



# Clinical Research Excellence 09

**Clinical Research: Expanding Australia's  
Place In The World**

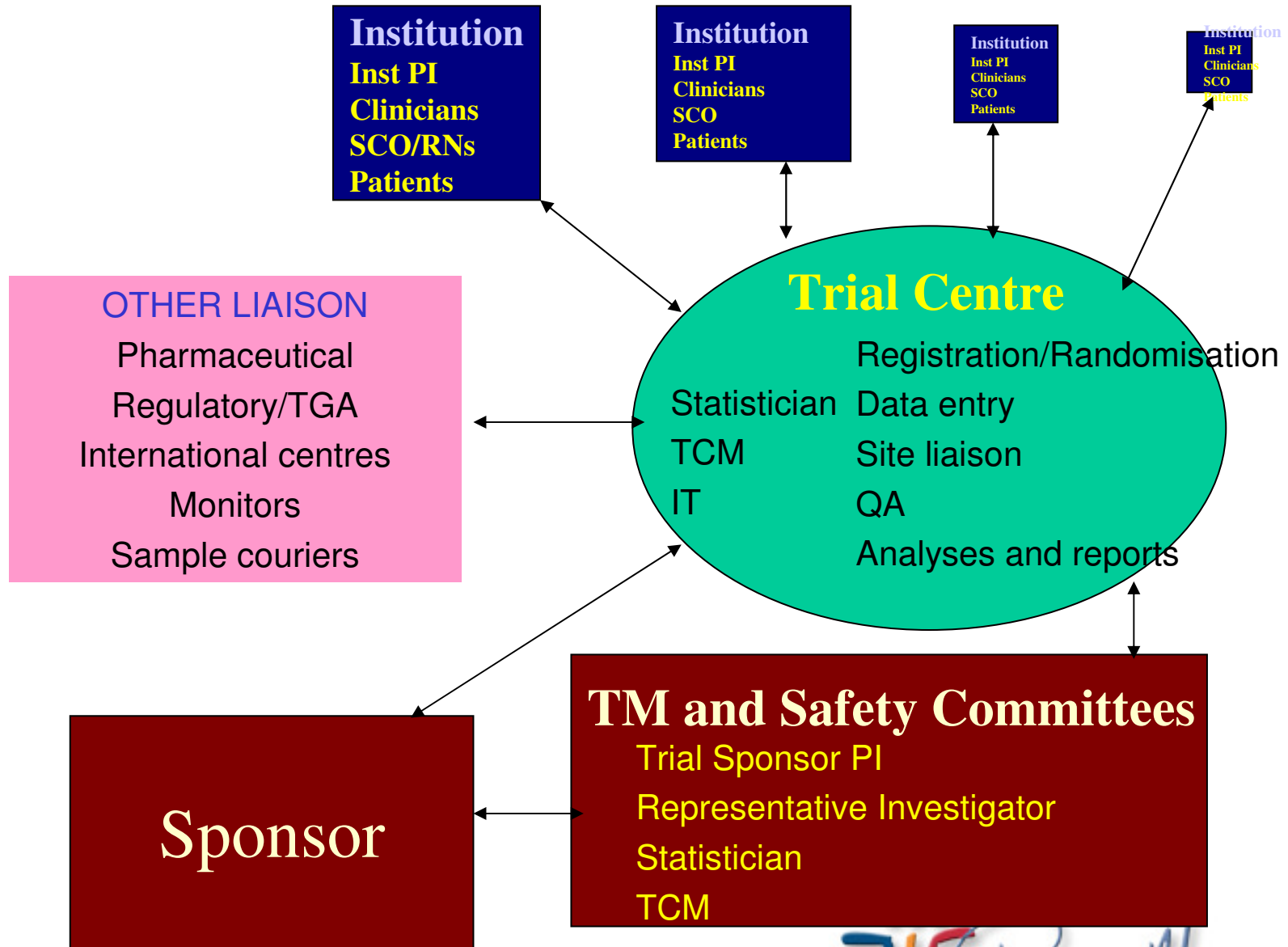
**A CCRE Conference**

20 August 2009 • Melbourne Cricket Ground • Australia

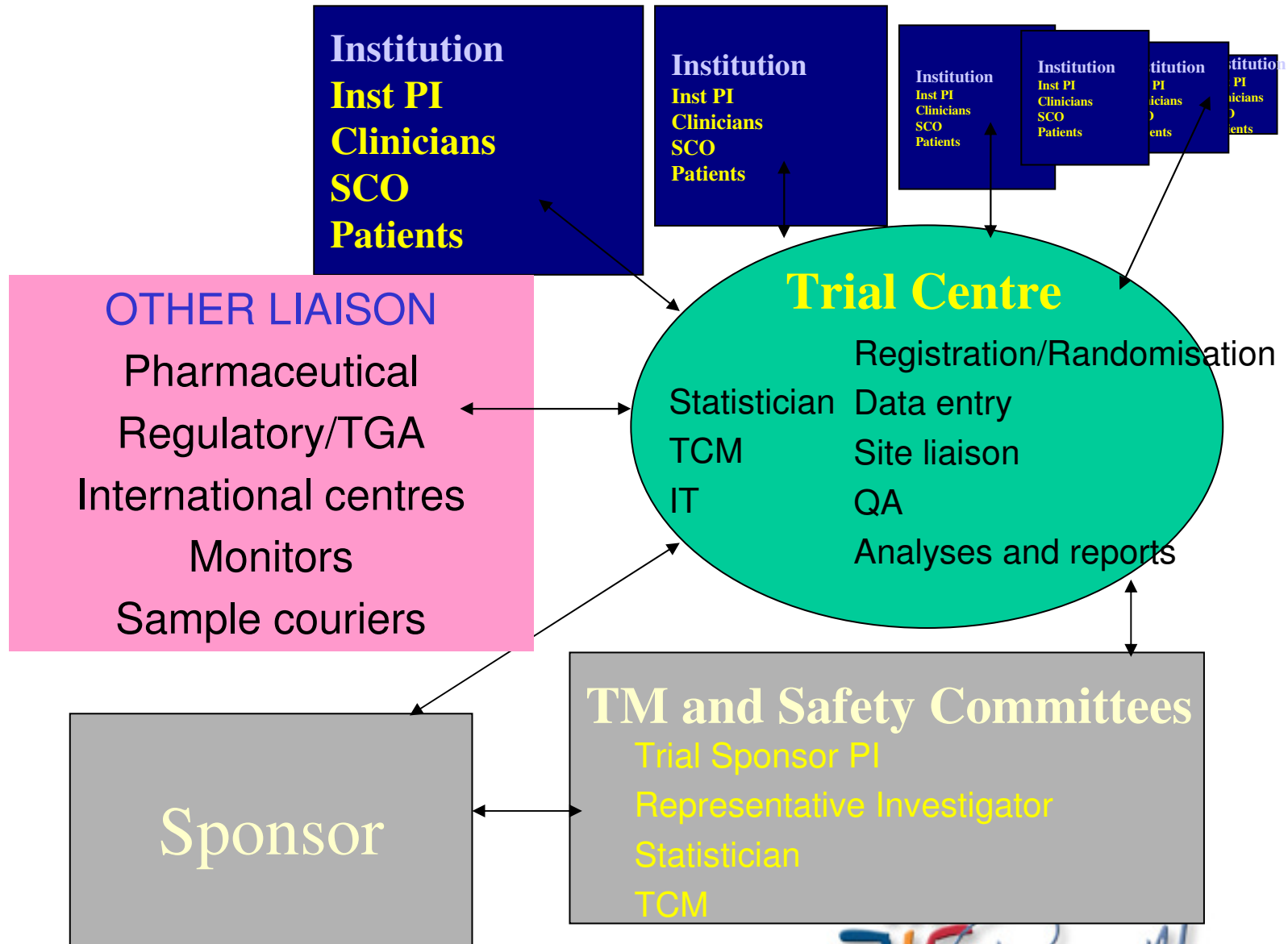
**Cost containment  
Recruitment and motivation  
Adverse Event management**

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# Cost containment



# Cost containment



# Breakdown

- Development
- Conduct
- Finalisation and analysis
- Site payments
- Third parties eg couriers, labs, monitoring
- Drug and/or supportive care costs
- Finally, all contracts take time – a lot of time!

# Recruitment

- Two main factors
  - Good question
  - Motivated and engaged sponsor-investigator

# Motivation to participate

- Scientific
- Site resources
- Authorship
- Communicate during trial conduct via Newsletters

# Safety – Adverse Events

- Adverse Events (AE) – any untoward medical occurrence, not necessarily a causal relationship with the treatment

When is an AE classified as “serious”?

# Safety - SAE

- Serious Adverse Event (SAE)
- An AE that
  - results in death
  - is life threatening
  - requires hospitalisation or prolongation of hospitalisation
  - results in significant disability or incapacity
  - Is a congenital abnormality or birth defect

# Safety - SUSAR

- Suspected unexpected SAE
  - Suspected
    - Suspected that it is related to the treatment, or the relationship is **unknown**
  - Unexpected
    - Is not documented in the protocol or other publications as expected.

What are your responsibilities as the sponsor-investigator?

