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Ensuring the quality use of medicines in clinical trials: A review and perspective on optimising the role of pharmacists

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ABSTRACT

Objectives: Given that a most clinical trials investigate potential or established medicines, it should be obvious that pharmacists, as '*medicines experts*', would play a key role in such. The aim of this article was to narrate a perspective on the role of the pharmacist in clinical trials, drawing out the way that pharmacists are currently represented within clinical trials guidance documents.

Methods: This narrated review and perspective explored relevant international literature relating to clinical trial governance, particularly from the Australian setting where such documents have been recently developed and/or revised, providing a contemporary representation.

Results: Clinical trial guidance documents describing the role of pharmacists show that quality use of medicines principles are not well applied to the trial context. As such, pharmacists are underutilised in their role as medicines experts and as clinicians supporting optimal medicines use along the medication management pathway. Presently, guidance documents portray pharmacists as having largely administrative roles, focused on compliance with trial protocols, policies and legislation. Any clinical role appears relatively limited to drug handling. There is a need for capacity building in clinical trial to better recognise and utilise pharmacists' expertise, including them in the design, conduct, and leadership of clinical trials.

Conclusions: There is both scope and need to more directly include pharmacists in clinical trials. Wherever medicines are used, a pharmacist should be present and/or substantively involved in assuring the quality use of medicines, including within the full range of clinical trials. To support pharmacists, part of the global investment into clinical research should include an investment into clinical pharmacy services to ensure the quality use of medicines throughout the trial process alongside effective translation into clinical practice.

1. Introduction

Clinical trials are vital to the advancement of therapeutics and health care. As per the World Health Organisation's (WHO) definition, a clinical trial is *"any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc"*. In approximately half of all clinical trials, the intervention is a drug, i.e., a pharmacological compound, intended for use as a medicine (medication) to prevent, cure, or treat a specified health condition.[1,2]

Given that a large proportion of clinical trials investigate potential or established medicines, it should be obvious that pharmacists, defined as '*medicines experts*' - commensurate with their specialised education, training, and competency[3] - would play a key role in such. Calls to recognise pharmacists' value and role in clinical trials have been present for years.[4] In clinical practice broadly, pharmacists maintain key roles in the appropriate and optimal use of medicines, including the supply of medicines, patient-level activities, clinical governance, and education and training.[5] As experts, pharmacists provide medication management services built around a partnership between the pharmacist, patient (or caregiver), physician/clinician and others in a patient's health care

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team.[6] Pharmacist-led services ensure that medicines are used appropriately and optimally to effectively and safely achieve targeted therapeutic outcomes.[6] Therefore, it should be expected that pharmacists are *"embedded wherever medicines are used – from the point of prescribing, through to supply and administration, and monitoring health outcomes"*.[5] In most countries, the custodians of medicines and stewards of the quality use of medicines are pharmacists.

The pharmacist's role in the quality use of medicine (QUM)[7–9] has been well documented, with robust evidence of their impact, including on medication safety, treatment adherence and cost-savings to the health system.[10] The value of pharmacists in health care has been particularly highlighted in the response to the COVID-19 pandemic.[11] Pharmacists impact on medication safety is particularly notable, reducing medication-linked harms – including death – caused by adverse drug events and medication misadventure. For this reason, pharmacists have been charged with stewardship of medication safety, especially in countries such as Australia where medicines safety has been recognised as a national health priority. Medication safety is a primary focus of clinical trials investigating new and relatively unknown therapeutic compounds, often drawing and depending on core pharmacological and pharmaceutical principles to anticipate potential risks and inform study protocols and procedures – this expert knowledge is within the domain of pharmacists.[12]

Roadmaps have been designed to help coordinate and streamline the complexities of conducting clinical trials, and have sought to identify the people, departments, and the processes involved. Yet, in the context of clinical trials, the pharmacist is seldom recognised as the medicines expert with a core role in the quality use of investigational products. Observations of practice, anecdotal evidence, and descriptors of clinical trials practice indicate that pharmacists are engaged in the conduct of trials in a relatively limited way within their scope of practice, utilising only a fraction of their clinical expertise. Even in the context of medication safety within clinical trials, the focus is largely limited to risks relating to protocol complexity, medication ordering, and processes for packaging, storage, and dispensing investigational medications.[13–19]

