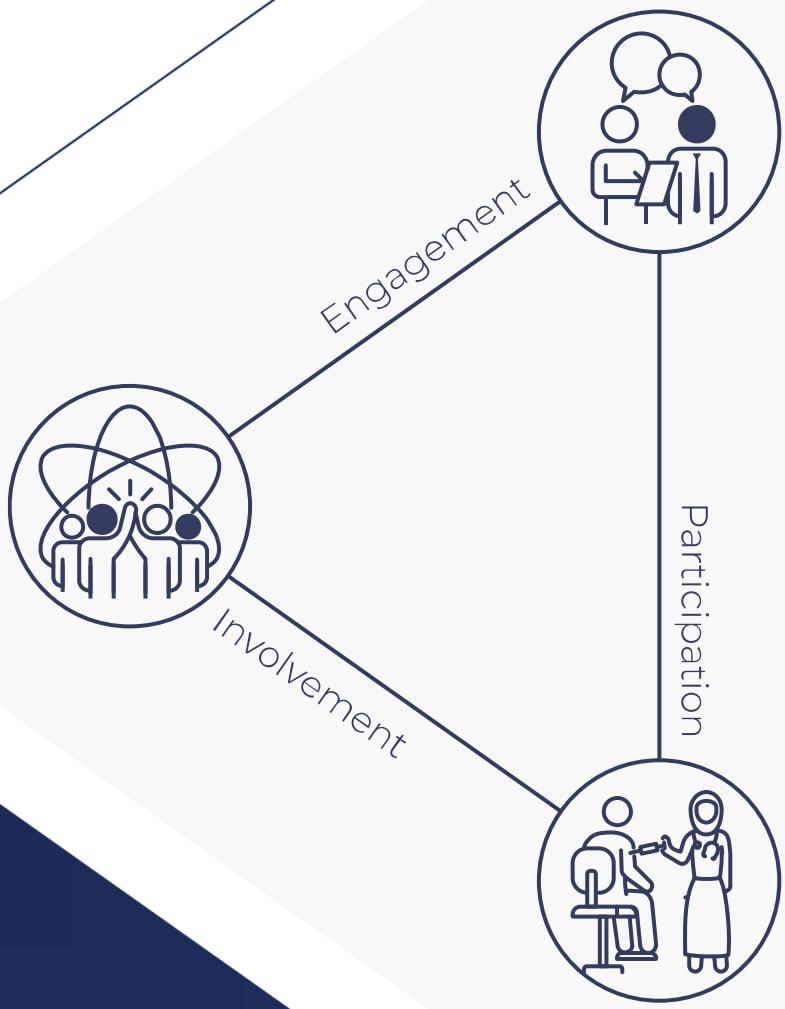
Australian Clinical Trials Alliance



Advancing clinical trial engagement, involvement, and participation for people from culturally and linguistically diverse backgrounds

Research reported in this publication was supported by the Medical Research Future Fund under grant number MRFTA000001

Contents

Acknowledgements

Lead Author: Ms Maria Mahony

ACTA is grateful for the thoughtful contribution of insights and time from:

Ms Anne McKenzie, AM	ACTA Board Member, Consumer Representative, Co-Chair of ACTA's Consumer Engagement, Equity and Diversity Working Group
Dr Janelle Bowden	Consumer advocate, AccessCR, Co-Chair of ACTA's Consumer Engagement, Equity and Diversity Working Group
Prof John Zalcberg, OAM	ACTA Board Member, Monash Health
Dr Shyamsundar Muthuramalingam	Australia and New Zealand Dialysis and Transplant Registry and consumer
Mr Daniel Coase	Federation of Ethnic Communities Councils of Australia (FECCA)
Mr Mitch Messer	Consumer representative, Telethon Kids Institute
Ms Merilyn Heuschkel	NHMRC Clinical Trials Centre, The University of Sydney
A/Prof Reema Harrison	Macquarie University
Dr Ben Smith	Cancer Institute NSW Career Development Fellow, University of New South Wales
Mrs Nicole Scholes-Robertson	Consumer representative, Australasian Kidney Trials Network, University of Sydney
Mr John Stubbs	Consumer representative, Cancer Community Network Australia
Dr Nicola Straiton	Research fellow, Implementation Science Platform, Maridulu Budyari Gumal Sydney Partnership for Health, Education, Research and Enterprise (SPHERE), Nursing Research Institute, St Vincent's Health Network Sydney
Dr Fiona Nemeh	Australian Clinical Trials Alliance
Prof Bianca Brijnath	National Aging Research Institute
Prof Carmel Hawley	Australasian Kidney Trials Network
Mrs Hayley Candler	University of Queensland
Ms Mary Rydberg	Mildura Base Public Hospital and DFFH Human Research Ethics Committee
Mr Jeremy Kenner	National Health and Medical Research Council (NHMRC)
Dr Megan Sanders	Thoracic Oncology Group of Australasia (TOGA)
Mr Constantine Tablan	Medicines Australia
Dr Megan Sanders	Thoracic Oncology Group of Australasia (TOGA)
Dr Fadwa Al-Yaman	Australian Institute of Health and Welfare
Ms Lillian Leigh	Lawyer, Consumer Panel Chair and Non-Executive Director of TOGA, NHMRC Consumer and Community Advisory Group Member
Ms Anna Parker	University of Melbourne

As part of the sector-wide consultation process that supported the development of this document, ACTA was pleased to have received written submissions from a range of individuals and organisations including:

- CALD consumers and consumer advocates
- Dr Marina Skiba
- Sheetal Challam
- Dr Julia Ellis
- Brigitte Sigl, Consumer Consultant
- Dr Jodi Glading, Tasmanian Deputy Chief Medical Officer
- Maria Mury, Cancer Institute NSW
- Dipti Zachariah, Multicultural Health Services, Western Sydney Local Health District
- Angela Todd, Sydney Health Partners
- Vicki Bennett, Australian Institute of Health and Welfare
- Ms Mariam Hachem, University of Melbourne and The Australian Lebanese Medical Association of Victoria
- Alan White, Peter MacCallum Cancer Centre
- Kyung Ha (Kathy) You, Royal Brisbane Women's Hospital
- Rare Voices Australia
- Cancer Council Australia
- Cancer Council Queensland
- Cancer Council Victoria
- McCabe Centre for Law and Cancer
- Hunter Medical Research Institute

Acronyms

ABS	Australian Bureau of Statistics
ACTA	Australian Clinical Trials Alliance
AMHC	Australian Multicultural Health Collaborative
CALD	Culturally and linguistically diverse
CC	Coordinating Centre
CTN	Clinical trial network
FDA	Food and Drug Administration, United States
FECCA	Federation of Ethnic Communities' Councils of Australia
MRCT	Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard
NIHR	National Institute Health for Health and Care Research, United Kingdom
NHMRC	National Health and Medical Research Council, Australia
PhRMA	Pharmaceutical Research and Manufacturers of America
RRDN	Regional Research Delivery Networks, United Kingdom

1. Introduction - ACTA's commitment to action

It is the Australian Clinical Trials Alliance's (ACTA) view that participants in clinical research should reflect the diversity of our society and cultures. The failure of research to be inclusive of people from diverse backgrounds, cultures, and languages, limits the generalisability of its results to those populations. Australia's culturally and linguistically diverse (CALD) populations are significantly underrepresented in health and medical research, including in clinical trials, revealing a gap in equitable access to clinical trials, and the opportunities and benefits of research for their health.[1]

Various demographic factors including age, sex and gender, and ethnicity have been associated with clinically significant differences in risk factors, screening, diagnosis and prognosis, treatment and management related to a range of diseases and conditions.[2,3] Failure to identify, examine and respond to these differences can ultimately compromise the quality of care and treatments that are available now and into the future.

