How COVID-19 has changed clinical trials in Australia

Medicines Australia

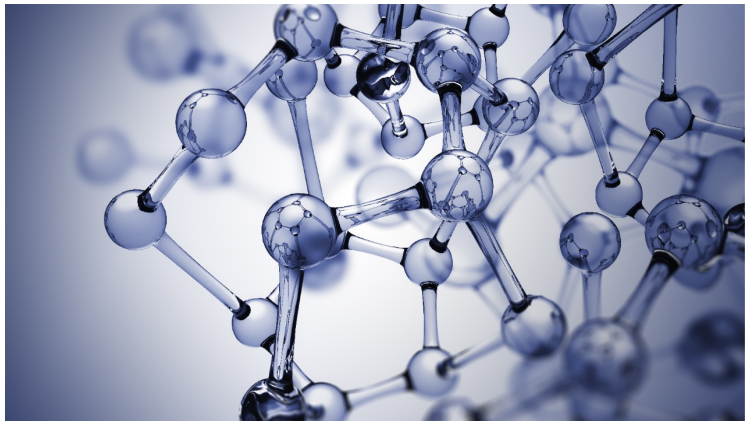
Agenda

- Introductions & Objectives of webinar (5 min)
- Clinical Trials Overview – **Elizabeth de Somer, CEO of Medicines Australia** (5 mins)
- How has the pharmaceutical industry managing clinical trials during COVID-19– **Sarah Loomes, Novartis** (10 mins)
- What has changed since COVID-19 – technology and policy – **Prof John Zalcberg, Australian Clinical Trials Alliance**(15 mins)
- From a patient and carer's perspective, what does this means for patients moving forward – **Richard Vines, Rare Cancers Australia** (15 mins)
- Q&A Session (10 mins)

Medicines Australia

Objectives of the webinar

- Assure patients/participants that clinical trials are open for business and what measures have been put in place during the past months to ensure continuity and safety
- To provide an opportunity to enhance clinical trial reputation, understanding and importance of the value they can bring to patients and Australia



The importance of clinical trials (general)

Clinical trials play an important role in improving Australia's healthcare system because they:

- Lead to the development of new and innovative treatments
- Allow patients early access to potential life-saving medicines at no cost
- Help retain specialised and highly-trained researchers in Australia
- Provide experience with novel and emerging therapies for Australian clinicians
- Links Australia to international scientific development and the latest thinking
- Create employment for research organisations, universities and hospitals

The importance of clinical trials – COVID-19

- During COVID-19 we did see significant disruption to clinical trials
  - No new clinical trials were commenced; recruitment to new trials postponed
  - Existing clinical trials continued through remote monitoring mechanisms

- The main reason for this was to maintain **patient safety**

- Except for Victoria, all other states are running clinical trials as per normal

- It is important to have a fully functioning clinical trial sector to ensure:
  - Patients continue to receive innovative medicines and not have disruption to their treatment plan
  - We are ready to conduct clinical trials for COVID-19 vaccines or treatments
  - Australian clinical trials sector becomes an even more attractive destination market

What have we done to ensure minimal disruption?

- Effective communication between company sponsors and clinical trial sites
- Supporting clinical trial sites communicate with their patients
- Developed remote monitoring, tele-trials and Telehealth consults to maintain patient and clinical trial site safety
- Looking a clinical trial harmonisation across states
- Working with patients to ensure their treatment is minimally disrupted
- Commenced clinical trials (new and recruitment) as soon as was feasibly possible

Sarah, John and Richard will go into more detail on the above.

Questions and Answers Session

- Please submit your Q&A in the chat function and will try and answer them during question time at the end of the session.

THANK YOU!

Global Drug Development (GDD)/
Oncology

How has the pharmaceutical industry managed clinical trials during COVID-19?

Sarah Loomes – Clinical Study Manager
Medicines Australia Clinical Trials Webinar
20 August 2020

NOVARTIS | Reimagining Medicine

Novartis Overview

Novartis has a significant ongoing commitment to Australia*:

- 101 clinical trials ongoing at over 300 centres
- 600 patients ongoing
- 74 new patients recruited to clinical trials in 2020

Every clinical trial patient had ongoing care and treatment available to them.

*YTD 2020 – Data on file.

NOVARTIS

Supporting Clinical Trial Centres?

