IAOCR
The International Accrediting Organization for Clinical Research

gcsa Global Clinical Site Accreditation

Site Best Practice & Innovations Industry Leaders Think Tank 2022

29 June 2022 - 8.45am to 6.00pm

Beaumont Estate, Windsor, United Kingdom

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Contents

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Welcome to the Think Tank

On behalf of the IAOCR and GCSA teams, a very warm welcome to the Industry Leaders Think Tank 2022! It's great to finally be able to see our Think Tank regulars in person and we're also delighted to be joined by a number of new industry leaders and best practice pioneers.

Think Tanks provide networking opportunities and bring together leaders from a broad range of clinical research organisations to focus on the leadership and business operations of clinical research (generally not the clinical side). Think Tanks share challenges and opportunities, ideas, innovations and inform the direction of the industry. We are looking forward to sharing with you the progress we have made since our joint meeting with the NIHR in 2018, the subject of which was 'Positioning UK PLC as a Primary Choice for Clinical Trials.' We will also be sharing with you new global best practice standards for assessing, developing and accrediting clinical research staff and clinical trial sites.

I'd like to take this opportunity to say a very big thank you to today's speakers, the members of the GCSA Global Advisory Board (GAB), and the IAOCR Taskforce for Core Competencies for Clinical Trial Site Staff. I would also like to thank their organisations for enabling them to work with us and their commitment to improving standards. These inspiring groups of specialists have given their time and expertise, some over the course of a number of years. They have helped us better understand some of the industry's biggest risks and challenges as well as working collaboratively on solutions for the benefit of patients and all stakeholders. Their enthusiasm and dedication for driving best practice is second to none.

I'd also like to thank everyone in the GCSA and IAOCR teams for their resilience, creative thinking and tenacity, which has been needed more than ever during the pandemic. In particular I'd like to recognise Angela O'Connell for her insightful

Jacqueline Johnson North
CEO, IAOCR and Chair, GCSA

leadership and integrity, Sarah Everitt for her tenacity and passion, Gary Bradder who is always a pleasure to work with, Colette Donaghy for being a consummate professional, and Vicki Booth for her endless dedication, insightfulness and support. I would like to mention our former Chairman, Richard Brown. Sadly, Richard is no longer with us, we lost him last year to pancreatic cancer. However, his example of great leadership and his drive to "help shape a better future" lives on with us.

To quote Rosalynn Carter, former first lady of the United States and advocate for mental health and equal rights *"A leader takes people where they want to go. A great leader takes people where they don't necessarily want to go, but ought to be."*

The IAOCR and GCSA teams wish you a very enjoyable and thought-provoking day. We hope you build new connections and great collaborations – and that you leave inspired to pioneer change and make a positive difference!

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Morning Agenda

08:45 – 09:00 *Registration, refreshments, exhibits & networking*

CONFERENCE START

09:00 – 09:15 Welcome

Jacqueline Johnson North and **Angela O'Connell** - GCSA and IAOCR Executive Team

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09:15 – 09:45 Clinical Trials Under the Global Spotlight - Pioneering Best Practice Standards

Alistair Macdonald - Advisor to CEO, Syneos Health

09:45 – 10:15 Re-Imagining Clinical Trials - Partnerships with Sites, Patient-Centricity and New Technologies

Agnieszka Gackowska - Senior Director & Global Head - Site Solutions, Parexel

Dace Dimza-Jones - Industry Facilitator, NIHR Clinical Research Network Greater Manchester

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10:15 - 10:45 Recovery of NHS Capacity for Clinical Research

Jayne Goodwin - National Head of Research Delivery for Health and Care Research Wales, NHS R&D Forum

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10:45 – 11:00 *BREAK*

11:00 – 11:30 Globally Promoting the UK's Clinical Research Expertise

Soraya Mitchard - Head of Life Sciences, Portfolio Delivery & Strategy Team, Department of International Trade

Mohammed Isalm - Deputy Head of Healthcare - Healthcare UK, Department of International Trade

