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ORIGINAL ARTICLE

Resource management and capacity planning for clinical trial sites

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ABSTRACT

Background: Since 2020, the number of registered clinical trials has surged by over 30%, significantly increasing the demand for skilled coordinators. Despite this growth, a national shortage of qualified coordinators remains, driven by escalating responsibilities and workloads. Effective resource management is crucial for retention. While the Ontario Protocol Assessment Level (OPAL) helps quantify trial complexity, it overlooks key factors such as organizational structure and budget constraints that impact coordinator productivity. This project aims to refine the OPAL score by integrating it with longitudinal coordinator effort data, improving resource allocation, operational efficiency, and job satisfaction, thereby reducing burnout and turnover.
Aim: The aim of this study was to reduce burnout and turnover, ultimately contributing to the overall success of clinical trials.
Methods: Actively enrolling interventional studies with corresponding coordinator effort tracking from June 1, 2022, to December 1, 2022, were included in the database. Protocols were graded using an adapted protocol assessment tool. Descriptive statistics compared protocol characteristics to the adapted assessment score and tracked coordinator hours, while Student's t-test and univariate analysis evaluated differences in continuous variables. Linear regression analysis assessed the association between the adapted score and the coordinator effort.
Results: Seven protocols were analyzed: five (71%) were federally funded, two (29%) were industry-sponsored; four (57%) were behavioral interventions, and three (43%) were drug studies. Significant differences were observed between industry-sponsored and federally funded studies (7.25 ± 1.77 vs. 6.45 ± 1.65; $P < 0.0001$) and between behavioral interventions and drug studies (6.88 ± 1.56 vs. 6.42 ± 1.91; $P < 0.0001$). Linear regression revealed the adapted OPAL score significantly predicted coordinator hours ($\beta = 77.22$; $P = 0.01$; $R^2 = 0.78$).
Conclusion: The adapted protocol complexity scores predict coordinator effort, aiding in capacity assessment and objective project distribution.
Relevance for Patients: The findings from this project can inform more precise resource allocation, potentially leading to higher-quality studies and enhanced participant safety.

1. Introduction

Despite a failure rate of approximately 90%, the number of clinical trials conducted has continued to grow consistently over time [1]. According to ClinicalTrials.gov, there has been over a 30% increase in registered clinical trials since 2020 [2]. The increase in the number of trials has also brought about greater complexity. Contributing factors include more frequent protocol amendments and the challenges of shifting to remote studies during the COVID-19 pandemic. These factors have not only added to the complexity but also escalated study costs, caused delays, and increased regulatory burdens. Moreover, sites that primarily serve underrepresented communities face unique

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challenges, such as mistrust of medical systems, socioeconomic barriers, and the lack of health-care access. These challenges necessitate tailored recruitment strategies, adding another layer of complexity to conducting clinical trials. Thus, both the logistical challenges of remote studies and the specific needs of underrepresented communities contribute to the increasing complexity of trials [3-5].

The Clinical Research Coordinator (CRC) plays an integral role in the success of clinical trials and manages various aspects of studies. Core responsibilities often include recruiting subjects, conducting study visits, maintaining study documents, and acting as a liaison between clinical, regulatory, and administrative personnel. However, additional responsibilities such as regulatory submissions, budget development and negotiation, and managing study finances may be required [6-9]. This role requires specialized skills, training, and medical knowledge due to increased protocol complexity and regulatory oversight [6]. Given the 65% increase in the number of clinical trials registered between 2015 and 2019 [2], the pool of clinical trial workforce professionals has steadily decreased since the nineties resulting in a national shortage of qualified professional coordinators. The shortage is partly attributed to increased regulatory burdens, protocol complexity, and staff burnout [6-7,10,11]. Increased responsibilities and workload have negatively affected job satisfaction, leading to coordinators remaining in the position for a shorter time. This high turnover rate is costly and adversely affects the timely management of clinical trials [6,11]. Organizations such as the Association of Clinical Research Professionals and the Society of Clinical Research Associates attempt to grow the clinical trial workforce by validating staff qualifications, defining competencies, and establishing clear career paths. However, despite these efforts, the professional workforce continues to diminish. Furthermore, the COVID-19 pandemic complicated trial management and disrupted operations, preventing many sites from continuing their existing trial activities [12,13]. As institutions resume regular operations, many are now facing staffing shortages [12,14]. Therefore, clinical trial leaders must develop tools to assist with managing workloads to help combat burnout.

