

More and better clinical trials in health care: focusing on people, not just systems and processes

Clinical trials improve care and save lives but need more clinician and consumer engagement

Clinical trials provide essential evidence for more effective and lifesaving therapies and identify ineffective and unnecessary interventions.¹

Patients taking part in clinical trials learn more about their health, play a more active role in decision making, and have better health outcomes.² Hospitals that conduct clinical trials tend to provide better care, have more rapid uptake of newer treatment strategies and technologies, and have lower mortality rates.²

Australia is a leading destination for clinical trials, with over 1000 new trials commencing each year, representing over \$1 billion in direct expenditure.³ Contributing to our success are a world-class health system, high quality research infrastructure, skilled health and research workforces, and tax incentives for research investment.^{1,3} For each dollar invested in clinical trials, estimated benefits worth \$5.80 are realised, mostly from improved patient outcomes and higher quality health care.^{1,4}

The Australian Government, in partnership with state and territory governments and other stakeholders, has introduced several reforms to increase competitiveness for clinical trial activity, including seeking to embed research as essential health system business, developing simplified and more standardised research ethics and governance systems, and making it easier to find, conduct, participate and invest in clinical research (including the National One Stop Shop and the National Clinical Trials Front Door initiatives led by the Australian Commission on Safety and Quality in Health Care).^{3,5} Substantial funding has also been committed through the Medical Research Future Fund to stimulate more clinical trial activity.⁶

Improving the infrastructure for clinical trials is important but may fail to adequately address the most consistent impediment to clinical trial success: the failure to recruit patients, with only about half of all trials achieving the target sample size.⁷ The Australian governments' collective attention to systems and infrastructure is necessary but not sufficient; it needs to be matched by a focus on the people who make clinical trials work. Too often trial recruitment planning occurs without significant input from the clinicians and the population of patients on which it depends.^{8,9}

Awareness of and participation in clinical trials among the public is low in Australia. An estimated 95 000 Australians participated in trials in 2019, representing 0.4% of the population.³ By comparison, the per capita rate is 1.5% in the United Kingdom³ and around 2% in the United States.¹⁰ Women and vulnerable and minority groups are even less likely to be recruited,^{7,8,11}



limiting generalisability of results across patient groups.¹¹ Even in oncology, which has actively attempted to address participation rates,^{8,12} only 3–5% of eligible adult patients with cancer are enrolled in trials.¹³

In Australia, successful growth in trial activity has yet to be matched by meaningful engagement of patients and clinicians. General practitioners, specialists and other health professionals have a fundamental role in guiding patient participation in clinical research. The advice of a trusted clinician is a significant factor in a patient's decision to participate.¹¹ The Australian Clinical Trials Networks include hundreds of clinician researchers who collaborate to design and conduct trials that address important clinical questions and who play an active role in promoting trials to patients.¹⁴ However, most clinicians are not affiliated with these networks and face several barriers to engaging in clinical research and clinical trials. These include insufficient time to discuss trial participation with patients and inadequate information to support those discussions, and a work culture that does not promote and support research as part of health care delivery.^{3,15} These and related issues are described in the recent Australian Academy of Health and Medical Sciences' report on integrating research into health care.¹

It has been argued that clinicians should be taught the fundamentals of clinical trials through university courses and clinical specialty and certification programs delivered by professional bodies,¹³ and the topic of clinical trials should be routinely embedded in conversations between clinicians and patients.^{7,16} Finding trials relevant to individual patients needs to be easier, along with access to succinct information about them. The Australian Clinical Trials website (www.australianclinicaltrials.gov.au), managed by the Australian Government, is intended to provide information and resources for consumers, health

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care providers, researchers and industry, but much of the information is not written in a way that is sympathetic to the needs of either patients or clinicians.^{7,16} Multiple Australian websites and online resources provide general information about clinical trials including short videos in English and other languages.¹⁷⁻¹⁹ Some have been supported by time-limited advertising campaigns, such as the “Helping our Health” campaign in Australia in 2017–18.²⁰ These communications can inform consumers but rarely integrate patients’ perspectives on clinical trials or address known concerns.⁷

