

Clinical Trials in a Primary Care Setting

A perspective based on the
University of the Sunshine Coast Clinical Trials Centre (USC CTC)
experience

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Workshop Presentation Agenda



1: We are USC Clinical Trials Centre

2: Healthcare in Australia

3: Primary Care Clinical Trials

4. USC CTC Case Study

5: Future Directions

We are USC CTC

A world-class clinical trial site network bringing advanced treatments and breakthrough therapies to the Sunshine Coast – and beyond

Topic 1/5



A Strong Start has led to Strong Growth

- University initiative launched in 2015
- Initiated broad ranging engagement to foster strong connection with community
- Extended clinical trial capabilities in QLD
 - 2 USC Clinical Trial Centres
 - 20 Partner Sites
 - 50+ Principal Investigators & 22 Clinical Operations Staff
- Potential participant pool > 1 million
 - Acute & Chronic Indications
 - Healthy Volunteers

Solid Team, Infrastructure & Track Record

- Every site operates seamlessly under the USC CTC Banner
 - Standard SOPs, Equipment and Quality Control
 - E-Source, E-Monitoring (E-Consent coming soon)
 - CTMS (accounting, scheduling, recruitment, regulatory site/master file)
- Cloud-based tech → operational efficiency across locations
- 35+ clinical trials in 4 years
 - General Practice vs Specialist (30:70)
 - Therapeutic vs Device/Diagnostic (95:5)
 - Treatment vs Prevention (90:10)
- ~90% of completed trials reach or exceed recruitment targets

This screenshot shows the 'Check-In and Consent' form within the USC CTC Banner system. The form is titled 'Check-In and Consent' and includes a 'Monitor Reviewed' status. It contains several sections for data entry, including 'Check in Questions and Informed Consent' with fields for 'Were all of the subject's medications recorded?', 'Was the subject's medical history reviewed?', 'Did the subject make the required informed consent?', and 'Did the subject sign the latest version of the informed consent?'. Each field has 'Yes', 'No', and 'NA' options. There is also a section for 'Blank Copy of Consent Form' with a file upload field and a date field. A 'Source Document Notes' section at the bottom contains a table with columns for 'User' and 'Note', showing two entries from 'Dr. John Smith' dated 08/04/2018 and 08/04/2018.

This screenshot shows the 'REALTIME Study Documents (Enrolling)' interface. The interface has a sidebar with navigation options: STUDIES, SUBJECTS, CONTACTS, REPORTS, MY DOCS, MY TASKS, CALENDAR, UNIVERSITY, ACCOUNTING, and ADMINISTRATION. The main content area is titled 'Study Documents (Enrolling)' and includes a search bar and a list of documents. A table titled 'HREC Composition' is visible, with columns for 'Doc', 'Version', 'File', 'Document', 'Status', and 'Expires'. The table shows one document, 'TobaccoUse...', with a status of 'Green'.

Our Mission Encompasses 5 Key Aims

Bridge the access gap between innovative medicine & our community

*

Foster economic growth in the clinical research sector

*

Develop next generation of clinical trial workforce

*

Deliver the maximum ROI for each client on every trial

*

Challenge conventional clinical trial operating models

Our Vision is to Deliver Innovation in Trials

To demonstrate that innovative clinical trial models
deliver increased medical, operational, social & financial benefits

*

A leader in changing clinical research paradigms for greater good

Our Strategy is to Create New Trial Capacity

- Need: Increase capacity to meet industry demand to conduct more trials
- Aim: Operationalise clinical trial-naïve sites
- Goal 1: Build on QLD capability
 - Specialist Hospital Development
- Goal 2: Expand operations into Victoria
 - Metropolitan vs Regional
 - Primary Care vs Specialist
 - Acute vs Chronic Indications
- Status: Environmental scan and relationship building

Take home message:

“Our drive is to increase clinical trial capability and capacity. Inequity in trial accessibility is particularly felt in outer-metropolitan, regional and rural areas.”

Lucas Litewka

Healthcare in Australia

Australia is home to a high-quality universal healthcare system that ensures all Australians have access to health services. This system is further supplemented by a range of private providers.