To address these issues and retain staff, sites should effectively assess workloads and capacity [15]. Workload assessments help provide validation to increase staff, evaluate and ensure equal distribution of work, and assist with budget justifications. Multiple tools have been created to calculate the workload of a clinical trial and measure the CRC's capacity to manage it, aiding in study assignments [11,16-20]. The Ontario Protocol Assessment Level (OPAL) is designed to quantify the complexity of clinical trial protocols by analyzing factors such as the trial phase, the type of intervention, and the number of special procedures. In addition, the OPAL score has been validated in oncology and non-oncology studies [7,16,21-25]. The tool can also be adapted to calculate optional elements that may affect complexity, such as high enrollment requirements with short recruitment timelines. By assigning a complexity score to each protocol, the tool helps identify trials that may require more resources or present higher risks of delays and increased costs. This quantitative assessment allows for better planning and distribution of workloads among CRCs, ensuring that each coordinator's capacity is optimally utilized without overburdening them [16,20].

In general, the OPAL score is calculated based on a pyramid scale from one to eight of incremental procedures representing an increase in trial complexity (Figure 1). Scoring ranges from non-treatment trials with low contact (OPAL score = 1) and increases to the more complicated Phase I trials (OPAL score = 8). The number of contacts, study type, study phase, number of special procedures, and the number of central processes are considered when reviewing the protocol. Examples of central processes and special procedures are outlined in Table 1. The tool allows for calculating optional elements that may influence complexity, such as adding or decreasing weight in 0.5 increments to account for the number of study visits or the increased administrative work required when managing industry-sponsored trials. This allows sites to adapt the tool to account for unique protocols and institutional needs. In addition, the tool measures case, total, and departmental workloads. The case workload represents the participant management component of the trial. The number of participants and their study status, such as on or off intervention, affect the case workload score. Active case workload is defined as the number of subjects on study intervention. It is calculated by multiplying the number of participants on intervention by the OPAL score. For example, if a trial is considered to have an OPAL score of 4 and has five active participants on study intervention, then the active case workload score would be 20 (4 [OPAL score] × 5 [active subjects]). If a participant has completed study treatment, but follow-up visits continue, they are now considered a follow-up case. A trial can have both active and follow-up cases. The follow-up case workload is also calculated using OPAL. The OPAL score is divided in half due to the reduced workload. The score is then multiplied by the number of participants in the follow-up phase of the study. For example, if a study has an OPAL score of 4 and has one participant in follow-up, then the follow-up case score would be 2 (4 [OPAL score]/2; then 2 × 1 [follow-up participant]). The case workload score can now be calculated by adding the active and follow-up case scores. OPAL score and case workload are added to create the total workload. This score represents an objective measurement of the research coordinator's workload. The total workload for each protocol is then summed to represent the department workload [16]. Factors such as protocol amendments, increased or decreased target enrollment goals, and changing study timelines can alter the complexity score throughout a study so it is suggested to assess the workload at least quarterly [16,20]. Understanding the OPAL calculation provides insights into how integrating longitudinal data on coordinator efforts modifies traditional complexity assessment, justifies OPAL score adaptation, enhances resource allocation and workload management, and ensures methodological transparency. In addition, it contextualizes the adapted OPAL score within the broader framework of clinical trial management, highlighting its potential to improve trial efficiency and coordinator satisfaction.

