SEARCHING FOR CLINICAL TRIALS: WHAT PATIENTS WANT

Report from a Think Tank Exploring the Issues Finding and Providing Information About Clinical Trials, and How They Might Be Solved

August 2018

Research4Me

Searching for Clinical Trials: What Patients Want.

Report from a Think Tank Exploring the Issues Finding and Providing Information About Clinical Trials, and How They Might Be Solved.

This report was compiled by Dr Janelle Bowden, with significant input from Dr Lisa Briggs, and review and comment by attendees of a Think Tank held on 11 April 2018.

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1 FORWARD

As a patient living with cancer, dealing with the diagnosis and the disease can often be difficult enough, let alone worrying about what the road ahead might look like. Some patients are quite happy to let their medical team take the driver's seat, and they be the passenger, whilst other patients, like me, want to get behind the wheel and drive themselves. Either way, it shouldn't matter which category you fit into, the outcomes should still be the same. But unfortunately they are not. Time and time again, we are seeing the current systems fail the people they are designed to help, with many often left stranded, either as the passenger or the driver!

If you're 'lucky', you will be part of a team who can chauffeur you around. But they tend to be the ones with roadmaps and navigation intel, who understand the backstreets, alleyways & shortcuts. If not, you could be taking the bumpy, dirt roads and double the time to get there!

I'm sure many of you can relate to being in situations where you are driving around, lost and confused, trying to make sense of which road you need to take in order to get you back on track towards your destination. For many patients searching for clinical trials, this is exactly what it feels like. Stressful, confusing, complex and deflating as you hit dead end after dead end after dead end.

Developing the Think Tank event was an absolute necessity, and first step needed to overcome the challenges faced by both patients & researchers.

Our hope was to shine a spotlight on the issues faced by patients and carers, searching for clinical trials on a regular basis in hope that this would at some point lead to improved access to potentially life saving therapies and therefore improve overall survival and/or outcomes. Having all the key stakeholders in one room was a real opportunity to utilize the patient experience to demonstrate these issues and raise some red flags regarding the current systems in place. These conversations were aimed at encouraging each person in the room to start thinking about the 'real' problems at hand & discuss potential solutions to overcome them. For some Lung Cancer patients, clinical trials can sometimes be their only lifeline, whilst for others it can be about accessing the most cutting edge treatment available.

When reading this report, please keep in mind the analogy of being lost. When we can't take control of our disease, the next best thing is to take control of navigating our own path. Hopefully this is the start of a bigger conversation which ultimately changes the way for all involved.

- *Lisa Briggs*

2 EXECUTIVE SUMMARY

We are in an era where clinical trials are saving lives. They are the best way to access promising treatments in cancer and other conditions. Patients are grateful for clinical trials. Trials provide hope. But, hope is stripped away when it is not easy to access clinical trials.

Patients are looking for trials. For some patients, clinicians never discuss clinical trials and the only way they find them is through online groups. On the flip side, triallists are looking to find patients but often struggle to do so. Many clinical trials take longer than they should, and even fail, due to recruitment difficulties. If it's not through lack of trying on the part of both patients and researchers, then what's the issue? That's the problem the Think Tank sought to investigate.

Through prior survey, panel discussion, individual presentations and group discussion, the Think Tank sought to draw out the perspectives and experience of those looking for trials and those providing information about trials. The objective was to reach a common understanding of the issues and brainstorm potential solutions together.

Key messages from patients and carers include:

- While thankful for clinical trials, people are frustrated at the sense of 'randomness' in how they find out about them;
- Patients and carers trust in their clinicians for information about clinical trials. Yet, due to a disconnect in getting this help, patients and carers are getting more empowered to look out for themselves, and find their own trials, often from other patients;
- There are too many places to look for clinical trials, and when you do search a database, search output can be confusing to interpret;
- While patients and carers have diverse information needs that can be a challenge to meet, trial registers/websites should present more participant-relevant information in lay language.
- Without dispute, the algorithms and tools used to search clinical trial registers and websites need improvement.
- Trial registration must be mandatory. Researchers need to understand the value of clinical trial registers to patients and carers, and to their own trial recruitment, by registering, providing lay language summaries and keeping information about their trial up to date.
- It's time to address the issues preventing more accessible public access to information on clinical trials – patients' lives depend on it.

The clinical trial registry a trial sponsor (academic or commercial) will choose to use will differ across organisations and trials. For global industry sponsors, ClinicalTrials.gov is usually the primary registry chosen because of the US government's policies mandating its use for any trials in the US. But that does create some issues for Australian patients in their ability to find where in Australia those trials are happening. For the Melanoma Trials Group, where trials are registered depends in part on where the trial is running, and what international partners might be involved.

Some of the issues trial sponsors and researchers identified as challenges to providing better information about trials included:

- The need to enter clinical trial information into multiple systems (eg HREC forms, TGA, ANZCTR) and having the resourcing and time to register and keep information up to date;
- Compliance with privacy legislation and having the right to provide site contact details;
- An empathy for the impact of patient and carer enquiries on resource-strained clinical trial sites;
- How to ensure trial information is in a patient-friendly format, and sponsors/institutions are well enough informed to be able to connect patients and carers with trial sites;
- Where to put trial information such that patients and carers can effectively access it;
- For those involved in multi-country studies, how to keep multiple registries up to date and consistent;
- Perceptions around the commercial advantage or risk of making information about a clinical trial public;
- Having the trials available to meet the hopes and expectations of patients for access to trials;
- Determining which initiatives will make an impact to trial recruitment to justify applying resources to those efforts;
- From an industry perspective, are they self-imposing restrictions (for example, in complying with the Medicines Australia Code of Conduct) that limit their ability to provide the information patients and carers want about clinical trials?

There is a clear need to reduce the burden of multiple data entry, to introduce incentives or sanctions to encourage compliance with trial registration and keeping records up to date, and to continue the conversation about how to help bring patients and trials together. Embedding clinical trials into routine clinical care, rather than seeing research as something separate, is a cultural change both clinicians and the public need to embrace.

ANZCTR, AustralianClinicalTrials.gov and the Cancer Council Victoria spoke of their history, current state of play, and shared a look toward the future for each of these platforms. The importance of having complete, current and quality data in their respective databases was a common theme across each of these speakers.

TransCelerate, ClinTrial Refer and Tim Churches presented ideas to inspire thinking about what the future could look like, both from a technical point of view, and ease of access and use perspective for patients and carers.

The facilitator identified 4 key themes raised through the group work for attendees to problem-solve:

1. How to get good data into the register to begin with;
2. Plain language vs clinical language;
3. Database solutions and who owns the data;
4. Getting doctors on board.

The solutions proposed by groups varied from simple process suggestions, through to more complex ideas and infrastructure changes.

At the end of the day, there was a clear mandate from the group that change is needed to make sure better information is available, and that this was an engaged group that was interested in being a part of the change.

Research4Me recommends the 5 following actions (in no particular order) as the foundations for improving public access to more comprehensive, user-friendly, understandable, relevant and up-to-date information about clinical trials:

1. **That a financially supported and resourced working group/collaboration is formed** (if not already in existence) inclusive of patients and carers and their representative health/disease groups, commercial and non-commercial sponsors, trial registers and portals and government agencies, focused on coordinating effort and ideating, testing, measuring and advocating for solutions that help improve the access of patients to appropriate trial information, and speed up trial recruitment.

2. **That ANZCTR is supported with the funding and resources needed** to ensure its integrity as the primary government-owned database of clinical trial information in Australia, one that is complete, up-to-date, user-friendly and has exceptional search capabilities.

3. **That the mandatory requirement for prospective clinical trial registration is** supported by audit, incentives and/or sanctions to drive compliance and maintain up-to-date clinical trial registry records.

4. **That greater effort is made to coordinate databases and reduce duplication of effort for researchers.** Providing a single point of data entry for multiple agencies such as the TGA, ANZCTR, ethical review, grant systems would reduce trial site workload and frustration, and make it easier to get a consistent, quality, current repository of clinical trial information.

5. **That a Clinical Trials Hotline is pilotted** to help answer the public's questions about clinical trials, and provide them with assistance in finding clinical trials.

Research4Me is actively looking at how it can help progress these recommendations and welcomes collaboration with other like-minded individuals and organisations.

3 ACKNOWLEDGEMENTS

Research4Me would like to thank the following for their investment of time, resources and openness in the Think Tank and preparation of this report:

Lisa Briggs. You are an inspiration. You picked up the phone and started a conversation, sharing the desperation felt by patients like you and the need for an urgent fix to help patients find trials. This conversation is what compelled us to further investigate and run this Think Tank in the hope we could help uncover some new ways forward. But, you didn't stop there. At every step of the project, from developing the idea and content, encouraging survey completions and event attendance, to preparing this report, you were active partner. For the time and energy you have devoted to this project in light of your own challenges, thankyou. Your support and the friendship that has developed mean more than words can express.

Our speakers. We appreciate the time you took out of your busy schedules to prepare for and present the Think Tank, some of you from many miles and/or timezones away. Thankyou for taking a chance on being part of this event, and so openly sharing your time, thoughts, experiences and ideas.

Our survey and event participants. Sometimes it takes a leap of faith to contribute to something new, and we are glad you made the jump with us. Thankyou for registering, turning up and actively participating in the Think Tank. We hope you felt it was a good use of your time and that your contributions have been represented in this report. We look forward to what might be achieved if we continue this conversation together.

Our sponsors. Thankyou to SPHERE, TrialDocs and Lung Foundation Australia for the financial support that helped make this event, and its inclusiveness possible.

Sara Weidenhaefer. Thankyou for stepping in at short notice to facilitate this event when a previous facilitator needed to withdraw. We appreciate the flexibility you showed in adjusting the process we were following as the day progressed.

Victor Roberts.– At very short notice you sacrificed time with work and the grandkids to help manage our online participants, despite your own recovering injury. We are very grateful for your kindness and helpful online moderation.

Fiona Harmsworth. You are a true friend for jumping in and applying your professional editing skills at short notice to help make sure our report was error free.

Our Venue. Thanks to staff and venue at Cliftons for your support in helping to plan and execute the virtual and in-person Think Tank event. We appreciate you had our backs.

4 CONTENTS

5 ABBREVIATIONS

The following abbreviations can be found in this report:

AHRTC	Academic Health Research Translation Centres
ANZCTR	Australian New Zealand Clinical Trials Registry
ANZ MTG	Australian New Zealand Melanoma Trials Group
GCP	Good Clinical Practice (An international guideline for the conduct of trials)
GP	General Practitioner
HREC	Human Research Ethics Committee
KPI	Key Performance Indicator
LCPAG	Lung Cancer Patient Advisory Group of Lung Foundation Australia
MA	Medicines Australia
MBS	Medicare Benefits Scheme
MTAA	Medical Technology Association of Australia
NHMRC	National Health and Medical Research Council
RDTF	Medicines Australia/Medical Technology Association of Australia (MA/MTAA) Research and Development Taskforce
TGA	Therapeutic Goods Administration (Australia)
US	United States of America

6 DEFINITIONS

For the purposes of this report, the following definitions were used:

Clinician	This term is used in the broadest sense to describe those who provide health care (eg general practitioners, physicians, specialists, and allied health professionals).
Patient(s) & Carer(s)	In Australia, the preferred term for users of the health system is 'Health Consumers'. However, it is not a term that resonates with or is broadly used in the general community. As such, for clarity in this report, the term "patients and carers" has been used as a descriptor for people that may be looking for clinical trials for themselves or others they care for.
Lay language	To aid understanding in the community, technical / scientific terminology and complex scientific concepts should be translated into simple concepts. We use the term lay language to mean non-technical, jargon-free language written in plain English. An Australian example list of lay terminology to use can be found at: https://www.abmdr.org.au/lay-language/.
Sponsor	A trial sponsor is an individual, institution, company or organisation (for example, a pharmaceutical company, contract research organisation, academic group or health organisation) that takes the responsibility to initiate, manage or finance a clinical trial.

7 THE EVOLUTION OF THE THINK TANK

7.1 THE SPARK OF AN IDEA

In June 2017, Lung Foundation Australia formed the Lung Cancer Patient Advisory Group (LCPAG) which led to the collaboration of strong advocates looking to make a difference. A survey was released to the wider lung cancer community to ask them 'what their priorities were'. Out of the 76 patients that responded to the survey, 76% revealed access to clinical trials is extremely important. Additional feedback included:

1. Clinical trials are not transparent or easy to understand without a medical background;

2. Access to clinical trials beyond metropolitan areas continues to be an issue for patients;

3. Research from clinical trials provides patients with hope. So if they are not easy to access, hope is stripped away.

Being aware of Research4Me, Lisa Briggs (on behalf of the LCPAG) contacted Janelle Bowden at Research4Me to discuss what was known about the systems currently available to find trials, and where the duplication and gaps were. After a long discussion, Lisa and Janelle resolved that something needed to be done to make it easier for people to find clinical trials, and it would require collaboration.

7.2 A PRE-SURVEY TO VALIDATE THE PROBLEM

To get a sense of whether the problem of finding trials was unique to lung cancer patients, Research4Me released an open survey publicised through social media channels asking for people in its community to feedback on their experiences looking for trials. Between 13 Dec 2017 and 9Feb 2018, 17 people responded to the survey. Despite a small number of respondents, findings paralleled those raised in the LCPAG survey (and coincidentally, TransCelerate surveys[1]).

The survey found:

- People have a desire to be able to search on a broad range of parameters to better target trials that might be suitable for or of interest to them. The search parameters included location, health condition, inclusion/exclusion criteria, gene mutations, drug names, age, trial status, trial name, and type of trial.
- There is a diversity of information needs around clinical trials. These included: trial phase, background to and evidence to date justifying the trial, access to the trial protocol, trial objectives and endpoints/outcomes, clear eligibility criteria, trial locations, trial status, duration of the trial overall and for each participant, how health will be monitored throughout, a clear description of the nature of the commitment for the participant, cost of participation, reimbursement offered, who is running/funding the trial and what would happen to personal data after the trial.
- People want the trial information available to be current and complete. They want a register that includes all trials in all locations.

- There was mixed awareness of the websites where people could look for clinical trials, with ClinicalTrial.gov (the US website) most mentioned. For the websites that people were aware of, there were both positive and negatives noted about them. The most frequently mentioned negative issues include the lack of being user-friendly, lack of up to date information and inconsistent search results across different websites.
- Other information people felt could be useful included links to patient communities that may be able to connect people with others going through similar trials, questions to ask a researcher on the first visit, making it clear if a trial was accessible only to those local to the trial site (or if travel costs were supported for those from a distance away, eg interstate), and how participants can provide feedback to sponsors about a trial protocol.