- Maintaining safety of patients and scientific integrity of trial data is paramount during COVID-19 interruptions
- Ongoing studies and patients:
  - Focused and balanced communication
  - Study monitors contacting trial centres to
    - check on progress, assure patient safety/quality maintained
    - identify and help solve challenges associated with COVID-19
  - Study drug delivery uninterrupted
- New studies:
  - Continuing to open new clinical trials is essential
  - Remote opening of new clinical trials as/when clinical trial centres are comfortable

Supporting Clinical Trial Patients

Supporting patient safety by avoiding visiting the clinical trial centre/hospital, however ensuring valid trial data still collected.

- Tele-health (phone calls, video calls)
  - allows study doctors to check on patient's progress and safety remotely
- Hospital in the home (HITH)
  - allows some trial treatments/care/tests at home
- Local pathology laboratory tests
  - allows patients to get tests done outside hospital for safety monitoring
- Study drug delivery to home/local pharmacy
  - avoids the need to go to hospital to collect study drug

Opportunity for Australia

We have the opportunity to take on more clinical trials in Australia, allowing new medicines to come to market safely and to be available to patients.

Australian Clinical Trials Alliance

What has changed since COVID-19: technology and policy

Prof John Zalcberg

Chair, Australian Clinical Trials Alliance

Better health through best evidence

ACTA gratefully acknowledges operational funding from the Australian Government's Medical Research Future Fund

How COVID 19 has changed medical care

Principles:

1. Protect the safety of staff
2. Protect the safety of patients
3. Protect the safety of the community

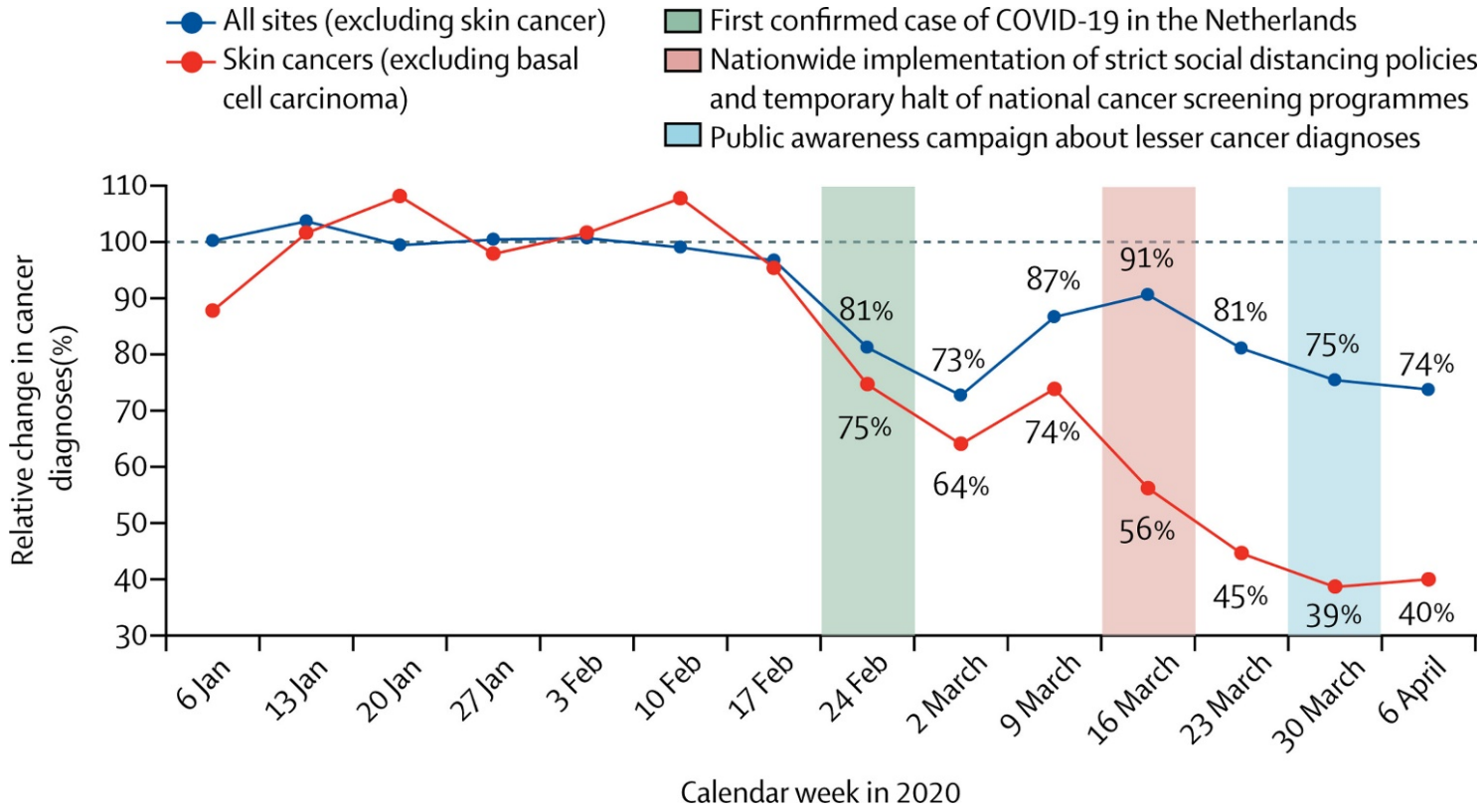
Risks

- Risk of under-treatment/delaying treatment/ prolonging treatment
- Risk of making medically-oriented decisions about value of treatment
- Risk of minimizing the value of life-decisions in certain sub-groups
  - Age: older vs younger; metastatic disease vs earlier stages

Risks (cont'd)

- Risk of using "unproven" therapies in order to comply with "principles"
  - Dose reductions, alternative XRT regimens, etc
- Inadequate evaluation of patients status
  - Pathological, Medical, Psychosocial (panic, etc)
- Risks of downstream impacts, still impossible to measure
  - Medical students, Registrars, Fellow training, routine care

Fewer cancer diagnoses during the COVID-19 epidemic in the Netherlands



Australian Clinical Trials Alliance

www.clinicaltrialsalliance.org.au

Risks (cont'd)

- Risk of changes in our ethical framework
  - as individuals/society
- Risk to clinical research frameworks
  - Should research be done at all?
  - Which trials should be prioritised? How can recruitment, management of investigational products, compliance, audit etc., be maintained?
- Ethics committees
- Reallocation of resources

Overall Impact on trials

Existing Trials

- Many trials suspended or terminated
- As of 15 May 2020 - nearly 100 companies and 240 trials have experienced disruptions

Source - BioPharmaDive

Overall Impact on trials

Explosion of COVID 19 Trials

Over 100 research projects relating to COVID-19 including trials for

- treatments and vaccines
- diagnostic tools
- data modelling
- resources for mental health, indigenous health and more

