Dear Dr Aliprandi-Costa,

RE: National Clinical Trials Governance Framework for health services conducting clinical trials

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional, for-purpose organisation for over 5,300 leading pharmacists and pharmacy technicians working across Australia’s health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care. SHPA convenes a Clinical Trials Specialty Practice stream, with over 360 members with expertise and practising in clinical trials, who have informed this submission.

SHPA supports the development of the National Clinical Trials Governance Framework as the first step towards a nationally consistent approach to accreditation of health services undertaking clinical trials in Australia. According to the Australian New Zealand Clinical Trials Registry, drugs are the most commonly researched intervention in Australian clinical trials and accounted for 47% of all clinical trials registered between 2006 and 2015. Clinical Trial Pharmacists are imperative to the governance and success of all drug and many non-drug clinical trial services in hospitals. The National Clinical Trials Governance Framework must adequately describe and acknowledge the importance of Clinical Trial Pharmacists in ensuring and delivering governance in clinical trials services, which is elaborated on in our responses to the consultation questions below.

1. Will the National Clinical Trials Governance Framework help health service organisations deliver efficient and effective clinical trial services?

SHPA believes that the National Clinical Trials Governance Framework will help health service organisations in the efficient and effective delivery of their services. It will prompt health service organisations undertaking clinical trials to review and analyse their current services and operations to achieve a national standard and establish or improve their governance frameworks going forward. The enforcement of this framework is just as important as its establishment, and SHPA welcomes the Australian Commission for Safety and Quality in Health Care’s (the Commission) intent for it to be aligned with the National Safety and Quality Health Service (NSQHS) Standards for hospital accreditation.

2. Do you think the core principles of the National Clinical Trials Governance Framework appropriately express the expectation of the community for clinical trial services? If not, how could the core principles better articulate these expectations?

SHPA suggests elaborating on the following core principles to better articulate the intent of the framework:
▪ “The patient is at the centre of clinical trials”
   This principle should emphasise patient safety as a fundamental part of patient-centred care.

▪ “Clinical trials are undertaken in a safe environment and foster a culture of quality and innovation”
Suggest amending this to ‘Clinical trials are undertaken in a safe environment, enforced and maintained by robust clinical governance systems, within which a culture of quality and innovation is fostered’. Anecdotal member feedback indicates that whilst it is assumed by the general population that robust governance systems are in place, this is often not the case. The suggested amendment will improve clarity and expectation standards for both patients and consumer groups.

3. The suggested roles and functions for identified positions relating to the conduct of clinical trials are provided in the National Clinical Trials Governance Framework. Do you agree with the roles and the description of functions? Should other roles and functions be included?

Please specify the roles you are commenting on e.g. patients and consumers, clinical trial site staff, trial investigators, clinical trial coordinators, managers, research governance officer, HREC executive officer, site-specific assessment officer, governing bodies, sponsors.

In the roles and functions section of the National Clinical Trials Governance Framework, it is essential that Clinical Trial Pharmacists are explicitly acknowledged as a core part of Clinical trial site staff, especially given that 47% of all clinical trials registered between 2006 and 2015 were for drug trials where Clinical Trial Pharmacists are integral to their success and governance.

Clinical Trial Pharmacists have specialised training and expertise to clinical trial participant care and are intimately involved in the research and development of new and investigational drugs. Clinical Trials Pharmacists are responsible for procuring, storing, dispensing, manufacturing and compounding investigational medications according to practice standards, local and national legislation. This ensures the safe and quality care for clinical trials participants taking investigational medicines.

The Standards of Practice for Pharmacy Investigational Drugs Services developed by SHPA is the official document guiding professional practice for over a decade and is currently under review. This Standard of Practice is the only document in Australia that guides Clinical Trials Pharmacy Practice and includes guidance on:

▪ Safe and ethical use of investigational drugs
▪ Pharmacy practice for evaluation of new drugs
▪ Compliance with legislation, standards and guidelines
▪ Safety and welfare of participants and protection of their rights, confidentiality and privacy

Clinical Trials Pharmacists have a professional duty and responsibility to provide monitoring and medication counselling for all medications a participant is taking, not just investigational medicines. Clinical Trial Pharmacists are responsible for overall compliance to trials which is essential in measuring the effect of causality and clinical trial results.

