ICU MANAGEMENT & PRACTICE

Survey Shows Need for Greater Consistency in "Real World" Observational Research

According to a recent survey, the pharmaceutical, biotech, and medical device industries are aware of the benefits of observational research in better understanding the real world value of their products; however, there is continued need to improve the design and implementation of the studies.

Results from the 9th Annual Survey on Observational Research conducted by Continuum Clinical were released in a white paper.

While more traditional controlled clinical trials are the conventional pathway for regulatory approval of drugs, observational studies are increasingly viewed as essential for companies interested in understanding how their products perform under actual medical conditions.

"Controlled clinical research remains the gold-standard for regulatory approval," said Jeff Trotter, President of Continuum Clinical, and author of the survey. "But other stakeholders including payers, physicians, and patients need to understand a product's clinical, economic and humanistic value once it is approved and being prescribed and utilized in the 'real world.' As a result, drug and device companies must generate these data through studies that are designed and implemented under post-approval conditions."

The survey reveals ten key findings about prospective observational studies, and identifies opportunities for drug and device companies to improve the implementation of real world research. Among the key findings were:

- 70% of respondents see their organizations becoming increasingly involved with observational studies, and 75% see their company "comfort level" improving
- Less than half of respondents indicated that their organizations had Standard Operating Procedures (SOPs) specific to observational studies
- 83% of respondents felt constrained in utilizing vendors [for observational research] that don't understand observational research
- A vastly underutilized source for enrolling patients into observational studies was "patients interested in but not qualifying for pre-approval clinical trials"

Trotter added, "What we're seeing is that there's strong consensus that observational research is critical, but a lot of confusion regarding how to efficiently and effectively implement the studies."

Over its nine iterations, the survey has enjoyed the participation of approximately 2,000 respondents worldwide who represent a cross-section of the pharmaceutical industry and job functions.

For complete survey results and to download the 9th Survey on Observational Research, visit http://www.continuumclinical.com/research.

About Continuum Clinical

Continuum Clinical is a global healthcare research and communications company. With over thirty years of experience, Continuum Clinical brings together a unique blend of world-class experience in key disciplines, including post-approval research, marketing, communications, health economics, and outcomes research. We excel in providing seamless resources for pharmaceutical and biotech products — from patient recruitment and retention for clinical trials to late stage studies and health economics and outcomes research, as well as medical communications. Continuum Clinical provides a unique blend of resources and perspectives, proven expertise, and innovative solutions throughout the entire continuum of a product's lifecycle — from pre-launch into the real world. Headquartered in the US, Continuum Clinical has employees in Europe and expanded worldwide network of resources.

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