IAOCR
The International Accrediting Organization for Clinical Research

gcsa The Global Quality Standard for Clinical Research Sites

Working Together to Deliver a World-Class Destination for Clinical Research

Industry Leaders Think Tank 2023

Teresa May (MP), Alistair MacDonald (former CEO, Syneos Health), Jaqueline Johnson North and Angela O'Connell (IAOCR and GCSA)

Thank you to everyone who took time to complete our survey on the UK CLINICAL TRIALS ECOSYSTEM 2023. Your input has provided valuable insights, which we are sharing (anonymised) with UK Parliamentarians

The R&I Department at Royal Berkshire NHS Foundation achieving the GCSA quality certification for Patient Engagement

Putting Patients First: Royal Berkshire NHS Receives Accolade for Commitment to Patient Engagement: The Royal Berkshire NHS Foundation Trust R&I department has been awarded GCSA certification for demonstrating global best practice standards in 'Patient Engagement' for their Cancer Centre, showing that clinical trials are not just for larger teaching hospitals

AGA Clinical Trials become the FIRST US Site to achieve GCSA Certification

The Grounded Research Team @ RDaSH become the FIRST NHS Trust to achieve the GOLD standard in IAOCR Workforce Quality Accreditation

The Grounded Research Team at RDaSH achieving the GOLD Standard for IAOCR Workforce Quality Accreditation

The R&I Department at Sherwood Forest Hospitals NHS Foundation Trust receiving their award

Midlands Elevates Standards for Clinical Research as Sherwood Forest Hospitals NHS Foundation Trust Achieves Globally Recognised Industry-Leading IAOCR Workforce Quality Accreditation

Re:Cognition Health Become the FIRST UK Commercial Site Network to Achieve GCSA Certification

Re:Cognition Health has undergone a rigorous evidence-based assessment to become the FIRST UK Commerical Site network to achieve GCSA Certification

9th November 2023

The Spine, Liverpool UK

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Thank you!

Thank you to the IAOCR Taskforce for Core Competencies for Clinical Trial Site Staff and the founding and current members of the GCSA Global Advisory Board. Their time, expertise and support for GCSA and IAOCR has been invaluable in the development of global best practice standards for clinical trial sites and competency frameworks for site nurses, coordinators, site managers and investigators.

Note: The organisations listed below represent the employer organisation of the individual GAB/Taskforce member at the time they were/are active participants in these collaborative initiatives.

Allen, Teresa – HRA
Austin, Philip – Parexel
Balendra, Suki – Life Sciences Lead, Imperial College Healthcare & North West London NIHR Clinical Research Network
Bjornstead, Lisa – Parexel
Bodfish, Paul – Independent Consultant
Bufferd, Gary – Lightship
Cloete, Karen – TASK and TASK Academy
Demarest, Helen – GHCC/Medicines for Malaria Venture
Donaghy, Colette – IAOCR
Du Toit, Lauren – Independent Consultant
Edwards, Elizabeth – Biomat USA (a Grifols Company)
Eyre, Vicky – Re:Cognition Health
Gackowska, Agnieszka – Parexel
Grace, Clare – Syneos Health
Harris, Jennifer – ABPI
Johnson, Sandra – Medicines for Malaria Venture
Langley, Jamie – Parexel
Leuvennink-Steyn, Mildie – IAVI
Lewis, Simon – London Northwest Healthcare Trust
MacSweeney, Emer (Dr) – Re:Cognition Health
McIntyre, Karen – Syneos Health
Mellelieu, John – Allergan, then Pfizer
Messer, Janet – HRA
Mpagama, Stellah – Kibong'oto Infectious Diseases Hospital
Nixon, Shanna – Parexel
O'Connell, Angela – GCSA
Palmer, Maria – NHS R&D Forum
Ramrahcheya, Reshma – University of Oxford, CIPD
Ruthven, Karen – IAOCR
Saeed, Samin – Novartis
Siedel, Stephanie – Global Alliance for TB Drug Development
Spahn, Jennifer – Illingworth Research Group
Warnes, Alan – London North West Healthcare Trust

If you are interested in becoming a member of the Global Advisory Board for GCSA, or a Taskforce for IAOCR, please contact Lauren Gledhill, **lgledhill@iaocr.com**

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NHS Royal Berkshire NHS Foundation Trust

NHS Research and Development Forum

NHS Sherwood Forest Hospitals NHS Foundation Trust

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Welcome to the Think Tank

On behalf of the IAOCR and GCSA teams, a very warm welcome to the Clinical Research Industry Leaders Think Tank 2023.

The Think Tank is a not-for-profit event organised by IAOCR and GCSA to facilitate networking, innovation and sharing of best practice between clinical research industry leaders.

Based in the heart of the Knowledge Quarter Liverpool Innovation District, the venue for today's meeting, The Spine, is home to the Royal College of Physicians. The building was designed to be one of the healthiest workspaces in the world. It therefore seemed a fitting venue for for the Think Tank – with a shared purpose of shaping a better future through outcomes-based thinking, innovative solutions, and a vision of being best-in-class.

I'd like to say a huge thank you to our sponsors, speakers and supporters for making the event possible, and especially to Vicki Booth, our Marketing Executive and Business Support, who works diligently and tirelessly to ensure the success of the Think Tank.

The theme of today's meeting is **"Working Together to Deliver a World-Class Destination for Clinical Research"** and we are delighted to welcome a number of speakers from a range of organisations – both NHS and commercial, to share their experiences and insights. However, the intention for the Think Tank is for it to be interactive, to spark creative thinking and create momentum for change. Therefore, everyone is encouraged to ask questions, share thoughts and ideas and to build collaborative relationships to help improve the ecosystem for clinical research.

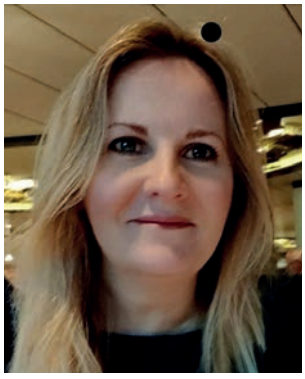
This is the first Think Tank that we have hosted in the Northern Powerhouse region, and I'd like to say a special thank you to Dace Dimza-Jones, Deputy Head of Northern Powerhouse Life Sciences, for her ongoing support. Dace is truly committed to doing the right thing for patients and the UK and shares our passion for making clinical research accessible to everyone. According to Alison Austin from NHS England, research is beneficial in a number of ways:

- to people and patients, with breakthroughs enabling earlier diagnosis, more effective treatments, prevention of ill health, better outcomes and faster returns to everyday life.
- to healthcare professionals who are able to develop imaginative solutions for real NHS problems, improving care and increasing job satisfaction.
- to the NHS systems – we know that hospitals that are more 'research active' have lower mortality rates than those that are not. This effect is not limited to research participants.

The term "levelling up" is often associated with the North. However, there are many areas of the UK, and indeed the world, where patients don't benefit from access to quality clinical research. IAOCR and GCSA work in partnership with employers and clinical research leaders around the globe to embed quality and consistency. We do this to ensure that regardless of location, diverse patients can access quality assured clinical research sites, and research run by internationally qualified, competence-verified clinical research professionals.

GCSA's process of assessment, gap analysis, process improvement, certification and continual best practice sharing, provides reassurance to everyone that patients and research are in safe hands. We are extremely grateful to our Global Advisory Board of industry leaders (please see inside front cover for details) that helped us shape the registered certification standard, which is now being adopted in the NHS and commercial sites in the UK, USA, New Zealand and Australia. We are delighted that the UK is leading the way with site certification, once again evidencing the desire to be a world-class destination for clinical research.

Finally, I'd like to say a big thank you to the GCSA and IAOCR teams and to our clients, who work in collaboration with us providing valuable feedback and helping us to evolve our processes. Immense progress has been made since the last Think Tank and it has only been possible due to the support and commitment from people that have a genuine passion for clinical research and providing better opportunities for patients.