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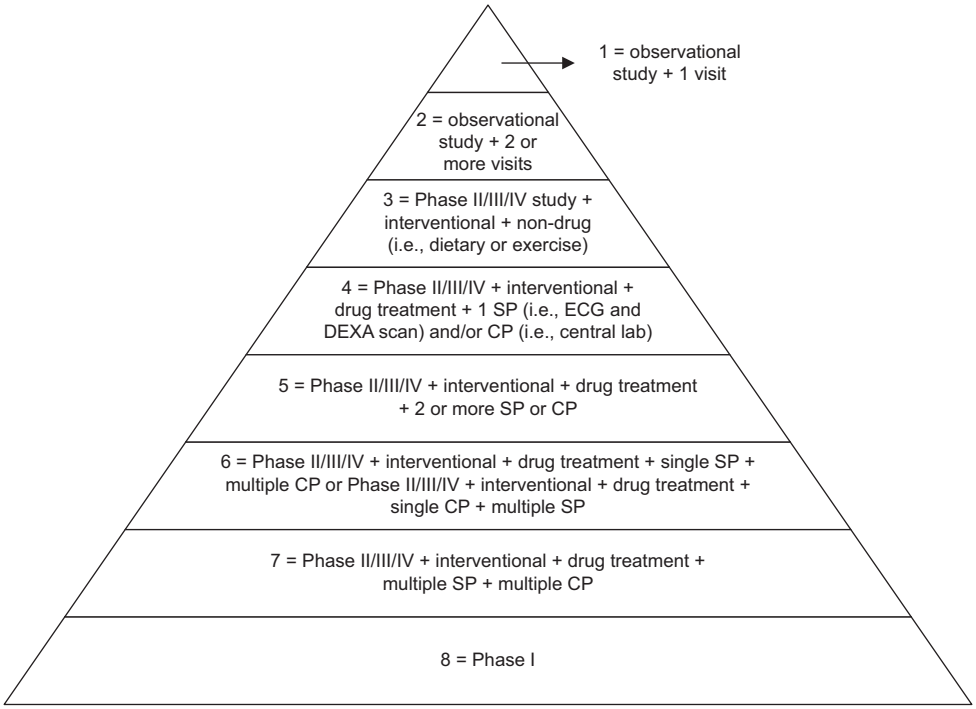

Figure 1. Ontario Protocol Assessment Level (OPAL). Adapted from Smuck *et al.* [16]
Abbreviations: ECG: Electrocardiogram; DEXA: Dual-energy x-ray absorptiometry; CP: Central processes; SP: Special procedures

Table 1. Examples of CP and SP

CP	SP
Use of central laboratory; central eligibility review; central tissue review; and central ECG review	Imaging (i.e., MRI); ECG; biopsy; and cognitive testing

Abbreviations: CP: Central processes; SP: Special procedures; ECG: Electrocardiogram; MRI: Magnetic resonance imaging

However, the OPAL tool has limited sensitivity in differentiating workloads between studies with the same score. Moreover, the utilization of the OPAL tool fails to consider crucial factors, such as organizational structure, budget constraints, and patient demographics, all of which significantly impact the effort and productivity of research coordinators [11,20,21]. These limitations suggest that the tool alone may not provide a comprehensive assessment of workload. To address these shortcomings, enhancements such as linking the research coordinator's tracked effort over time with an adapted OPAL score may provide a more accurate assessment of workload. The data can then be used to establish a precedent for the site and assist in budget negotiations with sponsors. Tracking actual effort may help capture hidden costs associated with internal processes due to real-time dynamic tracking allowing clinical research leaders to make better-informed decisions to assess capacity and improve operational efficiency. Richie *et al.* [15] demonstrated the utility of this integrated approach, but assumed that estimated effort from past contracts was not over or underestimated instead of using actual effort. Likewise, in addition, measuring coordinator activity over time can provide a pattern demonstrating where study assignments result in maximum productivity [20]. The historical data can then be used to establish a precedent for the site and assist in budget negotiations with sponsors. Tracking actual effort may help capture hidden costs associated with internal processes due to real-time dynamic tracking allowing clinical research leaders to make better-informed decisions to assess capacity and improve operational efficiency.

To date, there have been no known attempts to link the OPAL score to the coordinator's effort. Therefore, this study applies resource management and capacity planning principles to examine the workload of research coordinators at an academic research center by linking an adapted OPAL score with tracked coordinator effort. In detail, this study will map an adapted OPAL score for clinical trials to actual coordinator hours from a single site to determine if the adapted OPAL score can be a predictor of coordinator hours. With this strategy, research sites can better allocate resources and improve operational efficiency, reduce burnout and turnover among CRCs, and ultimately contribute to the success of clinical trials. By systematically evaluating the complexity and demands of the CRC's workload, we aim to provide insights into the specific resource needs. Furthermore, the data from this project can highlight trends and areas where additional training or support may be needed for CRCs to better equip them with the necessary skills and knowledge. This targeted approach to capacity planning and resource management will not only enhance the efficiency of clinical trials but may also improve job satisfaction and retention rates among CRCs.

2. Methods

2.1. Research design

The Morehouse School of Medicine (MSM) Clinical Trials Management System (CTMS) was queried for actively

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enrolling interventional studies with corresponding coordinator effort tracking from June 1, 2022, to December 1, 2022. Studies that had <6 months of coordinator hours logged against it were excluded from the study. A total of seven studies were included in the data set. A committee comprised personnel from the MSM Clinical Trials Office then reviewed and graded each study protocol using an adapted OPAL tool.

