Australian Clinical Trials Alliance

# Advancing clinical trial awareness, involvement and access for people from culturally and linguistically diverse (CALD) backgrounds: National workshop report

**Version 1**
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# ACKNOWLEDGEMENTS

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Led and developed by the ACTA Strengthening Consumer Engagement in Clinical Trials National Reference Group.

With thanks to workshop attendees including:

- CALD consumers (from diverse CALD backgrounds and communities)
- National Health and Medical Research Council (NHMRC)
- Federation of Ethnic Communities Councils of Australia (FECCA)
- National Aging Research Institute (NARI)
- NHMRC National Institute for Dementia Research (NNIDR)
- Ingham Institute for Applied Medical Research
- NSW Multicultural Health Communication Service
- Cancer Council Victoria
- McCabe Centre for Law and Cancer
- University of Melbourne
- PRAXIS Australia
- Consumers Health Forum
- Australian and New Zealand College of Anaesthetists (ANZCA)
- Research Australia
- White Coats Foundation
- Medicines Australia (Representing Research and Development Taskforce)
- Epworth Healthcare
- St Vincent's Hospital Melbourne
- South West Sydney Local Health District
- NSW Ministry of Health (Office of Health and Medical Research).

# BACKGROUND

In Australia, as well as overseas, there are underrepresented individuals and groups in clinical trials, in particular, people from culturally and linguistically diverse (CALD) backgrounds. The Australian Clinical Trials Alliance (ACTA) is committed to ensuring that health consumers (patients and people who use healthcare services) from CALD backgrounds have greater awareness of, involvement in, and access to clinical trials, with opportunities to shape research that develops new ways to treat or prevent diseases and health conditions.

On 18 June 2020 ACTA held a virtual clinical trial diversity workshop with the following objectives:

- Bring together a diverse group of stakeholders from CALD backgrounds to share experiences and activities to improve clinical trial diversity.
- Discuss opportunities to improve clinical trial awareness, involvement, and access for people from CALD backgrounds within the Australian context
- Develop a national position statement to support the development of recommendations to improve clinical trial (research) awareness, involvement and access for people from CALD backgrounds.

More than 40 people attended the three-hour workshop. They included participants from a diverse range of local and national health and research organisations and the clinical trials sector. More than a third of participants were CALD representatives, consumer organisations or individual consumers.

This report summarises key information and views shared with and by presenters and participants during the workshop, including a post feedback survey.

# WELCOME AND INTRODUCTION

**Professor John Zalcberg, ACTA Chair and Ms Nicola Straiton, ACTA Project Manager**

ACTA is the national peak body for clinical trial networks, clinical trial coordinating centres and clinical quality registries. It aims to transform healthcare through better evidence and strengthen its impact on everyday practice. ACTA has established eight reference groups to grow, strengthen and support Australia's clinical trials sector. The Strengthening consumer engagement in developing, conducting, and reporting clinical trials reference group was formed in 2017. One of the group's current projects is exploring why, despite making up almost a third of the population, Australians from CALD backgrounds are often excluded from Australian research, including clinical trials.

The project focussed on several activities over 12 months to explore this further, including:

- **Preliminary mapping of initiatives:** Seeking to improve clinical research participation with and for people from CALD backgrounds (outlined below).
- **Environmental scan:** Clinical trial awareness and access CALD populations highlighting national and international approaches and findings, published on the ACTA website here: https://clinicaltrialsalliance.org.au/resource/acta-clinical-trial-awareness-and-access-amongst-culturally-and-linguistically-diverse-cald-populations-environmental-scan/
- **Building relationships and engaging with key sector stakeholders:** To progress the issue and, when relevant, contributing to ongoing sector projects to enhance clinical trial diversity for people from CALD backgrounds. The organisations included COSA, Ingham Institute, FECCA, NSW Multicultural Health Communication Service, NNIDR, NARI, AKTN and TKI locally and internationally we linked with the United States (MRCT, CTTI) and Canada.
- **Delivering a clinical trials awareness education session for people from CALD background:** For those who were participating in the National workshop, enabling an informed and engaged dialogue.

