

TR-ANZGOG Key Principles Snapshot

What is TR-ANZGOG?

The Translational-ANZGOG (TR-ANZGOG) initiative is being developed to facilitate the collection of biospecimens associated with ANZGOG trials. TR-ANZGOG aims to maximise the information provided from investment in clinical trials by supporting the translational aspects of trial design. Importantly, TR-ANZGOG also aims to maximize the use of biospecimens and to facilitate translational research beyond the trial by ensuring that scientific, ethical and legal requirements for future research are met.

AIMS

TR-ANZGOG will value-add to ANZGOG clinical trials and the contributions that patients have made by enabling further research:

For example, by identifying

- Predictive biomarkers of exceptional treatment response
- Mechanisms of treatment resistance
- Predictors of toxicity etc

Thereby contributing to implementation of new treatments and design of future trials.

TR-ANZGOG aims to enable and actively facilitate translational aspects of ANZGOG-approved clinical trials by:

- Providing guidance and recommendations to ANZGOG members regarding collection of specimens for a wide range of translational studies
- Co-ordinating a network of laboratory-based facilities for collection of specimens from patients on behalf of ANZGOG trials
- Providing centralised processing and storage of specimens from ANZGOG trials
- Provide long-term custodianship of clinically annotated specimens collected through ANZGOG trials and a mechanism for dissemination for translational research.

OVER-ARCHING THEMES

- Maintains a focus on improving outcomes for women with gynaecological cancers
- Implements 'light touch' and 'can-do' processes to facilitate translational research in a timely manner

- Inclusive, transparent, with good governance and strong engagement with stakeholders. Key positions on governance committees rotate (limited terms) and are open to all disciplines.
- Will promote large 'question-driven' collaborative clinical and translational research projects.
- Undertaken in an ethical approach, with respect for privacy and consideration of equity and cultural values
- Consistency in quality

CLINICAL TRIAL SUPPORT AND BIOSPECIMEN ACCESS PRINCIPLES

- If TR-ANZGOG facilities have supported the management of biospecimens the expectation would be that the remaining samples will be made available for future research, with appropriate governance, once the requirements of the trial have been met.
- Access to TR-ANZGOG support will be via a transparent and equitable application process.
- Patient consent and HREC approvals will be consistent with allowing samples to be made widely available for future research, subject to scientific review, HREC approval and well-executed governance.
- TR-ANZGOG trials protocol would include representative tumour sample and a blood sample, where available.
- Samples will be embargoed until specific translational aspects of the clinical trial are complete. The scope of translational studies to be undertaken related to the trial, and samples to be embargoed, will be agreed for each trial separately, to maximise translational outcomes.
- Approval for use of samples outside the scope of the original trial aims would require peer-review, HREC approval and approval from the TR-ANZGOG Trial Support and Sample Access Committee, which would include the trial Principal Investigator, if available.
- ANZGOG, the TR-ANZGOG laboratories network and the trial Principal Investigators from which the biospecimen collection is acquired will be acknowledged in any publications utilising TR-ANZGOG biospecimens and data.