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ORIGINAL RESEARCH

Overcoming Barriers in Incentive Management: Organizational Empowerment Enhancing Patient Engagement in Clinical Research

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Video abstract

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Aims of Research: Expanding global trial access ensures sustainability by incorporating local contexts and prioritizing patient engagement. This research explores how Organizational Empowerment (OE) and incentive management enhance patient involvement in clinical trials, with Contract Research Organizations (CROs) playing a key role. We propose a paradigm shift based on Grothe-Hammer's organizational contributorship, where participation replaces formal membership, enabling active decision-making and engagement.

Methods: This qualitative research with holistic case study approach explores the role of incentive management in Organizational Empowerment (OE) within Contract Research Organizations (CROs). Through interviews and analysis, it examines the impact of incentive structures on both employees and patients, assessing their effectiveness in aligning organisational goals with patient-centricity principles.

Results: A key outcome of the study is the call for a shift in patient roles, proposing that patients transition from non-contributing to contributing members within the organization. The study demonstrates that patient-centered interventions, including logistical and financial support through third-party organizations, can enhance patient retention, engagement, and diversity in clinical trials. These interventions benefit both patients and the organizations by improving trial efficiency and reducing dropout rates. In advancing the field, this research makes a contribution by integrating organizational theory with clinical research management practices, a perspective that has been underexplored. The application of institutional theory to understand regulatory frameworks and their impact on incentive management reveals how external constraints shape organizational behavior.

Conclusion: The clinical trial ecosystem relies on collaboration among stakeholders to enhance patient care, requiring a shift toward a patient-centric model for better treatment adherence and outcomes. This study highlights the role of Organizational Empowerment (OE) and incentive management in fostering inclusivity, advocating for contributorship over traditional membership to strengthen stakeholder engagement in clinical research.

Keywords: incentive management, organisational empowerment, patient centricity, clinical trials, CRO

Introduction

The inaugural World Health Organization (WHO) Global Clinical Trials Forum, held in Geneva, Switzerland, on November 20–21, 2023, brought together a diverse group of stakeholders to advance sustainable global clinical trial infrastructure.[1] This event was in response to the World Health Assembly's 2022 mandate to "strengthen clinical trials" and established a vision of "always on, always busy" clinical trial.[2] This vision aims to integrate clinical research seamlessly into health systems to improve outcomes continually.[1,3] The Forum emphasized the need for infrastructure that supports continuous clinical trial operations, addressing critical questions in patient care while embedding equity in research-oriented health systems. Ensuring global access to trial capacities will enable health workers to participate in multicenter trials, incorporating local languages and contexts to maintain functional and efficient systems. By avoiding inefficiencies and expertise loss, this approach ensures trials are sustainable and impactful. Central to this vision is patient and community

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engagement. Trials must prioritize patient and community needs, ensuring inclusive participation and prompt communication of results. While trust in science faced challenges during the COVID-19 pandemic, the Forum highlighted increased interest in evidence-based decision-making and trial participation as a foundation for rebuilding trust.

