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ABORIGINAL AND TORRES STRAIT ISLANDER NATIONAL TECHNICAL SERVICE

CONSULTATION PAPER

Fostering meaningful engagement with Aboriginal and Torres Strait Islander people for the *Support for Cancer Clinical Trials* (SCCT) program

Statement of Acknowledgement

Cancer Australia acknowledges Aboriginal and Torres Strait Islander people as the Traditional Custodians of Country throughout Australia. We pay our respects to Elders, past and present.

We celebrate the ongoing connections of Aboriginal and Torres Strait Islander peoples to Country, culture, community, family and tradition and recognise these as integral to health, healing and wellbeing.

Cancer Australia acknowledges great diversity among Aboriginal and Torres Strait Islander peoples, and the contribution of the many voices, knowledge systems and experiences that guide all efforts to create a culturally safe and responsive cancer system that is equitable to all.

Aboriginal and Torres Strait Islander National Technical Service - Consultation Paper was prepared and produced by:
Cancer Australia
Locked Bag 3 Strawberry Hills NSW 2012 Australia
Tel: +61 2 9357 9400 Fax: +61 2 9357 9477
canceraustralia.gov.au

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1. Introduction

This Roundtable has been called to provide advice to Cancer Australia on the establishment of a new National Technical Service to foster meaningful engagement with Aboriginal and Torres Strait Islander people for the *Support for Cancer Clinical Trials* program. This technical service will be designed to give expert advice to Cancer Clinical Trials Groups on embedding cultural safety into clinical trial protocols and provide best practice guidance concerning engagement, data collection and submitting applications for funding. Ongoing support and advice from this technical service will strengthen and promote equitable access to cancer clinical trials across Australia to ultimately increase Aboriginal and Torres Strait Islander participation.

Cancer Australia will publish an outcome summary from this Roundtable on its website. Any resulting Approach to Market for a new service will include an industry briefing for all interested parties.

Roundtable participants may, on occasion, be provided with confidential information. Participants must not disclose confidential information to any person outside of the Roundtable, unless required to by law. The participant shall not use any confidential information except for the purposes of the Roundtable. Cancer Australia will take all reasonable steps to advise participants of the confidentiality status of information and/or documents provided.

Roundtable participants warrant that, to the best of their knowledge, no conflicts of interests exist or are likely to arise. If a conflict of interest does arise, or appears likely to arise, participants must disclose this to Cancer Australia immediately in writing.

This Consultation Paper has been prepared by Cancer Australia, in collaboration with Cancer Clinical Trials Groups under the *Support for Cancer Clinical Trials* program and Cancer Australia's Advisors on Aboriginal and Torres Strait Islander Cancer Control.

1.1 Current State

Overall, Australia has one of the highest survival rates from cancer in the world. However, improvements in cancer survival rates are not experienced uniformly within the Australian population. Cancer is the leading cause of death for Aboriginal and Torres Strait Islander people, and the gap in cancer mortality between Aboriginal and Torres Strait Islander people and non-Indigenous Australians is widening.

At the population level, clinical trial participation is positively associated with increased survival, access to new and cutting-edge treatments, exposure to leading experts, and can accelerate advances in treatment. However, there are significant disparities in equitable access to trials with low participation of some population groups. Of note, Aboriginal and Torres Strait Islander people access cancer research and clinical trials at a reduced rate when compared with the non-Indigenous population. For example, the Alan Walker Cancer Care Centre in Darwin conducted 23 ongoing clinical trials in 2023 (43% of all clinical trials in the Northern Territory) with 6% of participants identified as Aboriginal and/or Torres Strait Islander[1]. With one-third of the NT population identifying as Aboriginal and/or Torres Strait Islander, there is a significant opportunity to increase their participation in these clinical trials, ensuring that the benefits of innovative cancer treatments are more widely shared within the broader community. Given the clear disparities in cancer outcomes experienced by Aboriginal and Torres Strait Islander people, increasing participation in clinical trials is critical for reasons of equity and social justice[1]. It is imperative that clinical trials include diverse populations to accurately represent those most affected by the disease being studied. This approach ensures that interventions or treatments are trusted and effective for all patients, including Aboriginal and Torres Strait Islander people.

