TR-ANZGOG CONSENSUS WORKSHOP

Summary of a workshop held 7 November 2019

INTRODUCTION

Translational ANZGOG (TR-ANZGOG) is an initiative that emerged from strategic planning activity undertaken by the Australian New Zealand Gynaecological Oncology Group (ANZGOG) in 2018, which identified the need to build capacity for translational research in gynaecological cancer.

TR-ANZGOG has been established to:

- meet the strategic goal of building capacity for translational research by supporting collection of biospecimens associated with all ANZGOG trials
- provide enduring custodianship for biospecimens
- maximise the use of biospecimens through research.

Over the past 12 months, work has commenced to build the strategies and processes needed to support TR-ANZGOG activity. On 7 November 2019, ANZGOG held a consensus workshop to achieve insight and agreement from relevant experts on key processes and considerations for TR-ANZGOG. The workshop was attended by 32 people representing a range of relevant clinical, scientific and consumer perspectives (see attendance list in Appendix I). The workshop agenda is provided in Appendix II.

The aims of the TR-ANZGOG consensus workshop were to:

- create a robust foundation for TR-ANZGOG and its activities
- achieve clarity/consensus on key governance and process issues
- agree the engagement and communication needed to support TR-ANZGOG and empower the TR-ANZGOG community.

Focus areas covered during workshop discussions were:

- custodianship / governance of data and specimens
- biospecimen collection
- data management
- considerations for a TR-ANZGOG laboratory network
- consent guidelines.

This report provides a summary of the workshop feedback. It incorporates feedback from pre-workshop consultation with participants unable to attend.

TR-ANZGOG ROLE AND PROGRESS

Opening the workshop, TR-ANZGOG Chair Professor Anna deFazio reflected on the changing clinical trial landscape, noting that translational research is now a core part of clinical trial activity. She emphasised a commitment by TR-ANZGOG to build on existing foundations, learn from other translational research initiatives and ensure that processes are practical and straightforward.

Other relevant initiatives

- ABN-Oncology – GynBiobank, PeterMac Tissue Bank, kConFab
- Australian Ovarian Cancer Study (AOCS)
- NHMRC Clinical Trials Centre
- Canadian Cancer Trials Group (CCTG)
- National Biobanking Summit – Scoping Study

Professor deFazio described how TR-ANZGOG aims to achieve its goals through four core components:

- **ANZGOG Trial Investigators**: providing a mechanism for ANZGOG trial investigators to obtain support to manage biospecimen collection and processing, and facilitate translational aspects of clinical trials
- **TR-ANZGOG laboratories:** building:
    - a national network of laboratory-based facilities to participate in collection and processing of biospecimens on behalf of ANZGOG trials
    - a designated biobank/laboratory for long-term custodianship and dissemination of clinical trial related biospecimens to facilitate future translational research
- **Translational Investigators:** providing a mechanism for investigators to apply to TR-ANZGOG for use of biospecimens and data for research, with feedback of research results to TR-ANZGOG from translational studies to build knowledge base
- **TR-ANZGOG Information and Resource Portal:** creating a portal to house:
    - research methods and standard operating procedures (SOPs)
    - document templates for trial protocols, PICF
    - advice for grant / trial budgets
    - an inventory of clinically annotated specimens
    - application process for support, biospecimens, data etc
    - publications.

She noted that the TR-ANZGOG initiative has the potential to improve outcomes in gynaecological cancer in three key ways:

- to understand the clinical and molecular drivers that underpin response to current and novel therapies
- to collaboratively investigate the novel clinical and scientific questions that need to be addressed in future clinical trials, and
- to promote research into the “big questions” that can only be addressed by large collaborative clinical translational studies.

Claire Davies, Project Manager for TR-ANZGOG presented a brief overview of progress to date with the TR-ANZGOG initiative, acknowledging input from the TR-ANZGOG Steering Committee (see Appendix III). Key progress milestones and anticipated next steps are provided in Appendix IV.

BUILDING EFFECTIVE PLANS AND PROCESSES FOR TR-ANZGOG: ISSUES TO CONSIDER

Workshop participants identified a range of issues and considerations to be factored into plans and processes for TR-ANZGOG. Opening perspectives presentations from A/Professor Philip Beale, Professor Susan Ramus, A/Professor Lyndal Anderson and Catherine Kennedy highlighted key clinical, scientific, pathology and biobank considerations that were then built on by other participants.

Common themes highlighted:

- the importance of keeping focused on the value to women with gynaecological cancer of the research that is being undertaken
- the need to ensure that biospecimens collected are used proactively, both within existing ANZGOG trials as well as in future research (and that approach to collection, annotation and storage supports future as well as current use)
- the need to ensure that limited availability of biospecimens and/or a woman's decision not to consent to collection and use of biospecimens for future research does not compromise the ability of a woman to be registered on a clinical trial
- the importance of recognising and responding to cultural values (for example preferences by some communities for biospecimens not leaving the country)
- the value of building on ANZGOG's track record and processes
- the importance of drawing on experience from other translational research collaborations (national and international, e.g. AOCS, Ovarian Tumor Tissue Analysis (OTTA))
- the importance of trust that specimens will be used appropriately
- the need for timely communication and feedback between all relevant stakeholders
- the importance of clear language that will support understanding by clinicians, researchers and patients of the goals of TR-ANZGOG and the processes underpinning its work.