The pre-survey raw results are available at: https://research4.me/Think Tank-11apr18/. Summarised pre-survey results are included in the Introductory Presentation slides, available at the same link.

When Janelle and Lisa discussed the survey results, the idea of holding a Think Tank to bring together all those that had a stake in making it easy for patients to find clinical trials was committed to. The hope was that use of a design thinking framework might generate new ideas and momentum to help solve the problem patients and carers have finding clinical trials, and in the process reduce the problem researchers and industry have finding volunteers.

7.3 The Think Tank

The date of 11 Apr 2018 was set to fit in with the availability of key speakers and avoidance of public/school holidays.

With time limited, Research4Me invited speakers known and introduced to them who were able to represent the perspectives of those looking for trials (ie patients and carers), those providing information about trials (ie various clinical trial portals, and academic and commercial organisations running trials), and those that might inspire thinking about how trial information portals might be improved. The biographies for the final speakers are available in Appendix 1.

A panel discussion with clinicians not involved in clinical trials but who had looked for trials for their patients was also planned. However, due to difficulty identifying representatives of this group in the time available, this panel did not proceed. This is a noted gap in the stakeholder representation at the Think Tank and hence perspectives represented in this report.

Sponsorship was sought to help cover costs for the venue and online meeting facilities, minimise attendee costs to broaden participation (ensuring patients and carers could attend for free). The profile of each of the Event Sponsors is available in Appendix 2.

Tickets were released a month prior to the event, and the event advertised through Research4Me's personal and social media networks. Anyone with an interest in the discussion was welcome to attend.

Further information on those that registered for the event is available in Appendix 4.

7.3.1 Meeting Scope, Objectives and Agenda

The scope of the meeting was to look at the issues surrounding finding and providing information about clinical trials, as one of the barriers to trial recruitment. Other barriers to trial recruitment, including general awareness of clinical trials in the community, and issues in the design, conduct and resourcing of clinical trials were out of scope for the discussion.

The objectives of the meeting as described to attendees on the day were to:

- Hear and feel the experience of those looking for trials
- Hear and feel the challenges in providing information about trials
- Use a design thinking framework to find desirable solutions.

The agenda included introductions and context from Lisa Briggs and Janelle Bowden, two separate panel discussions with patients and trial information providers, presentations from the ANZCTR, AustralianClinicalTrials.gov.au, TransCelerate, ClinTrial Refer, and Tim Churches on behalf of a HealthHack 2017 team. Janelle Bowden moderated the panels and speakers. Sara Weidenhaefer facilitated the group discussion, loosely based on the start of a design thinking process. The full agenda and a link to access the slides and videos (where speakers provided consent) is available in Appendix 3.

7.3.2 Post Meeting Follow-up

Subsequent to the meeting, attendees were sent PDF copies of presentations made available by speakers, and follow-up information requested during the meeting.

7.3.3 Preparation of the Report

Janelle and Lisa Briggs consolidated information and themes that came out of pre-event surveys and Think Tank into a draft report. Supportive background information to improve context, and relevant post-meeting updates were incorporated.

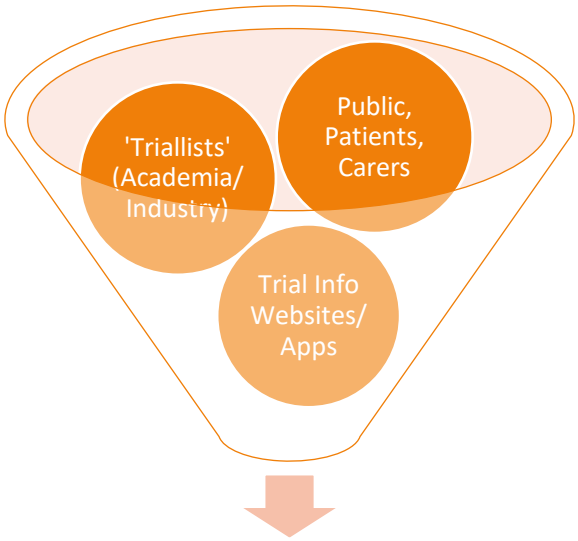
The draft report was issued for review by speakers and meeting attendees, to ensure the content represented the discussion and outcomes of the day. Attendees were given 2 weeks to provide their feedback.

Demonstrating the level of engagement of attendees in this issue, twenty four attendees took the opportunity to provide feedback and/or make suggestions, which was both further explored if necessary and/or largely included. Gratitude is extended to the Department of Health and NHMRC for providing additional comment in response to questions raised during the review period. Content that clarifies or provides updates subsequent to the ThinkTank is included as Post Meeting Notes.

It is acknowledged that one attendee (in conflict to all other feedback received) did not feel the recommendations made were supported by the day's discussion.

The final report was published on the 17 August 2018.

8 Understanding the Issues



Improving clinical trial access and participation is a 'wicked' problem[2], and the issues change depending on the perspective you bring to the problem. The purpose of this meeting was to gain a common appreciation of the issues experienced by different stakeholders specifically around accessing and proving information about clinical trials to see if it might generate ideas or solutions not previously considered.

The following outlines the perspectives of patients, those running trials, and those providing information about trials (government, non-profit, trial databases). What is not represented, but is an important stakeholder group, is the views of clinicians that are *not* involved in clinical trials. Though their participation in this meeting was sought, finding appropriate clinicians interested in being involved in this discussion at short notice was difficult. As such, the perspective of the non-triallist clinician who may need to search for trials for their patients is missing from this report.

8.1 Patient Perspectives

Adrian Eisler, Adam Johnston and Marilyn Nelson shared their health stories and clinical trial experiences through a panel discussion. Some clear messages came out of their experiences.

Patients are thankful for clinical trials. Clinical trials provide hope, close monitoring, a way for patients to potentially help themselves, or others, and a sense of control. There is a need to better share these benefits and feelings to increase awareness of clinical trials.

> *"I owe so much to the world of research and clinical trials, literally. Otherwise I would not be alive."*
>
> *– Adrian Eisler*

But, hope is stripped away when finding and accessing clinical trials is difficult.

There is 'randomness' in how people find out about clinical trials, that being offered a trial is a matter of chance. *"Did I go to a doctor who knew about clinical trials, and offered that choice to me?".*

Clinicians are still the most trusted source of information about clinical trials for patients. There is a patient expectation that doctors are aware of all available trials. Patients rely on their doctors to tell them about trials. But, in reality, many doctors aren't aware of trials, unless they are directly involved in them or part of a Multidisciplinary Team (MDT) and are therefore not routinely offering them to patients. There is a perceived disconnect between clinicians and patients where clinical trials are never discussed as an option.

> *"I got involved in a clinical trial at the behest of my doctor who was forensic in his search for something for me. I was on a downhill slope at that time. I might have been thinking I was clutching at straws at that time, in the hope that something would be of help to me, or at least others that followed. The prospect of being monitored closely was a benefit, as well as the hope of getting access to these new experimental drugs at an earlier point.*
>
> *I had no experience, no knowledge of trials, I completely relied on my doctor for his advice and recommendations."*
>
> *– Adrian Eisler*

> *"It turns out there was a trial in my home city, but nobody told me about it."*
>
> *- Marilyn Nelson*

Patients are finding the need to be their own advocates. Patients are increasingly aware of the need to advocate for their own healthcare and navigate solutions for themselves. Being an educated patient has its advantages. Patients now attend conferences, join online support groups, and can network with other patients. Patients are helping patients find clinical trials.

There needs to be a stronger connection between patients, clinicians and the clinical trials available. Clinicians should be better educated about trials during their training, and clinical trials mentioned to patients at their time of diagnosis.

> *"How does an average person, patient or family/carer, work out which website is right?"*
>
> *- Marilyn Nelson*

There are too many places to look for clinical trials. Patients are looking for information on clinical trials, are desperate for this information. But where do they go to look for trials? Which site can they trust to have complete information? Government owned registries are 'trusted' sources, but still patients struggle to find what they want, when they need it. Why is there no one source of truth for all – patients, researchers and clinicians.

From a patient perspective, it is unclear for whom registries are designed and whether researchers are uploading information to the registry with the end user in mind. Do researchers and industry appreciate the value of clinical trial registers as a trial recruitment resource?

It is complex to meet the needs of different patients for information about clinical trials. The public have varying levels of literacy around science, research and health. Different patients have different information needs and capacity to search for information about clinical trials. They also have different abilities to understand the technical and scientific language used.

BOX 1: Example: ISCRTN Definition of Plain English Summary

The plain English summary describes your research to the non-expert public and should be written in easily understood plain English in under or around 1000 words. It should encapsulate your research and is the first item listed on a registered study record. We ask that you present the information under the following headings:

- Background and study aims (brief description of the disease or area of study, what are the objectives/aim of the study)
- Who can participate? (what are the age range and gender of the participants, can they only participate if they have a certain condition or if they are healthy volunteers?)
- What does the study involve? (what interventions will be compared, will all participants receive the same treatment?)
- What are the possible benefits and risks of participating? (what can participants gain from enrolling, are there any side effects of the treatments and if so, what are the symptoms?)
- Where is the study run from? (what are the approximate number and names of centres taking part in this trial, if there is a lead centre, which one is it?)
- When is the study starting and how long is it expected to run for? (what is the anticipated start date and the approximate duration of the trial?)
- Who is funding the study? (who will be paying the costs that the trial will incur during its lifecycle?)
- Who is the main contact? (if this is the same as the contact in the record, please provide the name and email address only, if different to the contact in the record, please provide the name, position they hold at the institution/organisation and their email address)

Source: ISRCTN[3]

Interpreting publicly available information about trials is not easy. Frustration and confusion arise when different websites have different trial listings, search outputs from the same website can yield different results (somewhat illogically), lay language isn't used, and trial information is incomplete and/or out of date. These factors all contribute to making trials inaccessible for the public.

BOX 2: How patients and carers would like trial registers improved

- Lay language, multiple languages
- Clearer eligibility criteria
- Additional search criteria to minimise output (eg age eligibility, location)
- Geo-location maps of trial sites
- Information on trial commitment needed/impact (length, visit frequency and length, expense)
- Effective search algorithms
- Inclusion of prior evidence/data to justify trial
- Ability to hide/bookmark/compare trials
- Future alerts & Shareable links

Trial registers could better meet the information needs of patients (see Box 2). The information presented about trials needs to be more inclusive – use of lay language, and multi-language capabilities are important. Providing clearer information about eligibility criteria, and being able to narrow search output based on common eligibility criteria, like age, would be helpful. The data in trial registers must be robust, accurate and current, and provide trial site contact details, including phone numbers. Other valued content included information on why this trial might work for a patient, the impact of the trial on a patient's time (eg number, frequency and length of visits) and finances (eg medication, procedure, parking and travel costs), terminology for health conditions that is user friendly, and a description and links to prior evidence and data (preclinical and clinical) that justifies the conduct of the trial and the safety of the intervention. Having capabilities to hide or bookmark trials, compare trials, register for future alerts, search on location and share links to trials with others were thought desirable.

> *"Different websites output different search results for the same terms and it is not clear why. There is wide variation. A normal person who doesn't know anything about clinical trials and faces that, as well the technical and awkward descriptions, it is like a bit of a mountain to climb."*
>
> *– Marilyn Nelson*

Clinical trial website search tools need to be improved. Patients can be overwhelmed when there are many or poor results outputted from a website database search.

> *"I searched on ANZCTR for 'HIV'. That brought up 25 pages of results, which wasn't helpful. I feel like the default search page should be the Advanced Search page. Some trials found were completely unrelated. For example, a trial for "Post Spinal Anaesthesia Shivering" was included because it had a word which contained 'hiv'."*
>
> *– Adrian Eisler*

Confusion can occur when the same trial has different titles on different websites and there is inconsistency in the search output generated by different websites or within websites depending on the search term used (see Boxes 3 and 4). There is a need to make the search fields more relevant to what patients and carers might be thinking about, for example an ability to search on known genes/biomarkers or age eligibility criteria for a trial.

BOX 3: Example of inconsistency in search results across platforms

"Using the same terms of "lung cancer" and "EGFR":

- Clinicaltrials.gov.au: selected "Cancer", then "Lung", then keyword "EGFR", returned only 15 records
- ANZCTR.org.au: typed in "lung cancer EGFR", returned 39 records
- Australiancancertrials.gov.au: selected "Lung" plus keyword of EGFR, returned 69 records

So ...15 vs 39 vs 69 trials listed. Why the difference? Transparency is needed regarding what trials are included on the database being searched and the default search parameters so users have a context for and can interpret the search output."

- Marilyn Nelson

BOX 4: Example of inconsistency in search results within a platform

"Using the platform: Victorian Cancer Trials Link (http://trials.cancervic.org.au/)

1. selected cancer type "lung" and it returned only 51 records; BUT,

2. selected cancer type "non small cell lung cancer" (a sub-type of lung cancer) returned 73 records; AND,

3. selected cancer type "small cell lung cancer" (another sub-type of lung cancer) returned 39 records

So, why weren't 112 records found with the cancer type search term "Lung" when that was the combined totalnumber of records found for the two subtypes?"

- Marilyn Nelson

Registration of clinical trials open to recruitment should be mandatory. Patients did not understand why this was not the case in Australia, and thought we could learn from the legislation and sanctions used overseas to achieve researcher compliance (see Box 5).

Post Meeting Note: Subsequent to the Think Tank, it has become mandatory all clinical trials in Australia to be prospectively listed on a WHO-authorized clinical trial register (see Box 10, Section 8.4.1.3).

BOX 5: US Approach to Trial Registration

ClinicalTrials.gov is the clinical trial registry and results data bank operated by the US National Library of Medicine (NLM) of the National Institutes of Health (NIH). Since 18 Jan 2017, the Final Rule made it mandatory for all applicable interventional clinical trials to be registered not later than 21 days after the first participant is enrolled, and updated at least annually if there are changes (more frequently for some data elements). There are potential civil or criminal actions, civil monetary penalty actions, and grant funding actions that may be taken if responsible parties fail to comply with the rule's requirements.

Source: ClinicalTrials.gov Background[4]

It's time to address the issues hindering the provision of more accessible public information about clinical trials – patient's lives depend on it. Patients have a perception that researchers lack consideration for the barriers patients experience to trial participation. Patients are perplexed at organisations working in silos (organisational, geographical, state/federal, therapeutic area, etc), developing their own initiatives, duplicating effort, causing disconnect, and ultimately frustration and confusion for patients. Transparency around the completeness of the trials listed on a website, and how the trial search algorithms work would help alleviate confusion, but not the current need to visit multiple websites to find a suitable trial.