This research examines how Incentive management as a important segment the Organizational Empowerment (OE) facilitates patient engagement in healthcare, focusing on human resource management and empowerment theory. Empowering patients enhances their involvement in healthcare decisions, fostering ownership and improving outcomes.[4] OE initiatives aim to empower individuals within organizations, aligning with goals such as patient-centric clinical research. Contract Research Organizations (CROs) are pivotal in this context, managing clinical trials and supporting industries like pharmaceuticals and biotechnology. Their role in fostering OE contributes to efficient research processes and enhanced patient engagement. Empowerment theory, supported by Peterson and Zimmerman's (2004) model, underpins this study, exploring how CROs act as change agents in advancing patient-centric care. Incentive management plays a critical role in fostering engagement by aligning member motivations with organizational objectives. Incentives, whether tangible (eg, financial rewards) or intangible (eg, recognition), enhance participation and productivity when tailored to members' values. Non-monetary rewards, in particular, can drive intrinsic motivation, promoting autonomy and competence. Effective incentive strategies must adapt to external factors like economic conditions and cultural norms, leveraging technological advancements for personalized approaches. Gamification and data-driven methods can enhance engagement, while leadership and positive organizational culture remain vital for success.[5] Incentive management is a cornerstone of organizational empowerment (OE) as it drives motivation, participation, and alignment with organizational goals. In clinical research, where the stakes involve patient outcomes and public health advancements, incentives play a dual role in engaging both healthcare providers and patients. Well-structured incentive programs not only enhance productivity and efficiency but also foster a culture of collaboration, which is critical for achieving patient-centric goals. By addressing intrinsic and extrinsic motivators, organizations can cultivate a sense of purpose and responsibility among stakeholders, ultimately improving engagement and outcomes. Patient engagement is a dynamic process requiring active participation and collaboration between patients and healthcare providers. Incentive management helps bridge gaps in this process by providing clear benefits for involvement. One of the critical challenges in clinical research is ensuring diversity and inclusion among trial participants. Incentive management can address this by tailoring programs to appeal to underrepresented populations, offering meaningful rewards that resonate with cultural, economic, and social contexts. This inclusivity not only improves the quality of research data but also strengthens trust and collaboration between organizations and communities. Sustained engagement in clinical trials and healthcare initiatives requires ongoing commitment, which incentive management supports by fostering a sense of value and belonging. Programs that recognize and reward long-term participation encourage continued involvement, reducing dropout rates and ensuring the continuity of research efforts. In clinical research, where timelines can span years, maintaining participant interest is critical. Incentive management strategies that offer progressive rewards or recognition milestones can sustain motivation and reinforce the importance of long-term engagement. Incentive management must align with ethical standards to ensure that participants are respected and their contributions are valued appropriately. Transparent and equitable incentive structures foster trust between organizations and participants, mitigating concerns about exploitation or coercion. In clinical research, ethical incentive practices enhance the reputation of organizations, making them more attractive to both participants and collaborators. This trust is fundamental to building a robust clinical trial ecosystem that prioritizes patient engagement and empowerment. By integrating effective incentive management into organizational empowerment strategies, clinical research organizations can create environments where patients, providers, and stakeholders collaborate seamlessly. This alignment fosters innovation, improves health outcomes, and advances the broader goals of patient-centric healthcare systems. This research underscores the importance of integrating OE and incentive management within clinical trial systems. By fostering patient engagement and aligning organizational strategies, the healthcare sector can achieve sustainable and inclusive progress in clinical research.

Literature Review

Contract Research Organizations (CROs), specializing in clinical research activities, possess significant potential for empowerment within the clinical research ecosystem due to their strategic roles and operational practices. Identifying effective change agents in this context can elucidate the characteristics of organizational empowerment and highlight the underlying causes of patient engagement, especially in the ongoing shift toward patient-centric approaches.[6–8] Incentive