Whilst there is some diversity in practice across countries and clinical settings in terms of the role of the pharmacist within clinical trials, including any distinctions in approaches to supporting sponsored drug trials versus investigator-initiated trials, the broader underutilisation of the pharmacist's practice is reinforced by the limited research and reporting in this context. A structured database (Medline, Embase, Allied and Complementary Medicine) search of the literature over the past decade (January 2015 to August 2025), using the search terms *"clinical trials", "clinical research", "pharmacist", "pharmacy", "pharmacy practice"* and *"role"* in the databases, yields only 24 articles (including 5 commentaries), with the majority 79 % (19/24) focused on 'medication handling' processes and related costs/workload: 2 audited the types of products dispensed and prepared (± associated costs)[20,21]; 6 audited the range of activities performed in a clinical trials unit[20,22–26]; 3 reported the development of scoring tools to assess clinical trial complexity and/or process improvements to create efficiencies and guide workload[27–29]; 1 reported on the costs of investigator-initiated trials as relevant to pharmacy services[30]; 1 commented on updates in technology and regulatory requirements[31]; 1 commented on the role of clinical trials pharmacy in advancing safe medical research[32]; 1 commented on the European regulations around clinical trials of medicinal products and specified role of pharmacies[33]; 1 commented on the role of the pharmacist in reducing errors relating largely to medication ordering, supply, packaging and dispensing[34]; and 1 commented on the role of clinical pharmacy in decentralised trials.[35] These 24 articles included some limited attention to the role of pharmacy technicians: 1 article described the potential role of the pharmacy technician in clinical trials[36] and 1 other described the development of a clinical trials training program for pharmacy technicians and other community health workers.[37] Only 21 % (5/24) of articles explored more clinically-oriented roles to any extent: 2 reported on the experience of

Table 1
Descriptors of 'pharmacy' and 'pharmacist' within a clinical trial governance framework.

Term	Section in Framework	Context
"Pharmaceutical"	Introduction	The International Conference on Harmonisation of Technical Requirements for **Pharmaceuticals** for Human Use (ICH)3, European Committee for Standardisation and the International Organization for Standardization (ISO) provide standards of conduct for clinical trials (and clinical investigations) which are the basis for regulation across most regions under the remit of the major regulatory agencies world-wide.
	Glossary (table) *Investigational product*	The Investigational Product (IP) includes any product, or intervention being investigated, tested or used as a placebo or reference point in a clinical trial. This includes a **pharmaceutical form** of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
"Pharmacy"	Glossary (table) *Health service organisation*	A separately constituted health service that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body. A service unit involves a group of clinicians and others working in a systematic way to deliver health care to patients. It can be in any location or setting, **including pharmacies**, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms.
"Pharmacist"	Clinical Leadership – Action 1.6 Bullet under *examples of evidence*	Employment documents that describe the roles and functions of clinical leaders who undertake roles and functions such as: trial investigators, trial coordinators, trial managers **and/or clinical trial pharmacists**
	Safety and Quality Training – Action 1.20 *GCP training for trial investigators and their clinical trial teams*	The clinical trial team includes individuals, identified by the investigator on the site staff personal log, and may be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator, **and/or clinical trial pharmacist**
	Appendix 1: Roles and functions of identified positions *Clinical Trial Site Staff*	Clinical trial site staff includes, but are not limited to the following: • Principal investigators and co-investigators • Study coordinators/clinical trial coordinators/trial nurse/ **clinical trial pharmacists.**
	Glossary (table) *Clinical trial team*	The clinical trial team includes individuals, identified by the

(*continued on next page*)

Table 1 (*continued*)

