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Achieving & Recognizing Operational Excellence

A joint response from clinical research industry leaders, submitted by Jacqueline Johnson North, CEO & Founder of the International Accrediting Organization for Clinical Research (IAOCR) in collaboration with:

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Introduction

This joint response has been provided in response to AMRC's consultation on **how multisite networks can better define and demonstrate quality in clinical research**.

The AMRC (Association for Multisite Research Corporations) consultation document states that:

- Sponsors and CROs most value speed, consistency, and efficiency when working with clinical research sites.
- Academic Research Centers remain the preferred model for many decision makers, due to the perception of quality.
- The performance of multisite clinical research corporations (MCRCs) is close to the performance of Academic Medical Centers (AMCs) across 23 operational areas and site attributes.
- MCRCs were particularly associated with consistency, faster start-up, scalable infrastructure, and access to diverse patient populations.
- Operational excellence is not yet recognized as a marker of quality, and MCRCs remain under-credited for the very attributes that drive reliable data and better patient outcomes.

About the Respondents

Collectively the respondents are industry leaders from a broad range of clinical research organizations around the globe; they incorporate sites/SMOs, sponsors, CROs, independent consultants, and other supply chain organizations. The respondents participate in the International Accrediting Organization for Clinical Research (IAOCR) Industry Leaders Think Tank, a collaborative global initiative that is run on a not-for-profit basis.

The International Accrediting Organization for Clinical Research (IAOCR) was established in 2011 and provides international accreditations and certifications to clinical research professionals and organizations in over 55 countries. All standards are developed with the industry, for the industry.

The IAOCR competency frameworks were reviewed and edited by the MHRA in 2014, and shared with the FDA. They have now been adopted by many of the world's leading CROs, Sponsors, Clinical Packaging, Sites, & Membership Organisations (including the USA), and are subject to regular review and revision in response to industry best practice requirements.

IAOCR's best practice standards underpin many of the training frameworks, certifications, and approaches that are operated by membership organizations and employers in the USA, and globally.

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About this Response

IAOCR believes that clinical research best practice standards should be available to everyone, anywhere in the world. Therefore, responses to the consultation apply broadly across the industry, globally. They are not specific to sites of any particular size, location, therapeutic area, or to specific trial types.

This response shares insights, testimonials and information gathered by IAOCR from key industry stakeholders during the development of global industry standards, in addition to other IAOCR information that is in the public domain.

"IAOCR continues to create meaningful collaborations to shape the evolution of the industry to deliver meaningful results for patients. This includes delivering best-in-class programs to support the expansion of clinical trials into new and emerging regions, continually elevating the level of experience and work quality."

"[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 – Global CRO

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Responses to AMRC Questions

1. Defining Quality: When you think about 'quality' in clinical research, what comes to mind?

1.1 Should quality be measured through investigator experience, or are other factors, such as staff retention, training, patient outcomes and data consistency, equally or more important?

Response:

1.1.1 Compliance with ICH-GCP - ensuring the protection of the rights, safety, and well-being of trial participants and ensuring the integrity and reliability of clinical trial data is of paramount importance to all clinical trials.

- Transparency in terms of Regulatory Inspection findings varies around the globe. In countries where findings are not publicly available, it is not possible for patients and sponsors to access information to aid their assessments of safety and quality.
- The current situation is that industry audits identify issues, but there is no standard for auditing, no universally agreed requirements, no "sign off" standards and no qualified auditor standards. In such a highly-regulated industry, this presents a fundamental gap in quality approaches.
- In 2020, IAOCR partnered with Pharm-Olam to deliver the "Audit Academy" initiative; a 12 week program to provide training followed by competence-based assessment leading to an international qualification (providing internationally valid Learning Credits and CPE points) https://www.linkedin.com/pulse/accredited-internationally-qualified-clinical-auditor-burgess-frqa
- Given the international nature of the clinical research industry, a global initiative to deliver auditing standards, coupled with internationally qualified auditors could make a meaningful difference to all key stakeholders - reducing time, costs, and improving quality.
- This could be a potential area for collaborative work between AMRC and the IAOCR Think Tank community.