4. Health service organisations conducting clinical trials will be required to meet the actions outlined in the National Clinical Trials Governance Framework. Are these actions feasible and able to be met by health service organisations? If not, how could health service organisations be assessed against the governance standards?

Conditional on adequate funding and resource allocation, the actions described in the National Clinical Trials Governance Framework are reasonable and appropriate and should be met by health service organisations.
Anecdotal member feedback indicates that whilst research and undertaking clinical trials is often a strategic priority for health service organisations, they are not provided the necessary resources to be sustainable. Sustainability of clinical trial services and ability to meet standards and legislative requirements is often through health service organisations own source revenue. Without certainty in operational funding, the governance and integrity of clinical trials is subject to risk.

Furthermore, in the constant environment of fiscal pressure in public health funding, research is not always considered a core activity for health service organisations, often to the detriment of clinical trial services. This is at odds with the Australian government’s intention to be a global leader in medical research, as evidenced by the establishment of the Medical Research Future Fund and the Australian Medical Research and Innovation Strategy 2016–2021. SHPA hopes that the development of the National Clinical Trials Framework will lead to discussions around sustainability and funding models to enable health service organisations to achieve the actions described.

5. What strategies would enable health service organisations to meet the actions outlined in the National Clinical Trials Governance Framework?

As mentioned above, sustainable and sufficient resource allocation to Clinical Trial Pharmacists and health service organisations undertaking clinical trials is imperative. Furthermore, a strong focus on quality improvement projects and processes for health service organisations undertaking clinical trials would be beneficial.

Given that this is the first iteration of the National Clinical Trials Governance Framework, a thorough self-assessment by health service organisations will be required to assess compliance and areas for improvement. This will include:

- Gap analyses against the National Clinical Trials Governance Framework and the current state of operations and service provision
- Assessment of risks to the health service organisation associated with the gaps, and prioritisation of risks to be addressed
- Construction of a road map prioritising key actions to addressing the key gaps and risks (this will likely be conducted in stages due to resource limitations and to enable effective change management)
- Determination of resourcing required for each stage

6. Do you think aligning the National Clinical Trials Governance Framework with clinical and corporate organisational governance will improve clinical trial service provision? If not, should other factors be considered to support embedding clinical trials into routine health service provision?

SHPA believes that initially, the aligning the National Clinical Trials Governance Framework with corporate organisational governance will stimulate discussion in health service organisations on clinical trial service provision and begin the resource allocation to enact changes required to be compliant with the framework. However, health service organisations will need to be adequately and sustainably financially supported to embed clinical trials into routine health service provision. SHPA suggests that under Organisational Leadership on page 40, the action described should explicitly mention that they are responsible for driving sustainability of clinical trials services. Please refer to our response to Question 4 for further information.

8. Do you have any other comments?

- In the ‘Functions’ section for Managers (clinical and non-clinical) on page 35, there is reference to ‘…indications of clinical trials operations and underperformance’. However, in the absence of key performance indicators (KPI), assessing underperformance can be arbitrary and subjective. SHPA
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believes work needs to be undertaken at a national level to create a series of relevant KPIs to enable this assessment. This should include consideration of determination of standards for staffing requirements for the management of clinical trial services.

- In the ‘Functions’ section for Governing bodies on page 36, consider inclusion of ‘Ensure that there are defined formal channels for reporting and escalating risks and issues that arise during the course of a clinical trial outside the remit of a HREC’

As mentioned previously, SHPA’s Standards of Practice for Pharmacy Investigational Drugs Services is currently under review and will factor in the National Clinical Trials Governance Framework. We would welcome an opportunity to discuss this Standard with you and ensure that these two important documents are synergistic in nature and support optimal Clinical Trial Pharmacy Practice. If you have any queries or would like to discuss our submission further, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership on jdewever@shpa.org.au.

Yours sincerely,

Kristin Michaels
Chief Executive

References

2 SHPA Committee of Specialty Practice in Investigational Drugs. (2006). ‘SHPA Standards of Practice for Pharmacy Investigational Drugs Services’