks to the project, and suggests strategies to minimise those risks. The approach taken and a detailed risk assessment are provided at Appendix 1.

**Figure 10: Key risks and mitigating strategies**

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigating strategies</th>
</tr>
</thead>
</table>
| **Staff recruitment**                                               | - Involve industry advisors in drafting the position description  
- Promote involvement of senior industry representatives on the Centre’s Advisory Committee  
- Promote attractive career opportunity associated with the growth of USC and the University Hospital  
- Allocate attractive salary package, towards the top end of industry standard range  
- Use professional recruitment approach, including using network referrals to identify attractive candidates  
- Run a professional selection process, including an industry representative(s) on selection panel and make prompt offer to selected candidate |
| Not attracting suitable candidates for USC CTC Manager position     | - Define very clear selection criteria in recruitment process and do not appoint unless a very strong candidate is available  
- Attempt to avoid any issues by professional recruitment process, assistance in relocation and a well planned orientation process across the critical first 90 days to get the person up to speed quickly  
- Clear KPIs in place and good performance review and feedback processes  
- Identify alternative areas within USC that CTC could add value to, e.g. QMNI, if industry connections do not work out as expected |
| USC CTC Manager does not perform to expectations of USC or industry partners | - Focus: use strategic planning and demographic and disease data analysis to identify research areas with sufficient patients in the area, do not over promise  
- Systematically build relationships with key stakeholders and patient referral sources across the Sunshine Coast and wider region  
- Maximise use of ICT to identify and stimulate referrals  
- Tap into USC’s existing goodwill, community connections, media and communication channels |
<table>
<thead>
<tr>
<th>Industry support</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Failure to win industry funding for specific clinical trial</strong></td>
</tr>
<tr>
<td>• Establish centre operations and ethos based upon industry input and needs</td>
</tr>
<tr>
<td>• Close involvement by industry on Advisory Committee</td>
</tr>
<tr>
<td>• Recruitment of a USC CTC Manager with a track record of securing industry funding</td>
</tr>
<tr>
<td>• Focus on niche areas with industry demand and where the Sunshine Coast has clear strengths</td>
</tr>
</tbody>
</table>

| Industry partners dissatisfied with service or operations and terminate support |
| • Establish good communication and partnership systems |
| • Ask for and act on industry feedback |

<table>
<thead>
<tr>
<th>ICT systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inadequate planning or funding</strong></td>
</tr>
<tr>
<td>• Good planning up front to identify ICT best practice and systems set up of other CTCs and to meet recommendations of the CTAG</td>
</tr>
<tr>
<td>• Early involvement of USC IT Services to ensure integration with USC and any external networks</td>
</tr>
<tr>
<td>• Adequate funding built into initial budgets, spread over first three years to respond to emerging needs</td>
</tr>
</tbody>
</table>

| Breach of confidentiality |
| • Early involvement of USC IT Services regarding network security |
| • Review industry standards and operations of other leading centres |

<table>
<thead>
<tr>
<th>Regulatory approval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethics compliance</strong></td>
</tr>
<tr>
<td>• Initially, use services of an external accredited centre</td>
</tr>
<tr>
<td>• Training for all staff</td>
</tr>
</tbody>
</table>

| Not gaining approval as a CTC site from ARCS Australia |
| • Clarify criteria and likely fit as a matter of priority |

<table>
<thead>
<tr>
<th>External issues</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delay in SARC or SCPUH construction and opening</strong></td>
</tr>
<tr>
<td>• Clinical trials are already running in the region, identify areas of interest from research staff and have some trials in the pipeline that are independent of the SCPUH opening date</td>
</tr>
</tbody>
</table>

<p>| Strong competition from other Universities, or lack of cooperation from Griffith University or Sunshine Coast Hospital and Health Service |
| • Build open relationships with Griffith University, Sunshine Coast Hospital and Health Service and others |
| • Seek opportunity for collaboration |
| • Differentiate by focusing on different areas of strength |
| • Leverage industry support |</p>
<table>
<thead>
<tr>
<th>Reputation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative community reaction to clinical trials in general or to a specific adverse event</td>
</tr>
<tr>
<td>• Community education program to build understanding of the role of clinical trials and their benefits</td>
</tr>
<tr>
<td>• Good processes and training in place for USC CTC Manager and Marketing and Communications to respond to any negative issues</td>
</tr>
</tbody>
</table>
11. References

The 2010 R&D Scorecard, The Top 1,000 UK and Top 1,000 Global Companies by R&D investment, Department for Business Innovation & Skills, UK Government

Exceptional Returns, The Value of Investing in Health R&D in Australia II, prepared for the Australian Society for Medical Research by Access Economics, June 2008


Access Economics, June 2008, Exceptional Returns: the value of investing in health R&D in Australia II, prepared for the Australian Society of Medical Research


Australian Government Clinical Trials Action Group Report, 2011

Sunshine Coast University Hospital Preliminary Masterplan Executive Summary, April 2010


Meeting Report from the USC CTC Discussion Forum held on 28 June 2011 (prepared by Professor Karen Woolley, ProScribe Medical Communications)

Discussion Forum Papers on Background Information, June 2011 (prepared by USC)
Concept Paper: Planning for the Development of a Clinical Trial Centre, October 2010 (prepared by Dr Mark Holmes, USC)
APPENDIX 1 – Detailed risk analysis

Approach
Any risks identified should be quantified in terms of the likelihood of an event occurring and the possible impact or consequences should it occur. The following tables outline the categories used to identify the level of a risk.