Finding them is not the only issue patients and carers have with clinical trials. The scope of the Think Tank was to explore the issues associated with finding and providing information on clinical trials. The discussion at times did briefly move in directions beyond this remit. Though the Think Tank attendees did not deep dive into any one of the following issues, they are noted for the benefit of anyone looking to improve clinical trial awareness, access, participation and conduct:

- Clinical trials need to be more inclusive. Eligibility criteria are very complex, and often exclusionary of populations that might benefit from the trial.
- Consideration needs to be given to patients who may be screened for eligibility for a trial, but may then not fit the trial, that they don't turn into 'disgruntled customers' who spread the word not to get involved in trials.
- Access to trials for patients in non-metro centres remains a barrier.
- Patients questioned whether private patients, whose clinicians may not be involved in clinical trials, could be at a disadvantage and how to make sure this wasn't the case.
- Trial results need to be published, and this is not consistently happening.
- Metrics are important for demonstrating the impact of initiatives to connect patients to studies. It was felt there was a need for better measurement of outcomes of projects to increase awareness and improve trial recruitment.
- Are the outcomes that matter to patients driving funding decisions?

8.2 Industry and Academic Perspectives

The following summarises perspectives raised during a panel discussion involving representatives from Eli Lilly Australia, Medtronic and the ANZ Melanoma Trials group (ANZ MTG), as well as subsequent discussion during feedback sessions by attendees.

8.2.1 Trial Registration – Where and How

In general, the multinational companies represented use the US register ClinicalTrials.gov as the primary and only register for all their trials. Some companies will also use this register even if the trial is only running in Australia. There is a belief that because ANZCTR draws data from ClinicalTrials.gov, then Australian patients are still able to find the trials occurring in Australia.

There were some differences in the level of detail provided by different companies about Australian sites on ClinicalTrials.gov. For example, Medtronic lists the Institution name for all Australian sites, whilst Eli Lilly provides a city and postcode. A single email or phone number is listed as a contact point for any global enquiries about a trial.

> *"The onus is on the patient to contact an institution if they are interested in a trial. There is however potential for disconnect if the hospital doesn't know where to send them."*
>
> *– Anita van Der Meer, Medtronic*

Eli Lilly also has their own company trial portal, which aims to help explain the clinical trial process to patients (Lilly Trial Guide[5]). It includes a tool to search and get more patient-useful information about the predominantly US trials they are running. There are plans to extend this portal to help patients search for Eli Lilly trials in other countries, including Australia.

Medtronic indicated their support for US efforts to increase the level of transparency around registered clinical trials, including provision of protocols and results reporting, as a positive for patients.

ANZ MTG register trials on ClinicalTrials.gov and ANZCTR irrespective of whether they are running in Australia. This is usually completed by the person responsible for all the trial's startup processes.

8.2.2 Barriers to providing more information or getting information to patients

The need to enter trial data in multiple systems. One barrier from a researcher perspective is the need to data entry in multiple places and the challenges of time in a research group with stretched resources to do it.

Privacy. Industry representatives raised the need to comply with Australian Privacy Laws. To provide more extensive trial site details on public registries (eg personal information like trial staff names and phone numbers), trial sponsors require the permission of those trial staff. This adds to the complexity of adding and maintaining detailed site level information in registries.

Impact of patient enquiries on site resources. Industry acknowledged that some trials can elicit a lot of patient enquiries, and many may not suitable for the trial. It was felt that filtering enquiries through a centralized contact point, rather than providing the contact details for each site, was a way to help protect trial sites that may not have the resources to handle multiple direct enquiries.

Getting trial information into a patient-friendly format. Industry are compliant with providing the information they need to. They acknowledge however that the information they are asked to provide right now is not patient friendly, which is a problem.

Ensuring trial contacts can connect patients with a trial site. Once a patient has information about a trial, there is an issue connecting with the trial site. Are sponsors and institutions well enough informed such that if they receive an enquiry from a patient looking for a specific trial, they can connect them with the trial site staff running that trial?

Finding where to put trial information. It is not a matter of not having the trial information or the resources to do it, it is about where to put that information that patients can effectively find it. This is the challenge.

Keeping multiple registries updated and penalties for discrepancies. There is a challenge for anyone running multi-centre, multi-country clinical trials in coordinating the update of multiple trial listings. In some countries (eg US), there is a risk of penalty if there is discrepant information on different websites. As a result, ClinicalTrials.gov is often used as the primary and only trial register, to simplify updating and avoid risk of penalty for discrepant information.

> *"How does a global company like mine keep all the different country listings and registers up to date at the same time. If there is a discrepancy between ANZCTR and clinicaltrials.gov for example, the company can potentially be fined."*
>
> *– Zoe Armstrong, MSD Australia*

The potential barrier to free flow of information due to commercial advantage/risk. There was an unresolved discussion about whether an assessment of potential commercial advantage/risk, especially if working in a unique or competitive therapeutic area, could be a barrier to better information about commercially sponsored trials. Given registries are now well established, there is less industry concern providing general trial information and most companies have established processes for listing trials and study reports on ClinicalTrials.gov. However, there can be sensitivities with providing trial site details as competitors (and new entrants to a therapeutic area) can see which study sites are being used. In the case where a registry is unlikely to generate meaningful recruitment (for example acute stroke or myocardial infarction studies as compared to chronic disease trials), it is perceived adding site location offers no value for the public and only creates additional workload for sponsors.

Sometimes there just aren't trials available. Sometimes there aren't trials available in Australia, or available in the places the patients live. Initiatives like telemedicine provide a hope for making trials more accessible.

A need to measure outcomes of any initiatives implemented. Given providing better information and databases does require an investment and money, whether that be by government, trial sponsors, etc, what's missing in the space is good measurement of outcomes eg impact on recruitment. That would help drive and justify the need for more funding for this better capability.

The self-imposed restrictions industry might place on itself about talking to patients. Though industry may have the resources, information and global reach to connect with patients, the language they can use and the information they can provide to a patient is highly restricted compared with the discussion a clinician can have. There is good reason for some restriction, but maybe restrictions have gone too far. Practices aimed at compliance with the Medicines Australia Code of Conduct[6] (to avoid promotion of commercially available drugs to patients) have crept into clinical research, hampering the ability to communicate with patients.

8.2.3 What might help?

Reducing data entry burden. From a researcher's perspective, there is a need to reduce the requirement for multiple data entry of similar information in different places.

Developing new tools to share trial information. The Melanoma Trials group for example are working toward developing an app that can be used to search for melanoma trials across the world, by location.

Creating ANZCTR records for trials registered on ClinicalTrials.gov. ANZCTR highlighted a new feature had been recently launched that enables trials registered on ClinicalTrials.gov to have additional Australian specific information added. Once a ClinicalTrials.gov registration has been made, a new linked record prepopulated with information from ClinicalTrials.gov can be created to enable the addition of the additional ANZCTR fields (see Box 7, Section 6.3.2).

Providing information in plain English. Researchers need to appreciate the value of communicating in plain English, and provide at least summary information in lay language. This helps make trials more accessible for, and shareable by, people looking for trials.

Starting the conversation to help bring patients and trials together. For many years there has been a considerable disconnect between large sponsors and patients who are looking for alternative options in terms of trials. Having the conversation about how to bring groups together and help patients find trials is the starting point.

Is there a role for legislation and sanction in compliance? Or incentives? There was discussion of the need to look at what measures were being used overseas to drive trial registration and reporting to inform how this could drive compliance in Australia.

Greater investment in early career researchers and physicians to educate them about clinical trials. There is a lack of basic clinician and investigator awareness about clinical trials. We need to publicly debate and address the competing views of whether clinical trials are a hope for patients, or a scourge of medicine.

Embedding clinical trials into clinical care. There is a need to educate the public and clinicians that clinical trials are a routine part of care, and not a bolted on extra.

8.3 ANZCTR PERSPECTIVES

As a primary register for clinical trials in Australia, the ANZCTR was invited to provide a context for the development of this register, how it works, and the challenges it faces.

8.3.1 The Evolution of Trial Registration and Reporting

In 2005, the International Committee of Medical Journal Editors (ICMJE) initiated a policy[7,8] requiring investigators to deposit information about trial design into an accepted clinical trials registry before the onset of participant recruitment, in order to publish in their journals. As a result, registries around the world were established, including the Australian New Zealand Clinical Trial Registry (ANZCTR) in 2005.

ANZCTR currently receives funding from the Australian Government via the Department of Health, Therapeutic Innovation Australia and the National Collaborative Research Infrastructure Strategy (NCRIS), and the Health Research Council of New Zealand.

As at July 2018, prospective trial registration (ie registration before any participants are enrolled) has been endorsed in Australia through the National Statement. It was also previously referenced in the Australian Code for the Responsible Conduct of Research. However, across the 250+ human research ethics committees (HRECs) in Australia, trial registration is not monitored equally. There is no requirement to demonstrate on the annual report to an HREC that you have registered and/or updated the trial information on the register. There are currently no sanctions in Australia for noncompliance, though there are a number of initiatives to encourage and enforce prospective registration (See ANZCTR Frequently Asked Questions[9]).

There is an important role for the public in advocating why it is important that researchers register their trials, provide lay summaries and answer questions about the trials such as age limitations and locations, as well as report their results. Examples of lobbying efforts to increase trial registration and reporting include the UK's AllTrials[10] activities, and TranspariMED's Clinical Trials Transparency Guide for Policy Makers[11] produced in collaboration with Transparency International, The Collaboration for Research Integrity and Transparency (CRIT) and Cochrane.

8.3.2 The ANZCTR Trial Registration Process

The ANZCTR accepts trial registrations from anywhere, but prioritises those from Australia and New Zealand. It is recognized by the World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP[12]) as a Primary Registry.

Technically, if you search the WHO ICTRP search portal, to which the registries upload their trials, you should be able to find any trial. However, this portal has known search issues and uses different search algorithms to other registries. Despite being one of their highest accessed sites, WHO has very little funding to support this portal.

WHO mandate 24 items[13] that must be collected for all trials on a register (Box 6). ANZCTR collects additional data (Box 7). ANZCTR is the only international registry which makes a lay language summary mandatory.

BOX 6: Mandatory WHO data items

1. Primary registry and trial ID
2. Date of registration in primary registry
3. Secondary ID
4. Source(s) of monetary or material support
5. Primary sponsor(s)
6. Secondary sponsor(s)
7. Contact for public queries
8. Contact for scientific queries
9. Public title
10. Scientific title
11. Countries of recruitment
12. Health condition(s) or problem(s) studied
13. Intervention(s)
14. Key inclusion & exclusion criteria
15. Study type
16. Date of first enrolment
17. Target sample size
18. Recruitment status
19. Primary outcome
20. Key secondary outcomes
21. Ethics Review
22. Completion Date
23. *Summary Results*
24. *Deidentified individual participant-level data sharing statement*

Source: WHO Data Set v1.3.1, ICTRP[13]

BOX 7: Additional ANZCTR data items

1. Plain language summary (mandatory)
2. Trial acronym
3. Trial design information e.g. allocation concealment, sequence generation, blinding
4. Planned statistical methods
5. Phase (drug trials only)
6. Date last participant enrolled
7. Participant accrual to date
8. Final sample size recruited
9. Recruitment states, hospitals, postcodes (Aus only)
10. Recruitment sites outside Australia
11. Ethics committee info e.g. name, address, submission date, approval date, approval ID
12. Trial website
13. Trial publications
14. Attachments e.g. trial protocol, statistical analysis plan, participant info sheet, consent form

- Lisa Askie, ANZCTR

Post meeting communication: ANZCTR currently complies the WHO data set v1.3.1 items 1-22 and is working to comply with items 23-24 by the end of the year, if not before.

It is important to understand how the data gets into the register to understand the output at the other end.

Registrants have to get a username and password in order to register a trial. A quality control check is performed by the ANZCTR on the trial information entered and any quality issues or missing data is queried and resolved before publishing to the register (Figure 1).