Different strategies will be needed for different target groups. National initiatives that deliver sustained and consistent messages could be funded by governments. More targeted messaging would best be developed through clinical trial researchers and networks that are better connected and more able to involve specific patient groups. Patients who have never heard of clinical trials, are not interested in participating, or fear being an experimental “guinea pig” may need rudimentary information and core messages that provide reassurance about health care quality and safety during a trial.¹¹ Among minority groups, feelings of mistrust towards research and unproven interventions and a lack of accessible information can be major barriers to conversations about trial participation.²¹ Educating community leaders about research and clinical trials so that they can champion awareness and interest in culturally appropriate ways has been shown to build trust in the research process.^{7,11} Translating information in multiple languages and involving bilingual health professionals

can also support more effective communication about trials with non-English speaking patients.⁷

People who are already interested in participating in clinical trials may do so for different reasons and require differentiated communication strategies that reinforce existing perceptions. Healthy volunteers may be motivated by altruism, helping others, and contributing to fighting disease. Patients with health conditions may want to help others like them but may also be hoping for access to new treatments that have the potential to improve their health.¹¹

The current Australian governments’ investments in improving systems and processes for clinical trial activity need to be matched by investment in coordinated and sustained engagement with the people who are essential to successful clinical trials: clinicians and patients. There are working examples. The British governments have further strengthened their collective commitment to patient-focused clinical research across the UK. This includes active engagement at multiple levels with health care providers and members of the public as well as other stakeholders.²² Australian governments need a similar focus on clinician and consumer engagement. We provide examples of possible actions in the [Box](#).

Greater consumer involvement in all aspects of clinical trial design and conduct has the potential to deliver improved trial participation and ensures that clinical trials are dealing with issues and interventions that matter to patients. Consumers can help to make sure that potential participants are provided with relevant, understandable information to aid decisions about

Recommended actions to improve clinician and patient engagement in clinical trials in Australia

Actions	Led by	Supported by
Development of national coordinated, sustained marketing campaign to promote awareness of and participation in clinical trials	Australian, state and territory governments	Professional health colleges, peak clinical trial-related organisations (eg, ACTA*), peak health consumer groups
Development of educational tools and resources that: <ul style="list-style-type: none"> • normalise clinical trials as part of high quality health care for clinicians and patients; • encourage effective conversations between clinicians and patients about clinical trials; and • include options tailored for under-represented and hard-to-reach groups 	ACSQHC [†]	State and territory governments, professional health colleges, universities, peak health consumer groups
Implementation of incentives for clinicians engaging in clinical research including protected time, and CPD professional recognition	State and territory governments	Health organisations, professional health colleges
Provision of information about active clinical trials for clinicians and consumers that is accurate and up-to-date and uses accessible language, including non-English versions	Australian New Zealand Clinical Trials Register [‡]	ACTA and clinical trial networks, commercial sponsors of clinical trials, peak health consumer groups
Addition of metrics on clinician and patient engagement in existing reporting of clinical trial activity	ACSQHC, health organisations	Professional health colleges, peak health consumer groups

ACSQHC = Australian Commission on Safety and Quality in Health Care; ACTA = Australian Clinical Trials Alliance; CPD = continued professional development.
 * <https://clinicaltrialsalliance.org.au/>. † <https://www.safetyandquality.gov.au/>. ‡ <https://www.anzctr.org.au/TrialSearch.aspx>. ◆

participation in a trial. Reducing the length and complexity of clinical trial information sheets and consent forms represents an important step in this process.²³

A national, consumer-facing one stop shop could meet the needs of patients and consumers who are looking for trustworthy, reliable, and understandable information about clinical trials. The National Clinical Trials Front Door is intended to be “a public facing website that acts as a central access point to facilitate connectivity for health researchers, sponsors, industry, primary carers, allied health and the community”.⁵ This leaves out many clinicians, including hospital-based doctors and nurses, and specialists in private practice.⁵ Such a resource needs to be designed with clinicians and consumers, and needs more than “one door” to allow consumers with different languages, information needs, and interests to enter.

Even with these improvements, more is needed. Sustained marketing and education campaigns are necessary — funded by federal, state and territory governments and delivered nationally as well as locally — to raise awareness of the benefits of clinical trials and how people can get more information. Clinicians also need accessible, easy to understand information about clinical trials, and need to be incentivised to talk with their patients about them, for example, by changing job descriptions to include opportunities and time for clinical trial engagement and annual reporting of such activity, such as using existing continued professional development mechanisms.

Once patients join a clinical trial, researchers need to ensure that participants have positive experiences, and that both participants and their clinicians are well informed about the outcomes so that they become advocates for participation in the next trial. If we really want more successful clinical trials in Australia, we need more focus on the people who need to be engaged. If trials remain dominated by researcher and industry cultures and address only systems and infrastructure, we are unlikely to break the cycle of poor recruitment and less definitive outcomes.

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