management comprises organizational strategies that promote participation by offering various rewards and minimizing associated costs.[9] In clinical research, these incentives range from social engagement opportunities and skill development programs to access to valuable medical insights and advanced treatments. On the other hand, costs might include personal sacrifices like time, childcare, and logistical challenges. Effective incentive strategies, as demonstrated by Prestby et al in collective action settings, enhance member perceptions of benefits and ensure organizational sustainability. Effective incentive management aligns participant and stakeholder motivations with organizational goals, fostering sustained engagement. Tangible rewards, such as monetary compensation, gift cards, or resources, are crucial for many stakeholders. However, intangible rewards, such as professional development opportunities, peer recognition, and enriched social interactions, are often equally impactful.[10] Luthans and Stajkovic (1999) emphasize that non-monetary incentives can, in some cases, surpass the effectiveness of financial rewards by tapping into intrinsic motivators and reinforcing organizational commitment.[11] Economic conditions, cultural norms, and external market forces significantly influence the effectiveness of incentive programs. During economic downturns, financial rewards may hold higher value, while in periods of growth, opportunities for career progression and professional recognition become more desirable.[12] Hofstede's cultural dimensions theory (1980; 2010) underscores the necessity of culturally sensitive approaches, where collectivist cultures may respond better to group-oriented incentives, while individualistic societies prioritize personal achievements. Technological advancements have revolutionized incentive management, enabling CROs to adopt personalized, data-driven approaches. Big data and analytics allow for tailored reward programs that meet the unique preferences of participants and staff.[13] Gamification—integrating game design elements like challenges, leaderboards, and reward systems—has emerged as an effective technique to boost motivation and engagement by leveraging individuals' competitive instincts and desire for recognition.[5,14] The psychological underpinnings of incentive management, rooted in Self-Determination Theory (SDT), highlight the importance of intrinsic motivation over extrinsic motivators. Intrinsic motivation, derived from autonomy, competence, and relatedness, fosters sustainable engagement and satisfaction. CROs can implement strategies that promote autonomy by involving stakeholders in decision-making processes, provide opportunities for skill enhancement, and create environments that encourage collaboration and mutual support. Regulatory frameworks and leadership styles significantly influence the success of incentive programs in CROs. Regulations often dictate permissible incentives, necessitating a balance between compliance and stakeholder engagement.[14] Transformational leadership and participative styles, as highlighted by Yukl (2013), amplify the effectiveness of incentives by fostering trust, clear communication, and genuine recognition of contributions.[15] Additionally, cultivating a positive organizational culture, characterized by inclusivity and collaboration, enhances the appeal and impact of incentive strategies. Incentive management intersects with change management, particularly during significant organizational transformations such as mergers, restructuring, or strategic realignments. Well-designed incentives during such periods can mitigate resistance, foster acceptance, and maintain cohesion.[16] Regular assessments, feedback loops, and data-driven adjustments are essential for ensuring that incentive programs remain relevant and effective.[17] Incentive management in CROs is a multifaceted strategy that bridges the needs of stakeholders with organizational objectives. By integrating psychological insights, leveraging technology, and addressing contextual nuances, CROs can enhance engagement, boost productivity, and drive long-term success. These strategies not only empower organizations but also contribute to the broader goal of advancing clinical research and fostering patient-centric approaches. We initiated a research framework based on its nomological network arguing that contribution through qualitative research remains as requirement for further conceptualisation of the OE, but also to potentially understand the limitations of the model as indicated by Peterson (2014) and others.[5] This network outlines OE's essential features, observable manifestations, and interconnections. Zimmerman and Peterson's paper provides a foundational review of empowerment literature justifying the organizational level features which are characteristic for the empowered organizations.

Methodology and Data Analysis

The problem addressed by this research is the challenge of ensuring sustained patient engagement in clinical trials by considering empowered Contract research organisations and available incentive settings. Despite the importance of patient-centric models, there are barriers to engaging underrepresented populations and maintaining participant interest throughout long research timelines. This research aims to explore how CRO organisation facilitate OE contributing to

patients' engagement through incentive management supporting a patient-centric model. Empowerment theory offers a framework for understanding how Contract Research Organizations (CROs) can promote patient engagement. This includes improving access to information, involving patients in decision-making, building support networks, developing self-efficacy, and enabling collective action to address health challenges. On the other hand, patient engagement involves developing the capacities of patients, caregivers, families, and healthcare providers supporting the active participation of patients while in treatment. By this approach it aims to improve safety and overall person-centeredness of healthcare services. Patient-centeredness originates mainly from healthcare providers and can enhance patients' attitudes, competencies, and behaviours concerning their healthcare. Empowering patients promotes greater engagement and involvement, which can lead to improved adherence to treatment plans. Ultimately, patient engagement represents a critical and progressive strategy for transforming patients into active, proactive participants in their healthcare journey.[5] On the other hand, Organisational empowerment (OE) is the efforts within an organisation that promote individual empowerment among its members while enhancing its overall effectiveness to achieve its goals.[6] In addition, the causality between organisational empowerment and patient engagement is evident within the context of CRO. Patients are vested in the organisational processes and decisions that affect their healthcare experiences as consumers. Thus, exploring how organisational empowerment within CRO facilitates patient engagement provides valuable insights into the concepts through which service consumers become more actively engaged in their healthcare provision. In this research we were using exploratory qualitative research as a methodological approach We found this approach as beneficial considering that human experiences and social contexts play a crucial role in understanding the subject matter. Also, we used the holistic case study focused on examining a phenomenon within its real-life context, considering the entire system rather than isolating parts of it. This approach is appropriate when the boundaries between the context and phenomenon are unclear.