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11:30 – 12:00 Reducing Risk - Core Global Competencies for Clinical Trial Site Staff

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

Sarah Everitt - Vice President, Operations, IAOCR

Colette Donaghy - Accreditation Quality Manager, IAOCR

12:00 – 13:00 *LUNCH*

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Afternoon Agenda

PROCESS IMPROVEMENT

13:00 – 13:20 Valuing and Protecting the Clinical Trial Participant
(virtual presentation from Australia)
Janelle Bowden - Managing Director and Consultant, AccessCR

13:20 – 13:40 Improving Outcomes for Patients, Staff & the System
Steve Boam - CEO, Develop Consulting

13:40 – 14:00 Quality Assured Training for Clinical Trial Site Staff
Karen Cloete - Director, Task Academy

14:00 – 14:15 The Third Place - Improving Access, Choice and Equity in Clinical Trials:
Kristin Croucher - Vice President & Head of Clinical Operations (Europe), Lightship

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14:15 – 14:30 *BREAK*

INDUSTRY INSIGHTS AND CASE STUDIES

14:30 – 14:55 GCSA: Pioneering a New Global Standard for Clinical Trial Sites
Angela O'Connell - Board Member GCSA and IAOCR
Gary Bradder - Managing Consultant, Develop Consulting

14:55 – 15:20 Working Example of Global Clinical Site Assessment in the NHS
Sunder Chita - Health Service Research Manager, London North West University Healthcare NHS Trust,
Trish Winn - Head of Nursing, Clinical Quality & Innovation, London North West University Healthcare NHS Trust,
Alan Warnes - Independent Clinical Research Consultant and GCSA Global Advisory Board Member.

15:20 – 15:45 Working Example of Global Clinical Site Assessment in Commercial Sites
Dr Emer MacSweeney - CEO & Medical Director, Re:Cognition Health

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15:45 – 16:00 *BREAK & Reflection Form & Orders for Drinks Reception*

16:00 – 16:45 PANEL SESSION AND CLOSING REMARKS
Alistair Macdonald - Advisor to CEO, Syneos Health, **Agnieszka Gackowska** - Senior Director & Global Head, Site Solutions, Parexel, **Dace Dimza-Jones** - Industry Facilitator, NIHR Clinical Research Network Greater Manchester, **Dr Suki Balendra -** Life Sciences Lead, Imperial College Healthcare NHS Trust; LCRN North West London Core Team, **Dr Emer MacSweeney** - CEO & Medical Director, Re:Cognition Health, **Jacqueline Johnson North** - CEO, IAOCR and Chair, GCSA

16:45 - 17:00 Wrap-up/close

17:00 - 18:00 *DRINKS RECEPTION*

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- Support professional development

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Together, we're shaping the new generation of therapies.

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Reimagining clinical trials through partnerships with sites, patient-centric approaches, and the implementation of new technologies

With Heart™

www.parexel.com

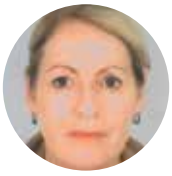
Today's Speakers

Agnieszka Gackowska - Senior Director & Global Head - Site Solutions
Parexel

Alan Warnes - Independent Clinical Research Consultant and GCSA Global Advisory Board Member

Alistair Macdonald - Advisor to CEO
Syneos Health

Angela O'Connell - Board Member
GCSA and IAOCR



Colette Donaghy - Accreditation Quality Manager
IAOCR

Dace Dimza-Jones - Industry Facilitator
NIHR Clinical Research Network Greater Manchester

Dr Emer MacSweeney - CEO & Medical Director
Re:Cognition Health

Gary Bradder - Managing Consultant
Develop Consulting

Janelle Bowden - Managing Director and Consultant
AccessCR

Jayne Goodwin - National Head of Research Delivery for Health and Care
Research Wales
NHS R&D Forum

Karen Cloete - Director
Task Academy

Kristin Croucher - Vice President & Head of Clinical Operations (Europe)
Lightship