Clinical considerations

- As TR-ANZGOG plans are developed and implemented, it is important to maintain a focus on the clinical relevance of the research and how findings will translate into improved outcomes for women. In describing the purpose of TR-ANZGOG we should not lose sight of the end goal which is to:
    - better understand the biology of different gynaecological cancers
    - identify targets for new treatments or more effective use of existing treatments
    - better understand the factors that influence cancer outcomes for women with gynaecological cancer.
- Insights into challenges and enablers for translational research in gynaecological cancer to date have been drawn primarily from studies in ovarian cancer. TR-ANZGOG will need to identify any additional or different considerations for translational research in other gynaecological cancers. For example, for endometrial cancer, diagnosis may be made through a separate centre to treatment (via dilatation and curettage) and this may influence the availability of biospecimens. Consideration of needs may require engagement and clinical input from relevant specialists, including surgeons, to ensure approaches are feasible and clinically appropriate.

Scientific considerations

Considerations for biobank advisory boards

- Different stakeholders may have different views on what projects are worth undertaking
- Some studies may require combination in order to gain sufficient power and / or validate findings
- Power calculations need to be considered carefully (giving consideration to heterogeneity / histotypes / survival analysis)
- It is important to maintain a balance between using biospecimens within existing research projects and having material available for later projects

Benefits of working at scale

- Large numbers of biospecimens increase power and ability to assess heterogeneity
- Shared resources create efficiencies and support centralised activity

Challenges of working at scale

- Delays in finalising agreements with different organisations
- Costs can be prohibitive (e.g.costs for shipping biospecimens and making biospecimens available for research)
- Variation in quality:
  - tissue microarray (TMA) quality
  - biospecimen fixation
  - annotation of biospecimens
  - amount of clinical data provided

Pathology considerations

Enablers

- It is important that pathologists trust that use of tissue will be meaningful, including provision of feedback to patients and to pathologists
- A good track record for researchers is viewed positively
- The ability to update data associated with biospecimens as tumour classifications change is important

Challenges

- Pre-adjuvant tissue biopsies are small, and specimens may be exhausted
- For some gynaecological cancers, pre-treatment specimens may only be cytology from ascites
- Post-chemotherapy specimens may have limited utility because of the effect of chemotherapy on DNA
- Some pathologists are reluctant to release blocks
- Some laboratories/pathologists charge unreasonable costs for processing and accessing specimens

Biobank considerations

Enablers

- Local biobank may have pre-treatment biospecimens
- Strategies for sharing biospecimens to avoid multiple biospecimen collection events from the same patient
- Clear and consistent standard operating procedures (SOPs) that can be applied to ensure consistency across multiple sites
- Centralised data portal
- Biospecimen tracking / barcoding
- Storage and batch shipment costs

Challenges

- The impact of neo-adjuvant treatment on biospecimen availability
- Competing studies mean that the same biospecimen is in demand for multiple studies
- Costs include biospecimen processing, tracking and retrieval, data entry; the cost of running biobanks is increasingly challenging with initial grant funding drying up
- Ensuring strict adherence to SOPs (local laboratory biobank certification)
- Inconsistent labelling
- Not all sites will release formalin-fixed paraffin-embedded (FFPE) blocks for TMA construction

HOW WE WANT TO WORK: GUIDING PRINCIPLES AND GUIDELINES

Guiding principles

Participants reviewed draft guiding principles for TR-ANZGOG and recommended ways to strengthen these.

Draft principles reviewed during the workshop

TR-ANZGOG:

- implements 'light touch' and 'can-do' processes to facilitate translational research
- is inclusive, transparent, with good governance and strong engagement with stakeholders
- has key positions on governance committees that rotate (limited terms) and are open to all disciplines
- will promote large 'question-driven' collaborative clinical and translational research projects.

Participants recommended:

- inclusion of a principle highlighting a commitment to maintaining a focus on improving outcomes for women with gynaecological cancers
- inclusion of wording to emphasise the importance of and commitment to:
  - timeliness
  - an ethical approach and respect for privacy
  - consideration of equity and cultural values
  - collaboration
  - proactive use of biospecimens to generate new knowledge
  - consistency in quality
- inclusion of a statement that clinical trial takes precedence over biobanking; collection and use of biospecimens should not compromise the study (e.g. Investigator may need all biospecimens or have competing priorities for available samples).

Clinical trial support and biospecimen access guidelines

Participants provided the following feedback on the draft guidelines.

