

Case Study : Determining excellence – pioneers of the GCSA global quality standard for clinical research sites in the Americas region.

Executive Summary

In September 2023, AGA Clinical Trials (AGA) became the first site organization in the Americas region to achieve GCSA Certification, with the GCSA Global Quality Standard for Clinical Research Sites being awarded across its sites in Ecuador and Miami, USA.

AGA’s Drivers for GCSA Certification

Dedicated to being a global center of excellence and driven by their mission to *improve health and quality of life for participants*, AGA wanted to evidence to patients and sponsors that they were truly world-class. Operationally it was important for them to ensure streamlined and consistently high-quality service delivery across both their sites. Therefore, they engaged GCSA for assessment, gap analysis, and consulting support to achieve Certification.

About GCSA Certification

The GCSA Certification process was developed by IAOCR (the International Accrediting Organization for Clinical Research) in collaboration with global CROs, sponsors, regulators, and sites, over a five year period. It evaluates 7 business operations areas that are critical to the success of sites and clinical trials.

GCSA’s independent assessment, gap analysis, process improvement, and Certification process, established consistency across both of AGA’s sites. It identified several areas of operational excellence, where AGA exceeded the GCSA standard, as well as providing recommendations for further development.

Triple-Certified Lead Investigators

Committed to quality at both a site and workforce level, in addition to achieving GCSA Certification, AGA’s two Lead Investigators also underwent rigorous assessment to achieve IAOCR Internationally Qualified Clinical Research Professional Accreditation (QM-IAOCR); building on their existing CCRP certifications awarded by SOCRA, and CPI certifications awarded by ACRP.

Key Results

Increased Business Opportunities and Visibility

- Certification supports BD and contributed to an increase in new business of approximately 20%
- Raised profile through IAOCR marketing support and international networking opportunities supports and improves visibility of AGA internationally

AGA - Independently Verified as a Trusted Partner

- Compliance with the GCSA Global Quality Standard provides reassurance to patients, CROs and Sponsors that AGA is a trusted partner for clinical trials

Foundations for Scalable Growth & Competitiveness

The GCSA process:

- Ensured operational excellence & global consistency through centralized best-practice business processes
- Enabled increased efficiency and competitiveness through streamlined quality operations
- Provided a detailed gap analysis and a clear pathway for continuous improvement beyond certification

AGA – Areas of Excellence Beyond Certification

In addition to verifying compliance with the global quality standard, GCSA assessors identified a number of areas where AGA excels *beyond* the industry certification criteria:

- Participant engagement and experience
- Organizational communication
- Strong leadership



CEOs Dr Maria Graber (AGA) & Jacqueline Johnson North (IAOCR) celebrating AGA’s success at SCRS Global Summit 2024



Dr. Maria Graber, CEO, AGA Clinical Trials, speaking at the IAOCR Clinical Research Industry Leaders Think Tank

“At AGA Clinical Trials, we are dedicated to being a global center of excellence. The GCSA Certification and IAOCR Professional Accreditations enabled us to demonstrate our commitment to best practice. They were the logical next step for us to achieve our mission of improving health and quality of life for our patients.

The processes were in-depth and detailed, which allowed our team to reflect on our working processes beyond the core assessments.

We’re delighted with the results. The awards have independently validated that we are working to the highest Industry standards.” Dr Maria Graber, CEO, AGA

The GCSA Certification journey includes expert analysis of all documented processes, and conducting surveys, and discussions with site staff to ensure that processes and procedures are fully embedded. Feedback is confidential, yielding rich insights and ensuring that staff feel able to speak confidently and honestly. The independent assessment objectively reviewed and critiqued AGA’s business operations processes. Following evaluation, insights and recommendations were shared to enable the basis for a continuous quality improvement journey.

The GCSA process also highlighted areas of excellence for AGA to leverage in business development and marketing activities as part of AGA’s differentiated service offer.

