Research Business Development: Challenges and Solutions

Catholic Health Australia Research Symposium
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Research Directorate @SVHM

- SVHM is renowned for excellence of clinical care
- Mission states “innovative care enabling hope”
- Research is one of 5 pillars of SVHA strategic plan: enVision 2025
Group Strategy

As a Catholic health care service we bring God's love to those in need through the healing ministry of Jesus. We are especially committed to people who are poor or vulnerable.

Vision
We lead through research driven, excellent and compassionate health and aged care.

Values
// Compassion
// Justice
// Integrity
// Excellence

Creed
We believe in the dignity of all people because each one is created in God's image. We are committed to justice and compassionate care for all.

Our Focus
We prioritise serving five key groups:
// Mentally ill
// Drug and alcohol addicted
// Homeless
// Aboriginal & Torres Strait Islanders
// Prisoners

SERVING SOMETHING GREATER

Formation
in Catholic health and aged care

Serving and advocating for poor and vulnerable

Public Hospitals
// Centres of Excellence
// Invest in existing facility growth
// Expand footprint in growth corridors
// Building partnerships

Private Hospitals
// Strengthen and grow existing hospitals by 500 beds
// Expand into strategic growth corridors
// Market leaders in private health
// Operate collaborative business
// Financial strength and flexibility

Aged Care
// Expand to 15,000 places by 2025
// Grow to 5,000 places by 2020
// Strengthen and grow existing facilities
// Innovative and best practice models of delivery
// Trusted members of the communities we serve

Research
// Increase funding and publications
// Strengthen collaboration with universities, co-located partners and between States
// Mission-related research

STRIVING FOR SOMETHING GREATER

Person Centred Care
// Respectful, compassionate, culturally safe & competent

Clinical and Research Excellence
// Deliver best clinical outcomes

Operational Excellence
// Efficient services
// Continuous productivity improvement

Best People in health and ageing
// Keeping our people safe

‘One SVHA’
Research Directorate @SVHM

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• Mission states “innovative care enabling hope”
• Research is one of 5 pillars of SVHA strategic plan: enVision 2025

• Facilitate research, grow our research culture
  Advocate for research as core component of hospital business
  Expect all clinicians to be involved in research: support/undertake
  Expect all patients to be offered the opportunity to participate in research

• Research Directorate is an independent business unit within hospital
  Control over our own financial state, no block funding
  Generate our own income to fund activities
Research BD Challenges

• Research is not core business for hospitals
• Lack of trust and mutual understanding between academics/clinicians and industry
• Mal-alignment between industry and hospital on key drivers, time frame and disposable resources
<table>
<thead>
<tr>
<th>Stage</th>
<th>% change</th>
<th>Average days taken pre- and post-Good Practice Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date CDA sent to PI → Date CDA returned to Sponsor</td>
<td>44.6% decrease</td>
<td>20.6 / 11.4</td>
</tr>
<tr>
<td>Date Sponsor releases study protocol and feasibility assessment form to PI → Date PI returns completed feasibility assessment to Sponsor</td>
<td>0.7% increase</td>
<td>14.6 / 14.7</td>
</tr>
<tr>
<td>Date PI returns completed feasibility assessment to Sponsor → Date of site selection visit</td>
<td>35.4% increase</td>
<td>58.2 / 78.8</td>
</tr>
<tr>
<td>Date of site selection visit → Site selection notification by sponsor</td>
<td>44.8% decrease</td>
<td>36.6 / 20.2</td>
</tr>
<tr>
<td>Date site selection is confirmed by sponsor → date valid site assessment/ethics review documentation is submitted to institution (whichever is later)</td>
<td>21.7% decrease</td>
<td>199.6 / 156.2</td>
</tr>
<tr>
<td>Date valid ethics review documentation submitted to institution → Date ethics approval letter is provided to PI</td>
<td>24.9% decrease</td>
<td>59.9 / 41</td>
</tr>
<tr>
<td>Date valid site assessment documentation submitted to institution → Date site assessment is finalised</td>
<td>33.8% decrease</td>
<td>21.9 / 30.3</td>
</tr>
<tr>
<td>Date from completed site assessment (including ethics approval) → Date site authorisation is granted by the CEO or delegate</td>
<td>32.5% decrease</td>
<td>44.9 / 65.5</td>
</tr>
<tr>
<td>Date site authorisation granted by CEO or delegate → Date the first participant is recruited into the study</td>
<td>33.7% decrease</td>
<td>43.4 / 65.5</td>
</tr>
</tbody>
</table>