1.1.2 Over-reliance on training certificates, experience and lists of training content places patients and clinical research at risk. Whilst investigator experience, staff retention, training, and other organizational development matters are ways to help ensure quality, in themselves they are not measurements of quality.
E.g.:

- An investigator may be very experienced, but not competent and fit for purpose
- Staff retention might be high, but potentially the staff could be of poor quality
- A list of training content provides a list of the inputs provided, but not the quality of the inputs provided in terms of the quality of the training materials or the quality of the trainer.

- Training certificates can be in place, but there is no evidence of the quality of the inputs of the training, or evidence that participants have paid attention during the training and can apply what they have been trained on in real world situations.

1.1.3 The term "patient outcomes" requires careful definition.

1.1.4 Patient outcomes can be indicators of quality, however there are numerous factors (both clinical and non-clinical) that affect patient outcomes and the retention of patients in the trial from first visit to last visit. Many patient outcomes could be outside of the control/influence of the unit.

1.2 Are there any quality metrics that clearly distinguish top performing clinical trial providers? What examples of metrics can you point to?

Response:

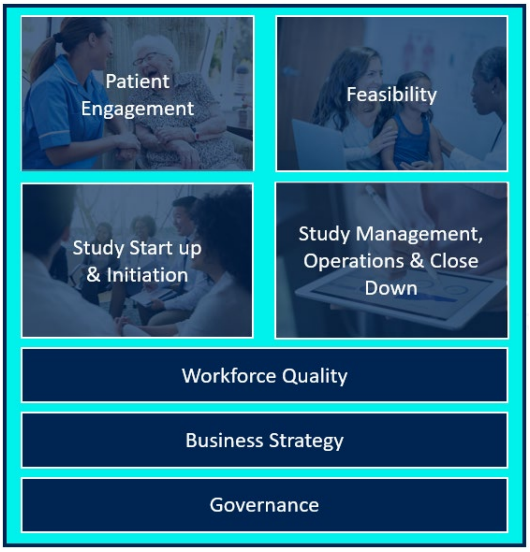
1.2.1 In addition to the standard quality approach in relation to ICH-GCP, quality can be measured through quantitative and qualitative measures that are focused on the experiences of four key stakeholder groups:

- Participant experience
- Employee experience
- Commercial client experience
- Supplier experience

1.2.2 Following broad and in-depth consultation with a large group of global industry stakeholders from sites, CROs, sponsors and other supply chain organizations, IAOCR facilitated the development of GCSA – the global certification standard for clinical research sites. Founding members of the Global Advisory Board consisted of senior representatives from Novartis, ABPI, NIHR, HRA, Syneos Health, Parexel, Allergan, PCMG, Biomat USA, MMV, Re:Cognition Health, and the NHS. Since launching in 2023 the standard has been adopted by sites across USA, Europe, South America, Middle East, and APAC – from small independent sites, and public health providers, to large multisite corporations.

1.2.3 As an evolution of the Global Advisory Board, the IAOCR Clinical Research Global Best Practices Board (launched in 2025) now works collaboratively to help shape best practice standards. The Board supports clinical research organizations of all sizes and maturity levels to adopt and embed best practice standards, to benefit participants and to enable delivery of high quality, effective and efficient clinical trials https://iaocr.com/leadership/

1.2.4 Research conducted by the Founding Members of the Global Advisory Board https://iaocr.com/gcsa-global-advisory-board/ determined that a certification standard for clinical research sites should focus on the business operating procedures that underpin the successful delivery of clinical trials, enabling sponsors, CROs and sites to work synergistically together and ensure a truly patient-centric experience. Hence, the industry worked together to develop GCSA – ***the most globally accepted certification standard for clinical research sites.***



1.2.5 The aim of the standard is to ensure that all sites, anywhere in the world, are operating to consistently high standards that can be trusted by participants, sponsors and CROs.

"As a sponsor of dermatology trials, the GCSA Certification Standard gives me confidence that sites are working to a global quality standard and have been independently audited by IAOCR. When a site is GCSA Certified I have confidence that they will be a high-quality partner for our clinical trials."

Chief Scientific Officer, Merz Aesthetics

"Accreditation through 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."