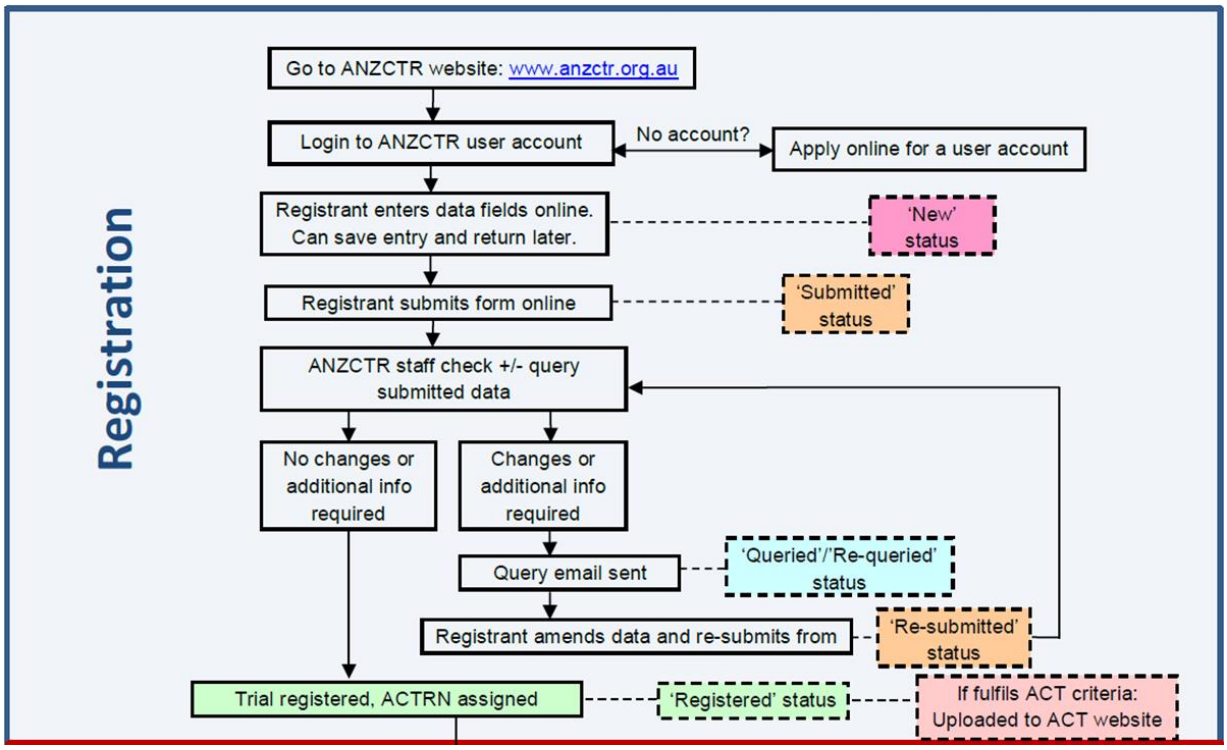


FIGURE 1: ANZCTR Trial Registration Process

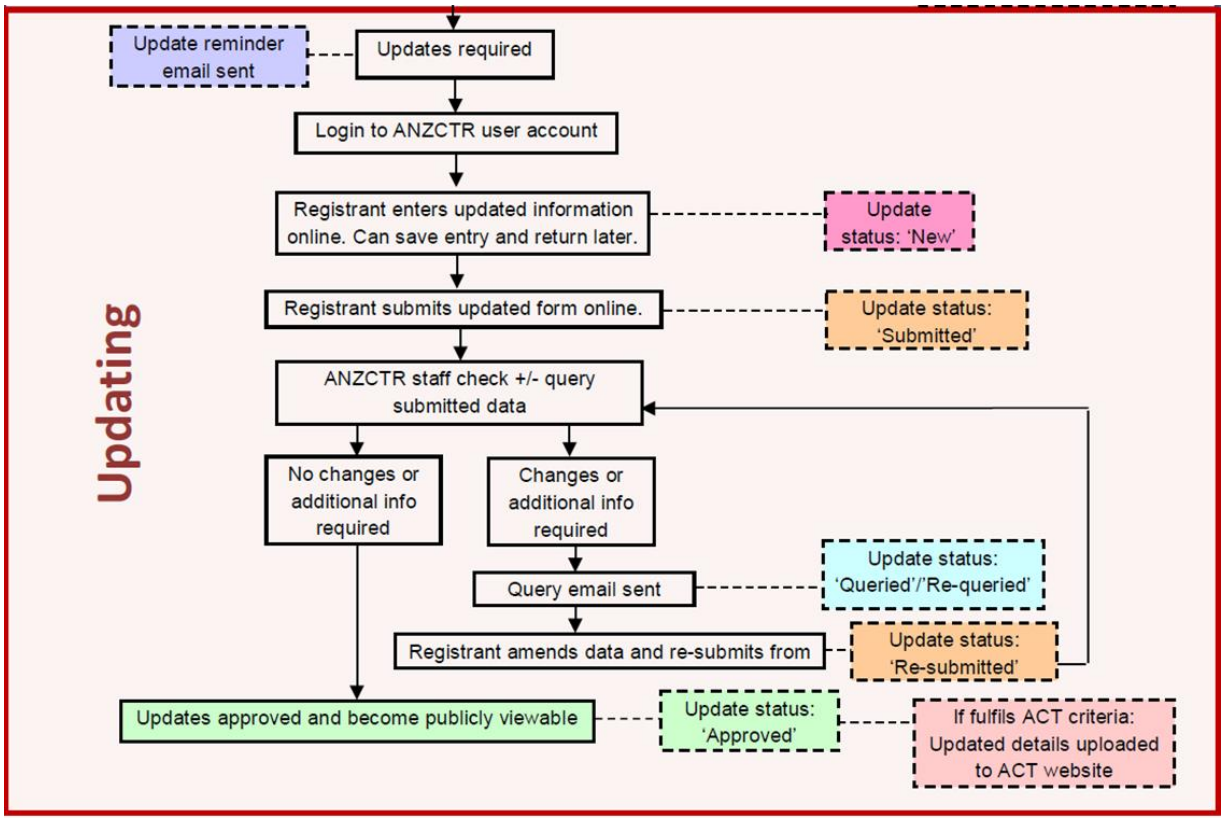


FIGURE 2: ANZCTR Trial Updating Process

The same process happens when the trial information is updated in terms of checking the quality and querying data entered (Figure 2).

Data from ANZCTR is shared with other organisations that use and present it in different ways, depending on their specific audience (Figure 3).

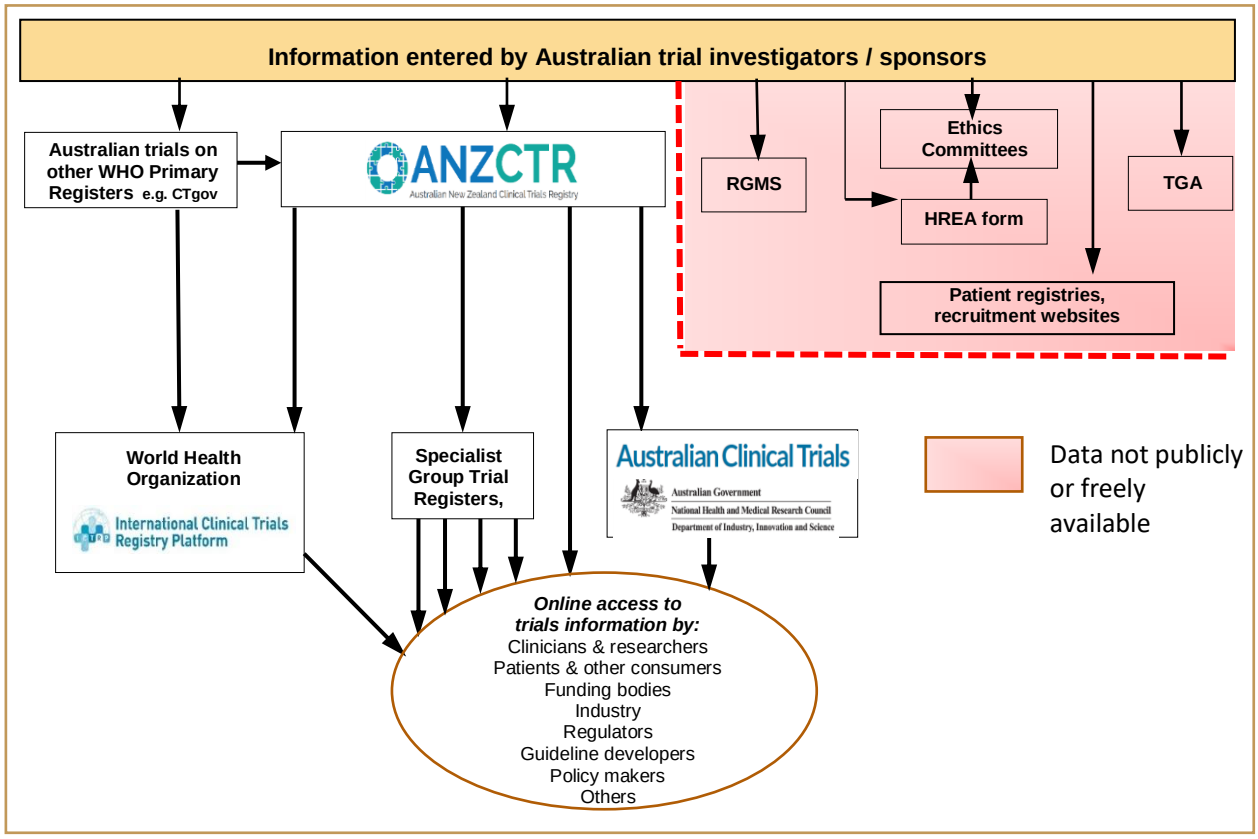


FIGURE 3: Trial Information Repositories and ANZCTR Data sharing

Examples where data is shared include AustralianClinicalTrials.gov (discussed below) and the AustralianCancerTrials.gov.au. For reference, when researchers register a cancer trial, additional fields are collected such as cost, reimbursement, travel, cancer stage etc that are then displayed only on AustralianCancerTrials.gov.au, not ANZCTR. ANZCTR encourages other therapeutic areas to consider creating similar modules specific to their own field of research which can then feed into the trial listings on their own websites.

ANZCTR can potentially be a useful resource for identifying research gaps and directing research funding by looking at the quantum of trials compared to the burden of disease[14,15].

8.3.3 The Challenges for ANZCTR

Getting trials registered & updated is challenging. On average, around 180 trials are registered each month. ANZCTR encourages all trials to be registered prior to enrolment, but not all are. The proportion of Australian studies registered each year before the first participant is enrolled has increased from 48 per cent in 2006 to 67 per cent in 2012. This has since plateaued at around 65–70 per cent16. Once trials are registered, there is then a problem keeping them updated, even with 12-monthly automated reminders.

Poor quality data is entered. According to Prof Askie, the trial information initially submitted upon registration often needs to be queried because it hasn't met an acceptable level of quality or data. Often there are multiple rounds of queries both when the trials are first registered, as well as when the records are updated.

Trial registration is perceived as an administrative burden. Whilst the principal investigator is ideally the most appropriate person to register a trial as a scientific and ethical responsibility, in reality it is a task that is usually delegated to coordinators or administrative personnel. This can result in some of the quality issues around getting the right data in.

Trial information needs to be entered into multiple systems. Researchers are tired of entering the same/similar information into multiple systems, for example grants systems, the TGA, Human Research Ethics Applications, and other trial registers. This adds to the administrative burden for researchers/sponsors and creates challenges in keeping different systems updated.

Mandatory trial information fields vary between different registers. The difference in fields between registers adds to the complexity of combining data from different registers into a 'single source' for Australian trials.

There are challenges improving ANZCTR with available resources. The US register ClinicalTrials.gov uses mesh headings and have 20 staff and $5million/year to ensure things are coded properly and can be searched well. ANZCTR has 2.7 staff, 0.5million/year to do the same job. It doesn't have the technical resources to build Google-like algorithms to enhance search functionality.

How best to involve more consumers in ANZCTR activities. There is a consumer representative on the ANZCTR advisory board – John Stubbs, but there is more that could be done to include consumers. For example, ANZCTR would like to see consumers write the lay summaries, but issues include how to fund it and the very tight turnaround times required.

8.3.4 Looking to the Future

ANZCTR is trying to be all things to all stakeholders. Ideally, ANZCTR aims to position itself as the primary repository of information for Australian trials such that different platforms can then access and present that information according to the needs of their own end users and duplication of effort is minimized.

By the end of 2018, results reporting functionality should be available. Other plans include working with the different organisations requiring trial data to harmonise requirements and help reduce the administrative burden for researchers.

The ANZCTR team acknowledge that more could be done to improve the register. The Federal Department of Health is currently undertaking a review of the ANZCTR for performance, appropriateness, value for money and the extent to which it is meeting the needs of stakeholders. The review will use the findings to develop and test options for a potential next generation Australian clinical trial registry with key stakeholders. Attendees were invited to contribute to the review of the register by sending comments to ANZCTR.

***Post Meeting Note*:** The ANZCTR review has been completed and at the time of publication of this report is currently being considered by the Commonwealth and state and territory governments prior to release and response. Of note, is that in the Federal Government announced in the 2018-19 Budget, there is an intention to develop a National Clinical Trials Front Door concept that will seek create a consolidated interoperable platform that will make it easier for investigators, sponsors and participants to engage and conduct clinical trials in Australia. Broad stakeholder engagement on this concept is expected in 2018-19. – *Update provided by Erica Kneipp, Department of Health, 6Aug18.*

8.4 Other Trial Portals

8.4.1 AustralianClinicalTrials.Gov.Au

8.4.1.1 Background and Purpose

The National Health and Medical Research Council (NHMRC) have multiple touchpoints with clinical trials. They oversee the ethics approval process, fund research projects, coordinate the National Statement, and are involved in policy initiatives around clinical trials. The NHMRC operate in this space in recognition of the fact that the evidence gained from clinical trials underpins our entire health system.

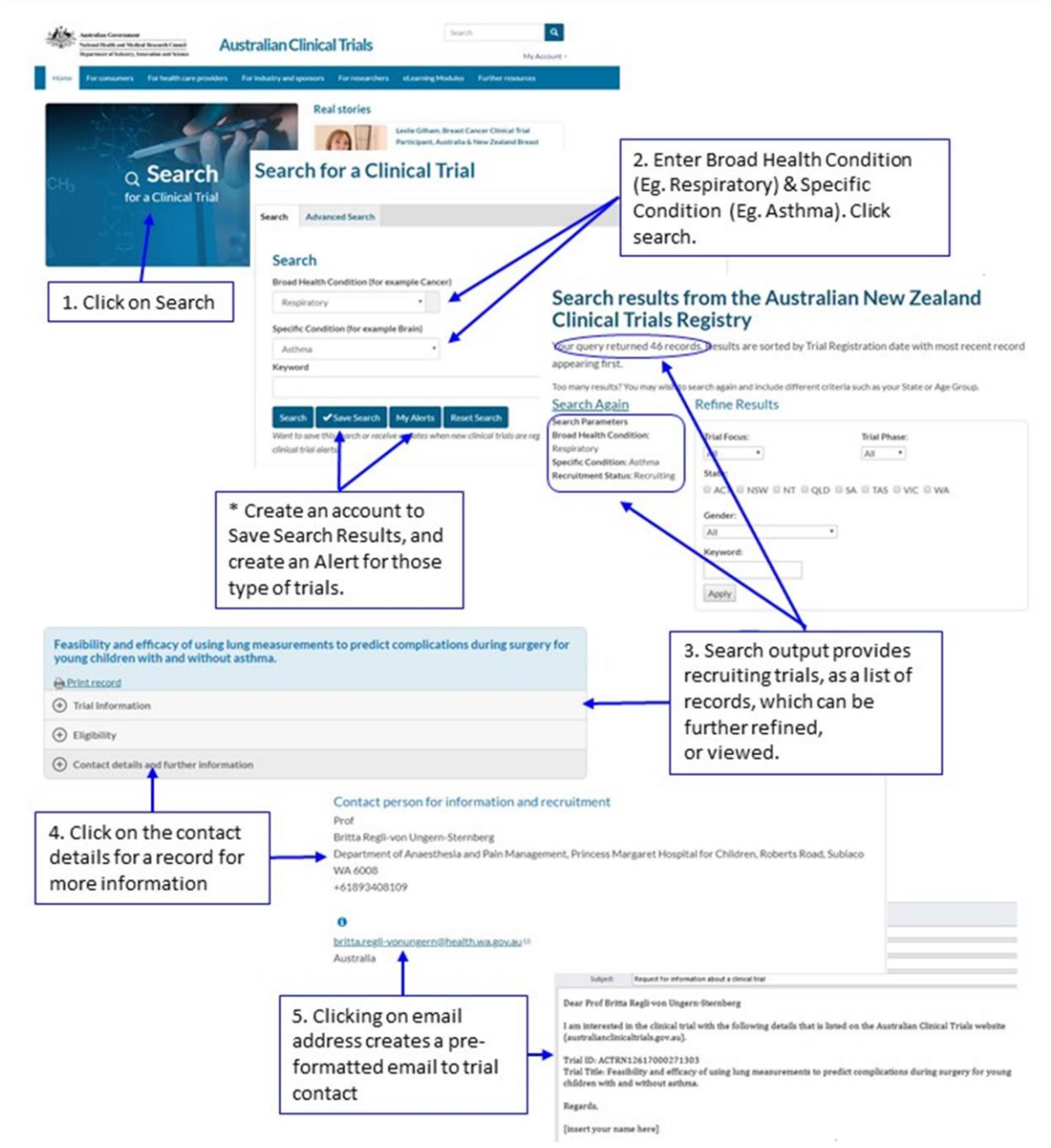
It is well recognised that one of the significant issues leading to poor trial recruitment has been the lack of access to trusted, impartial information about clinical trials. Patients and carers must be able to access this information for themselves.