There are opportunities to increase participation of Aboriginal and Torres Strait Islander people in clinical trials. Research can become more accessible and facilitate meaningful change through improvements in study design, such as removing strict inclusion or exclusion criteria, particularly for those with co-morbidities; prioritising research into the most common cancers experienced by Aboriginal and Torres Strait Islander people; and integrating cultural aspects of Indigenous life. Using virtual care or addressing logistical challenges, such as personal costs or transportation difficulties, can make participation more feasible for those living in rural and remote areas or for delivering care on Country. Additionally, building trust through embedding culturally safe care and acknowledging the historical significance of colonisation and harmful research practices can build stronger partnerships between Aboriginal and Torres Strait Islander communities and the research sector[1], [2]. To assist with the Roundtable discussion, a case study has been provided to illustrate barriers commonly experienced by Aboriginal and Torres Strait Islander people and help pinpoint where potential changes can be made to improve clinical trial participation (Appendix A).

The healthcare sector is implementing strategies to embed culturally safe practices to overcome mistrust in research and improve clinical trial recruitment and retention. Access to research and clinical trials during diagnosis, staging and treatment planning is a key principle in the recently revised *Optimal care pathway for Aboriginal and Torres Strait Islander people with cancer*[3]. Some promising strategies that have been adopted by the sector include:

- Improving communication with Aboriginal and Torres Strait Islander people by using medical and cultural interpreters; using diagrams, illustrations and plain language; demonstrating procedures; allowing extra time for Indigenous patients to respond or tell their stories; and integrating culturally meaningful analogies[1].
- Re-examining recruitment and retention protocols to include consultation with Aboriginal community champions; encouraging word-of-mouth spread of recruitment; advertising in local newspapers, radio shows or flyers; regular communication with participants; and encouraging relationship building with participants regularly throughout each phase of follow-up[4].
- Employing an Indigenous Liaison Officer (ILO) or Indigenous Health Worker (IHW) to oversee care and ensure it is culturally appropriate as well as to provide emotional, social and cultural support to patients, their families and carers. This has a two-fold benefit of improving Aboriginal and Torres Strait Islander patient satisfaction in their care and by building the Indigenous workforce[5]. However, it should be noted that the responsibility for ensuring cultural safety of cancer services for Aboriginal and Torres Strait Islander people is a shared responsibility between all healthcare workers, regardless of Indigenous status.
- Collaborating with Aboriginal and Torres Strait Islander-led organisations to build capacity of the Aboriginal and Torres Strait Islander cancer research sector, including through Cancer Australia's *Partnerships for Cancer Research* grant program, a new $9.6 million initiative to facilitate partnerships between Aboriginal and Torres Strait Islander-led organisations and community to deliver research activities.
- Arranging home visits or telehealth to support Aboriginal and Torres Strait Islander participation in trials on Country, or as close to home as possible, reducing travel costs, waiting time and stress[3],[5].

1.2 Why is the Support for Cancer Clinical Trials program important?

The *Support for Cancer Clinical Trials* (SCCT) program provides funding to Australia's 14 Multi-site Collaborative Cancer Clinical Trials Groups (CTGs) to develop investigator-initiated and led cancer clinical trial protocols. The program is globally unique, designed specifically to fund the development of clinical trial protocols and build sector capacity through core infrastructure funding.

The SCCT program recognises the importance of supporting advancements in cancer prevention, treatment and care to address important questions in patient treatment and care which may not be of commercial interest to industry. This program focuses on developing clinical trials to address unmet needs, including rare and less common cancers, and provides vital funding to CTGs, especially to smaller groups with narrow or underfunded research focuses, enabling a strong pipeline of cancer clinical trials.