Term	Section in Framework	Context
		investigator, who are responsible for study coordination, data collection and data management. Members of the clinical trial team may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator**, clinical trial pharmacist** and may have various roles in the clinical trial
	Glossary (table) *Clinical trial workforce*	The clinical workforce includes, but is not limited to: trial investigators, trial sub-investigators, **clinical trial pharmacists**, trial managers, trial coordinators HREC executive officers, research officers, research office staff.
"Pharmacologist"	Appendix 1: Roles and functions of identified positions Clinical Trial Site Staff *Sponsors and contract research organisations*	For example, when designing a trial, the principles of Good Clinical Practice requires trial sponsors to use a multi-disciplinary team of qualified individuals (for example, biostatisticians, **clinical pharmacologists**, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and case report forms to analysing and preparing interim and final clinical trial reports.

Reference document: National Clinical Trials Governance Framework (NCTGF) (11).

integrating a pharmacist into patient-care activities within specific clinical trials or units[38,39]; 1 reported on the role of the pharmacist in detecting medication errors in clinical trials[40]; 1 assessed medication lists to identify the potential role of pharmacists for the purpose of medication reconciliation within clinical trials[41]; and 1 surveyed secondary care pharmacists about the perceived benefits and barriers to developing their role in regard to facilitating patient participation (e.g., recruitment) in clinical trials.[42] This limited range of articles originated from a range of countries, most commonly within the European and North American continents. None of the articles originated in Australia, despite the country's increased drive from both public and private sectors for increased clinical trial activity.

Noting this apparent underutilisation, the aim of this article is to narrate a perspective on the broader clinical role of the pharmacist in clinical trials, by drawing out the way that pharmacists are currently underutilised and/or represented within clinical trials guidance documents. It also highlights the potential opportunities for pharmacists to facilitate the quality use of medicines in this clinical context. Accordingly, this commentary is presented in two parts, focused on: a) clinical trial guidance documents on the role of pharmacists and b) utilising Pharmacists to facilitate the quality use of medicines in clinical trials. Given the scarcity of research publications on this topic, a systematic review was not feasible. Instead, this narrated perspective draws on relevant international literature relating to clinical trial governance, whilst using the Australian context as a particular example of where opportunity for a greater clinical role in trials exists and where supporting documents have been recently developed and/or revised, providing a contemporary representation of practice. The goal of this article is to motivate a greater focus, as well as research and action, on clinical pharmacy practice in clinical trials.

1.1. Clinical trial guidance documents on the role of pharmacists

Comprehensive guidance documents have been developed over the years to support the conduct of clinical trials, helping those involved to navigate the complexity of clinical, research, ethical, and regulatory processes and standards that guide and govern clinical trials globally.[43] Within each country, these guidance documents are further operationalised for local implementation, taking into account jurisdictional requirements, and workforce structure. In Australia, for example, the National Clinical Trials Governance Framework (NCTGF) was implemented in 2022, aiming to "*embed clinical trials into routine health service provision and strengthen the clinical and corporate governance arrangements for governments, hospital administrators, health services, private companies, trial* sponsors *and trial investigators*".[44] This detailed governance framework also outlines the "*roles and functions for identified positions relating to clinical trial service provision within a health service organisation*". However, the role of the pharmacist is sparsely considered.

A word search through this document reveals a sporadic acknowledgement of pharmacists, without any reference of the pharmacist's specific expertise (Table 1). "Pharmacists" are mentioned only 5 times, noting that 3 of these citations are in the Appendix and Glossary. For both mentions of the "pharmacist" within the main document, the term is listed last in a list of team members and preceded by "and/or", suggesting that the inclusion of a pharmacist is somewhat optional. In contrast, the term "clinician" is used 54 times and "nurse" 7 times, both being particularly associated with 'leadership' and 'clinical' role descriptors. In the glossary, the term "clinician" is accompanied by the following definition: "*A clinician is a healthcare provider, trained as a health professional, including registered and non-registered practitioners. Clinicians may provide care within a health service organisation as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. They include nurses, midwives, medical practitioners, allied health practitioners, technicians, scientists and other clinicians who provide health care and students who provide health care under supervision*". There is no explicit mention of the pharmacist here.