2.2. Statistical analysis

Descriptive statistics were used to compare the protocol characteristics to the adapted OPAL score and tracked coordinator hours using Student's *t*-test to compare averages. A univariate analysis was performed using non-parametric tests for the differences in the continuous variables. Linear regression analysis was also performed to assess and quantify the association between the adapted OPAL score and tracked coordinator hours. This study is considered a quality improvement study and was not subject to IRB review or approval.

2.3. Time- and task-tracking application

The research coordinators at MSM used a time- and task-tracking application to monitor the total time spent conducting study activities. The application is accessible through TEAMS, is mobile optimized, and links to the MSM CTMS in real time. Study activities are tracked in broad categories: recruitment, communication, scheduling, subject visits, regulatory/compliance, sponsor visits, sponsor training, and data entry/query resolution.

2.4. Adapted OPAL tool calculation

Research protocols were graded using an adapted OPAL tool. The base score for the adapted tool is derived from the standard OPAL pyramid scale of 1 – 8 (Figure 1). Weighted elements were then added to the base score to calculate the adapted score. A summary of these weighted elements is outlined in Table 2.

Table 2. Summary of the adapted OPAL-weighted elements

Positively weighted elements	Negatively weighted elements
(+) 0.5: On-site monitoring (every 3 months or more) or 100% source document submission; industry sponsor/Clinical Research Organization (CRO); multiple surveys or questionnaires (>3 time points); duration of follow-up visits >2 years; management and oversight of one subsite; management and oversight of >1 subsite; management of study visits requires travel between campuses; study requires fresh tissue biopsy; requires sample processing (clotting, centrifuging, aliquoting, packaging, and shipping); requires pharmacokinetics (PK) or pharmacodynamics (PD) labs; length of treatment >18 months (or until disease progression); inpatient days; study requires specialized personnel (i.e., blinded coordinator or needs more than 1 coordinator); enrollment periodc ≤2 months; and investigator-initiated or pilot study	(-) 0.25: Length of treatment within 0 – 3 months (-) 0.5: Visits less frequent than every 4 weeks; no data entry

Abbreviation: OPAL: Ontario Protocol Assessment Level

It should be noted that this modification of the OPAL tool was previously tested by the team comparing 11 interventional protocols [26]. There was a statistically significant difference between the average standard OPAL score (3.64 ± 0.5) compared to the adapted OPAL score (7.45 ± 1.64; $P < 0.0001$). Therefore, the adapted score could differentiate between sensitivities between protocol workloads with the same standard OPAL score.

3. Results

A total of seven protocols were included in the dataset. Of these, 5 (71%) protocols were federally funded compared to 2 (29%) that were industry-sponsored; 4 (57%) studies were behavioral interventions compared to 3 (43%) drug studies. The range of the adapted OPAL scores was 4.75 – 9.0.

There were significant differences between sponsor and intervention types when compared to the adapted OPAL score. Industry-sponsored studies yielded a higher workload estimate than federally-sponsored studies (7.25 ± 1.77 vs. 6.45 ± 1.65; $P < 0.0001$). In addition, behavioral interventions (i.e., exercise and diet) were estimated at a higher workload assessment than drug studies (6.88 ± 1.56 vs. 6.42 ± 1.91; $P < 0.0001$). These findings are summarized in Table 3.

Although industry-sponsored studies and drug studies had more coordinator hours tracked against them, there was no significant relationship between the number of hours tracked and the study sponsor type. Industry-sponsored studies had an average of 181 ± 152.7 h compared to federally sponsored studies with 98 ± 142.6 h tracked ($P = 0.06$). Drug intervention studies had an average of 128.7 ± 141 h tracked compared to behavioral interventions with 116.5 ± 157.6 h tracked ($P = 0.06$). These findings are summarized below in Table 4.

Table 3. Protocol characteristics compared to the adapted OPAL score

Protocol characteristics	Adapted OPAL score	*P*
Sponsor type		
Industry (*n*=2)	7.25±1.77	<0.0001
Federal (*n*=5)	6.45±1.65	
Intervention type		
Drug (*n*=3)	6.42±1.91	<0.0001
Behavioral (*n*=4)	6.88±1.56	

Abbreviation: OPAL: Ontario Protocol Assessment Level.

