Australian Commission on Safety and Quality in Health Care (ACSQHC)

National Clinical Trials Governance Framework Consultation

Clinical Oncology Society of Australia

Submission from Clinical Oncology Society of Australia (COSA), the COSA Clinical Trials Research Professionals Group and the 14 Cooperative Cancer Trials Groups (Appendix A)

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

We note that the draft National Clinical Trials Governance Framework has received general support at a number of workshops attended by representatives of the Collaborative Cancer Trials Groups and COSA. The aim of the Framework was clearly described as encouraging executive engagement and top down support for clinical trials specifically; however it is likely also to have a flow on effect to other clinical research and quality improvement projects.

We acknowledge that the Framework aims to help standardise and streamline governance processes to make Australia a more attractive place in which to conduct clinical trials research. Additional guidelines need to be developed to conduct health services, cohort studies and quality improvement research because the requirements of these studies require a different approach.

However, we also note that clinical services and supporting research governance infrastructure will need to be adequately resourced to ensure existing clinical trials activity is not in itself jeopardised by the need to divert resources to meet additional accreditation requirements.

Within the Framework a focus needs to be placed on supporting investigators to conduct and complete clinical trials. Steps are needed to ensure that for individual trials the proposed governance process is timely in order to increase Australian participation in international and local trials. Emphasis also needs to be placed on supporting the translation of clinical trial results into clinical practice.

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?*

The core principles do not address the expectation of the community that equal access to clinical trial services exists in regional and remote areas. This was raised at the Brisbane workshop and the Australasian Tele-Trials Model, developed by COSA, was given as an example of how regional capacity can be strengthened.

At the Perth workshop it was also highlighted that the Framework needs to be extended beyond considering Aboriginal and Torres Strait Islanders to also consider the needs of Culturally and Linguistically Diverse Populations (CALD) and other minority groups. Equity for

all consumers should be a priority. Both patients and carers need to be considered with carers also contributing to the conduct of trials.

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.

An alternative to defining specific roles and functions in the Framework is to document a process that enables health service organisations to demonstrate existing capacity for research governance review and the conduct of clinical trials. Health service organisations with existing capacity to successfully undertake trials of investigational agents in the phase I-IV setting will have effective procedures in place to undertake research governance review in a timely manner. Staff in roles other than those defined in the current framework may support research governance review, provide oversight of clinical trial conduct and report via metrics to a Board. The Framework could be modified to support the continuation of systems/mechanisms that are currently working, or to improve efficiency, at health service organisations within the accreditation process.

It may be difficult for smaller, regional health service organisations to employ staff in all the various positions currently included in the Framework. While it may be reasonable to expect accredited clinical trials units to be in place in large regional cancer treatment centres, the logistics of maintaining a suitably trained workforce to undertake the ethical and regulatory responsibilities of clinical trials may be difficult in smaller rural and regional sites with limited resources and low patient numbers. Initiatives such as COSA Tele-Trials Model demonstrate that regional sites can be involved in clinical trials with support from a lead site using a streamlined approach to addressing governance and other regulatory requirements.

The COSA Tele-Trials Model aims to simplify site accreditation, research governance and contractual matters to reduce cost and workload, and to expedite approval processes. The lead site undertakes research governance and contractual matters and the regional site is sub-contracted to participate as a satellite under supervision of the lead site. Under the current Framework, these efforts to increase access to clinical trials for people diagnosed with cancer who live in remote and regional areas are not acknowledged and may no longer be feasible.

A mechanism to streamline research governance review based on the risk level of trials and/or risk appetite of the health service organisation could be considered, given that trials are diverse and may vary from high risk ‘first in man’ phase 1 studies of unapproved medications to non-pharmacological, basic science discovery and behavioural interventions. A tiered accreditation level for health service organisations based on risk and capacity to undertake various portfolios of clinical trials may be a more practical approach. This type of Framework is likely to be useful for other studies including health services research and cohort studies.

If the roles as described are retained, the following additions would be beneficial. The position of clinical trial manager should be expanded. People in this role assess trials to ensure adequate resources are available to support participation and that participant recruitment targets can be met. This review needs to be completed in a timely fashion and incorporate discussion with the clinical staff that will conduct the trial and may be facilitated by the site clinical trials coordinator or principal investigator. Collaborative Cancer Trials Groups and Universities (where many CCTGs are based) also need to be included as sponsors. The role of the Coordinating Principal Investigator of a multi-centre trial should be included.

Managers are also responsible for the safety of staff and workplace. Adequate facilities must be available to support the administration and conduct of clinical trials at each site for the expected duration of each trial.

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?

The governance standards seem to be a logical extension of accreditation standards already in place.

The costs that may be incurred by individual sites to participate need to be considered prior to implementation. For example, the costs incurred by small providers may prohibit their participation in clinical trials.

