





Re:Cognition Health Becomes the First Organization to hold Internationally Recognized GCSA Standard in US and Europe

Maidenhead, UK and Washington D.C., USA, 23 September 2024 – Re:Cognition Health USA today announced it has achieved the prestigious GCSA Clinical Trial Site Certification, becoming the first organization to achieve GCSA Certification in both the US and Europe. GCSA certification recognizes sites that are operating to the highest quality global best-practice standards according to an independent assessment.

The GCSA Global Quality Standard for Clinical Research Sites was awarded following an independent review, assessment and gap analysis process carried out by the International Accrediting Organization for Clinical Research (IAOCR). The GCSA standard demonstrates excellence in clinical research operations across seven essential areas identified by sponsors and CROs as being critical to the delivery of world-class clinical trials: Feasibility; Study Start-Up and Initiation; Patient Engagement; Study Management, Operations and Close Down; Workforce Process Quality; Site Business Strategy and Governance.

Re:Cognition Health USA clearly demonstrated an engaged workforce who are committed to the organization's growth and encouraged to contribute ideas for improvement. Furthermore, there was a strong organization-wide commitment to patient diversity and ethnic inclusion, as well as effective patient feedback mechanisms and well-documented processes ensuring clarity of roles and responsibilities.

"We are thrilled to have achieved the GCSA quality standard and certification – it's truly a testament to the hard work and dedication of the entire Re:Cognition Health US team," explains Mostafa Hassan, MBBCH, Director of Clinical Trials, USA at Re:Cognition Health USA. "We are incredibly proud of this accomplishment and are excited about the opportunities this certification opens up for us moving forward. We're confident that this achievement will further enhance our commitment to excellence in clinical trials and patient care."

The GCSA quality mark provides reassurance to sponsors, CRO's, staff and ultimately to patients, that these research sites have been independently quality assured against the robust global quality standards that have been developed and ratified by the industry. The quality mark indicates the site is a 'Trusted Global Partner' for the delivery of clinical trials.

"It was a delight to work with the Re:Cognition Health US team on the GCSA certification journey; everyone we spoke with was professional, positive, supportive and made valuable contributions throughout. It is clear employees feel very enthusiastic about their work and are very supported by their managers," summarizes Sarah Everitt, Chief Quality & Client Officer at IAOCR.

The GCSA standard was developed with the support of a global advisory board of key stakeholders and experts from across the industry. Whilst clinical research is a highly-regulated industry, until now there have been no established standards by which sites can demonstrate 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 criteria which have been independently assessed at the organisational level. GCSA sets this much-needed industry standard for research sites, enabling 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 works collaboratively with sites that need help to achieve certification.







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

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About Re:Cognition Health USA:

Re:Cognition Health is an internationally recognized leader in the diagnosis, treatment, and clinical trials for Alzheimer's disease and other neurological conditions. With centers located in Washington DC, Houston, Chicago, and Dallas-Fort Worth and UK Clinics in Birmingham, Bristol, London, Guildford, Plymouth and Winchester, the company is at the forefront of medical research and innovation.

Re:Cognition Health's multidisciplinary team collaborates to deliver cutting-edge, patient-centered care, offering access to groundbreaking clinical trials for disease-modifying and symptomatic treatments. The team plays a pivotal role in the global mission to discover new treatments for Alzheimer's by leveraging the latest in progressive medical research and evidence-based interventions.

For more information, visit www.recognitionhealthusa.com.

About the International Accrediting Organization for Clinical Research (IAOCR)

The International Accrediting Organization for Clinical Research (IAOCR) is the only organization in the world to provide internationally recognized accreditations for clinical research professionals that assess competency standards set by the global clinical research industry.

Through robustly accrediting clinical research professionals based on evidence of competence, IAOCR reduces risk to patients, clinical research, and organizational reputations - whilst improving compliance and bringing valuable new treatments to market more quickly and safely.

IAOCR competency verification, accreditations and certifications are built specifically for the clinical research industry. They work collaboratively with industry experts and organizations globally to provide quality standards and visible professional certification marks that are the hallmarks of quality for people and organizations working in the clinical research space.

IAOCR believes that clinical trial patients anywhere in the world deserve the best protection in terms of rights and wellbeing.

About GCSA

GCSA is the global quality standard for clinical research sites. Consisting of seven key modules agreed with the industry, it ensures clinical research sites are working to robust and effective processes so that they can deliver world-class services to patients and sponsors.







The GCSA framework was developed over four years with industry research and engagement and continues to evolve with the support of a global advisory board of leading industry representatives from the not-for-profit and commercial sector, including leading global Sponsors and CROs, NHS, charitable and commercial clinical research sites, patient groups and other leading healthcare organizations.

The standard has been built to ensure that sites build their processes with the patient experience as their primary focus, and also to 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, which also increases opportunities for participation and inclusion.