ACTA is committed to improving clinical trial engagement, involvement, and participation for people from CALD backgrounds within Australia.[1]

These terms are defined by ACTA as:[4]

- *Engagement* is where information and knowledge about research is shared with consumers and the community so that they are better informed on why, how, where and by whom research is conducted. It involves creating a dialogue with consumers and the community to improve research literacy and increase trial awareness to encourage trial participation as a routine care option.
- *Involvement* is where consumers and community representatives actively work with and are involved in decision-making processes with researchers and research organisations about health research priorities, policy, and practice. This can include (but is not limited to) defining research questions, identifying outcomes of interest, and improving the content and readability of participant information. The aim of better involvement is that research priorities are reflective of the population and may more effectively improve health outcomes.
- *Participation* is where patients or healthy volunteers take part in research. Consumer participation can include being recruited to take part in a clinical trial, completing a questionnaire or attending a discussion group as part of a research study and/or providing data or tissue that is analysed as part of a research study.

It stands to reason, that if you have people from CALD backgrounds involved in the design and conduct of research, then that research may be better suited to recruit and retain people from CALD backgrounds. ACTA recognises the reciprocal benefits to both research and CALD communities that can be achieved through collaboration and partnership. In addition, evidence generated from all trials, including investigator-led trials, has the potential to be more generalisable to and relevant for the broader Australian population.[5]

In October 2020, ACTA published a Position Statement [1] supporting the equitable and inclusive engagement and involvement of people with CALD backgrounds in clinical trials. The development of this position statement was led by the ACTA Reference Group on Strengthening Consumer Engagement in Clinical Trials in consultation with a wide range of national stakeholders. Stakeholders included individuals or groups from within and/or outside research organisations with an interest in research, from members of consumer organisations, professional bodies, government representatives, non-government organisations, industry, consumers, and consumer advocates. The statement provides the principles, together with a framework and rationale, for further action by all stakeholders involved in the clinical trial lifecycle.

As a next step, this project aims to facilitate a clinical trials system that will work cohesively to improve participation in clinical trials for people from CALD backgrounds, with the development of recommendations underpinned by community and sector consultation. This paper builds on previous work by ACTA and many others, to design a way forward to promote systematic and sustained change that will increase the participation of people from CALD backgrounds in clinical trials.

2. The environmental context for clinical trials in Australia

Since the Position Statement was developed, there has been more local and international focus on the lack of diversity in clinical trials, and the need for more equitable and inclusive approaches to clinical research.

2.1 Australia's population is increasingly diverse

The 2021 Census conducted by the Australian Bureau of Statistics (ABS) has confirmed the proportion of Australian residents that are born overseas (first generation) or have a parent born overseas (second generation) has increased to 51.5%. English is the dominant language, however 22.3% of people speak a language other than English at home, with the top five languages being Mandarin (2.7%), Arabic (1.4%), Vietnamese (1.3 %), Cantonese (1.2%) and Punjabi (0.9%).[6]

While the Census provides some insights, the variables that indicate cultural and linguistic diversity consider ancestry and country of birth, rather than ethnicity. There is not an agreed and consistent set of data routinely collected in either health or research in Australia. This is important, particularly in the context of a shift to big data research. Reporting on the health needs of CALD populations in Australia is complex and inconsistent. The term CALD can have multiple definitions, and includes aspects such as cultural and ethnic background, where a person's parents were born, languages spoken at home and their religious affiliation.[2,7,8] Responding to this complexity, the newly established Australian Multicultural Health Collaborative (AMHC) has an aim to improve collection and reporting of multicultural data, to inform a strategic research agenda for multicultural health.[9] A number of stakeholders have also indicated they are undertaking or considering projects to clarify requirements for CALD data collection.

2.2 A global focus on diversity in clinical trials through policy and guidance

A number of overseas organisations have also taken proactive stances on diversity, such as the US Food and Drug Administration (FDA) draft guidance issued in 2022 to increase enrolment of underrepresented populations,[10] and the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard extensive practical guidance in "Achieving Diversity, Inclusion, and Equity in Clinical Research" (2020).[11] The UK National Institute for Health and Care Research (NIHR) Trial Forge INCLUDE project provides guidance and a framework to prompt trial teams to think about who should be involved as participants, and how to facilitate their involvement as much as

possible.[12] In February 2022, the Diverse and Equitable Participation in Clinical Trials (Depict) Act was introduced for consideration in the US, to increase diversity in clinical trials through enhanced data reporting.[13]

These policy changes will certainly influence diversity requirements for global trials with potential implications for Australian clinical trials. Beside the health imperative for the populations currently underrepresented, it will likely become an academic and commercial imperative (and potential competitive advantage) for Australian researchers to be able to demonstrate recruitment of diverse populations to trials.

The NHMRC and Community Health Forum (CHF) Statement of Consumer and Community Involvement in Health and Medical Research (currently under review) recognises the obligation for researchers to support accessibility regardless of cultural and linguistic backgrounds.[14]

2.3 Emerging models that drive CALD access through trial infrastructure

Internationally, models are emerging that drive systematic improvements in access for underrepresented populations through improved clinical trials infrastructure. The NIHR Clinical Research Network (CRN) is mapped to the National Health Service regions in England and will be transitioning to Regional Research Delivery Networks (RRDNs) in 2024. The model aims to bring research to under-served regions and communities. It integrates research into the health care system, improving recruitment practices, driving efficiency and improved delivery of research with consistent funding.[15] A similar model has been proposed in New Zealand.[16]

The Pharmaceutical Research and Manufacturers of America (PhRMA) proposes dedicated resources supporting a network of clinical trial sites in the communities that serve underrepresented populations across the US. These may over time, create a sustainable national infrastructure focused on enhancing clinical trial diversity.[17]

Clinical trial networks (CTNs) in Australia formed around a disease or discipline area have a number of benefits including the expertise, resources and efficiencies generated by a shared clinical trial infrastructure within the network. Although barriers such as inadequate resources exist, models such as the RRDNs may provide a viable mechanism to support engagement, involvement, and participation of CALD groups in the Australian context using a shared infrastructure across all trials.[18]

The emerging Australian Teletrials Program may also improve CALD access to clinical trials. The Program aims to expand the reach of clinical trials to those living in regional, rural, and remote areas, and to build a clinical trial system that is better connected.[19]

2.4 Lessons from COVID-19 for engagement with CALD populations

Insights from a study considering the challenges of communicating COVID-19 directives to CALD communities in Australia, highlighted the importance of partnerships between community leaders, communities, and government for effective health communication. Importantly, sustained behaviour change requires tailored solutions that recognise the diverse needs and circumstances of people and communities.[20] It is not a one size fits all approach.