Although, the document glossary mentions pharmacists as potentially being *part of* the clinical trial 'team', the relevant roles that may pertain to them appear to be largely administrative and focused on compliance with protocols, policies, and legislation:

- *Study coordination and data collection*
- *Participant recruitment and enrolment*
- *Obtaining consent from prospective participants*
- *Undertaking study visits with research participants, and collect and record information from research participants*
- *Maintain consistent trial conduct*
- *Handling specimens*
- *Data management*
- *Dispensing and administering the investigational product*
- *Compliance with regulatory and reporting requirements.*

Whilst the governance framework is an incredibly helpful document and has been instrumental in streamlining and supporting local processes in Australia, it is only one example of similar documents in which the pharmacist is seemingly regarded as an ancillary, replaceable or optional member of the clinical trial team, with no specific expertise. The "pharma" link between the investigational pharmaceutical product and the pharmacist seems to have been missed, excluding them as critical and qualified members of a multi-disciplinary team that should be engaged "*throughout all stages of the trial process, from designing the protocol and case report forms to analysing and preparing interim and final clinical trial reports*".

One might postulate that documents principally written by non-pharmacists may reflect a lack of insight and understanding of the pharmacist's specific expertise. However, guidance documents written by pharmacists themselves also tend to downplay the pharmacist's expertise. Staying within the Australian context, the Society of Hospital Pharmacists of Australia (newly renamed Advanced Pharmacy Australia - AdPha) has published a standard of practice in clinical trials for

Table 2
Descriptions of selected minimum service requirements for clinical trials pharmacists, extracted from published Standard of Practice.

Under the section titled "Clinical Trial Participant Care":
Clinical Trial Participant Education The clinical trials pharmacist needs to work closely with the clinical trial team to ensure that education for the participant, regarding investigational products, is adequate and appropriate. The participant will have been given written information, by the investigator, during the informed consent process. However, supplementary education by the clinical trials pharmacist is considered the best practice to ensure protocol compliance and safe and appropriate use of investigational products. An information leaflet may be used to assist this process and verbal education should reinforce written information. Information leaflets provided to participants will require HREC and sponsor approval.
Monitoring Compliance Ensuring participant compliance and monitoring compliance are vital in clinical trials. To promote and monitor compliance clinical trials pharmacists should: • ensure participants understand the education given and the importance of investigational product compliance • check that each participant is following instructions for the correct use of the investigational product, at intervals specified by protocol/sponsor requirements • counsel participants to return all investigational product at each visit • ensure that records are kept for returns of used and unused supplies and/or packaging, as required by the sponsor • notify the study staff if a participant has not adhered to the protocol or sponsor requirements • attempt to recover all investigational products from participants at the end of each treatment period.

Extracted from: P. Slobodian et al. Standard of practice in clinical trials for pharmacy services[45]

pharmacy services.[45] This written standard is "*intended for both pharmacists involved in clinical trial services and pharmacists whose area of specialisation is clinical trial services and for consistency refers to both as 'clinical trials pharmacists' …* ", and acknowledges that a "*clinical trial team includes doctors, nurses and pharmacists in addition to other health care professionals, social workers, biostatisticians and trial coordinators and monitors*". It importantly highlights that "*Pharmacists are essential to clinical trials, not only to meet regulatory requirements related to the possession, dispensing and supply of investigational products but also to ensure the safe and ethical use of investigational products*" and that "*Clinical trials pharmacists must provide the service as part of multidisciplinary collaboration and within the framework of evidence-based and patient-centred healthcare, in order to deliver optimal care to participants*".