Mohammed Isalm - Deputy Head of Healthcare – Healthcare UK
Department of International Trade

Sarah Everitt – Vice President, Operations
IAOCR

Soraya Mitchard - Head of Life Sciences, Portfolio Delivery & Strategy Team
Department of International Trade

Steve Boam - CEO
Develop Consulting

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

Sunder Chita - Health Service Research Manager
London North West University Healthcare NHS Trust

Trish Winn - Head of Nursing, Clinical Quality and Innovation
London North West University Healthcare NHS Trust

For further details on all our Speakers:

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About GCSA

A global standard that puts patients at the heart of clinical research.

GCSA (Global Clinical Site Assessment) provides a system of assessment, gap analysis, improvement support and independent quality assurance 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.

The modular assessment system covers :

- R&D Commercial Strategy
- Project Management Office
- Patient Engagement
- Feasibility
- Study Start-Up and Initiation
- Study Management Operations and Closedown
- Workforce Quality Accreditation.

Commitment to the GCSA journey demonstrates dedication to quality, the desire for ensuring high-quality patient experience, and the aspiration to be a clinical trial site of choice.

Distinctive certification marks are awarded on a modular basis, evidencing that participating sites have met rigorous, independently assessed quality standards.

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 startup
- Get innovative treatments to patients more quickly and safely
- Increase income for clinical trial sites

* See inside back cover for information on the GCSA Global Advisory Board

Contact us to find out how you can get involved:

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About GCSA (continued)

GCSA's ambition is to play a significant role in creating a clinical research ecosystem which builds back better, and which will shape the future of healthcare and improve people's lives in the UK and across the world for years to come.

GCSA facilitates networking of people and organisations to expedite best practice sharing and innovation, through training and development activities, Taskforces, Global Advisory Boards, and Think Tanks.

Why GCSA?

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

"We are really proud of what we do and proud of what our team do as well. We are always looking for areas for improvement and development and this process really supported that for us. It was an encouraging process to take a step back and really appreciate what we were doing well and identify the areas where we just needed to make amendments and adjustments. I think it's really easy to put things off when everyone is really busy. But when something is so important, and this was something that would help us, we made that commitment of time and resources."

Vicki Eyre
Director Clinical Operations

Re:Cognition Health

"As a global clinical research organisation, Parexel is focused on working with sites as a partner in the clinical development process. To this end, the ability to pivot quickly in pandemic situations and conduct trials seamlessly in potentially unpredictable situations - implementing new approaches like decentralised clinical trials - is key.

Accreditation through Global Clinical Site Assessment (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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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 has been 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 accreditation in one or more modules demonstrates that your site has met stringent assessment criteria, is committed to quality and has the desire to attract more clinical trials.
By evidencing your achievement of global standards, potential sponsors will be able to more easily identify areas of capability and feel reassured in terms of your site's 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 you to gain a thorough understanding of any R&D pathway problems and formulate an action plan to address them.

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

A. Usually site assessment takes about 1 - 4 weeks and the time between the initial kick-off meeting and the final/gap analysis report takes up to 14 weeks. This depends on the complexity of the site and the number of modules selected. Speaking with site staff is an integral part of the process and this can be done virtually. Staff members involved should expect to dedicate about 1 - 2 hours each in total.

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, the cost of which is variable depending on size and complexity of site, but generally would range between £2,000 and £8,000 per annum.

* See inside back cover for information on the GCSA Global Advisory Board

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North West London Clinical Trials Alliance



The North West London Clinical Trials Alliance is dedicated to delivering commercial and non-commercial sponsored clinical trials. We can run early phase and late phase trials in any therapeutic area.

