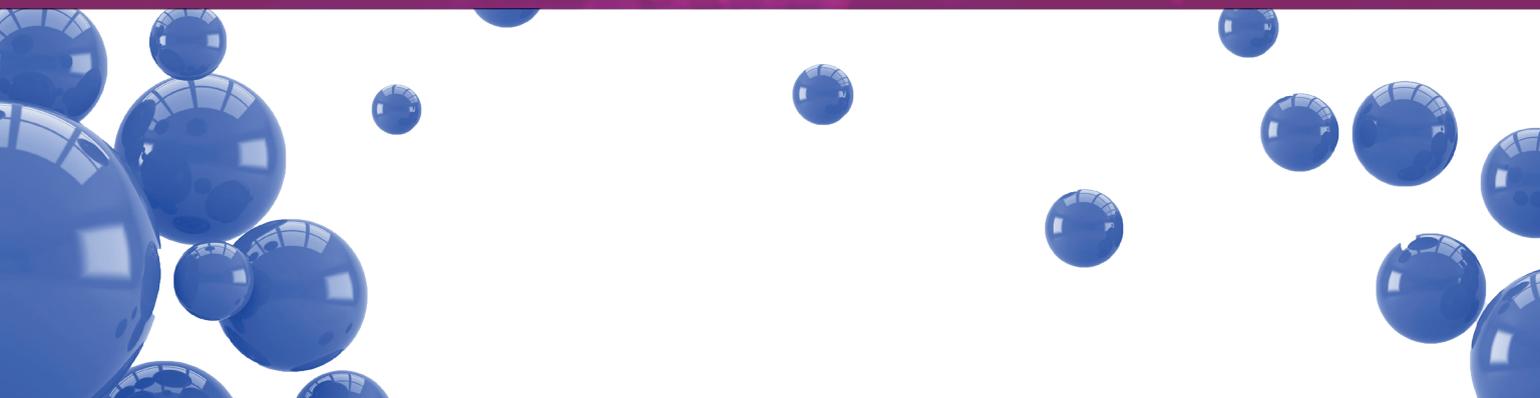




# The Risk-Based Data Management (RBDM) Revolution



## UNDERSTANDING RISK-BASED DATA MANAGEMENT

Risk-Based Data Management (RBDM) applies Risk-Based Quality Management (RBQM) to clinical data management. The RBQM methodology impacts all clinical research stages, departments, and stakeholders. With several components in practice, there are two simple principles to follow:

**1 Think before you act**

**2 Focus on what matters most**

RBQM encourages clinical research teams to carefully assess what study success looks like and identify the most significant risks that could impede this success. Once these risks are identified, plans should be established to focus on controlling and minimizing their impact. This requires a mindset change for the entire organization.