However, in defining the minimum and additional services required for a clinical trials pharmacy as part of this standard of practice,[45] the major focus is on the handling of medicines (dispensing, storage, supply) and regulatory processes related to this; far less relates to using the pharmacist's unique expertise in QUM. Among the 8 'minimum services' listed, only 2 are QUM-focused, that being 'patient counselling' (coupled with health professional education) and 'monitoring of participant compliance' (taken to mean participants' adherence or persistence to the investigational product being trialled). Within each of these, the descriptions provided suggest that pharmacists assume an adjunct role rather than a lead role (Table 2). Among the 14 'additional' services listed, '*adverse event reporting*' and '*therapeutic drug monitoring*' would most directly align to QUM activities. Other pharmaceutical expertise is recognised via services described as "*involvement in compounding or manufacturing investigational products*" and "*preparation of placebos and special dosage forms*". Similar service activities are outlined in the UK's Royal Pharmaceutical Society's (RPharmS) National Pharmacy Clinical Trials Advisory Group's *'Professional Guidance on Pharmacy Services for Clinical Trials'*.[46]

Of course, the services listed within standards of practice, such as this example, are all appropriate and important activities in supporting clinical trials, and to ensuring robustness and quality. One can argue that all of the administrative or technical activities/services (e.g., procedures regarding compliance with protocols, blinding/unblinding procedures, randomisation codes) also contribute to QUM and are

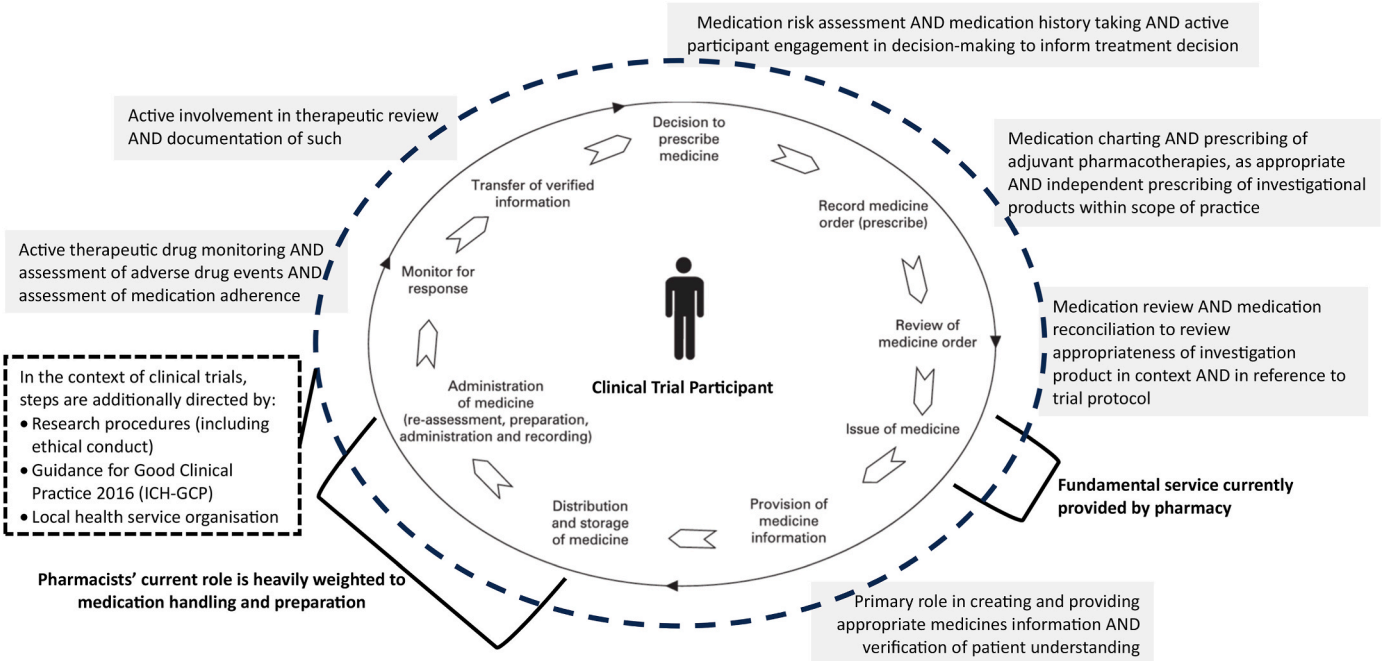

Fig. 1. The role of the clinical trials pharmacist along the medicines management pathway (MMP).
Adapted with permission from Stowasser et al. Understanding the Medicines Management Pathway, JPPR 2004[48].

within the pharmacist's scope of practice as custodians of medicines. However, they appear to portray pharmacists more as providers of adjuvant, and somewhat optional, services in clinical trials. In being medicines experts, we would expect pharmacists to be necessary and core members, acting as stewards for QUM, within a multidisciplinary clinical trials team.

