

Research Ethics and Governance

– state initiatives for global trials



Dr Suzanne Hasthorpe
Coordinating Office for Human Research Ethics

AusBiotech 2010

Guiding principles

Streamlining ethical review of multi-site clinical trials

- Separation of ethics review from research governance
- Common IT platform, AU RED
 - integrated application and administration processes
 - common database functionality
- Standard application forms - across state boundaries

Separation of ethics review from research governance

- Only one HREC will receive an *ethics application* in a single ethical review system
- Assessment is required by all participating sites:
 - to inform the health organisation of proposed clinical trials
 - ensure compliance with regulations
 - ensure site policy is considered
 - manage risk for the organisation

Site Specific Assessment/Research Governance

Linkage of the two processes is through the IT platform, **AU RED**

Common IT platform, AU RED

Integrated electronic application & administration processes

- Online Forms website
 - used by applicants to complete NEAF and SSA applications
 - data is transferred electronically via the IT platform to administrators

- AU RED website

Ethics administrators

- Data entry for ethics applications
- access to the NEAF and supporting documents (electronically)

Research Governance Officers

- Data entry for SSA applications
- access SSA supporting documents including the NEAF & NEAF supporting documents (electronically)

SSAs are linked to the NEAF application – allows tracking

Common IT platform, AU RED

Common database functionality

- For the first time, **data on clinical trial activity** will be available
- Powerful reporting functionality for **Government & Public Service Health Organisations**
- Comprehensive clinical trial information for **industry**

Standard application forms

Across states

- **National Ethics Application Form (NEAF)**
- **Site Specific Assessment Form**
 - common framework (some individual state differences)

Still some 'bumps in the road'

There has been a concerted effort by the states to develop single ethics review using common principles

BUT

there are differences between the states

WHY?

State single review policies have developed over different timeframes
A national initiative did not precede and could not lead the way forward

RESULT

Uniform approach with some 'process differences' between the states

Smoothing the 'bumps'

- State support services are available
 - central offices (Vic and Qld)
 - state-website information
 - communications
 - training
 - presentations
 - Cooperative and consistent policy development

Victorian initiative

Streamlining ethical review of multi-site clinical trials

Commencement of single HREC review of multi-site clinical trials in
December 2009

Victorian Innovation Statement (VIS) 2008

Innovation: Victoria's Future

Streamlining ethical review of multi-site clinical trials was included in the *Biotechnology Bridges* initiative

Objectives:

- Grow clinical trials activity and attract trials to Victoria
- Provide new treatments to patients sooner, improve health outcomes and quality of life

Streamlined system for clinical trials

- Structure of the system:
 - Consultative Council & Sub-committee
 - Central Coordinating Office
 - Reviewing HRECs
- Participation — Memorandum of Understanding with public health organisations
- Standard application forms:
 - NEAF v2
 - Victorian Specific Module
 - SSA Form
- Information technology platform – AURED/Online Forms
- Benchmark of 30 working days for ethical approval

Coordinating Office for Human Research Ethics

Coordinating Office support for the streamlined system

- Standard Operating Procedures
- AU RED licence/agreements
- AU RED training
- Website – step by step guide
- Streamline E-bulletin
- Central Allocation System (CAS) – to distribute ethics applications
- Information & Enquiry phone lines - for users in all sectors
- Annual May Workshop
- Forums for – education/training & networking for all sectors
- Information Sessions
- Over 30 'roadshows'
- Conference presentations

Reviewing HREC and Research Governance Standards Sub-Committee

Support for the streamlined system

Developed:

- Standard Operating Procedures (SOPs) for:
 - Coordinators of reviewing HRECs
 - Research Governance Officers
- Checklists - Ethics and Research Governance
- Standard templates for reporting/monitoring

Coordinating Office for Human Research Ethics

Developed enhancements to the IT platform working cooperatively with:

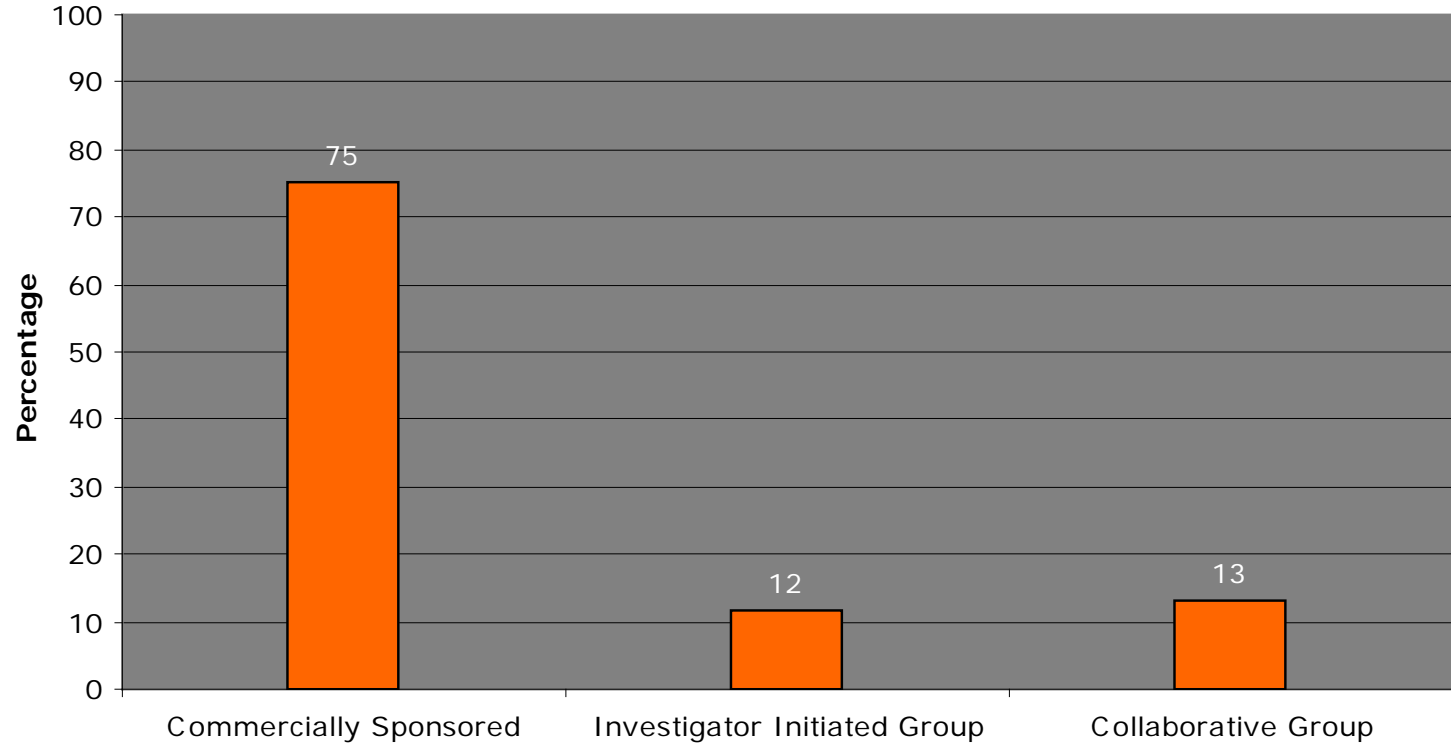
- NSW Health
- Queensland Health

Cooperatively developed the new:

