National Health and Medical Research Strategy Survey

February 2025

Response to survey questions

Question 13: In considering the following list of focus areas, please indicate the top three that should be considered in developing a National Health and Medical Research Strategy? *(Answers in bold)*

- **Health and Medical Research Workforce**
- Funding across the research pipeline
- Collaboration across jurisdictions/organisations and individual researchers
- Avoiding duplication of research
- **Regional, rural and remote health**
- Burden of disease
- Data access and sharing facilitation
- Community need
- Aboriginal and/or Torres Strait Islander health
- Health inequity
- Supporting and increasing collaboration
- Early-mid career researchers
- Commercialisation and translation of research outcomes
- **Other (please specify)**

Question 14: If you Chose 'other', please specify what else you would rank in the top 3 focus areas

Quality and safety of unregistered medicines

Question 15: Please feel free to elaborate on your response to questions above

Health and Medical Research Workforce

The Health and Medical Research Workforce in clinical trials faces several challenges,

including workforce shortages, lack of specialised training, high turnover rates, and limited career development opportunities. The shortage of researchers, pharmacists, clinical trial coordinators and data managers limit the capacity of high-quality trials. As mentioned below, the lack of training in regulatory compliance for unregistered medicines further risk non-compliance with industry standards.

There is also a lack of funding and resources, making it difficult to conduct high-quality trials. Professionals often struggle to balance clinical and research roles, and there is limited collaboration between institutions. Ethical and regulatory compliance can also be inconsistent, and rural areas face gaps in trial access due to geographic disparities.

To address these challenges, solutions include investing in workforce training, create clear career pathways, increasing funding for research, promoting collaboration to share knowledge across research sites, expanding access to clinical trials in rural areas, and streamlining compliance processes.

AdPha is addressing one of these challenges by helping to create clear career pathways for pharmacists into research and clinical trials. Launched in 2019, AdPha's two-year Registrar Training Program (previously known as Advanced Training Residencies), targeted towards pharmacists with general foundation level expertise and experience in hospital practice seeking to advance their practice towards the Australian and New Zealand College of Advanced Pharmacy (ANZCAP) Registrar status in line with the *National Competency Standards Framework for Pharmacists in Australia 2016* and provide expert care and service delivery in their defined practice area such as clinical trials and research.

Through advanced training and education, the establishment of a permanent clinical trial pharmacist workforce, with positions independent of study-specific funding, should be aligned with the National Health Medical Research Strategy restructure. This would provide greater stability and continuity within the clinical trial sector, ensuring a skilled workforce is consistently available to support ongoing research efforts.

Regional, rural and remote health

Clinical trials in rural and remote Australia face several unique challenges, which can impact patient participation, research quality, and the overall success of trials. Some of the key issues include limited access to healthcare facilities, long travel distances for appointments, workforce shortages (as outlined above), and lack of awareness about available trials.

Financial barriers, especially related to travel, time away from work and accommodation, also prevent participation. These areas often lack the necessary research infrastructure and trained staff such as pharmacists and trial coordinators to manage and monitor clinical trials, leading to potential gaps in patient care and data collection.

In addition, Indigenous and culturally and linguistically diverse (CALD) populations may

experience additional cultural and linguistic barriers. While digital tools such as telehealth and remote monitoring can improve access to clinical trials, rural and remote areas may have limited access to the necessary technology or internet infrastructure to support these tools effectively. This limits the potential for remote trial management and patient monitoring. Logistical issues, such as coordinating trials and maintaining compliance and retention, further complicate the process.

To address these challenges, solutions like investment in telehealth, mobile clinics, financial support for patients, and culturally sensitive approaches are essential to improve access and participation in clinical trials for rural and remote populations.

Quality and safety of unregistered medicines

Clinical trial pharmacists are facing considerable challenges due to non-compliance with Good Manufacturing Practice (GMP) for clinical trial medications, especially for those that are not industry sponsored. Non-industry medicine sponsors and their facilities often lack the resources and expertise to fully meet GMP requirements for their investigational medicinal products (IMPs), and in Australia, the Therapeutic Goods Administration (TGA) does not assess the clinical trials' adherence to GMP for these medicines. As the TGA has a role in providing approval for clinical trials to proceed for IMPs, AdPha believes it also has a role in ensuring GMP requirements are adhered to for any IMPs used in clinical trials in Australia.