Cancer Australia has awarded a total of $22.19 million (GST excl.) over the next three financial years (2024-25 to 2026-27). The following CTGs are currently being funded by Cancer Australia:

1. Australasian Gastro-Intestinal Trials Group (AGITG)
2. Australasian Leukaemia and Lymphoma Group (ALLG)
3. Australia and New Zealand Sarcoma Association (ANZSA)
4. Australian and New Zealand Children's Haematology and Oncology Group (ANZCHOG)
5. Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
6. Australia New Zealand Gynaecological Oncology Group (ANZGOG)
7. Breast Cancer Trials (BCT)
8. Cancer Symptom Trials (CST)
9. Co-operative Trials Group for Neuro-oncology (COGNO)
10. Melanoma and Skin Cancer Trials (MASC)
11. Primary Care Collaborative Cancer Clinical Trials Group (PC4)
12. Psycho-oncology Co-operative Research Group (PoCoG)
13. Thoracic Oncology Group Australasia (TOGA)
14. Trans-Tasman Radiation Oncology Group (TROG)

All CTGs participate in an Executive Officer Network, which evolved organically within the SCCT program as a channel to leverage knowledge sharing and capacity across the organisations. This Network supports CTGs to share ideas, documents and minimise duplication of work, particularly in new areas of research.

THE OBJECTIVES OF THE SCCT PROGRAM ARE TO INCREASE:

- The number of cancer clinical trials conducted in Australia.
- **Participation** in clinical trials by people affected by cancer*.
    - Specifically, to increase the participation of all Australians with cancer in clinical trials; encourage clinical trial representatives of the socio-demographic distribution of specific cancer types in Australia; and improve equitable access to clinical trials for priority population groups, especially for **Aboriginal and Torres Strait Islander people**, those in rural or remote areas, adolescents and young adults, older Australians and those with culturally and linguistically diverse backgrounds.

- The number of clinical sites actively participating in cancer clinical trials.
    - Specifically, to increase the involvement in cancer clinical trials of public and private hospitals or centres, and sites in regional and remote areas of Australia including through tele-trials.

- The involvement of policy makers, clinicians, researchers and consumers in the development of cancer clinical trials.
- CTG participation in national multi-group or international cancer clinical trials in Australia.

The intended **outcomes** of the SCCT program are to:

- Guide scientific improvements in cancer prevention, treatment and care.
- Build the evidence-base for best practice cancer care across all aspects of the cancer continuum.
- Reduce cancer incidence and mortality.
- Achieve equity in cancer outcomes and improve quality of life for Australians affected by cancer.

**CTGs are required to report on clinical trial participation, including participation of numerous underserved populations. However, there are no current Indigenous participation metrics that CTGs must meet.*

1.3 Role of the National Technical Services

Through the SCCT program, Cancer Australia provides CTGs access to expert advice and services in areas of common need to ensure that clinical trial protocols which are developed are competitive and of high-quality. Cancer Australia is currently funding three National Technical Services (NTS) for the 2024-25 financial year, these services are:

1. **Health and Pharmaco-economic Technical Services** provide CTGs with services relating to the consistent inclusion of appropriate health and pharmaco-economic measures or sub-studies into all new industry-independent cancer clinical trials protocols developed. These services assist the CTGs to incorporate appropriate health and pharmaco-economic analyses into new cancer clinical trials leading to greater economic evidence for future decision-making.
2. **Quality-of-Life Technical Services** provide CTGs with services relating to the consistent inclusion of appropriate patient-reported outcome and health-related quality of life measures or sub-studies into all new industry-independent cancer clinical trial protocols developed. These services will help identify effective interventions which can improve cancer outcomes whilst ensuring that the patient impact of new or modified interventions is assessed and understood.
3. **Genomic Cancer Clinical Trial Initiative** provides CTGs with services relating to the development of cancer clinical trial protocols that specifically target cancer mutations/molecular markers across a range of tumour types. Many tumours from different sites of origin have cancer mutations/molecular markers in common and the prognostic outcomes of treatment can often be improved by targeting these mutations/molecular markers.

1.4 Key findings from previous consultations

In 2023, Cancer Australia undertook a review of the SCCT program which revealed, among other things, that the CTGs require support and coordinated specialist advice on Aboriginal and Torres Strait Islander engagement.

The program's capability gaps identified in this report were:

- Designing and co-designing clinical trial protocols to respond to the needs of Aboriginal and Torres Strait Islander people with the aim of improving access to, and increase participation rates in, cancer clinical trials among Indigenous populations.
- Appropriately engaging with Aboriginal and Torres Strait Islander people to assist with defining priority outcomes.

