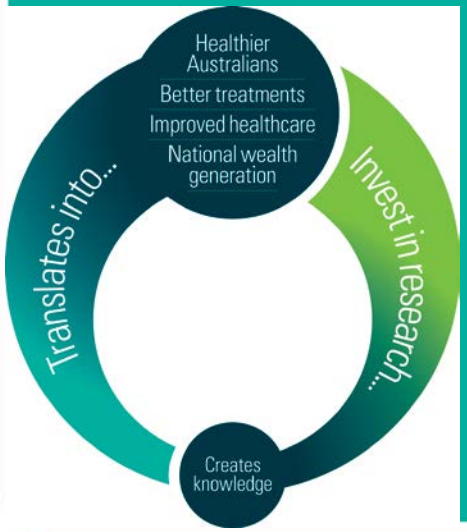
Australian Government
National Health and Medical Research Council

NHMRC

Clinical Trial Timeliness- venimus vidimus sed vincimus?



Gordon McGurk
Director, Clinical Trials Section
May 2017

WORKING TO BUILD A HEALTHY AUSTRALIA

NHMRC's Government funded initiatives

Australia is competitive globally and delivers clinical trials of high quality

QUICKER AND MORE EFFICIENT RESEARCH GOVERNANCE AUTHORISATION

Good practice process for site assessment

- >> Emphasis on preparation
- >> Clear roles and responsibilities
- >> Standard list of costs[1]
- >> Pilot studies

Awareness of

- >> Insurance and indemnity issues
- >> Relevant Cwth and State legislation

INCREASED READINESS AND TRANSPARENCY

Clinical Trials Ready

EFFICIENT ETHICS APPROVAL

- >> Single ethical review
- >> Credentialling of HRECs
- >> Human Research Application Form

BETTER TRAINED STAFF

Learning modules

- >> The clinical trials environment
- >> Ethical aspects of clinical trials
- >> Research governance related to clinical trials

V.E.T. accredited course[2]

INCREASED RECRUITMENT AND AWARENESS

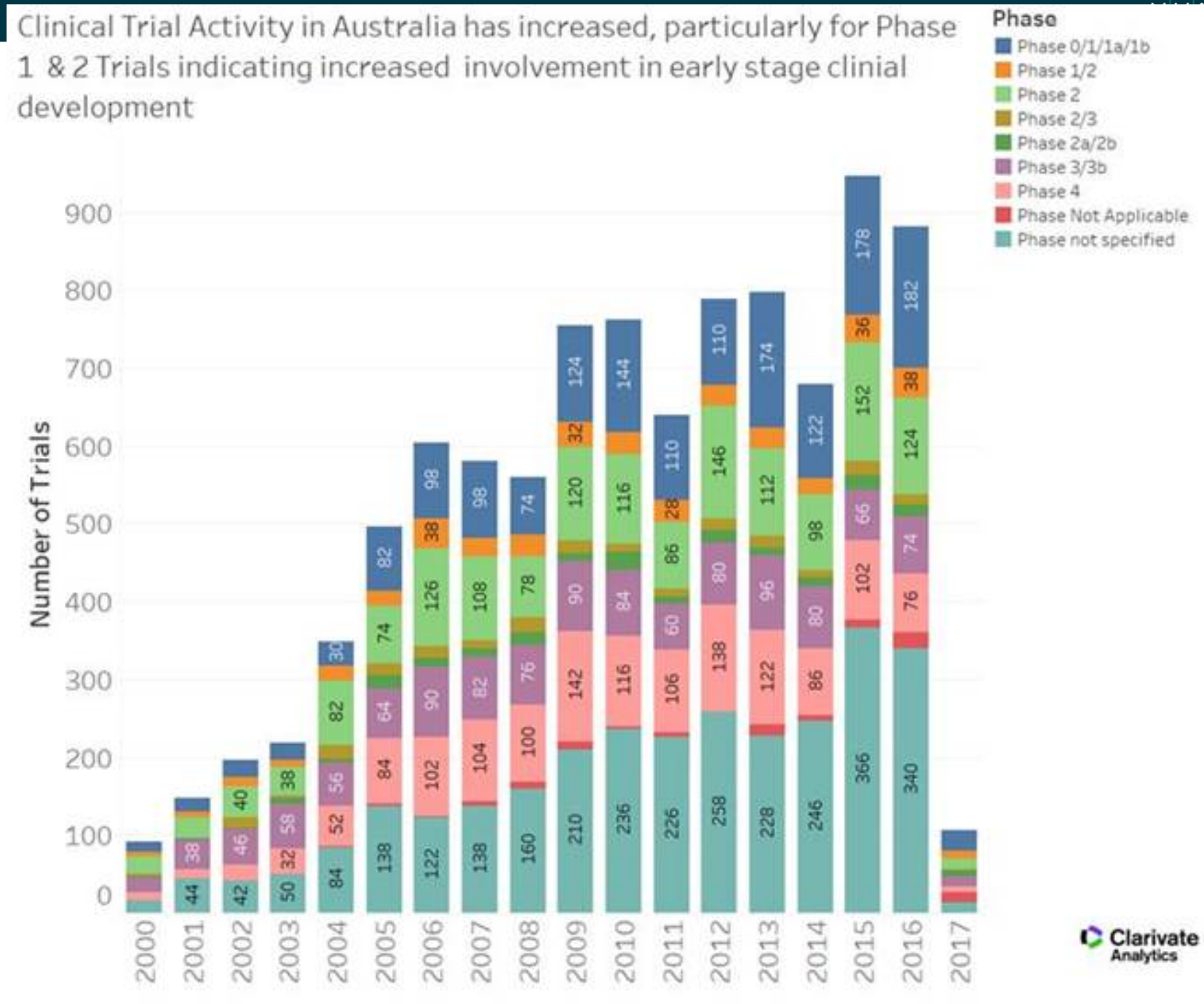
- >> Access to trial information and to register participant interest