COVID-19 heightened population interest in listening to health information. New frameworks were developed for communicating with CALD populations which may be applicable to the context of clinical trials.[21]

Stakeholders interviewed have noted improved ability to engage through technologies, devices, apps, and social media as one of the positives out of COVID-19. It is timely to leverage the new skills that people gained in an online environment, and their fresh understanding of what a trial is, and why trials are important to health. However, technologies may not always be appropriate for consumer engagement, especially for people with language or communication barriers, and for older people,[22] which is why ACTA has proposed a multifaceted approach.

An initiative that began during the pandemic, was the sharing of translated COVID-19 information between Australian jurisdictions to reduce duplication of efforts. Sharing translated consent forms, and/or other clinical trial and health information between jurisdictions would offer further efficiencies and support the delivery of improved outcomes.

CASE STUDY - Lessons from the COVID-19 Small Grants Program[23]

Language and translation issues were a significant concern early in the COVID-19 pandemic, with translated information about COVID-19 and vaccines not easily accessible or with translation errors. Many people of CALD background were hesitant to act on the health messages because they are from countries that had little trust in government and authorities.

The COVID-19 Small Grants Fund was launched in June 2021 to address barriers to accessing information on COVID-19 and the vaccination program. The grants were targeted at grassroots multicultural organisations across Australia to reach out to communities with public health messaging, in a manner they can relate to and understand. This initiative was funded by the Federal Department of Health.

The small grants enabled communities to develop their own approaches using codesign and consultation, with the freedom to communicate in their own way. From music and dancing, cooking classes, sporting events, comedy, and even simple conversations over a cuppa, communities have rallied together to make sure everyone can access accurate public health information.

These projects have helped build trust within multicultural communities in the Government and the Australian health system. For many organisations, this was their first time engaging with Government agencies. It provided them with a platform to voice their concerns, as well as an opportunity to be part of the solution. It showed how collaboration can work towards solving those issues.

3. Perspectives and insights to create momentum for change

The national and international evidence of the need for greater CALD engagement, involvement, and participation in clinical trials is widely accepted. A number of recommendations, guidance, and toolkits to enhance consumer and in particular, culturally and linguistically diverse, engagement and involvement in clinical trials have been developed by various agencies such as the FDA, MRCT, NIHR, PhRMA,and ACTA, including practical 'how to' support needed at each stage of the clinical trial process. An example of a set of strategies to increase participation of people from CALD backgrounds in cancer research was developed by CONCERT, Ingham Institute for Applied Medical Research, NSW Multicultural Health Communication Service and South Eastern Sydney Research Collaboration Hub (SEaRCH) UNSW.[24]

A Consensus Study Report published in 2022 by the US National Academies of Science, Engineering, and Medicine, has detailed recommendations to improve consumer representation in clinical trials and research, which highlights the necessity of focusing on the priorities, interests, and voices of the community rather than institutions, to achieve equity, and the need to apply a systems approach that involves all stakeholders responsible.[25]

There are also several studies and initiatives shining a light on required support for CALD consumers and researchers throughout the clinical trials process. International literature reviews identify the key evidence-based strategies that promote inclusion in clinical trials, including improving cultural competency and sensitivity of all clinical trial staff through training and ongoing personal development, the need to establish diverse community advisory panels for ongoing input into the research process, and increasing recruitment of staff from under-served groups.[2,26]

For sponsors, better CALD engagement may go some way to improving recruitment into studies but more importantly, it offers the opportunity to determine how specific ethnic groups respond to new interventions. Additionally, particularly for Phase III studies, it provides the opportunity for biotechnology, pharmaceutical and medical device companies to build trust through helping to address health inequities, an area of growing interest from both investors and the community. McKinsey & Company state, 'it's unrealistic to expect that people will seek out health solutions if they distrust medicines and providers'.[27] CALD engagement in the process of developing and optimising new interventions offers the opportunity for downstream benefits to both sponsors and the community.

Yet while there are active advocates and people with ideas to support both people of CALD background and researchers, the barriers are still too high and limited progress has been made. To better understand the situation in Australia, ACTA has sought perspectives from a wide range of stakeholders, including people of CALD backgrounds, across the clinical trial lifecycle, looking for linkages, lessons and relationships that can amplify the value of the work being undertaken to improve the clinical trial system.

The key themes from these interviews are illustrated in the following (figure 1) and explored in the following discussion. These span the different phases of the clinical trial cycle, noting the importance of beginning engagement of people from CALD backgrounds earlier.

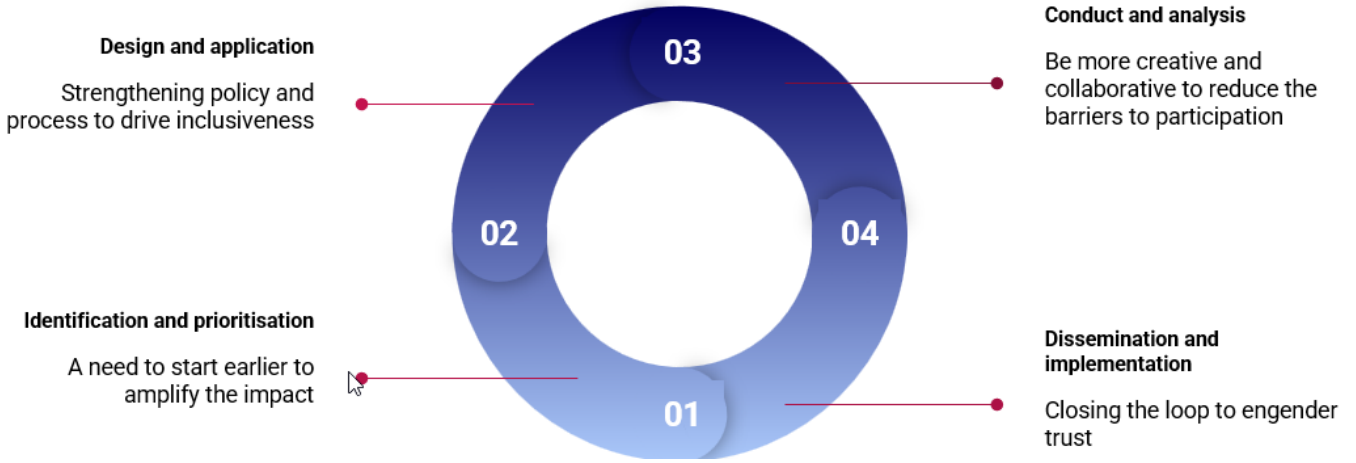


Figure 1: The clinical trial lifecycle

3.1 Starting earlier in the process to amplify the impact

"Meet people where they are."

Partnering with the community.

There are many differences, needs and behaviours for each cultural community and each individual. Stakeholders universally agreed that it is vital to engage with people from CALD backgrounds as early as possible, with the aim of building a collaborative relationship rather than one based around the needs of a particular trial. Investigators cannot assume they know what is good for communities, and there is often a mismatch of priorities. Barriers to participation extend beyond language, to social, cultural, and familial factors. To build trust, which will be necessary to increase participation and involvement, a deeper understanding of these issues is needed.

Community leaders, representative organisations and trusted local health care practitioners who speak the relevant language and are culturally aware, are well positioned to address fear, misconceptions and build trust. However, stakeholders also emphasised the need to bring researchers into communities. Encouraging CALD researchers to help build bridges with communities with whom they share a common background may also help build credibility.