Jacqueline Johnson North
CEO and Co-Founder
IAOCR and GCSA

IAOCR

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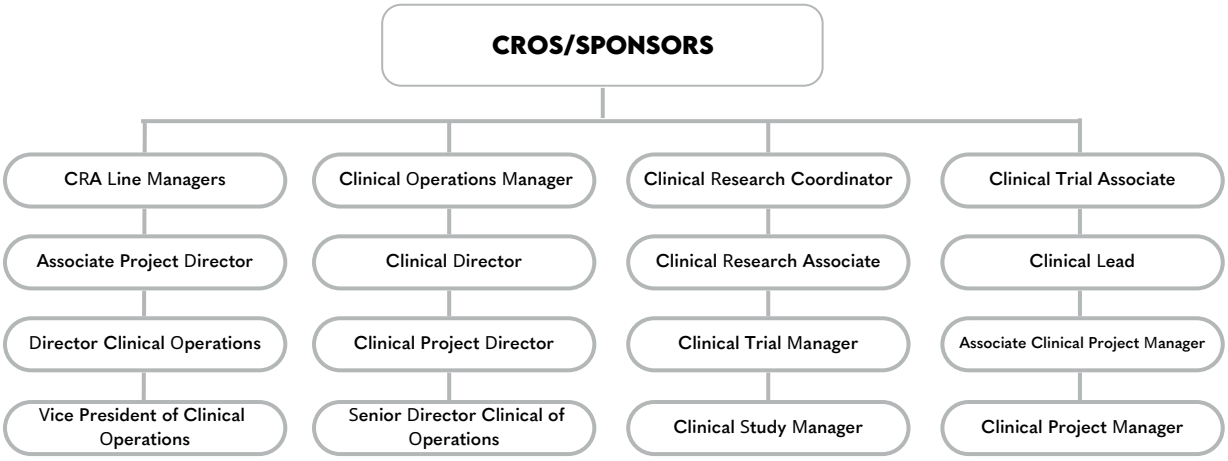
CLINICAL TEAM



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Morning Agenda

REGISTRATION, NETWORKING & WELCOME	
08:15 – 08:45	**Registration, Networking, Exhibits** *Breakfast refreshments sponsored by: University of Kent and Re:Cognition Health*
08:45 – 09:00	**Welcome** • David Holloway – Board Member, IAOCR & GCSA • Dace Dimza Jones – Deputy Head of Northern Powerhouse Life Sciences: Biotechnology & Pharmaceuticals Investment Hub, Department for International Trade

UK & EU REGULATIONS	
09:00 – 09:30	**Clinical Trials: UK Regulators – Making it Easy to do Research that People Can Trust** • Matt Westmore – CEO, NHS Health Research Authority
09:30 – 09:45	**Investigating the Impact of the Proposed Changes to ICH E6, particularly its Effects on How Sponsors Plan for Upcoming Studies and How it will Affect Sites** • Simon Taylor – European Strategy Lead, Florence Healthcare
09:45 – 10:00	**How Has the Change in EU Regulations, in Terms of the CTR Submission Process Affected the UK? Has this Benefitted the UK's Position and Attractiveness for European trials?** • Andrew Bradshaw, Director of Business Development for UK and Nordics, Clinscience
10:00 – 10:30	**PANEL SESSION: UK and EU Regulations** *Facilitated by Sarah Everitt – VP Operations, IAOCR & GCSA* • Andrew Bradshaw – Director of Business Development for UK and Nordics, Clinscience • Melissa Melton – Co-Founder/CEO, Momentum Pharma • Trish Parry – Founder/Managing Director, INDICRO • Simon Taylor – European Strategy Lead, Florence Healthcare • Matt Westmore – CEO, NHS Health Research Authority
10:30 – 11:00	**Break, Exhibitions and Networking** *Refreshments sponsored by: University of Kent and Re:Cognition Health*

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Morning Agenda (Continued)

IMPROVING UK & GLOBAL CLINICAL RESEARCH DELIVERY	
11:00 – 11.45	**How Can the UK Achieve a Best-in-Class, Holistic Ecosystem for Clinical Research Talent Attraction, Development, Professional Recognition, and Retention to Support the UK's Desire to be a World-Class Destination for Clinical Research?** • Angela Topping – Chair NHS Research & Development Forum, and Co-Chair of Clinical Research Talent Taskforce • Jacqueline Johnson North – CEO & Co-Founder, IAOCR & GCSA, and Co-Chair of Clinical Research Talent Taskforce • Lyne Jossé – Senior Lecturer in Applied Biosciences, Director of Studies for Clinical Trials Specialist, Divisional Director of Education (UG) at Lifelong Learning, University of Kent
11.45 – 12.15	**Enabling Best Practice and Patient Centricity with GCSA – Be Part of the Change!** • Maria Palmer – Co-Chair, GCSA Global Advisory Board • Angela O'Connell – Co-Chair, GCSA Global Advisory Board, Board Member, IAOCR and GCSA
12.15 – 12.45	**PANEL SESSION: Improving UK Clinical Research Delivery** *Facilitated by Colette Donaghy – Quality Accreditation Manager, GCSA & IAOCR* • Angela Topping – Chair NHS Research & Development Forum, and Co-Chair of Clinical Research Talent Taskforce • Lyne Jossé – Senior Lecturer in Applied Biosciences, Director of Studies for Clinical Trials Specialist, Divisional Director of Education (UG) at Lifelong Learning, University of Kent • Yvette Ellis – National Head of Research Delivery Operations, Health and Care Research Wales • Maria Palmer – Co-Chair, GCSA Global Advisory Board • Angela O'Connell – Co-Chair, GCSA Global Advisory Board, GCSA & IAOCR Board Member • Kate Greenwood – Senior Improvement Delivery Manager, Health Research Authority • Lauren Tough – Industry Operations Manager & National Service Development Lead (NCVR), NIHR Clinical Research Network North East and North Cumbria
12:45 – 13:30	**Lunch, Exhibitions and Networking** *Lunch sponsored by: PharmEXCEL & Barrington James*

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Afternoon Agenda

GLOBAL STANDARDS FOR CLINICAL RESEARCH SITES AND PROFESSIONALS

13:30 – 14:30	**Showcase with Parexel: Award-Winning Sites** *Facilitated by Karen McIntyre – VP Global Site Alliances, Parexel* • Jodie Keyworth, Head of Business Development, Grounded Research, Rotherham, Doncaster & South Humber NHS Foundation Trust • Vicky Eyre – UK Director of Clinical Trials, Re:Cognition Health • Leslie Mokogwu – Head of Research & Innovation, Royal Berkshire NHS Foundation Trust • Rebecca Garfield – Lead Commercial Clinical Research Facilitator, Royal Berkshire NHS Foundation Trust • Alison Steele – Head of Research & Innovation, Sherwood Forest Hospitals NHS Foundation Trust • Terri-Ann Sewell – Research Operations Manager, Sherwood Forest Hospitals NHS Foundation Trust
14:30 – 15:00	**Best Practice in Competence Verification and Professional Recognition for Clinical Research Professionals** • Sarah Everitt – VP Operations, GCSA & IAOCR • Colette Donaghy – Accreditation Quality Manager, GCSA & IAOCR
15:00 – 15:30	**Break, Exhibition & Networking** *Refreshments sponsored by: University of Kent and Re:Cognition Health*

SHARED INSIGHTS AND LEARNINGS: PROCESS EVOLUTION, IMPROVEMENTS & CHALLENGES

15:30 – 15:45	**NIHR LCRN – The National Contract Value Review : Building a World Class System for Costing Commercial Studies in the UK** • Lauren Tough – Industry Operations Manager, NIHR Clinical Research Network North East and North Cumbria
15:45 – 16:00	**Using AI/NLP/Free Text Clinical Notes for Feasibility and Study Start-Up** • Benjamin Fell – Head of Research, AKRIVIA
16:00 – 16:15	**Benefits and Challenges of Virtual Trials** • Hannah Swayze — Associate Director, Study Management, Lindus Health
16:15 – 16:30	**NHS Galleri Trial: Revolutionising Clinical Trial Delivery and Research Participation through Mobile Units** • Helen Jones – Clinical Divisional Director, EMS Healthcare

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Afternoon Agenda (Continued)