Table 4. Protocol characteristics compared to the tracked coordinator hours

Protocol characteristics	Tracked hours (h)	*P*
Sponsor type		
Industry (*n*=2)	181±152.74	0.06
Federal (*n*=5)	98±142.62	
Intervention type		
Drug (*n*=3)	128.67±140.99	0.06
Behavioral (*n*=4)	116.5±157.61	

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A simple linear regression was utilized to examine the relationship between adapted OPAL scores and tracked coordinator hours. The fitted regression model is defined as:

Coordinator hours = (77.22 × Adapted OPAL score) – 394.03

The overall regression was statistically significant (R^2 = 0.78; P = 0.01). It was indicated that the adapted OPAL score significantly predicted tracked coordinator hours (β = 77.22; P = 0.01), indicating that for every 1 unit increase in the adapted OPAL score, there is an expected increase of 77.2 min in coordinator hours (Figure 2).

Table 5 displays the estimated coordinator hours for the adapted OPAL score ranges using the fitted regression model.

Clinical trial leaders must first have an understanding of the existing operational capacity of each coordinator before reviewing new studies. The maximum CRC capacity can be determined by multiplying the number of full-time hours per day (i.e., 7.5 h) by the number of working days per month (Table 6). The average working hours per month (i.e., 163 h) is used as a guide for assessing current capacity.

According to James *et al.* [27], 25 – 30% of effort should be allocated to non-study activities, such as general office meetings, sick time, and vacation; the remaining effort is then assigned to study management activities for full-time equivalent (FTE). Table 7 displays coordinator hours logged over 6 months from June 1, 2022, to December 1, 2022. An additional 25% effort was added to account for non-study activities (163 h × 0.25 = 41 h). This calculation represents an estimate of the current operational capacity of each coordinator. At this point, clinical trial leaders can decide if project reallocations are necessary.

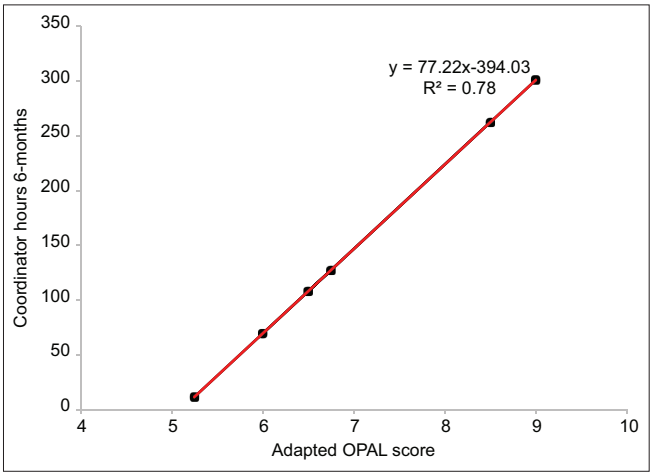

Figure 2. Regression model of charted coordinator hours to the adapted Ontario Protocol Assessment Level score

Table 5. Estimated coordinator hours for the adapted OPAL score

Adapted OPAL score	Estimated hours (h) over 6 months	Estimated hours (h) per month
5.5	30.7	5.1
6.0	69.3	11.5
6.5	107.9	18.0
7.0	146.5	24.4
7.5	185.1	30.9
8.0	223.7	37.3
8.5	262.3	43.7
9.0	301.0	50.2
9.5	339.6	56.6

Abbreviation: OPAL: Ontario Protocol Assessment Level

4. Discussion

Integrating adapted OPAL scores with tracked coordinator effort enhances decision-making in resource allocation. Historical data on CRC effort, including hours spent per study, provide valuable insights into actual workload distribution and productivity patterns. This empirical approach supports more accurate forecasting of staffing needs and ensures that workload assignments align with CRC capacity, thereby optimizing operational efficiency [11,19-20]. It offers a systematic approach to evaluating the workload associated with prospective projects once the current operational capacity has been assessed. By quantifying factors such as trial phase, intervention type, and procedural demands, the adapted OPAL score offers a numerical measure that correlates with administrative workload [16]. This allows clinical research leaders to identify trials that may require additional resources or present higher risks of delays and increased costs at an early stage.