As an example, the Cancer Symptom Trials (CST) is undertaking a program of work to investigate the underrepresentation of CALD communities in cancer clinical research in Australia. To understand the barriers and enablers, they have a project targeting Arabic speaking communities and are seeking to collaborate with multilingual healthcare professionals working with these communities to bring their insights.[28]

Early, culturally appropriate engagement and involvement is important to achieve effective collaboration between researchers and CALD communities. It was suggested by some stakeholders that the clinical trials workforce lacks training in cultural sensitivity, and it was proposed that shared resources and training could be provided cost effectively at a national level.

Embedding clinical trial resources in communities.

For research to be community led, stakeholders suggested communities are not equipped or resourced well enough. Community leaders and local health care providers are already time poor and tackling a range of issues which may be prioritised over access to clinical trials. Consumer involvement in clinical trials can be undervalued by the clinical trial sector considering that the time and energy required to be involved in clinical trial design is often expected to

be voluntary. ACTA, alongside a number of stakeholders, believe that Consumer involvement should be reimbursed and that Government should support any additional costs.

Some stakeholders interviewed proposed that properly paid representative positions with training and a position description would help to forge the connection between CALD communities and researchers undertaking clinical trials. These representatives could help both CALD individuals and researchers with navigating the clinical trial process end to end. Scaling this support offers efficiencies by supporting multiple trials or CTNs in their research, rather than each trial needing to assign resources, and set up and decommission infrastructure. A program of services may be offered such as community engagement and education, governance, co-design with CALD representatives, translation and advice on trial materials, videos in various languages exploring clinical trials, recruitment, support for participants throughout their trial journey, and assistance for researchers with reporting back to communities.

The Commonwealth Government funded Advanced Health Research and Translation Centres aim to embed research into healthcare through collaborations to accelerate translation of research into clinical care.[29] The members collectively identify and develop solutions for systemic problems relevant to all members.[30] Their experience could offer lessons and opportunities for how to create a model to embed local clinical trial resources in CALD communities.

Leveraging existing structures, networks and relationships, community-based trial resources could be developed and scaled over time, and potentially form a national network of community-based trial sites in underserved communities.[15]

3.2 Strengthening policy and process to drive inclusiveness

"It doesn't change because we don't require it."

Internationally, regulators like the FDA, research funders, and journal editors have been instrumental in driving changes in the conduct and reporting of research, including more recently, expectations regarding inclusive research and reporting on diversity.[31] Without these imperatives, stakeholders agree that researchers are unlikely to engage and involve people of CALD backgrounds. They have neither the time nor the funds, and they do not collect the data in a consistent way.

Trial design and study population.

Sponsors and ethics committees could play an active role by applying a consistent inclusivity policy requiring justification for trials that restrict diversity or fail to adequately encourage diversity. Stakeholders proposed that funders require investigators to give consideration and provide justification of trial selection criteria and study population. The 2022 FDA draft guidance requires sponsors to develop and submit diversity plans to enrol adequate numbers of participants in clinical trials from underrepresented racial and ethnic populations in the United States.[10] Some stakeholders believe this will begin to have an influence in Australia, but that mandating population criteria would be impractical because of the difficulty with recruiting the right profile within tight timeframes.

However, Australia's diversity represents an opportunity to attract more international clinical trial sponsors looking to meet their diversity targets for the FDA. If Australia was to resource, educate and engage/partner with our diverse CALD populations more effectively in clinical trials, it might prove another additional benefit to placing trials in Australia, attracting more economic and health benefits for our population.

Under NHMRC guidance, consumer involvement is a requirement of planning and design of research. There is an

opportunity to strengthen policy supporting engagement, involvement, and participation of CALD communities as part of the review of the Statement on Consumer and Community Involvement in Health and Medical Research currently underway, to place more emphasis on specific actions that support inclusion as part of grant applications. Without this 'stick', and supportive funding, stakeholders suggest that researchers won't make it a priority.

Additional support through CALD advisory committees.

The involvement of consumers through trial advisory or steering committees has become more prevalent, although there is some way to go. CALD consumer representatives are fewer, because of the inherent barriers of language, education, and social factors. Stakeholders indicated that a power imbalance between consumers, and the academics and researchers in this context can limit the consumer/CALD voice.

A survey of member CTNs by ACTA further highlighted the complexity, because of a belief that consumers do not have adequate skills or consistent involvement in advisory groups. Additional support is needed to move beyond simply having CALD representatives on consumer committees, to raising awareness amongst decision makers of what true engagement involves, and then subsequently empowering consumers to meaningfully contribute across the clinical trial process. The intersection of CALD engagement in this process, together with scientific/clinical expertise requires careful consideration to ensure both trial and inclusivity outcomes are met.

Along the lines of the infrastructure being established to support engagement, involvement, and participation from underrepresented groups overseas, a more structured approach to CALD advisory groups for clinical trials could be considered. Stakeholders felt that centrally driven CALD advisory support for the clinical trial process would be more effective to achieve sustained engagement, involvement, and participation of CALD communities than the current piecemeal approach. The centralised CALD advisory groups could be used as a national network for all trials, including in specific disease areas. CALD advisory group members can be trained and developed so that their skills and knowledge are not lost once a trial is closed.

Furthermore, the quality of engagement could be supported through ensuring representatives bring strong grassroot connections and that there is a mix of new views together with views of experienced CALD representatives across the sector.

Supportive organisational culture and a diverse research workforce.

Structural enablers of consumer engagement include best practice standards, resource allocation, training, and organisational commitment in the form of a supportive culture and policies.[32] These approaches need to be consistently applied across the full lifecycle of a clinical trial. Studies have discussed that diversity, equitable access, and inclusion principles can be core institutional values, and a philosophy embedded within organisational culture. It is suggested that when diversity principles are embedded within the fabric of an organisation, staff can be held accountable for making efforts to increase diversity, resources are allocated to diversity initiatives, and diversity and inclusion principles serve as "guideposts" for decision making.[3]

Specific support for increasing workforce diversity is also an immediate opportunity. Australia could leverage our highly skilled and increasingly diverse research workforce who understand the culture and language within particular communities. This would enable researchers with a CALD background to be champions of communities, but also to network with each other, and share their knowledge with researchers of all backgrounds. They could have input to the development of culturally sensitive frameworks and tools shaped around particular CALD backgrounds, which could be shared through the ACTA and CT:IQ Consumer Involvement and Engagement Toolkit, [4] referred to as the Consumer Involvement and Engagement Toolkit.

Other steps organisations can take are to actively recruit for diversity and create supportive policies and development opportunities for their researchers from CALD backgrounds. In addition, they can include routine cultural sensitivity training for all clinical trial staff, potentially using a shared resource designed for the sector.

3.3 Be collaborative and creative to reduce the barriers to participation

The barriers to CALD participation in clinical research are widely documented and include lack of trust, the complexity of written documents, language and health literacy issues, and poor understanding of the benefits. Familial and cultural beliefs and practices concerning health and research, health literacy, trust, together with financial and time constraints, mobility, accessibility of trial sites and research staff interest, all contribute to the underrepresentation of CALD people in clinical trials.

More contemporary models of consent.

