

Overview for ANZUP Concept Development

All members are invited to submit ideas for clinical trial concepts at any time. This can occur through the annual Concept Development Workshops (CDW) or any time throughout the year, where ideas would generally be discussed at various Subcommittee meetings. The aim is to encourage members to consider submitting their ideas/ concepts for broader feedback from a multidisciplinary panel including senior investigators, statisticians, consumers, trainees and operational staff **with the aim of becoming an ANZUP sponsored Protocol**. The resulting discussion is often wide-ranging and aims to define clear “next steps.” These might include forming a working party to support the member submitting the concept to create a protocol, or refining of the concept with the help of newly identified collaborators, or sometimes moving the idea in a different direction. Once approved the concept is presented to the Scientific Advisory Committee (SAC) for further review /consideration and endorsement.

ANZUP encourages and supports those concepts that are:

- Investigator Initiated
- Multidisciplinary
- Multicentre ie ideally across multiple ANZUP sites (4-6 minimum)
- Inclusive where appropriate of Quality of Life, Translational Research, or Health Economic components
- Capable of leading to changes in practice
- Promote a culture of research amongst all clinicians involved in the care of patients with urogenital cancers
- Able to help build systems to simplify and streamline clinical trial research of the highest quality

Initial concepts need to consider:

- Does the concept address a scientifically and clinically valid and important question?
- Has the question taken into account the most current research and “horizon scanning” for opportunities?
- Is the design likely to answer the primary question?
- Is the question relevant to current international initiatives, and will the question remain relevant at the time that the outcome is expected to be known?
- Is the accrual target reasonable and achievable?
- Have opportunities for translational, Health economic, quality of life or supportive care studies been considered?

Later in development concepts need to consider:

- Has there been appropriate statistical input into the protocol?
- Is a funding source available? Note: ANZUP discourages contact with potential industry supporters early in the concept process, as this should only occur once the concept design is mature and all budget aspects can be considered.

Other things ANZUP considers:

- Does the study involve a junior researcher?
- Gender balance
- Opportunities for innovation e.g. Teletrials
- New Zealand engagement
- International engagement