- Advanced Reporting capability

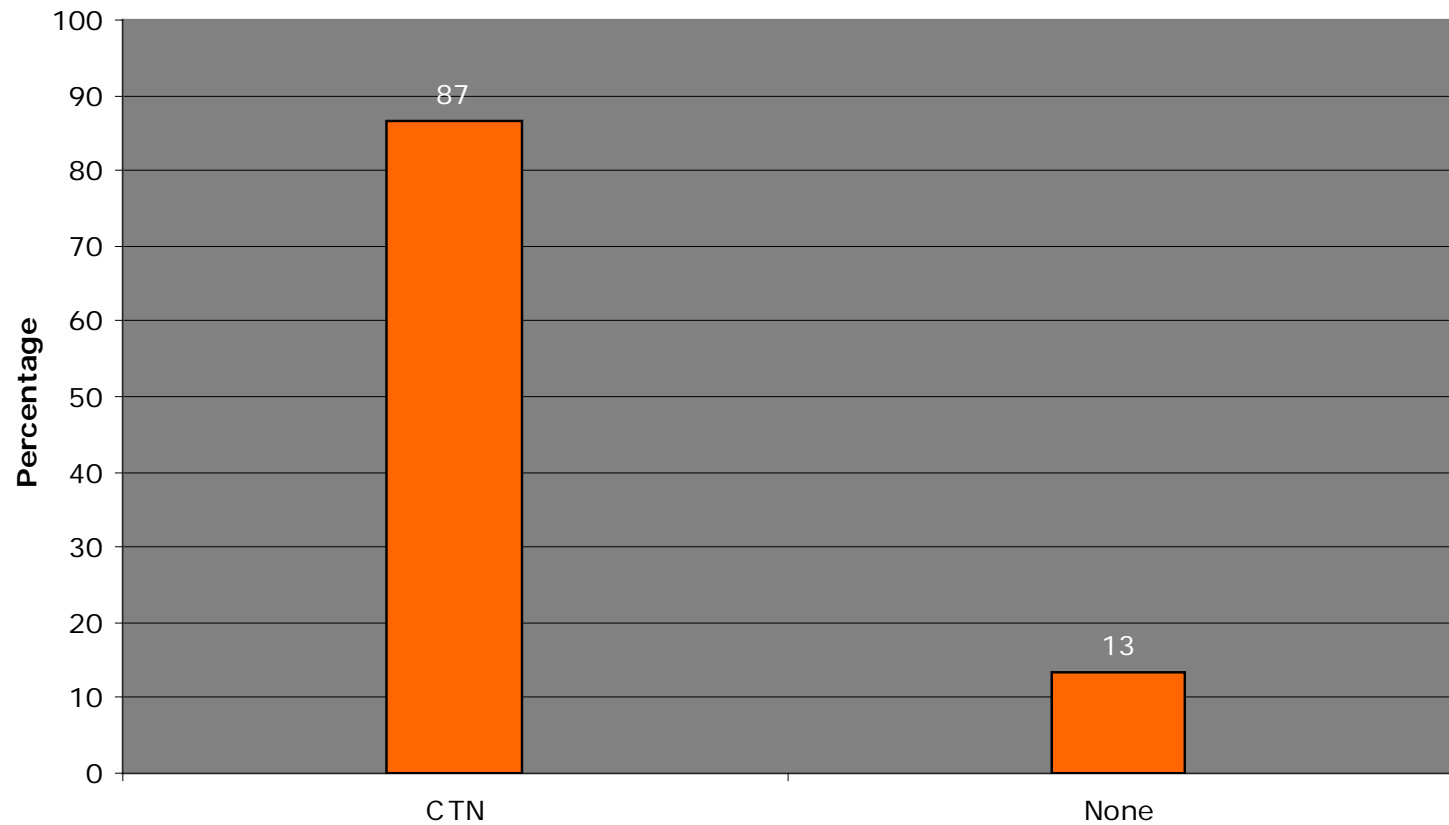
Reporting - Clinical trial applications

Up to 30 Sept 2010



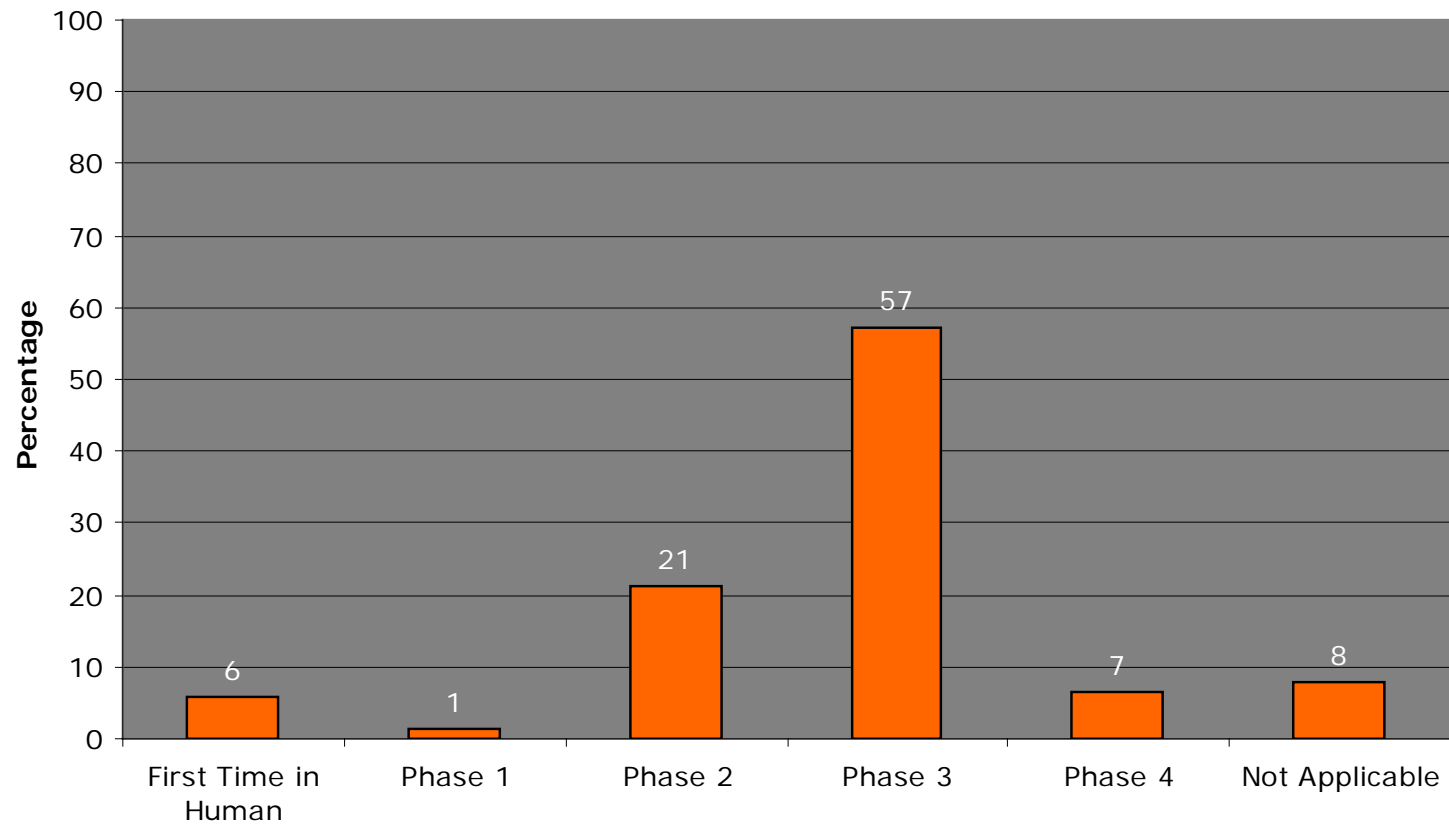