Stakeholders discussed the use of more contemporary models of consent including in digital format, to be considered by ethics committees. Stakeholders believe laborious consent, pages long, are too complicated particularly for benign research and should be simplified. Consent mechanisms could be assessed against risk, and where strong governance exists, adult populations should be given more agency in their choice. Verbal consent may also be considered for vulnerable CALD populations. CT:IQ are currently redesigning consent to research, through their *InFORMed Project*, to improve the participant information and consent form (PICF) template.[33] This template should increase the readability of PICFs for all consumers as well as the feasibility of generating translated versions for those from different language backgrounds.

ACTA has developed a more simplified consent (see the case study box below) to explore this potential.

Case study: A risk moderated approach to informed consent

ACTA's integrated (simplified) consent approach was applied in the design of the investigator-initiated SNAP clinical trial (a study exploring the most effective treatments for staphylococcus aureus bloodstream infection). The research team, which included consumers, created a short, tiered participant information sheet and consent form (PICF), to make this trial more accessible to end-users and to ensure effective and efficient recruitment of participants. The model enables valid consent to be obtained using a proportionate, risk-based approach and is within the guidelines of the NHMRC national statement.[34]

Social and financial barriers.

Considered to be a significant barrier, stakeholders agreed that more funding be allocated to support CALD participation in clinical trials. In particular, the cost to ensure that potential participants have access to educational materials and support in their preferred language, hiring interpreters, and offering language-specific informed consent processes and financial support such as transportation assistance, childcare or payment for time not spent at work can help to increase participation and retention in clinical trials. Commercial trial sponsors could fund travel and accommodation assistance for clinical trial participation, and State Government patient travel assistance schemes should be amended to include non-commercial clinical trial participation as an eligible treatment option. Involving people from diverse CALD backgrounds in the development of trial protocols and materials will also help identify where specific supports could make a difference to trial participation. It is proposed that trial applications should include a budget to support both CALD involvement and participation in funding applications.

3.4 Closing the loop to engender community trust

"People don't want researchers to just 'take' the information, the benefit should flow back. They must feel that their community is heard and seen, and actions are developed around that."

Closing the loop at the completion of a trial is vital to establish trust and understanding for any community, but especially CALD communities where trust of the medical or research establishments might be lower. Stakeholders emphasised the importance of access to the outcomes of research in meaningful ways, both for the CALD individual and their community. Generating evidence will help to reinforce the value of clinical trials within CALD and research communities. This transparency and reciprocity will further enhance future trial design and promote trust.

This feedback needs to be shaped in a way that is relevant to the community, with patient stories considered a powerful tool to embed authenticity and create connection. Stakeholders emphasised that CALD people involved in the trial can take the lead to design the most effective messaging and communication pathways relevant to their community.

From a researcher's perspective, some proposed that funders should require measurement of CALD community engagement as part of the grant process, and in terms of the outcome of the grant. However, whilst acknowledging the potential value in performance measures, we note that this may result in potentially unforeseen secondary effects such as a reduced capacity to open sites in regional, rural, and remote areas or a reduced capacity to recruit in disease areas which have a high prevalence in specific ethnic populations. However, at minimum, a requirement to report on diversity in trials (even if there aren't quotas).

In general, implementation of policies that encourage the inclusion of CALD populations promise improved health outcomes for people from various ethnic backgrounds. However, consideration in implementation should also be given to issues associated with health literacy in CALD populations to ensure that clinical trial participants are adequately informed of risks, particularly those associated with the early phase clinical trials (where there are low levels of evidence regarding safety and efficacy and where most therapeutics fail to meet clinical trial endpoints).

4. Recommendations

With a growing intensity and focus on CALD inclusion both internationally and locally, and the desire to provide equity of access, improve CALD health outcomes and build Australia's ability to attract national and international clinical trials, we are at an inflection point. Stakeholders agree that system level change is needed to achieve sustainable long-term engagement, involvement, and participation of CALD people in clinical trials.

The following draft recommendations provide practical pathways and building blocks to realise a CALD inclusive clinical trial system over time. Action to implement these recommendations should drive measurable improvement in involvement of CALD people in trial design, and access through their participation in trials, together with enabling changes in the clinical trials system.

4.1 Summary of Recommendations

1. **Community led engagement and involvement.**
   - 1.1. Enable CALD communities to actively participate in early decision making around research priorities, policy, and practice.
   - 1.2. Establish communities of interest for CALD people.
   - 1.3. Explore the potential for community-based clinical trial resources.

2. **Embedding learning and building capability to support sustainable CALD inclusion.**
   - 2.1. A research workforce actively embracing diversity.
   - 2.2. Diversity integration into organisational culture and values.
   - 2.3. A network of CALD advisory groups equipped and resourced as a shared service.

3. **Strengthening a National Clinical Trial System to promote inclusion for CALD people.**
   - 3.1. Advocacy for a systems response to CALD engagement and inclusion.
   - 3.2. Collaborative development of inclusive clinical trial policy, guidance, and processes at a national level.
   - 3.3. To develop a consistent methodology and requirement for CALD data collection and measurement in clinical trials.

4.2 A systems approach to improve CALD engagement in clinical trials

The proposed model seeks to establish a set of shared resources, rather than each CTN, Coordinating Centre (CC) or industry sponsored trial needing to establish and then disband the services. The baseline infrastructure service could be set up using either a CALD specific virtual community and/or geographically located communities that will have a mix of CALD backgrounds but with local needs. There is potential to test the approach by engaging existing infrastructure and organisations, strengthening partnerships and formalising pathways for a systems approach.

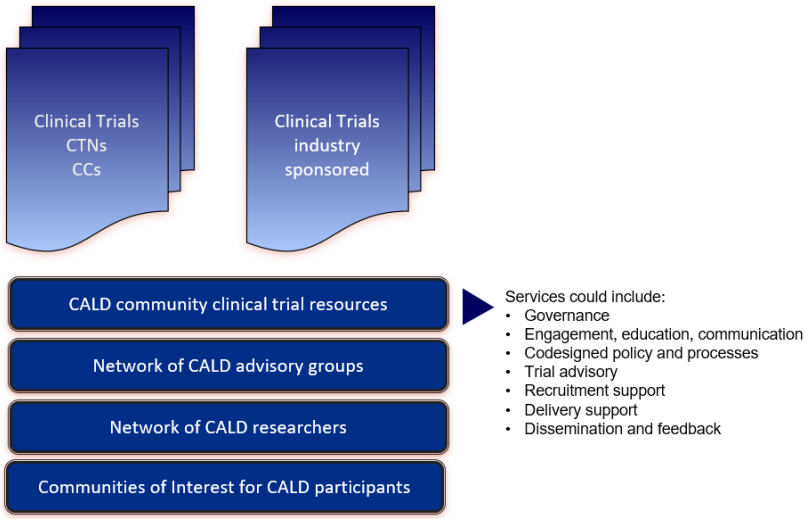


Figure 2: A shared CALD infrastructure to support clinical trials.

Selection of just a few actions from the recommendations, while creating value, risks adding to the piecemeal approach already in play. The recommendations lay out a systems approach through a set of strategies and pathways that collectively build up a cohesive CALD inclusive clinical trials system from the perspective of each of the CALD consumer, the investigator/trial team and from the funding and policy perspective where each can have a 'multi-way' positive influence on the other stakeholders within the system to support CALD engagement, involvement, and participation.