SPONSORS' AND CROS' PERSPECTIVES: WHAT MAKES A WORLD-CLASS CLINICAL RESEARCH SITE?	
16:30 – 17:00	**PANEL SESSION: What Does a World-Class Site Look Like from a Sponsor and CRO Perspective?** *Discussion facilitated by Lauren Gledhill – Director, Clinical Trial Partnerships, GCSA & IAOCR* • Sarah Martindale – Associate Director Clinical Operations, Country Operations & Start Up Manager UK & IRL, Syneos Health • Karen McIntyre – VP Global Site Alliances, Parexel • Jane Baxendale – Associate Director, Site & Resource – IQVIA • Yvanne Enever – CEO/Founder, PHARMExcel • Fiona Shields – Country Head UK (Trial Monitoring), Novartis • Yinka Cole – Associate Director Site Monitoring, Adaptimmune Therapeutics • Daniel Bamford, Director – Clinical Trial Partnerships, Moderna • Paula Underhill, Senior Director – Head of Strategic Site Collaborations, Sites & Patients Centre of Excellence, PPD

GCSA SITE NETWORKING AND CONNECTING	
17:00 – 17:15	**Summary and Close** *Jacqueline Johnson North – CEO & Co-Founder, GCSA & IAOCR*
17:15 – 18:00	**Drinks Reception, Canapes & Networking** *Drinks Reception sponsored by our premier sponsors PHARMExcel and Barrington James*

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Speakers and Panellists

Alison Steel
Head of Research & Innovation – Sherwood Forest Hospitals NHS Foundation Trust

Amy Moore
Senior Trial Manager
Lindus Health

Andrew Bradshaw
Director of Business Development for UK and Nordics – Clinscience

Angela Topping
Chair of NHS Research & Development Forum and Co-Chair of Clinical Research Talent Taskforce

Angela O'Connell
Co-Chair, GCSA Global Advisory Board and Board Member GCSA & IAOCR

Colette Donaghy
Accreditation Quality Manager – IAOCR and GCSA

Dace Dimza Jones
Deputy Head – Northern Powerhouse Life Sciences: Biotechnology & Pharmaceuticals Investment Hub, Department for International Trade

Daniel Bamford
Director UK Clinical Trial Partnerships – Moderna

David Holloway
Board Member – IAOCR and GCSA

Dr Benjamin Fell
Head of Research – AKRIVIA

Fiona Shields
Country Head UK – Trial Monitoring Novartis

Helen Jones
Clinical Divisional Director – EMS Healthcare

Jacqueline Johnson North
CEO & Co-Founder IAOCR & GCSA and Co-Chair of Clinical Research Talent Taskforce

Jane Baxendale
Associate Director, Site and Resource – IQVIA

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Speakers and Panellists (continued)

Jodie Keyworth
Head of Business Development Grounded Research Team, Rotherham, Doncaster & South Humber (RDaSH) NHS Foundation Trust

Karen McIntyre
VP Global Site Alliances
Syneos Health

Kate Greenwood
Senior Improvement Delivery Manger – Health Research Authority

Lauren Tough
Industry Operations Manager – NIHR Clinical Research Network North East and North Cumbria

Leslie Mokogwu
Head of Research and Innovation – Royal Berkshire NHS Foundation Trust

Lyne Jossé
Senior Lecturer in Applied Biosciences, Director of Studies for Clinical Trials Specialist, Divisional Director of Education (UG) Lifelong Learning – University of Kent

Maria Palmer
Co-Chair GCSA Global – Advisory Board & Independent Consultant

Matt Westmore
CEO
Health Research Authority

Melissa Melton
Co-Founder/CEO
Momentum Pharma

Paula Underhill
Senior Director – Head of Strategic Site Collaborations, Sites & Patients Centre of Excellence
PPD

Rebecca Garfield
Lead Commercial Clinical Research Facilitator – Royal Berkshire NHS Foundation Trust

Sarah Everitt
VP Operations – IAOCR and GCSA

Sarah Martindale
Associate Director Clinical Operations, Country Operations & Start Up Manager UK & IRL
Syneos Health

Simon Taylor
European Strategy Lead
Florence Healthcare”

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Speakers and Panellists (continued)

Terri-Ann Sewell
Research Operations Manager
Sherwood Forest Hospitals NHS Foundation Trust

Trish Parry
Founder & Managing Director
INDICRO"

Vicky Eyre
UK Director of Clinical Trials
Re:Cognition Health

Yinka Cole
Associate Director
Site Management Adaptimmune Therapeutics"

Yvanne Enever
CEO & Founder
PharmEXCEL

Yvette Ellis
National Head of Research Delivery Operations – Health and Care Research Wales

TMF UNIVERSITY

Developing qualified TMF professionals through certified accreditation.

TRIAL TO TRIUMPH

TMF University (TMFU) is the first and only internationally recognized accreditation program for TMF Professionals. It is accredited by IAOCR, the International Accrediting Organization for Clinical Research – the world's only organization that qualifies Clinical Research Professionals to international standards. TMFU engages students with a combination of high-quality, real-time virtual instruction along with standardized educational competency requirements to equip individuals with the required knowledge, skills, and behaviors to properly organize, assess and manage their TMFs.

CERTIFICATION & ACCREDITATION OPTIONS

Students can choose their learning pathways, TMF University offers the following flexible learning options to best meet the needs of learners:

Option 1 - Certificate of Participation: Earned for each course module attended within a learning level without the completion of the related competency assessment.

Option 2 - International Accreditation: Earned for completion of all course modules and related competency assessments within the learning level (Discovery, Immersion, Mastery).

DISCOVERY:

Introduction to TMF: Learn the importance of the TMF and appropriate oversight of TMF activities.

Document QC: Learn how to successfully complete quality checks of clinical trial documentation, as well as, the importance of issue remediation.

TMF Indexing: Learn how the TMF Index should be utilized as a resource for effective TMF Management and QC.

IMMERSION:

TMF QC: Learn the comprehensive approach organizations should take to ensure an effective and efficient review of the TMF.

Audits and Inspections: Learn how organizations can ensure that the TMF is always inspection ready.

TMF Technology: Learn the key steps for successful selection and implementation of eTMF technology.

MASTERY:

Current Regulations: Learn the TMF expectations of various global regulatory agencies and how organizations can use this guidance to remain inspection ready.

TMF Process: Learn how organizations can create, or improve, SOPs for effective TMF Management and Oversight.

TMF Metrics: Learn the importance of implementing a comprehensive TMF Metrics program, including the types of metrics that are important to generate.

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About IAOCR

Professional Recognition and Internationally Qualified Status for Clinical Research Professionals

IAOCR works with industry to develop global best practice frameworks and assessments to verify the competence of professionals working in a broad range of research roles (including clinical research trial site staff), and award them with internationally recognised accreditation. We do this because education, training and experience (as stipulated in ICH-GCP) does not ensure that people are competent – and when there are competence gaps, patients, research and industry reputations are at risk.

"Qualifying staff to work in clinical trials based on number of years' experience provides false reassurance of quality and also fuels the industry's talent crisis. Working in senior leadership positions in a number of sponsor organisations, I have experienced first-hand the issues that arise through relying on the length of tenure of CRAs and other clinical research staff…When an individual gains IAOCR accreditation I know they have been robustly competence checked…The IAOCR approach reduces risk to clinical research and provides a reliable and trusted pathway for new talent." **Sam Kerr PhD, Chief Scientific Officer, Merz Aesthetics**

QM-IAOCR
Internationally Qualified Clinical Research Investigator

"Having worked in clinical research for several years I decided to complete the IAOCR investigator accreditation to ensure that I could demonstrate formal recognition of an internationally accepted program that proves my competence and ability to work to best practice global standards. I found the online assessment straight forward and the staff at IAOCR to be very responsive to my enquiries. Having now gained accreditation, I believe that Sponsors, CROS and other stakeholders within the clinical research space will have utmost confidence that they are collaborating with a globally recognised Clinical Research Investigator".
Dr Nischal Sahai Principal Medical Investigator – Clinical Research UniSC, Clinical Trials – Brisbane, Australia

Benefits of Competence Verification and Professional Recognition for Clinical Research Professionals	
For Clinical Research Professionals	**For Employers**
Advance your career; demonstrate your ability to work to global best practice standards through internationally recognised accreditation.	Reassure stakeholders by evidencing your independently competence verified and quality assured clinical research workforce.
Gain confidence in competence. Reassure sponsors, CROs, patients and employers that you are competent to work safely and credibly.	Improve employer brand experience, staff attraction, engagement and retention through defined career development pathways and professional recognition for staff.
Certificate of Accreditation, distinctive 'Professional Accreditation Mark', designatory letters and unique professional registration number.	Facilitates quality compliance – evidences a 'right first time' and 'quality built in' approach through robust independent accreditation.
Earn Continuing Professional Education (CPE) points and accredited learning credits.	Reduces risk and cost through increased workforce effectiveness, improved performance and efficiency.