The outcome of the initial activities generated three central themes for discussion:

- **Research awareness:** How can we increase CALD community awareness about the role, process, and value of clinical trials?
- **Research involvement:** How can the research sector support the involvement of consumers from CALD backgrounds and CALD communities in all stages of the clinical trial lifecycle and the research process?
- **Research access:** How do we ensure individuals from CALD backgrounds have equal opportunities to participate in clinical trials (research) and have access to the results of research?

# WORKSHOP PANEL PRESENTATIONS

| | |
|---|---|
| 1. Why does clinical trial diversity matter? The participant's perspective | Ms Lillian Leigh |
| 2. Overview of Australian initiatives to improve awareness, involvement, and access to clinical research with and for people from CALD backgrounds | Ms Nicola Straiton |
| 3. The CALD Dementia Research Action Plan: a roadmap | A/Prof Bianca Brijnath |

## 1. PARTICIPANT PERSPECTIVE – LILLIAN LEIGH

Through sharing a very powerful and personal story, Lillian Leigh provided a patient perspective on why clinical trials matter, and why diversity matters.

In 2014, when she was just 34, Lillian was diagnosed with a rare form of lung cancer. Lillian is a lawyer, mother and cancer patient advocate who now serves on several advisory groups related to cancer, clinical trials, and research.

After her diagnosis, Lillian did her own research and connected with others, eventually finding a clinical trial of a new drug that offered some hope. She described the courage it took to mention the trial to her oncologist, given the cultural respect for elders she held as someone who grew up in Hong Kong. Now, five years later, Lillian is still on that drug, despite a 3% five-year survival rate for people in her situation. She believes she is still alive due to the opportunity to participate in that clinical trial.

Diversity in clinical trials matters, Lillian argued, because there can be differences in the required dosage and effectiveness of some drug treatments among some population groups as well as the side-effects experienced. Lillian questioned whether it was ethical to approve a drug for use based on clinical trials that only involved homogenous populations, without knowing its safety for CALD population groups. She argued that everyone has a right to be treated with respect and given equal and inclusive access to the opportunities such trials offer.

## 2. OVERVIEW OF AUSTRALIAN INITIATIVES TO IMPROVE AWARENESS, INVOLVEMENT, AND ACCESS TO CLINICAL RESEARCH WITH AND FOR PEOPLE FROM CALD BACKGROUNDS – NICOLA STRAITON, ACTA PROJECT MANAGER

ACTA has sought to identify Australian initiatives that aim to increase CALD diversity and inclusion across the clinical trial and broader research sector.

### i. Towards Consistent National Data Collection and Reporting on Cultural and Linguistic Diversity – FECCA

FECCA has identified a key problem: there is inconsistent, inadequate, or non-collection of data related to ethnic and cultural diversity in Australia in all realms of research. FECCA is working to publish an issues paper on data collection based on wide consultation with key data collection agencies, researchers, and academics and CALD community organisations. Potential recommendations may include strategies to improve the visibility and inclusion of CALD populations in all data collection and research activities, including clinical trials. As one workshop participant observed, "There's no one CALD variable or guidance on how to collect, analyse and report on CALD."

### ii. Ingham Institute for Applied Medical Research, NSW Multicultural Health Communication Service and South Eastern Sydney Research Collaboration Hub (SEaRCH) University of New South Wales

This joint initiative included a workshop and several surveys to identify strategies to improve research participation for people from CALD backgrounds affected by cancer. Seven co-designed strategies were identified. These included increased representation of CALD people in key networks and committees, advocacy for funding initiatives, and the need to build the knowledge and skills of health professionals and researchers.

### iii. CALDER: Culturally and Linguistically Diverse Ethics Resources – University of Melbourne

The program aims to increase research equity (involvement and recruitment) for CALD patients by developing and trialling information in different formats (such as short videos) that are accessible, culturally appropriate and patient-centred. The program includes trialling digital technologies to address communication barriers, including for consent.

### iv. Legal and Policy Review – McCabe Centre for Law and Cancer, Cancer Council Victoria and Western Health

The project investigated whether existing laws and policies could support strategies to promote access to clinical trials for CALD people. It identified that such approaches offered limited support, and that a multi-pronged, multi-disciplinary and collaborative approach is needed to address existing barriers.