Hospitals are Typical Clinical Trial Locations

- 695 Public Hospitals
 - 35mil outpatient services¹
 - 10.2mil admissions¹
 - 7.4mil presentations to A&E¹
- Significant Private Hospital System
 - 630 private hospitals¹
 - Private health insurance rebate
- Both secondary and tertiary hospitals are currently involved in clinical trials

Primary Healthcare is Community Based

- Primary health care is external to the hospital environment
- Includes a range of community-based providers:
 - General Practice
 - Urgent Care Centres – Health Hub Morayfield
 - Super Clinics
 - Community Health Centres
 - Allied Health services e.g. Optometry, Pathology, Physiotherapy
 - Retail Health Services e.g. Pharmacy
 - Telehealth and Video Consults
 - Primary Health Network (phn) hospital in the home services

Primary Health in the Medical Ecosystem

- Entry point into the healthcare system
 - Prevention of illness
 - Diagnosis of disease
 - Treatment of early stage disease
 - Health promotion

- Ongoing management of health
 - Management of chronic disease
 - Generate referrals to specialists, allied health, social services, hospital-based services
 - Support specialist care
 - Follow-up post hospital discharge

The Scale of Primary Healthcare is Significant

- Primary healthcare is an important economic force
 - Annual expenditure is over \$55bil¹
 - Accounts for over 1/3 total health expenditure²
 - Similar level of expenditure to hospital spending
 - \$30bil on GP services + medications²
- 85% population visit GP each year
 - 33,279 GPs²
 - 139mil consultations²
 - 83% of consultations were bulk-billed¹
 - 117mil prescriptions + 13mil medications provided directly

Primary Care has appeal for clinical trials

- Electronic (and searchable) Medical Records > 20 years
- Frequent touch points with Patient
 - Multi-disciplinary care environment
 - Increase in care for complex conditions/patients
 - High volume of Patients
 - Newly diagnosed Patients
- Corporatisation of primary care
 - Rely on business efficiency
 - High volume of Patients
- Good access to GPs = Good access to Trial Investigators

Trials can benefit Primary Care Centres too

- Provide access to novel treatment modalities
- Opportunity to be involved in research
- Introduce new patients to practice
- Measurable benefits
 - Financial e.g. additional revenue stream
 - New relationships with industry stakeholders
 - Publication/Speaking opportunities

Research Shows Need for Primary Care Trials

- Burden of disease > No. of clinical trials in disease²
- Frequency of disease > Publication of research²
- Lack of translation of research findings to primary care^{2,3,6}
 - Based on secondary/tertiary RCTs
 - Different patient population in same disease
 - Bias based on case selection and referral
- Publication rates for GPs is very low²
 - Trebled from 1990-1997 to 2000-2007
 - GP Publications (3/1000) < Surgeons (68/1000) < Specialists (160/1000)

Interest in Australian Clinical Trial Sites is Clear

- 400+ feasibilities sent to USC CTC → 35 clinical trials
- Currently turn away 90%+ of feasibilities
 - No follow-up from Sponsor
 - Lack of resource
 - Protocol or Budget issues
 - Standard of Care is too compelling
 - Limited scientific interest



Positive Forecast for the Local Sector

Sponsor Companies

Biotech
Pharmaceutical
Medical Device
Nutraceutical
US\$150b by 2020

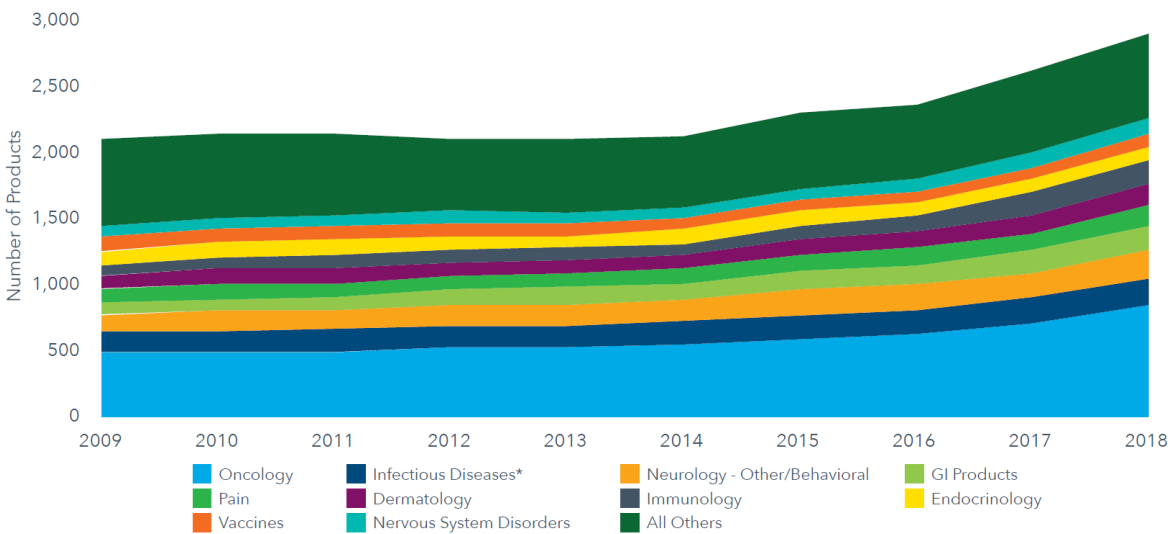
Contract
Research
Organisations
US\$36.7b by 2020

