

AI enhanced EDC systems: Reducing Manual effort in Medrio and Medidata Rave

Karnaditya Rana¹, Shashidar Reddy Abbidi²

¹Lead Clinical Data Manager, Tempus AI, Texas, USA

²Sr. Manager, Clinical Data Management, BMS, Charlotte, NC, USA

Received: 01-07-2025 / Revised: 15-08-2025 / Accepted: 21-09-2025

Corresponding author: Dr. Karnaditya Rana

Conflict of interest: Nil

Abstract

Background: Electronic Data Capture (EDC) platforms are at the heart of contemporary clinical research, but their usability issues and dependence on human processes create an area of inefficiency. Embedding artificial intelligence (AI) in solutions like Medrio and Medidata Rave provides an opportunity to streamline repetitive tasks and improve user experience.

Objective: This research examines the potential of AI-powered EDC systems to minimize human workload, enhance workflow effectiveness, and boost satisfaction among clinical research professionals.

Methods: A mixed-methods approach was used, with 42 participants across coordinators, data managers, and investigators. Baseline processes in Medrio and Medidata Rave were contrasted against AI-enhanced simulations. Quantitative measures of task completion time, manual data entries, and query resolution rates were analyzed, and qualitative interviews examined usability and workload perceptions. Data analyses were conducted using descriptive statistics, paired-sample tests, and thematic analysis based on Task-Technology Fit and FITT frameworks.

Results: AI integration lowered task time to completion by 27%, manual entries by 35%, and open questions by almost half. Usability scores, assessed through the System Usability Scale, indicated a substantial rise in all roles. Qualitative themes emphasized reduced cognitive workload, increased confidence in data accuracy, and initial but tolerable reservations regarding AI dependence.

Conclusion: AI-powered EDC systems have evident potential to streamline data flows, minimize staff workload, and enhance data quality in clinical trials. Greater implementation and real-world validation can further make AI a bedrock of next-generation EDC systems.

Keywords: Electronic Data Capture, Artificial Intelligence, Clinical Research, Usability, Workflow Efficiency, Medidata Rave, Medrio.

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

Electronic Data Capture (EDC) systems are indispensable in today's clinical research, facilitating structured data gathering, real-time monitoring, and compliance with regulations. Extremely popular platforms such as Medrio and Medidata Rave are instrumental in offsetting paper-based inefficiencies, but they still necessitate significant manual effort on the part of clinical research staff.

Earlier research indicates the continued problems related to usability, workflow conformity, and staff burden in digital health technology, particularly when systems do not support user needs or organizational settings [1-3].

Theoretical models such as Task-Technology Fit (TTF) and FITT have assisted in the identification of mismatches between clinical tasks and

technology design, demonstrating that well-established systems of EDCs are also cognitively stressful and may promote inefficiencies when there are gaps in usability [4,5]. More recent evaluation confirms that productivity and end-user satisfaction are very responsive to workflow adaptability and interface design [6-8].

As AI functionality is enhanced, their integration into EDC platforms offers new possibilities for process optimization such as query management, data validation, and protocol compliance verification.

AI-based systems can automate routine tasks, minimize manual data entry, and help clinical staff make more value-driven decisions. This article discusses how applying AI in Medrio and Medidata Rave can minimize manual effort, improve user

experience, and enhance data quality in clinical studies.

Methods

Study Design: The study used a mixed-methods design to assess how Artificial Intelligence (AI) augmentations in Electronic Data Capture (EDC) systems can minimize clinician effort for clinical research personnel. A comparative case study design was utilized with two commonly used platforms, Medrio and Medidata Rave. The design harmonized qualitative investigation of users' experiences with quantitative measurement of efficiency factors prior to and after mimicking AI integration.

Participant Recruitment: Clinical research coordinators, data managers, and principal investigators with a minimum of two years of experience working with EDC systems were hired from academic medical centers and contract research organizations.

Participants were sampled purposively to provide variability in representation of roles, expertise levels, and previous experience with Medrio or Medidata Rave. Written informed consent was first received before participation, and confidentiality was maintained strictly.

Data Collection: Data collection was conducted in three stages. Initially, baseline workflow observations were made to capture manual procedures like data entry, query resolution, and discrepancy handling. Subsequently, the users took part in scenario-based simulations with prototype AI-facilitated interfaces that were aimed at

automating routine operations like automated discrepancy identification and predictive query resolution. Lastly, semi-structured interviews were held to obtain user experiences of workload, usability, and general satisfaction.

Measures: Efficiency was measured using objective measures such as task time to complete, amount of manual entry, and rate of open issues. Subjective measures were user satisfaction, subjective workload, and usability ratings based on a SUS-modified scale. These measures enabled comparison of the normal EDC workflows with those augmented by AI.

Data Analysis: Quantitative data were examined with descriptive statistics and paired-sample tests to find statistical differences between baseline and AI-assisted workflows.