Draft guidelines reviewed during the workshop	Feedback
• Access to TR-ANZGOG to manage the translational aspects of a clinical trial will be via a transparent and equitable application process.	•
• If TR-ANZGOG facilities have supported the management of biospecimens the expectation would be that the biospecimens will be made available for future research, with appropriate governance.	•
• Patient consent and HREC approvals will be consistent with allowing biospecimens to be made widely available for future research, subject to scientific review, HREC approval and well-executed governance.	• Consider consent implications on an individual's insurance (noting that the impact for people with cancer is likely to be less than for people with other health conditions – given that cancer diagnosis will already have influenced insurance) • Consider inclusion on consent forms for permission to recontact patient/family to access biospecimens

Draft guidelines reviewed during the workshop	Feedback
• TR-ANZGOG trials protocol would include access to a representative tumour sample and a blood sample.	• Agree and document a position on making biospecimens available for people with advanced cancer, and after death (i.e. when samples are no longer needed to inform clinical care); note that even if consent forms cover this, pathologists may still refuse to release samples, potentially due to legal requirements
• Biospecimen will be embargoed until specific translational aspects of the clinical trial are complete.	• Ensure that wording around timing of use of specimens does not preclude ability to undertake adaptive trial design • OTTA wording is not that biospecimens cannot be accessed but that publication cannot occur until the original trial has been completed and published (i.e. the work is not delayed but release of findings does not compete with the original research)
• Approval for use of biospecimens outside the scope of the original trial aims would require peer-review, HREC approval and approval from the TR-ANZGOG Biospecimen Resource Access Committee, which would include the trial Principal Investigator, if available.	• Agree and document a position around use of biospecimens in relation to commercial activity (i.e. on selling of biospecimens by biobanks)
• ANZGOG and the trial Principal Investigators from which the biospecimen collection is acquired will be acknowledged in any publications utilising TR-ANZGOG biospecimens and data.	• Clarify wording around acknowledgement (reflecting the longer form version of the guidance that notes that usual guidelines for authorship apply) • Add biobanks to the list of people who would be acknowledged • Acknowledgement of people who have contributed material is important (not via authorship but through acknowledgements)

Additional feedback highlighted a need to:

- include a commitment to communication/feedback – to patients and to pathologists, as well as broader communication of findings to community.
- consider whether biospecimen collection should be limited to ANZGOG trials or whether TR-ANZGOG could be used to create a bank of control-matched and/or primary-metastases matched biospecimens for rare cancers. The view from participants was that this could be a longer-term ambition but that collection of biospecimens outside a clinical trial setting could be undertaken as part of an ANZGOG-funded research project.

AGREEING TR-ANZGOG PROCESSES

Participants participated in small group discussions to review and recommend additions or revisions to draft recommendations in four areas:

- biospecimen collection
- custodianship / governance of data and biospecimens
- data management
- TR-ANZGOG laboratory network.

A plenary discussion allowed all participants to contribute additional views. This was followed by a plenary discussion on the implications of changes to the process recommendations for consent guidelines.

BIOSPECIMEN COLLECTION

Participants provided the following feedback on the draft recommendations relating to biospecimen collection. The importance of building trust with pathology laboratories was noted.

Draft recommendations reviewed during the workshop	Feedback
Guidelines for optimum samples to collect	
1. Guidelines for optimum samples to collect for each ANZGOG trial patient (as outlined below)	• Guidelines should be described as optimal rather than minimal, noting that they may not be feasible in some circumstances and this should not preclude participation in trials and the current associated translational research projects. • Aim to avoid onerous requirements • The process will require good communication, optimal operating times and adequate personnel
2. TR-ANZGOG will only collect dedicated additional specimen/s for TR-ANZGOG in instances where there are gaps in the clinical trial's collection	• Agreed that care should be taken around collection of dedicated additional specimens if not associated with a trial • Include a TR-ANZGOG role for supporting researchers to identify meaningful questions
Access to FFPE blocks for TMA construction	
3. FFPE blocks will be accessed for construction of TMAs comprised of trial cohorts, subject to local pathology department approvals	• TR-ANZGOG to consider providing funding to facilitate block preparation and release of biospecimens • Suggestion for TR-ANZGOG to develop a cost-recovery template indexed to current rates • Consider encouraging use of digital scanning technology so that TR-ANZGOG and the pathology laboratory can retain a permanent digital copy of biospecimens (TR-ANZGOG could consider facilitating this by providing funds for digital image scanners at laboratories – which may relieve some concerns over sample release • Include a recommendation to ensure block is returned in a timely fashion at the end of the study (6–12 weeks referenced from the Queensland guidance is too restrictive) • An MTA/ guidelines document developed with pathology laboratories that includes block return procedures, timelines, minimal/ maximal cutting/coring guidelines, fees for service and annual reporting of blocks held and returned is seen as important and adequate to facilitate release of blocks. • Pathologists agreed that where adequate tissue exists, blocks may be punched for TMA construction