Contact us to start your accreditation journey:

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info@iaocr.com | **www.iaocr.com**

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About IAOCR (continued)

Which roles does IAOCR Accredit?

IAOCR offers professional accreditation across a broad range of clinical research roles including both site and non-site staff. Accreditations include: ICH-GCP, Foundations in Clinical Research, Clinical Research Nurse, Site Manager, Investigator, Site Coordinator, Clinical Research Associate, Project Manager, Central Monitor, Data Manager, Auditor, TMF Professional and many others! We also work with employers to build bespoke accreditations, gap analysis tools and career pathways.

How are standards developed and accredited?

IAOCR works with Taskforces comprised of industry experts and representatives from leading global clinical research organisations, ensuring broad input from both the commercial and not-for-profit sector. Once core competencies have been ratified, learning outcomes and assessment criteria undergo independent accreditation and mapping to the International Standard Classification of Education framework developed by UNESCO.

IAOCR
ICH GCP Accredited

What is the accreditation process

- IAOCR provides accreditation based upon verification of competence (gained through either prior training and/or on-the-job experience). Training is not provided as part of the assessment and accreditation process unless explicitly stipulated (or offered through one of our IAOCR Certified Academy Partners). Participants must check they meet the entry requirements for their chosen accreditation prior to enrolling.
- Participants can register directly with IAOCR via the website, or as a cohort through their employer for their chosen accreditation.
- Accreditation assessments are completed online and then reviewed by the IAOCR accreditation team.

Clinical Research Professionals successfully passing the accreditation are awarded:

- ✔ Certificate of Accreditation
- ✔ Accredited learning credits and CPE (Continuing Professional Education) points
- ✔ Unique professional registration number
- ✔ Electronic 'Professional Accreditation Mark' for use in email signatures, CV's and professional social media profiles

Contact us to start your accreditation journey:

Tel (UK) **01628 784906** | Tel (International) **+44 1628 784906** | Tel (US Toll Free) **+1 (855) 209 2335**
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About IAOCR (continued)

What our clients and accredited professionals say about us….

ICON

"IAOCR helped ICON to design and implement the first ever competence-based training for safety associates. A key requirement was to make it available across the globe through ICON's IT training environment. It also had to get aligned with staff's daily workload. Both objectives got addressed – we managed to train and formally accredit 155 of 173 assigned Safety Associates in 4 continents in 18 groups, each group starting a month apart."

Peter Schueler – Senior VP Drug Development Services, ICON Plc

Case Study

Syneos Health

The industry has come to realize that more training and more experience does not necessarily equate to competence in the field. By being able to measure competence against globally recognised best practices, we're able to give our customers the confidence to know that the staff assigned to their studies have not only been trained in the field and demonstrated competence in the latest processes and technologies, but that their skills have been validated against an independent quality standard."

Alistair Macdonald, CEO, Syneos Health

QM-IAOCR
Internationally Qualified
Clinical Research Project Manager

"The IAOCR Project Manager accreditation provided me with a great platform to evidence my experience and skills through a formal independent assessment, as well as providing an excellent opportunity for me to use this accredited status to help grow my career and network in global clinical research!"

Liam Mistry – Clinical Operations Lead, Parexel

"It has been an absolute privilege to contribute to the frameworks that GCSA and IAOCR have developed for clinical trial sites and staff. Ensuring best-in-class global standards in terms of people and processes plays a big part in reducing risk in clinical research".

Dr Suki Balendra, Life Sciences Lead LCRN North West London Core Team, Imperial College Healthcare NHS Trust

NHS
Central London Community Healthcare
NHS Trust

"Quality is at the heart of everything we do, IAOCR accreditation values and empowers research professionals to deliver high quality and safe clinical studies which is vital for participants and the wider R&D ecosystem"

Simon Lewis – Head of Research & Development at Central London Community Healthcare NHS Trust

Re:Cognition Health
Brain and Mind Experts

"At Re:Cognition Health, we are always working on ways to improve quality and efficiency in our clinical trials, which means having a fantastic team and maintaining them. We implemented the IAOCR individual accreditations this year, as a way of externally assessing our staff team's understanding and application of ICH GCP to their roles and duties, as well as assessing their wider understanding of clinical trials. We also want to support professional development, and this accreditation, if achieved, provides a personal professional accreditation which will stay with them. We have implemented this enrolment and assessment after staff have completed their induction and probation training, as a minimum. This process has helped us recognise, company-wide, our wonderful staff who work hard and have also successfully achieved the accreditations, supporting their professional development. But, more importantly, it has helped us identify training gaps, so we can consider additional training needs, with staff who deserve the accreditation, but didn't pass on the first attempt." **Vicky Eyre – UK Director of Clinical Trials, Recognition Health**

PHARMExcel

NHS
University Hospital Southampton
NHS Foundation Trust

"The personal approach and attention to detail from PHARMExcel have given us the upmost confidence"

Prof Saul Faust (OBE)
and Karen Underwood
NIHR Southampton Clinical Research Facility

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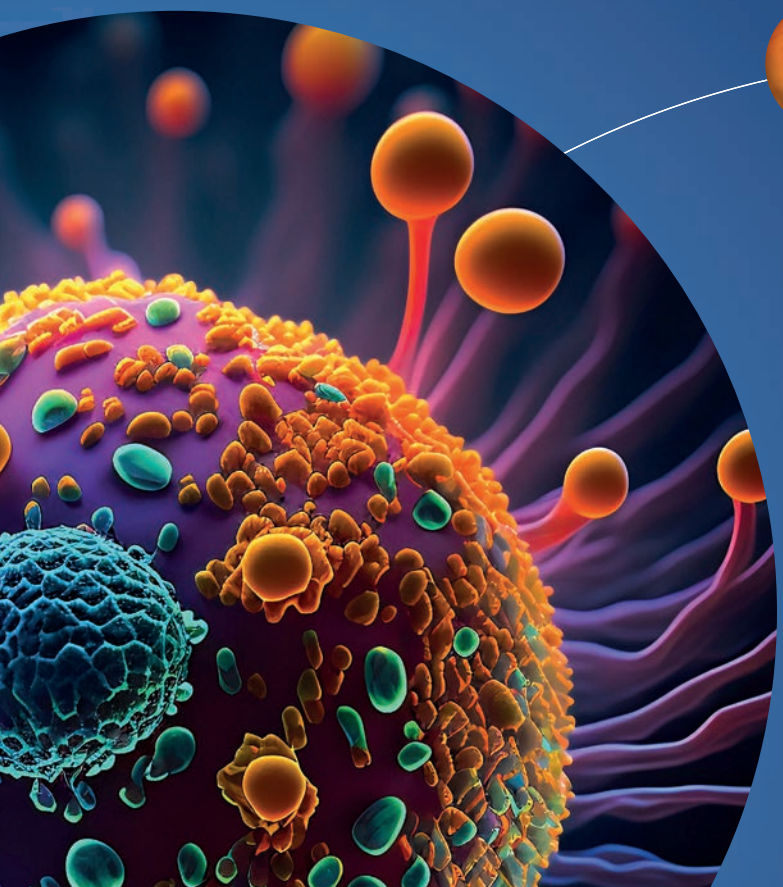