NHMRC in partnership with the Department of Industry, consumers, and other key stakeholders helped develop Australian ClinicalTrials.gov.au as the user/consumer-friendly front end that enables people to learn about clinical trials, and search for clinical trials listed on the ANZCTR (including those on ClinicalTrials.gov listing an Australian site).

8.4.1.2 Functionality

To search for a trial, click on 'Search', and then enter the broad health condition and specific condition. The NHMRC note that this terminology is not very user friendly, but it is how the data can be accessed from ANZCTR. Search results are then displayed as a list, which is mobile responsive (if you are using a phone or tablet to search). If you expand the contact details, then click on the email address for the site contacts, it will bring up a preformatted email with the trial details you are requesting information about (see Box 8).

BOX 8: Example process to search for an asthma clinical trial on Australianclinicaltrials.gov.au



You can also create an account to save your search results, and receive trial alerts based on a saved search.

Importantly, the site has key impartial information about clinical trials for consumers, clinicians and researchers. It aims to empower consumers to make their own decisions and do some of the research, so they are not just relying on others for information.

There are videos with real stories from participants to help demystify the process of clinical trials, along with stories from health care providers to help their peers better understand the role of clinical trials in health. It adds a face to the researchers involved in this important work.

8.4.1.3 Next: A clinical trial awareness campaign

Now that the central website is available, a marketing campaign is set to drive traffic and help raise awareness of the role and value of clinical trials .

The idea of the campaign is to change the narrative people have about clinical trials as a negative thing for themselves or their patients. The key messages of this campaign are:

1. Clinical trials ensure the treatments and medicines that can improve the quality of our health are safe and effective for all;
2. If you participate in a clinical trial, you may be monitored more closely than those receiving standard treatments;
3. AustralianClinicalTrials.gov.au provides a one-stop information source to enable consumers and their physicians to make informed choices about clinical trials.

Given the anecdotal evidence that clinicians can be a barrier to clinical trials for multiple reasons, this group are a key audience for the campaign. Champions will be identified who can promote the value of clinical trials amongst their clinician peers, engaging them at conferences like AMA, and RACGP.

Post Meeting Note: The Hon. Greg Hunt, Federal Minister for Health, launched the Helping Our Health campaign at the ACTA Trial Awards on 16 May 2018. Branding and information is available on the AustralianClinicalTrials.gov.au website, which organisations can use through a free licensing agreement (See Box 9).

BOX 9: Helping Our Health – A Public Campaign to Raise Awareness of Clinical Trials.

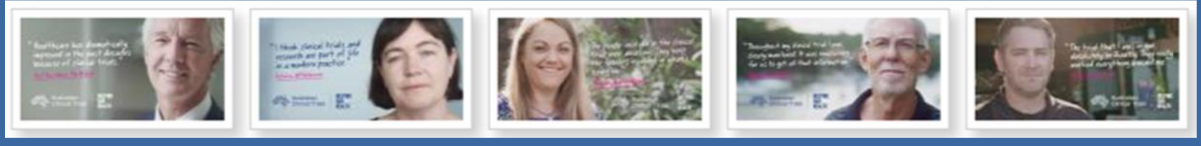
The aim of the 'Helping our Health' campaign is to raise awareness of the role and value of clinical trials. Organisations that wish to get involved in the promotion of clinical trials in Australia are encouraged to download and display the material on this page:
https://www.australianclinicaltrials.gov.au/helping-our-health

Jarryd Roughead is the official ambassador of the campaign. Through his own health scare and resulting treatment, Jarryd gained an understanding of the importance and benefits of clinical trials.

Jarryd Roughead is one of the AFL's cult heroes and has carved a place amongst the competition's elite. Captain of the Hawthorn Football Club since 2017, Jarryd's career has been in the spotlight for more than 12 years.

Jarryd Roughead | Captain of the Hawthorn Football Club

Images are available for social media:



Posters are available for printing and co-branding:

Campaign posters Size: A4 | Campaign posters Size: A4 | Campaign posters Size: A4 | Campaign posters Size: A4 | Campaign posters Size: A4

The NHMRC recognizes one of the issues, as already eluded to, is the quality of data in the registry. Stakeholders need to understand the value of the register as a recruitment tool, not just a tick-a-box exercise. It can help potential participants find your trial.

There are very few 'sticks' in Australia to make researchers register and keep their data current on the registers. The NHMRC hope that by publicising the website and attracting visitors (ie making it the place patients and carers know to look for trials), they can demonstrate the value to researchers in maintaining complete, up to date information on the register, and providing a lay summary that is easy for people to understand. It will provide a carrot to researchers to register and update their trial information.

***Post meeting note*:** As a result of the ongoing rolling review of The National Statement on Ethical Conduct in Human Research (2007) (National Statement (2007)[17]), the NHMRC released an update to the National Statement which has changed the requirement for registration of trials on a WHO registry (eg ANZCTR) prior to first recruit from being 'recommended' to 'mandatory'.

BOX 10: Prospective clinical trial registration becomes mandatory in July 2018. Update to National Statement[17], to be fully implemented by 1 January 2019.

"Section 3.1.7: For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant."

8.4.2 Victorian Cancer Trials Link

8.4.2.1 Why Another Trial Portal? What's Different?

The Victorian Cancer Trials Link (http://trials.cancervic.org.au/) is an online portal that supports Victorian patients and clinicians in their search for a clinical trial. The Victorian Cancer Trials Link was originally developed based on an identified need, from senior Victorian clinicians, for a resource that allowed Victorian cancer trial sites to provide information about the trials they are conducting, promoting referral between Victorian sites. It initially started with breast cancer trials, but in 2009 was expanded to include all other types of cancer trials with the support of the Victorian government. In 2015, a Victorian Cancer Trials Link mobile app was also introduced.

The thought then and now is that the Victorian Cancer Trials Link would provide an easy access portal for clinicians and patients to look up appropriate information about the cancer trials available in Victoria, based on some of the clinical characteristics of the patient, including their age, diagnosis and treatment history.

Data is sourced directly from Victorian cancer clinical trial sites, through Cancer Council Victoria's Cancer Trials Management Scheme. Essentially, this is a stratified funding model where Cancer Council Victoria provides trials sites in Victoria with a small amount of funding to provide them with regular trial updates which are used to inform the Victorian Cancer Trials Link. Further, this data is used for monitoring and analysis purposes. Cancer Council Victoria recently engaged consumers to assist in the redevelopment of the Victorian Cancer Trials Link, with the aim of making the online portal truly patient accessible. Both clinicians and consumer audiences were engaged through multiple mechanisms including a user survey prior and post transition, user testing interviews with consumers, and oversight in an advisory group containing senior clinician, researcher, consumer, IT, and Cancer Council representatives.

Features of the Victorian Cancer Trials Link include: include an intuitive search bar function; an advanced keyword search; simplified trial information and headings; an interactive hover glossary to help people translate some of the clinical information that remains on the website; quick access to Cancer Council Victoria's experienced cancer nurses; and a suite of resources that provide patients with general information about cancer clinical trials, prompting patients to start a conversation about trials with their doctor. Patients can also access information about Trial Connect, a peer support program for people considering participation in clinical trials

8.4.2.2 Specific Challenges

Catering to different audiences. Balancing the information needs of clinicians and patients is a challenge, especially when in clinical trials, the eligibility criteria and language used is becoming ever more complex. Trying to provide a level of information that can be used effectively by both user groups is something that the Cancer Council Victoria is constantly trying to improve.

What to do with information that is challenging to provide? Eligibility criteria is challenging, as it is something that patients and carers would like to see, but due to the increasing complexity and rapidly evolving nature of eligibility criteria, it is difficult to maintain and provide in an easy to understand format.

8.4.2.3 Is the solution scalable nationally, or to other therapeutic areas?

The Victorian Cancer Trials Link has a Victorian, national and international user base, despite only containing Victorian trials information. This suggests there is potential for it to be scaled more broadly. However, good collaboration with Victorian trial sites and dedicated funding is key to the effective delivery of this platform. This is something that would need to be considered in other jurisdictions before expansion could occur. A key feature of the Victorian Cancer Trials Link is the data comes directly from the local source, i.e the trial site. This allows us to keep local information about each trial as up to date as possible. ANZCTR is often used as a way of checking this information.

Developing and maintaining a resource that is consumer friendly with quality data is no small undertaking, and it requires investment.

9 INSPIRING CHANGE

To inspire what might be possible, a selection of other initiatives aiming to provide different or more user friendly access to clinical trial information were invited to present.

9.1 TRANSCELERATE – CLINICAL TRIALS REGISTRY OF THE FUTURE

TransCelerate (http://www.transceleratebiopharmainc.com/) is a non-profit collaboration of pharmaceutical companies established in 2012 with a mission to collaborate to identify, design and facilitate implantation of solutions to drive efficient, effective and high-quality delivery of new medicines, improving the health of people around the world.

It was identified that although 80% of people were willing to participate in clinical trials, and even more if they actually had a health condition (CISCRP[18]), health care professionals don't usually have the information that helps them talk about trials with their patients, patients don't have great tools for finding trials, and trial registry listings are generally full of jargon meant for a scientific audience.

TransCelerate sought out patient experiences around clinical trials via a survey and a patient advisory board. It found many are interested in clinical trials, think it is important to be aware of trials and are open to being informed about trials via a variety of methods, but most are still unaware of trials that might be suitable for them. The current situation means that patients are having a frustrating and exhausting experience looking for trials, something that might be good for them.

Having identified through the surveys that government funded trial registries are the most trusted source of information, TransCelerate thought about how they could influence improvements in those registries. What resulted was a vision document, set of wireframes for what a future registry could look like, and demonstration videos and an eBook to explain the concept.

On the landing page, for example, it was suggested patients be able to get started quickly finding the information they want with a simple search based on location and medical condition/keyword. Then that results should be presented in a search grid that is easy to navigate with the fields most important to patients (Figure 4).

It was felt useful to be able to compare trials, and to register yourself to save searches, save information about yourself to facilitate trial searches in the future, and register for trial alerts.

More practical and patient-useful information about clinical trials could be added, and better ways to filter the data with maps to visualize the location of appropriate trials, and contact details to reach the site coordinator.

It is acknowledged that we can't rely on one person, or organisation to create a registry like this. It will take a combination of effort from champions to implement something like this – the organisations/researchers that provide the trial data, the organisations that host the data, patients and funding agencies. Each will have to give a little for the greater good of creating an information resource that is more broadly useful to a variety of stakeholders.

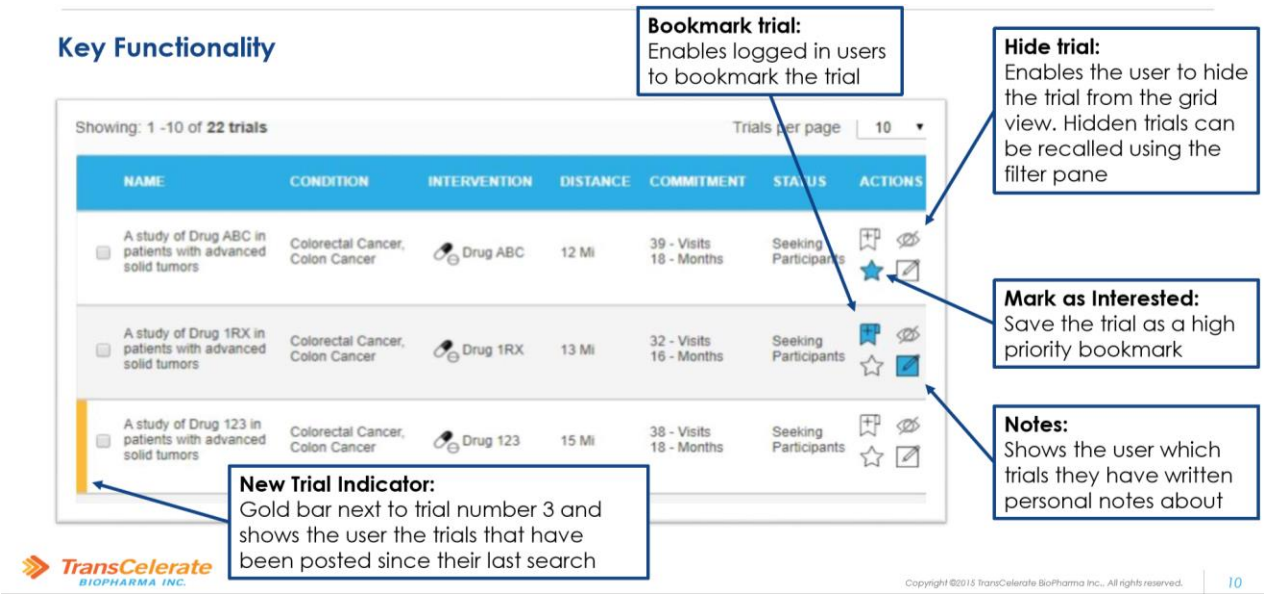


Figure 4: Proposed Search Grid – Registry of the Future

TransCelerate plans to identify the top data fields that are most important for patients, run a self-awareness survey for the industry to find out how often they update the fields that are already required, and publish how industry is doing on providing data to the registry as a call to action for making those registries as robust as possible. There is also an onus on the consumers of data to put the pressure on industry, researchers and government to provide better information.