The Alliance is a collaboration between the NIHR Clinical Research Network North West London, the local primary care network, Central London Community Healthcare NHS Trust, and the Clinical Research Facilities (CRFs) hosted by:

- Chelsea and Westminster Hospital NHS Foundation Trust
- Imperial College Healthcare NHS Trust
- London North West University Healthcare NHS Trust

Find out more:

industry.crnnwlondon@nihr.ac.uk

Scan the QR code below or visit:
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NHS Chelsea and Westminster Hospital NHS Foundation Trust

NHS Imperial College Healthcare NHS Trust

NHS Central London Community Healthcare NHS Trust

NHS London North West University Healthcare NHS Trust

NHS Manchester University NHS Foundation Trust

Clinical Trials Coordination Certificate (CTCC)

The aim of this Manchester University NHS Foundation Trust (MFT) delivered course is to standardise knowledge and practice, so that study coordinators (bands 5 and 6) can function at the same high level – regardless of the size or maturity of their team – and add further value to research in their specialty area, team and trust.

- The CTCC is delivered across three sessions, by Research and Innovation (R&I) delivery teams from MFT, based on their frontline experience in the UK's largest NHS trust.
- The sessions are a mix of virtual, self-directed learning and in-person.
- The course costs £425.

Book now for the November 2022 course via:
bookings.nowgen@mft.nhs.uk

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About IAOCR

Reduce Risk to Patients, Research and your Industry Reputation.

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 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!

Why Competence-Verify Clinical Research Professionals?

- Patients and their families expect and deserve competent clinical research professionals.
- Sponsors expect their trial delivery teams to be fit-for-purpose. They need high performing, competent professionals to avoid costly delays and risks to their research. They have often found that relying on number of years' experience alone is not enough to mitigate these risks.
- Competent clinical research professionals deserve professional recognition.

"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

What is the Accreditation Process?

- Participants can register with IAOCR as individuals or as a cohort through their employer.
- Training can be provided, but is not obligatory. Experienced professionals usually complete the process via the "portfolio-only route" which does not include training.
- IAOCR provides a role-specific accreditation portfolio to each participant.
- The portfolio details the assessment criteria which need to be met to achieve accreditation. The participant completes the portfolio, providing evidence of competence in the relevant areas detailed in the assessment criteria.
- Each participant is assigned to an IAOCR Verified Competence Assessor (VCA) who provides support and feedback to the individual. The VCA marks the portfolio once it is completed and provides a pass/fail recommendation to the IAOCR Accreditation Verifier.
- Upon passing accreditation, individuals are awarded IAOCR Internationally Qualified Professional status along with a Certificate of Accreditation, Designatory Letters and a Professional Certification Mark displaying a unique professional ID number.

Which Roles Does IAOCR Accredit?

IAOCR offers professional accreditation across a broad range of clinical research roles including: clinical research nurse, site manager, investigator, coordinator, CRA, project manager, central monitor, data manager, pharmacovigilance, auditor, TMF - and many others! We also work with employers to build bespoke accreditations, gap analysis tools and career pathways.

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Are Your Trials and Patients at Risk?

> *"If we go some way to standardising our competence checks, we can cut the paperwork elsewhere… and it would send a message that we are serious about quality assurance and reducing the regulatory burden on firms."*
>
> **Andrew Gwynne**, Shadow Minister - Health & Social Care

Your Responsibility to Reduce Risk and Support Your Team

All leaders working in the clinical research ecosystem have a responsibility to mitigate risks to patients and to strive for a 'right first time' and 'quality built in' approach desired by regulators.

If you don't know about the competence gaps in your team, how can you rectify them in a timely and efficient fashion? Independent competence verification by IAOCR enables you to take a targeted and pragmatic approach to staff development and career pathways. This ensures that competence gaps are identified and addressed, staff are fully supported, and professional recognition is awarded appropriately.

Utilising core global competencies and standards ratified by industry, IAOCR can work seamlessly with your organisation to embed a competence-based approach that reduces risk, increases efficiency and gives you and your team peace of mind.