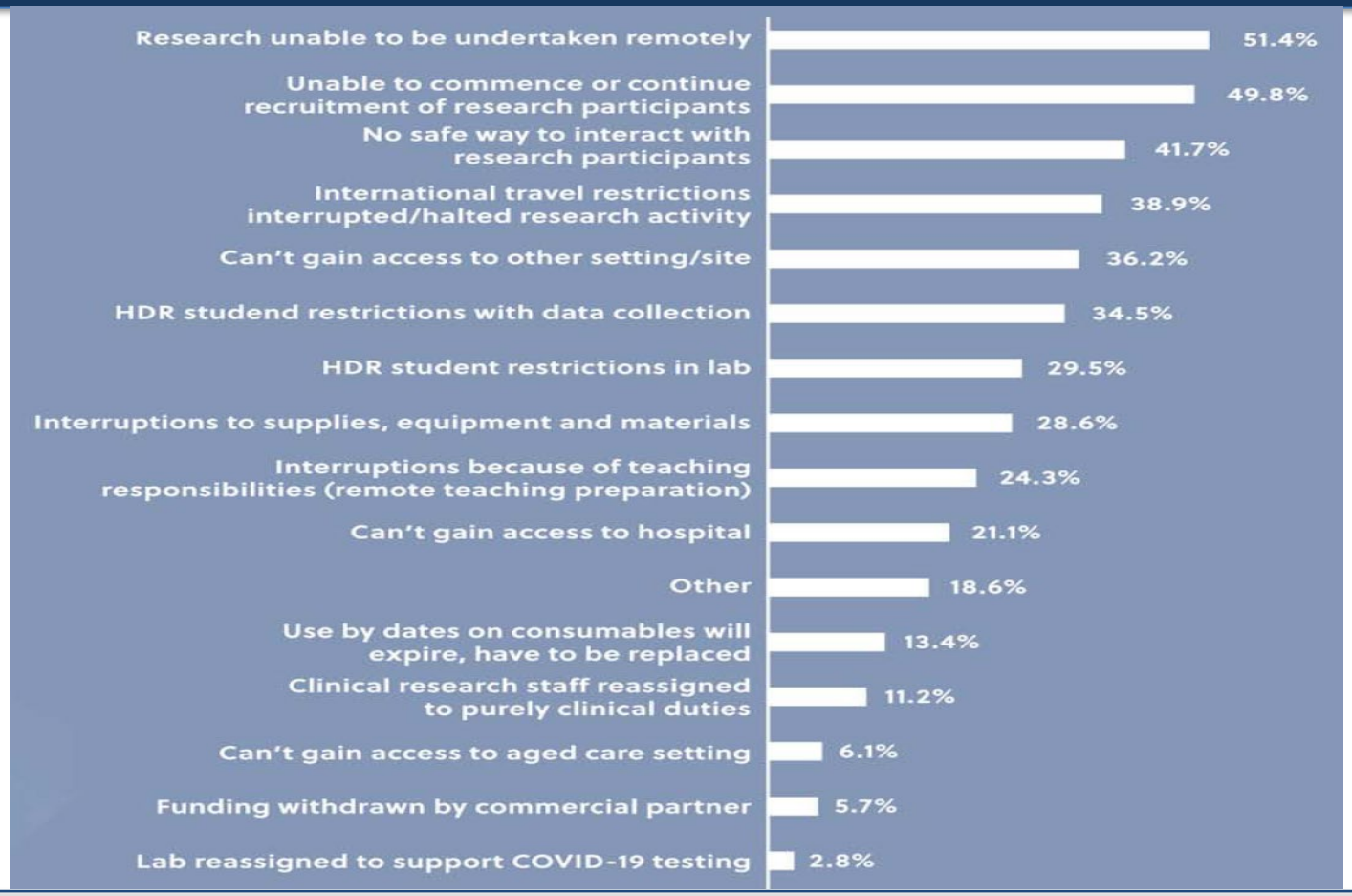
Source - AAMRI

Overall Impact – Cont'd

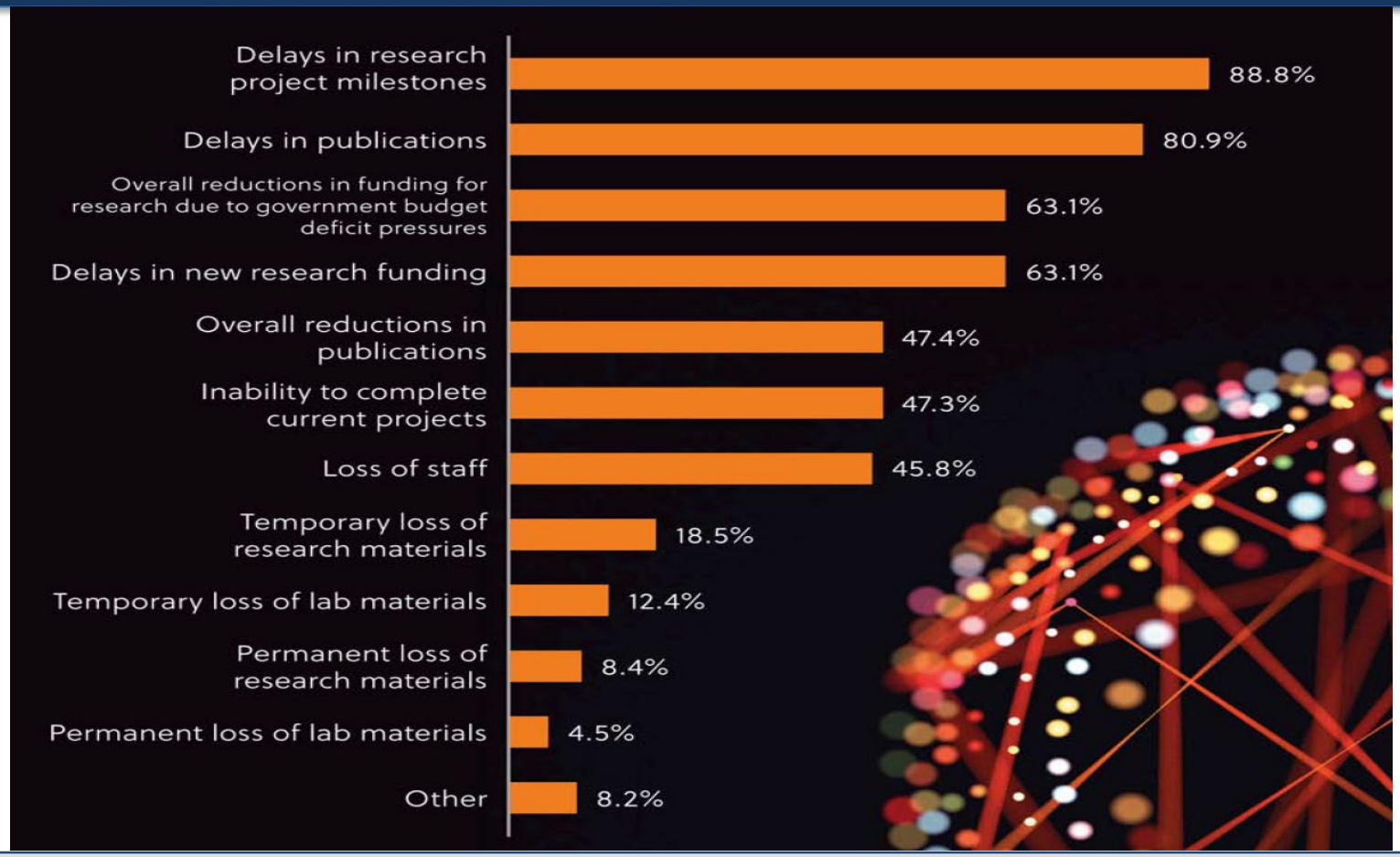
As a result of COVID 19, there have been changes in trial conduct including