Reporting -Use of the CTN scheme

Up to 30 Sept 2010



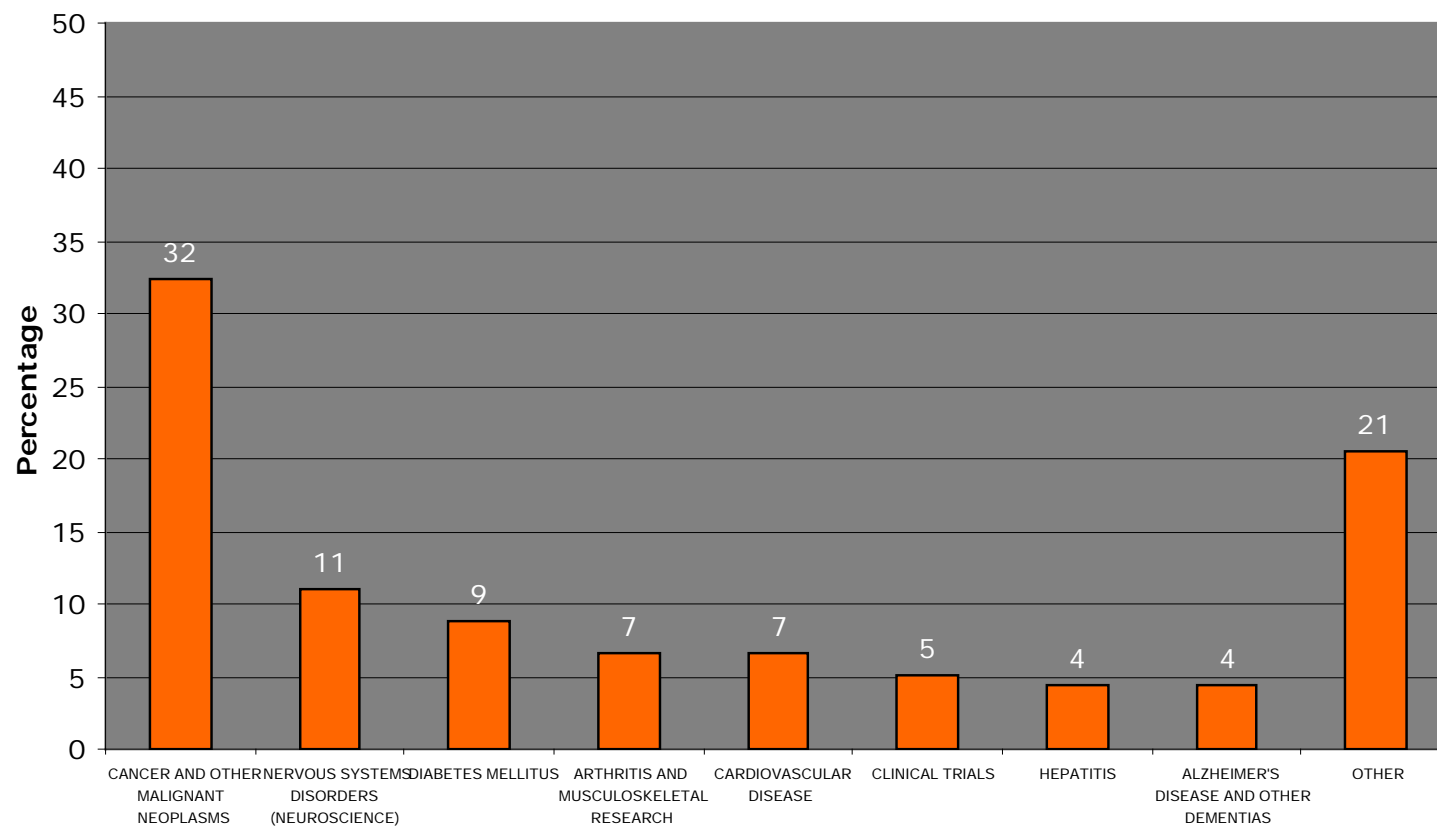
Reporting - HREC applications according to trial phase