“I’m proud to be part of the AGA Clinical Trials team, led by Dr. Graber and Dr. Aguirre. Achieving recognition and joining the IAOCR community of sites is an important milestone for AGA. It is testament to the outstanding leadership of our CEO to our dedicated team. Our unique recruiting and retention efforts, as well as our commitment to patient care, have helped establish a gold standard in clinical research.”

AGA Clinical Trials Employee

About GCSA Site Certification And IAOCR Internationally Qualified Professional Accreditation



Awarded in over 55 countries, IAOCR Accreditations (awarded to clinical research professionals) and GCSA Certification (awarded to site organizations) are based on robust and comprehensive assessment criteria developed with key industry stakeholders. Awards of Accreditation or Certification are made following rigorous evaluation of evidence by IAOCR qualified assessors and verifiers.

GCSA - The Global Quality Standard for Clinical Research Sites, is achieved through a journey of independent assessment, gap analysis, supported process improvement, prior to award of Certification. The GCSA process deep-dives into seven critical business process areas cited by sponsors, CROs and other key stakeholders as being significant to the success of clinical trials:

- Patient Engagement
- Feasibility,
- Study Start-Up & Initiation
- Study Management Operations & Close-Down
- Workforce Quality
- Site Business Strategy
- Governance

IAOCR Professional Accreditations carry internationally recognized Learning Credits and CPE Points (Continuing Professional Education Points). Assessment criteria is agreed with Global Industry Taskforce, prior to being mapped to international standards for qualifications and education to provide robust and globally valid professional standard.



Through the independent assessment process, AGA Clinical Trials fully evidenced compliance with the GCSA global quality standard for clinical research sites.

Additionally, AGA Clinical Trials was found to be exceptionally strong in documented and embedded processes, communication, leadership clarity, operational consistency, and participant experience.

Feedback from GCSA Assessors

AGA demonstrated **excellence in documented procedures** and the **workforce understanding** of them, with **robust systems** ensuring **trials run smoothly to timelines and budgets**. Whilst AGA is a small organization, there were many clear processes in place. It was evident that the Clinical Trial Management System played an important part in ensuring all trials run effectively.

Effective cascading of trial requirements for each new trial, and **clearly defined roles** for each staff member involved, supports the overall goals and direction for clinical trial operations.

The participant experience is a key strength and consistently high-quality across both sites. Participant feedback is prioritized through a clear feedback loop. An opportunity was identified to strengthen this further by more directly incorporating participant input into service improvements and closing the loop by communicating changes back to participants.

AGA's business operations processes are consistent across both site locations. **Centralized operating procedures ensure consistency for clients and participants, providing high-quality trial delivery**, and a solid foundation for scalable growth.

KPIs drive ongoing development; enabling the company to evolve and commit to continual quality improvement, rather than rest on their success.

AGA's **clinical trials intentionally address a wide range of ethnicities** (Latino, African American, Asian and mixed-race), backgrounds, and conditions to better meet objectives and deliver meaningful results.

AGA's leadership team plays a vital role in the company's success. Clear roles and responsibilities ensure **streamlined operations** and ensure that **everyone works toward a unified vision**. Leadership communication is crucial for fostering a culture of collaboration and efficiency.

"AGA's focus on diversity, leadership clarity and participant feedback loops, positions AGA as a forward-thinking, progressive organization that is clearly committed to advancing health outcomes through high-quality clinical research."

Since achieving GCSA Certification, AGA's certified status has supported them in business development activities and contributed to a 20% increase in new business.



"GCSA Certification is not a destination but a milestone on our ever-evolving journey. Under our CEO's visionary leadership and with our team's dedication, we remain committed to pushing the boundaries of what's possible in clinical research – always with our patients at the heart of everything we do. Advancing health - one breakthrough at a time, but more importantly, one patient at a time. Together, we're exploring the unknown and achieving the extraordinary."

Dr Roberto Aguirre - VP & Global Medical Director, AGA Clinical Trials