Clinical Trials in the Private Hospital Setting

Sonya McColl  Clinical Research Manager
The labour was short, the delivery hard, the result spectacular

Sonya McColl
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The Wesley Hospital

- One of Queensland’s largest private hospitals
- Employs about 2,000 staff and services over 75,000 patients annually
- 35 areas of specialty with over 900 accredited referring specialists
- Four pillars of Oncology, Cardiology, Surgery and Women’s Health
- Part of the UnitingCare Health group of hospitals
- The Wesley Research Institute is collocated with The Wesley Hospital

The Wesley Research Institute

- Not-for-profit medical research institute in Queensland
- Actively committed to fundraising for medical research to improve patient care and quality of life in the here and now
- Primary focus to support Investigator Initiated Research and engaging hospital clinicians in research
- Basic clinical trials service commenced in 1998
- Modern Clinical Trials Centre and Tissue Bank opened in 2007
- Health and Medical Research Centre, supporting Investigator Initiated Research, opened in 2009
Conception of a Clinical Trials Centre

Why Conceive?

Is the Ground Fertile?

What are your Parental Responsibilities?
Why Conceive?

• Benefit to the Patients/Community

• Benefit to the Clinicians/Researchers

• Benefit to the Hospital
Is the Ground Fertile?

• Market Need

• Resources

• Support

- Funding

The Wesley Research Institute Expansion
What are your Parental Responsibilities?

**Ethical**

Therapeutic Goods Administration (TGA)
- Good Clinical Practice (ICH-GCP-TGA)
- The Australian Clinical Trial Handbook

National Health and Medical Research Council
- National Statement on Ethical Conduct in Human Research 2007
- Australian Code for the Responsible Conduct of Research

Declaration of Helsinki

Human Research Ethics Committees

**Legal**

Medicines Australia
- Code of Conduct

- Form of indemnity

- Clinical trial agreement

National Privacy Act 1988
as amended from time to time

State Privacy Act
Queensland Information Privacy Act 2009
# What are you in for?
## How to Set Up a Clinical Trial

### Sponsor
- Protocol
- Investigator Brochure
- Participant Materials
- Drug/Device
- Case Report Forms
- Protocol/site training
- Budget/Clinical Trial Agreement

### Ethics
- Sponsor documentation
- National Ethics Application Form
- Medicines Australia Clinical Trial Agreement
- Medicines Australia Form of Indemnity
- Clinical Trial Insurance - Certificate of Currency
- 1572 and Financial Disclosures (if FDA IND)
- Investigator CV’s
Site Responsibilities

- Reviews feasibility of conducting trial
- Reviews target population and entry criteria
- Identifies appropriate/interested Investigator
- Allocates research staff
- Ensures proposed budget is adequate (negotiate with sponsor)
- Allocates research staff
- Provides required documentation
- Ensures required equipment available
- Pharmacy and pathology requirements
Birth of a Clinical Trials Centre

Preparation

Delivery
Preparation

Governance & Systems

Resources

Business & Professional Relationships

$Funds$
Standard Operating Procedures
The happy family...
Growth of a Clinical Trials Centre

Stages of Development

Peer Pressure
Stages of Development

Trial Suitability

Staffing

Business Management

Financial
Peer Pressure

- Competition from 3rd World Countries
- Niche Market
- Support the Industry
- Private Hospitals
Is it Worth the Pain?

- Rewards
- Milestones
- Outcomes
The Clinical Trials Centre

Contact Information

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