To maintain methodological rigour, we use a mono-method approach and openly disclose our research roles while adhering to ethical standards, including ensuring participant confidentiality. The research involves collecting data through 15 semi-structured interviews with Ergomed Clinical Research employees. The sample size was determined through saturation analysis, consisting of three groups with five interviewees each, ensuring that all relevant concepts emerged and no new themes or descriptions were introduced in the final interview. Also, effective memos were used throughout to track the development of ideas and confirm saturation. With interviews 14–15 new data only reinforced existing findings, rather than introducing novel perspectives and this was considered as confirmation and redundancy check. Study timeframe was in period from February 2023 until September 2024.

Given Ergomed's global operations and the geographic dispersion of interviewees, all interviews were conducted online to accommodate these logistical challenges. For this research Internal review process was established prior research to address ethical, legal and data protection compliance while the participants used informed consent included publication of anonymized responses and direct quotes. Ergomed Clinical Research has approved interviews based on their company policies, including the rights to carefully review and amend content involving appropriate Legal, Data Protection Officer, Operational and Marketing/Business Development team members. The policies strictly prohibit sharing client information, patient information, personal data, and confidential business information or know-how. Selected candidates were in V-level or management roles with relevant international expertise in domain of research (purposive sample who confirms eligibility and availability for this study). This approach allows for a flexible yet structured exploration of the topics under study. Before interviews, we addressed theoretical and practical considerations, including potential epistemological biases, to ensure the research process was as objective and comprehensive as possible.

By focusing on Ergomed's experiences and practices, this study aims to contribute to the broader understanding of organizational empowerment and patient engagement. The insights gained from these interviews are intended to inform academic research and practical applications within the field. Throughout the study, we adhered to rigorous ethical standards and methodological practices to ensure the validity and reliability of the data. Using semi-structured interviews and a well-defined research framework allowed us to explore the research questions effectively. This case study methodology provides a robust framework for examining complex organizational phenomena. By leveraging qualitative data collection methods and maintaining methodological rigour, the research offers valuable insights into the practices and perceptions related to organizational empowerment and patient engagement. This approach enriches the academic

understanding of these concepts and offers practical implications for organizations seeking to enhance their strategies and practices in these areas. The findings from this study are expected to contribute to both theoretical and applied aspects of organizational empowerment and patient engagement.

As mentioned, the transcripts were systematically organized into three sets containing five interviews and arranged sequentially. In this way, the research team could track the frequency with which participants discussed certain concepts across the sets. Comparisons were then made across these sets to identify recurring themes and determine when data saturation was achieved—when no new relevant concepts were emerging. The inclusion of all 15 participants in this qualitative study was required to reach data saturation. While early interviews provided valuable insights, the final set of interviews ensured that a comprehensive understanding of the research topic was obtained. Saturation was achieved by interviewing a diverse sample of V-level and upper management professionals, ensuring the study captured common themes and cultural variations (through sample selection and comparative analysis), leading to a thorough exploration of incentive management, organizational empowerment, and patient engagement.

Additionally, process included cleaning the transcripts to ensure they were accurately prepared for coding. The cleaning involved creating a clean verbatim transcript. This version of the transcript excludes stutters, filters out non-speech sounds, and removes false starts, which was particularly important given the relatively long duration of the interviews. Additionally, all interviews were carefully reviewed to ensure that no personal or confidential data was included before proceeding with the analysis.

This research subject the interview data to thematic analysis to identify patterns. The thematic analysis involves examining transcripts to identify codes or patterns, which are then be refined and combined to form themes reflecting the language used by the participants. A codebook is established to aid in code development. We used this codebook to code the interview transcripts and identify any new codes emerging in subsequent interviews. Any revisions to the coding structure were reviewed to ensure consistent application of all codes. Following coding, similar codes will be merged, and a code pathway will be created to visualize this process. The frequency of the most relevant codes will be summarized, and participant quotes will be provided to illustrate how the searched terms were discussed.