A common finding from meetings with CTGs is that they would benefit from having access to a new NTS to provide coordinated and consistent advice on engaging with Aboriginal and Torres Strait Islander people, embedding cultural safety and co-design principles in the design of clinical trial protocols, and to reduce the burden for Aboriginal and Torres Strait Islander contacts and advisors who are contacted by all the CTGs separately under current arrangements.

1.5 Consideration in advancing the Australian Cancer Plan

In November 2023, the Minister for Health and Aged Care released the Australian Cancer Plan (the Plan), designed to improve cancer outcomes for all Australians, and particularly for those groups whose health outcomes are poorest. Achieving equity in cancer outcomes will be a fundamental measure of success for the Plan and will align Australia with global calls to improve cancer outcomes for all people.

Please note that the following text is an excerpt from the Australian Cancer Plan

Action 4.2.2 *Ensuring targeted and innovative research investment into areas of unmet and emerging need; and improve clinical trial design and equitable access.*

Clinical trials provide an opportunity for consumers to benefit from the latest cancer care innovations and technologies. However, there are significant disparities in equitable access to clinical trials. Clinical trials research should align with unmet needs and accelerate translation of innovative research into clinical practice. There is also a need to increase community awareness of eligibility for clinical trials to improve equitable access for consumers.

Considerations to implement Action 4.2.2 may include:

- Appropriate application of virtual care and telehealth across the cancer care continuum and different cancer types.
- Cancer risks, incidence, experiences and outcomes for priority population groups, including considerations around intersectionality.
- Methods to improve equitable access to clinical trials, especially for Aboriginal and Torres Strait Islander people, those in rural or remote areas, adolescents and young adults, and older Australians.
- Build a culture within the cancer system that values and supports research and collaboration, including building staff capability to engage in research.

Action 6.2.3 *Establish and enhance collaborative partnerships with communities and Aboriginal and Torres Strait Islander-led organisations.*

Trusted relationships between Aboriginal and Torres Strait Islander people and organisations within the broader healthcare system are critical to improving cancer outcomes and experiences for Aboriginal and Torres Strait Islander people. Collaborative partnerships with Aboriginal and Torres Strait Islander-led organisations are an important basis for all culturally safe, trauma-aware, healing-informed approaches to cancer prevention, screening, treatment, care and support, as well as research.

Considerations to implement Action 6.2.3 may include:

- Extending assertive community outreach to promote awareness of cancer prevention, screening and treatment through culturally safe Aboriginal and Torres Strait Islander-led engagements with individuals and communities (e.g., yarning circles).
- Ensuring Aboriginal and Torres Strait Islander representation across all levels of service design and/or decision making related to cancer prevention, care delivery, and standards for Aboriginal and Torres Strait Islander people with cancer, including their carers and families.
- Promoting Aboriginal and Torres Strait Islander community-led research to better understand community perspectives on cancer, identify strengths and challenges, and determine how best to tailor cancer care services to address this.
- Embedding principles and standards of Indigenous Data Sovereignty into cancer data initiatives.

Through the adoption of co-design approaches to achieve the priority actions in the Plan, Aboriginal and Torres Strait Islander people will have a genuine say in the design and delivery of policies, programs and services that affect them to achieve better life outcomes.

1.6 Alignment with the Aboriginal and Torres Strait Islander Cancer Plan

In 2023, the National Aboriginal Community Controlled Health Organisation (NACCHO) developed an Aboriginal and Torres Strait Islander Cancer Plan to improve cancer experiences and create a new foundation for partnership in Australia's national approach to cancer control[6]. This Aboriginal and Torres Strait Islander Cancer Plan complements the Australian Cancer Plan and, by working together, these two plans will lead to improved cancer outcomes and experiences for Indigenous Australians, their families and communities.