> *"Each person working in clinical research plays a critical role in protecting patient wellbeing and data integrity. The independent quality assurance and accreditation programs offered by IAOCR are instrumental in helping organisations and individuals achieve these goals (and reduce risk), which ultimately builds confidence and trust in patients, sponsors, and regulators"*
>
> Clinical Operations & Training Leader (Global CRO)

Examples of risk…

Global Pharmaceutical Company Relying on Experience

A global pharmaceutical company client of IAOCR's was utilising the staff of two CROs under a functional service provider (FSP) model. The pharmaceutical company stipulated that all CRAs must be highly experienced and assumed this would result in staff that were competent and fit-for-purpose. Unfortunately, performance issues soon arose and delays ensued.

The pharmaceutical company engaged IAOCR to run a full accreditation check. Patterns materialised identifying gaps in specific competence areas across the entire workforce. Detailed feedback was provided to the CROs and targeted remedial training and process improvements were implemented.

When sponsors use IAOCR accredited staff they can be assured that their team have been robustly and independently competence checked to globally consistent standards.

Investigator Risk - Informed Consent

IAOCR was made aware of a woman, pregnant with twins, having an appointment with her NHS obstetrician. The obstetrician talked to the woman about enrolling her for a new procedure and asked her to sign a form. The woman was not informed that she would be participating in a clinical trial and was very concerned about her experience. IAOCR was able to verify that it was a clinical trial and the woman decided not to participate. The patient lost trust in her obstetrician.

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Why Work with IAOCR?

Established since 2011, IAOCR is a world leader in independent competence verification, providing internationally recognisable accreditations for clinical research professionals. With a global spotlight on clinical research as a result of the Covid-19 pandemic, there is a sharper focus than ever on professional standards and patient safety. IAOCR Internationally Qualified Professional status provides much-needed reassurance that the people running clinical trials are safeguarding patients, clinical research and the industry's reputation.

Here's what the industry says about us…

"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, ICON Plc

"Only about 10% of learning is done in the classroom, the learning really happens afterwards within the workplace and IAOCR offered a great solution to this. This kind of structure is necessary for it to be a success. Our clients have been impressed that we have listened to their feedback and put a consistent process in place to address their concerns. We have also had some great feedback internally that the process has been successful."
Client Services, Thermo Fisher Scientific

"We have used IAOCR for a considerable number of years and it has been a very successful partnership. They worked closely with us to develop a bespoke programme that delivered an accredited industry-specific Project Management course for those working in the Clinical Trials Industry. The course itself provided both the knowledge and skills required by our Project Managers unique within our industry and provided them with accreditation based on successful implementation of the project management competencies. The courses were delivered to a high standard and were very well received by the target group. As such, we have now extended the training delivered by IAOCR globally – covering North America and Switzerland. I have no reservations in recommending them."
Mike Yellow, Director, Global Talent Solutions, Thermo Fisher Scientific

"IAOCR accreditation is really valuable - it means we are all talking the same language when it comes to hiring, developing and describing talent. Currently, how we hire and develop people varies widely across the industry. With the accreditation process we know that each individual is qualified and competent and the whole industry will have the same benchmark. Also, we can work with each individual team member to develop them."
Drug Development Operations, EMEA & APAC, Allergan

"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 monitors 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, Advisor to CEO, Syneos Health

"*As we have worked with IAOCR for some time now, they have never wavered in their support of our needs; they continually adapt to our ever-changing business environment. I would recommend any biotech or pharma company of any size to work with IAOCR to improve their organisation and build a solid value proposition for employees and their development."*
Director Global Operations Management, Global CRO

"The TMF University accreditation program that LMK has created with IAOCR is the first of its kind for TMF professionals. While LMK had a wealth of training materials for TMF, the partnership we have established with IAOCR and their robust accreditation programme has enabled us to provide a training program that ensures consistency in the knowledge and skills of our graduates. This has been a terrific opportunity to ensure that we are aligning TMF professionals on best practices, so individuals completing the program walk away with the right knowledge, skills, and behaviours to be successful working in the TMF space"
Jackie Morrill, Executive Director, LMK

"I have worked closely with the IAOCR team for a number of years and I have to say their passion for quality and improving standards in the Life Science industry is inspiring. Accreditation across the industry is required, regardless of the quality of learning and development, to ensure standards are constantly reviewed and improved to support growth. They are happy to support not just the clients running clinical trials but companies supporting the industry, taking a view that we all play a part."
Stuart Britton, former CEO, SEC Recruitment

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Partner with us and Lead the Change

Are you interested in pioneering best practice standards with your organisation or for the wider industry? IAOCR is seeking NHS sites, commercial organisations and individuals that are passionate about pioneering best practice to decrease risk and improve quality and capacity of clinical research.