It is crucial to demonstrate that all pertinent concepts have surfaced in the interview sample, through saturation. We assessed whether concept saturation has been achieved in the interviews, ensuring that no new themes or descriptions of relevant concepts are introduced in the final interview. In addition, results were presented and discussed with interviewees as experts in the field for validation purposes. While secondary data set was not available (including quantitative data) due to nature of work and confidentiality, validation of results had confirmatory purpose.

In inductive research, the theoretical framework emerges from observed data and as illustrated in Figure 1, the theoretical framework for this study highlights the components of organizational empowerment, encompassing its core elements, processes, and outcomes. This framework serves as a guide to interpret and organize findings as they emerge through the research process and It supports the study's aim to explore how empowerment manifests within organizational settings.

Results and Discussion

Before conducting the analysis, we applied Grothe-Hammer's concept of organizational contributorship, which emphasizes that contributorship, rather than membership, is the foundational premise for constituting any organization. This concept was integrated into our findings to elucidate the roles of participants and their interactions with the components of Organizational Empowerment (OE). Through this lens, we examined the nuanced dynamics of contributorship, distinguishing between internal contributors (employees) and external participants (patients) in clinical research settings.

Our analysis revealed that all interviewees (N=15) were familiar with the concept of incentive management, including its causes and effects, within the organizational framework. However, a more nuanced understanding emerged through the interviews. Internally, incentive management is directed at employees operating within the intra-organizational component of the OE model. Externally, it pertains to patients or consumers who, while not contributing organizational members, hold a pivotal role in clinical trials. By incorporating Grothe-Hammer's framework, patients can be understood as non-contributing organizational members whose influence is limited in organizational decision-making processes, whereas employees, as active contributors, directly shape these decisions.

