



Aotearoa Clinical Trials Becomes First Site in New Zealand to Achieve both GCSA Certification and Silver Workforce Quality Accreditation

Certifications demonstrate Aotearoa Clinical Trials is working to the highest global best-practice standards, ratified by the industry.

Auckland, New Zealand and Maidenhead, United Kingdom, 21 February 2024 – Aotearoa Clinical Trials (ACTT) has undergone a rigorous evidence-based assessment process to become the first organization in New Zealand to successfully achieve the GCSA's Global Quality Standard for Clinical Research Sites. This is further bolstered as ACTT has also achieved the Silver Workforce Quality Accreditation (WQA) from IAOCR, the International Accrediting Organization for Clinical Research, the first New Zealand Organization to achieve this. These accomplishments demonstrate that ACTT is consistently working to the highest global quality best-practice standards for workforce and research operational processes.

"Aotearoa Clinical Trials is a network of hospital based clinical trial sites with over 20 years' experience in clinical trials in Aotearoa - New Zealand. We are proud to be the first site in Aotearoa – New Zealand to be accredited to this international standard of quality," explains Dr Edward Watson, CEO, Aotearoa Clinical Trials. "The GCSA endorsement of our processes, systems and team are testament to the value we place on high quality outcomes to ensure patient safety and high-quality data and provides assurance to our partners and the Industry that we run our clinical trials to an internationally recognized standard."

These two certifications were awarded following a robust evidence-based assessment of their site business operational processes (for GCSA) and workforce processes (for WQA). The GCSA assessment involved a review of business operational procedures and discussions with staff to gain a full understanding of how ACTT works as an organization in terms of trial delivery. The review looks at seven key impact areas that underpin the safe, effective delivery of clinical trials and the quality of both patient and sponsor/CRO journeys. Combined with this, ACTT also underwent the WQA assessment, which follows a similarly robust process, but focuses more specifically on workforce processes and the frameworks required for ensuring a high-performing, engaged, committed and competent workforce which is crucial for reducing risk and delivering high quality clinical research.

"Our team are at the heart of the business. We are constantly looking for innovative ways to ensure our team are competent, confident, and supported to provide the highest quality service to our patients, their whanau/ family, sponsors and partners. I am proud to be part of an entity that not only talks about quality and standards but can tangibly demonstrate that commitment," comments Karen Carter, Director Clinical Operations.

"Working with ACTT was a really positive experience, and it was clear that the organizational values are widely known and adhered to, forming an excellent cultural platform to work from, and this stems from the strength of the leadership," comments Sarah Everitt, VP Operations, IAOCR and GCSA. "ACTT has spent a significant amount of time in developing a specific organizational identity and culture driven by a passionate leadership team and this approach is definitely paying dividends in the organization. They really deserve these awards."

Both IAOCR and GCSA use comprehensive assessment frameworks, that have been developed with and ratified by Industry experts. The GCSA quality standard for clinical



research sites was developed with the support of a Global Advisory board of key stakeholders and experts from across the industry. In addition to the IAOCR Investigator Accreditation, all seven areas of the GCSA quality standard were met which included: Governance; Site Business Strategy; Workforce Quality; Patient Engagement; Feasibility; Study Start-up & Initiation; and Study Management, Operations & Close Down. WQA provides a clear benchmark of the highest workforce standards for both those working within the organisation to pride themselves on, as well as for sponsor's and CROs looking to partner with an organisation who want to see formal evidence of the workforce standards that are being delivered.

Whilst clinical research is a highly-regulated industry, until now there have been no established standards by which sites can demonstrate that they are able to meet the expectations of sponsors, CROs and patients, and no way for sponsors or CROs to select clinical research sites based on clear quality standards which have been independently assessed at the organizational level. GCSA sets this much-needed industry standard for research sites to strive for and achieve; It allows sites to evidence and communicate their capabilities and differentiate in a crowded and increasingly competitive marketplace. Beyond the assessment and certification process, where required, GCSA will deliver individual, practical support on the areas for development to meet the standards and will work collaboratively with sites to achieve certification.

To learn more about IAOCR and GCSA how we can support your business please visit iaocr.com and gcsaassessed.org, or email info@iaocr.com or info@gcsaassessed.org. Alternatively, for both organizations you can call:

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Notes to editors

About Aotearoa Clinical Trials

Aotearoa Clinical Trials Trust (ACTT) is an independent charitable trust that specialises in managing both commercial (Phase I to IV) and grant funded (investigator initiated and collaborative group trials) trials in partnership with public hospitals in New Zealand. ACTT has over 20 years of experience in clinical trials in New Zealand with trial sites located at Middlemore Hospital and Whangārei Hospital. At Middlemore and Whangārei Hospital's we work across 23 different therapeutic areas and are currently running over 150 clinical trials. Middlemore Hospital is New Zealand's largest and advanced tertiary hospital located in the region of Counties Manukau serving a population of over 600,000 people. Whangārei Hospital, the largest healthcare facility in Northland, New Zealand, offers an extensive range of services and serves as a vital support hub for smaller hospitals in the region.

About IAOCR

IAOCR is The International Accrediting Organization for Clinical Research. We are the only organization in the world to Qualify Clinical Research Professionals to international standards. Through robustly accrediting competence, IAOCR reduces risk to patients, clinical research and professional reputations - whilst improving compliance and bringing valuable new treatments to market more quickly and safely.



IAOCR competency verification and assessment processes and accreditations have been built specifically for the clinical research industry in collaboration with industry experts globally. They provide a quality standards and visible professional certification marks to organizations committed to globally consistent, high quality clinical trials workforces.

We believe that clinical trial patients anywhere in the world deserve the best protection in terms of rights and wellbeing. Therefore, in addition to providing accreditation, training and consultancy services, IAOCR works with industry leaders and regulators around the globe to develop best practice guidelines. To find out more visit: iaocr.com/resources/

About Workforce Quality Accreditation (WQA)

The Clinical Research Workforce Quality Accreditation was developed in collaboration with industry experts in response to demand from CROs and pharmaceutical companies. Awarded at the organisational level, IAOCR Workforce Quality Accreditation delivers:

- A systemised approach to achieving employer goals through increased workforce performance & engagement.
- Differentiation for service providers.
- Transparency for clients.
- Independent verification of embedded workforce competence and engagement of best practices.
- Reassurance of workforce quality globally.
- Improved employee attraction, engagement and retention through an enhanced employer brand experience.
- Improved workforce effectiveness and efficiency leading to reduced costs and reduced risks.
- Embedding of a 'right first time' and 'quality built in' approach through workforce best practice processes.
- Expediting new treatments to market.
- A distinctive and clearly recognizable quality mark.

About GCSA

GCSA is a global quality standard for clinical trial sites set across seven key areas. It ensures clinical trial sites are working to robust and effective processes so that they can deliver best-in-class services to patients and sponsors/CROs. The GCSA framework was developed over 4 years with industry research and engagement. It has been ratified by a Global Advisory Board of leading industry representatives from the not-for-profit and commercial sector, including leading global Sponsors and CROs, the NHS and other leading healthcare organizations.

The standard has been built to address key industry challenges and facilitate synergistic working between sites and sponsors to enable better patient outcomes. It provides potential sponsors with an assurance of capability through passing independent assessment based on standards and expectations specified by sponsors. Furthermore, GCSA aims to increase clinical research through alignment with commercial requirements.