

RE:COGNITION HEALTH

*EVIDENCING COMMITMENT TO CONTINUAL
ENHANCEMENT AND OPERATIONAL
EXCELLENCE IN CLINICAL TRIALS*

Re:Cognition
Health
Brain and
Mind Experts

EXECUTIVE SUMMARY

Re:Cognition Health is an established and well-respected commercial research provider, who prides themselves on delivering the highest quality clinical research, across all therapeutic areas covered by their service. The GCSA certification provided Re:Cognition Health a clear standard, demonstrating their commitment to elevating standards to the highest level and a defined benchmark of these internationally recognized standards. This certification has served to enhance the overall business offering with benefits positively impacting relationships, providing direct improvements to the business operations, and contributing to an improved business which collectively is reaping the rewards from Sponsors, CROs, and employees alike.



About Re:Cognition Health

Re:Cognition Health operates in the UK and US, with UK clinics in London, Guildford, Birmingham, Bristol, Winchester and Plymouth. Re:Cognition Health specializes in the diagnosis, treatment and care of people with Alzheimer's disease, dementia, cognitive impairment and other neurological concerns.

They are leaders in Alzheimer's research and are recognized as an award-winning cognitive health provider, branding themselves as 'The brain and Mind Experts'.

In addition to offering their service users access to a wide range of commercial clinical trial opportunities, their services also include ADHD assessment, autism assessment, mild traumatic brain injury assessment and memory services.

Re:Cognition Health wanted to demonstrate how exacting their end-to-end clinical trial operational processes and standards are, which is why they sought GCSA accreditation. GCSA accreditation serves to provide Re:Cognition with a clear quality standard and has led to an increase in positive feedback from patients, a reduction in data-specific enquiries from Sponsors and a demonstration of the overall quality, performance and Industry-leading standards Re:Cognition Health delivers.

Approach and Implementation

The GCSA certification collectively assesses core business components that ensure the overall quality of an organization, ensuring performance and standards are at the Industry-leading internationally recognized standards. Re:Cognition Health collated all relevant process information and associated evidence to share with the independent GCSA Assessors. The team at Re:Cognition Health then participated in a comprehensive interview process to evidence both the planned processes and practical application of their clinical research operational processes.

The GCSA certification process offers a supportive and consultative approach. Assessing seven core business areas, the certification provides a comprehensive understanding of the business, how it performs and the quality standard to which it operates. Assessors observed **the Re:Cognition team were really energized and engaged with the process and team members fed back that the accreditation values were well-aligned with their individual values, particularly in relation to putting patients at the heart of clinical research.**

"The GCSA Certification process has led to so many quality improvements: from staff performance, evolved processes, enhanced quality reporting in trials, fewer data queries, it has been across the board."

– Vicky Eyre, UK Director of Clinical Trials, Re:Cognition Health

The strong, positive culture at Re:Cognition resonated through their success and clear, defined leadership was prevalent with strong objectives driving the organization. This was further supported through the certification as management noted that as a direct result of the certification there has been a 40% increase in awareness of different company processes, e.g. the feasibility processes across the RCH workforce, enhancing the overall business offering.

The GCSA assessment process includes a thorough review of all the submitted information and operational processes, helping to identify areas for development and improvement whilst also highlighting areas of achievement, across the end-to-end pathway. Its aim is to support the delivery of the best possible study process so that both patient and sponsor experiences are high quality. The approach looks beyond pure trials and an independent inspection, adding credibility.

Many sites do not receive accreditation immediately. In Re:Cognition Health's case they scored very highly in the initial assessment, but work was required to meet the standard in a small number of areas. GCSA provided a clear gap analysis report and recommendations, providing Re:Cognition with a clear roadmap to accreditation. The Re:Cognition team further developed some processes to meet the GCSA accreditation criteria before being re-assessed and achieving GCSA Accreditation.

“The accreditation was an enjoyable process for the defined accreditation team, with the GCSA team. Having an external team, who aren't part of a sponsor/CRO audit or regulatory inspection, really meant that all our processes, through from HR and general compliance, and all our clinical trials processes, were reviewed, with feedback provided to support the necessary improvements. It is certainly an all-rounder accreditation process which has certainly aided us to make improvements across the board.”

