AGA Clinical Trials raises the quality standards for Clinical Research Sites in the US and Latin America with two milestone achievements

Hialeah, Florida, USA and Maidenhead, United Kingdom, 10 October 2023 – AGA Clinical Trials has become the first organization in the US and Latin America to successfully achieve GCSA's Global quality standard for clinical research sites. The high standards at AGA Clinical Trials are further demonstrated with the additional success of two of their lead Investigators being individually awarded internationally recognized IAOCR Clinical Research Investigator accreditation; making them the only physicians in the world to date with triple certification as Principal Investigators[1], cementing AGA Clinical Trials' market-leading position within the Industry.

In order to secure both achievements, AGA Clinical Trials has undergone a rigorous evidence-based assessment of their site business operational processes (for GCSA) and core role-specific competencies for the Clinical Research Investigators who participated in the individual IAOCR accreditation assessment. This joint achievement provides reassurance to sponsors, CROs, staff and ultimately the patients, that trial sites have been independently assessed against robust global quality standards and that research is in safe hands.

"At AGA Clinical Trials, we are dedicated to demonstrating how we are a global center of excellence and the GCSA and IAOCR certifications were the logical next steps for us to achieve our mission of improving health and quality of life for our patients," remarks Dr. Maria Graber, CEO, AGA Clinical Trials. "The GCSA and subsequent IAOCR certification processes were in-depth and detailed, which allowed our team to reflect on our working processes beyond the core assessment. We're delighted with the results because we are truly committed to working to the highest Industry standards and we are committed to showing this as more of our investigators undergo the IAOCR accreditation assessment."

The GCSA assessment involved a review of business operational procedures and processes and interviews with staff to gain a full understanding of how AGA Clinical Trials works as an organization in terms of trial delivery. The report concluded; "Even though AGA Clinical Trials is a small organization there are many clear processes in place and it is evident [the] Clinical Trial Management System plays an important part in ensuring all trials run smoothly to timelines and budget."

"The whole AGA Clinical Trials team were extremely responsive to the assessment process and facilitated us in every way they could to ensure we could meet their aim to achieve their GCSA certification in a timely manner," explained Colette Donaghy, Quality Accreditation Manager, GCSA & IAOCR. "We saw a cohesive team with strong clarity on the aims of the organization and their mission of improving health and quality of life for the patients they treat. The whole organization is committed and dedicated to achieving their mission which is why they have achieved both milestones through these certifications."

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.

[1] IAOCR [QM-IAOCR]; SOCRA [CCRP] and ACRP [CPI]

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.

For more information on AGA Clinical Trials please contact: raguirre@agaclinicaltrials.com

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 AGA Clinical Trials

AGA Clinical Trials is a Global, Leading Clinical Research Organization that is committed to advancing the boundaries of Medical Science and Diverse Volunteer participation through innovative Research and Development and out of the box standards.

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 standard 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 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 sectors, 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.