1.2. Utilising pharmacists to facilitate the quality use of medicines in clinical trials

Globally, there is much focus on building and increasing sustained capacity for conducting clinical trials, as highlighted by the World Health Assembly (2022) and the WHO's Global Clinical Trials Forum (2023),[47] to ensure responsiveness to emerging health needs alongside increasing access to efficacious medicines for the world's population. To this end, the consensus vision is for clinical trials to be integrated into, and sustained within, all health systems as part of core clinical care. The term "*trials as therapy*" – coined decades ago - has gained increasing momentum, referring to increased accessibility to trial participation and increased community awareness, albeit with appropriate precautions to navigate therapeutic misconceptions.[15] In building this capacity within core clinical care, there must be better recognition and utilisation of pharmacists.

The pharmacist's application of QUM in the context of clinical trials can be visualised via the medicines management pathway (MMP).[48] The MMP outlines the core patient (person)-centred cognitive and physical steps in the management of any pharmacotherapy – these steps do not differentiate approved/marketed products from investigational products under trial. In the context of clinical trials, these steps are additionally governed by standards and frameworks that integrate research processes with clinical practice (Fig. 1). Bringing clinical trials into core clinical practice means placing the MMP at the centre of trial protocols and optimally utilising pharmacists within it. Engaging pharmacists at each step, and from the outset in clinical trial planning, also assists in the translation of trial outcomes to practice, where pharmacists can advise on the realistic application and use of these medicines, taking into account real world prescribing, dispensing, counselling, monitoring, adherence, access to medication support services, and common drug-related problems. In particular, they have a direct understanding of the diverse populations (often vastly different to clinical trial samples, historically) in which medicines are used and how ethnocultural factors, socioeconomic factors, cognitive and functional capacity, healthcare access, health complexity, and polypharmacy, may impact trial participation, medication use, and health outcomes. The importance of medication adherence in the context of clinical trials has been recognised (15). However, clinical trial protocols are rarely framed in terms of QUM principles and rarely explicitly consider the full range of steps along the MMP.

Beyond medication management, pharmacists provide comprehensive medication review services,[14,18,49] within primary (community), secondary (clinic) and tertiary level (hospital) care. Within such services, the pharmacist is presently limited to making therapeutic recommendations that are published in evidence-based or consensus-based clinical guidelines. But what if the pharmacist had the ability to identify potential therapeutic options beyond the published guidelines for those patients who have failed guideline treatments, identifying and flagging potential clinical trial opportunities? Whilst therapeutic benefit from trials is not guaranteed, such an approach would – as a minimum – increase access to, and equity within, clinical trials for a broader range of persons, arguably those most in need, within the community setting. This is also important in the context of an expanding range of therapeutic products and pharmacological approaches (e.g., advanced therapeutics, gene therapies) which largely originated in the haematology and oncology fields but which now have a broader range of clinical indications, extending to the management of other chronic diseases and health priority areas. Within the hospital setting, having all pharmacists aware of existing clinical trial opportunities within their therapeutic area, not just dedicated pharmacists in clinical trial units, would similarly improve access. In both settings, pharmacists would be able to screen for clinical appropriateness and support patients with medicines information and medication management support.

