Evaluation of Metrics in a Clinical Research Center: Comparison of Resource Utilization Before and After the Implementation of a Digital Protocol Management System

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01. Hypothesis

The implementation of a digital protocol management system in a clinical research center improves key performance metrics, optimizes resource utilization, reduces costs, enhances data quality, accelerates query resolution, facilitates data transmission to the sponsor, and strengthens the Principal Investigator's oversight.

02. Objective

To demonstrate the improvement in different indicators reflecting the performance of a clinical research center following the implementation of a digital protocol management system.

03. Materials and Methods

In a clinical research center with 19 years of experience, metrics were compared over a 4-year period (November 2020 to October 2024), divided into two phases.
Until October 2022 (Period A), data collection from patient records was paper-based, and all protocol management tasks were performed manually using standard resources.
From November 2022 onward (Period B), the Brainmart MED CT protocol management system was implemented. Among its functionalities are: electronic medical records, adverse event management, visit-window scheduling, pharmacy and laboratory kit inventory, the ability to generate comments/queries with response alerts, and user credential management.
Center productivity was measured as the number of monthly visits per resource (investigator, study coordinator, pharmacy staff, and laboratory staff), data entry time, number of generated queries, and query response time across both periods.
Economic performance of the center and monitoring-related costs for the sponsor were also compared.

04. Statistical Analysis

Continuous variables are summarized as mean (SD) or median [IQR], depending on distribution.
Categorical variables are presented as n (%).
Comparisons between periods were performed using Welch's t-test, Wilcoxon rank-sum test, or Fisher's exact test, according to variable type and assumptions, all of which were verified and met.

An alpha level of 0.05 was established. Analyses were performed using R [R Core Team (2022). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria] and RStudio [RStudio Team (2023). RStudio: Integrated Development Environment for R. RStudio, PBC, Boston, MA. URL https://posit.co/].

05. Results

The following parameters were compared. The main difference between both periods was the use of Brainmart MED CT during Period B.

Variables are summarized in Table 1.

Table 1.

Variable (1)	Period A (2)	Period B (3)	p-value
Monthly visit rate	193 [189, 207]	445 [445, 516]	<0.001
Data loading time (days)	7.00 [7.00, 7.25]	1.00 [1.00, 2.00]	<0.001
Monthly quert rate	93.04 [88.58, 97.70]	39.00 [39.00, 43.70]	<0.001
Query response time (days)	7.00 [7.00, 7.00]	2.00 [2.00, 2.25]	<0.001

(1) Continuous variables are summarized as mean (SD) or median [IQR] according to their distribution. Categorical variables are summarized as n (%).

(2) November 2020 to October 2022 inclusive.

(3) November 2022 to October 2024 inclusive.

The number of laboratory technicians increased from 2 to 3, while the number of medical investigators, study coordinators, and pharmacy staff remained unchanged.

Figure 1.

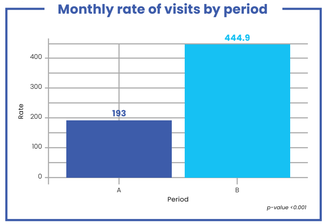


Figure 2.

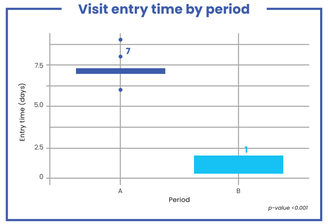


Figure 3.

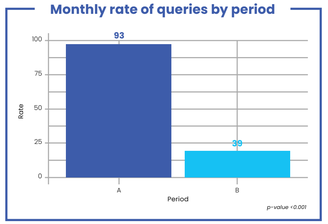
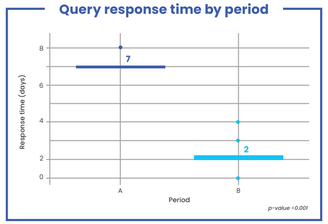


Figure 4.



06. Conclusions

The implementation of a digital protocol management system in an experienced clinical research center significantly improved performance regarding recruitment potential, resource optimization, and operational metrics.
A substantial increase in overall research output was achieved without any significant change in staff numbers.
Estimated monitoring costs for sponsors should be re-evaluated downward, considering the improved speed of data verification and control.
Data quality improved through the use of digital medical records with management and audit trail capabilities.
The digital management system enabled comprehensive process enhancement, from patient selection and visit scheduling to event reporting, data recording, and verification.
Altogether, this allowed the Principal Investigator to strengthen protocol oversight, while reducing costs for both the research center and the sponsor.