# TROG Cancer Research – Capability Summary

**Executive Summary:** TROG Cancer Research is a global leader in radiation oncology clinical trials, backed by over 35 years of experience and a network of more than 1,600 experts. With over 200 trial sites worldwide, we excel in driving collaborative research, offering comprehensive support from initial concept through to trial conduct and publication. Our commitment to innovation and excellence ensures impactful contributions to the field of cancer research with a history of conducting practice changing clinical trials.

**Our Expertise:**

- **Extensive Track Record:** With over 35 years of leadership in radiation oncology, we have conducted more than 115 clinical trials many which are practice changing.
- **Global Reach:** Collaborations with 200+ sites across Australia, New Zealand, Singapore, Europe and other international locations.
- **Participant Recruitment:** Successfully recruited over >15,300 research participants across a wide range of cancer types and indications.
- **Diverse, multidisciplinary team conducting clinician led research**

## TROG Background:

The Trans Tasman Radiation Oncology Group (TROG) is a multidisciplinary, member-driven organisation with a network of over 1,600 professionals, including radiation oncologists, radiation therapists, medical physicists, statisticians, medical oncologists, cancer nurses, and allied health specialists. Our dedicated membership offers direct access to radiation oncology centres across Australia and New Zealand, while our extensive global network fosters international collaboration and engagement.

## Our Services:

## Collaborative Group Services:

TROG Cancer Research Collaborative Group Services provide oversight for the sponsorship of clinical trials and clinical research projects. This includes:

- Regulatory Submissions and Compliance: Guidance and management of regulatory submissions to ensure compliance with local and international regulatory bodies.
- **Data Safety Monitoring:** Ongoing safety monitoring including facilitation of an Independent Data and Safety Monitoring Committee (IDSMC).
- **Insurance and Indemnity:** Comprehensive insurance coverage and indemnity.
- **Publication and Dissemination of Results:** Support in preparing manuscripts, abstracts, and presentations for scientific conferences and publications to disseminating trial findings.
- **Grant Administration:** Management of the grant lifecycle, from identifying opportunities, providing support to Investigators in submitting applications to tracking funds and ensuring compliance with funding requirements.
- **Legal contracting and financial oversight:** Legal contracting and financial oversight, ensuring compliance, managing budgets, and maintaining accountability throughout the clinical trial process.

## Research Development:

TROG Cancer Research fosters and promotes the design of high-quality investigator-initiated cancer collaborative clinical trials. The Research Development team supports proposals throughout their development from a new concept or idea to a complete robust protocol. Our services include:

- **Scientific/Expert Review:** Expert guidance on trial design, methodology, and statistical analysis to ensure high-quality research outcomes.
- **Feasibility Assessment:** Conducting comprehensive feasibility studies to evaluate potential trial sites, participant recruitment strategies, logistical & budget requirements.

- **Partnership Building:** Establishing collaborations with academic institutions, industry partners, and healthcare organisations to enhance trial scope and impact.
- **Trial Budgets:** Development of comprehensive trial budgets and strategies to maximise financial viability of research projects.
- **Funding Support:** Assistance with developing and co-ordinating research funding applications.
- **Protocol Development:** Expert advice, co-ordination and design of clinical trial protocols via multidisciplinary working party committees
- **Document Templates:** Access to essential trial document templates, including protocol, patient information and consent forms (PICF) trial manuals (including Radiation Therapy Planning, Delivery and Quality Assurance) and other documents (such as trial logs) required for the site activation pack.
- **Database Development:** Services and advice on database development including a range of integrated management systems; serious adverse event (SAE) tracking; online pre-screening and screening logs, in-built registration and randomisation systems; drug management and logistics.
- **Collaboration Promotion:** Facilitating collaboration between other cancer trial groups and international organisations.
- **Vendor Selection:** Comprehensive vendor selection processes, including established collaborative relationships for drug logistic management and central laboratory facilities.
- **Workshops:** Proven track record, conducting concept development workshops to foster new trial concept development including mentorship and expert advice.

## Research Operations:

The Research Operations team plays a pivotal role in managing our clinical trials from startup to completion within the TROG Central Trial Coordinating Centre. Our comprehensive suite of services ensures the highest standards of excellence and efficiency in clinical trial execution.

