Australian Clinical Trials Alliance

Advancing clinical trial awareness, involvement and access for people from culturally and linguistically diverse (CALD) backgrounds: position statement

Version 1.0

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PURPOSE OF THIS DOCUMENT

This document is a position statement of equity in clinical trials developed by the Australian Clinical Trials Alliance (ACTA). This statement provides the foundational and core principles supporting the equitable and inclusive engagement of people from culturally and linguistically diverse (CALD) backgrounds in clinical trials.

ACKNOWLEDGEMENTS

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The development of this position statement was led by the ACTA Reference Group on Strengthening Consumer Engagement in Clinical Trials National, in consultation with:

- Australian and New Zealand College of Anaesthetists (ANZCA)
- CALD individuals (from diverse CALD backgrounds and communities)
- Cancer Council Victoria (representatives)
- Centre for Oncology Education and Research Translation (CONCERT), Ingham Institute for Applied Medical Research
- ClinTrial Refer
- Consumers Health Forum (CHF)
- Epworth Healthcare
- Federation of Ethnic Communities Councils of Australia (FECCA)
- McCabe Centre for Law and Cancer (representatives)
- Medicines Australia, Medical Technology Association of Australia and AusBiotech, as represented by the Research and Development Taskforce
- National Health and Medical Research Council (NHMRC)
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DISCLAIMER

DOCUMENT HISTORY

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INTRODUCTION

Australia's CALD population are significantly underrepresented in health and medical research, including clinical trials. This concerns ACTA and other key stakeholders engaged in, or supportive of, such research: consumers and consumer advocacy groups, researchers, ethics and governance systems, industry, policymakers, health professionals and funding bodies.

People from CALD backgrounds constitute a significant proportion of the Australian population. The collective term 'CALD' used in this paper includes many diverse ethnic and cultural groups within Australia, reflecting differences in language, family, and community structures. However, despite this diversity, descriptions of CALD populations are often limited to categories of people born overseas (28%) or who have at least one parent born overseas (an additional 21%), and who speak languages other than English at home (20%).[1]

While this position paper seeks to increase CALD participation in clinical trials, ACTA acknowledges the heterogeneity within and between Australia's many people from CALD backgrounds. It also recognises the intersections of ethnicity with sex, gender, age, sexual orientation, education, geographic location, and other social determinants of health.

ACTA is committed to improving clinical trial awareness, involvement, and access, with and for people from CALD backgrounds within Australia. It recognises the reciprocal benefits to both research and CALD communities that can be achieved through collaboration and partnership. Participants in research should reflect the diversity of our society and culture, and evidence generated from real-world investigator-led trials has the potential to be more generalisable and relevant for the broader Australian population, including the more vulnerable groups in need of high-quality care.

This Position Statement developed in consultation with National stakeholders as listed above describes the key principles which provide the framework for further action. ACTA's commitment is guided by an analysis of current evidence (refer to ACTA's environmental scan), and consultation with key stakeholders in Australia and internationally (refer to ACTA's National workshop report).

BACKGROUND

There are important ethical, clinical, and social reasons why the adoption of more equitable and inclusive approaches to clinical research are essential.

Ethical

- In Australia, ethical conduct in human research requires that the selection, inclusion, and exclusion of participants is just and fair.[2]
- The exclusion of certain population groups from research potentially denies them access to the opportunities and benefits of research, as both individuals and collectively.

Clinical

- 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.
- 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.
- The generalisability of research results to people from CALD backgrounds, and the translation of results into health care improvements for people from CALD backgrounds are limited if CALD people are not involved in the original research.

Social

- Failure to consider cultural diversity can limit the understanding of social barriers that can negatively impact health outcomes, treatments, and interventions.
- Research that fails to address the issues of diversity can undermine CALD communities' trust or confidence in outcomes or the research process more broadly.

There are a range of reasons contributing to the under-representation or absence of people from CALD backgrounds in clinical trials. These include:

- The routine exclusion of participants who are not proficient in English from many clinical trial protocols, as well as eligibility criteria that negatively impact on recruitment opportunities for people from CALD backgrounds.
- Culturally dominant research approaches (e.g. one size fits all) that do not actively encourage or support the inclusive participation of diverse groups and populations.
- Limited or negligible research funds allocated to strategies that would promote and enable the inclusion of diverse communities and the dissemination of the research outcomes to these populations.
- Data collection strategies utilised by researchers can be inconsistent or fail to consider and/or include pertinent variables in relation to ethnicity and cultural affiliation.

The equitable inclusion of people from CALD backgrounds in clinical trials (and health research) requires committed action by all stakeholders involved in the clinical trial lifecycle, to promote and facilitate clinical trial awareness, involvement and access.

To drive positive change, ACTA has adopted the following foundational and guiding principles. These principles are interconnected and mutually support a framework for action.

PRINCIPLES

FOUNDATIONAL PRINCIPLES

- Enhancing diversity and inclusion in clinical trials promotes a fair and just distribution of the benefits of research while also strengthening the overall clinical research endeavour.
- Respect for diversity and inclusion requires recognition of the underrepresentation of people from CALD backgrounds in clinical trials, and an active commitment to supporting and enabling the right to equitable participation.

GUIDING PRINCIPLES

1. Awareness

Recognition and obligation by key research stakeholders to build knowledge about the existence, value, and importance of (and trust in) clinical trials so that people from CALD backgrounds can ask about, or consider clinical trials, with their clinicians.