Draft recommendations reviewed during the workshop	Feedback
4. Where FFPE blocks are provided to researchers, retain clinical identifiers on block (surname and accession number) and affix a label on top of block with the unique trial participant ID number and TR-ANZGOG number	• Include guidance around annotation of biospecimens (e.g. on-slide annotation) • Viewed as appropriate for TR-ANZGOG to see identified blocks and use a temporary TR-ANZGOG identifier which can be removed when biospecimens are returned
Management of proportion of trial samples or all trial samples?	
5. ANZGOG trial samples will be governed by ANZGOG upon completion of the trial and associated translational sub-studies	• Include a TR-ANZGOG role for facilitating links to other relevant studies

Participants provided the following feedback on the optimal sample collection requirements.

Draft requirements reviewed during the workshop	Feedback
Representative tumour tissue sample/s (order of preference)	
1. Archival FFPE block, primary and/or relapse 2. Temporary retention of FFPE block to create Tissue Microarray (up to 100 FFPE cores in duplicate per block) *e.g.* from each specific cohort of ANZGOG clinical trial participants 3. If FFPE block not provided: Unstained slides, Cores and/or Curls 4. Where feasible, Ascites, for example: • Purified tumour cells for future DNA/RNA extraction • Cell block for future IHC/DNA/RNA extraction • establishment of permanent tumour cell lines	• Reflect that these are optimal requirements • Identify minimum and maximum guidelines • Tissue from the primary is ideal but is not possible for all patients • Pre-neoadjuvant tissue is best • TMAs construction must be compliant with patient consent (e.g. shipment of tissue overseas)Polymer TMA templates may appeal to pathology laboratories who won't release blocks • Consider wording to allow for future biospecimen opportunities (e.g. circulating DNA, expansion beyond FFPE and blood including microbiome samples for immunotherapy trials)
Blood	
Examples: • 1 x 9 mL ACD sample (whole blood, white blood cells) • 1 x 5 mL EDTA sample (Guthrie cards, plasma, buffy coats)	• Reflect that these are optimal requirements • Identify minimum and maximum guidelines • In providing examples, recognise technology will change over time

CUSTODIANSHIP AND GOVERNANCE OF BIOSPECIMENS AND DATA

Participants provided the following feedback on the draft recommendations relating to custodianship and governance of biospecimens and data.

Draft recommendations reviewed during the workshop	Feedback
During and after trial completed	Change to reflect the importance of TR-ANZGOG involvement from the outset
1. Upon completion of the ANZGOG clinical trial through which biospecimens are collected, TR-ANZGOG will manage associated biospecimens and associated data, sharing custodianship where applicable with other entities.	• Use clear definitions to ensure universal understanding of the intent of recommendations, for example: ○ the distinction between 'custodianship' and 'possession' and between 'custodianship' and 'sponsorship'

Draft recommendations reviewed during the workshop	Feedback
	○ the fact that custodianship can change over time ○ obligations of custodianship (e.g. managing withdrawal of consent) ○ clear definition of 'trial completion' ○ implications of shared custodianship
2. Where shared custodianship is feasible, TR-ANZGOG will have access to a minimum sample requirement with matched clinical data, recommended to be: • 1 x 10 mL EDTA • 1 x 10 mL ACD • 2 x cores from FFPE block for TMA construction	• Discussion focused on the need for a consistent approach and robust systems to ensure utility of specimens • Useful to consider selection of an appropriate database housing relevant information about biospecimens (with an ability for the database to adapt over time) • Importance of clear pathways for provision and incorporation of findings into the database as well as provision of feedback to patients via an ethically defensible plan (EDP). • Change to 3 x cores
Application processes/ MTAs	
3. Access of researchers to biospecimens and data will be via a transparent, well-governed mechanism, as outlined in attached Governance Reporting Structure (V1.5; 26 July 2019)	• The Governance Reporting Structure is very clear • Schematic could be visually simplified • Participants were happy to see the multidisciplinary nature emphasised • Recommended that it is important to leverage processes that ANZGOG already has in place • Timeliness and transparent processes are supported • Eligibility criteria speak to the ethos of ANZGOG and TR-ANZGOG
4. Access of trial investigators to TR-ANZGOG resources for management or biospecimens and clinical trial support will be via a transparent, well-governed mechanism, and include consultation with TR-ANZGOG	• Important to leverage TR-ANZGOG to help investigators identify questions and understand what is possible from a translational perspective • Investigator should have first rights to use of biospecimens collected during the trial; TR-ANZGOG may need to play a role in moderating requests where there are multiple requests to use the same samples • TR-ANZGOG to provide guidance on appropriate budgets for translational research • Trusted relationships with pathology will be important to ensure the success of proposed approaches
5. The TR-ANZGOG Access Policy will be compliant with NSW Health State-wide Biobanking Access policy	• Recommended that rather than aiming for compliance with the NSW State Biobank, TR-ANZGOG should work proactively with the biobank to influence policies as they evolve • **Action for the governance group to review the access policy in detail** • Important to develop agreements with biobanks that define expectations around collaboration
6. TR-ANZGOG will permit industry access to specimens on a case by case basis	• Need to define 'industry' recognising that there are different industry components (not just pharma) but groups with a commercial interest