SVHM = 355, 249

Contact clinicaltrials@nhmrc.gov.au for more information
Research BD Enablers

- St Vincent’s Research® Valet Service
- Research Ethics & Governance KPI & Targets
- Research Support and Facilitation
Research Valet® Service

The key feature of this unique service is close communication between sponsors/researchers and the Clinical Trials Business Development Manager, Dr Wade Kruger, at each step of the process.

With over 10 years in biomedical research and project management, Wade combines analytical skills with a strategic outlook and a mature capacity to engage and collaborate effectively with stakeholders at all levels. He has a Bachelor of Biomedical Sciences, Bachelor of Science with Honours (Pharmacology) and a PhD in Physiology. Wade possesses an overall passion for facilitating and streamlining quality clinical research.

Testimonials

“We have used St Vincent’s Valet Service on many occasions and found this to be an efficient, timely and high quality service leading to faster start up timelines in Australia.”

- International Contract Research Organisation

“At first we were doubtful about the service, but our experiences surpassed our expectations. The service we were provided was excellent with high quality submissions and approval within 14 days of the meeting. We will be using the service on any future studies.”

- Project Manager International Pharma Co.

For more information contact:

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Research Valet™ Service at St Vincent’s Hospital Melbourne

‘Your lead site solution’

- Single point of access for all regulatory/IRB advice for Australia
- Speed startup time for Australian clinical trials (Ph I-IV)
- Final IRB/Ethics outcomes within 30 days of committee meeting
- Startup to full study management options
- IRB/Ethics approval from single HREC/IRB for all Australian states (except WA and NT)
- St Vincent’s Hospital not required to be a participating site
Research Valet® Service

- Since implementation in early 2015, strong uptake from all stakeholders, even established departments
- Sponsors and CROs – preferred service
- 30 days timeframe is on par with industry recommendation
Research Ethics & Governance KPIs and Targets

• **Clear HREC KPIs**
  – All documents circulated 12 days prior to the meeting
  – Queries back to PI within 48 h meeting
  – Target 30 day final response to submission

• **Governance targets**
  – Completed governance assessment within 5 days

• **Audit and track start-up process timeline**
  – Good Practice Pilot (NHMRC)
  – From feasibility to first patient enrolled
Research Advocacy and Facilitation

• **External**
  – Promotion of SVHM as a research active hospital
  – Reputation reinforcement
  – Identification of stakeholders or external collaborators
  – Active business development
  – Active innovative solutions to cross-sectoral interfaces

• **Internal**
  – Lifting administrative burden off researchers
  – Re-focus clinicians and researchers on conducting research eg recruitment, participant relationships, dissemination of results
  – Facilitator rather than barrier
Research Advocacy

• **State government**
  – Department of Health and Human Services
    – Minister opens ACMD Research Week
  – Department of Economic Development

• **Federal Government**
  – Department of Health
    – Innovation
    – Sector Strategy – Medical Technologies and Pharmaceuticals

• **Peak bodies**
  – State – BioMedical Research Victoria, BioMelbourne Network, MACH,
Victorian Clinical Trials Gateway

Connecting industry with Clinical Trials in Victoria, Australia

Victoria, Australia is home to some of the world’s best researchers and health professionals, boasting industry leading research infrastructure, a stable socio-political environment and favourable regulatory incentives.