Up to 30 Sept 2010



Reporting - Trial applications and NHMRC research discipline

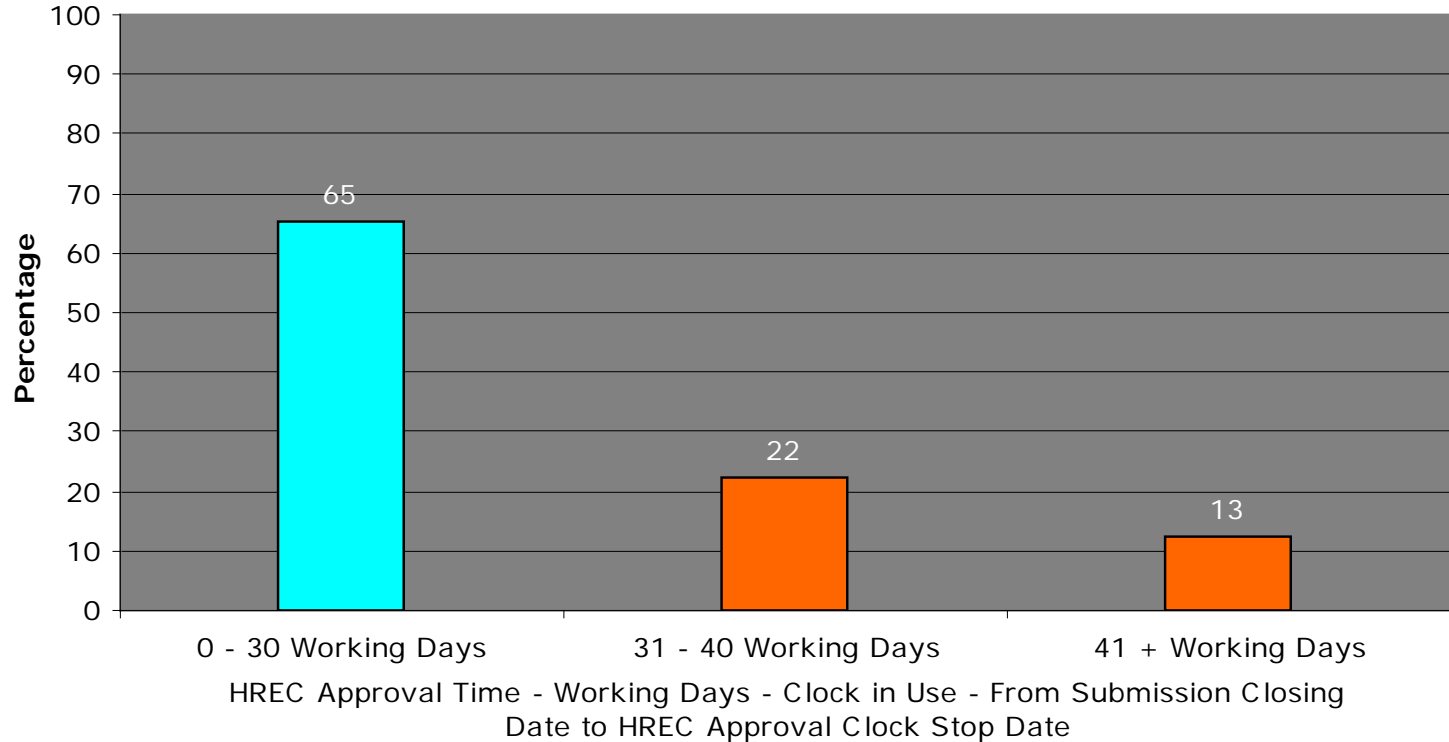
Up to 30 Sept 2010



Reporting - 30 working day benchmark for HREC approval

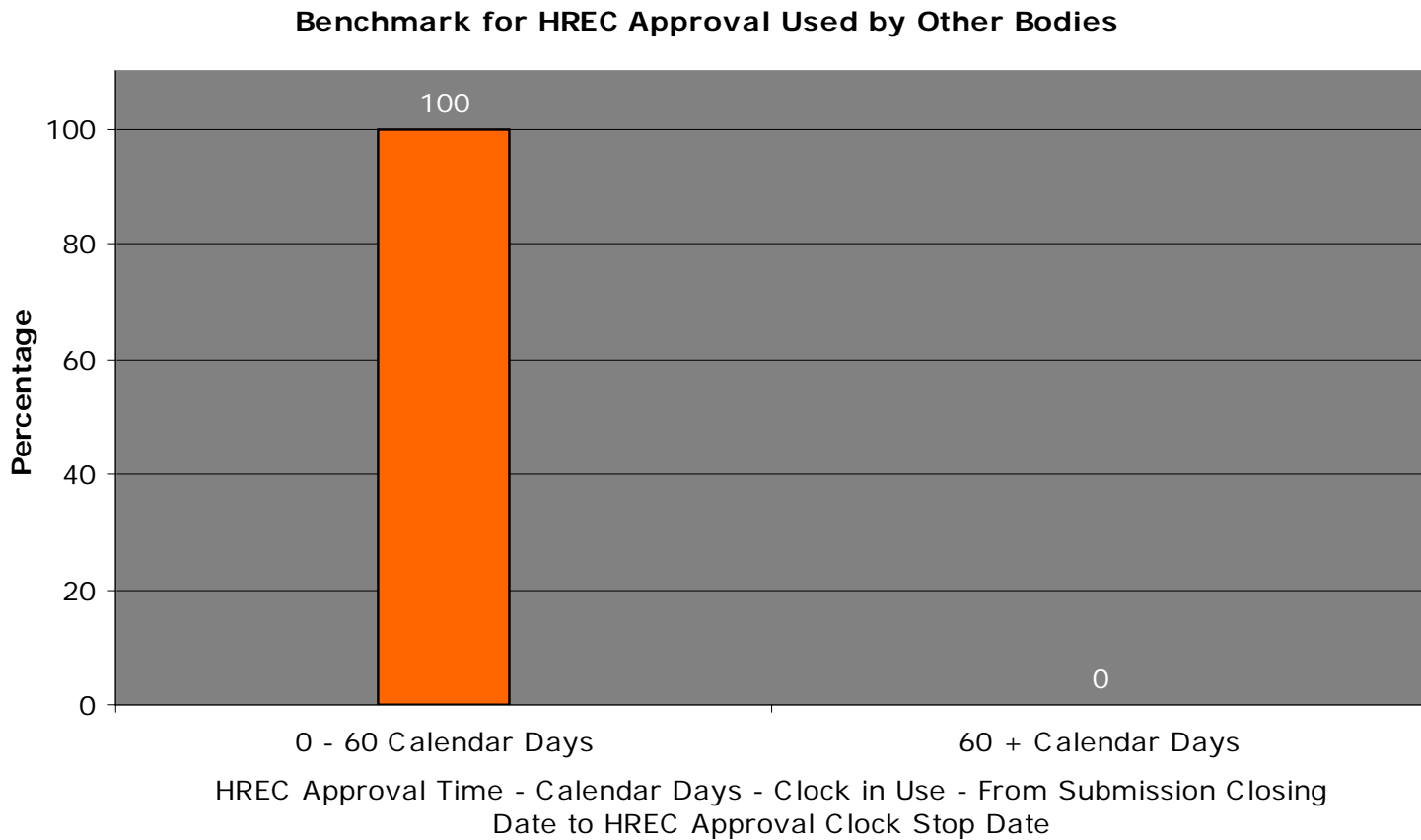
Up to 30 Sept 2010

Victorian Benchmark for HREC Approval



Reporting - 60 calendar day benchmark

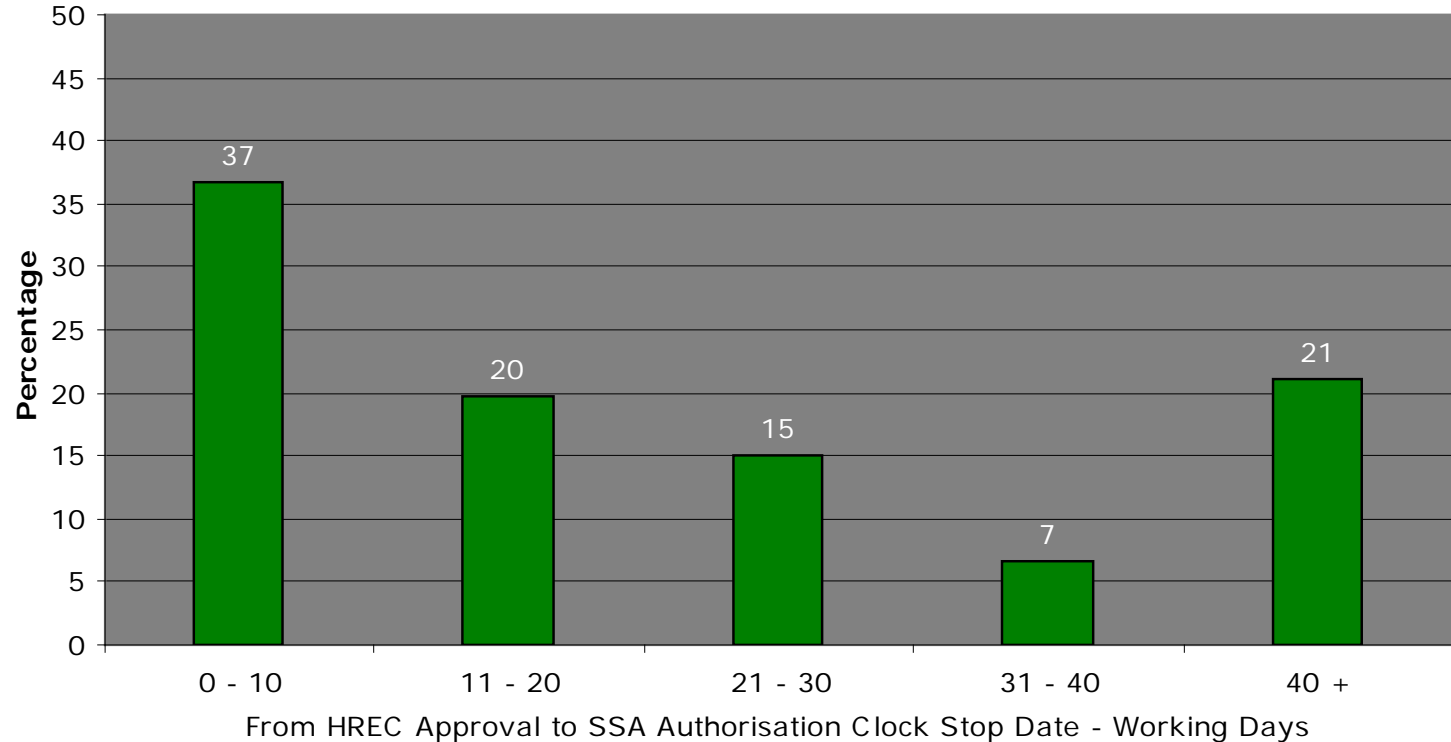
Up to 30 Sept 2010