Regulatory
Agencies
Ethics Committees

Local Industry
Host Institutions and Sites
Annual Value
~AUD\$900m

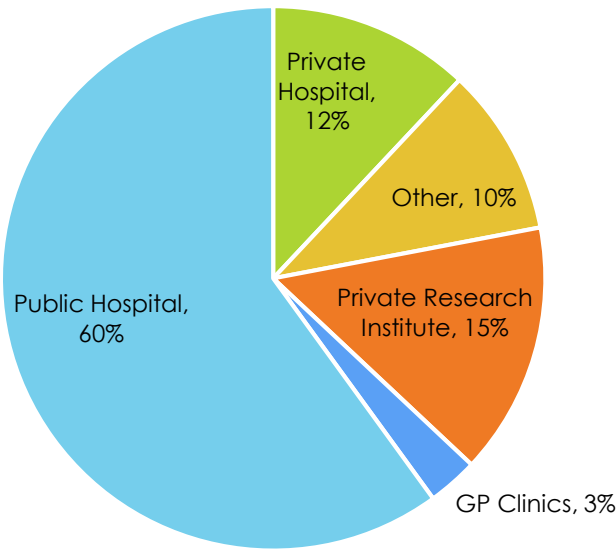
The late-stage development pipeline has expanded steadily over the past four years with 11% growth in both 2017 and 2018

Exhibit 6: Number of Late-Stage Pipeline Products by Therapeutic Drug Class, 2009–2018



Source: IQVIA Pipeline Intelligence, Dec 2018; IQVIA Institute, Mar 2019

Host Organisation - trial site



Take home message:

“The Australian clinical trial environment coupled with our first-class primary healthcare system offers many benefits. Organisations around the world recognise this. We need to capitalise on this.”

Nicole Bechaz

Primary Care Clinical Trials

Establishing clinical trial capacity within a primary care setting represents a new paradigm in clinical research. At the same time, tangible investment is required to overcome the inherent challenges.



Considerations for Establishing Trial Sites

- Identification & due diligence
- Location & demographics
- Available infrastructure
- Legal relationship
- Compensation
- Timelines
- Training and competencies

Legitimate Site Concerns About Clinical Trials

- Patient privacy concerns⁴
- Voluntary consent^{3,4}
- Total indications in patient population > Clinical trial indication^{2,3}
- Perception that research is theoretical⁵
- Standard care vs protocol care^{3,5}
- Complex patient populations with multiple co-morbidities³

Workflow balance is key but not always easy

- Standard care vs. Clinical Trial Load vs. Administrative Tasks
- Business Development
- Infrastructure Development e.g. SOPs
- Quality Assurance & Control
- Site / Team / Network Management
- Short timelines dictated by external factors

Patient Recruitment is Never Guaranteed

- Time & workforce constraints^{2,3,5}
- Lack of remuneration⁴
- Lack of recognition of GPs as investigators⁴
- Lack of interest in the research question^{4,5,6}
- Lack of infrastructure support for GPs participating in data collection and research^{2,4,6}
- Reduction in Government & Member Group funding support²
- Lack of research collaboration (clinical trials) between tertiary and primary care²

