

## **CluePoints and Widler & Schiemann Collaborate on Complete Risk-Management Solution for Clinical Trials in Line with New Industry Guidance**

*Partnership will combine CluePoints' Risk-Based Monitoring Software with Widler & Schiemann's Consultancy Services*

### **2 November 2015**

Cambridge, MA - CluePoints, a leading software provider of risk-based monitoring (RBM) solutions for clinical trials, today announced a strategic collaboration with clinical trials business solutions consultancy, Widler & Schiemann Ltd. The collaboration will bring together CluePoints' award-winning RBM software with Widler & Schiemann's risk-assessment consulting expertise, to deliver a comprehensive solution that covers all elements of risk and quality management. From software implementation through to operational considerations and meeting regulatory requirements, the partnership will support customers in integrating all-inclusive RBM strategies within their clinical trials.

Widler & Schiemann's experts work with clients to identify how workflows, processes and systems need to be adapted to support more targeted approaches to monitoring in clinical trials. The company's services complement CluePoints' Central Statistical Monitoring (CSM) software, which provides an agnostic approach to RBM by using statistical methodology to identify unexpected patterns in trial databases and focus monitoring efforts. To accompany the statistical analysis of data, the software also defines and deploys key risk and key performance indicators, allowing sponsors to set their own subjective thresholds. Combining the expertise of the two companies now offers customers a complete risk-management solution with expert guidance on how to implement CluePoints' software, helping improve trial oversight while driving quality and patient protection.

"As RBM approaches become the standard for today's clinical trials, it is vital that sponsors have the support they need both in terms of practical technology solutions and the knowledge to guide the implementation of these new methods of analysis within their organizations. In addition, the CluePoints solution allows sponsors to base their RBM decisions on facts and figures rather than opinions", comments Dr. Peter Schiemann, Managing Partner and Co-founder of Widler & Schiemann. "We are delighted to be collaborating with CluePoints to provide customers with a true end-to-end solution that helps them in the complete risk assessment of their quality management in clinical trials. As well as helping customers harness the power of the CluePoints solution in the most effective way possible, we can ensure that they do so in line with the GCP ICH E6 guideline, including its new amendment, and the new clinical trial regulation that is due to come into effect soon."

CluePoints' CEO, François Torche, said: "We work with many customers who are looking for strategic advice on adapting their organization and updating their internal policies to meet the needs of new RBM strategies. By bringing in the consultancy expertise of Widler & Schiemann we can work together to support customers and ensure they have both our industry-leading software and the expertise and guidance necessary to successfully implement a comprehensive risk-management solution."

For further information on CluePoints' solutions, please visit [www.cluepoints.com](http://www.cluepoints.com)

For further information on Widler & Schiemann's services, please visit [www.wsqms.com](http://www.wsqms.com)

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**About CluePoints**

CluePoints® is a Central Statistical Monitoring solution that has been designed and perfected over the last 12 years and is available to companies as cloud-based software to drive Risk-Based Monitoring (RBM) and Data Quality Oversight. It employs unique statistical algorithms to determine the quality, accuracy and integrity of clinical trial data both during and after study conduct. Aligned with guidance from the FDA and EMA, CluePoints® is deployed to support traditional on-site monitoring and to drive a Risk-Based Monitoring strategy. The value of using CluePoints® lies in its powerful and timely ability to identify anomalous data and site errors allowing improvement in clinical data quality, optimization of on-site monitoring and a significant reduction in overall regulatory submission risk.

**About Widler & Schiemann Ltd**

Widler & Schiemann are customer-focused thought-leaders in clinical development. Their consultants have over 100 years of professional experience (combined) and support their clients in all aspects of clinical development from pre-clinical studies to post approval commitment trials. Widler & Schiemann provides their clients with innovative, creative and cost effective answers to their questions and needs in the areas of Clinical Development in general and Clinical Quality Management in particular. One of their specialties is Risk Management for Clinical Trials with particular emphasis on Risk-based Monitoring. With their vast experience and extensive network in the industry and the regulators Widler & Schiemann are uniquely positioned identifying and providing clients with the best solutions, the latest development in methodologies and keeping them abreast of changes in laws and regulations.

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