Senior Director, Global Site Solutions, Parexel

"The GCSA Certification process offered more than just validation, it was a true opportunity for reflection and growth. It enabled us to celebrate areas of strength whilst also identifying opportunities to further refine and enhance our processes. The Certification reinforces the credibility and quality of our research operations through independent external review. Ultimately, it supports our continued commitment to delivering high-quality experiences for both patients and sponsors."

Group Executive Manager - Research, Icon Group

(Australia's largest private cancer clinical trials program)

1.3 **How does staff certification impact your perception of site quality?**

1.3.1 Assessments and certifications by recognized and respected organizations (such as membership bodies) can provide a good starting point as an indicator of workforce quality.

1.3.2 IAOCR works collaboratively with employers, training companies, membership organizations, and other bodies, providing internationally recognized accreditation and qualifications underpinned by industry-ratified competency frameworks.

Some examples of collaborations with US organizations are as follows:

- ACRP (membership organization) : https://www.appliedclinicaltrialsonline.com/view/iaocr-and-acrp-announce-collaboration-0#:~:text=IAOCR%20and%20the%20Association%20of,programs%20in%20the%20US%20market
- Syneos Health (CRO) : https://www.syneoshealth.com/solutions/clinical-development/clinical-development-services
- LMK (TMF University - training provider) : https://www.lmkclinicalresearch.com/tmfu/
- Joint Task Force for Clinical Trial Competency : https://mrctcenter.org/resource/moving-from-compliance-to-competency-a-harmonized-core-competency-framework-for-the-clinical-research-professional/

1.3.3 IAOCR assesses professionals against the core competency standards defined with industry. The accreditations and assessment processes are subject to quality assurance and oversight by Government-regulated institutions. This ensures fairness of assessment, rigor, and the award of professional qualifications that have an international value across education institutions and employers via the award of recognized Learning Credits that are rated in terms of size and difficulty (mapped to international education awards systems).

IAOCR Accreditation Marks and Internationally Qualified Clinical Research Professionals Marks for clinical research site professionals

1.3.4 All professionals achieving IAOCR Internationally Qualified Professional Accreditation must evidence competence, because of this, only experienced professionals are eligible for IAOCR assessment. This therefore this compliments the foundational level training and assessment delivered by other recognized and respected organizations.

1.3.5 IAOCR accreditation is proven to improve the quality of clinical research professionals. An example of this is a drug safety program run in collaboration with ICON PLC; the results of which are shown below:

	Pre Program Quality Report	Post Program Quality Report	Improvement	Percentage Improvement
Major Errors	93	16	77	83%
Moderate and Minor Errors	138	97	41	29%
TOTAL	231	113	118	51%

2. People and Professionalism: MCRCs are often recognized for efficiency, but less often for professionalism.

2.1 What cultural or operational practices (e.g. standard operating procedures (SOP) adherence, staff development, site oversight) best communicate professionalism from trial sites?

Response:

2.1.1 Whilst there are some common desirable attributes and expectations in relation to professionalism, it is important that each organization develops its own identity in terms of culture and operational practices. This is essential for commercial differentiation.

2.1.2 To effectively integrate organizational values and behaviors, they need to be embedded throughout the DNA of an organization. This can be effectively achieved through the adoption of organizational design and development best practices, which are also evidenced through the IAOCR Workforce Processes Quality Certification (WPQC). The WPQC assessment examines organizational development maturity at three levels: Bronze, Silver and Gold.

IAOCR Workforce Process Quality Certification Marks

2.1.3 The Workforce Process Quality Certifications have been adopted by multisite organizations, CROs, and supply chain organizations as an effective tool for process improvement and independent verification of best practices.

The IAOCR – Syneos Health joint case study **"Workforce Excellence - A Business and Clinical Trials Imperative"** provides a deeper dive in this regard https://iaocr.com/wp-content/uploads/2022/09/Case-Study-SyneosHealth-Workforce-Excellence.pdf

"This 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 Certification] really means something!"

Senior Director, Global Operations, Syneos Health

"The IAOCR process also showed us areas where we have opportunity to improve so we can remain a provider of high-quality research for all our communities and can continue to make a real difference to patients' lives."

"Shortly after achieving [the Certification] we were approached to undertake a study with potential to generate £80,000 income for the Trust... [it] has helped to build a pipeline of four further studies which could generate an income of between £250,000 - £400,000."