Australianclinicaltrials.gov.au

Clinical trials portal[2]

1. Dept of Health leads

2. Dept of Industry leads

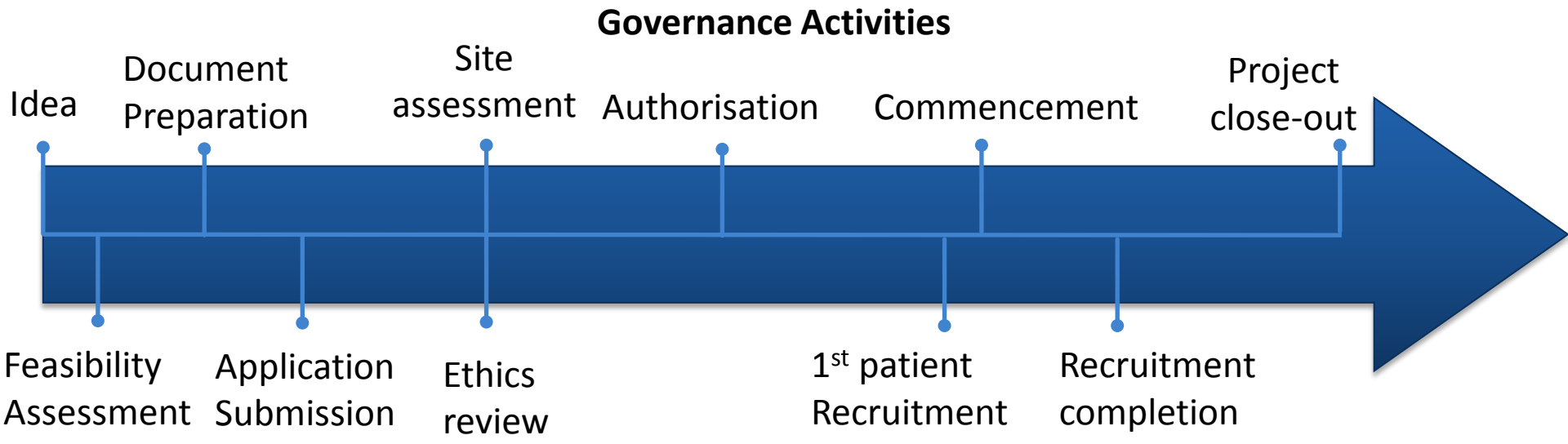

Clinical Trial Activity in Australia has increased, particularly for Phase 1 & 2 Trials indicating increased involvement in early stage clinial development
Phase
Phase 0/1/1a/1b
Phase 1/2
Phase 2
Phase 2/3
Phase 2a/2b
Phase 3/3b
Phase 4
Phase Not Applicable
Phase not specified
Number of Trials
0
100
200
300
400
500
600
700
800
900
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017
Clarivate Analytics

Leading and supporting- Quicker & more efficient research governance authorisation

Good Practice Process for the Site Assessment and Authorisation of Clinical Trials

- **Aim** : To reduce clinical trial start-up times
- ***Principles***:
  - Timeliness, Transparency and communication
- ***Critical success factors*:**
  - Clearly documented roles and responsibilities
  - Early determination of the feasibility
  - Conduct of site assessment before or in parallel with ethics review
  - Use active management strategies for key steps in the process
- ***Testing***
  - Test implementation at 16 sites round Australia
  - Collect data on metrics and impacts on process improvement
  - Provided resources for the appointment of a clinical trials liaison officer (CTLO)

Metrics collected during pilot studies



1 → Feasibility assessment- 4 metrics to be collected

2 → Document preparation and submission

3 + 4 → HREC Review/ Site assessment

5 → Application submission – site authorisation

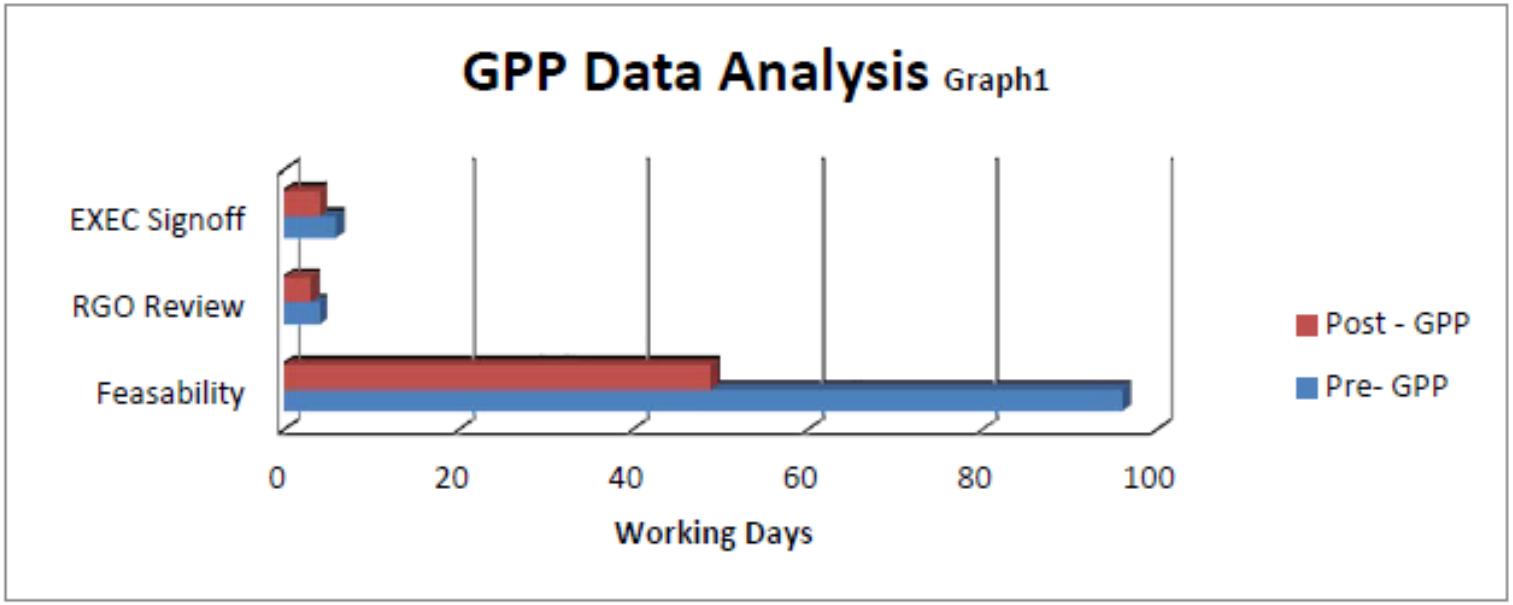
6 → Site authorisation – site activation