Commitment to improve health and research literacy amongst people from CALD backgrounds and to develop culturally informed research stakeholders, further achieved by communicating in ways that are accessible and appropriate for different CALD communities.

Responsibility to ensure that the promotion of research awareness to CALD communities is pro-active, continuous and sustained.

2. Involvement

Recognition of the need to increase the involvement of people from CALD backgrounds in all stages of the research cycle, including the communication of research findings to participants and public dissemination of outcomes.

Commitment by funders and all institutions conducting research to hold researchers accountable for demonstrating the involvement of CALD consumers throughout the clinical trial lifecycle.

Responsibility of key stakeholders to incorporate approaches that promote the involvement of people from CALD backgrounds, including:

- Development of long-term and sustainable partnerships.
- Co-design of research strategies and agendas that reflect CALD communities' priorities.
- Design research studies (including study materials) that are more collaborative, shared, and inclusive in their approach.

3. Access

Recognition that current practices and ethical frameworks that centre the individual in terms of autonomy and consent are culturally based concepts that may not be appropriate, applicable, or relevant to individuals from diverse cultural communities.

Commitment to develop approaches which seek to:

- Redress language and health literacy barriers, including community engagement, innovative recruitment, and consent strategies.
- Provide the resources (including financial) that are essential to support approaches that will enhance the access of people from CALD backgrounds and their communities.

Responsibility of researchers to demonstrate that their approach to research participation is equitable and inclusive, as well as justifiable and defensible on ethical grounds.

ACTA'S COMMITMENT TO ACTION

ACTA is committed to the development of a program of action, based on the stated principles of awareness, involvement, and access. In doing so, ACTA aims to drive positive outcomes for people from CALD backgrounds in relation to all aspects of clinical trials (Figure 1).

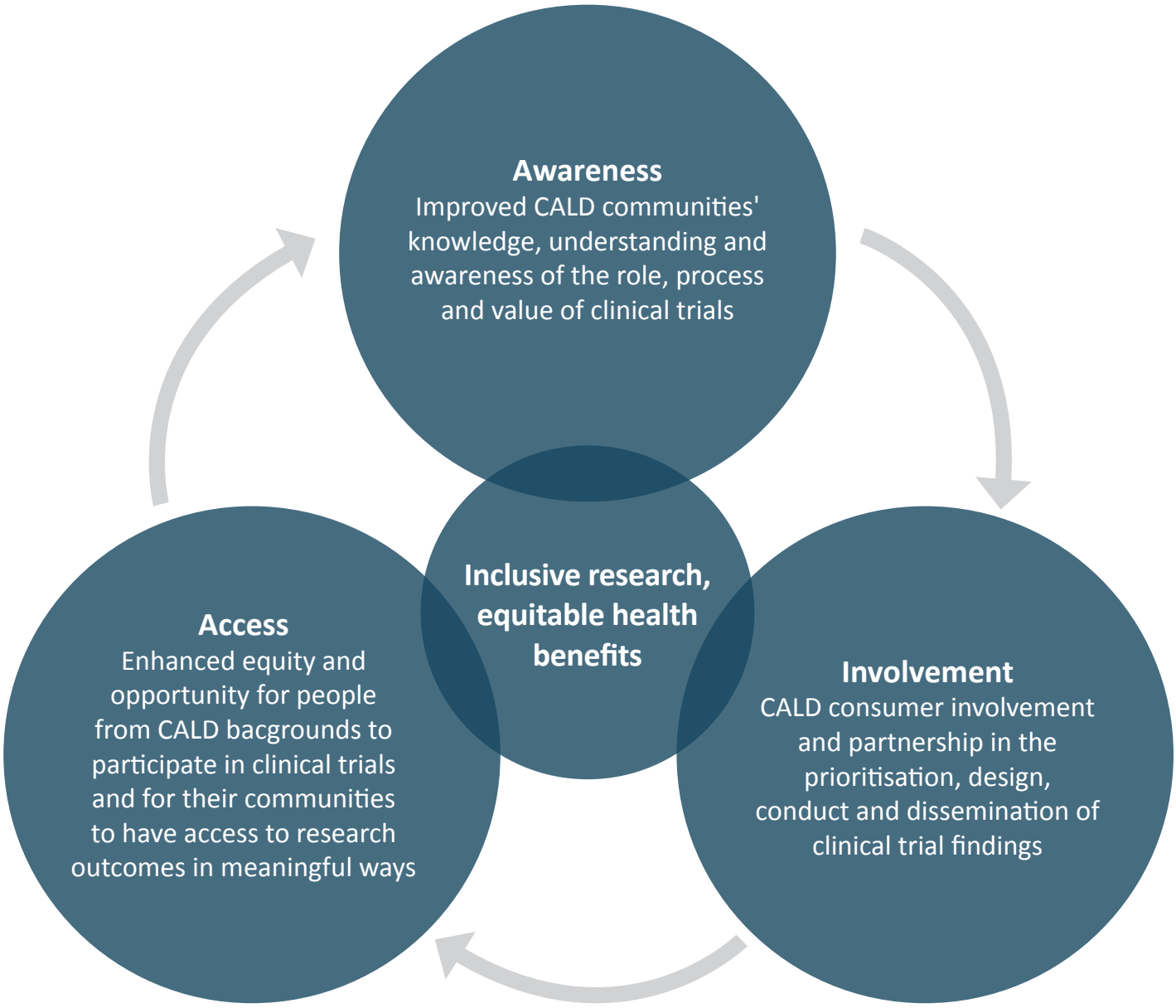

Figure 1: Principle Pillars

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