- **Increased collaboration and cooperation e.g. patient co-enrolment**
- Existing studies have **adapted** to include COVID 19 patients

Initial Impact



Overall Impact – beyond 2020

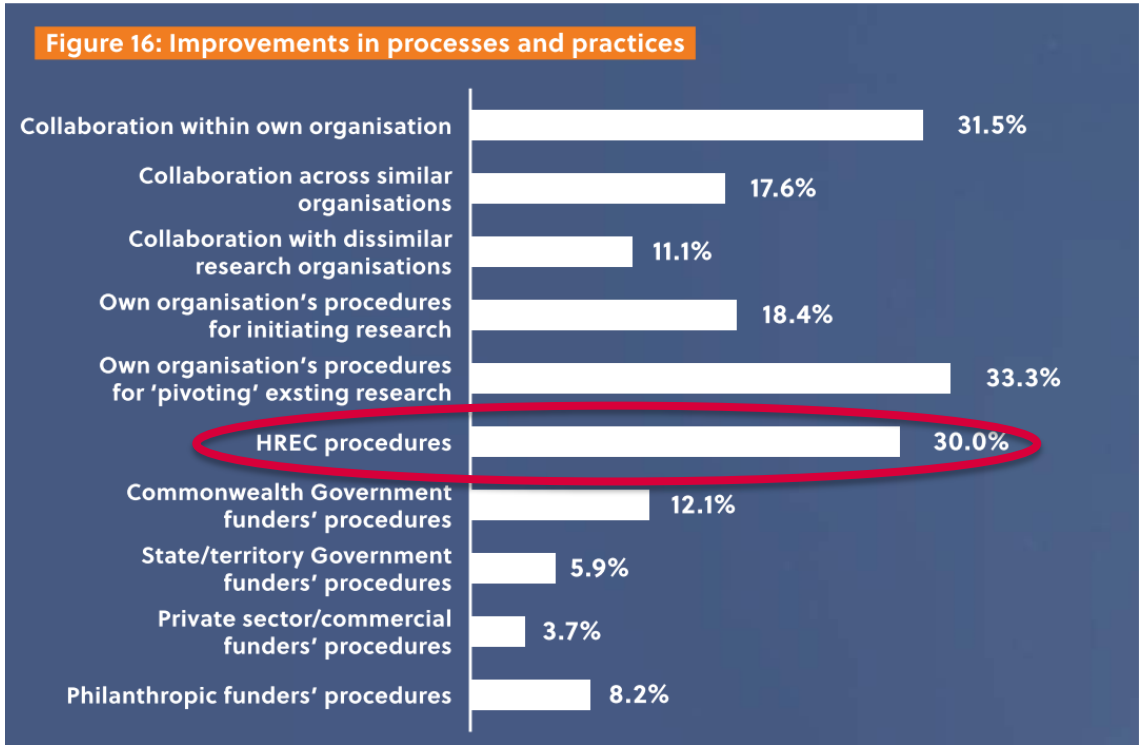


Australian Clinical Trials Alliance

Overall Impact – Cont'd

As a result of COVID 19, researchers felt there may be some enduring benefits beyond 2020

Image Source- Research Australia



What has changed since COVID-19 : Policy

- Lack of policy – Routine health care stopped
- National Medical Stockpile – The government prioritised access to the national medical supplies for clinical trials

What has changed since COVID-19: Policy

Joint statement by NHMRC, TGA and CTPRG provided guidance to institutions, HRECs, researchers and sponsors:

The conduct of research related to COVID-19 is a significant priority; however, the initiation and continuation of other ongoing and proposed research may also be critical for the well-being of patients, participants, communities and the research sector.

https://www.nhmrc.gov.au/sites/default/files/documents/attachments/ctprg-statement-clinical-trials-covid.pdf

Clinical trial harmonization across states

- 30 June 2020 CEDA address buy Minister Hunt

Mr Hunt also discussed Australia's research and clinical trial system.