Measures of likelihood

<table>
<thead>
<tr>
<th>Level</th>
<th>Descriptor</th>
<th>Example detail description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rare</td>
<td>May occur only in exceptional circumstances</td>
</tr>
<tr>
<td>2</td>
<td>Unlikely</td>
<td>Could occur at some time</td>
</tr>
<tr>
<td>3</td>
<td>Possible</td>
<td>Might occur at some time</td>
</tr>
<tr>
<td>4</td>
<td>Likely</td>
<td>Will probably occur in most circumstances</td>
</tr>
<tr>
<td>5</td>
<td>Almost certain</td>
<td>Is expected to occur in most circumstances</td>
</tr>
</tbody>
</table>

Measures of consequence/ impact

<table>
<thead>
<tr>
<th>Level</th>
<th>Descriptor</th>
<th>Example detail description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Insignificant</td>
<td>No injuries; low financial loss</td>
</tr>
<tr>
<td>2</td>
<td>Minor</td>
<td>First aid treatment; on-site release immediately contained; medium financial loss</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Medical treatment required; on-site release contained with outside assistance; high financial loss</td>
</tr>
<tr>
<td>4</td>
<td>Major</td>
<td>Extensive injuries; loss of production capability; off-site release with no detrimental effects; major financial loss</td>
</tr>
<tr>
<td>5</td>
<td>Catastrophic</td>
<td>Death; toxic release off-site with detrimental effect; huge financial loss</td>
</tr>
</tbody>
</table>

Qualitative risk analysis matrix – level of risk

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Insignificant</th>
<th>Minor</th>
<th>Moderate</th>
<th>Major</th>
<th>Catastrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Unlikely</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Possible</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Likely</td>
<td></td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Almost certain</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>5</td>
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</tbody>
</table>

1 Low Risk
2 Moderate Risk
3 High Risk
4 Very High Risk
5 Extreme Risk
<table>
<thead>
<tr>
<th>Risk</th>
<th>Likelihood</th>
<th>Consequence/Impact</th>
<th>Assessment</th>
<th>Mitigating strategies (summary)</th>
<th>Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff Recruitment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Not attracting suitable candidates for USC CTC Manager | 3          | 3                  | 3          | 1. Involve Industry Advisors  
2. Professional recruitment, selection and orientation processes                                | TBC by USC   |
| USC CTC Manager does not meet expectations   | 3          | 4                  | 4          | 1. Clear selection criteria  
2. Clear KPIs  
3. Add value to key USC areas                                                                |              |
| **Patient Recruitment**                      |            |                    |            |                                                                                               |              |
| Insufficient number or type of patients      | 3          | 4                  | 4          | 1. Good planning will identify numbers and target areas  
2. Maximise use of ICT  
3. Build referral sources                                                                 |              |
| **Industry support**                         |            |                    |            |                                                                                               |              |
| Failure to win industry funding for trial    | 2          | 4                  | 3          | 1. Establishment based on industry needs  
2. Focus on niche areas in demand                                                               |              |
| Industry partners dissatisfied               | 3          | 4                  | 4          | 1. Good communications  
2. Industry feedback                                                                          |              |
| **ICT systems**                              |            |                    |            |                                                                                               |              |
| Inadequate planning or funding               | 2          | 3                  | 2          | 1. Good planning  
2. Early involvement of USC IT Services                                                        |              |
| Breach of confidentiality                    | 1          | 4                  | 3          | 1. Early involvement of USC IT Services  
2. Review industry standards                                                                   |              |
<table>
<thead>
<tr>
<th><strong>Regulatory approval</strong></th>
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<tr>
<td>Ethics compliance</td>
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<td>4</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Initially, use externally accredited centre</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Training for all staff</td>
</tr>
<tr>
<td>Not gaining approval as a CTC</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Clarify criteria and build to fit</td>
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<tr>
<td>Delay in SARC or University Hospital construction</td>
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<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Identify some early trials which could run independently of hospital</td>
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<tr>
<td>Strong competition from other universities</td>
<td>3</td>
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<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Build open relationships</td>
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<td></td>
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<td></td>
<td></td>
<td>2. Collaborate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3. Differentiate</td>
</tr>
</tbody>
</table>

<table>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative community reaction</td>
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<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Community education</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Processes and training to manage risk</td>
</tr>
</tbody>
</table>