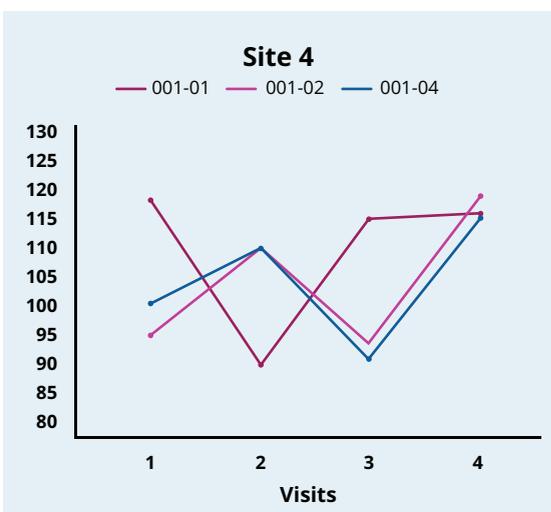
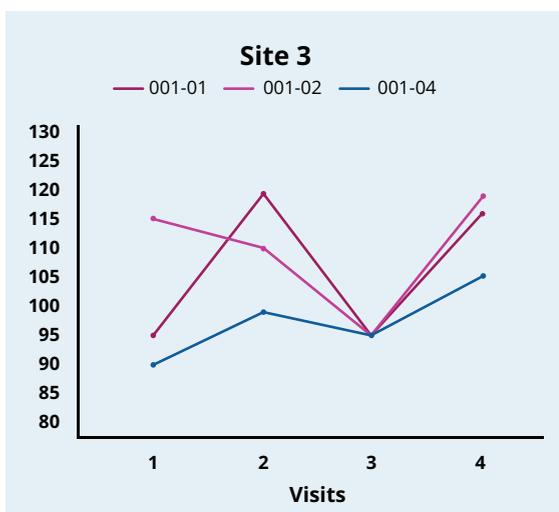
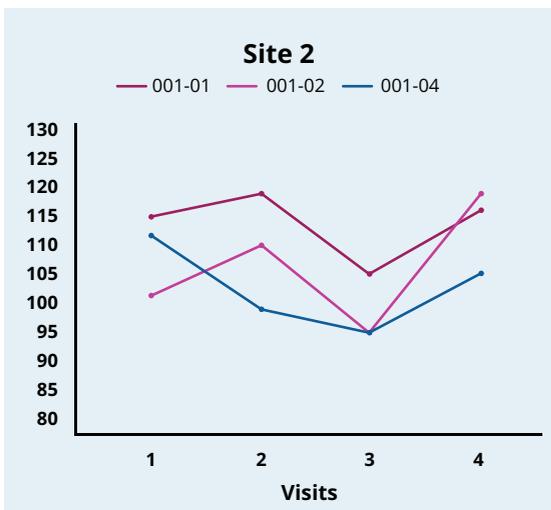
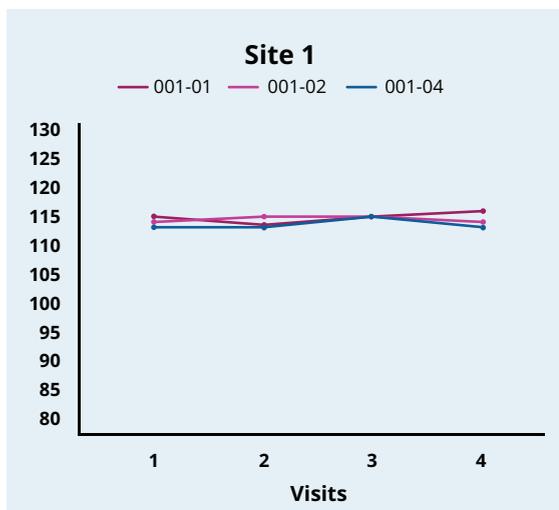
For clinical data management, teams must move away from “cleaning the data” and toward ensuring data reliability by identifying, addressing, and mitigating data quality risks, which means focusing review efforts on the most critical data and risks involved. There’s growing recognition that the most significant risk to overall data reliability goes beyond individual data discrepancies and originates in systemic errors in study conduct. This can take various forms, such as the behavior of site personnel, patients, and stakeholders and the misconfiguration of technologies being used to generate or deliver clinical data.



## SYSTEMIC DATA ISSUES

### DATA IS COMPLETE & COMPLIANT BUT NOT RELIABLE

The figure below provides an example of a systemic issue: the systolic blood pressure data from Site 1 is too similar across the board. This is likely linked to the behavior of site personnel—perhaps they copied measurements from one visit to the next rather than re-measuring each patient’s blood pressure. **Since all individual measurements are within an expected range, they wouldn’t typically be identified by traditional data management checks or site monitoring reviews.** Yet, the potential impact of this issue on overall data reliability is much greater than that of an individual data error.



For data management and data sciences organizations, centralized monitoring has enabled the detection of these more systemic data issues. Teams can review and assess data trends in the aggregate through statistical data monitoring, key risk indicators (KRIs), quality tolerance limits (QTLs), and data visualization.

While transactional data cleaning and other data management processes are still relevant to ensuring data quality, emphasis is now being placed on making these processes more efficient and focused on the most critical data.