Such facilities may lack stringent quality controls, potentially resulting in IMP of unacceptable quality. Historic issues with products from such facilities have included counterfeiting, variations in potency, and microorganism or other contamination. Large and well publicised clusters of injury and death have resulted from products produced at such facilities. The current lack of standardised GMP training for the pharmacy workforce exacerbates this problem, leading to variable identification of non-compliance and limited authority to rectify these issues.

Mandatory safeguards have been established within the clinical trial governance system to ensure compliance with GMP in accordance with TGA regulations. However, currently, the guidance remains unclear and compliance is not actively evaluated. The regulatory requirements for imported IMPs are limited to notifications, such as the Clinical Trial Notification (CTN), whereby the sponsor must only notify the TGA that they are using the product, the responsibility of GMP assessment then falls to the sponsor and Human Research Ethics Committees (HREC), which may not necessarily have the requisite skills and knowledge required for assessment of an IMP.

This presents subsequent risk to public safety when GMP assessments are not completed to the highest standards. It is therefore crucial that GMP adherence be assessed as part of the approval process, alongside evaluating the feasibility and viability of organisations responsible for preparing and handling the materials before patient use.

With mainly large pharmaceutical industry sponsors equipped with the required resources

to complete GMP obligations, this further highlights the needs adequate funding for vital cutting-edge non-industry research so that local sponsors are able to conduct high quality and safe trials in Australia.

Question 16: How often should a National Health and Medical Research Strategy be reviewed?

Once every 5 years minimum.

Question 17: If you chose 'other', please specify frequency of updates

No comment.

Question 18: Please feel free to elaborate on your response to Q16 or Q17

If novel therapies emerge, stakeholder engagement should be sought within that year.

Question 19: When a draft National Health and Medical Research Strategy is released to the sector for review and feedback, what is your preferred method of consultation?

A complete document review.

Question 20: If you chose 'other', please specify preferred feedback method

No comment.

Question 21: What is the most important benefit which should be achieved through the National Health and Medical Research Strategy?

The key benefit is ensuring equitable and safe access to clinical trials for all patients across Australia, with representative samples in clinical trial populations across ethnicity, gender and age.

Question 22: Is there anything you would like to raise that is not otherwise captured by these questions?

AdPha's role in research

Formerly known as the Society of Hospital Pharmacists of Australia (SHPA), Advanced Pharmacy Australia (AdPha) is the progressive voice of Australian pharmacists and technicians, built on 80 years of hospital innovation that puts people and patients first. AdPha supports all practitioners across hospitals, transitions of care, aged care and general practice clinics to realise their full potential. We are the peak body committed to forging stronger connections in health care by extending advanced pharmacy expertise from hospitals to everywhere medicines are used.

AdPha convenes a Clinical Trials Specialty Practice stream, with over 500 members who are leaders and experts in the provision of quality and safe clinical trials pharmacy

services to clinical trial participants in Australian hospitals. Further, AdPha also convenes a Research Specialty Practice stream equally with over 500 members with an interest in research, working in a range of settings including hospitals and other healthcare settings, research organisations and universities, undertaking research in medicines use as well as pharmacy services.

Most recently, AdPha has advocated for the national approach to establish a consistent and harmonised operating environment for the approval and management of clinical trials and health-related research in Australia, through supporting the National One Stop Shop platform across Australia[1]. Recommendations, as outlined in the identified priorities above, include implementing mandatory GMP assessment of IMP in the development of the One Stop Shop HREC application platform to improve patient safety in clinical trials.

AdPha's annual publication of *Pharmacy Forecast Australia* is a strategic thought leadership piece on emerging trends and phenomena forecasted to impact pharmacy practice and the health of Australian patients in the near future. It is intended to help equip hospital pharmacy departments to proactively position themselves and their teams for potential emerging trends and focus on healthcare that may inform future research, in most recent years identifying trends in pharmacogenomics and precision medicine.

AdPha hosts an annual *Medicines Management* conference - the largest scientific pharmacy conference in Australia, showcasing member research into clinical pharmacy practice and services. AdPha is the only pharmacy organisation to publish a peer review journal – the *Journal of Pharmacy Practice and Research* (JPPR), publishing high-quality evidence to promote excellence in medicines management for better health outcomes through cutting-edge practice and research.