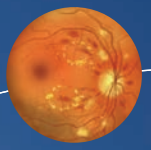

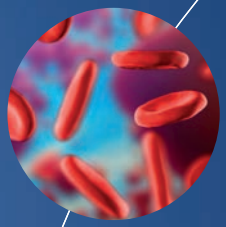

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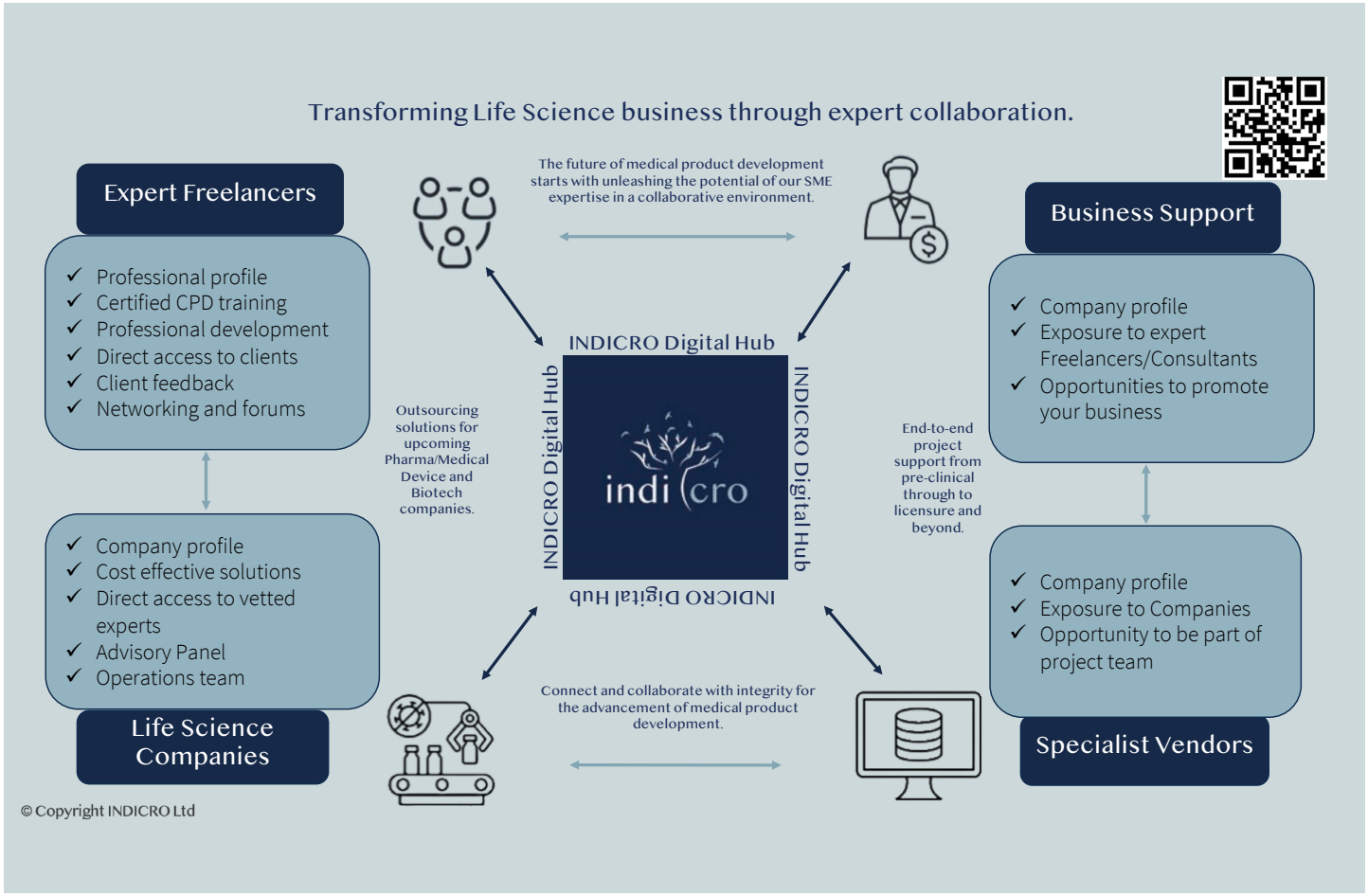
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✓ Exposure to Companies
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AKRIVIA HEALTH
Supporting industry and healthcare organisations to utilise real world data for mental health and dementias research.
Akrivia Health delivers unprecedented depth of data, enabling our partners to better understand disease and patient outcomes, and optimise service improvements through insights drawn from decades of medical history
https://akriviahealth.com/
contact@akriviahealth.com
REAL WORLD DATA | CLINICAL TRIALS | PRECISION MEDICINE

gcsa | The Global Quality Standard for Clinical Research Sites

About GCSA Certification

A global standard that supports a best-in-class experience for Sponsors, CROs and patients

GCSA – The Global Standard for Clinical Research Sites, provides a system of assessment, gap analysis, process improvement support and certification.

The best practice standard was developed with a Global Advisory Board* of clinical research industry stakeholders. Their shared ambition is to ensure process excellence that facilitates synergistic partnerships between sites and sponsors to ensure true patient centricity.

CERTIFIED CLINICAL RESEARCH SITE • QUALITY STANDARD COMPLIANT • gcsa
TRUSTED GLOBAL PARTNER

The GCSA Certification Mark evidences that your site or site network:

- ✔ Is a trusted partner for clinical research
- ✔ Has undergone rigorous, objective & independent assessment of quality
- ✔ Works to global quality standards endorsed by sponsors and CROs
- ✔ Is a member of a global best practice sharing community

Key benefits include:

- Improved quality and reduced risk
- Reassurance for sponsors and CROs of best-in-class trial delivery
- Improved efficiency, reduced costs and enhanced profit
- Enhanced site business strategy
- True patient centricity and high quality patient journeys
- Engagement, empowerment and reward for clinical research team

The GCSA Assessment Process:

GCSA's evidenced assessment process reviews seven high impact areas of research operations to understand performance, highlight improvement opportunities and certify quality performance.

Contact us to find out how you can get involved:

Tel (UK) **01628 784906**
Tel (International) **+44 1628 784906**
Tel (US Toll Free) **+1 (855) 209 2335**
info@gcsaassessed.org
www.gcsaassessed.org

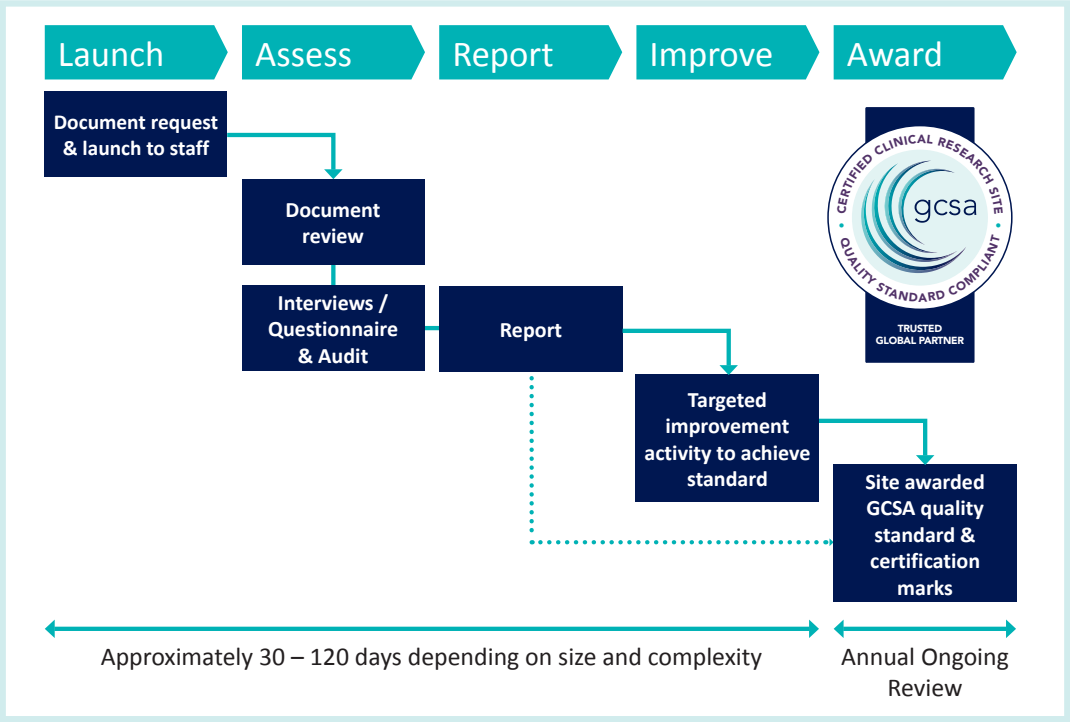
*See inside front cover for information about the Global Advisory Board

gcsa The Global Quality Standard for Clinical Research Sites

About GCSA (continued)

The assessment process is inclusive and supportive; it highlights where a site is performing well and identifies any areas for improvement, to facilitate compliance with best practice standards.