In terms of implementation, the approach should be scaffolded to optimise existing resources; work through existing organisations, use pilots, leverage learning and digital environments, to refine and scale the strategies as they are implemented.

The recommendations contained within this document do not fall solely under the purview of ACTA, but rather are a collective responsibility of various stakeholders, including the clinical trials sector, the broader Australian community, and the healthcare system.

4.3 Recommendations, actions, and outcomes

1. Community led engagement and involvement	**R1.1**	**Enable CALD communities to actively participate in decision making around research priorities, policy, and practice.** ***Actions:*** ● ACTA to collaborate with interested CALD representative organisations to undertake a study at scale to engage CALD individuals and community representatives, potentially through a national survey, focus groups or workshops. The study provides an opportunity for CALD people to collectively participate in decision making processes around research priorities, processes, or methods to enhance their engagement, involvement, and participation in clinical trials. ● ACTA would develop a report bringing CALD consumer perspectives to inform future policy, guidance, and process development within the sector. ● The Consumer Involvement and Engagement Toolkit to be updated with guidance/tools to support researchers to recruit and involve people from CALD backgrounds in their trials. ***Outcome:*** *Research is relevant to and supports CALD communities to improve their health outcomes* This information will inform strategies for creating inclusive research and practical approaches to involve and support CALD people in clinical trials. This report would complement strategic considerations regarding the burden of disease and research feasibility. Greater relevance of research may enhance CALD uptake of the opportunity to be involved and participate in clinical trials.
	R1.2	**Establish communities of interest for people from CALD backgrounds.** ***Actions:*** ● ACTA explores interest in building direct connections within and across CALD communities, which would be tested as part of the national survey (proposal 1.1 above) and more widely promoted through CALD relevant communication channels (trusted health providers, social media, apps, existing community representative organisations, Multicultural health services etc). ● ACTA seeks to partner with CALD representative organisations, such as FECCA, the peak body that represents Australians from CALD backgrounds, to foster communities of interest facilitated through an app, website, or other media, to offer the opportunity for CALD people with special interests to connect with each other. These groups could be curated by CALD consumer representatives, health, research, and communication professionals, and possibly hosted by established organisations who are known for leadership in CALD or disease specific areas. Services and information provided through the communities of interest could build up over time as defined by participants' interest. Examples of services that

		could be valuable include information on disease and clinical trials, education, seminars, workshops and videos across languages and cultures. People could also link up with others who have shared interest in personal support and advice, both with their health situation, but importantly with avenues of assistance to overcome their cultural, social, and economic barriers. ***Outcome:*** *Connection and trust between CALD communities and researchers* The communities of interest would help to link CALD people with each other to share personal stories and demonstrate the value and importance of participation in a clinical trial. It could support CALD people in their health literacy, awareness, engagement, and trust of the clinical trial process. Communities of interest would provide researchers with an opportunity to engage and inform CALD communities, building a more sustained relationship that in turn supports recruitment and enhanced equity of access to more relevant and better designed trials.
	R1.3	**Explore the potential for community-based clinical trial resources.** ***Actions:*** ● ACTA to consider national and international models on how these collaborations could inform the feasibility and design of embedded community-based clinical trial infrastructure and resources dedicated to support people of CALD backgrounds. The support would extend beyond any one clinical trial. Initially, it could seek to embed people trained in clinical trials within existing infrastructure and build on established relationships within specific communities in partnership with local trusted health care providers. ● ACTA would seek Department of Health support and partners to test the concept in a pilot site with a defined set of services. If feasible, it could be scaled to create a series of shared community based clinical trial sites, physically and/or virtually, and with an expanded service set. ***Outcome:*** *Integration of clinical trials in community settings to activate CALD involvement and participation* Efficiency generated for the clinical trial system through the use of centralised and CALD trained/ clinical trial trained resources across multiple trials, embedded within CALD communities. A model that creates a sustained relationship and builds trust of CALD people in clinical trials, with the agility to continuously improve engagement, create more tailored approaches to overcome barriers to participation, foster innovation in trial design, improve CALD enrolment and retention, and expand trial diversity.

2. Embedding learning and building capability to support sustainable CALD inclusion	**R2.1**	**A research workforce actively embracing diversity.** ***Actions:*** ● Through its members, ACTA would explore interest from researchers of CALD background in communities of practice. This would aim to enable CALD researchers to facilitate relationships within their own cultural communities and champion community led engagement activities. ● Researchers from a CALD background could support initiatives to deepen the understanding of cultural diversity within the clinical trials workforce by sharing their personal stories and experience of what works to best engage and include CALD people in clinical trials, recognising that unique approaches may be needed for different backgrounds. ● Working with CALD researchers, ACTA will bring their perspective to improve the Consumer Involvement and Engagement Toolkit, to help researchers generally to better involve and engage people from CALD backgrounds in clinical trials. ***Outcome:*** *Enhanced connection to, and understanding of CALD communities within the clinical trial workforce* Strengthened appreciation and insight among researchers of the opportunities, challenges, and importance of diversity within clinical trials and how to engage at a community and individual level with people of CALD backgrounds to support equity and access to, and participation in clinical trials in a sustainable way.
	R2.2	**Diversity integration into organisational culture and values.** *Action:* ● Clinical Trial Organisations undertake routine cultural awareness/competency training as a required professional development area for all clinical trial staff. This would be underpinned by a learning needs assessment. ● Clinical Trial Organisations are encouraged to actively recruit, train, and develop researchers from CALD backgrounds, with support and pathways for career development and leadership. ● Clinical Trial Organisations create policies and processes that promote the value of and provide supporting structures for people from CALD backgrounds within their workforce. ***Outcome:*** *Diversity within the workforce is valued and strengthens CALD inclusion in the clinical trial sector* Heightened awareness and cultural sensitivity within the clinical trial workforce and their organisations, together with the right skills and capability, will drive better engagement and involvement of CALD people in clinical trials.

	R2.3	**A network of CALD advisory groups equipped and resourced as a shared service.** ***Action:*** ● Working with the Government, ACTA explores the potential for CALD clinical trial advisory groups as a shared and appropriately resourced service for all trials. Members would be trained and developed to build CALD capacity, retain skills and knowledge within the system. ● If feasible, the CALD advisory groups could be further developed and scaled either geographically or in disease areas. ***Outcome:*** *CTN & CC access to CALD expertise delivering better outcomes and management efficiency* The CALD advisory groups would help to build capacity within the system. They could deliver advice of greater relevance, quality, and impact to engage and involve CALD communities in clinical trials, realisation of efficiencies for clinical trial management, expanding trial access and uptake, supporting consistent participation, and delivering better health outcomes for CALD individuals and communities.
3. Strengthening a National Clinical Trial System to promote inclusion for culturally and linguistically diverse people	**R3.1**	**Advocacy for a systems response to CALD engagement and inclusion.** ***Action:*** ● ACTA to advocate for CALD engagement, involvement, and participation in clinical trials, by supporting policies, initiatives and/or incentives to support CALD participation and involvement in trials, with commensurate funding. This may help ensure that as a system, an equitable stance on the inclusion of people in trials is taken. This would include CALD community groups, CTNs, Ethics Committees, TGA, funders, peak bodies, foundations, and charities, all of whom would be encouraged to adopt consistent policies, and development initiatives to foster diversity in clinical trials. ***Outcome:*** *The principle of health equity with a focus to support CALD inclusion in clinical trials is applied in policy initiatives* A shared understanding of, and commitment to, diversity in clinical trials through cross-sector collaboration. The principle of health equity whereby participants in clinical research should reflect the diversity of our society and culture, is applied to national policy and infrastructure development, in considering and promoting CALD inclusion in all aspects of the clinical trial system.
	R3.2	**Collaborative development of inclusive clinical trial policy, guidance, and processes.** ***Action:***