For more detail about the clinical trial registry of the future project and related resources, visit: http://www.transceleratebiopharmainc.com/clinical-research-access-information-exchange-assets/

9.2 ClinTrial Refer

9.2.1 Why an App?

The problem: There were some 90 haematology trials occurring in NSW. But, Haematology Unit doctors didn't know where the trials were, including those within their own trial centre.

The haematology units, led by Prof Judith Trotman (Concord Hospital) and Ros Ristuccia (St George Hospital) collaborated to build a haematology trials app called ClinTrial Refer. They were told it wouldn't work because haematologists wouldn't cross refer patients, and patients wouldn't travel. When they developed the app, they created metrics to test those assumptions.

The initial audience for the app were the haematology specialists. They created a simple interface with 4 search fields – Disease, Location, Trial Status and Sponsor. The Disease listing is devised by the specialists themselves, rather than using the WHO criteria (as used by ANZCTR), which is not language clinicians or patients want to use to describe the diseases.

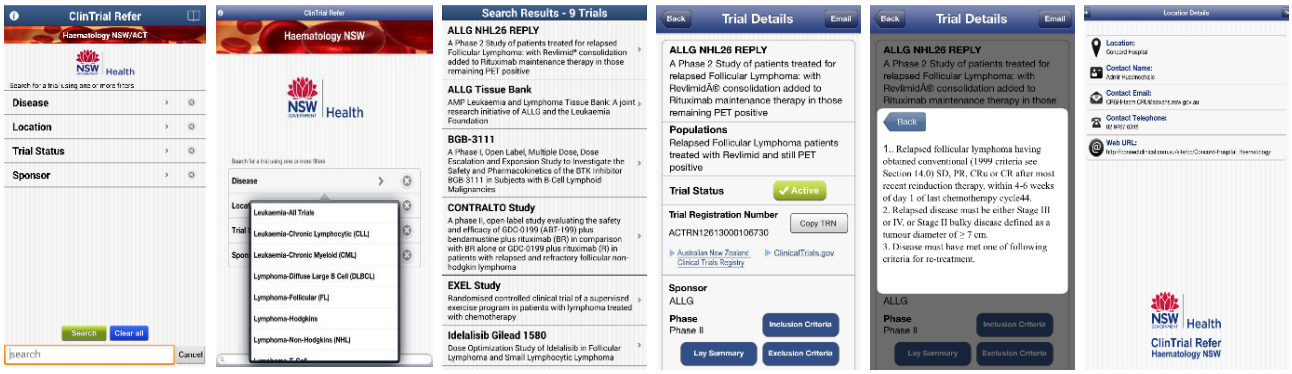


Figure 5: Sample ClinTrial Refer Screens

Data about the status of the trial, trial site location and contact, is entered directly from the trial site, rather than from the sponsor of the trial, which has led to greater currency of information. The data entered by a site is cross-checked for quality against the ANZCTR (as they have the quality checks). ClinTrial Refer then creates value by adding the extra fields that doctors and patients want to know.

There has been a deliberate decision to list the trial unit managers as the primary contact for any trial at a site. This single contact has worked effectively to build relationships with doctors referring patients between sites (which had not really happened before) as they get used to dealing with the one person at a site for questions about trials.

9.2.2 Measuring success

The Haematology ClinTrial Refer app resulted in a 64% increase in haematology trial recruitment between 2012-16, and a 60% increase in clinical trial full-time equivalent staff in NSW haematology clinical trial units. The app has been rolled out for a number of other disciplines which have seen similar increases in recruitment post implementation of the app.

Over time, the active cross-referral has enabled sponsors to open fewer sites, reducing sponsor cost and effort. While this was originally thought a problem, the increased recruitment has still meant there is plenty of work for all sites, and has enabled sites to be more focused on the smaller diversity of trials they have open.

The ease of use and speed with which information can be accessed has helped encourage doctors to use the app. The average time doctors spend on the app is 60sec, compared to trying to search everything on the ANZCTR. It means that doctors are able to quickly identify trials, their locations and site contact details while a patient is sitting in front of them, increasing the access of patients to trials.

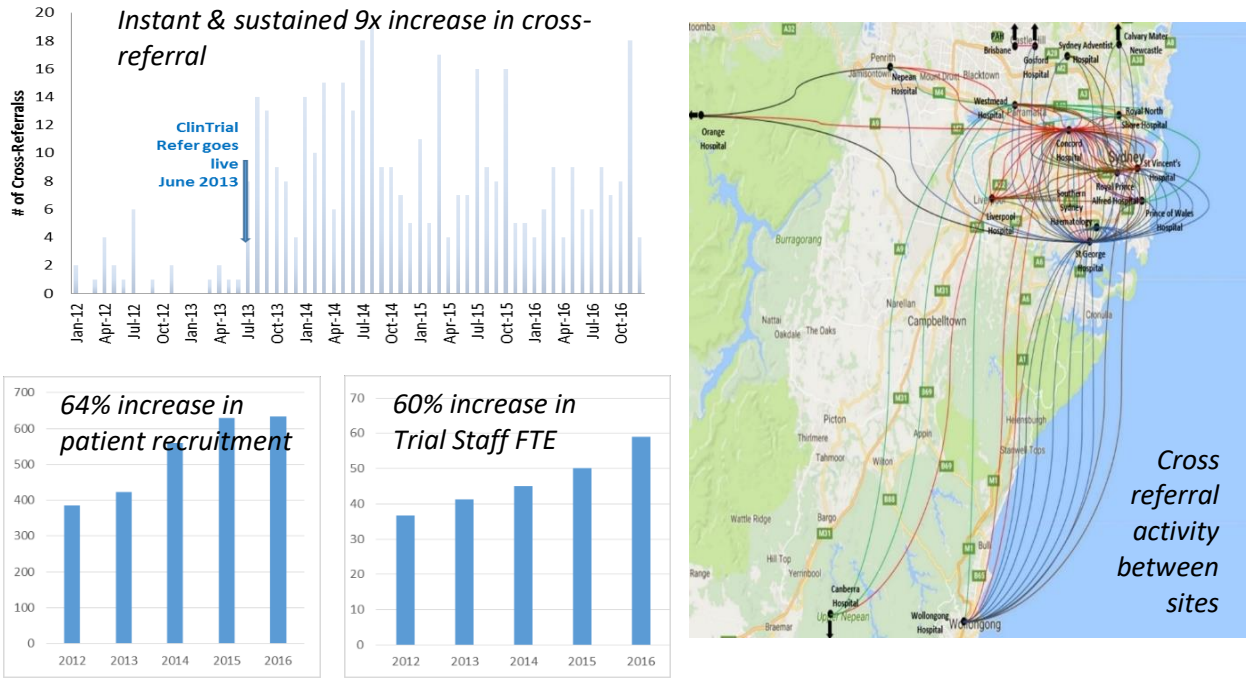


Figure 6: Impact of ClinTrial Refer Haematology app 2012-2016

9.2.3 The future

The ClinTrial Refer team were awarded MTPConnect project funding to expand their app nationally. However, their plan is still to provide individual apps serving the needs of different groups as they believe that has contributed to the app's success. All the apps are slightly different and tailored to the needs of a specific group. They haven't built a single solution and expected it to fit all people. It's about catering for a network of people with like interests, and they have found that the faster way to build connections and trust.

There are now 15 apps (and growing) covering different disease areas or collaborations, spanning either local, national or international geographies. The ClinTrial Refer apps are free to download from the Apple Store and Google Play.

Other networks and organisations are encouraged to contact ClinTrial Refer (https://www.clintrial.org.au/) to discuss use of the template for their trials.

***Post Meeting Note*:** ClinTrial Refer will launch nationally at the Australian Clinical Trials Alliance (ACTA) SUMMIT in November. Covering all disciplines, and all areas, and linked to the ANZCTR as a value add-on, this will be a national approach to finding clinical trials in Australia. The app has been endorsed by the Federal Health Minister Greg Hunt. Both Academic Health Research Translation Centres (AHRTC's) - Sydney Health Partners, and SPHERE - have committed to using ClinTrial Refer and others AHRTC's are considering.

9.3 TIM CHURCHES – G2D2T: GENES TO DRUGS TO TRIALS

9.3.1 Health Hack: The Problem Pitched

A Health Hack competition was run at the Garvan Institute for Medical Research in 2017. These intensive 24hour events are run by Health Hack around the country to bring researchers, students and healthcare professionals together to pitch health problems looking for a computer science or informatics solution. Together with other scientists, software developers, educators, engineers and designers, the teams work together to create innovative solutions for these problems.

Tim's team was attracted by the problem pitched by Dr Mark Cowley and Dr John Grady, geneticists working with the Garvan Institute and St Vincent's Hospital: How to match patients who have had their tumor and whole genome sequenced with relevant clinical trials.

Currently, Drs Cowley and Grady search for trials by hand once the genome information is known.

There are existing solutions such as IBM Watson (which is costly) and molecularmatch.com in the US, but no effective solution for Australian clinical trials.

9.3.2 The Competition Scope

The scope of the project for the purpose of Health Hack was to extract information about each cancer clinical trial from ANZCTR and translate important information (eg drug, gene, cancer type) into a machine readable form using text mining or natural language processing, ideally in a way which can be constantly kept up to date. That database should then be searchable so that once they have identified gene variants for a patient, those variants can be searched via the interface.

Individual clinical trial records may have incomplete information, so additional details like which gene a given drug targets may need to be obtained from drugbank.ca.

9.3.3 The proposed solution

The team planned to develop a web application, written in a mixture of R and Python (both free, open source programing languages and data science environments) to create an open source solution when ready. Ideally it would download drugbank.ca data, ANZCTR data, and other gene annotation databases to support the trial search.

In the period of the 24hour event, drugbank.ca data was used to train a model to recognize drug names in all relevant ANZCTR fields and annotate them (which is needed for machine learning), and a basic search interface created.

The idea was that post event, the model would be used to train a more sophisticated machine learning model to tag all drug names in the ANZCTR and provide them with a unique drugbank.ca ID number. The drugbank.ca information could then be leveraged to link to the genetic information, from which links to various genetic databases could be made.

The search interface would then be designed to enable a user to search for trial records mentioning drug names, trial records that mention drugs that target candidate gene symbols, variants or sequences, and additional filtering for age, sex, location, trial status, etc.

As the project currently stands, there is a basic search interface, and they are still validating the machine learning model, but it looks promising.

9.3.4 What's next?

The app needs to be finished, a validation study of the natural language processing aspects completed, field tests done and the code published as open source. Small grants and philanthropic funding are currently being sourced to complete the (unfunded) project.

The app may need to be submitted at the TGA as a class 1 application, because it is recommending a treatment.

Ideally, in the future, rather than someone manually entering data into a search field, patients who have been sequenced should be able to subscribe to a service in the cloud and be sent information about suitable trials as they become available.

More data is needed to better train the model, and so it will need to be extended with ClinicalTrials.gov data. It would also make sense to work with the ANZCTR to make improvements centrally rather than in the app and look at other ways to leverage the latest deep learning methods and natural language processing to add value to ANZCTR records.

10 POTENTIAL SOLUTIONS?

As a result of the presentations, panel discussion and group work, in the interests of time, the facilitator identified four themes to concentrate group discussion about solutions:

1. How to get good data into ANZCTR to begin with.
2. Plain language vs clinical language
3. Database solutions and who owns the data
4. Getting doctors on board

Each table was assigned one theme to own and given about 20mins to brainstorm possible solutions to address that theme. The solutions were then presented back to the wider group and discussed.

10.1 THEME 1: HOW TO GET GOOD DATA INTO ANZCTR

Solutions proposed included:

- Mandating the completion of fields on ANZCTR that are missing from ClinicalTrials.gov records, to ensure ANZCTR is a comprehensive dataset for Australian patients.
- Ensuring there are appropriate triggers in place to get people to update the data once registration has been completed.
- Educating commercial and academic sponsors to complete and update ANZCTR in real time, to facilitate patient access to comprehensive information about trials where they are looking ie the AustralianClinicalTrials.gov.au portal.

In thinking through potential processes, an attendee offered:

"In global pharma, there are centralised groups entering data into ClinicalTrials.gov. It would be helpful if they could notify at the APAC level that a ClinicalTrials.gov record had been created, such that locally companies can then update the ANZCTR record for completeness. You would however still need to evaluate the impact (cost and resources) to implement that process change."

- Suggesting HRECs require evidence of an updated clinical trial registration record, including the addition of patient recruitment data into the register, when researchers submit their annual report to HRECs. Alternatively, HRECs could use the ANZCTR as their source for annual trial updates and require the ANZCTR to be updated at least each 12 months for HREC to access for this purpose (and to maintain ethics approval).

10.2 THEME 2: PLAIN LANGUAGE VS CLINICAL LANGUAGE

> *Giving people information in a way that is readily accessible and understandable empowers them to be able to make decisions about their health."*
>
> *- Samantha Miles, NHMRC*

The solutions proposed included:

- Funding clinical trial networks, etc to have groups of people that are skilled and experienced in preparing lay (plain English) summaries. Theoretically, the lay summaries from trial Patient Information Sheets could be used, however often these are still not patient-friendly enough.

- Considering whether there is a role for psychologists and sociologists in helping find the appropriate plain language, or marketers who are good at breaking down complex information and presenting it in a simple way.

  For Noting: Producing good and accurate lay summaries of (potentially complex) clinical trial protocols is not simple. Lay summaries must be factual, not over-promise and not be a hard sell. Good governance processes need to be in place by registries and/or website/app providers to ensure summaries are an acceptable quality and accurately reflect the trial in lay terms, as failure to do so may well undermine public confidence in the clinical trial process. It may also be that the lay summary should undergo HREC approval if considered a part of a trial recruitment strategy

  Post meeting note: A trial sponsor would never wish to be seen to be providing information to trial participants that has not received appropriate ethics review/approval and put at risk data acceptability for publishing purposes or global regulatory authorities.

  Given the increased use of information provided on clinical trial registries by patients and digital platforms seeking to improve trial recruitment, it would be timely and extremely useful for trial sponsors, sites, ethics committees and companies providing trial recruitment services to get clarity on when lay summaries require ethical approval.

  To this end, the NHMRC was contacted post meeting to provide advice around ethical review requirements for lay summaries (See Box 11).

- Ensuring there are quality system standards in place for data managers, and that they are audited to those standards. One attendee noted that in some cases, the people employed in data manager roles within health systems may not be working in that capacity. Auditing those roles could assist in improving quality.

Box 11: NHMRC Advice re Lay Summaries and HREC review

Do the lay summaries that are entered onto the ANZCTR require approval by an HREC?