Tools will need to be provided to complement the Framework and assist research teams and research governance officers to meet research governance requirements. The governing body where the trials are being conducted will need to implement strategic plans to ensure compliance with governance requirements. Individual sites will then be assessed using key performance indicators. Training will need to be provided for research teams and research governance officers.

Health Service investment will be required to ensure adequate ancillary services are in place to support the Framework, including human resources, finance personnel with trials expertise, information technology, and data systems to produce metrics.

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

The Framework is expected to be published on the Commission website late in 2019 and health service organisations will be assessed against the actions from 1st January 2020. This does not appear to provide sufficient time for health service organisations to review the Framework or to ensure that actions outlined in the document are addressed, particularly where implementation of new/updated systems/processes and/or positions may be required.

As above, training and tools will need to be provided to complement the Framework and its implementation.

Guidance on Information and Communications Technology (ICT) use and data sharing is needed. There is currently considerable variation between clinical trials sites as to which ICT platform should be used and how data is to be shared between sites. A national, integrated approach would assist researchers and sponsors to meet clinical trial timelines, increase efficiency, reduce costs and make Australia a more attractive place in which to conduct clinical trials research.

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?*

In a smaller organisation the current draft National Clinical Trials Governance Framework may further complicate the provision of clinical trial services and require the employment of additional staff for administrative or oversight roles. This could result in a reduction of direct research support and capacity to undertake clinical trials to improve patient outcomes.

7. *If you have comments on the language and/or terminology of the content, please provide suggested replacement text.*

Comments on the language and terminology have been addressed during workshops attended by people representing COSA Groups. Several items including role recognition, credentialing of site staff and language barriers around informed consent could be modified or strengthened.

8. *Do you have any other comments?*

There is currently no consistent framework for research governance across Australian health care organisations. We agree in principle that the draft Framework goes a long way towards beginning to address this lack of consistency, however it needs further work. We look forward to working with the ACSQHC to review and comment on the next version of the draft Framework.

Contact
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Submitted on behalf of COSA and the 14 Australian Cancer Cooperative Trials Groups

COSA
The peak Australian body representing health professionals from all disciplines whose work involves the care of cancer patients.

COSA Clinical Trials Research Professionals Group
COSA members in clinical cancer research involved in the collection and management of oncology data. The group is committed to achieving and promoting excellence in clinical cancer research by supporting research professionals through education, information, leadership, and by providing networking opportunities.

Australasian Gastro-Intestinal Trials Group (AGITG)
The AGITG is Australia's largest independent non-profit organisation conducting clinical trials into gastro-intestinal (GI) cancers.

Australasian Leukaemia & Lymphoma Group (ALLG)
The ALLG is the only not for profit organisation designing and delivering investigator initiated clinical trial research into blood cancers.

Australasian Lung Cancer Trials Group (ALTG)
ALTG is Australia and New Zealand's lung and thoracic cancer clinical research group.

Australasian Sarcoma Study Group (ASSG)
The aim of the ASSG is to improve outcomes for sarcoma and related tumours in the Australian community by undertaking outstanding international basic, translational, clinical and supportive care research.

Australia and New Zealand Melanoma Trials Group (ANZMTG)
ANZMTG coordinates and conducts quality research for melanoma control with researchers and health care professionals, support networks and consumers.

Australian and New Zealand Children's Haematology/Oncology Group (ANZCHOG)
ANZCHOG is the leading body representing the interests of children and adolescents with blood diseases and cancer, and their families.

Australian and New Zealand Gynaecological Oncology Group (ANZGOG)
ANZGOG is a not-for-profit organisation dedicated to gynaecological cancer research.

Australian and New Zealand Urogenital & Prostate Cancer Trials Group (ANZUP)
ANZUP conducts clinical trial research to improve treatment of bladder, kidney, testicular and prostate cancers.

Breast Cancer Trials
Breast Cancer Trials is the largest independent, oncology clinical trials research group in Australia and New Zealand.

Cancer Symptom Trials (CST)
CST research options for improved management of symptoms that can occur due to a cancer diagnosis and related treatments.

Cooperative Trials Group for Neuro-Oncology (COGNO)
COGNO's main aim is to conduct investigator-initiated and collaborative group trials addressing important clinical questions in patients with brain tumours.

Primary Care Collaborative Cancer Clinical Trials Group (PC4)
PC4 is funded by Cancer Australia to develop and conduct cancer research in primary care.

Psycho-oncology Co-operative Research Group (PoCoG)
PoCoG aims to improve outcomes for people affected by cancer by developing and facilitating high quality, collaborative and clinically relevant research that focuses on interventions and services to optimise psychosocial and supportive care.

Trans-Tasman Radiation Oncology Group (TROG)
TROG Cancer Research is Australia and New Zealand's specialist clinical research group for cancers that can be treated with radiotherapy.