7 → Site activation – 1st patient recruitment

General Outcomes

- Reductions in timeframes for completion of 7 of the 9 phases
- Adoption of the process led to a decrease in trial commencement time by over 100 days
- Includes ethics review and site specific assessment phases,
- Time to confirm the site selection increases,
- Basis for improved communication
- Importance of feasibility- metrics not previously collected

‘Days between PI returning feasibility and Site Selection Visit was greatly improved post intervention (60.7% improvement) – due to central coordination point between Sponsors and PIs.’

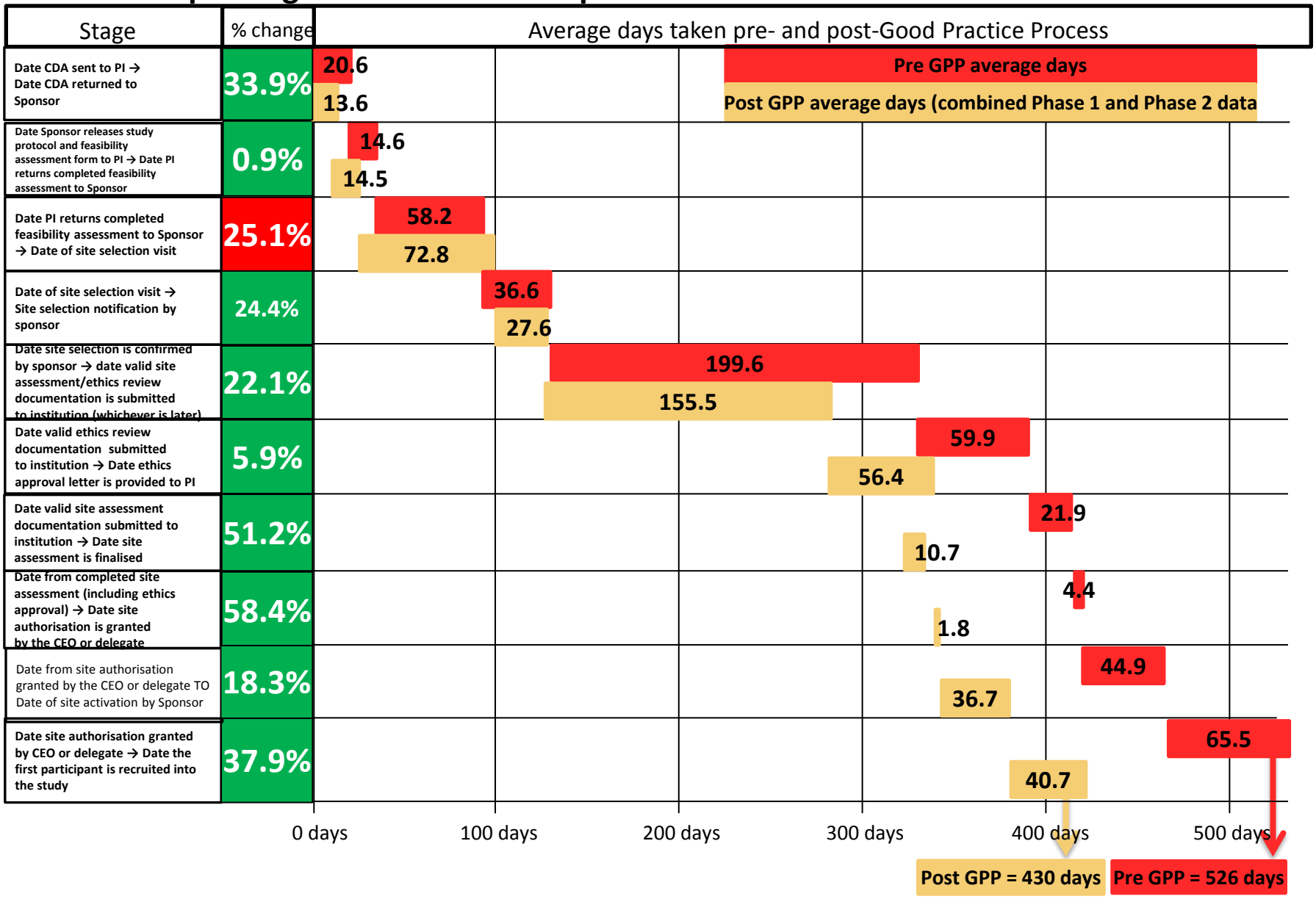


Phase 2

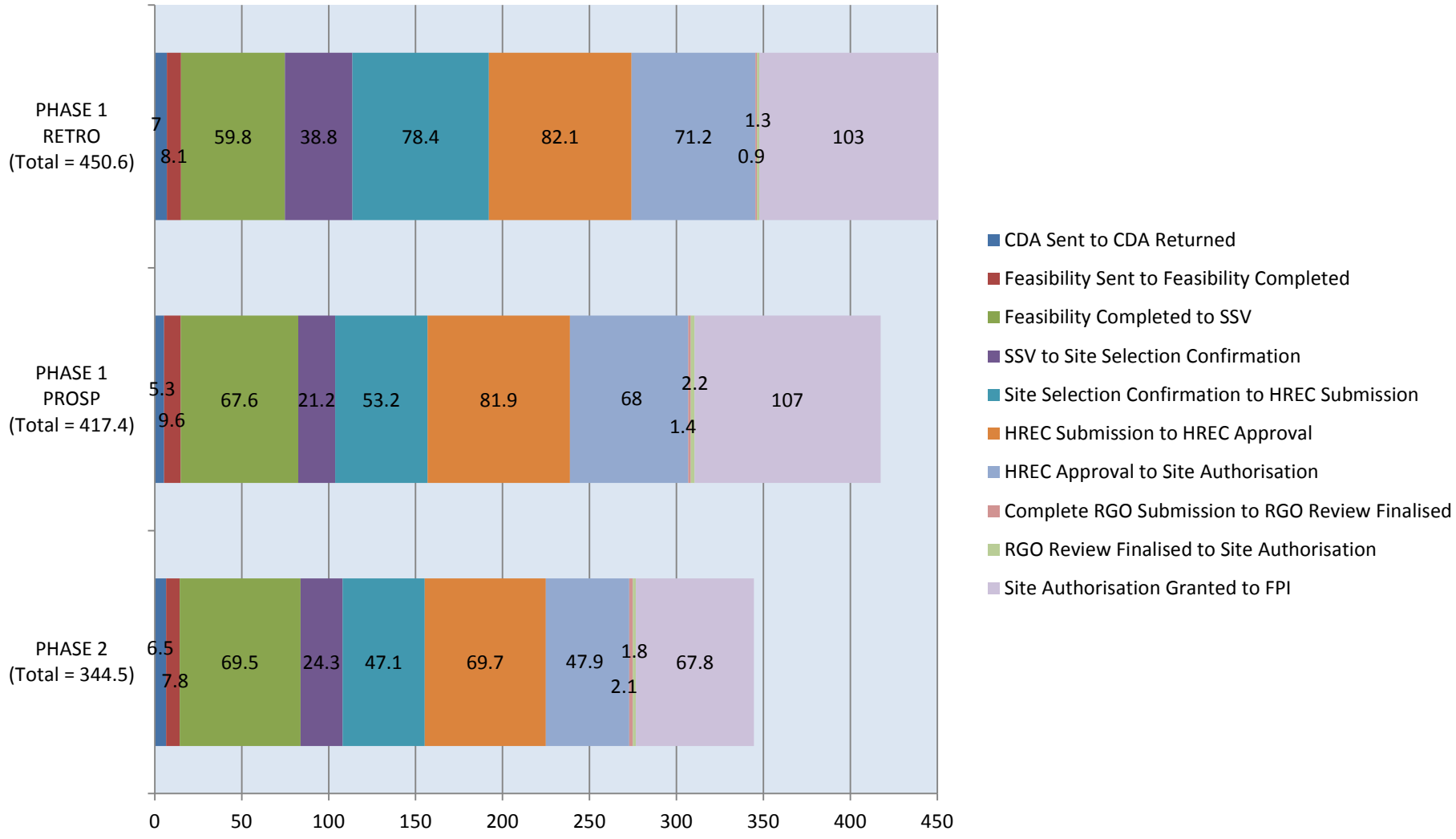
- Collect further data- 9 sites
- Target activities to those areas that need further work