"What we have now is a high degree of international interest, building on what was already a high degree of interest for clinical trials and for re

"Many of the systems in other countries for non-COVID research have had to be put on deep pause and as a consequence of that, we know interest in rapid movement for phase one, phase two and parts of phase three trials to Australia.

"We are now moving with the states and territories to set up a one-stop-shop for ethics approval.

"If there's a standard and institutions are included, then that will expedite that investment process.

"The pharmaceutical companies have said that will bring a more general investment in basic research as well as potential for advanced manu

Looking ahead Mr Hunt discussed Australia's borders.

- …National Front Door

Australian Clinical Trials Alliance

www.clinicaltrialsalliance.org.au

What has changed … : Policy & *Technology*

- Remote Monitoring
- Tele-trials

Source - https://www.nhmrc.gov.au/sites/default/files/documents/attachments/ctprg-statement-clinical-trials-covid.pdf

What has changed … : Policy & Technology

Remote Monitoring

- Need for effective risk assessment prior to conducting remote monitoring

- Remote monitoring procedures involve
  - alternatives to in-person safety assessment (e.g., phone contact, virtual visits etc)
  - centralized monitoring of trial documents
  - remote data source verification
  - additional safety monitoring of trial participants if the trial is halted or treatment is discontinued.

What has changed … : Policy & Technology

- Remote access to patient eMRs for SDV is feasible and is potentially an avenue through which resources can be more efficiently used.

› J Oncol Pract. 2013 Jan;9(1):e13-6. doi: 10.1200/JOP.2012.000666.

Reducing clinical trial monitoring resource allocation and costs through remote access to electronic medical records

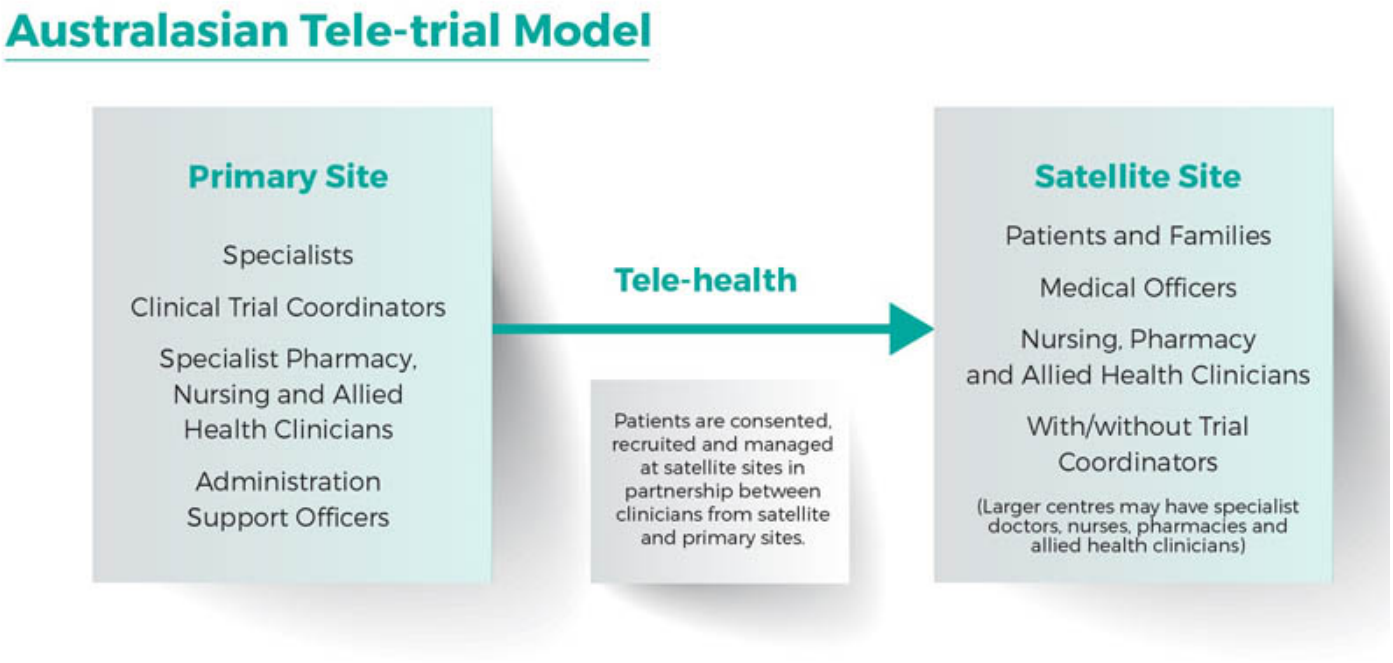
Shannon C Uren [1], Mitchell B Kirkman, Brad S Dalton, John R Zalcberg