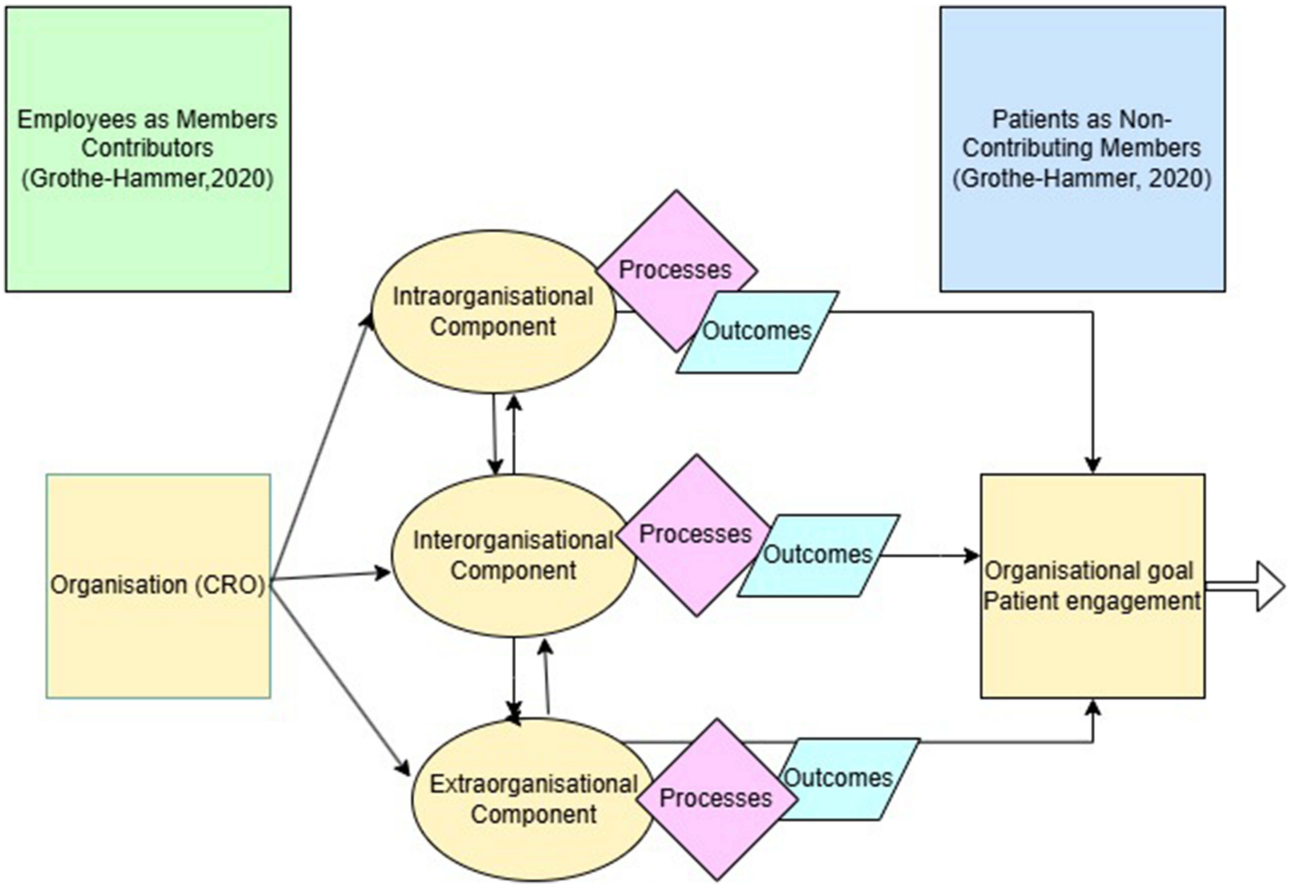

Figure 1 Theoretical Framework showing inductive research based on organisational empowerment and interconnectedness among the OE Components, created by author.

The distinction between contributors and non-contributors is particularly complex in clinical research due to the unique dynamics of the healthcare industry and stringent regulatory requirements. Patients, as voluntary participants, do not directly contribute to organizational decision-making within Contract Research Organizations (CROs). While CROs are designed to support and prioritize patients throughout clinical trials, regulatory and industry constraints limit patients' direct influence. Nevertheless, their conditions as research subjects indirectly shape organizational practices and decisions.

The interviews also highlighted how participants connected incentive management not only with internal organizational processes affecting contributing members (employees) but also with non-contributing members (patients). To reflect this duality, the analysis was structured into two sections: the internal implications for employees and the external relevance to patients. This approach helped conceptualize the current state of incentive management across the organization. In addition, Figure 2 presents a color-coded flowchart structured by relationships defined in the codebook, effectively visualizing the connections between key concepts identified during data analysis. Each concept within the flowchart is accompanied by two sets of data points: the first representing the number of resources, and the second indicating the number of references linked to that concept. This visual representation helps clarify how frequently certain themes appeared across different sources and how often they were referenced, offering insight into the relative significance and interconnections of each concept within the dataset.

Figure 3 illustrates the Word Frequency Query, showcasing the most commonly occurring terms within the collected data. This visual output highlights key themes and recurring language patterns, offering an initial insight into participants' priorities, perceptions, and areas of focus. By identifying frequently used words, the analysis supports the development of more detailed coding and theme-building in subsequent stages, aligning with the inductive nature of the research.