AdPha is involved in several federally funded and state funded research projects on pharmacy practice research areas such as transitions of care and opioid medicines use. In previous years, under the National Translational Research Collaborative (NRTC), AdPha has also awarded research grants to promote clinical pharmacy research, some of which have been pharmaceutical industry supported.

Advancing the research workforce

To support and reflect the expertise of AdPha members, AdPha's *Clinical Pharmacy Standards*[2] outline Quality Statements and Quality Elements for Prioritising Clinical Pharmacy Services relating to research such as:

- Quality statement 22: Research can improve medication safety, use of medicines, therapeutic options and the patient and other healthcare providers' experience of clinical pharmacy services.
- Quality element 2.5: Practice is evidence-informed, relevant, current, supported by best practice consensus and guides program design, communication, and collaborative research.
- Quality element 11.6: Additional dedicated pharmacy workforce resourcing is

provided for clinical pharmacy management, medicines governance, research, and training and education relevant to the scope and size of the clinical pharmacy service.

AdPha has also developed a *Standard of Practice in Clinical Trials for Pharmacy Services*[3] which describes best practice for the provision of clinical trials pharmacy services by clinical trials pharmacists, technicians and the pharmacy department or employer. It relates to the management of both the investigational products used in clinical trials and the facilities required for a clinical trials pharmacy services, in order to align with the principles of Good Clinical Practice (GCP).

Pharmacists provide expert medicines knowledge, therefore interprofessional collaboration is essential for successful research into clinical practice and therapeutics, as outlined in AdPha's *Clinical Pharmacy Standards*[1].

Workforce capacity for research

The public sector conducts the majority of clinical trials in Australia. However, without redesigning the public sector clinical trial workforce model and investing in readily available digital tools to enhance productivity and the quality of trial conduct, Australia risks becoming a less attractive option for employees compared to competitor countries like the UK and South Korea, which are shaping their national clinical trial strategies around these initiatives.

Pressures on healthcare funding and shortages in the pharmacy workforce are limiting the capacity for research, making it more difficult to support and advance clinical trials and other critical studies. As many pharmacists may participate in research as part of their broader clinical or academic responsibilities, it can make it challenging to determine the precise number involved in research activities. In 2019, just 1% of registered pharmacists identified research as their principal role.[4]

Workforce shortages in this highly skilled area can lead to increased workloads for existing pharmacists, potentially affecting their capacity to participate in or support clinical research activities.

The research ecosystem should encourage and facilitate collaboration across jurisdictions and sites, utilising multi-site research models. The COVID-19 pandemic has demonstrated that such collaboration, including the sharing of information and data, is feasible. However, to ensure the success of collaborative multi-site research, dedicated funding is essential.

Addressing these challenges is crucial to ensure that Australia's healthcare system can continue to support and advance research efforts effectively.

References

[1] Advanced Pharmacy Australia. (2024). National One Stop Shop Phase III consultation. Available at: https://adpha.au/publicassets/14d22b0b-d8e0-ee11-9134-00505696223b/Summary-of-SHPA-views-on-National-One-Stop-Shop-Phase-III-consultation--March-2024.pdf
[2] Dooley, M., Bennett, G., Clayson-Fisher, T., Hill, C., Lam, N., Marotti, S., O'Hara, K., Potts, C., Shum, B., Tong, E., Trevillian, S., Sharp-Paul, N., Newman, S. and Mellor, Y. (2024), Advanced Pharmacy Australia Clinical Pharmacy Standards. J Pharm Pract Res, 54: 446-511. https://doi.org/10.1002/jppr.1959
[3] Slobodian P, Challen J, Ching M, Hong E, Nikolajevic-Sarunac J, Shum B, Vosk C, Munro C. Standard of practice in clinical trials for pharmacy services. J Pharm Pract Res 2020; 50: 429-44. https://doi.org/10.1002/jppr.1676
[4] Australian Government. Department of Health. (2019). Pharmacist Workforce. Available at: https://hwd.health.gov.au/resources/publications/factsheet-alld-pharmacists-2019.pdf