Metric Number	Description	Pre GPP			Post GPP (Phase 1 and 2 combined)			Change in mean time	Reduced variation?
		N	Mean	SD	N	Mean	SD		
1a	Date CDA sent to PI TO Date CDA returned to Sponsor	149	20.6	94.2	187	13.6	37.8	33.9% decrease	YES
1b	Date Sponsor releases study protocol and feasibility assessment form to PI TO Date PI returns completed feasibility assessment to Sponsor	128	14.6	41.4	165	14.5	27.1	0.9% decrease	YES
1c	Date PI returns completed feasibility assessment to Sponsor TO Date of Site Selection Visit	132	58.2	79.8	149	72.8	110.7	25.1% increase	NO
1d	Date of Site Selection Visit TO Date of Site Selection Notification by sponsor	156	36.6	59.8	196	27.6	47.8	24.4% decrease	YES
2	Date site selection confirmed by sponsor TO date valid site assessment/ ethics review documentation submitted to institution (whichever is later)	95	199.6	141.9	127	155.5	86.5	22.1% decrease	YES
3	Date valid ethics review documentation submitted to institution TO Date ethics approval letter is provided to PI	233	59.9	54.6	306	56.4	53.7	5.9% decrease	YES
4	Date valid site assessment documentation submitted to institution TO Date site assessment finalised	273	21.9	41.5	457	10.7	25.9	51.2% decrease	YES
5	Date from completed site assessment (including ethics approval) TO Date site authorisation granted by the CEO or delegate	269	4.4	27.2	370	1.8	7.3	58.4% decrease	YES
6	Date from site authorisation granted by the CEO or delegate TO Date of site activation by Sponsor	214	44.9	53.1	210	36.7	39.9	18.3% decrease	YES
7	Date of site activation by Sponsor TO Date the first participant is recruited into the study	169	65.5	78.8	91	40.7	66.9	37.9% decrease	YES

Improving clinical trial start-up times with the NHMRC Good Practice Process



Comparison Timeline Between Data Sets



Data from Melbourne Health showing continued improvement

Metric Number	Description	Change in mean time	Reduced variation?	Main responsibility
1a	Date CDA sent to PI TO Date CDA returned to Sponsor	33.9% decrease	YES	Site
1b	Date Sponsor releases study protocol and feasibility assessment form to PI TO Date PI returns completed feasibility assessment to Sponsor	0.9% decrease	YES	Site
1c	Date PI returns completed feasibility assessment to Sponsor TO Date of Site Selection Visit	25.1% increase	NO	Sponsor
1d	Date of Site Selection Visit TO Date of Site Selection Notification by sponsor	24.4% decrease	YES	Sponsor
2	Date site selection confirmed by sponsor TO date valid site assessment/ ethics review documentation submitted to institution (whichever is later)	22.1% decrease	YES	Sponsor and site
3	Date valid ethics review documentation submitted to institution TO Date ethics approval letter is provided to PI	5.9% decrease	YES	Site
4	Date valid site assessment documentation submitted to institution TO Date site assessment finalised	51.2% decrease	YES	Site
5	Date from completed site assessment (including ethics approval) TO Date site authorisation granted by the CEO or delegate	58.4% decrease	YES	Site
6	Date from site authorisation granted by the CEO or delegate TO Date of site activation by Sponsor	18.3% decrease	YES	Sponsor
7	Date of site activation by Sponsor TO Date the first participant is recruited into the study	37.9% decrease	YES	Site