		• ACTA could lead a national multistakeholder workshop, to bring CALD researchers together with CALD community representatives and interested stakeholders, in a deeper dive to address specific problem areas (as informed by CALD consumers in recommendation 1.1), to improve design, broaden clinical trial criteria, and improve consent, barriers to participation and other processes as necessary to support CALD inclusion. • ACTA would develop a report to inform policy and guidance updates across the sector, including CALD specific updates to the Consumer Involvement and Engagement Toolkit. ***Outcome:*** *Removal or minimisation of policy and process barriers to CALD engagement, involvement, and participation in clinical trials* Trial design and processes that reduce or eliminate inbuilt and unforeseen disadvantage and inequity for CALD people as a clinical trial system, enhancing access and supporting participation for CALD individuals in the clinical trials, and encouraging clinical trial staff to be more inclusive in their approach to design and delivery of clinical trials.
	R3.3	**A consistent methodology and requirement for CALD data collection and measurement in clinical trials.** **Action:** • ACTA, and the sector, to support the Australian Multicultural Health Collaborative project to improve collection and reporting of multicultural data, particularly as it applies to clinical trials. • NHMRC guidance is strengthened to support CALD in trial selection criteria, study population and requirement to report CALD participation in clinical trials. ACTA will continue to advocate for this. • Trial organisations develop policy, processes, and resources to support researchers in CALD data collection and evaluation. ***Outcome:*** *Ability to track CALD engagement, involvement and participation, and their health outcome associated with clinical trials.* Agreed variables to identify people of CALD backgrounds, and greater consistency in data collection strategies utilised by researchers. This will support better measurement of CALD engagement, involvement, and participation in trials to enable target setting and monitoring of progress. It will enhance and provide evidence for the impact of clinical trials on health outcomes for people of various CALD backgrounds, improving the quality of care and treatments for the diverse Australian population. Ideally, a participatory action approach will be used to design how this data is collected, reported on, and shared with diverse audiences from policy makers to the public.

4.4 Potential indicators demonstrating the impact of these recommendations

The ACTA position statement provides the rationale and principles for a fair and just distribution of the benefits of research in Australia, while also strengthening the overall clinical research endeavour. It states that participants in research should reflect the diversity of our society and culture. The exclusion of certain population groups from research potentially denies them access to the opportunities and benefits of research, as both individuals and collectively, and contributes to inequity of access for CALD populations. [1]

In evaluating success as a system, indicators should highlight improvements from the perspectives of each of CALD people, the clinical trial workforce and their sponsor organisations, and the organisations responsible for policy development, guiding, and funding the clinical trials system. It is proposed that indicators could include:

CALD consumers.

- A shift in attitudes and improvement in the understanding and trust that people from CALD backgrounds have in clinical trials, demonstrated by their level of awareness and willingness to become involved in, and participate in trials. This can be measured via survey, and performance metrics of online engagement apps and resources (R 1.1, 1.2).
- Evidence of the numbers of people of CALD background involved and participating in clinical trials over time compared to a baseline estimate, (R 3.3).

The clinical trials workforce and their sponsor organisations.

- Evidence of regular education undertaken to culturally inform the clinical trial workforce and support them in their learning with tools and techniques, measured through course participation metrics, and participant evaluations of course content (R 2.2).
- An improvement in applied CALD engagement and involvement skills within the research workforce measured by the overall number of trials with representation of people from CALD backgrounds on advisory groups and the percentage participation of CALD people in their trials (R 2.1, 2.2, 3.3).
- The number of trial organisations with policy and processes designed to support their CALD researcher workforce in CALD leadership and in their career development (R 2.1, 2.2).
- Workforce diversity data capturing percentage of people with a CALD background (R2.2)

Organisations responsible for policy development, guiding, and funding the clinical trials system.

- Infrastructure to support partnerships with CALD communities is established with ongoing funding, promoting research and enabling CALD people in their involvement and participation in clinical trials (R 1.3, 2.3)
- Changes to trial application and assessment requirements to foster CALD involvement and participation, evidenced in strengthened policy and guidance provided to the sector (R 3.1, 3.2, 3.3)
- The number of trial organisations with policy and processes specifically designed to encourage the engagement of CALD consumers throughout the clinical trial lifecycle, including participants on advisory committees, focus groups undertaken and numbers of trials (R 3.1, 3.2).
- Longer term funding is available to involve, and support CALD participation and involvement in trials (R 1.3, 2.3, 3.1, 3.2, 3.3).
- Availability and quality of resources and support (including financial) to enhance health literacy (including in the value of clinical trials), measured against what is currently available via literature reviews, survey and performance reporting of online resources (R1.1, 1.2, 3.2).

5. Next steps

ACTA believes these recommendations will stimulate CALD engagement, involvement, and participation in clinical trials, and this is supported in the feedback provided by the sector and individuals to the draft report. It is helpful that ACTA has received detailed insights and advice from organisations and individuals within the clinical trials sector highlighting their experiences, various studies and initiatives within this space. This is highly valued and has been reflected in this final report or will inform the more detailed planning and development of the scope of work required to take forward these recommendations.

6. References

1. Australian Clinical Trials Alliance. Advancing clinical trial awareness, involvement and access for people from culturally and linguistically diverse (CALD) backgrounds: position statement. ACTA; 2020. Available from: https://clinicaltrialsalliance.org.au/wp-content/uploads/2020/10/ACTA-Clinical-trial-diversity_CALD-Position-Statement-V1.pdf

2. U.S Department of Health and Human Services Food and Drug Administration. Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry. FDA; 2020. Available from: https://www.fda.gov/media/157635/download

3. Corneli A, Hanlen-Rosado E, McKenna K, Araojo R, Corbett D, Vasisht K, Siddiqi B, Johnson T, Clark L.T, Calvert S.B. (2023). Enhancing Diversity and Inclusion in Clinical Trials January. American Society for Clinical Pharmacology & Therapeutics (ASCPT). 2023 Jan 11;113(3):489-499. Available from: https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.2819

4. Australian Clinical Trials Alliance and CT:IQ. Consumer Involvement and Engagement Toolkit. Available from: https://involvementtoolkit.clinicaltrialsalliance.org.au/toolkit/understanding/

5. Australian Clinical Trials Alliance. Clinical Trial Diversity: CALD project. ACTA; 2020. Available from: https://clinicaltrialsalliance.org.au/resource/acta-clinical-trial-awareness-and-access-amongst-culturally-and-linguistically-diverse-cald-populations-environmental-scan/