Vicky Eyre – UK Director of Clinical Trials, Re:Cognition Health

“Clinical research can be hit by huge pressures at times, from COVID-19 to MHRA inspections and everything in between, but a well-ordered organization, that achieves GCSA certification, is able to inject space and resource into that moment to deliver those projects exactly as Re:Cognition health has done, and is able to do in the future.” **RCH team member**

An Evolving Business

The assessment process allowed Re:Cognition to reflect on their business, engage employees in this dedication to standards in a new way, and led to direct improvements in the operational side of the business, including:

- the implementation of new communication tools within the organization to aid Governance communication and ensure business-wide alignment and awareness;
- additional processes have been established to support documentation of meetings and streamline meeting insights;
- the introduction of a UK quality assurance manager and a clinical trials quality administrator to further support the consistent delivery of the highest international standards.

The Insights

- The **enthusiasm and support** for the accreditation process was apparent across the whole site network, demonstrating **the depth of Re:Cognition Health's culture**.
- Re:Cognition Health's business operations process standards are very well written, meaning necessary enhancements were small modifications rather than complete re-writes. **This validated the strength of Re:Cognition Health's operational delivery**.
- Quality comes out of direct reporting in trials. Data queries and feedback from Sponsors and CROs are key quality indicators and for Re:Cognition Health there has been **a positive reduction in the amount of data queries and deviations** across the board.
- Re:Cognition Health works with **clearly defined Roles and Responsibilities** across their whole site network, this allows for clear processes to be developed and delivered, and enabled efficient accreditation.
- There is a direct **correlation between staff education and training with positive patient feedback** because it builds a meaningful, trusting relationship. Re:Cognition Health offers their staff a plethora of comprehensive training that was endorsed through the assessment and has subsequently been expanded on, contributing to continually improved patient satisfaction.
- The GCSA and Workforce Quality Accreditation modules have **improved productivity and capacity** due to the training required which feeds into the experience of the staff; this has also achieved an increase in positive staff feedback.

- The certification report serves as a useful **tool to facilitate internal management discussion** about resources, prioritization and advancements for the better of the organization.

The Benefits

- The accreditation process allows for an **independent assessment of all our processes**, beyond the pure trials processes reviewed in audit and inspection.
- The process **identified areas for improvement**, so we could improve consistency across sites and departments.
- The outcome was a tangible accreditation mark, for all the staff to really feel that their **hard work has been recognized externally**.
- **Staff retention has improved by ~60%** due to the promise and delivery of quality training because Re:Cognition offer all staff a comprehensive training program as well as the opportunity of IAOCR foundation courses; which for employees who are committed to their career is a huge asset.
- There has been a notable **improvement in site level responses** due to the **improved business-wide understanding of processes**, commitment to quality through the certification and improvements that have followed.



“Working with Re:Cognition Health was a pleasure and the whole team’s enthusiasm was clear to see. Everyone was supportive of the GCSA accreditation process, and we were extremely impressed that their processes were already strong prior to assessment. With strong leadership and very engaged staff they have been able to move forward very quickly. We developed a gap analysis for the areas of improvement, and RCH have worked hard to address the identified areas to enhance its processes. It was a positive experience, and they are a great team to work with.”

Jacqueline Johnson North – Co-Founder and Chief Executive of IAOCR and GCSA

Re:Cognition Health has achieved full GCSA accreditation, and maintained their certification following the annual review process.

GCSA Top Tip: For the best ROI, undertake the GCSA assessment process when you’re not operating at your best as it is invaluable for highlighting areas for improvement to help you get to your best.

About GCSA:

GCSA is a global standard that enables and enhances synergistic working between sites, sponsors and CROs. The GCSA standard was developed over a four-year period with input from key stakeholders from the global clinical research industry. It focuses on the business operating procedures of clinical trial sites (not the clinical procedures); considering the journey of patients and sponsors.

GCSA helps identify gaps and improve processes across the end-to-end study pathway, to support delivering a best possible study; putting the patient at the heart of what a study is striving to achieve.