## 3. THE CALD DEMENTIA RESEARCH ACTION PLAN: A ROADMAP – A/PROF BIANCA BRIJNATH, NARI

The NHMRC National Institute for Dementia Research (NNIDR) and the National Ageing Research Institute (NARI) acknowledge that current dementia research does not reflect the diversity of the Australian population. It therefore does not capture the spectrum of issues faced by older people from CALD backgrounds and their families, such as different understandings of needs, delayed diagnosis, culturally inappropriate services and disparities in specialist referrals and medication usage. NNIDR and NARI have published a CALD Dementia Research Action Plan – a roadmap towards improved health and wellbeing of Australians from CALD backgrounds at risk of developing or living with dementia, together with their carers, families, and communities. The project resulted in 21 national dementia research priorities for people from CALD backgrounds and will be essential for researchers, research leaders, funders, and policymakers.

# BREAKOUT SESSIONS

Three facilitated breakout groups were held, with all workshop participants allocated to one of the three themes of awareness, involvement or access. Participants were asked to discuss two questions:

- **Question 1:** What does AWARENESS/INVOLVEMENT/ACCESS mean to you and why does this matter?
- **Question 2:** What are the key principles you believe need to be included in the position statement for this area?

Workshop participants' ideas regarding key principles will be synthesised in the ACTA position statement on clinical trial diversity. Below is a summary of each breakout room discussion, including direct participant quotes, and supplemented by relevant comments from the virtual chat and post-workshop feedback survey options.

## GROUP 1: AWARENESS

Awareness is not a simple concept and can include a number of elements:

- The concept of 'awareness' can require further clarification. For instance, whose awareness? awareness of what? what is the potential scope, scale, and outcomes of 'awareness' initiatives?
- The *purpose* of awareness is 'a call to action'.
- The act of *creating* awareness is not a single event, it involves continuity and sustainability of actions.
- It is mostly associated with 'knowledge' and 'understanding' but what is it what we want people to understand? Awareness about the role of clinical trials, awareness about how to access information to learn more about the clinical trial process, or awareness about resources to access current clinical trial opportunities or all of the above?

Too often awareness is seen as responsibility of consumers alone; the onus is often on their communities to become informed. However, researchers and the broader research sector have an ethical obligation to take more responsibility for the inclusion of CALD populations. This requires researchers to have more focus on elements such as:

- Why it is important to address inclusion and equity in their research.
- How to engage with and communicate with CALD populations about their research in ways that are simple, clear, and appropriate to the specific communities.
- Recognise that developing awareness is not just about knowledge and understanding but also about navigating the process (e.g. how do participants sign up for a clinical trial?).

From the perspectives of individuals from CALD backgrounds and their communities, awareness is about information and knowledge, but also being able to take action. This is often predicated on people having a *meaningful* awareness of the research: ask why should people care about research projects? Do people understand the potential benefits of clinical trials to themselves and others? As one participant commented, "Instead of creating awareness, make people care."

The development of consumer trust in research involves relationship building. Researchers need to:

- Go outside current ways of building relationships and think about strategies that are specific to particular communities
- Respect other people's values and views which may be different to theirs
- Recognise the importance of "reciprocity in relationships"
- "Build **trust**, not just awareness".

Researcher communication with consumers from CALD backgrounds needs to be multi-pronged to recognise different levels of language capacity, literacy (including health literacy), and education. Strategies to raise awareness go far beyond the translation of information to the understanding of deeper cultural issues by and among researchers. As one participant noted, "Many researchers [tell] us that they don't receive funding/time for translating and interpreting... but it's more a culture change that's needed." Key strategies can include 'storytelling' activities, supporting CALD communities to lead projects, and identifying and resourcing patient research advocates from CALD backgrounds.

## GROUP 2: INVOLVEMENT

Involvement is predicated on acknowledging that all CALD communities have a right to a voice in all elements of health care, including research. This right includes:

- A voice in setting research priorities – what is important, what matters most to CALD communities.
- Consultation in the design and development of research projects.
- Representational and proportional involvement in HRECs, hospital committees and consumer groups.