" Improvements made as a result of [the process] have led to an increase in positive feedback from client meetings."

" Staff have reported increased confidence in their own ability to deliver excellent client service."

"Process improvements galvanized through the process have fostered improved career development and cross-departmental cooperation."

NHS Clients

2.2 How important is research staff's experience, tenure, and training to perceptions of quality?

Response:

2.2.1 Experience, tenure, and training records in themselves do not provide reliable evidence of quality - many people can remember a work colleague who has been in the organization for a long time, and attended a lot of training courses, but who is not a good example of a high quality employee.

Robust and meaningful competence evaluation is key. To achieve this, organizations need to have good understanding of the competency requirements for all roles, in terms of skills, knowledge and behaviors. Ideally, the organizational values should also be embedded in the organization's framework so that performance of individuals is not just focused on 'what' to do, but also 'how' it should be done.

2.2.2 A key purpose of the competence evaluation is to enable the organization to identify development gaps, which can often (not always) be addressed by targeted learning interventions.

2.2.3 IAOCR competency domains for clinical research site professionals are freely available via the IAOCR website and can provide a foundation block from which sites can tailor their own competency frameworks https://professionals.iaocr.com/pages/accreditations.

2.3 In what way can networks better demonstrate professionalism to customers and the wider industry?

Response:

2.3.1 As for any commercial company, it's essential to have a clear vision, mission and values and then to ensure that these become 'lived' and demonstrated as part of the company's brand identity. In a highly competitive market, winning new clients can be challenging. Therefore, it is essential that once new relationships have been established, professionalism, consistency, trust, and reliability are demonstrated.

2.3.2 Recognized independent certifications, awarded at an organizational level e.g. ISO, GCSA, IiP, BCorp, AAHRPP, etc. Can be a good way of evidencing professionalism and competence at an organizational level.

2.3.3 When employers invest in credible training programs, development activities, qualifications, certifications, accreditations, etc. in order to support the development of their workforce, it evidences that they take staff competence and professionalism seriously.

3. Data Maturity & Technology: MCRCs are one of the few groups within the industry with the resources to develop and deploy purpose-built technologies at site level.

3.1 Are technologies, such as operational AI solutions, an effective measure of 'quality' among trial providers?

Response:

3.1.1 Whilst MCRCs have greater resources to invest in technologies and tech workforce, AI is democratizing access to tools in ways that will also be beneficial to all organizations. AI is advancing at such a rate that employers onboarding early talent with AI skills 'built in' will be able to leverage a tech-savvy generation, without the need for the large-scale investment that was once needed.

3.1.2 With regard to measuring the 'quality' of trial providers, based on their operational AI solutions, key questions include how the quality and consistency of AI outputs are being validated and what human oversight processes are in place. The Economic Times recommends a 30:70 rule with regard to reliance on AI https://economictimes.indiatimes.com/wealth/earn/be-human-stay-relevant-the-30-rule-in-ai-and-top-entry-level-jobs-for-the-future/what-is-the-30-rule-in-ai/slideshow/124378673.cms

3.2 What evidence, tools, or benchmarks would help validate data quality across networks?

Response:

3.1.1 No response is provided - this is an extremely broad question to answer.

4. Patient Recruitment & Outcomes: MCRCs have access to a diverse, and often international, patient population.

4.1 To what extent do patient outcomes and trial experience influence perceptions of 'quality' from a clinical trial provider?

Response:

4.1.1 Research conducted by the IAOCR Global Advisory Board, ahead of developing the GCSA Site Certification standard, identified participant experience as a key quality measure, it is therefore one of the foundation stones of the GCSA global quality standard.

4.2 In what ways can MCRCs demonstrate their value in providing accessible, consistent, patient-centred research at scale? How should these be measured and evidenced?

Response:

4.2.1 Independent certification of operational process quality. E.g. through GCSA Site Certification

4.2.2 MCRCs should provide evidence that participant feedback is not only collected but also utilized as part of a continuous quality improvement approach.

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Publication & Use of Intellectual Property

In the spirit of openness and collaboration, IAOCR respectfully requests that AMRC references IAOCR when using any IAOCR materials and/or information contained in this document.

This document will be published on the IAOCR website, following its submission to AMRC.

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