Increasing awareness of clinical trials

- Australianclinicaltrials.gov.au
- Marketing campaign
- Advertising site capability and capacity

Melbourne Children's Campus (incorporating The Royal Children's Hospital Melbourne, Murdoch Childrens Research Institute and University of Melbourne Department of Paediatrics)

Remove from comparison

Site Details +

Capability Information +

Clinical Trials +

Contact Details +

	Melbourne Children's Campus (incorporating The Royal Children's Hospital Melbourne, Murdoch Childrens Research Institute and University of Melbourne Department of Paediatrics)	St Vincent's Hospital Melbourne	The Lyell McEwin Hospital
Anasthaesia and pain	✓ 🛏	✓	✓
Cardiology	✓ 🛏	✓ 🛏	✓ 🛏
Dermatology	✓ 🛏		
Diabetes	✓ 🛏	✓	✓
Endocrinology	🛏	🛏	🛏
Gerontology	🛏		
Hematology	✓ 🛏	✓ 🛏	✓
Hepatology	🛏	✓	✓
Human genetics	✓ 🛏		
Immunology and inflammation	✓ 🛏		
Infection and infectious diseases	✓ 🛏		
Maternal and child health	✓ 🛏		

Some milestones- 2014-2017

Task	2014	2015	2017
Research Governance	Process finalised	Setting up pilots	Phase 2 complete
Standard costs	1st costing available	Costing redone	Available
Streamlined ethics	Design/ consult on HREA	Build HREA	HREA released
Training/education		E-learning modules	Competencies
www.australianclinicaltrials.gov.au	Static website	Register for a trial	• Real Stories • Browse Functionality • Trial site capability • Route map/ Toolkit
HREC Credentialing		Feasibility study	Established scientific committees
Legislative guides	Paper on Insurance and Indemnity arrangements		Develop resource on S&T Guardianship Provisions
Safety monitoring Guidance		Review international requirements	Guidance Issued, Supplementary

It's a complicated place

- Department of Health- MRFF/ CTJWG
- CTJWG
- MTP Connect
- AusBiotech
- BTF
- State and Territory Reform Initiatives

…But what is the industry doing?

The Clinical Trials Team

Joel, Sam, Zeinab, Kate, Tim, Alex, Gillian

…and Rob, with Jeremy *in absentia*

Why Clinical Trials Matter | Why Clinical Trials Matter - Google Chrome

whyclinicaltrialsmatter.org

Free Hotmail | Newsgroups | Windows | Imported From IE

#WhyClinicalTrialsMatter

WHAT'S IT ALL ABOUT | TOOLKIT | BLOG | LINKS

A Social Campaign to Share the Value of Clinical Trials

Clinical Trials help researchers discover which treatments and approaches work and are safe. Clinical trials provide the evidence medical practitioners need to make better decisions about how to treat different medical conditions. Every single one of us either indirectly, or directly, benefits from the advances made to medicine as a result of clinical trials. Whether their outcomes are positive or negative, researchers will learn something from every clinical trial.

First launched May 2016, this campaign is all about raising awareness of and celebrating the value of clinical trials.

We encourage you to join in by sharing #WhyClinicalTrialsMatter to you via social media and helping to spread the message.

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LATEST TWEETS

Janelle Bowden Retweeted

Research4Me @Res4Me

Remembering #whywedoresearch #whyclinicaltrialsmatter on International Paediatric #clinicaltrialsday 9May. #clinicaltrials

Keep up to date with NHMRC Clinical Trial activities

www.Australianclinicaltrials.gov.au

Twitter - @AustCT

ClinicalTrials@nhmrc.gov.au