Reporting - SSA authorisation time – days after HREC approval

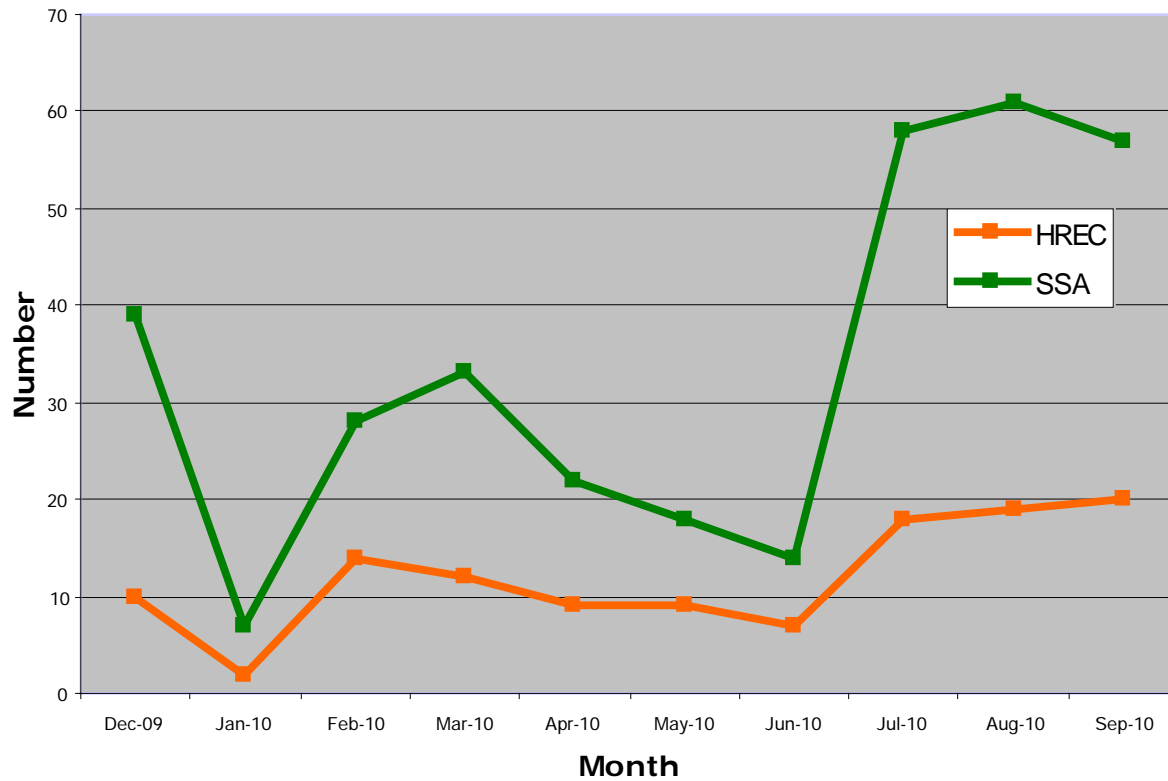
Up to 30 Sept 2010

SSA Authorisation Time - Working Days (No SSA Clock Stop)



Reporting – the trend in HREC and SSA applications/Month

Up to 30 Sept 2010



Benefits – so far

Up to 30 Sept 2010

Saved 242 additional HREC reviews

- 65% HREC approvals within 30 working days
- 57% of SSAs were authorised within 20 working days (post-HREC approval)