Please note that the following text is sourced from the Aboriginal and Torres Strait Islander Cancer Plan by the National Aboriginal Community Controlled Health Organisation

The Aboriginal and Torres Strait Islander Cancer Plan highlights the need for a culturally informed evidence base and identifies this as Area of Focus 5, in which there are the following implementation considerations:

5.1 Indigenous Data Sovereignty and timely data sharing across sectors

- To improve Indigenous Data Sovereignty so that Aboriginal and Torres Strait Islander health data – including cancer data – are used for shared decision-making, co-design and local leadership
- To strengthen stakeholder engagement and adoption by mainstream health systems and data custodians of the five agreed principles for Indigenous Data Sovereignty

5.2 Indigenist research and evaluation methods

- To ensure cancer research and evaluation focuses on priorities identified and led by Aboriginal and Torres Strait Islander Communities
- To increase the number of Aboriginal and Torres Strait Islander academic scholars and their access to research infrastructure

5.3 Sharing stories of lived experience

- To acknowledge, share and respect Aboriginal and Torres Strait Islander peoples' cancer journeys and celebrate positive experiences to change the cancer narrative and remove the stigma and fear associated with cancer
- To listen to and incorporate views and feedback of Aboriginal and Torres Strait Islander peoples affected by cancer and the workforce who manage these issues every day

5.4 Information systems strengthened, including Patient Information Management Systems, and users supported to access data to identify Community needs

- To support organisations to apply Continuous Quality Improvement Frameworks in evaluating information management system software in order to identify data gaps
- To ensure Aboriginal Community Controlled Health Organisations receive adequate training and resources to effectively utilise Patient Information Management Systems

5.5 Safe and relevant cancer clinical trials with high participation rates of Aboriginal and Torres Strait Islander peoples

- To increase engagement of Aboriginal and Torres Strait Islander peoples in co-designed cancer clinical trials

1.7 Purpose of this Consultation Paper

Cancer Australia is seeking expert advice and experience to help develop and shape the scope of an Indigenous-led Aboriginal and Torres Strait Islander National Technical Service. Based on the scope of the existing National Technical Services and advice received by Cancer Australia, this Service may provide expert advice to CTGs on appropriately engaging with Aboriginal and Torres Strait Islander people, facilitating co-design, and embedding cultural safety in clinical trial design through:

- Auditing and reviewing clinical trial concepts and draft protocols from CTGs to ensure they are culturally safe or providing guidance on how a concept or protocol might be altered to improve cultural safety.
- Providing guidance on ethical requirements for research involving Aboriginal and Torres Strait Islander patients or communities.
- Reviewing patient materials developed by CTGs to ensure they are culturally safe and advising on best practices for clinical communication to patients, family, kin and community.
- Meeting regularly with CTG Executive Officers to discuss and agree on common needs or approaches.
- Participating in meetings held by CTGs and the other National Technical Services engaged under the SCCT program, such as Annual Scientific Meetings, Steering Group Committee Meetings, and Concept Development Workshops/meetings.
- Conducting core and advanced training workshops for CTG staff and members on culturally safe care. Ideally, workshops will also facilitate CTG connection with community at the researcher and general population level to promote co-design and empower Indigenous Australians to contribute to solutions of issues that negatively affect their community.
- Advising on best practices for trauma-aware and healing-informed data collection, analysis and translational research using biospecimens, particularly aligned to the principles of Indigenous Data Sovereignty.

- Promoting the work of CTGs in newsletters and other resources.
- Fostering collaborations and partnerships that could lead to the inclusion of Aboriginal and Torres Strait Islander researchers in the research team to facilitate meaningful co-design in clinical trial design.
- Fostering collaborations that could lead to avenues for community consultations to strengthen research design and applications, particularly where community consultation and the inclusion of Aboriginal and Torres Strait Islander researchers are common evaluation criteria for grant applications.

This new technical service will focus on supporting the CTGs to deliver the objectives and outcomes of the SCCT program. Acknowledging the program supports CTGs to operate within the broader healthcare system, there are challenges and barriers that fall outside the scope of this new service and are better addressed through other policy and program mechanisms. As such, this service will not:

- Design or develop new clinical trial concepts and protocols
- Perform clinical trials
- Establish new sites for clinical trials, either on-site or through tele-trials
- Develop broader systemic solutions to improve health literacy or awareness, or address mistrust in the wider healthcare system
- Develop broader strategies to build the Aboriginal and Torres Strait Islander workforce.