GCSA's ambition is to play a significant role in creating a clinical research ecosystem which will shape the future of healthcare and improve people's lives in the UK and across the world for years to come. The GCSA standard is now being adopted by sites in the UK, New Zealand, USA and Australia.



Re:Cognition Health Brain and Mind Experts

"We take what we do very seriously, because of the impact our trials can have on our patients and their families. We wanted to ensure we were providing the best quality service to our patients, their families, the Sponsors and CRO clients, whilst also developing our team. Through the GCSA assessment, we have been able to demonstrate best practices and processes. We are very proud of our fantastic team and we are delighted that their hard work has been recognised with this certification." **Vicky Eyre, Director of UK Clinical Trials**

"Ensuring high quality in clinical research is vital to safeguard patient safety and to provide confidence in the data produced, so that important advances in patient care can be implemented. Certification through Global Clinical Site Assessment (GCSA) helps to demonstrate a commitment to high quality and encourages the whole team to keep quality at the centre of everything they do." **Maria Palmer, Member of GCSA Global Advisory Board, Independent Consultant, Former Director of NHS Research and Development Forum**

*See inside front cover for information about the Global Advisory Board

Contact us to find out how you can get involved:

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gcsa | The Global Quality Standard for Clinical Research Sites

GCSA – Frequently asked questions

Q. How was the GCSA standard developed?

A. GCSA was developed over a number of years in response to recommendations and issues raised by a broad range of global industry stakeholders, including sponsors, CROs, NHS, NIHR, HRA and other healthcare organisations. The standard is endorsed by the GCSA Global Advisory Board*.

Q: How can GCSA help us attract more trials and improve our chances for site selection?

A. Successfully achieving GCSA certification demonstrates your site's commitment to quality and the desire to attract more clinical trials. By evidencing achievement of the global standard, sponsors and CROs can be reassured of competence and performance.

Q. How can GCSA help drive efficiency?

A. There are many different reasons why sites embark on the GCSA journey. The assessment and gap analysis process will enable sites to gain a thorough understanding of any R&D operational gaps and formulate an action plan to address them. Smaller sites and/or start-up sites may participate in GCSA to embed a 'quality built in' approach from the beginning. More established sites may choose to formally evidence that their already high-performing operational processes are aligned with the quality standards developed and endorsed by the industry.

Q. Is the process time consuming? Will it take up a lot of staff time?

A. The GCSA process diagram on page 21 indicates average length of the assessment process. The duration of the process depends on the size and complexity of the site. Speaking with site staff is an integral part of the process and this can be done virtually. Staff members involved in the dialogue process should expect to dedicate about 1 to 2 hours each in total. For larger organisations, only a selection of staff need to be interviewed.

Q. Can GCSA help us to make improvements needed to achieve the standard?

A. Following assessment and gap analysis, sites have the flexibility to work on process improvements in-house or with an external specialist provider of their choice. If desired, GCSA can help process improvement, but this service is optional.

Q What happens after GCSA certification?

A. GCSA is part of an ongoing annual quality assurance review to ensure standards are being upheld. The re-assessment follows a risk-based approach and the cost is variable depending on the size and complexity of the site, but generally would begin from £2000 per annum.

Q I have a site network with more than one site – do they all have to go through the GCSA process separately?

A. Providing all sites within your network are following the same operating procedures, each site does not have to be assessed separately as the process will treat 'all sites as one'. The GCSA assessment team will however identify a selection of staff to speak with from sites across the network.

*See inside front cover for information about the Global Advisory Board

Contact us to find out how you can get involved:

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IAOCR
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Workforce Quality Accreditation

The Workforce Quality Accreditation (WQA) is suitable for sites, CROs, sponsors and supply chain organisations.

Investing in your workforce by embarking on the WQA journey results in far-reaching benefits for staff and the wider organisation. The WQA assessment, gap analysis, process improvement and certification process delivers:

- Improved attraction, engagement and retention of staff
- Established mental health and wellbeing processes to safeguard your team
- Workforce best practices which reduce risk to patients and your organisation through a 'right first time' and 'quality built in' ethos
- Reassurance to sponsors & CROs that your workforce processes have been independently assessed and certified against the quality standards developed with the industry
- Improved performance, cost reduction and increased efficiency

Bronze

Appropriate job descriptions
Access to core technical skills training programs
'Red flag' system for identifying lack of competence in high risk areas (patient safety, data integrity, business critical areas)
Robust and systematic performance management systems
Active line management support processes in relation to employee mental health and wellbeing
Regular 1:1 line manager communication on work and non-work related matters

Silver

Employee engagement is an organisational priority
Organisational vision, values, goals and objectives are communicated, and individuals understand the importance of their contribution
The organisation invests in developing skills and professional skills appropriate to the role
The organisation positively promotes and monitors the mental health and wellbeing of its employees
All employees have access to resources to facilitate understanding of mental health challenges affecting colleagues

Gold

Competence of each individual is rigorously assessed against core global standards
Assessments are documented and development plans are in place to address competence gaps
Competence assessment is part of an ongoing process that occurs annually (as a minimum) and is linked to the organisation's performance management processes
Recognised mental health and wellbeing support structures are in place
Positive work life balance culture is fully embedded within the organisation
Robust framework to support employees with mental health difficulties

Contact us to start your accreditation journey:

Tel (UK) **01628 784906** | Tel (International) **+44 1628 784906** | Tel (US Toll Free) **+1 (855) 209 2335**
info@iaocr.com | **www.iaocr.com**

Workforce Quality Accreditation (continued)

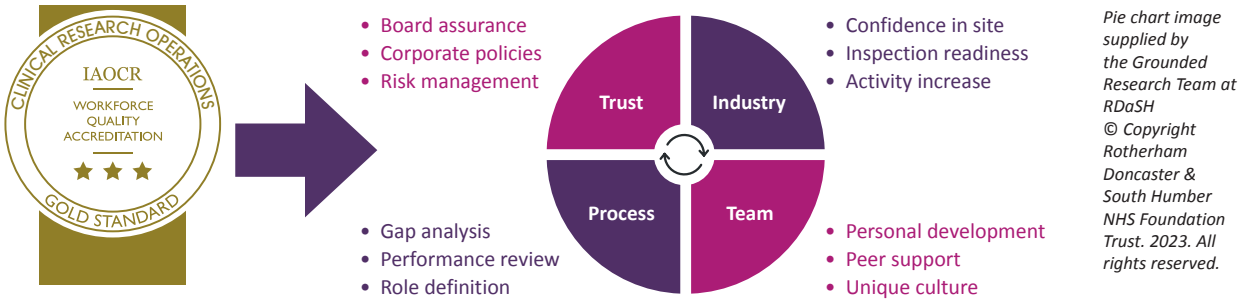
What our WQA clients say:

NHS Rotherham Doncaster and South Humber NHS Foundation Trust

Grounded Research

"Going for gold – we did it! It has been such a positive experience working with the IAOCR team on externally assessing the quality of our workforce and associated processes. We wanted to showcase the positive culture of our Research and Innovation team at Grounded Research to the wider clinical research community and this Gold Accreditation award will enable us to do that and to recognise the hard work and dedication of our team. The process also highlighted the areas of opportunity for us to continually improve our workforce and processes and the team are keen to accomplish this so we can continue to be a provider of high quality research for our communities." **Jodie Keyworth, Head of Business Development, Grounded Research at RDaSH.**

"This Gold award allows us to market for commercial research, as it's an indicator of our quality. It provides a layer of assurance for the Trust in terms of an external assessment and where we're at in terms of our clinical research workforce" **Heather Rice, Director of Research & Innovation at RDaSH**