6. Australian Bureau of Statistics. Snapshot of Australia. ABS; 2021 Aug. Available from: https://www.abs.gov.au/statistics/people/people-and-communities/snapshot-australia/2021

7. Australian Institute of Health and Welfare. Reporting the health of culturally and linguistically diverse populations in Australia: An exploratory paper. AIHW; 2020 Aug. Available from: https://www.aihw.gov.au/reports/cald-australians/reporting-health-cald-populations/summary

8. Federation of Ethnic Communities' Councils of Australia. CALD Data Issues Paper. FECCA; 2020 Sep. Available from: https://fecca.org.au/if-we-dont-count-it-it-doesnt-count/

9. Australian Multicultural Health Collaborative. Our cultures, Our Languages, Our Health. AMHC; 2021 Dec. Available from: https://multiculturalhealth.org.au/wp-content/uploads/AMHC-Foundation-Document.pdf

10. U.S Department of Health and Human Services Food and Drug Administration. Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry. FDA; 2022 Apr. Available from: https://www.fda.gov/media/157635/download

11. Multi-Regional Clinical Trials. Achieving diversity, inclusion and equity in clinical research. MRCT; 2020 Aug. Available from: https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/11/2021/09/MRCT-Center-Diversity-Guidance-Document-Version-1.2.pdf

12. Trial Forge. The Include Ethnicity Framework. Available from: https://www.trialforge.org/trial-forge-centre/include/

13. Eshoo, Kelly, and Fitzpatrick Introduce Bill to Strengthen Diversity in Clinical. 2022 Feb 3. Available from: https://eshoo.house.gov/media/press-releases/eshoo-kelly-and-fitzpatrick-introduce-bill-strengthen-diversity-

clinical-trials

14. National Health and Medical Research Council and Consumer Health Forum of Australia. Statement on consumer and community involvement in health and medical research. NHMRC; 2016 Sep. Available from: https://www.nhmrc.gov.au/about-us/publications/statement-consumer-and-community-involvement-health-and-medical-research

15. National Institute for Health and Care Research. Clinical research network. NIHR. Available from: https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm

16. University of Auckland. Enhancing Aotearoa New Zealand Clinical Trials. 2022 Jul. Available from: https://cdn.auckland.ac.nz/assets/liggins/docs/HP8537%20-%20LIG_Clinical%20Trials_FINAL_v6.pdf

17. Deloitte. Enhancing clinical trial diversity. 2021 Nov. Available from: https://www2.deloitte.com/uk/en/insights/industry/life-sciences/lack-of-diversity-clinical-trials.html

18. Nemeh F, Buchbinder R, Hawley C.M, Nelson M.R, Waterkeyn J.G, Reid, C.M. Activities supporting the growth of Clinical Trial Networks in Australia. Trials Journal. 2022 Jan 28; 23(81). Available from: https://doi.org/10.1186/s13063-021-05974-3

19. Australian Teletrials Program. Available from: https://australianteletrialprogram.com.au/

20. Wild A, Kunstler B, Goodwin D, Onyala S, Zhang L, Kufi M, Salim W, Musse F, Mohideen M, Asthana M, Al-Khafaji M, Geronimo M.A, Coase D, Chew E, Micallef E, Skouteris H. Communicating COVID-19 health information to culturally and linguistically diverse communities: insights from a participatory research collaboration. Public Health Res Pract. 2021 Mar 10;31(1):3112105. Available from: https://pubmed.ncbi.nlm.nih.gov/33690789/

21. Kayrouz, R, Schofield C, Nielssen O, Karin E, Staples L, Titov N. A Review and Clinical Practice Guideline for Health Professionals Working with Indigenous and Culturally and Linguistically Diverse (CALD) Populations During COVID-19. Front. Public Health. 2021 Jun 25;9. Available from: https://www.frontiersin.org/articles/10.3389/fpubh.2021.584000/full

22. Cancer Council Victoria. Cancer, COVID-19 and You - 2022 Report. 2022. Available from: https://www.cancervic.org.au/downloads/get-support/covid-19/Cancer-COVID-You-Report.pdf

23. Federation of Ethnic Communities' Councils of Australia. Australian Mosaic. 2022 Jun. Available from: https://fecca.org.au/wp-content/uploads/2022/09/FECCA-mosaic-Issue-56-1.pdf

24. CONCERT, Ingham Institute for Applied Medical Research, NSW Multicultural Health Communication Service, South Eastern Sydney Research Collaboration Hub (SEaRCH) UNSW. Overview: Increasing participation of people from CALD backgrounds in research. 2020. Available from: https://cphce.unsw.edu.au/sites/default/files/event_file_attachments/Workshop%20Summary%20Report.pdf

25. National Academies of Sciences, Engineering, and Medicine. Recommendations for Improving Representation in Clinical Trials and Clinical Research. In: Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington, DC: The National Academies Press; 2022. p. 127-134.

26. Bodicoat D.H, Routen A.C, Willis A, Ekezie W, Gillies C, Lawson C, Yates T, Zaccardi F, Davies M.J, Khunti K. Promoting inclusion in clinical trials-a rapid review of the literature and recommendations for action. Trial. 2021 Dec 4; 22(1), 880. Available fom: https://doi.org/10.1186/s13063-021-05849-7

27. Health Equity: A framework for the epidemiology of care. 2022. Available from: https://www.mckinsey.com/industries/life-sciences/our-insights/health-equity-a-framework-for-the-epidemiology-of-care

28. UTS. Cancer clinical trial participation in the Australian Arabic-speaking community. UTS. Available from: https://www.uts.edu.au/research/impacct/cancer-symptom-trials/cst-projects/diversity-and-inclusion-cancer-clinical-trials/cancer-clinical-trial-participation-australian-arabic-speaking-community

29. National Health and Medical Research Council. What are the translation centres doing and why? NHMRC. Available from: https://www.nhmrc.gov.au/about-us/resources/what-are-translation-centres-doing-and-why

30. Melbourne Academic Centre for Health. Advanced Health Research Translation Centres. MACH. Available from: https://machaustralia.org/about-us/advanced-health-research-translation-centres/

31. Royal Society of Chemistry. Joint commitment for action on inclusion and diversity in publishing. RSC. Available from: https://www.rsc.org/new-perspectives/talent/joint-commitment-for-action-inclusion-and-diversity-in-publishing/

32. Anderst A, Conroy K, Fairbrother G, Hallam L, McPhail A, Taylor V. Engaging consumers in health research: a narrative review. Australian Health Review CSIRO Publishing. 2020; 44. 806-813. Available from: https://www.publish.csiro.au/ah/pdf/AH19202

33. Clinical Trials: Thinking Smarter (CT:IQ). Project 7 - The InFORMed Project: Redesigning Consent to Research. CT:IQ. Available from: https://ctiq.com.au/current-projects/project-7/

34. Australian Clinical Trials Alliance. Discussion Paper: integrated consent – a tiered approach to consent for comparative effectiveness trials. ACTA. 2020 Jun. Available from: https://clinicaltrialsalliance.org.au/wp-content/uploads/2021/07/ACTA-Discussion-Paper-integrated-consent-a-tiered-approach_June-2020.pdf

Australian Clinical Trials Alliance

www.clinicaltrialsalliance.org.au

Research reported in this publication was supported by the Medical Research Future Fund under grant number MRFTA000001