Improving performance

Starting research governance (SSA) early

Sponsors & Investigators

Who is involved in research governance?

Key role

- Principal Investigator(s)/Coordinating Principal Investigator

Support role

- Research Governance Officer

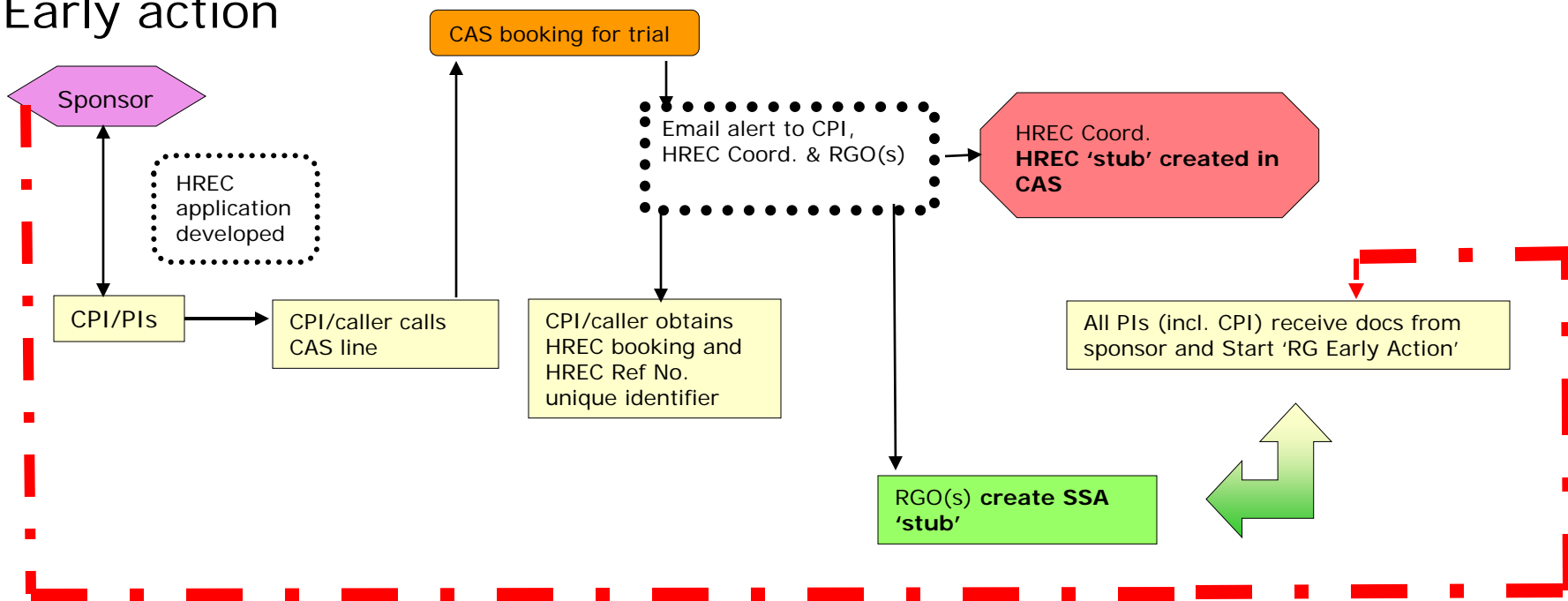
Allied role

- Sponsor – provision of trial documentation, 'early action'
- Organisation's governance – delegation of authority for SSA authorisation