Affiliations + expand

PMID: 23633977 PMCID: PMC3545670 DOI: 10.1200/JOP.2012.000666

Free PMC article

What has changed … : Policy & Technology

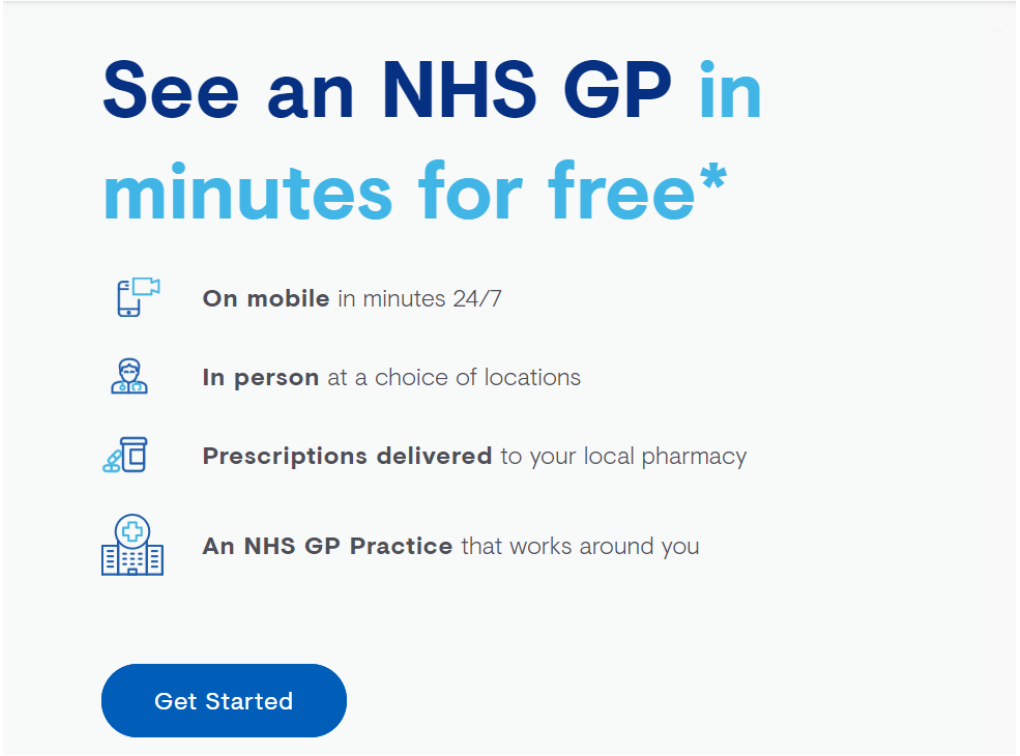


Lessons Learned:

- Recognition of the different requirements of each site
- Clear communication and expectations from all involved