Draft recommendations reviewed during the workshop	Feedback
	• Considerations around collection and access may be different for different commercial uses • Fee structure for commercial use of biospecimens should be agreed with a discounted fee for non-commercial uses

Feedback collected prior to the workshop suggested that, at a designated timepoint, the trial investigator should be emailed to check whether remaining samples can be released to other investigators and if samples are not yet available, a time agreed for when this will be.

It was also noted that transfer of custodianship can occur at the time of biospecimen transfer.

DATA MANAGEMENT

Participants provided the following feedback on the draft recommendations relating to data management. Participants agreed with the suggestion of establishing a TR-ANZGOG Data Working Group to consult with other consortia and collaborations about data items collected.

Draft recommendations reviewed during the workshop	Feedback
Essential data set	

1. The minimum data set collected will include core data items and cancer type-specific data items. TR-ANZGOG will call on the expertise of ANZGOG members to determine the minimal data set (MDS)	• Participants agreed to the recommendation
	• Suggested revisions to the supporting information included:
	  ○ making a clear distinction between clinical data and trial data (and defining what these are)
	  ○ considering tiers of information within the MDS (essential, highly desirable, optional)
	  ○ providing guidance to investigators and sites ensures consistency in how data are provided
	  ○ providing advice on where data linkage may act as a proxy for information that is not available (e.g. linkage to Medicare data and the National Death Index)
	• Participants suggested that TR-ANZGOG could:
	  ○ work with investigators from the early stages of planning to help define what data are needed and the feasibility of collecting this
	  ○ play a role in supporting logistics around consistent data collection

Mechanisms/ barriers to clinical data collection	

Longitudinal follow-up
2. TR-ANZGOG Project Manager (and designated TR-ANZGOG data manager, as required) will have access to identifiable patient information to facilitate longitudinal follow up and re-identification in the instance of findings of actionable, clinical significance. Access to patient identifiable information is also required for instances of requesting FFPE blocks and maintaining patient consent records.
	• Participants recommended splitting this recommendation into two parts:
	  ○ preclinical data
	  ○ information to support longitudinal follow-up
	• The role of TR-ANZGOG in providing resource to support ongoing data collection was noted

Draft recommendations reviewed during the workshop	Feedback
Integration of platforms 3. Biospecimens will have matched clinical data sourced through integration with clinical trial databases (CTC and BaCT) and biospecimen metadata from the PIs/TR-ANZGOG lab. Raw data from any translational substudy will be returned to TR-ANZGOG but likely to be stored separately rather than integrated to the main LIMS/ clinical trial database	• Matched data – raw data and data derived from that • Participants recommended that the Data Working Group should develop definitions and guidelines on how data are provided to TR-ANZGOG (recognising that trial data are likely to be good quality while translational data are likely to be variable in quality) • Participants agreed that a separate database is needed for raw data from translational sub-studies
Researcher access to data 4. TR-ANZGOG will hold the data and investigators will work with statisticians and bioinformatics provided via TR-ANZGOG resourcing to analyse data. This is contingent on TR-ANZGOG have the resources to perform the analysis	• This recommendation generated the most debate amongst the small group and will require further consideration by TR-ANZGOG and by the Data Working Group. • Issues discussed under this recommendation included: o the project-specific nature of decisions and requirements for analysis o the need for up-front data analysis protocols o the need for investigators to provide TR-ANZGOG with data and codes used if analysis is undertaken by the investigator o the importance of TR-ANZGOG and investigators working together o the aim of avoiding dependency on third parties o standards will be important to ensure longevity of data
Sustainability Funding will be required for the following resources: • maintenance of the IT platforms, • longitudinal follow up & data entry • bioinformatics	• Add data manager as a funding requirement • Include biostatistics as well as bioinformatics • Cost for IT platforms will require consideration of database requirements (with specimen tracking requirements considered separately from housing trial data)

TR-ANZGOG LABORATORY NETWORK

Participants provided the following feedback in relation to questions posed about a TR-ANZGOG laboratory network.

There was broad agreement to the concept of a national (including NZ) network of TR-ANZGOG 'designated' laboratories to:

- facilitate collection and processing of specimens from trial participants for the purposes of the clinical trial and future research, on behalf of TR-ANZGOG
- agree to be the designated short-term and/or long-term home for a specific clinical trial collection
- agree to manage the provision of samples to researchers, contingent on appropriate approvals.