A NOTE ON INDIGENOUS DATA SOVEREIGNTY

Cancer Australia recognises the importance of Indigenous Data Sovereignty in improving health outcomes for Aboriginal and Torres Strait Islander people. Cancer Australia's recently developed draft National Cancer Data Framework was guided by the Maiam nayri Wingara principles on Indigenous Data Sovereignty and Governance, ensuring Aboriginal and Torres Strait Islander peoples' rights are respected and enabled throughout the entire data lifecycle. These principles assert that Indigenous peoples have the right to:

- Exercise control over the data ecosystem, including creation, development, stewardship, analysis, dissemination, and infrastructure
- Access contextual and disaggregated data at individual, community, and First Nations levels
- Ensure data relevance that empowers sustainable self-determination and effective self-governance
- Establish data structures accountable to Indigenous peoples and First Nations
- Protect and respect individual and collective interests in data[7],[8]

Ensuring that data governance practices within the CTGs align with Indigenous Data Sovereignty principles will be essential in addressing the unique health challenges of Aboriginal and Torres Strait Islander communities and enhancing service delivery improvement.

1.8 Clinical Trial Concept Development Process

The Clinical Trials Groups have advised the typical process followed to develop clinical trial concepts is as follows:

1. Invite clinical trial concepts from members or design concepts reflecting prioritised research areas, which can often be done at concept development workshops.
2. Ensure statistics are robust to confirm sample sizes.
3. Undergo a peer-review from members, including consumers or multi-disciplinary teams when appropriate, for scientific merit, equipoise and to determine feasibility, often in recruitment or likelihood of being awarded funding and receiving drug supply. This review can occur at Annual Scientific Meetings, working groups or concept development workshops.
4. At this stage, Clinical Trials Groups may begin formally surveying their membership for interest.

5. If the concept has received support, additional reviews may be progressed through the National Technical Services, consumers or other disciplines. At this stage, the inclusion or design of sub-studies can also occur, for example additional lab research on collected samples and quality-of-life or supportive care studies.
6. Applications for funding are submitted, accompanied by a study budget which includes quotes for trial centre conduct or site payments.
7. Once funding is confirmed, the protocol will be developed based on the initial concept.
8. *(Generally, beyond the scope of funding under the SCCT program)* To activate a study, Clinical Trials Groups must:

    a. Develop and submit a Participant Information Sheet and Consent Form and Investigator's Brochure to the Human Research Ethics Committee, along with the protocol itself.
    b. Register the trial.
    c. Arrange drug supply, if needed, including any parameters around safe drug transit or drug labelling.
    d. Submit a Clinical Trial Notification to the Therapeutic Goods Administration for drugs to be used for experimental purposes.
    e. Undergo safety review processes, for example through the formation of an Independent Data Safety Monitoring Committee.
    f. Send questionnaires to select sites to determine interest and feasibility in participating in the study.
    g. Complete site set-up, including site initiation visits, governance approvals and contract signing with any sponsors.
    h. Develop a database.
    i. Develop Standard Operating Procedures for trial centres, if they do not have any existing procedures.
    j. Begin patient recruitment once approved by sponsor.

2. Issues for Consideration

2.1 Fostering meaningful engagement and genuine collaboration to define priority outcomes in clinical trials: "the what?"

As stated in Section 1.2, the outcomes of the SCCT program are to guide scientific improvements in cancer prevention, treatment and care to achieve equity in cancer outcomes and improve quality of life for all Australians affected by cancer.

Clinical Trials Groups have self-identified a need for expert guidance on how to effectively engage with Aboriginal and Torres Strait Islander people to define priority outcomes in the development of cancer clinical trials. CTGs highlighted that assistance is required in:

- Engaging with Aboriginal and Torres Strait Islander communities to identify and define priority health outcomes and research questions.
- Ensuring research design is inclusive and culturally safe to increase Indigenous participation.
- Implementing methodologies to identify and prioritise outcomes that matter most to Indigenous communities.
- Ensuring outcomes measured in clinical trials are relevant and beneficial to Aboriginal and Torres Strait Islander people.
- Connecting with Aboriginal and Torres Strait Islander communities or researchers to enable co-design and inclusion on research teams. CTGs find it difficult to find Aboriginal and Torres Strait Islander researchers to facilitate co-design and meet requirements for specific grant applications, for instance the AIATSIS Code of Ethics.

