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OmniComm Systems[®] Announces Results of Risk-Based Monitoring Survey: Industry Poised for Significant Movement Towards RBM Adoption

Process Complexity Cited as Major Barrier to Adoption

Fort Lauderdale, FL, August 11, 2015 - OmniComm Systems, Inc. (OmniComm) (OTCQX: OMCM), a global leading provider of clinical data management technology, announced survey results representing leading clinical research and development organizations. The survey respondents included 16 sponsor organizations and 13 contract research organizations (CROs). The results indicate a significant movement forward in the industry towards active risk-based monitoring (RBM) adoption with 76% of the organizations reporting that they are either already executing RBM studies (45%) or planning to initiate RBM studies during this year (31%). The survey further elucidated differences in RBM adoption between CROs and sponsors. 33% of CROs have already initiated RBM studies compared to 53% of sponsors. This result re-enforces the relative hesitance that many have observed from the CRO industry with respect to RBM. The value potential of RBM is often less immediately recognized by CROs vs. sponsors, and many instead perceive a threat to study revenues related to site monitoring. Given the inevitable full adoption of RBM across the industry, CROs who pro-actively embrace this new paradigm will undoubtedly see a competitive advantage in the coming years.

Collectively, the respondents also indicated that the biggest barrier to successful RBM adoption is the perceived complexity and associated burden with implementing an RBM methodology – 63% of all respondents.

“These results reflect what we have assessed to be a key challenge for organizations moving forward. There has been a significant volume of RBM methodology guidance and advice emerging over the past couple of years, following the regulatory papers issued by FDA and EMA,” states Steve Young, senior director of transformation services, OmniComm Systems. “And while much of the advice has been helpful, there has been an unfortunate – and mostly unintended – level of over-engineering in this methodology support. Our OmniComm RBM consulting team understands the source of this over-engineering, and has developed a methodology framework that – together with the RBM-enabling functionality built directly into our advanced TrialMaster[®] EDC solution - is helping our clients cut through all of the guidance and focus on a simple, thoughtful approach to ensure RBM success.”

Supporting Information

[RBM Adoption – Taking the Industry Pulse](#)

[Risk-Based and Centralized Monitoring](#)

[RBM Enablement Services Solution Brief](#)

[Risk-Based Monitoring with TrialMaster[®] Whitepaper](#)

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[Enable Centralized Source Review Whitepaper](#)
[Ensuring RBM Success Webinar](#)

About OmniComm Systems, Inc.

OmniComm Systems, Inc. is a leading strategic software solutions provider to the life sciences industry. OmniComm is dedicated to helping the world's pharmaceutical, biotechnology, contract research organizations, diagnostic and device firms, and academic medical centers maximize the value of their clinical research investments. Through the use of innovative and progressive technologies these organizations drive efficiency in clinical development, better manage their risks, ensure regulatory compliance and manage their clinical operations performance. OmniComm provides comprehensive solutions for clinical research with an extensive global experience from over 4,000 clinical trials. For more information, visit www.omnicomm.com.

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