The overarching principle that TR-ANZGOG network laboratories would need to be reimbursed for the costs of collection/ storage/ supply of samples and data was agreed to. It was suggested that while a network of laboratories may be useful for collection of biospecimens, there is benefit in centralising storage of biospecimens (either in one biobank or in one location in each state) so that access to samples in the longer term is not hindered due to changes in research group funding or staffing.

It was agreed that a Laboratory Network Working Group should be established to further work through the questions and considerations.

Questions posed during the workshop	Feedback
MOU	
1. A standard Memorandum of Understanding (MOU) would be required between all TR-ANZGOG network labs and ANZGOG	• There was a preference for a service agreement rather than an MOU. • Where a 'network lab' is a biobank with multiple pathology providers, consideration will need to be given to ensuring that the head agreement covers the relationship with individual laboratories
Sustainability	
2. How would reimbursement to TR-ANZGOG network labs be best standardised? In-kind support and/or direct payment. Other models?	• There was a preference for direct funding; however, it was noted that 'in-kind support' was mis-interpreted and there was subsequently support for provision of staff • There was support for the concept of TR-ANZGOG undertaking a review/benchmarking of current costs and cost effectiveness to inform a standard cost for the agreed optimal biospecimen collections • It was noted that in developing a standard cost template it will be important to ensure that: o costs are not driven upwards in a bid to achieve standardisation o costs can be justified o different factors that may influence costs are considered (e.g. differences between public and private pathology services)
3. Industry access to TR-ANZGOG resources will be at TR-ANZGOG discretion. Where industry access is approved, higher user fees may apply than user fees by academic users. Note. NSWHSB has a multiplier of 1.56 for For-Profit requests	• There was support for higher costs for approved industry access (note previous comment about a preference to provide a discount for non-commercial uses rather than a higher fee for industry)
4. Further to TR-ANZGOG Guiding Principles, the TR-ANZGOG network labs associated with the biospecimen collection and management for any research resulting in publication utilising those specimens would be acknowledged using TR-ANZGOG approved wording. Note: Children's Cancer Care Tissue Bank stated that acknowledgments of their tumour bank (and funding sources) in publications promoted philanthropic donations. Publication acknowledgement is a KPI for many biobanks	• It was noted that it may be appropriate to consider biobanks as authors (not just acknowledgement) in line with the agreed authorship guidelines
Capacity	
5. TR-ANZGOG SOPs will be developed in conjunction with TR-ANZGOG network laboratories to facilitate uniform biospecimen collection and data management	• The approach to supporting uniform biospecimen collection across the network was not discussed in depth • The question of facilitating uniform collection and data management raised the question of requirements for auditing and long-term ambition for accreditation of TR-ANZGOG laboratories

Questions posed during the workshop	Feedback
6. TR-ANZGOG network labs may not have the capacity to support every new trial request and they should be provided an opportunity to approve acceptance of workload on a case by case basis. However, distribution of specimens would be a requirement, if that was originally agreed	• The differing capacities of different laboratories were acknowledged (designated biobank vs hospital laboratory). Consider mechanisms in instances of end of capacity. • The risk of bias in types of research undertaken if laboratories have a choice over whether to participate was noted with a view that this could be tracked over time so that adjustments could be made to address any underserved areas
Custodianship/ access	
7. Would a standardised TR-ANZGOG Access policy (e.g. NSWHSB document) be acceptable with individual labs given their existing access policies (*this topic overlaps with the custodianship/ governance small working group)?*	• Early engagement of translational researchers with clinical researchers so that questions can be designed appropriately, and requirements of the labs can be defined • Surgeons want to be involved – provide a more patient-focused view • Consider requirements across all cancer types • Be realistic regarding number of biospecimens at any site and what is going to be most efficient
Potential TR-ANZGOG network laboratories	

Proposed assessment criteria:
• Resources
  ○ Staffing/ time
  ○ Facilities
  ○ Equipment
  ○ Experience
• QA and accreditation framework
• Location
	• Option for a phased approach – start with labs that have the necessary resources/an existing relationship and use the agreements with these labs to inform approaches for future laboratories
	• In states without a central storage facility, identify where biospecimens would be sent
	• Recognise that some advocacy may be needed within hospitals to persuade leaders of the value of translational research activity and to encourage their involvement

CONSENT

Recommended TR-ANZGOG patient consent guidelines

1. Consistent with a TR-ANZGOG guiding principle, consent will allow for indefinite retention for HREC-approved, future unspecified research (FUR)
2. TR-ANZGOG will participate in a process to notify participants if findings have been made that may have clinical significance, where verified and actionable, compliant with NSW Health State-wide Biobank requirements.
3. Include opt-in consent to re-contact participant as required, e.g. for additional trial screening purposes
4. Consent forms will include the required text to request permission to access Medicare/ PBS data.
5. Patients are provided with information to explain that biospecimens will be managed under TR-ANZGOG governance structures.