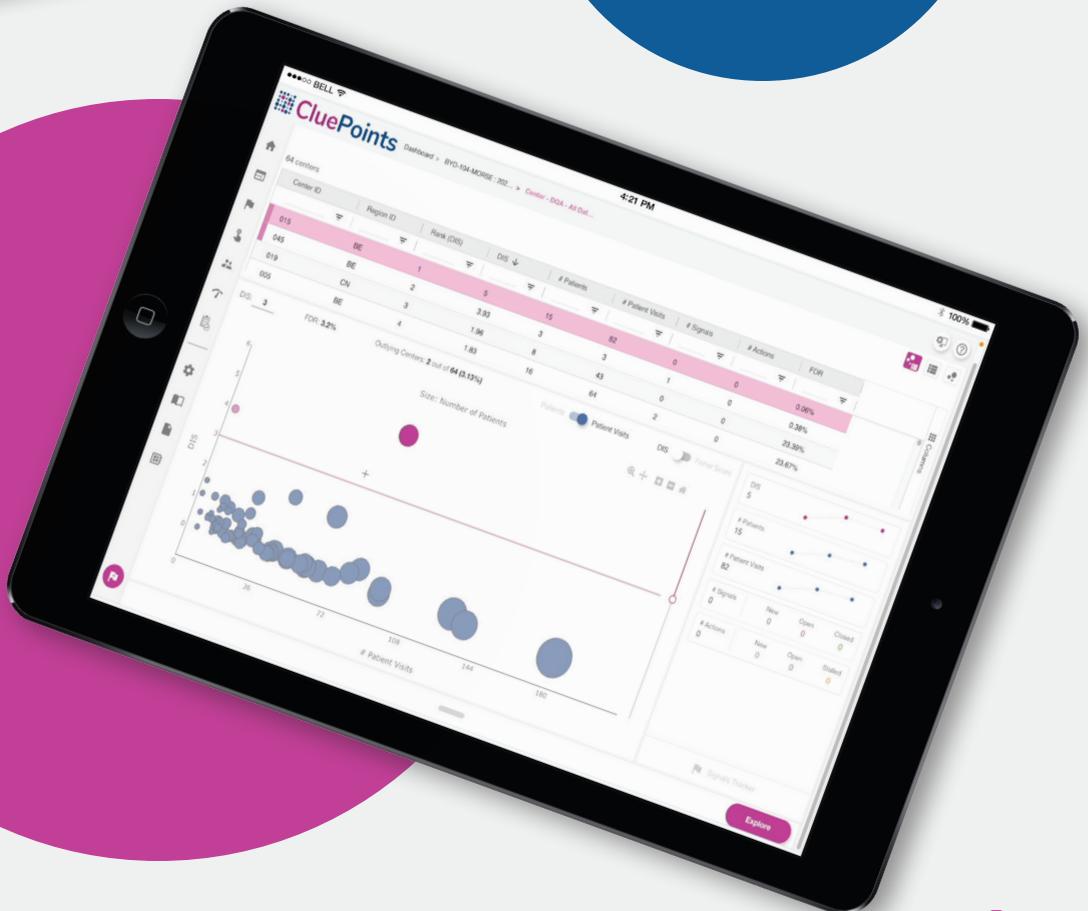
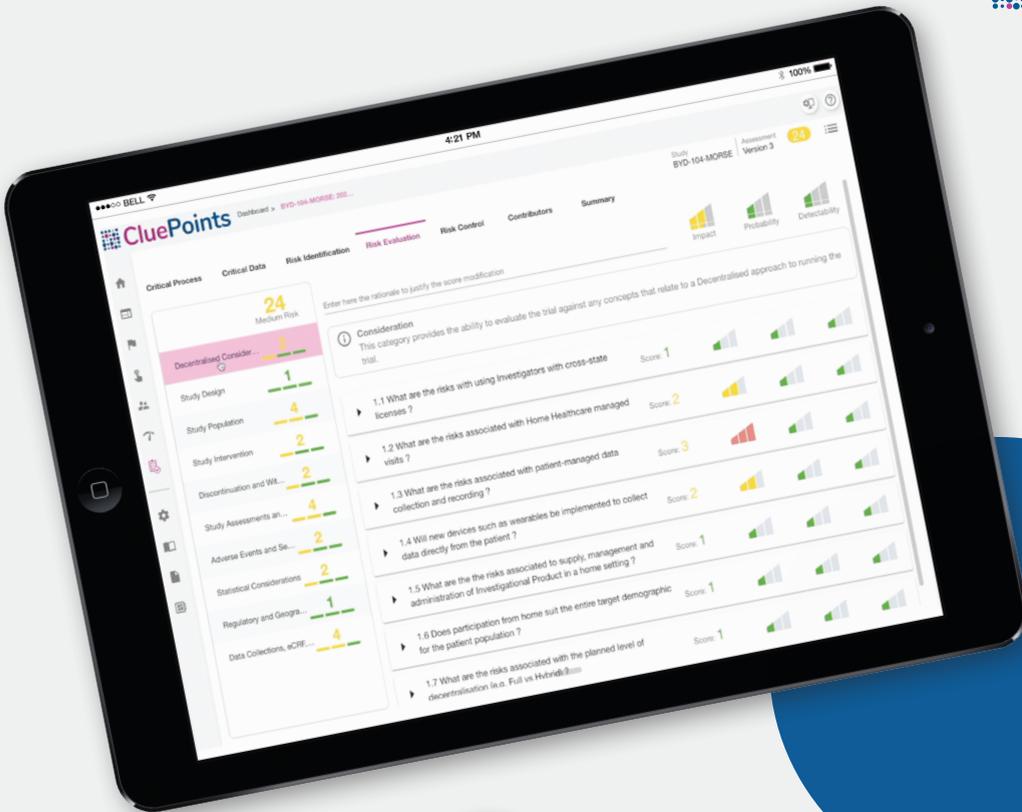
## **CLUEPOINTS SOLUTIONS FOR RBDM**