Key services include:

- **Central Trial Coordination:** Our team offers expert central trial coordination and oversight, ensuring efficient collaboration and implementation of clinical trials across all sites and phases.
- **Data Management:** We offer comprehensive data management services utilising custom built trial databases (including electronic data capture, serious adverse event (SAE) tracking; online pre-screening and screening logs, in-built registration and randomisation systems; drug management and logistics), maintaining stringent oversight and data cleaning to guarantee data accuracy and integrity.

- **Comprehensive Site Support:** Support for participating sites in all aspects of clinical trial conduct- including providing resources, training, and assistance to ensure protocol adherence and regulatory compliance.
- **Patient Recruitment:** Our team actively engages with participating sites to support them in meeting enrolment targets. We provide comprehensive resources, including informative infographics, to equip sites with the tools they need. This support enables sites to effectively communicate to potential participants and implement successful recruitment strategies.
- **Risk-Based Monitoring:** To prioritise patient safety and data integrity, addressing critical issues promptly.
- **Regulatory Compliance:** Ensuring regulatory compliance, ensuring strict adherence throughout all phases of the trial.
- **Communication Experts:** Our team is comprised of highly skilled professionals that are adept at facilitating seamless coordination between all stakeholders, including sponsors, sites, and regulatory bodies.
- **Tailored Solutions:** The Research Operations team can tailor services that meet the specific needs of different trials, ranging from small-scale studies to large, multi-centre clinical trials.
- **Continuous Improvement and Planning:** Resulting in streamlined, robust and transparent processes to ensure efficient trial activation, conduct and reporting.
- **Reporting and Analysis:** Comprehensive reporting and analysis services that ensure accurate, timely data insights to support efficient decision-making throughout every phase of the trial lifecycle.
- **Administrative Support:** Support to the Trial Chair and Trial Management Committee enhancing operational efficiency.
- **Oversight**: Our operations include continuous oversight by multidisciplinary TROG Committees and stakeholders, ensuring trials remain on track and meet all specified goals.

By leveraging our extensive expertise and flexible resources, the Research Operations team enhances the overall success and impact of the clinical trials managed.

## Radiation Therapy and Imaging Quality Assurance:

TROG's Radiation Therapy Quality Assurance (RTQA) and Imaging Quality Assurance (IQA) programs provide a framework to monitor protocol compliance and data quality. With advanced software and customised databases, the quality assurance team ensure medical imaging and radiation therapy planning and treatment data can be collected and analysed.

Key services include:

- **Risk Assessment and Monitoring:** Development of comprehensive risk assessments to guide the creation of tailored QA programs, ensuring continuous monitoring and high data quality.
- **Data Collection, Storage, and Management:** Robust data processing pipelines, including automatic anonymisation of DICOM data, and secure, centralised storage of medical imaging for reliable data management, analysis and protocol compliance monitoring.
- **Customisable QA Databases:** Development of flexible databases for efficient data collection, tracking and analysis to facilitate central peer review and the provision of detailed site feedback and reporting.
- **Secure and Reliable Data Transfer:** Our systems ensure the safe transfer of medical images and related electronic data to maintain the integrity and security of trial information.
- **Integration of Advanced Technologies:** Our team utilise cutting-edge software and automation to enhance QA processes and support the incorporation of new and complex techniques in radiation medicine.
- **New Technology and Techniques Leadership:** Leaders in the development of guidelines and recommendations for integrating new techniques and technologies into clinical trials; leveraging a multi-disciplinary network of experts nationally and internationally.
- **Guideline and Protocol Development:** Expert advice and development of comprehensive imaging manuals, radiation therapy guidelines, and quality assurance protocols to support evolving best practices and compliance.
- **Credentialing and Educational Programs:** TROG has a proven track record in developing comprehensive credentialing programs and training to verify that sites and clinicians meet the required protocol specifications and maintain high standards.
- **Site Qualification and Support:** TROG credentialing programs also incorporate site qualification procedures and support frameworks to ensure participating sites have the necessary resources, equipment and experience to meaningfully participate in the trials that we facilitate.
- **Centralised Peer Review:** Our team of dedicated professionals are experts in developing and coordinating centralised peer review programs including the assessment of diagnostic imaging and radiation therapy planning data. This includes flexible real time pre-treatment review, timely and retrospective review options.
- **Protocol Compliance and Feedback:** Comprehensive monitoring and feedback on adherence to protocol specification, ensuring the highest quality in radiation therapy planning and imaging data.
- **Continuous Innovation and Planning:** Ongoing horizon scanning and forward planning to anticipate changes in national and international best practices as well as new and emerging technology, maintaining TROG's leadership in the field.
- **Comprehensive Support for Participating Sites:** Providing robust support and advice to ensure all participating sites adhere to high standards and maintain protocol compliance.