One of the critical benefits of integrating the adapted OPAL scores with tracked effort is the potential to mitigate burnout and reduce turnover among CRC's. By systematically assessing and aligning workload assignments with CRC capacity, this approach promotes workload fairness and job satisfaction. It enables clinical research sites to allocate resources more effectively, thereby supporting CRCs with appropriate training and support based on the complexity of assigned protocols. Furthermore, this approach facilitates strategic planning by providing longitudinal insights into workload patterns [20]. By analyzing historical data on CRC efforts alongside the adapted OPAL scores, clinical research leaders can make informed decisions regarding resource allocation and budget negotiations with sponsors. The data can also inform future capacity planning and strategies and

Table 6. Maximum working hours per month

Month	Working days per month	Maximum working hours (h) per month
January	21	158
February	20	150
March	23	173
April	21	158
May	22	165
June	22	165
July	21	158
August	23	173
September	22	165
October	21	158
November	22	165
December	22	165

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Table 7. Estimate of the current operational capacity

Coordinator	Total study hours (h) logged over 6 months	Hours (h) logged per month	Monthly hours (h) + 25%	Current monthly capacity (%)
1	651	109	150	92
2	967	161	202	124
3	305	51	92	56
4	439	73	114	70
5	222	37	78	48
6	145	24	65	40
7	14	2	43	27

help predict staffing needs. This data-driven approach enhances operational efficiency by identifying trends and areas where additional support or adjustments may be needed to optimize trial management [11,19,20]. Applying the regression model, it becomes feasible to estimate the anticipated coordinator hours necessary for conducting a study within a projected timeframe. For example, a new study with an OPAL score of 8.5 would yield total coordinator hours of 262.34 h, based on calculations using Equation I. The total hours can then be divided by six (i.e., Equation I is derived based on 6 months) to calculate the estimated hours per month (262.34/6 = 43.72 h). This data can now be used to assess whether a coordinator possesses adequate capacity for the project or if additional FTEs are necessary.

Clinical trial leaders can quantitatively conduct a coverage analysis to ensure that coordinator efforts adequately address unique infrastructure needs at the study site. This workload assessment method proves instrumental in capturing "hidden" efforts, which encompass tasks beyond standard study activities and participant recruitment milestones. Examples of hidden efforts include resolving queries in complicated or poorly developed electronic data capture systems, managing subject stipend activations and disbursements, participating in investigator meetings, and time spent with study monitors [28]. This is especially relevant for sites serving underrepresented populations, where additional time may be required to implement tailored recruitment strategies due to socioeconomic barriers, medical mistrust, and language challenges [5]. This methodology also proves advantageous for smaller institutions with decentralized processes, where coordinators assume broader responsibilities. In addition, underestimating these efforts during the budget development can lead to deficits in infrastructure funding, potentially exceeding allocated FTEs. Therefore, it is important to establish a precedent so sites can ensure comprehensive coverage of operational costs during sponsor negotiations.

The methodology detailed in this study is suitable for consistent application across multiple sites. Sites can adapt the OPAL tool to suit their specific requirements and integrate coordinator effort data from any time management application. This study is limited by its focus exclusively on drug and behavioral interventions, which may limit the generalizability of its findings to other types of clinical trials. In addition, the linear regression method employed in this study may require a baseline starting point for adapted OPAL scores (e.g., 5.5) to accurately estimate coordinator hours. Furthermore, the absence of a significant relationship between tracked hours and study sponsor type or intervention type suggests the potential influence of sample size limitations. Future research with larger cohorts could provide deeper insights into the variability observed across different study types.

5. Conclusion

The findings of this study indicate that the adapted protocol complexity scores can serve as an effective predictor of coordinator effort. This insight is valuable for assessing organizational capacity to undertake new projects. The implementation of a standardized study assignment process enables equitable distribution of projects, mitigating the risk of overburdening proficient coordinators. Consequently, this approach enhances coordinator satisfaction, reduces burnout, and potentially boosts productivity by preventing over-allocation. Future research endeavors will leverage insights from this study, alongside additional clinical trial metrics, to develop machine learning models aimed at optimizing workload assessment, coordinator allocation, and forecasting of study productivity.

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Conflicts of Interest

The authors declare that there are no conflicts of interest to disclose.

Ethical Approval and Consent to Participate

This project was deemed to be a quality improvement project and was therefore not subject to IRB review or approval.

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Consent for Publication

Not applicable.

Availability of Data

Data are available from the corresponding author on reasonable request.

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