In considering these steps and scenarios, two aspects around the conduct of clinical trials become more apparent – that is, the role of pharmacists in the design of clinical trial protocols (including relevant information and resources), particularly for investigator-initiated studies, and their role as clinical trial/site investigators in either investigator-initiated or sponsored drug trials. To ensure the quality use of medicines within a clinical trial, pharmacists should be engaged from the outset, that is, at the conception of a trial about an investigational drug. Whilst some pharmacists have appointments on institutional review boards, research ethics committees or other hospital committees that approve clinical trial conduct, or Data and Safety Monitoring Boards for trials in progress, their roles are largely focused on reviewing study protocols at the tail-end of the process (often, after an institution has already agreed to serve as a study site) or ensuring compliance with approved trial protocols (where a trial is already underway), rather than at trial conception/design and/or initial institutional decision-making. Engagement in trial design should include both community and hospital pharmacists, as appropriate to the setting where the therapeutic agent is intended to be trialled and/or ultimately used in practice. Involving pharmacists would ensure that trial protocols maintain patient-centricity (during conduct and for future translation) and deliver on all of the quality care steps and pharmaceutical care that is expected, and mandated by laws and professional practice standards, in the use of any other pharmacotherapy. This includes drawing on the pharmacist's medicines expertise to help devise and support: participant screening processes that are inclusive of the medication history, medication safety risk assessments, (drawing on pharmaceutical and pharmacological – pharmacodynamic and pharmacokinetic – knowledge), design of clinically-relevant comparator products and/or identical placebos, medication management support, medication adherence assessments, therapeutic monitoring protocols, and medicines information resources. Observations of current practice is that pharmacists are often engaged last in the trial process, once all other organisational and research processes have commenced (and often completed), and only to advise on the costs of medication handling procedures. In more recent times, there has been some additional consultation around the feasibility of storage, handling and preparation of more advanced therapeutics (e.g., biological compounds), and future thinking around the handling of potential gene therapies. This involvement in trial protocols might also extend beyond drug trials; in non-drug trials, the intervention efficacy may be affected by the concurrent use of pharmacotherapy by the patient as part of their background medication history – information that is not routinely collected in non-pharmacotherapeutic interventions. Further, among health interventions, pharmacotherapies may be used as pre- or post-intervention therapies, for example, analgesics, antithrombotics, antimicrobials – all areas of stewardship for pharmacists. Other health professionals often do not fully understand the pharmacological nuances between and within classes of medication, nor how these properties may confound trial findings.

Unfortunately, failure to engage pharmacists at the start of trial conception has, at times, meant that trials have been unable to proceed due to lack of planning around specific pharmaceutical needs and medication safety concerns, or trial findings have been relatively limited in their usability and translatability. This issue has been recognised in some settings, for example, in the United Kingdom where a Chemotherapy and Pharmacy Advisory Service was established by the UK National Cancer Research Network to optimise the so-called pharmacy-related content in clinical cancer research protocols. An evaluation of this service showed that the majority of recommendations made per protocol (mainly concerning drug regimen, support medication, frequency and type of monitoring, drug supply) were deemed clinically

BOX 1
Recommended approaches for optimising the role of pharmacists in clinical trials

- ☐ Inclusion of Clinical Pharmacists in clinical trial teams as core members and investigators
- ☐ Consultation with Clinical Pharmacists in the design of clinical trial protocols, supporting materials (e.g., investigational product information), medication management processes, and therapeutic monitoring (including medication adherence) from the time of initial conceptualisation
- ☐ Enablement of Clinical Pharmacists to lead clinical drug trials within their scope of practice and expertise
- ☐ Direct engagement between trialists and Pharmacists in both community and hospital sectors, and those providing comprehensive medication review services, regarding active clinical trial opportunities for their clients and patients
- ☐ Referral to, and engagement of, pharmacy services to optimally support medication management in clinical trial participants
- ☐ Optimally using Clinical Pharmacists in counselling trial participants regarding investigational products and supporting patient-centred decision-making
- ☐ Enlisting pharmacists in the education and training of clinical trial staff regarding investigational product characteristics, including pharmacological, pharmaceutical, and therapeutic features.

relevant with a high acceptance rate.[50] Such review by pharmacists of clinical trial protocols is feasible, exposing undetected but clinically relevant issues that could hinder efficient and safe trial conduct. Establishing a national or international panel for consultation at the protocol design phase would provide a much-needed 'pharmacy' voice.