## Business Services and Infrastructure:

TROG Cancer Research conducts essential business functions to support our staff, members, and research portfolio. Our infrastructure includes:

- **Trial Management Database (TMD):** Centralised project management tool for efficient trial management. This robust tool enhances project oversight and streamlines operations across all phases of the trial lifecycle.
- **Central Quality Management System (CQMS):** Purpose-built system for imaging and radiation therapy QA data management and peer review.
- **MIM Software:** Radiation therapy planning and imaging storage and peer review software.
- **Elekta ProKnow Software:** Clinical trial data management and analysis (imaging/radiation therapy planning and clinical trial participant data).
- **Online Patient Management System (OPMS):** Centralised trial management tool that tracks trial participants, including screening logs, registration & randomisation, safety reporting tracking and PI sign-off, drug management system for real time tracking of site and depot stock, dispensing, and batch issues.
- **OpenClinica:** Main customised electronic data capture platform for clinical trial data management.
- **IT Resources:** Including data storage, server and internet access, real-time data backup, and disaster recovery.

## Expert Advise and Oversight:

TROG's committees provide scientific integrity and oversight, including:

- **Scientific Committee:** Multidisciplinary committee overseeing TROG's research portfolio.
- **Working Parties:** Shaping research priorities and providing expert advice on specific cancer types.
- **New Techniques and Technologies Committee:** Overseeing the integration of new and complex technology into clinical trials, by ensuring that up-to-date guidelines and procedures are available to support implementation.
- **Special Interest Groups:** Multidisciplinary group of professionals with a shared interest in specific techniques/technology in radiation medicine and radiation oncology. These groups help drive new research concepts within their focus area.
- **Independent Data and Safey Monitoring Committee**: Multidisciplinary committee who monitors the progress of phase III and late phase II clinical trials in relation to quality processes and procedures and ensures the safety of patients and that, wherever possible, each trial meets its primary objectives.

- **Secondary Data Analysis Committee**: Focused on the development of guidelines and procedures to ensure TROG clinical trial data is findable, accessible, interoperable and re-usable, thereby maximising its utility for secondary data analysis.

## Testimonials:

**Professor Paul Keall, Director of the Image X Institute, University of Sydney**

The Image X Institute at the University of Sydney improves lives by inventing and advancing new ways to image and treat disease. TROG has partnered with Image X on two Cancer Australia-funded clinical trials to measure the benefit to patients of a new device that improves cancer targeting during radiation therapy. The success of these trials, TROG 15.01 and TROG 17.03, has led to the device being developed into a product that will impact the lives and livelihoods of millions of cancer patients around the world.

**Professor Sandro Porceddu, Head Radiation Oncology, Peter MacCallum Cancer Centre (PMCC)**

PMCC has been at the forefront of TROG since its inception, the strength of collaboration seeing members of the PMCC fraternity serve as past and current presidents of the TROG Board. Collaboration between TROG and PMCC has seen the rise of researchers into world leaders across all sectors of Radiation Oncology Research including Radiation Oncology Physics and Radiation Therapy. The advancements in Radiation Oncology across all disciplines within Australia and New Zealand, leading to improvements in patient outcomes, would not have not been possible without TROG's ability to bring together partner sites to collaborate in practise-changing research.

## Join Us:

Through flexible and tailored solutions, TROG Cancer Research is the ideal partner, to facilitate your next clinical trial project. Contact us today to learn more. Email: trog@trog.com.au