CONSULTATION QUESTIONS

- How could this National Technical Service help CTGs to identify priority cancer healthcare outcomes, define research questions and develop culturally safe protocols important to Aboriginal and Torres Strait Islander people? Who should this Service consult with to identify priority cancer healthcare outcomes and define research questions?
- How could this Service uplift the capability of the CTGs to help them mature and build their own expertise around culturally safe care and co-design?
- How could this Service help CTGs connect with Aboriginal and Torres Strait Islander researchers to identify priorities, facilitate co-design and meet requirements for specific grant applications?
- To prevent duplicative efforts, how could this Service help inform CTGs of existing activities or research determining priorities around cancer healthcare for Aboriginal and Torres Strait Islander people?

2.2 Fostering meaningful engagement and genuine collaboration to improve clinical trial design: "the how?"

Cancer Australia's review of the SCCT program highlighted a unanimous request from the CTGs for a coordinated technical service to guide them through how to appropriately engage with Aboriginal and Torres Strait Islander people in meaningful clinical trial design. It is essential to both improve health literacy around clinical trials and address fears from past assimilation policies and forcible child removal practices, as CTGs rely on healthcare infrastructure to deliver trials. The perception of clinical trials needs to move away from that of research being "conducted on" Aboriginal and Torres Strait Islander people. Instead, the CTGs propose to shift the paradigm by collaboratively working together to overcome current inequities and create meaningful change for Aboriginal and Torres Strait Islander people. Strategies should be aligned with NACCHO's Aboriginal and Torres Strait Islander Cancer Plan, to incorporate Aboriginal and Torres Strait Islander-led research and research methodologies; for cancer data to be used to positively influence change; and to share stories of lived experience[6]. Over time, embedding culturally safe care and co-design principles across the health and research sector will enable more Indigenous-led clinical trials, or at least various aspects of trials, to empower Aboriginal and Torres Strait Islander people to address health issues that most affect their communities.

Key themes that emerged from the feedback from CTGs were:

- Genuine collaboration with Aboriginal and Torres Strait Islander communities in the design phase of clinical trials, including Aboriginal and Torres Strait Islander governance, to support cultural safety and knowledge.
- Enhancing understanding and respect for cultural practices, beliefs and values of Aboriginal and Torres Strait Islander people to design trials that are culturally appropriate and meaningful.
- Building trust and strong relationships between CTGs and Aboriginal and Torres Strait Islander communities, especially through addressing ethical considerations specific to Indigenous Australians, including issues of consent, data sovereignty, storage of samples and community beliefs.
- Understanding barriers to access and participation in clinical trials for Aboriginal and Torres Strait Islander people and designing trials to be more accessible, considering factors such as location, language, cultural safety and socioeconomic status.
- Understanding Aboriginal and Torres Strait Islander perception of, and experience with, the healthcare system, including women's cancers, smoking-related stigma for lung cancer, fatalistic beliefs or concerns around genomic testing. Specifically, CTGs may benefit from hearing and learning from positive experiences in engaging with the healthcare system generally, and with clinical trials specifically.
- Improving communication about clinical trials to be clear, culturally sensitive and accessible.

- Establishing an avenue for CTGs to seek advice, ask questions and initiate conversations with Aboriginal and Torres Strait Islander people and communities. Ongoing guidance across different aspects of clinical trials and a range of patient needs would be of great value.

CONSULTATION QUESTIONS

- What are the barriers to accessing clinical trials for Aboriginal and Torres Strait Islander people? How could this Indigenous National Technical Service support CTGs to address these barriers in the development of clinical trial concepts and protocols?
- Is there an existing model for cultural safety training that this Service can provide to CTGs?
- How can this Service help CTGs understand the perception and culture around cancer, the healthcare system and the role of research?
- What other services could this Service provide to, or on behalf of, CTGs under the SCCT program?