There was agreement from participants on the need to:

- include specific lines within consent forms to allow patients to consent to individual statements rather than having one approval for a blanket consent statement with multiple components
- incorporate specific wording to provide consent to tissue being sent overseas for research (from New Zealand to Australia and vice versa)

- include wording about the importance of informing patients about incidental findings within the current trial and in future research (within the duty of care) with acknowledgement that individuals have a choice when contacted about what they are told
- include a line about consent for information to be provided to family
- ensure that clinical trial access is not restricted because of a lack of consent to secondary translational questions.

Issues for further consideration by a Consent Working Group (or by the TR-ANZGOG Steering Committee included:

- whether to include wording about use of tissue from people who have died (noting that pathology laboratories will still make their own determination about releasing tissue regardless of whether a patient has consented to making tissue available after death)
- how to future proof consent guidelines by including statements about what tissue could be used for (acknowledging that systems may not yet be in place and that action may need future policy change)
- the need to gain clarity around what is acceptable regarding use, storage and sharing of Medicare data or proxy information determined through Medicare data
- the value of exploring innovative models to support patient understanding of consent (e.g. videos).

NEXT STEPS

Agreed next steps to finalise guidelines and recommendations following the workshop will be:

1. The TR-ANZGOG Project Manager will work with the TR-ANZGOG Chair and ANZGOG CEO to review the workshop feedback and revise recommendations as required
2. Circulation of the revised recommendations to workshop participants for review
3. Establishment of working groups to assist in finalising definitions and other details relating to the different focus areas:
    - Data Working Group
    - Network Laboratories Working Group
    - Patient Consent Working Group

APPENDIX I: CONSENSUS WORKSHOP PARTICIPANTS

Name	Role	Institute/affiliation
Catherine Kennedy	Research Manager	Dept Gynaecological Oncology, Westmead Hospital
Nadia Traficante	Project Manager	Australian Ovarian Cancer Study
Wanda Lawson	Chair, Consumer Research Panel	ANZGOG
Kathryn Cornthwaite	Clinical Research Nurse	Flinders Centre for Innovation in Cancer
Mark MacLean	Head, Clinical Data Management	NHMRC Clinical Trials Centre The University of Sydney
Sanela Bilic	Project Manager – Gynaecological Cancer Research	St John of God Subiaco Hospital
Nicki Meagher	Project Manager, PhD candidate Molecular Oncology Group, Adult Cancer Program	UNSW
Pamela Provan	INOVATe Program Manager	Centre for Cancer Research, WIMR
Susan Ramus	Founder & co-lead	Ovarian Tumour Tissue Analysis (OTTA) consortium
Alison Choy Flannigan	Partner	Hall&Wilcox
Allison Black	Medical Oncologist	Royal Hobart Hospital
Michelle Wilson	Medical Oncologist	Auckland City Hospital
Kathryn Jenkins	Clinical Trials Coordinator	NSLHD Cancer and Palliative Care Network
Sue Brew	Clinical Trial Coordinator	Calvary Mater Newcastle
Rohan Lourie	Director, Anatomical Pathology	Mater Health Services, Brisbane
Adeline Tan	Co-Director	Western Women's Pathology
Kerryn Ireland-Jenkin	Anatomical Pathologist	Austin Health
John Hooper	Professor of Cancer Biology; Leader Cancer Biology Laboratory	Mater Research Institute University of Queensland
Val Gebski	Professor & Co-Director, Biostatistics and Research Methodology	NHMRC Clinical Trials Centre The University of Sydney
Haryana Dhillon	Associate Professor, Centre for Medical Psychology & evidence-based decision making	School of Psychology, Faculty of Science The University of Sydney
Penny Webb	Group leader, Cancer Aetiology and Prevention Laboratory	QIMR Berghofer Medical Research Institute
Danielle Miller	Business Director	NHMRC Clinical Trials Centre The University of Sydney
Alison Hall	Director, Centre for Biostatistics and Clinical Trials (BaCT)	Peter MacCallum Cancer Centre
Philip Beale	Director, Cancer Services and Palliative Care, SLHD Director Concord Cancer Centre Head of Medical Oncology, CRGH, Chair, ANZGOG	ANZGOG

Name	Role	Institute/affiliation
Lyndal Anderson	Senior Staff Specialist, Dept of Tissue Pathology & Diagnostic Oncology	Royal Prince Alfred Hospital
Anna deFazio	Sydney West Chair of Translational Cancer Research, USyd Co-Director, Centre for Cancer Research, WIMR Chair, TR-ANZGOG	University of Sydney WIMR ANZGOG
Pamela Pollock	Principle Research Fellow, Faculty of Health, Biomedical Sciences	Queensland University of Technology
Alison Evans	CEO	ANZGOG
Karen Livingstone	Head, Fundraising & Development	ANZGOG
John Andrews	Program Manager, Clinical Trials	ANZGOG
Claire Davies	Project Manager, TR-ANZGOG	ANZGOG
Attendance via Zoom:		
Amanda Spurdle	Group Leader, Molecular Cancer Epidemiology Laboratory	QIMR Berghofer Medical Research Institute
Yoland Antill	Medical Oncologist	Frankston Hospital
Chris Carter	Clinical Director, Cytopathology & Regional Services	SA Pathology