Researchers, clinicians, and policymakers have a responsibility to deliberately and ethically engage with diverse populations. Researchers should be required to demonstrate how their project will be inclusive of diverse populations (unless there is a genuine scientific reason for non-inclusion). This is already a requirement of all research involving First Nations People. Ideally, research, including clinical trials, should embrace a co-design approach.

Involvement includes the provision of opportunities for CALD communities to lead initiatives as well as contribute feedback where appropriate. Researchers' responsibilities include strategies for involvement that:

- Empower individuals from CALD backgrounds and CALD communities, enable people 'to feel part of the process or team'.
- Recognise broad diversities both **within** and **between** CALD populations.
- Invite and listen to communities' advice in relation to appropriate approaches to the conduct of research and the translation of outcomes.

An essential outcome should be that the profile of participants involved in trials, "should reflect the percentage of people from CALD backgrounds in the community, or be proportional to the burden of disease if required" (for example, those who have greater proportion of diabetes).

## GROUP 3: ACCESS

'Access' often refers to the extent to which clinical trials (research) are made available to individuals. There are a range of barriers, as well as enablers, that impact people's level of access.

Barriers can be at the level of the trial design itself. For instance:

- The inclusion and exclusion criteria often exclude some potential participants from CALD backgrounds by requiring fluency in English.
- Recruitment information is often too complex, not available in different languages, not accessible through interpreters or in translation, or culturally inappropriate for certain groups.

Clinicians, researchers and ethics committees can act as gatekeepers in ways that exclude participants from CALD backgrounds due to assumed 'vulnerabilities' of individuals. Stereotypes of CALD populations also play a role. As one participant observed, "Many of the researchers will not have even approached people who they **think** cannot speak English."

Consent protocols that require individuals' autonomous consent can also be culturally exclusionary. As one participant argued,

> *"Ethics are culturally defined. In many CALD cultures, care and consent goes beyond the individual. The principle of autonomy may be OK for a western Anglo-Celt … but it is not understood by indigenous and non-Anglo cultures."*

Participants also commented on the importance of understanding patients' needs throughout the consent process: researchers need to, "appreciate that language is not the only barrier; others include cognitive ability in times of stress and varying preferences in modality (e.g. use of infographics)."

Rather than maintaining a traditional 'mindset' to achieving participants' consent, i.e. 'we have always done it this way', researchers need to be more dynamic and culturally aligned in seeking consent through mutual learning with communities.

Barriers to inclusion of people from CALD backgrounds also occur at a more systemic level. For instance, despite in-principle acceptance of the values of justice and respect for all, these principles are not followed through in the research industry. Many funders and research programs do not allocate sufficient resources, such as time and money, to enable strategies that would enhance awareness and trust among individuals from CALD backgrounds. This was indicative of an embedded 'one size fits all' approach to much research. Consequently, one participant posed the important question: "How do you **not** have CALD representation in a trial? What's at play?"

Other elements of access, such as the fair dissemination of outcomes, can also be enhanced by consultation and connection with the many diverse CALD communities. As one participant observed: "Researchers also commonly report results with unhelpful categories like 'Asian', 'European', etc which mask immense diversity within these groups."

Participants acknowledged that all stakeholders – researchers, clinicians, funders, policymakers, consumers, CALD communities – need to share the efforts required to bring positive change to the clinical trials sector. Ultimately, as one participant stated, "A patient needs to want to go on a trial, and the trial needs to welcome them."

## SUMMARY AND EVALUATION

Workshop participants said they valued the opportunity to contribute to this important discussion and the development of ACTA's Position Statement.

The following key messages from the workshop participants sum up the overarching consensus messages from the workshop discussions and the panellists:

- "Acknowledging difference and cultural preferences is fundamental."
- "It is in everyone's best interest (and therefore everyone's responsibility) to ensure that our research priorities, participation are inclusive…and that access to clinical research is facilitated in a culturally safe and appropriate way."
- "We need to create a clinical research culture that is underpinned by principles of equity and justice, and to hold people accountable to this."

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