Outreach Activities are Essential to Every Trial

*“The days of enrolling patients
as they walk through the door are over.”*

Lucas Litewka

USC CTC Case Study

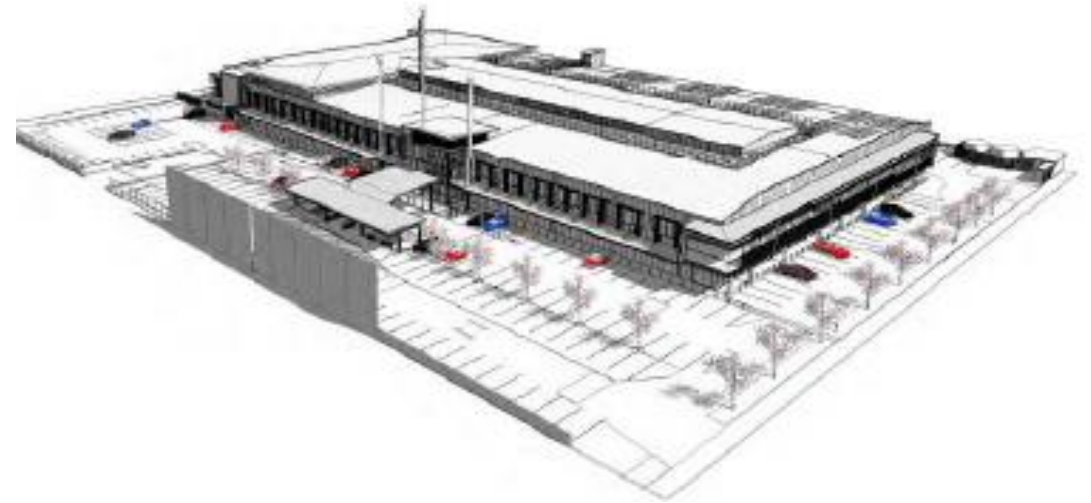
Health Hub Morayfield
Queensland, Australia

Topic 4/5



HHM represents a new paradigm in care

- Health Hub Morayfield opened in December 2017
- 40min from Sunshine Coast and Brisbane
- 14,000m² primary - urgent care facility
- Aim: 90 x GPs and 30 x Specialists
- 41,000 registered patients currently
 - >3000 patients week



USC CTC opened 2nd core centre at HHM

- USC CTC officially opened a 2nd primary centre here in April 2019
 - Operational for several months in temporary space
- Currently conducting 6 clinical trials
 - Additional 3 confirmed within the next quarter
- Burden of disease is high in this community
 - Large pool patients
 - Successful recruitment
 - High quality



Take home message:

“We value enthusiasm, a willingness to learn, an ethical outlook and a cultural fit over clinical trial experience. The successes of each of our clinical trial sites is testament to this ”

Lucas Litewka



Future Directions

Re-frame the chaos, uncertainty and challenges inherent in clinical research to create solutions and opportunities that can benefit all sector stakeholders.



Key activities will help to realise our strategy

- Pipeline Diversification
 - Drugs & Devices
 - Clinical guidelines, best practice & healthcare efficiency modelling
 - Lifestyle Medicine
- Funding Opportunities
 - Biopharma Companies
 - NFP & Corporates
 - MRFF & Government
- Extracurricular Activities
 - Business Development
 - Policy & Advocacy

Sector Wide Opportunities Exist

- Collaboration between primary and secondary/tertiary healthcare
 - Cross-referral of potential participants
 - Shared responsibilities on individual clinical trials
 - Satellite sites
 - Mentorship for clinical trial-naïve sites & staff
 - Development of research questions of mutual interest
 - Clinical research & patient care enhanced by 360 feedback

Take home message:

“There will always be risk. However, by committing to finding novel solutions and new pathways, we can take the Australian clinical trial sector to even greater heights - to the benefit of patients and organisations alike”

Nicole Bechaz



Clinical Trials Centre

Queensland, Australia

For further information on the Australian clinical research sector or our clinical trial capabilities, please contact

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References:

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2. <https://www.mja.com.au/journal/2016/205/2/prioritising-general-practice-research>
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5. <https://www.ncbi.nlm.nih.gov/pubmed/10758084>
6. <https://www.woncaeurope.org/sites/default/files/098%20%E2%80%93%20New%20Era%20for%20Clinical%20Research.pdf>