To our knowledge, there is no formal guidance in Australia that addresses the question of whether information that is part of registration on ANZCTR (or any other clinical trial register) should be considered to be research project-related material requiring HREC approval. We are also unaware of any trend on the part of HRECs or researchers to consider this to be a requirement. However, we would agree that an argument could be made that this information does not relate to the ethical acceptability of the research, nor is it directly related to recruitment into research, and, therefore, it does not require HREC approval.

If someone uses exactly the same lay summary that is on the clinical trial registry (ie therefore in the public domain already) on other materials which could be seen to be 'advertising' the trial, does it then require HREC approval?

The National Statement (updated 2018) at 5.2.25 states that

> All documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the review body.

In addition, paragraph 3.1.20 states that

> For many research projects, researchers should provide reviewers with proposed recruitment materials (eg notices, flyers, advertisements, and social media posts) prior to use, including those materials that are developed subsequent to the initial review of the research proposal. However, for some research designs or where recruitment material needs to be ad lib, adapted or tailored to the context (such as some social media, radio or other oral communication) a description of the strategy and broad messages is sufficient.

Thus, the fact that material used directly for recruitment, such as an advertising leaflet, includes the lay summary that was provided to a registry at the time of registration of the research project, does not mean that the lay summary, per se, requires review – it is the leaflet that requires review because it is advertising material. If that same lay summary is not used in the leaflet, then it wouldn't require review. To say that the lay summary requires review because it might, at some point, be used in advertising material is not supported by the National Statement or common practice.

So, the information on the register can be used for other purposes without ethics approval unless the 'other purpose' is direct advertising for recruitment purposes – at which time the advertising material is what requires review.

We would also advise that, while ANZCTR and other trial registries 'support' recruitment via information feeds into websites and portals that are oriented toward recruitment, this does not convert the content of the registries into advertising material.

Source: Personal Communication August 2018 between Research4Me and NHMRC, 10Aug2018.

10.3 THEME 3: DATABASE SOLUTIONS AND WHO OWNS THE DATA.

The discussion and solutions proposed included:

- It is the right choice for the government to own the ANZCTR. Government is a trusted source of information that carries less stigma than if a private organisation owned the data. It was suggested that having a national ethics committee could easily lend itself to compiling a national database of trials. Recognising that is unlikely, the next best alternative was for the National Statement to make trial registration mandatory (which has happened as of July 2018).

- Another patient-led suggestion was the creation of a national clinical trials hotline (like NSW's Health Direct hotline), which people could call to get help from someone experienced at search trial databases to find potentially suitable trials. Not all patients have access to technology or are computer literate, so having a hotline they could speak to could be useful.

  For noting: This was a hotly debated suggestion which sought to balance the desire of patients and carers for information against a concern about how clinicians might respond. It is important not to create a solution that could have unintended consequences. Having said that, most had an appetite to explore this suggestion further.

  Attendees who have fielded calls from patients looking for trials stressed the importance of properly training hotline staff to deal with many different types of people looking for trials, some who can be desperate, and ensuring they know where to direct people showing signs of distress (suicide prevention).

  Acknowledging the role of local community in health, the suggestion was made that local government authorities may be worth investigating as a possible support infrastructure for information about clinical trials. For example, the hotline could be a way to start to build a community network, where a search is done, information is mailed to patients and carers and they are put in touch with local contacts for further discussion (such as GPs and pharmacists).

  A missing piece of information is the extent to which hotlines for consumer and disease related organisations are asked about clinical trials, or if these hotlines proactively raise the possibility of clinical trials with callers.

  Post Meeting Note: The Victorian Cancer Council advised their 13 11 20 Cancer Nurses hotline does receive queries about clinical trials and these are appropriately addressed. The Cancer Council Victoria for instance provides a Trial Connect peer support program where people can talk to another person that has been in a clinical trial.

- Fees paid for ethical review. The suggestion was raised that greater transparency about how HREC application fees were used may lend itself to greater support for the registry. If for example, it was known that a portion of the HREC application fee was paid to the registry to help maintain its integrity and auditing of the registry, there may be commercial support for a small fee increase to cover that cost (eg $50-100).

10.4 THEME 4: HOW TO GET CLINICIANS ON BOARD

The proposed solutions included both top-down, and bottom-up approaches:

- Bringing the medical colleges on board to make it mandatory to maintain registrations for clinicians to earn CPD points for learning about clinical research, completing Good Clinical Practice (GCP) training or getting involved in research. It was felt this approach may help change culture and embed clinical research into healthcare.

- Including Key Performance Indicators (KPIs) for CEOs of local health districts/systems around clinical trial activity (as NSW is doing). It was felt this would help encourage CEOs to encourage their doctors to consider/get involved in clinical trials.

- Educating trainee doctors with information about clinical trials.

- Understanding better why most clinicians don't want to be involved in clinical trials. Is it because of the cumbersome paperwork involved in trials and could that be made less difficult?

  For Noting: It was recognized that not all clinicians want to, nor should they have to, participate in clinical trials.

- Creating a Medical Benefits Scheme (MBS) Item reimbursing clinicians for the time they spend discussing clinical trials with a patient.

> *"Clinical trials are not for everyone. But it is important clinicians are aware of the value of clinical trials for their patients, and why they might want to refer their patients into clinical trials. A doctor doesn't need to be running clinical trials to talk about them with their patients."*
>
> *- Mitch Kirkman, Novartis*

11 SUMMARY

There was a theme that consistently appeared throughout the Think Tank presentations: Patients struggle to find clinical trials and databases struggle to get quality, up-to-date information. We need to make it easier to connect patients and trials.

Key messages included:

- There is a role for patients and carers in lobbying for the information they want access to.
- Trial registration must become mandatory in Australia, and incentives/sanctions may be needed to drive compliance in registering and keeping trial records updated.
- Awareness needs to be increased with global trial sponsors of the existence of ANZCTR, and the case made to use it to help Australian patients find their trials more easily.
- Resources are necessary to maintain and update register information.
- There is a need for harmonization and coordination amongst sponsors, researchers and agencies to minimise duplication of effort by researchers and confusion for patients across different information sources. Having said that, there was no clear answer on whether a centralised approach is the right way forward for different therapeutic areas.
- It is necessary to measure the success of initiatives aimed at connecting patients with trials, to help make the business case that implementing those initiatives is justified.

The Think Tank demonstrated that bringing together a diversity of stakeholders can lead to new insights, communication channels, collaborations and potential solutions to otherwise wicked problems.

- Samantha Miles (NHMRC, Samantha.Miles@nhmrc.gov.au) and Lisa Askie (ANZCTR, lisa.askie@ctc.usyd.edu.au) publicly welcomed follow-up from anyone with input on AustralianClinicalTrials.gov.au and ANZCTR respectively.
- SPHERE invited Sydney Health Partners to explore how the ideas discussed might fit with what they are each doing locally and at the national level through the Australian Health Research Alliance (AHRA).
- Mitch Kirkman, on behalf of the Medicines Australia/Medical Technology Association of Australia (MA/MTAA) Research and Development Taskforce (RDTF), publicly invited an approach from anyone with ideas or initiatives to help increase recruitment in clinical trials. Please contact:
  Lauren Macnaughton, Clinical Operations Manager, Australia, New Zealand & India
  Eli Lilly Australia Pty Ltd/ Eli Lilly and Company (NZ) Limited
  P: +61 (0) 2 9325 4521 | E: laurenm@lilly.com
- Attendees expressed an interest in being further involved in the ANZCTR review and what might come out of that.

As the host of the meeting, Research4Me believe the meeting's success should not be judged by the insights, ideas and collaboration on the day, but on the action that occurs as a result. This report is the first step towards advocating for that action.

12 RECOMMENDATIONS

Research4Me recommends the 5 following actions (in no particular order) as the foundations for improving public access to more comprehensive, user-friendly, understandable, relevant up-to-date and searchable information about clinical trials:

1. **That a financially supported and resourced working group/collaboration is formed** (if not already in existence) inclusive of patients and carers and their representative health/disease groups, commercial and non-commercial sponsors, trial registers and portals and government agencies, focused on coordinating effort and ideating, testing, measuring and advocating for solutions that help improve the access of patients to appropriate trial information, and speed up trial recruitment.

2. **That ANZCTR is supported with the funding and resources needed** to ensure its integrity as the primary government-owned database of clinical trial information in Australia, one that is complete, up-to-date, user-friendly and has exceptional search capabilities.

3. **That the mandatory requirement for prospective clinical trial registration is supported** by audit, incentives and/or sanctions to drive compliance and maintain up-to-date clinical trial registry records.

4. **That greater effort is made to coordinate databases and reduce duplication of effort for researchers.** Providing a single point of data entry for multiple agencies such as the TGA, ANZCTR, ethical review, grant systems would reduce trial site workload and frustration, and make it easier to get a consistent, quality, current repository of clinical trial information.

5. **That a Clinical Trials Hotline is pilotted** to help answer the public's questions about clinical trials, and provide them with assistance in finding clinical trials.

Further to these recommendations, sponsors and trial websites are asked to reflect upon the following:

- Patients and carers are looking for clinical trials, and in Australia, ANZCTR is a primary source of information for many trial websites. Maintaining complete and current trial records on ANZCTR, with lay language summaries, potentially increases visibility of your trials, and hence supports your trial recruitment efforts in Australia.
- Databases and websites listing clinical trials need to include more patient-relevant information, presented in plain English, that is easily searchable, to improve access and understanding of the trials available for those looking. Websites should have user-friendly interfaces, use comprehensive search algorithms, and be transparent about the default search parameters and completeness of the trial dataset being searched. This will help reduce user frustration and confusion at search results obtained within, and from different, websites.

Research4Me is actively looking at how it can help progress the recommendations and ideas discussed. We welcome collaboration with like-minded partners seeking to address the problems of patients and carers around clinical trials, as one path to better, faster, more relevant research and treatments in the future.

13 REFERENCES

For reference, any websites listed were last accessed 31 Jul 2018.

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18. CISCRP 2015 Public and Patient Perceptions and Insights Study http://0393122.netsolhost.com/programs-events/research-and-studies/perceptions-and-insights/

14 Other Meeting Images

15 APPENDICES

The following appendices are included:

1. Speaker Biographies
2. Event Sponsor Profiles
3. Agenda with Presentation/Video links
4. Attendees

15.1 SPEAKER BIOGRAPHIES

Mrs. Lisa Briggs

Lisa Briggs is first and foremost a wife and mother of 2 young children, Osteopath and Exercise Physiologist. She is currently living with Stage IV Lung cancer and her first line of treatment was via a clinical trial for 3yrs which literally saved her life. As a result of this extra time she's been given, Lisa has become a passionate lung cancer advocate, currently on various committees including as co-chair of the Lung Cancer Patient Advisory Group. She hopes that one day, lung cancer patients can look forwards to a much brighter future than those currently diagnosed face. Collaborating with Research4me is only one of many steps Lisa hopes to take towards achieving her goal and paving the way for others in the future.

Dr. Janelle Bowden

Janelle is a scientist by training holding a Bachelor in Biotechnology (Honours) degree, and PhD in Immunology. She has worked in and around clinical trials in Australia and overseas for pharma, CRO's, hospitals and her own enterprises. The thought that a single person might die or live life without quality just because better treatments are delayed by slow clinical trials or people are unaware or misinformed about them has made her a passionate advocate for improving operational efficiency and patient/carer engagement in clinical research. Janelle founded Research4Me in 2017 as a social enterprise aiming to bridge the gap between the community and medical researchers, enabling connection and engagement in order to improve access to, as well as the experience, speed and relevance of health and medical research, especially clinical trials.

Ms. Sara Wiedenhaefer

With a career purely at SAAS companies, Sara has a proven background in customer acquisition, branding and integration partnerships across various industries targeting SMEs in global markets. She is passionate about helping businesses perfect their customer experience and grow their companies. She also greatly enjoys anything colour coded.

Ms. Samantha Miles	Samantha has worked in Clinical Trials at NHMRC for the last 4 years. She has been developing and implementing policies that help patient recruitment into trials.
Mr. Adam Johnston	Adam Johnston is a solicitor, holding a Masters in Law from the University of New England, Armidale, and a Graduate Diploma from the Australian Institute of Company Directors. During his studies, he was a Senate Intern, and a delegate to both the 1998 Constitutional Convention on a Republic and the 2001 Corowa People's Conference. He is a former long-term Member of the Government Solicitors Committee of the Law Society of NSW and has worked in various complaint handling roles for the NSW Ombudsman and the Energy and Water Ombudsman NSW (EWON). He serves on a number of advisory and governance committees of the Northern Sydney Local Health District, is a member of Health Consumers NSW, a Consumer Advisor to the Clinical Excellence Commission's Antimicrobial Stewardship Expert Advisory Committee, a member of the Consumer Advisory Council of the Sydney North Primary Health Network and a Community Member of the NSW Ministry of Health Clinical Ethics Advisory Panel. He is currently a PhD (Law) Student at Macquarie University. https://law.mq.edu.au/current_students/higher_degree_research_students/adam_johnston/
Mr. Adrian Eisler	Adrian is someone who has lived long term with HIV. Having survived a terminal AIDS diagnosis in 1995, he has experienced many ups and downs as HIV treatments have continued to evolve. This journey has also involved a number of clinical trials. But as you will hear, Adrian's journey – as a person living with HIV – has not yet finished!
Mrs. Marilyn Nelson	Marilyn Nelson is a cancer patient – she has lung cancer. Her personal experience with cancer has been over nearly 5 years, involving multiple types of treatment. The last 2.5 years have involved treatment via a clinical trial. Marilyn has become a patient-advocate, though the health world seems to call that being a "consumer", but dislikes that description as for most people "consumer" gives an immediate mental image of someone buying groceries or electronic gadgets. Marilyn set up an online support group for people with the same type of lung cancer she has, to connect people to the most relevant information, resources and to connect with each other for support, because most lung cancer patients struggle to find good information and usually feel quite isolated.

Prof. Lisa Askie

Professor Askie leads a team at the NHMRC Clinical Trials Centre, University of Sydney, which manages the Australian New Zealand Clinical Trials Registry, undertakes Health Technology Assessments for the Australian Federal Government, hosts two Cochrane Collaboration entities (Breast Cancer Review Group, Prospective Meta-analysis Methods Group) and has an extensive test evaluation research program. Lisa's clinical background is in perinatal medicine and she has worked in healthcare systems in Asia, Australia, UK and USA. She has Masters and Doctoral qualifications in epidemiology from Sydney Medical School, is a Senior Principal Research Fellow at the University of Sydney and has held an NHMRC Postgraduate Scholarship, a Sidney Sax Postdoctoral Fellowship, a Career Development Fellowship and currently, a Translating Research Into Practice (TRIP) Fellowship.