Here are 7 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 can work with you to embed a competence-based approach which is tailored to your needs and designed to increase engagement, 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/or quality assure your training and partner with you to provide a comprehensive programme of training and internationally recognisable accreditation for your clients.

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

IAOCR Core Global Competencies are built in consultation with industry experts and are the keystones of IAOCR accreditations.
The Taskforces provide great opportunities for networking and peer-to-peer learning. Upcoming Taskforces include:

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

5. Pilot Opportunities – Clinical Trial Sites (Commercial and NHS)

Utilising the IAOCR Core Global Competencies for Clinical Trial Site Staff, we are seeking expressions of interest from sites interested in piloting competence verification/accreditation of clinical research nurses, coordinators, site managers and investigators.

6. Join the Clinical Trial Innovation & Best Practice Think Tank (joint GCSA & IAOCR)

We are seeking clinical research industry leaders to help drive best practice and innovation for clinical research sites. Please submit your CV with a covering email to aoconnell@gcsaaccredited.org who will also be able to provide further information.

7. Make a Suggestion

Our frameworks and processes are built and updated in response to demand from industry.

Contact us to find out how you can get involved:

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IAOCR Core Global Competencies for Clinical Trial Site Staff

About the Competencies and Accredited Assessment Criteria

Working collaboratively under the guidance of IAOCR, the Clinical Research Site Competencies Taskforce commenced work in October 2021. The Taskforce worked in four groups to identify competencies for the roles below, and successfully delivered the most comprehensive competency framework ever developed for clinical research sites by an international group of broad ranging clinical research organisations.

- Clinical Trial Nurse
- Investigator
- Site Manager
- Co-ordinator

Building on the work of the Taskforce, the IAOCR Accreditation Team determined independently accredited assessment criteria for the competencies mapped to accredited learning outcomes. The industry can utilise these to run competence verification/accreditation and/or training Programmes. This can be achieved through IAOCR, or in partnership with their own training departments or third-party providers.

Role of Competencies in Reducing Risk

Each and every person working in clinical research plays an essential role in protecting the rights and wellbeing of clinical trial subjects and ensuring data integrity. Investigators can delegate tasks to other site staff, but training and education across the sector is inconsistent and competence-verification is not the industry norm. Introducing accredited assessment criteria, mapped to core competencies developed by industry, for industry, provides an opportunity for the adoption of a widely-accepted standard that reduces risk to clinical trial patients, clinical trial data, treatment innovation and organisations' reputations.

Awarding of Professional Status

Example of Investigator professional certification mark

Clinical research staff passing IAOCR competence verification achieve Internationally Qualified Clinical Research Professional status together with CPE points, learning credits, a Certificate of Accreditation, designatory letters and a professional certification mark baring their unique professional ID number.

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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.

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Bufferd, Gary - Lightship
Cloete, Karen - TASK and TASK Academy
Demarest, Helen - GHCC/Medicines for Malaria Venture
Donaghy, Colette - IAOCR
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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
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McIntyre, Karen - Syneos Health
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Ruthven, Karen - IAOCR
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In March 2022 the Global Advisory Board and Taskforce merged to become the Site Best Practices and Innovations Think Tank. To find out more about the Think Tank and how you can get involved please email aoconnell@gcsaaccredited.org

“A leader takes people where they want to go. A great leader takes people where they don’t necessarily want to go, but ought to be.”

Rosalynn Carter