

New clinical research measures needed to ensure patient safety and advance drug development

New campaign launches on inaugural World Patient Safety Day

Maidenhead, United Kingdom, 17 September 2019 – IAOCR has launched a new campaign calling on the industry to prioritize ensuring the competence of those undertaking clinical research in-line with upcoming guideline changes. The ‘Don’t Risk Your Research’ campaign, launched on World Patient Safety Day, further supports the imminent changes to ICH E8(R1) which focuses on factors improving the ‘quality’ of clinical research specifically around the “Right First Time” approach to quality assurance.

Competent individuals are imperative to patient safety and quality research. IAOCR is highlighting the need for all clinical trial Sponsors to ensure that the people conducting their clinical trials are rigorously checked and qualified by competence. A reputable and robust accreditation process has been in place for a number of years now, but unlike other industries the clinical research sector has been slow to proactively adopt professional standards. Currently resourcing decisions are often based on years of experience and CVs/resumes (which there is a reported fraud rate of approximately 17%) rather than evidence that people can perform the job competently.

Don’t Risk Your Research raises awareness of the risks incompetence poses to patients, clinical research and organizations and aligns with the ICH E8(R1) guidelines which focus on factors that are ‘Critical to Quality’ specifically ‘Patient Protection’, ‘Generation of Reliable’ and ‘Meaningful Data’. The individuals undertaking clinical research are ultimately managing patient safety, multi-million-dollar investments and future, advanced treatment options, which is why competence of these individuals is key.

“Clinical Research is central to the development of all upcoming treatment options. Incompetence places patients, clinical research and organizations at risk so it is shocking to us that the industry is not proactively ensuring that everyone involved in clinical research is qualified through competence” explains Jacqueline Johnson North, CEO, Future Shaper Holdings, IAOCR’s parent company. “At IAOCR we are dedicated to pioneering best practice and ensuring appropriate checks and balances are in place so that patients and Sponsors can feel confident and reassured. Our campaign coincides with the ICH E8(R1) guideline updates which we fully support. We are urging all sponsors and Clinical Research Organizations to ensure that their clinical research workforce has been robustly competence checked to international standards.”

IAOCR Internationally Qualified Professional status is a Regulated Accreditation. It is awarded to clinical research professionals that have demonstrated their competence and provides reassurance to patients, sponsors and employers. This internationally recognized accreditation is mapped to the International Standard Classification of Education Framework developed by UNESCO.

To learn more about how IAOCR can partner with your organization to ensure the “Right First Time” approach required by ICH E8(R1) get in touch: info@iaocr.com or call us on US Toll Free : +1 (855) 209-2335 or UK/International : +44 1628 784906.

The WHO (World Health Organization) has launched the first-ever World Patient Safety Day on 17 September 2019, to create awareness of patient safety and urge people to show their commitment to making healthcare safer.



To learn more about IAOCR please visit www.IAOCR.com or call:

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Notes to editors

About IAOCR

IAOCR is the international accrediting organization for clinical research. We are the only organization in the world to Qualify Clinical Research Professionals to international standards. Through robustly accrediting the competence IAOCR reduces risk - to patients, clinical research and organizations - whilst improving compliance and bringing drugs to market quicker.

IAOCR business processes and accreditations have been built specifically for the clinical research industry. They provide a quality mark to organizations committed to globally consistent, high quality clinical trials workforces.

We believe that clinical trial patients anywhere in the world deserve the best protection in terms of rights and wellbeing. Therefore, in addition to providing accreditation, training and consultancy services, IAOCR works with industry leaders and regulators around the globe to develop best practice guidelines and frameworks that are freely available to everyone. To find out more about the best practice initiatives visit <http://iaocr.com/resources/>