Pie chart image supplied by the Grounded Research Team at RDaSH

NHS Sherwood Forest Hospitals NHS Foundation Trust

"This accreditation is extremely important to us because it evidences the results of our dedication to work to the highest standards of practice, as well as demonstrating our drive, commitment and enthusiasm for delivering the highest-quality clinical research in our locality, both for our patients and sponsors. We wanted to have our internal efforts independently validated, but also thought this would be a good exercise to bring the team together, demonstrate we are open to challenge and making improvements, show the team how valued they are and provide them with the opportunity to have their say in a confidential and safe space. Research staff are often the unsung heroes of healthcare and being able to showcase this achievement across the organisation, the CRN region and the wider industry will help to solidify our position as a clinical trial partner of choice."
Alison Steel, Head of Research & Innovation, Sherwood Forest Hospitals NHS Foundation Trust

Syneos Health

Case Study

"Workforce Quality Accreditation is one of the most rewarding programs I have ever worked on. It is not a check box exercise, it's part of a continual improvement process—we learned a lot about ourselves: what we do well, what we can improve upon and how to fill gaps. IAOCR will not waiver from their standards—gaining the Clinical Operations Workforce Quality Accreditation really means something!" **Richard Wood Senior Director, Global Operations, Syneos Health**

"[Participating in the process] just made sense… it was clear that it would improve effectiveness and efficiency so, with a saving or improvement of 1 percent or 0.5 percent in a number of areas, it easily pays for itself while providing assurance of workforce quality to our customers." **Alistair Macdonald Chief Executive Officer, Syneos Health**

Award Winning Sites

Re:Cognition Health Brain and Mind Experts

Video

Case Study

Re:Cognition Health (RCH) have a network of award-winning clinical sites in the UK and the US, with their six UK sites holding the GCSA Global Quality Standard. **They were the first UK-based commercial site network to be awarded GCSA Certification.** The expert teams provide cognitive healthcare services for patients of all ages, through diagnosis and treatment of a wide range of neurological conditions, including Autism, Alzheimer's disease, Parkinson's and Traumatic Brain Injury. As part of their work as a world-leading memory clinic, RCH provide people with access to new generation treatments for neurological conditions and a variety of diseases, through international clinical trials. RCH are committed to changing the future of brain and mind health, by helping to find a cure for these diseases.

To find out more about Re:Cognition Health's GCSA journey scan the QR codes above.

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TRUSTED GLOBAL PARTNER

To contact RCH:
E: trialstartup@re-cognitionhealth.com
W: recognitionhealth.com

Press Release

NHS Royal Berkshire NHS Foundation Trust

The R&I Department for oncology research at Royal Berkshire NHS Foundation Trust achieved GCSA Certification for demonstrating global best practice standards in 'Patient Engagement'.

Royal Berkshire NHS Foundation Trust's vision is "working together to provide outstanding care for the community". Central to achieving this vision is working in partnership with patients and colleagues across health and social care and other organisations who share the same values, to support people in their community.

The Trust has an excellent multi-skilled workforce and a reputation for conducting high quality, innovative clinical research. Their aim is for everyone who comes through their doors to be offered an opportunity to participate in a research study, if they are eligible and choose to do so. Clinical research is an important part of their operation and their commitment to their patients was exemplified by their recent GCSA Certification in high quality standards for patient engagement. The Trust is now looking forward to completing the full GCSA Certification in 2024.

To contact the R&I Department Team at Royal Berkshire NHS Foundation Trust:
E: ResearchAndDevelopment@royalberkshire.nhs.uk
W: royalberkshire.nhs.uk/about-us/research-and-development

AGA CLINICAL TRIALS
NEOSTART CORPORATION

In October 2023, AGA Clinical Trials became the FIRST clinical research site based in the USA to achieve GCSA Certification, clearly demonstrating their desire to pioneer global best practice and lead the way in the US for ensuring the highest quality clinical research journeys for clients and patients. AGA Clinical Trials is a highly awarded clinical trial research site located within Miami, Florida, USA. Having conducted over 200 trials across various phases, AGA is dedicated to providing access to a highly diverse patient population. With a strong focus on patient retention, AGA has enrolled more than 13,000 participants, and is a trusted and reliable healthcare partner in their community.

AGA Clinical Trials boasts over 85 years of combined experience in clinical research and is committed to safeguarding patients' health. The clinic was developed as a result of three physicians united by a common goal: to help patients in need of affordable medical care. Many of AGA's studies offer compensation and access to free, study-related medical care. This often provides advanced medical options for patients and caregivers that are unavailable otherwise.

To contact AGA Clinical Trials:
E: Dr Roberto Aguirre raguirre@agaclinicaltrials.com **W:** www.agaclinicaltrials.com

Award Winning Sites

The Grounded Research Team at RDaSH became the FIRST NHS trial site to achieve the GOLD standard in IAOCR Workforce Quality Accreditation.

The name Grounded Research was chosen as it embodies the teams' intention to offer inclusive research that is grounded in their communities, that makes a positive difference to people's lives and works for the most vulnerable in their community. RDaSH believe that research can, and should, involve everyone. The team achieve this by taking their research into the field – visiting participants in their homes, in churches, schools and shopping centres; they take their Community Health Bus to unusual locations or special events.

Grounded Research has a fully staffed and operational community Clinical Research Facility (CRF) based in Doncaster as part of their larger network. The community CRF is a good example of the type of collaborative work they have undertaken – getting it up and running and operating vaccine trials within Doncaster to respond to the COVID 19 pandemic.

It has been designed with input from all parts of the local community, their staff and their patients, because the team want all their environments to be safe, welcoming and inclusive for everyone. It is an established, dedicated facility within an existing NHS Trust infrastructure.

To find out more about the Grounded Research Team's IAOCR WQA journey scan the QR code to read the case study:

Case Study

NHS Rotherham Doncaster and South Humber NHS Foundation Trust

Grounded Research

CLINICAL RESEARCH OPERATIONS IAOCR WORKFORCE QUALITY ACCREDITATION ★ ★ ★ GOLD STANDARD

To contact the Grounded Research Team at RDaSH:
E: rdash.groundedresearch@nhs.net **W:** www.rdash.nhs.uk/about-us/grounded-research

Sherwood Forest Hospitals NHS Foundation Trust successfully achieved Bronze status in the IAOCR Workforce Quality Accreditation standard, demonstrating their drive, commitment and enthusiasm to deliver the highest quality clinical research in their locality, as well as evidencing their dedication to supporting and investing in their clinical research staff.

Sherwood Hospital's Research & Innovation Department is a national and internationally recognised leading centre for clinical trials, offering a dedicated Clinical Research Facility alongside research-only rooms. They have achieved numerous world and UK firsts, and high recruitment rates. Study start-up is swift, typically confirming capacity within two weeks of approvals. Their diverse portfolio spans various specialties, including Urology, Rheumatology, Respiratory, Gastroenterology, Dementia, Mental Health, Endocrine, Oncology, Haematology, Dermatology, Paediatrics, Orthopaedics, and Reproductive Health. The integration of primary care patient identification sites and data-sharing agreements with Primary Care Networks enhance patient identification and efficiency across the region. Their future focus is on expanding commercial activities and bringing research to their communities.

Press Release

NHS Sherwood Forest Hospitals NHS Foundation Trust

CLINICAL RESEARCH OPERATIONS IAOCR WORKFORCE QUALITY ACCREDITATION ★ ☆ ☆ BRONZE STANDARD

To contact the R&I Team at Sherwood Forest Hospitals NHS Foundation Trust:
E: Alison Steel – alison.steel1@nhs.net **W:** www.sfh-tr.nhs.uk/get-involved/research-and-innovation

GCSA is now supporting and certifying sites in the UK, USA, New Zealand and Australia. To join the global community of quality assured sites, working to the industry-endorsed GCSA standard, contact Lauren Gledhill, **lgledhill@iaocr.com**

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gcsa The Global Quality Standard for Clinical Research Sites

Partner With Us and Lead the Change

You can help shape the evolution and future of the Clinical Research Industry by pioneering best practice standards for your organisation, or for the wider industry. All of our standards are built with the industry, for the industry, and we truly value our collaborations. We are seeking NHS sites, commercial organisations and individuals that are passionate about developing and embedding global best practice standards, to decrease risk and improve quality and capacity of clinical research.

Here are 6 ways in which you can get involved...