CluePoints is the industry leader in providing end-to-end RBQM technology and support, and we're being increasingly recognized for enabling RBDM. Our platform includes an advanced, flexible module for risk planning, empowering teams to manage components associated with Critical to Quality (CTQ) factors, including critical data and

process identification and study risk assessments.

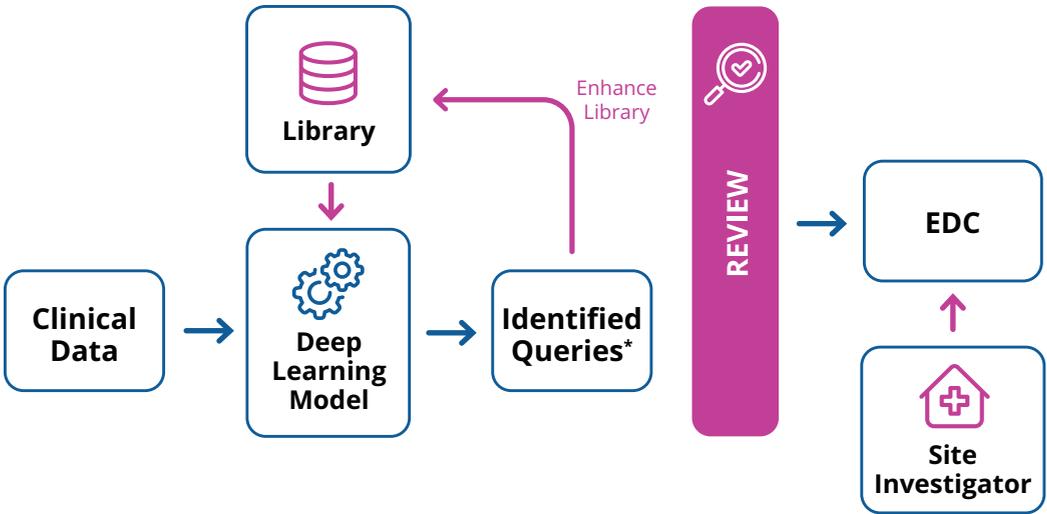


Our centralized monitoring platform (CMP) integrates highly effective tools to identify risks and systemic issues in study data, including our SMART statistical data monitoring engine, KRI and QTL dashboards, data visualization and exploration, and a module to check for duplicate patients. In addition, CMP is configurable, user-friendly, and integrates workflow and documentation support, enabling data managers and study teams to initiate and track risk and data issue resolution.



The CluePoints CMP platform also incorporates advanced Artificial Intelligence (AI) solutions based on machine learning (ML) and natural language processing (NLP) that further optimize the identification and processing of risks and issues.

CluePoints has developed several additional AI-driven solutions to further automate clinical data management processes and enable RBDM. Our **Intelligent Data Query Application** leverages Deep Learning techniques to automatically identify data anomalies and raise queries that are traditionally only identified through manual reviews.



Our **Intelligent Data Query Application** streamlines the review of predicted anomalies by identifying relevant data fields that should be queried together with supporting evidence and recommended query text that can be edited and sent back into the Electronic Data Capture (EDC) system.



1 Query Text

2 Evidence Data

3 Field to be queried

This approach enables the human end-user to efficiently explore each suggested data anomaly along with the associated evidence data and any relevant datasets. They can also accept, reject, or refer to the query, edit the proposed text, and submit it.

CluePoints is actively developing ML- and NLP-driven solutions to optimize medical coding, medical and safety data reviews, and data harmonization, including Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) mapping.



## **FOR GENERAL QUESTIONS OR DEMO REQUESTS**

If you have a general question, would like to discuss how CluePoints can support your upcoming clinical trial, or want to request a demo of our platform, please contact us and a member of our team will get back to you shortly.

**EMAIL:**

[contact@cluepoints.com](mailto:contact@cluepoints.com)

**CONNECT WITH CLUEPOINTS, FOR  
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