There is also an important role for pharmacists as clinical trial investigators, whether in investigator-initiated studies or as part of local trial site teams in sponsored studies. At the first level, pharmacists should necessarily be part of each clinical trial investigator team, as co-investigators or associate investigators, wherever any investigational drug is being trialled. This is critically important to the optimal utilisation of pharmacists' medicines expertise and application at all stages of clinical trial design and conduct – it is inadequate to engage 'pharmacy' – as is often the term used in clinical trials documents – simply as an adjunct service provider in the final stages. This is important given that clinical trial teams and protocols very often include non-clinical staff, such as data managers and statisticians, as co-investigators from trial conception. It, therefore, seems somewhat remiss to not include pharmacists in drug trial teams.

Second, pharmacists are clinical health professionals in their own right, providing clinical care and specialist consultation within their scope of practice in relation to the most ubiquitous health intervention of all – pharmacotherapy. Globally, in certain jurisdictions, pharmacists are also prescribers of pharmacotherapy. In this regard, pharmacists should be enabled to identify gaps in care that may be addressed through clinical trials and, in doing so, authorised to take a lead role as chief investigator. Whilst some clinical academic pharmacists are engaged in trials where interventions to support medicines use are investigated, with significant impact on health outcomes and changes to clinical practice,[17,19,51] few pharmacists are involved as leads in investigational drug trials across any trial phase (e.g., early phase to late phase clinical trials), as highlighted by pharmacists from the Mayo Clinic in the USA.[16] There is a need to explore the potential for pharmacists to lead clinical trials, including initiating studies of their own endeavour and design, to identify new approaches to pharmacotherapy and/or pharmaceutical services for specific patient groups or diseases, reflecting the evolving scope of pharmacy practice and its alignment with research leadership.

Further, there needs to be acknowledgement that most clinical trials investigate medicines that are intended for use in the primary care setting whereas most trials have traditionally been conducted from hospital-based clinical trial units. To this end, hospital pharmacists have maintained the primary responsibility and roles in supporting clinical trials, as also recognised by the European Association for Hospital Pharmacists.[13] However, with increasing use of virtual, remote, and telehealth trials to enable geographical outreach to communities, it seems obvious that community-based, primary care pharmacists take a more prominent role. Whilst community pharmacists are often engaged as trial participants when investigating the delivery of health interventions, they are seldom engaged as clinical trial service providers letalone as trial investigators. Clinical trials need to more directly engage those involved in facilitating the quality use of medicines at the point-of-care, including community pharmacists. Of course, this must come with appropriate supports, training, and remuneration as would be expected for hospital-based trialists and related services. This commentary does not seek to propose specifically how these functions, services, roles and relevant support frameworks (training, remuneration) are delegated, practically performed and implemented – this would require local consultation following implementation science co-design approaches. In the first step, we need to articulate the nature/scope of these roles; a more detailed discussion or critical analysis around infrastructure, training, and remuneration should then follow. This commentary makes a case for the need and opportunity for pharmacists to have greater roles in the clinical trials context, aligned to their expertise and within their scope of practice. Further, these considerations would necessarily take into account the important role of pharmacy technicians, not only in supporting clinical trial functions[36] but also in enabling the advancement of the pharmacist's role in clinical trials.

2. Conclusion & recommendation

There is both scope and need to more directly include pharmacists in the design, conduct, and leadership of clinical trials, with a number of core recommendations for their evolving role, drawing on their specific expertise (Box 1). Wherever medicines are used, a pharmacist should be present and/or substantively involved in assuring the quality use of medicines, including within the full range of clinical trials. To support pharmacists, part of the global investment into clinical research should include an investment into clinical pharmacy services to ensure the quality use of medicines throughout the trial process alongside effective translation into clinical practice.

Data access and availability

Copies of cited references can be provided on request.

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Declaration of competing interest

The author declares that there are no conflicts of interest.

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