Closing the GCP Loophole to Expedite Clinical Trials

IAOCR Is Lobbying For Change to ICH-GCP Guidelines

2 March 2017, Maidenhead, UK – the accrediting organization for the international clinical research industry, IAOCR, is lobbying for change to the ICH-GCP Guidelines to tighten regulations.
The intention is to close a small, but important, loophole in the ICH-GCP Guideline which will help to improve the efficiency in the way that clinical trials are conducted.

Currently, individuals involved in conducting a clinical trial are required to *be qualified by education, training, and experience*. However, there is no requirement for them to be competent to carry out each of their specific roles.

"The competence of those undertaking clinical trials is inherently important from both an ethical and commercial perspective" says Jacqueline Johnson North, CEO of IAOCR. "By including competence as a requirement the Guidelines will ensure clinical research is carried out more effectively and efficiently, thus enabling the bringing of new treatments to market quicker."

IAOCR is joining forces with other organizations to raise this important matter both locally and globally. Discussions have already begun with a number of UK Parliamentarians who have expressed their surprise in this loophole. Many other industries already require competence verification, considering what is at stake when conducting clinical trials it is essential that this loophole is closed.

Industry Readiness
Increasingly clinical research organizations are recognizing the flawed concept that education, training and experience is a reliable measure of expertise. Many are proactively adopting a competence-based approach to workforce quality with three of the top five global CROs and a number of industry membership bodies benchmarking against IAOCR's frameworks and processes. Furthermore, although not yet mandated by the Guidelines, Regulators are increasingly asking for evidence of competence.

Problems with the Status Quo
The current requirement for education, training and experience presents a number of issues for the industry:

a) Poor workforce effectiveness, leads to errors and inefficiencies thus delaying the successful completion of clinical trials.
b) Experience offers no guarantee of competence; it limits the talent pool and drives an employee-driven job market. This drives up the costs of clinical trials whilst reducing quality.
c) The combination of workforce inefficiencies and a restricted talent pool is a serious impediment to new treatments being made available to the patients who need them.

Addressing the Talent Crisis
Clinical research is a growing, fast moving industry, and becoming ever more complex. There are currently some serious issues around talent availability and retention. A competence-based approach, in place of an experience-based requirement reduces the risk when on-boarding and retaining the right type of new talent the industry so desperately needs. This not only helps to address the industry's

requirements but also helps young people and those with transferable skills to find employment within the sector.

Political Appetite
Speaking at IAOCR's Clinical Research Industry Leaders Think Tank in 2014, the then UK Shadow Health Minister, Andrew Gwynne MP said, "it is striking that clinical research is one of the only regulated industries without a uniform standard of competence. This is an anomaly that has no clear cause, but it is an anomaly that should be ended." Industry leaders showed unanimous support for the introduction of core competencies and subsequently IAOCR has released 5 core competency frameworks, which many leading organizations benchmark against today. These are free to download from http://iaocr.com/resources/

With Governments becoming increasingly focused on reducing red tape to bring new treatments to market quicker and at lower costs, there is growing pressure on sponsors and their partner organizations to increase efficiencies. Mandating an effective competence-based approach would ensure that resources are not wasted on ineffective working practices or redundant training, and vendor oversight activities could be reduced, whilst at the same time improving quality standards.

Next Steps
IAOCR is producing a positioning paper and lobbying action plan. To receive a copy of the paper, stay updated or get involved in awareness-raising or lobbying please contact us via <<website page to be setup>>

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About IAOCR
IAOCR is the accrediting organization for the international clinical research industry. We work with clinical research organizations that are passionate about improving the effectiveness and efficiency of clinical trials by addressing human factors that work alongside the technologies and processes.

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/