# Sponsor responsibilities and reporting requirements

- Documentation
  - SUSAR review form
- Communication
  - Trial Safety Committee
  - All investigators
  - Pharmaceutical company/manufacturer (IB update)
  - Listed in trial final report and any publications
- Regulatory oversight
  - Regulatory agency if drug is involved
  - Confirm ethics committee notification

# Adverse Event Management

- Begins with the protocol
  - Type of intervention
  - Dose of intervention
  - Part of the body involved
  - Intention of the treatment
  - Eligibility criteria indicating patient status
  - Risks of the intervention

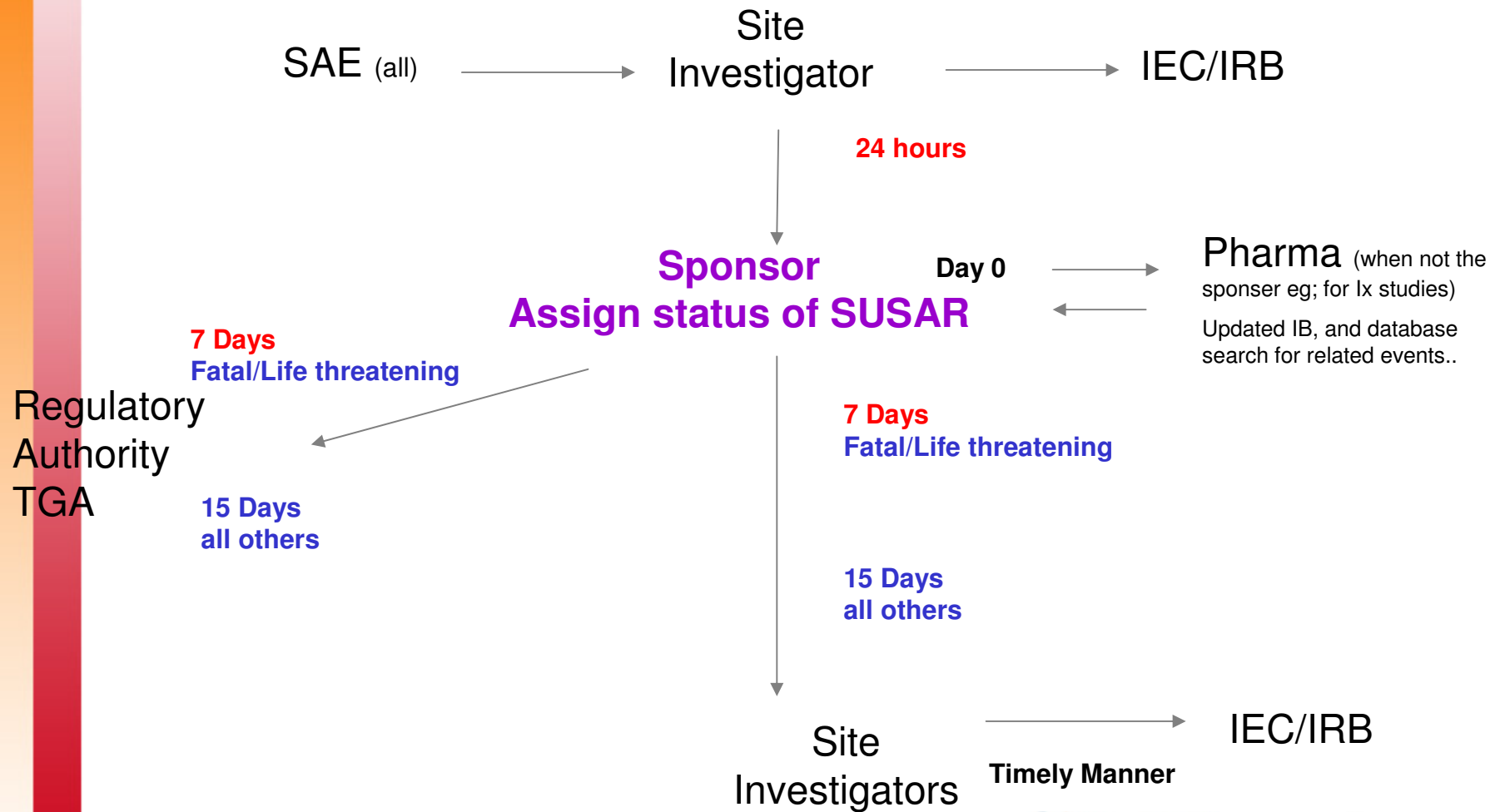
# Adverse Event Management

- Then the database
  - Adverse event data base
    - Stopping rules
    - Safety committee report
  - Serious Adverse event database
    - SUSAR reporting

# Adverse Event Management

- And also the regulatory requirements for drug trials (TGA)
  - Approved or unapproved drug (as per ARTG)
  - CTX Scheme - approval
  - CTN Scheme - notification
  - Gene therapy - Office of Gene Technology Regulator (NHMRC) for manufacture

# Sponsor responsibilities and reporting requirements – summary and timeframes



# Sponsor responsibilities and reporting requirements – summary and timeframes

## **72 hour**

Sponsor required to inform regulatory authority of **any significant issue** that has arisen from its analysis of overseas reports or action which has been taken by another country's regulatory authority.