APPENDIX II: WORKSHOP AGENDA

TR-ANZGOG: Building consensus for action

Date: Thursday 7 November 2019

Time: 9.30am to 4.00pm

Venue: Novotel Sydney International Airport

Time	Agenda item	Presenter/facilitator
9.00–9.30	**Arrivals and registration**	
9.30–9.40	**Welcome and introductions** Aims for the workshop	Anna DeFazio Chair, TR-ANZGOG
9.40–10.00	**TR-ANZGOG overview:** Progress and plans	Claire Davies Project Manager, TR-ANZGOG
10.00–10.45	**Building effective plans and processes for TR-ANZGOG:** issues to consider Perspectives presentations and group discussion	Alison Evans Consulting
10.45–11.15	**How we want to work:** Group discussion to agree ambition and guiding principles	Alison Evans Consulting
11.15–11.30	**Morning tea**	
11.30–12.40	**Agreeing our approach:** expert insights 1. Custodianship / governance of data and specimens 2. Specimen collection 3. Data management 4. Laboratory network	Small group discussion
12.40–1.15	**Lunch**	
1.15–2.15	**Agreeing our approach:** building consensus Small group feedback and consensus on the way forward	Alison Evans Consulting
2.15–2.45	**Consent guidelines:** Review and refinement	Small group discussion
2.45–3.00	**Afternoon tea**	
3.00–3.15	**Consent guidelines:** Agreement on changes	Alison Evans Consulting
3.15–3.50	**Taking plans forward** Agreement on priorities, timeframes, partners and communication	Alison Evans Consulting
3.50–4.00	**Recap and next steps**	Anna DeFazio and Claire Davies
4.00	**Close**	

APPENDIX III: TR-ANZGOG STEERING COMMITTEE

Name	Role	Institute
Professor Anna deFazio	Chair TR-ANZGOG Sydney West Chair of Translational Cancer Research, Centre for Cancer Research	Westmead Institute of Medical Research
A/Professor Philip Beale	Chair ANZGOG Director Cancer Services and Palliative Care, Sydney Local Health District	Concord Cancer Centre
A/Professor Lyndal Anderson	Gynaecological Pathologist	Royal Prince Alfred Hospital
Professor Clare Scott	Medical Oncologist	Walter and Eliza Hall Institute of Medical Research
A/Professor Pam Pollock	Principal Research Fellow	Queensland University of Technology
Professor David Bowtell	Head, Cancer Genomics and Genetics	Peter MacCallum Cancer Centre
A/Professor Alison Brand	Director, Gynaecological Oncology	Westmead Hospital
Dr Alison Davis	Medical Oncologist	Canberra Hospital
Dr Michelle Vaughan	Medical Oncologist	Canterbury District Health Board, New Zealand
A/Professor Linda Mileshkin	Medical Oncologist	Peter MacCallum Cancer Centre
Alison Evans	Chief Executive Officer	ANZGOG

APPENDIX IV: TR-ANZGOG PROGRESS MILESTONES AND NEXT STEPS

2018

- Seed funding received: July 2018
  - Rose Varga Bequest
- Project Manager appointed: August 2018
- 1st Steering Committee meeting: Sept 2018

2019

- Further funding received: November 2018
  - John T Reid Charitable Trusts
- Grant success: February 2019
  - Office for Health and Medical Research through the NSW Health State-wide Biobank (NSWHSB)
- NSW Biobank Certification Program
- Documents drafted
- Pilot study – SOLACE2
- ASM presentation – March 2019
- Board presentation – July 2019
- Consensus workshop – Nov 2019
- Finalise documents – Dec 2019:
  - Policies:
    - TR-ANZGOG recommended minimum biospecimen collection: tissue, blood, ascites
    - Clinical trial investigator support
    - TR-ANZGOG designated laboratories
    - Standard Operating Procedures
    - Templates
- Vendor assessment – Dec 2020:
  - LIMS, Database
  - Consumables
  - Shipment

2020

- Portal design & development – March Q 2020
- Agreements with designated TR-ANZGOG laboratories – March Q 2020

Working Group volunteers

Working Group	Members
Data Management	Pamela Provan Nicki Meagher Sian Fereday (nominated – to be confirmed) Penny Webb (Chair) Kathryn Jenkins Alison Hall
Laboratory Network	Sanela Bilic Nadia Traficante Cath Kennedy Pam Pollock Anna deFazio (Chair)
Patient Consent Guidelines	Haryana Dhillon Sue Brew Wanda Lawson Lyndal Anderson (Chair) Phil Beale (nominated – to be confirmed)