What has changed … : Policy & Technology

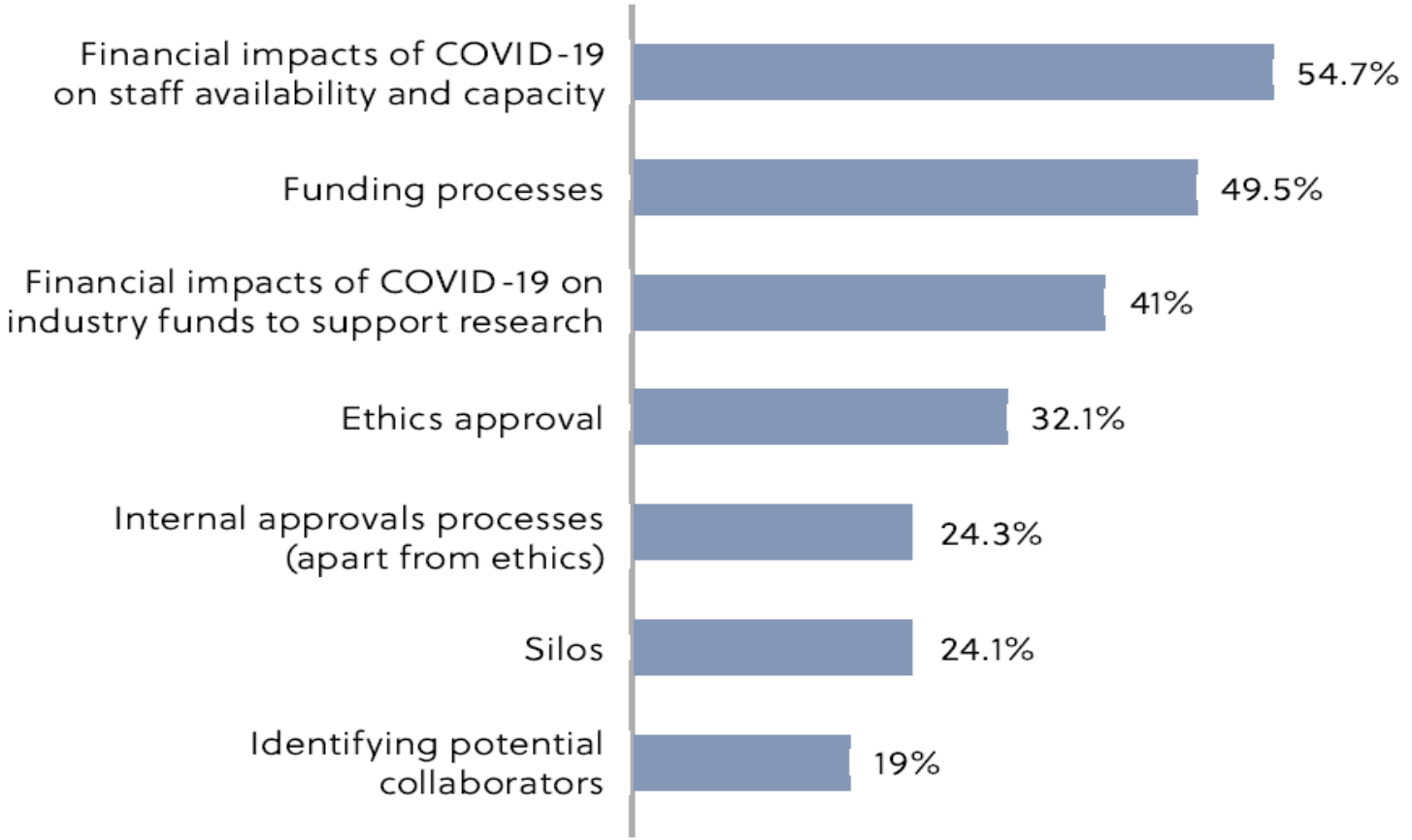
- Growing demand for delivery of clinical trials at home
- Hospitals adopting policies to enable trials at home



Barriers

- Lack of investment in clinical trial infrastructure
- Absence of clinical trial management system
- Remote monitoring policy is evolving – the Federation is alive and well!

Barriers to a rapid research response



Acknowledgements

- The community at large who have had to manage through these very difficult circumstances
- Many participants (and their families/carers and treatment teams) in clinical trials of treatments (for COVID19 and other conditions)
- Health care workers who have worked night and day to help those in need and keep the system working
- Many Government and other support services personnel who have worked day and night to keep us all safe
- Many others….

Clinical Trials 2020

Agenda

- Rare Cancers Australia Overview
- Clinical Trial Discussion
- Case Study
- Questions

Rare Cancers Australia (RCA) Today

Founded in June 2012
Founders: Kate &
Richard Vines

15 Staff

Work across the
cancer community

Bold, Diplomatic,
Innovative & Supportive

Patient support and advocacy
Timely and affordable
treatment

Clinical Trials in the COVID Era

- Clinical Trials are often the last/best chance for Patients
- Clinical Trials are “Standard of care” for rare cancer patients
- Suspending recruitment is denial of care.
- Is Covid-19 a valid reason to do this.
- Every patient is precious.

Caring for Patients on Trials

- Why did it take a pandemic to introduce remote monitoring?
- Clinical Trial Co-ordinators are not carers or case managers
- Who is looking after the whole patient? It's not all about quantitative elements

- Who is briefing and engaging the patients GP or Specialist?
- What happens when the patient progresses – who is there for them?

- Hypothesis: Should Investigators provide detailed briefings to the patient's GP

Case Study – Kate Vines

- Clinical Trial – Medullary Thyroid Carcinoma
- Monthly Visits to Sydney; Bi-monthly scans
- COVID meant switch to remote monitoring.
- Convenience, easier for Kate – why did it take a pandemic?
- Punctuality and Structure – Staff need to adapt to new model
- Challenges
  - When to present
  - Incorporating other specialists, therapies – heart, thyroid etc

A patient on a clinical trial shouldn’t feel alone!

Thank you

Questions