Prof Askie has a long-standing interest in the conduct and methodology of clinical trials and systematic reviews, especially regarding increasing research transparency and reducing waste. She has been involved with the Cochrane Collaboration since 1996 as a systematic review author and trainer. Lisa is the co-convenor of the Cochrane Prospective Meta-analysis Methods Group and member of the Cochrane Methods Editorial Board. During her postdoctoral fellowship in Oxford, Prof Askie undertook a meta-analysis using individual participant data from over 38,000 women. She and her team are currently involved in ten international individual participant data and prospective meta-analysis collaborations. Prof Askie has published over 80 scientific papers and is a member of various academic advisory boards.

Ms. Anita van der Meer

Anita is the Clinical Research Manager for Medtronic Cardiac Rhythm and Heart Failure Therapies in Australia and New Zealand. She has worked across the medical device and pharmaceutical industry in cardiovascular development for more than 15 years. She loves the complexities of device R&D and engaging with the many stakeholders involved in device development pathway. Anita supports patient advocacy for access to clinical trials and therapy innovation driven by pateint benefit.

Ms. Christie Allan

Christie has vast public health research, health promotion and advocacy experience in her personal and professional life. Having studied a Bachelor of Health Science, in 2016, Christie completed an Honour's thesis exploring the primary care engagement adolescents and young adults have with a general practitioner, during and beyond a diagnosis of cancer. She is also the past co-chair of the Victorian and Tasmanian Youth Cancer Advisory Board (YCAB); as a member and leader of the Board, Christie has been involved in the design of youth friendly spaces at major oncology centres, has advised on curriculum development and delivery in health professional education, and has collaborated on a series of patient information resources for young patients and their carers.

Christie's commitment toward bettering the lives of people affected by cancer further extends to her current role, as Program Coordinator - Clinical Trials, at Cancer Council Victoria, where she is responsible for the delivery of programs, including the Victorian Cancer Trials Link, that aim to improve patient access to cancer clinical trials and build the capacity of health services delivering cancer treatments through clinical trials research.

Mrs. Lauren Macnaughton	Lauren manages the Clinical Operations Team at Eli Lilly Australia. They implement clinical trials across a range of therapeutic areas at sites in Australia and New Zealand. A key focus area for the team is supporting our sites to find patients eligible for clinical trials. Eli Lilly has created a clinical trial's landing page with information for patients and their caregivers to provide information about clinical trials in general, and to help them find trials that may be appropriate for them to be a part of. Work is ongoing to make the page more applicable to patients outside the USA.
Mrs. Narelle Williams	Narelle Williams has a background as a Registered Nurse and moved into public health and clinical trials research in 2006. Narelle commenced her role as Project Officer at Australia and New Zealand Melanoma Trials Group (ANZMTG) in 2016 and is responsible for managing a portfolio of large multicentre, international, investigator-initiated clinical trials. Narelle has now moved into a senior role within the group and supports the current portfolio of trials and the development of high quality new melanoma and non-melanoma skin cancer trials.
Mrs. Christine Crandall	TransCelerate Clinical Research Access Workstream Lead - This workstream seeks to provide a better interface into the information about clinical research and trial options by facilitating a simpler, user-friendly clinical trial information search/navigation on clinical trial registries, providing more meaningful information exchanges between clinical researchers and trial participants and engaging and educating the public with respect to clinical trials as a care option.
Mr. T.J. Sharpe	T.J. Sharpe is a Stage IV melanoma patient who shares his journey through cancer in the Patient #1 blog. He was diagnosed in August 2012 with melanoma tumours in multiple organs, four weeks after his son was born, undergoing six surgeries and four immunotherapy treatments over two clinical trials. He is a writer, keynote speaker, and consultant to the biopharma/clinical research industries, bringing an educated patient voice as a true stakeholder in healthcare and drug development.
Mrs. Roslyn Ristuccia	Roslyn Ristuccia is a research manager who is part of a network of trial units that developed an app called ClinTrial Refer. This app enables doctors to see all trials available, and encourages them to cross-refer patients to get better access to trials.
Dr. Tim Churches	Tim Churches is a Research Fellow in Health Data Science at the Ingham Institute for Applied Medical Research at Liverpool Hospital, and at the Centre for Big Data Research in Health at UNSW. Previously he was an epidemiologist, a public health informatician, an occupational health physician and a GP. He recently led a team in the HealthHack 2017 Sydney event at the Garvin Institute, winning 2nd place overall and the Data Science medal for a prototype app that identifies drug names in clinical trials registration data and annotates the drugs with relevant gene symbols and target genomic sequence information, to permit faster and more complete trial-to-patient matching for patients who have undergone whole genome sequencing.

15.2 Event Sponsor Profiles

15.2.1 Host: Research4Me

Research4Me is a social enterprise aiming to break down the barriers between the community and researchers so as to improve awareness, participation and partnership in health and medical research.

We advocate for and empower patients, carers and the public with information, peer connection and opportunities to get involved in medical research and clinical trials.

We provide services to support researchers and industry to more easily connect and engage with patients, carers and the public as volunteers and partners in research, thereby helping improve the relevance and dissemination of their research, study recruitment and retention, and the participant experience.

Together, we can improve healthcare faster, and deliver outcomes that matter to patients and their families.

For more information, please visit: https://research4.me/

15.2.2 Engagement Champion: SPHERE

The Sydney Partnership for Health, Education, Research and Enterprise (SPHERE) is a partnership of 14 organisations including health services, universities and medical research organisations, established to deliver health improvements to the populations of NSW South East and South West.

SPHERE is an academic health science partnership accredited by the National Health and Medical Research Council as an Advanced Health Research and Translation Centre.

SPHERE aims to mobilise, drive and accelerate research translation towards improving healthcare outcomes and better value care. The support and facilitation of clinical trials, including fostering clinician, patient and public involvement in clinical research, is a priority strategic focus for SPHERE.

For more information, please visit: http://www.thesphere.com.au/

15.2.3 Morning Tea Sponsor: Trial Docs

TrialDocs is an Australian owned company, aligned with Sites, Sponsors and CROs with products and services to streamline clinical trials. Supporting with document management and site payments products with complementary services for these.

For more information, please visit: http://www.trialdocs.com.au

15.2.4 Afternoon Tea Sponsor: Lung Foundation Australia

Lung Foundation Australia is the only national charity dedicated to supporting anyone with a lung disease. We are a national first point-of-call for patients, their families, carers, health professionals and the general community.

We ensure lung health is a priority for all in Australia by:

- Promoting the importance of lung health
- Promoting early diagnosis of lung disease
- Supporting those with lung disease, their families and carers
- Promoting equitable access to evidence-based care
- Funding quality research

For more information, please visit: https://lungfoundation.com.au/

15.3 AGENDA

Think Tank: Searching for Clinical Trials - What Patients Want

11 April 2018 | Cliftons C-Suite, Level 3, 10 Spring St, Sydney

Time	Agenda Item	Led by:
9.30	Introduction: Welcome & Why	Lisa Briggs (online)
	Introduction: Scope, and Objectives of meeting	Janelle Bowden
9.50	Introduction to Design Thinking Process	Sara Wiedenhaefer
10.00	Consumer panel – exploring the issues of patients and their families in looking for and getting into clinical trials.	Marilyn Nelson (online) Adam Johnston Adrian Eisler
10.45	ANZCTR – The framework, challenges and immediate future	Prof Lisa Askie
11.00-11.10	Morning tea break	
11.10	Trial Info Providers Panel – The challenges and possibilities for providing information on trials	Lauren McNaughton, Eli Lilly Anita Van Der Meer, Medtronic Narelle Williams, ANZ Melanoma Trials Group Christie Allan, Cancer Council Victoria
11.45	Group Discussion – Empathy: Identifying Issues	Sara Wiedenhaefer
12.20	TransCelerate: Clinical Trial Registry of the Future	Christine Crandall, GSK + T.J. Sharpe (US Videolink)
12.45-1.30	Lunch	
1.30	ClinTrial Refer	Ros Ristuccio
1.45	Health Hack 2017 solution	Tim Churches
2.00	Group Discussion: Common Themes Identified	Sara Wiedenhaefer
2.20	Group feedback	
2.40-2.55	Afternoon tea break	
2.55	Current context and the months ahead for AustralianClinicalTrials.gov.au	Samantha Miles, NHMRC
3.10	Group Discussion & Feedback: Solutions	Sara Wiedenhaefer
3.50	Closing remarks & Next Steps	Janelle Bowden
4	Close	

For Noting: Report & all Speaker presentations are available at: https://Research4.Me/ThinkTank-11Apr18/

15.4 ATTENDEES

The following summarises the background of attendees. No-shows are excluded (8 online and 1 in person).

Type of Attendee	No.
Consumer - In Person	5
Consumer - Online	2
Professional Interest - Attend in Person	17
Professional Interest - Online	11
Speaker/Panellist – Online and In Person	16
Total Registered	**51**

Type of attendance	No.
In person	33
online	18
Total Registered	**51**

Type of Organisation working for/affiliated with	No.
AHRTC	2
Facilitator	1
Government	1
Hospital/Specialist Practice/Primary Health	2
Individual	9
Non-profit service provider	2
Non-profit representing health consumers and/or a specific health issue	4
Other	2
Other Clinical Trial Services Company	3
Pharma/ Medtech/ Biotech/ Generics/ etc Company that runs trials	20
Research4Me	1
University /Medical Research Institute	4
Total Registered	**51**

Have you personally looked for a clinical trial for yourself or someone you care for?	I am not sure	No	Yes
Consumer - In Person	1	2	2
Consumer - Online			2
Professional Interest - Attend in Person	3	9	5
Professional Interest - Online		2	9
Speaker/Panellist		6	10
Total Registered	**4**	**19**	**28**

Attendee list

Full Name	Interest	Job Title (if applicable)	Organisation (if applicable)
ATTENDED MEETING IN PERSON			
Mr. Adam Johnston	Speaker/Panellist	Consultant/Solicitor	ADJ Consultancy Service
Mr. Adrian Eisler	Speaker/Panellist	Treatments Officer	Positive Life NSW
Mr. Andrew Hart	Professional	Clinical Research Manager	MSD Australia
A/Prof. Angela Todd	Professional	Research	Sydney Health Partners
Ms. Anita van der Meer	Panellist/Professional	Clinical Research Manager	Medtronic
Ms. Debra Trutwein	Professional		Novartis
Ms. Eleanor McGregor	Professional	Site Monitor	Bristol-Myers Squibb
Miss Florence Bascombe	Professional	Clinical Trials Coordinator	St Vincents Hospital Translational Research Centre
Ms. Gabriela Rosa	Professional	Director/Naturopath	Natural Fertility and Health Solutions
Ms. Hayley Andersen	Professional		BMS
Ms. Jane KELLY	Professional	CEO	CMAX Clinical Research
Dr. Janelle Bowden	Facilitator	Founder	Research4Me
Mrs. Janet Moore	Consumer	General Manager Research	Lung Foundation Australia
Ms. Karyn Joyner	Professional	Chief Operating Officer	SPHERE
Mrs. Lauren Macnaughton	Panellist/ Professional	Clinical Operations Manager	Eli Lilly
Prof. Lisa Askie	Speaker/ Professional	Manager, ANZCTR	University of Sydney
Mrs. Lorena Figueroa	Professional	Clinical Operations Line Manager	Roche Products Pty Ltd
Mrs. Lucy LaCioppa	Professional	Business Support Manager	Roche Products Pty Ltd
Ms. Mercia Bush	Consumer	Retired manager	
Mr. Mitch Kirkman	Professional	Development QA Manager	Novartis
Mrs. Narelle Williams	Panellist/ Professional	Senior Project Officer	Australia and New Zealand Melanoma Trials Group (ANZMTG)
Ms. Poppy Diamantis	Professional	Communications Manager	AbbVie
Mr. Rolland Suen	Professional	Project Manager	ClinTrial Refer
Mrs. Roslyn Ristuccia	Speaker/ Professional	Executive Director	ClinTrial Refer

Full Name	Interest	Job Title (if applicable)	Organisation (if applicable)
Ms. Rowena Tucker	Professional	Strategic Program Manager, Clinical Trials	SPHERE
Ms. Samantha Miles	Speaker/ Professional	Assistant Director	NHMRC
Ms. Sara Wiedenhaefer	Facilitator	Consultant	Sara Wiedenhaefer
Mrs. Susan McCullough	Consumer	Lung Cancer Consumer Representative	ALTG
Dr. Tim Churches	Speaker/ Professional		UNSW Medicine/Ingham Institute for Applied Medical Research
Miss Valerie Carlioz	Professional	Snr DevQA Associate	Novartis Pharmaceuticals Australia Pty Ltd.
Vic Roberts	Facilitator	Consultant	
Ms. Ying Morgan	Consumer		
Mrs. Zoe Armstrong	Professional	Clinical Research Director	MSD Australia
ATTENDED ONLINE			
Mr. Andrew Pleasant	Consumer		Health Literacy Media
Mrs. Angela Radcliffe	Professional	GM Clinical Trial Solutions	PulsePoint (US)
Ms. Christie Allan	Panellist/Professional	Program Coordinator - Clinical Trials	Cancer Council Victoria
Mrs. Christine Crandall	Speaker/Professional	Head of Strategic Clinical Planning	TransCelerate Member Company/GSK (US)
Mrs. Christine Zahren	Professional	Trials Strategy and Development Consultant	Skin & Cancer Foundation Inc
Hariklia Nguyen	Consumer		
John O'Mahoney	Professional		MSD Australia
Justin Mavin	Professional		MSD Australia
Mrs. Lisa Briggs	Speaker/Consumer		
Maeve Hunt	Professional		MSD Australia
Mrs. Marilyn Nelson	Panellist/Consumer		
Nirupa Arolkar	Professional		MSD Australia
Ms. Pip Palmer	Professional	Therapeutic Area Head	MSD Australia
Ms. Rebecca Trowman	Professional	Programme Manager	Bellberry Limited
Mr. T.J. Sharpe	Speaker/Consumer	Patient Advisor	Starfish Harbor (US)
Mr. Oskar Buhre	Professional	CEO	E-Nome
Sara Derballa	Professional		MSD Australia
Ms. Sharmila Kumar	Professional		Bristol-Myers Squibb

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Facebook Group: Facebook.com/groups/Research4MeGameChangers

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