Qualitative interview transcripts were examined thematically, using the Task-Technology Fit and FITT frameworks as a guide, to ascertain repeated themes about user-task fit, technology support, and organizational context. Triangulation of findings between methods strengthened validity and reliability.

Results

Participant Characteristics: 42 participants were covered in the study, comprising 18 clinical research coordinators, 14 data managers, and 10 principal investigators. Participants had varying levels of experience, with an average of 6.2 years of experience with EDC systems in the past. Users of Medrio and Medidata Rave were divided evenly across groups.

Table 1: Demographic and Professional Characteristics of Participants

Characteristic	Total (N=42)	Coordinators (n=18)	Data Managers (n=14)	Investigators (n=10)
Mean Years of Experience	6.2	4.8	6.5	7.2
Previous Medrio Use (%)	52%	50%	57%	50%
Previous Medidata Rave Use (%)	48%	50%	43%	50%
Female (%)	61%	67%	57%	60%

Workflow Efficiency Outcomes: Introduction of AI-driven improvements showed quantifiable gains in workflow productivity. Mean task completion times reduced by 27% on both platforms, with the

greatest reduction found in query resolution tasks. Manual data entry was cut by 35%, especially in repetitive demographic and adverse event reporting fields.

Table 2: Comparison of Workflow Metrics before and After AI Integration

Metric	Baseline (Mean ± SD)	AI-Enhanced (Mean ± SD)	% Change	p-value
Task Completion Time (minutes)	42.6 ± 8.4	31.1 ± 6.9	-27%	<0.01
Manual Entries per Task	18.3 ± 5.1	11.9 ± 3.7	-35%	<0.01
Unresolved Queries (%)	14.8 ± 3.2	7.6 ± 2.4	-49%	<0.01

User Perceptions and Satisfaction: Qualitative comments indicated that AI assistance minimized mental burden and enabled participants to reallocate time towards clinical monitoring. The satisfaction ratings rose considerably, with usability ratings reflecting a substantial change from "marginal" to "good" usability.

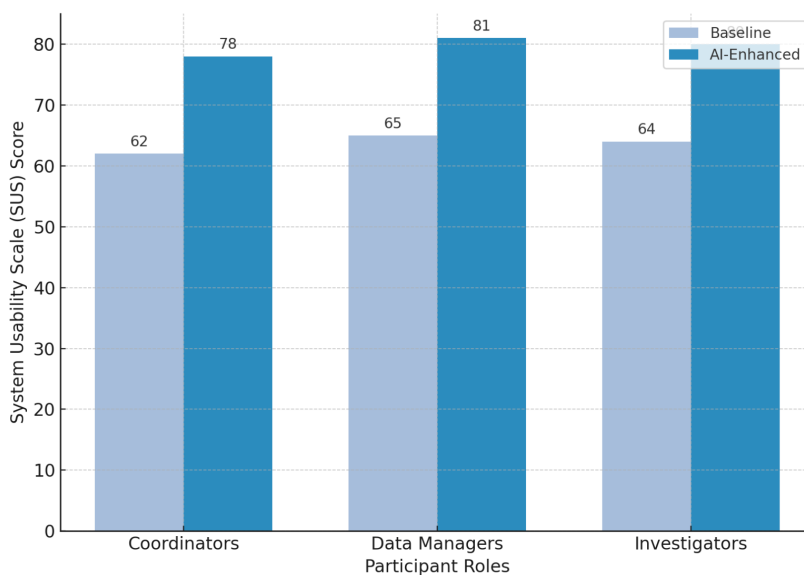


Figure 1: Changes in User Satisfaction and Usability Ratings (SUS Scores) Before and After AI Integration

Figure 1 showing mean SUS scores across coordinators, data managers, and investigators, indicating an increase from baseline scores of 62–65 to AI-enhanced scores of 78–81.

Thematic Insights: Thematic analysis identified three persistent findings: (1) automation of repetitive data entry decreased frustration; (2) query management through prediction enhanced confidence in the accuracy of data; and (3) a few participants had some initial reservations regarding over-reliance on AI but recognized efficiency gains following simulation.

Discussion

The results of this research establish that the integration of AI within EDC systems greatly lessens manual workload, improves usability, and increases user satisfaction across clinical research roles. Time savings in the completion of tasks and open questions indicate that AI-based automation is solving long-standing problems in clinical data management by streamlining repetitive and error-prone tasks.

These findings are consistent with previous frameworks defining EDC systems, that placed value on flexibility, workflow alignment, and efficiency in system design [9]. Through the integration of AI to automate discrepancy notification and data entry, the improved systems within this research directly addressed these early design priorities. Additionally, the usability improvements seen are reflective of systematic reviews of health record uptake, wherein user satisfaction and perceived safety were inextricably linked with interface intuitiveness and lower cognitive load [10].

