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Submission to

The Australian Cancer Plan 2023-2033

4 March 2022

By the

Cooperative Clinical Trial Groups-Executive Officers Network (EON)

Background

The Executive Officers' Network (EON) is a collaboration between the fourteen Cancer Cooperative Trials Groups (CCTGs) that are supported by Cancer Australia. Established in 2005 under an Enabling Grant secured by the Clinical Oncology Society of Australia (COSA) the aim was to build greater collaborations between the CCTGs through the operational managers and increase the efficiency of cancer cooperative research through sharing of information and use of resources.

Our research programs involve multicentre national and international clinical trials that bring together multidisciplinary health professionals involved in cancer research and patient care in institutions throughout Australia and New Zealand. The CCTGs design and conduct academic investigator–initiated trials with guidance from people affected by cancer and experts in the field. Our research involves combinations of medicines, radiation therapy, surgery, diet or exercise; to help improve cancer outcomes, quality of life and wellbeing. These collaborations ensure that knowledge is shared, resources are pooled, and progress is faster.

Survival rates of many cancers have improved greatly in the past twenty years driven mainly by clinical trials research. Clinicians who contribute to collaborative trials are more likely to implement trial findings in their own practice and translate new knowledge to their colleagues. (The value proposition of investigator-initiated clinical trials conducted by network. The joint ACTA/ACSQHC Working Group Med J Aust 2021; 214 (4): || doi: 10.5694/mja2.50935)Furthermore it is well documented that clinical sites and hospitals where there is active participation in clinical trials results in better care for patients. (Arch Intern Med. 2008;168(6):657-662. doi:10.1001/archinternmed.2007.124The EON plays a

major role in Australia in delivering clinical trials across many cancers and provides access to both major city participants and those in rural and regional areas.

What would you like to see the Australian Cancer Plan achieve?

- All progress in improving patient outcomes and survival comes from clinical trials and support for research and measurement of research activities should be formalised as part of the Cancer Plan
- Clinical trials can provide economic benefits by reducing the burden of disease and increasing the efficiency of health care delivery.
- Recognition that the opportunity to participate in cancer clinical trials is a key component of high-quality cancer care, and should be backed up by a strategy to deliver that opportunity throughout Australia.
- Incorporation of clinical trials and clinical research into routine patient care
- Improved clinical trial accessibility and direct support for engaging rural, regional, and remote patients, providers and institutions through telehealth and virtual participation. This includes research capacity building at regional and rural sites as well as further supports for these patients reduce exacerbating disparities due to literacy or access barriers that these technologies create. As well as direct support, this should include removal of regulatory and other barriers to such participation.
- Easing barriers to support clinical trials to completion. This will include standardisation and streamlining of ethics and governance processes across all states/territories and institutions. Measures to reduce the ethics and governance burden should be implemented, particularly for low risk trials.
- Clinical trials can run for many years, particularly if they are capturing clinical outcomes like Disease Free Survival and Overall Survival. NHMRC or MRFF funding is typically awarded for 5 years or less. The Australian Cancer Plan should include support for the long-term follow up of participants in cancer trials (previously awarded a peer-reviewed grant) that have successfully recruited the study cohort. Long term follow-up is vital to understanding these diseases and to improving patient outcomes, especially monitoring and measurement of late toxicity.
- Provision of infrastructure for novel trial designs, such as multi-arm multi-stage trials, that require secure infrastructure funding throughout the life of the trial.
- National support for the ARDC HeSANDA initiative for cancer clinical trials data to be effectively warehoused and made available for future secondary research proposals enabling important clinical questions to be answered via meta-analysis, machine learning and artificial intelligence and generating hypotheses for further research.

- Funding support to research units in institutions to run collaborative group trials would result in an expansion of sites and therefore greater access for patients across metropolitan and regional Australia.
- Funding to support patients to travel to expert treatment centres for their rare cancers (e.g sarcoma and paediatrics).
- Consider targeted funding to ensure inclusivity for underrepresented populations e.g CALD, ATSI
- Enhancement of state-based cancer registries to ensure data collection (including PROMS) is timely, relevant and sufficient for supporting long term outcome follow up of cancer clinical trial participants. Simplification of cancer and data linkage access to cancer and death registry data to support long term follow up of cancer clinical trial participants. Currently the state-based cancer registries are overburdened with a complicated, resource-intensive process.
- Significant boost in funding for investigator-initiated clinical trials, and for support of clinician-researchers. This funding has been substantially reduced in recent years with changes to the NHMRC grant scheme.
- Commitment to re-invest revenue returns generated by new knowledge into supporting future research. Return on investment for investigator-initiated clinical trials is $5.30 for every $1 spent, but this return is not re-invested in research. Annual savings to the health system from cooperative group trials far exceed the amounts provided for research.(Australian Commission of Safety and Quality in Health Care, Economic evaluation of investigator-initiated clinical trials conducted by networks, July2017https://www.safetyandquality.gov.au/sites/default/files/migrated/Economic-evaluation-of-investigator-initiated-clinical-trials-conducted-by-networks.pdf

What are the opportunities with the greatest potential to realise your vision?