Victorian Clinical Trials Gateway is your digital path to clinical trials in Victoria, allowing you to access useful information and experienced professionals to partner with.

victrials.com.au
Research Facilitation - External

- **Active Business Development process**
  - Identified stakeholders
  - Active program of meet-and-greet in person or teleconference
  - Asked what they wanted from us – looked to find our deficiencies
  - Told them what we wanted to achieve
  - Aimed for alignment of our goals, mutual benefits

- **Stakeholders – groups our researchers wanted to engage**
  - Large and small pharma
  - CROs
  - Design and development industry (bioengineering expertise)
  - Peak industry bodies
  - Collaborators – universities, MRIs, health services, CTGs, etc
Active Business Development

• Established Site Alliances with CROs
  – Aim is to simplify interactions from both sides – relationships
  – Aim to increase study offerings to our researchers
  – And to improve study performance by SVHM for CRO
  – Bidirectional information sharing
  – Regular scheduled meetings – F2F and teleconf

• Direct Benefits
  – Institutional CDAs and capability details (PI CVs target)
  – Research Directorate included in all site assessments and feasibility offers, can ensure more rapid turn-around
  – Single point of contact for both CRO and Site for problems
  – Participation in education and promotional activities on site
St Vincent’s Bridge™
Linking clinicians and industry

Access world leading clinical experts and key opinion leaders in Melbourne, Australia.

Facilitating the early integration of clinical alignment with industry, at every stage of your path to market.

St Vincent’s has proven expertise linking industry and clinical experts across many areas:
- Cardiology
- Endocrinology
- Gastroenterology
- Medical Devices
- Neurosciences
- Oncology / haematology
- Orthopaedics
- Psychiatry
- Mental health
- Addiction medicine
- Respiratory
- Rheumatology

Talk to our team to learn more about your area of interest.

Dr Megan Robertson
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Dr Tam C. Nguyen
Executive Officer Research
Tam.Nguyen@svha.org.au
Research Facilitation - Internal

• Research Directorate needs to be viewed as “facilitator”
  – HREC and governance processes traditionally viewed as “barrier”

• Communication essential
  – Updated website with ease of access to information
  – Fortnightly email Research Bulletin
  – Attendance at hospital meetings, events and grand rounds, etc
  – Easily contactable – business cards, mobile, email, etc all available
  – Research Report published annually – prospectus externally, launch internally
  – Annual Research Week – true celebration, events, speakers, networking, WINE
Research Facilitation - Internal

- **Aim to lift administrative tasks off the researchers**
  - Lead site solution via Research Valet Service
  - Centralised billing service (all funds return to department)
  - Single list of costs for standard services from pharmacy, pathology, radiology
  - Enable research teams to focus on what they do best - interaction with patients

- **Support decentralised model of researcher teams embedded in departments**

- **Encourage interaction between departments and staff**
  - CTQAC meets every 2 months – lunch and education session
  - Harmonising documents, streamlined SOPs, templates, budget determination

- **Education**
  - free GCP online, seminars and symposia in Research Week
  - CTMS provision planned
**Summary**

- **STOP**: Inefficient practices
- **STAY**: Promoting excellence; Build capability & partnership with Industry
- **START**: Team approach; Entrepreneurial mindset
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SVHM Precinct including Aikenhead Centre for Medical Discovery
• Founded in 1893. Mission-driven, with particular expertise in care for the disadvantaged.

• One of 5 tertiary teaching hospitals in Victoria – one of the 3 major CBD hospitals. Respected clinical education and research programs.

• Leadership:
  – First hand transplant in Australia
  – Biofabrication Suite
  – Islet cell transplantation
  – Squamous cell lung cancer
  – Ultrasound-guided anaesthesia
  – Mental health mentoring across Asia
St Vincent’s Health Australia

- Australia’s largest Catholic not-for-profit health provider
- $2 billion group
- 12th largest private company in Australia
- 27 facilities
- 17,000 staff
- > 1 million occasions of care/year
- St Vincent’s Hospital Melbourne is the largest entity in the group
The Aikenhead Centre for Medical Discovery (ACMD) will be Australia’s first hospital-based biomedical engineering facility that brings together medical practitioners, engineers, scientists and industry experts to solve real patient problems. It will help capitalise Australia’s position within an emerging new industry.