

inVentiv Health aims to help sponsors prepare for new E.U. regulations on observational studies

By Ronald Rosenberg
CenterWatch Staff Writer

inVentiv Health is cautioning its customers about the potential for confusion that could result from the European Union's first major regulatory change for clinical trials in 15 years.

The new regulations, set to take effect in May 2016, will cover new clinical research, but the biggest change is the E.U.'s plan to implement a new category of trials—non-interventional studies (NIS)—with its own compliance rules.

InVentiv recently expanded its business to provide compliance products and services to assist global biopharmaceutical companies conducting non-interventional

studies—also known as observational studies and which observe the “normal” usage of already approved medicines. The CRO's entry into the post-approval area of research and new services to clients in Europe include access to its NIS Regulatory Intelligence Database.

The regulations, which also overhaul existing clinical trial regulation for approvals of new medicines, are expected to override the current rules, which have been criticized for having excessive bureaucracy and increased administrative and regulatory burden. The new rules are aimed at streamlining trial authorization and harmonization requirements for trials in Europe. Additionally, all

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ACRP partners with CRO Analytics to measure investigative sites' views of clinical trial quality

By Ronald Rosenberg
CenterWatch Staff Writer

In an effort to directly measure the quality of clinical research, the **Association of Clinical Research Professionals** (ACRP) has formed a partnership with **CRO Analytics** to measure the views of investigative site personnel on clinical trial quality.

The collaboration is designed to provide important insights into the quality of specific trials, key drivers of that quality and methods to improve clinical research.

“While sites will benefit greatly from this tool, we are eager to use aggregate data to pinpoint methods to further our mission to promote excellence in clinical research,” said Terri Hinkley, ACRP's interim executive direc-

tor. “This partnership enables sites to track milestones and different deliverables and provide information about the quality of such measures as timelines, budget adherence, protocol deviation and data entry.”

Sites will work directly with CRO Analytics, a provider of an online validated performance data collection system that captures clinical trial performance assessments from biopharma and service personnel involved in trials. The company also will provide cumulative data from the sites to ACRP, from which it can help derive industry standards. CRO Analytics said it focuses on measuring the performance of organizations and the quality of the output—not the job perfor-

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CenterWatch Main and Editorial Offices
10 Winthrop Square, Fifth Floor, Boston, MA 02110
Tel (617) 948-5100 Fax (617) 948-5101
editorial@centerwatch.com / sales@centerwatch.com

ACRP

mance of clinical trial personnel.

CRO Analytics initially will develop statistically validated data collection software that will be used with Performer, its cloud-based software platform, which is designed to improve clinical research by assessing trial performance through a series of tools developed over a two-year validation process. The online software measures the quality of more than 70 functional areas, along with the professional skills involved. The company will work with ACRP to also collect assessments from site personnel. Those data will be analyzed to generate benchmarking, key driver analytics and predictive analytics.

“What we are doing is not operational metrics, but rather helping investigative sites get valid and reliable insights into what they believe to be critical success factors in delivering high-quality clinical trials,” said Peter Malamis, CEO of CRO Analytics. “It allows sites to better execute on those trials and relationships and standardize site performance. You know from trial to trial what sponsors, CROs and sites are doing. Now you

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— Peter Malamis, CEO, CRO Analytics

want to improve what is important to help all stakeholders understand what needs to be done to make clinical trials more efficient and effective.”

Malamis said concerns about quality stem from a lack of scientific quality measurement, which contributes to the industry’s struggles to address problems such as cost overruns and adherence to timelines.

Having valid and reliable quality measures allows managers to identify and adapt best practices to control costs and timelines.

The partnership also is part of a new ACRP strategic plan that has three key goals:

- ▶ Provide tools, resources and best practices for members and nonmembers
- ▶ Have the opportunity to exchange information and gain expertise from experts
- ▶ Understand how the clinical research landscape affects its members.

Hinkley said sites’ initial reactions to the partnership with CRO Analytics have been positive, since it also will enable them to learn from one another and, eventually, set standards for the industry. Sites also can benchmark themselves against others.

“I think this partnership and the data we hope comes out of it will help us with all three of our goals,” said Hinkley, “with better understanding of quality and advocating on our members’ behalf to perhaps change practices or influence others.”

Email comments to Ronald at ronald.rosenberg@centerwatch.com. Follow @RonRCW

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