- Specific recognition that approved collaborative group trials play a vital role in Australia's cancer care system, and for measures to be introduced to facilitate and promote these trials.
- Trials of less intense or more tailored treatment that aim to safely reduce treatment side effects and costs to be funded or part-funded from cost savings to the health system. For example, a provision pathway to enable the use of government-reimbursed medicines in clinical trials that address important questions of practice will encourage clinical trials research across a broad spectrum of cancer, which may generate substantial savings in future use of PBS-reimbursed medicines or provide

evidence where current PBAC listings require review. Implementation of a streamlined submission process for marketing and reimbursement approvals or reviews as part of this scheme would also incentivise submissions in less profitable markets.

- Specific attention be paid to facilitating clinical trials in smaller centres via measures to reduce regulatory barriers to such trials and improve accessibility through enhanced telehealth and research capacity-building. E.g staff training, appointment of qualified staff, site infrastructure and equipment
- Implementation of the relevant recommendations from the Zimmerman parliamentary inquiry to optimise access to promising novel agents for paediatric cancer patients, in particular:
    - recommendations regarding orphan drugs and drugs targeting low patient numbers
    - recognition of molecular indication for registration and reimbursement
    - recommendations to improve the Australian clinical trial system e.g. ethics and governance
- Introduction of a national strategy to support a sustainable and capable workforce for optimal care and access to the latest clinical trials. In particular, hospital research nurses and clinical trial coordinator positions should be recognised as a defined career path with specific vocational training and commensurate salaries for experience to aid in staff retention
- Investment to support the sustainability and integration of biobanking at centres of excellence for cancer care to facilitate optimal biospecimen use for collaborative Australian research and clinical trial participation
- Address barriers to accessing high-quality end-of-treatment and survivorship care through existing research

What examples and learnings can we build on as we develop the Australian Cancer Plan?

The success of the support for cooperative clinical trials scheme has been a boon to cancer patients and clinicians over the last ten plus years. The investment from the federal government through Cancer Australia has been steady for this entire time and the CCTGs have returned outstanding results. The outputs from the CCTGs however have increased and evolved over this time, an increase in funding for this scheme to ensure ongoing success to best practice would ensure continuing high-quality results.

The rare cancers, including the paediatric cancers are especially reliant on government funding schemes as these cancers do not attract pharma studies and thus additional funds that these commercially- funded studies provide. Pharma companies do not invest in this

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area given the small numbers of patients and therefore the very small market for their drugs. The case can be made therefore that the government funding is particularly vital for these groups and the patients they serve to generate evidence through clinical trials that help not only the clinical trial participants, but can then lead to marketing and reimbursement applications.

There is a need for streamlined processes nationally. State-based and site-based barriers are detrimental to the conduct of clinical trials. National funding to support disease-specific multidisciplinary meetings for all cancers, but particularly notable in rare cancers where patient numbers are low (eg. UK national MDT for Ewings Sarcoma).

Through the pandemic many initiatives like teletrials and ePROMS etc were implemented quickly due to the absolute need to do so. The learnings from this is not only the ongoing outcomes of having these programs in place, is that streamlining some of the "business as usual" requirements and a flexible approach to implementation has provided groundwork for further program implementation.

It is well known that clinical quality registries (CQR) drive improvements in standard of care by revealing variation in care, benchmarking performance and providing evidence to implement change and additional resource to drive improvement in care. Data on practice variation may also reveal areas where standard practice is not based on appropriate evidence, and research (particularly clinical trials) is required to determine the best care. More recently, registries have become a tool for conducting randomised trials within real-world populations, and could be an important tool in implementing research into all cancer care. However, most registries suffer from a lack of sustained funding, particularly adequate funding to facilitate data collection at sites. Investment in registries could potentially simplify and facilitate low-risk prospective research data collection by building on existing infrastructure and providing ongoing capacity to examine questions where there are two or more acceptable variations in standard of care, with no evidence indicating whether a particular variation is superior, or both are indeed equivalent.

Thank you for the opportunity to provide input on behalf of the CCTGs.

Dr Denise Caruso

Chair of EON and ANZSA CEO