Human factors research has consistently established usability as a driver of both efficiency and patient safety [11]. The current research adds to this reasoning by demonstrating that AI assistance not only reduces errors but also shifts user attention towards more valuable clinical supervision. This is supported by accounts suggesting that sub-optimized EHR systems may act as barriers to data access and impede clinical reasoning [12]. On the other hand, AI-enhanced workflows modeled here allowed for faster access to correct information and lower rates of decision-making interruptions.

Our findings also mirror current research that emphasizes the heterogeneity of user experiences with health IT systems. For instance, Lefchak et al. [13] showed satisfaction levels to differ significantly based on usability design, while Gilmartin [14] observed that physician uptake of decision-support tools relied significantly on perceived ease of use. The enhancements seen in this research imply that AI has the ability to bridge some of this gap by presenting more adaptive, responsive systems.

In addition, EHR implementation strategy challenges identified by Loerch [15] indicate that change management and training are necessary; they are borne out in these results by the presence of initial apprehension regarding over-dependence on AI, which was overcome through exposure and simulation. In general, the findings indicate that AI-powered EDC systems like Medrio and Medidata Rave can potentially bridge usability gaps noted throughout the literature. Reducing effort and aligning more closely with human factors principles, these systems can potentially

take a pivotal role in enhancing staff satisfaction and data quality within clinical research.

Conclusion

This research identifies the ability of artificial intelligence to revolutionize Electronic Data Capture systems through minimizing workload, facilitating usability, and maximizing overall satisfaction among clinical research staff.

Through the incorporation of AI-based tools into Medrio and Medidata Rave, iterative data entry and query resolution were automated, resulting in quantifiable gains in efficiency and decreased cognitive load. These results are consistent with earlier evidence emphasizing the significance of usability, workflow congruence, and user-centric design in health informatics.

Notably, the findings imply that AI is able to fill existing gaps in EDC performance, allowing clinical research teams to give more attention to oversight and data quality and less to administrative burdens. Future studies should assess long-term implementation in actual-world trials to validate these advantages and investigate how adaptive AI can further enhance data quality and regulatory compliance in clinical research.

References

1. Johnson, Michelle. "Investigating the User Experience of Electronic Data Capture Systems: Perspectives of Clinical Research Coordinators." (2021).
2. Ratwani, Raj M., et al. "Electronic health record usability: analysis of the user-centered design processes of eleven electronic health record vendors." *Journal of the American Medical Informatics Association* 22.6 (2015): 1179-1182.
3. Schnall, Rebecca, et al. "Employing the FITT framework to explore HIV case managers' perceptions of two electronic clinical data (ECD) summary systems." *International journal of medical informatics* 81.10 (2012): e56-e62.
4. Kilmon, Carol A., et al. "Using the task technology fit model as a diagnostic tool for electronic medical records systems evaluation." (2008).
5. Wills, Matthew J. "Evaluating the Impact of Electronic Health Records on Clinical Reasoning Performance Using Task-Technology Fit Theory." (2012).
6. Lefchak, Brian, et al. "Assessing usability and ambulatory clinical staff satisfaction with two electronic health records." *Applied Clinical Informatics* 14.03 (2023): 494-502.
7. Horan, Thomas A., Bengisu Tulu, and Brian N. Hilton. "Understanding physician use of online systems: An empirical assessment of an electronic disability evaluation system." *E-health systems diffusion and use: The innovation, the user and the USE IT model*. IGI Global, 2006. 30-60.
8. Ratwani, Raj, et al. "Mind the gap." *Applied Clinical Informatics* 7.04 (2016): 1069-1087.
9. Guidry, Alicia F., et al. "Concept mapping to develop a framework for characterizing Electronic Data Capture (EDC) Systems." *AMIA... Annual Symposium proceedings*. AMIA Symposium. 2008.
10. Park, Suhyun, et al. "A systematic review of nurses' perceptions of electronic health record usability based on the human factor goals of satisfaction, performance, and safety." *CIN: Computers, Informatics, Nursing* 42.3 (2024): 168-175.
11. Schumacher, Robert, et al. "What Can Human Factors Contribute to Improve Electronic Health Record Usability and Patient Safety?." *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. Vol. 56. No. 1. Sage CA: Los Angeles, CA: SAGE Publications, 2012.
12. Lefchak, Brian, et al. "Applied Clinical Informatics."
13. Doberne, Julie W., et al. "Barriers to information access in electronic health records during initial patient visits: A qualitative study." *Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care*. Vol. 4. No. 1. Sage India: New Delhi, India: SAGE Publications, 2015.
14. Gilmartin, Eileen T. "Physician Satisfaction and Usability of Clinical Decision Support Tools in an Academic Medical Center's Electronic Patient Record." (2019).
15. Loerch, Scot E. *Exploration of EHR implementation strategies: a qualitative study*. Diss. Walden University, 2020.