Research ethics & governance

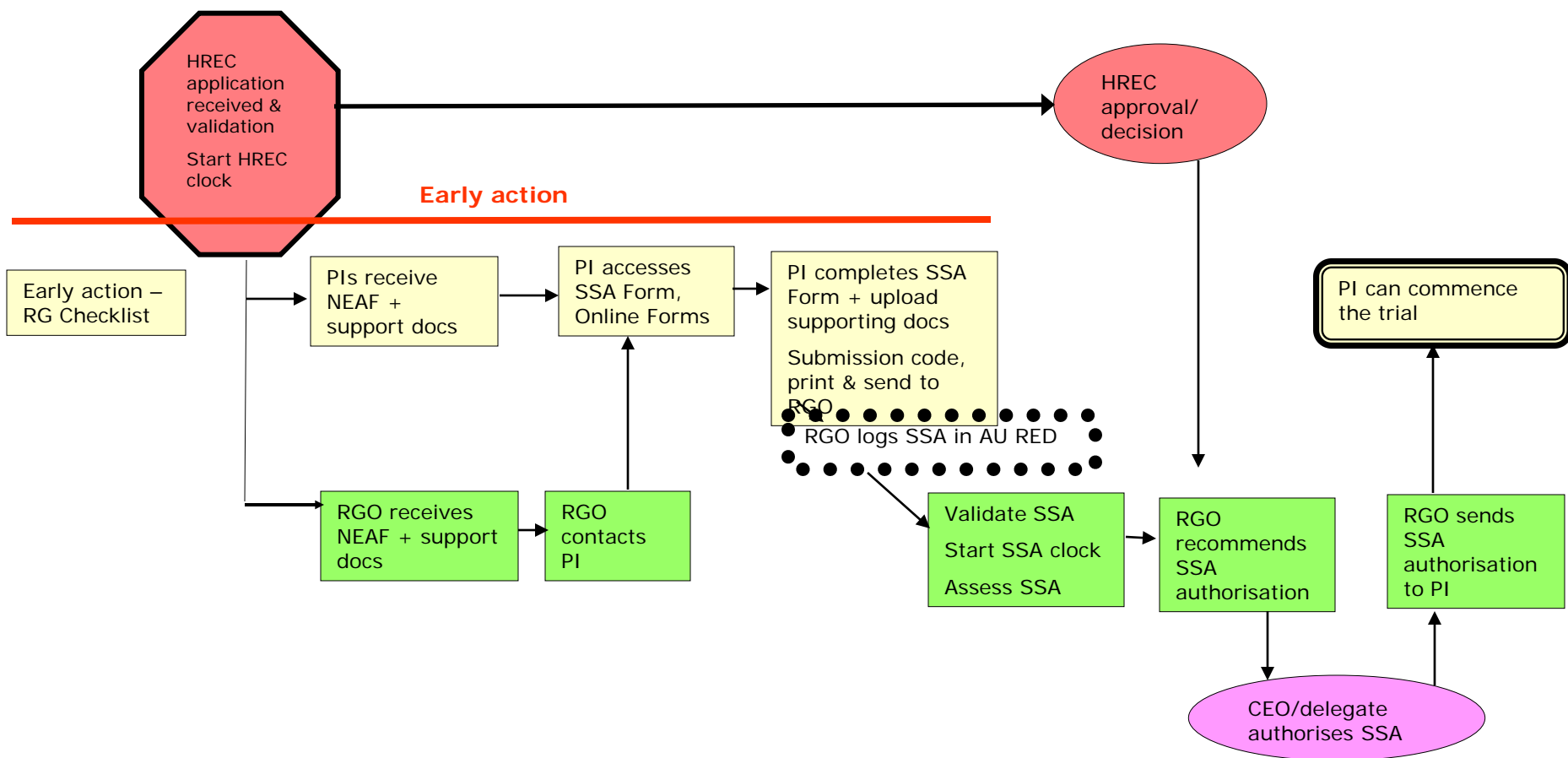
Parallel & interdependent process

Early action



Research ethics & governance

Parallel & interdependent process



Early Action - checklist

Research Governance Checklist for all Principal Investigators

A copy of this checklist must be included with every new research governance application submitted to your research governance office. All research projects require authorisation of research governance before a project can commence.

Research governance applications are the responsibility of Principal Investigators at each site participating in a research project. It is strongly recommended that research governance applications are submitted to the office for research/ethics as early as possible and before the HREC submission. Research governance applications can be submitted at any time and in parts (i.e. a complete application in one submission is not essential).

This checklist is divided into three parts: **A)** Items which need to be submitted before or at the same time as the HREC submission to commence the assessment process; **B)** Items which can only be submitted after the HREC application has been submitted; **C)** All documents approved by the reviewing HREC.

This Research Governance checklist should be submitted **once**, with completion of **Part A**

HREC Reference No. (AU RED)

Site Reference No.

PART A) Early Action

Submit these items before or at the same time as the HREC submission

YES

Office
Use Only

Mandatory components of all research governance applications

1. Explanatory cover letter (signed by the Principal Investigator)
2. Detailed budget (draft is acceptable)
3. Research Governance Review Fee
4. Study Protocol

For all items marked "NA" please provide a brief explanation below the item

NA YES

Office
Use Only

5. Investigator Brochure

6. Standard Form(s) of indemnity (Medicines Australia Standard Form of Indemnity for your site)

7. Insurance Certificate

Improving performance

- Development of **best practice for HRECs** – Colin Thomson
- **Evaluation** of the Victorian streamlined system – 3 phases:
 - Commencement to 30 June 2010
 - 1 July to 31 December 2010
 - 1 January to 30 June 2011
 - Reporting to the Consultative Council in late 2011

Coordinating Office for Human Research Ethics

Information & Contacts

Website: www.health.vic.gov.au/cchre

Email: Multisite.Ethics@health.vic.gov.au

E-bulletin: *Streamline E-bulletin*

Phone:

CAS Line	(03) 9092 1983
Information Line	(03) 9092 1987
General enquiries	(03) 9092 1981