2.3 Best Practices to Approach an Aboriginal and Torres Strait Islander National Technical Service Procurement

Following advice from this Roundtable discussion, Cancer Australia will develop and publish an Approach to Market on AusTender accompanied by a virtual industry briefing and advertisement on Koori Mail. As this technical service is unique and relies on the leadership and involvement of Aboriginal and Torres Strait Islander people and organisations, Cancer Australia is interested in considering whether there are additional avenues to optimise the promotion of this opportunity to interested and capable individuals or groups.

To evaluate responses, a panel of Aboriginal and Torres Strait Islander researchers or health providers, Indigenous consumers, representatives of the Clinical Trials Groups, and Cancer Australia representatives will be formed. Evaluation of each application will focus on the applicant's ability to meet the purpose of the technical service and support Aboriginal and Torres Strait Islander people with cancer by assessing their:

- Proposed methodologies, project plan and key performance indicators and whether they are aligned to the requirements listed in the Approach to Market.
- Proven capacity to provide the service supported by any relevant experience or previous performance.
- Alignment with the principles outlined in NHMRC's *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities* to ensure free, prior and informed consent; agreement on how researchers, organisations and communities are expected to work together; ownership of cultural and intellectual property; and strengthening cultural competency among researchers[9].
- Whole of project costs.

CONSULTATION QUESTIONS

- What avenues should Cancer Australia explore to target appropriate providers?
- How should the Panel consider applicant's previous commitment and capabilities to meet NHMRC's principles in ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities?
- What other considerations should the Evaluation Panel have when assessing applications?

Appendix A: Case Study "Jimmy"

CASE STUDY: "JIMMY"

"Jimmy" is a 51-year-old man who has lived on APY lands all his life. As a traditional man, he hunts and eats bushtucker and he works for the council as a ranger. When Jimmy feels unwell, he usually seeks the advice from traditional healers and uses bush medicine. Two years ago, while at work, Jimmy suddenly complained of chest pain and began vomiting. His co-workers took him to the clinic at Amata where the doctor examined Jimmy and wanted to "take some blood tests" to find a cause for his pain and vomiting. Jimmy was afraid of having his "blood taken away from him", as he grew up listening to stories of his grandparents and Elders being taken by the government and forced to be examined and give multiple blood samples in barbarous and degrading scientific experiments during the 1920s and 1930s.

Jimmy chose to see a traditional healer instead, and he left the clinic. Two years on, Jimmy still has ongoing pains in his chest and nauseous and has no appetite. He has lost weight and has no energy. A family member insisted that he go to the clinic in Amata again to be treated. This time Jimmy allowed the doctor to take some bloods and be referred to Alice Springs for radiology assessments. Jimmy didn't really understand why he had to travel to get help, but he went to please his family. In Alice Springs, the medical team did not have good news for Jimmy and his family, as all investigations showed that he had a rare form of stomach cancer in an advanced stage.

Jimmy immediately began treatment for this cancer (including aggressive chemotherapy and surgical procedures), which resulted in a long-term stay in Alice Springs hospital away from his family and country. The multi-disciplinary team eventually had discussions with Jimmy and his family about what options he had left, considering the advanced stage of his cancer. Jimmy just wanted to go home to country and didn't understand why the hospital had tried many treatments and now the doctors were saying that there no more options left for him. As Jimmy really wanted to go home with family on his country, the multi-disciplinary team then suggested that Jimmy be "enrolled" in a clinical trial out of Adelaide. Jimmy couldn't understand why he was told there was no more options left to treat his cancer but now was being told to enrol in a clinical trial. When he asked why he was being told to do so, the rationale given was "so they can see if new medications will work for this cancer". Jimmy and his family declined because they felt that the hospital didn't want to treat him anymore, but they were happy to "test" new medications on him, furthering his fear of "being tested on" like his ancestors.

At what stage of Jimmy's journey should he have been offered Clinical Trials?

Clinical trials are a component of optimal care. How can we help Jimmy follow the Optimal Care Pathway?

How does a research protocol determine what/when/where/ how a trial is offered to patients?

Jimmy died on Country with family caring for him and the help of a traditional healer to treat his symptoms. Jimmy's family refuse to engage with the clinic at Amata because of their experience of Jimmy's illness.

**Story recalled from an Aboriginal Health Worker from Alice Springs – names changed for privacy*

How can we ensure this new National Technical Service benefits people like Jimmy?

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