1. Embed a competence-based quality assurance system to de-risk your organisation

If you are responsible for the performance of your team or organisation, IAOCR and GCSA can work with you to embed a competence-based approach which is tailored to your needs and designed to increase engagement and productivity, and reduce risk.

2. Become an IAOCR Certified Academy Partner

Do you run high-quality training programmes or have specific expertise to share with clinical research professionals? IAOCR can help build and quality assure your training and partner with you to provide a comprehensive combined programme of training and internationally recognisable accreditation for your clients. IAOCR Certified Academy status positions your organisation as a 'centre of excellence' and can expand your business.

3. Become a Verified Competence Assessor

Verified Competence Assessors are intrinsic to the competence verification and accreditation process. We can train you how to do this in your organisation. We are also seeking dedicated professionals to join our expanding team.

4. Join a Core Global Competencies Taskforce or Review Committee

IAOCR Core Global Competencies are built in consultation with industry experts and are the keystones of all IAOCR accreditations.

The taskforces and review committees provide great opportunities for networking, peer-to-peer learning and raising your profile within the industry as a champion of best practice standards. Upcoming taskforces/committees include:

- Oncology CRA (framework creation)
- Clinical Research Project Management (framework review)
- CRA & Data Management (framework review)
- Risk-Based Monitoring & Project Management (framework creation)
- Clinical Research Nurse (Home-Based)
- Clinical Research Nurse (Mental Health)

5. Join the GCSA Global Advisory Board

Our GCSA Global Advisory Board (GAB) is central in ensuring the continuous improvement of our quality standards, assessment frameworks and development initiatives for clinical research sites across the world. GAB members include leaders and experts from across the industry and include sponsors, CROs, NHS and commercial sites, Government and Regulatory organisations. We are actively looking to expand our Global Advisory Board and invite you to consider this opportunity. For further information please see p.29 or email Lauren Gledhill – **lgledhill@iaocr.com**.

6. Make a Suggestion

Our frameworks and processes are built and updated in response to demand from industry. We are dedicated to enhancing the industry through the development of valuable resources and certification that put competency and quality at the centre of best practice. Please do share any ideas or areas that you believe may need improvement to continue to build the standards for the Industry.

Contact us to find out how you can get involved:

Tel (UK) **01628 784906** | Tel (International) **+44 1628 784906** | Tel (US Toll Free) **+1 (855) 209 2335**
info@iaocr.com | **www.iaocr.com**

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gcsa The Global Quality Standard for Clinical Research Sites

Invitation for Global Advisory Board Applications

Driving change and innovation through accreditation and certification of global best practice standards is at the heart of what we do at IAOCR and GCSA. These standards have been developed with, and informed by, industry experts like you. Input and guidance is crucial to ensure global recognition of the importance of global best practice standards and ensuring that these standards are adopted and upheld for the benefit of all patients, sponsors, CROs and staff engaged in clinical research.

GCSA (Global Clinical Site Assessment) provides a system of assessment, gap analysis, improvement support and independent quality certification, focused on workforce and operational processes across the end-to-end clinical trial pathway.

GCSA's 'right first time' and 'quality built in' ethos facilitates process excellence and seamless collaboration between sponsors/CROs and clinical trial sites to:

- Ensure a high quality patient experience
- Improve overall site competence and capacity
- Improve feasibility and study start-up
- Get innovative treatments to patients more quickly and safely
- Support site business strategy
- Increase margins for clinical trial sites

The best practice standard was developed with a Global Advisory Board (GAB) formed in 2020*, of clinical research industry stakeholders (sponsors, CROs, Regulators, NHS Trusts and commercial site organisations). Their shared ambition was to ensure quality through process excellence to facilitates synergistic partnerships between sites and sponsors, to ensure true patient centricity.

*See inside front cover for information about the Global Advisory Board

Membership of the Global Advisory Board (GAB)

We are delighted to announce that we are expanding the GAB, and this is an exciting opportunity for potential new members, including yourself.

The role of the GAB is:

1. To ensure the continuous improvement of the GCSA Standard to reflect best practice, relevance, and evolution appropriate to changing global, technological, workforce and regional perspectives
2. To raise awareness of the importance and adoption of Global Standards for clinical research sites to ensure true patient centricity, quality, and safety
3. To be the champions within own organisations and wider networks for the adoption of Global Standards for clinical research sites
4. To promote the benefits of GCSA Certification and encourage sponsors and CROs to place their clinical trials with GCSA certified sites
5. To encourage broader partnerships and wider opportunities and networking with other site bodies/organisations
6. To provide a 'Disputes Resolution Committee' (escalation committee) for sites

Commitment:

We recognise and appreciate that people have busy schedules; outlined below is the time commitment required in working with us as part of the GAB:

- Approximately 2 x online meetings per year
- An invitation to the annual Clinical Research Industry Leaders Think Tank (attendance is optional)
- Provision of quotes/testimonials to assist in the promotion of the value of GCSA to the industry

If you would like to express your interest in being part of this invaluable Industry asset, please contact Lauren Gledhill: **lgledhill@iaocr.com**, with your proposal/ideas on how you can work with other industry leaders to support and elevate the GCSA standard.

Care Access

Accelerating the Future of Medicine for *Everyone*

- GLOBAL NETWORK OF RESEARCH SITES
- COMMUNITY SCREENING PROGRAM
- SITE STAFFING AND TRAINING

Over 150 research sites around the world with a proven track record

- Global top-enrollers
- Serving diverse populations
- Fast activation turnaround
- Centralized quality oversight
- Dedicated point of contact

Contact

Rupi Bancil
SVP, Global Study Operations and Global Expansion
r.bancil@careaccess.com

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Testimonials

"Ensuring best-in-class global standards in terms of people and processes plays a big part in reducing risk in clinical research……The independent Global Advisory Board has unanimously ratified the GCSA standard for clinical trial sites, ensuring a robust standard for sites that can be adapted to fit with any country across the globe."

Dr Suki Balendra – Life Sciences Lead | LCRN North West London Core Team; Imperial College Healthcare NHS Trust

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"The industry has come to realise that more training and more experience does not necessarily equate to competence in the field……by being able to measure competence against globally recognised best practices, we're able to give our customers the confidence to know that the (skills of) staff assigned to their studies have been validated against an independent quality standard."

Alistair Macdonald – CEO, Syneos Health

"GCSA will provide for further development and alignment of site capabilities with the skill sets required related to quick start-up and implementation of projects – including patient recruitment, patient delivery, and everything in-between, as we work together to bring new therapies to patients in need."

Agnieszka Gackowska – Senior Director, Global Site Solutions – Parexel

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"Qualifying staff to work in clinical trials based on number of years' experience provides false reassurance of quality and also fuels the industry's talent crisis…… When an individual gains IAOCR accreditation I know they have been robustly competence checked…… The IAOCR approach reduces risk to clinical research and provides a reliable and trusted pathway for new talent."

Sam Kerr PhD – Chief Scientific Officer, Merz Aesthetics

"Re:Cognition Health wanted to join the GCSA scheme to really set ourselves the challenge of being reviewed and assessed from an external partner… ….GCSA has really supported Re:Cognition Health and our efforts to fine tune our processes, improve our teams' performance and their performance development as well".

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

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Research and Development Forum

NHS

Joint UK Clinical Trials Taskforce Launches to Support O'Shaughnessy's Ambition for "exceptional best practice" to become the norm

The UK Clinical Trials Talent Taskforce has launched today to support the development of a best-in-class holistic ecosystem for talent attraction, development, professional recognition and retention to support the UK's desire to be a world-class destination for clinical research. The collaboration between the NHS R&D Forum and IAOCR is a direct response to the recently published Lord O'Shaughnessy's review on Commercial Clinical Trials in the UK which called for "exceptional best practice" to become the norm so that patients, the NHS and the UK as a whole can benefit.

Industry-Leading Clinical Research Accreditation Now Available Via New Online Portal.

IAOCR has today launched a new online accreditation service marking a significant change in their mission to put patients at the heart of clinical research by reducing risk and improving efficiencies. The online portal will maintain IAOCR's industry leading global standards, whilst nurturing the wider adoption of accreditation to ensure sites, organisations and individuals are competent to safely and effectively expedite research.

www.iaocr.com | www.gcsaassessed.org