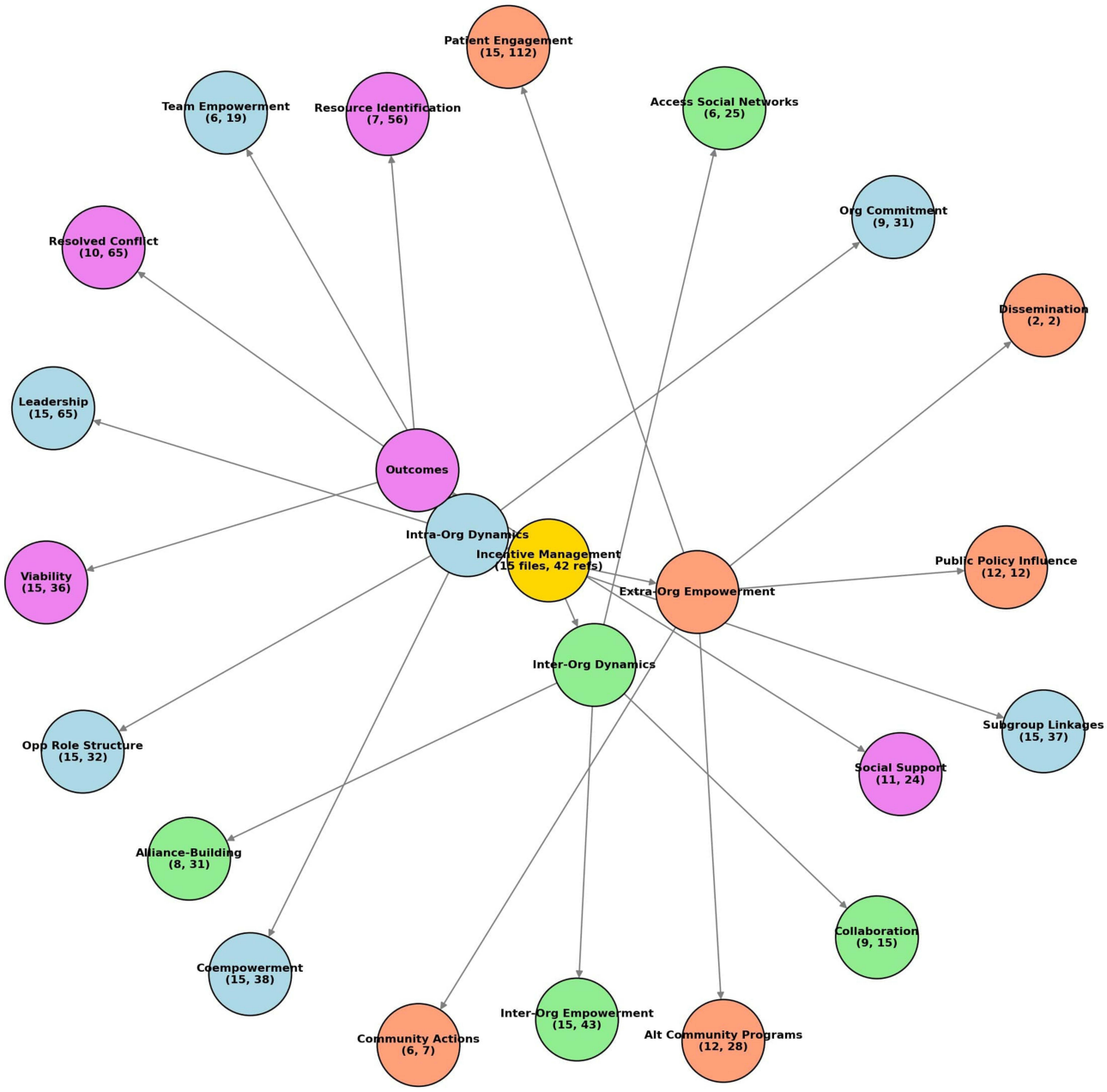

Figure 2 Color-coded flowchart by relationship (per codebook), with each concept showing data points: first (resources), second (references), created by author.

One notable finding was the active involvement and commitment of internal employees in developing incentive management practices. Incentive management was widely recognized and actively developed by all interviewees, with several contributing directly to specific aspects of these practices. It was based on the interview question: "How do organizations use incentive management in CRO settings, and what are some examples of such incentives?" For example, incentivizing employees to secure new business opportunities for the organization emerged as a prominent and effective strategy, demonstrates the tangible benefits of engaging employees in incentive design and implementation.

An example of this active involvement can be seen in the achieving new business for the organization where this is incentivized ERG4:

> The whole project team, regardless of the role, would get like an award once the project is a win which I think is so fair because they performed extremely well and it resulted in a win.

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Figure 3 World frequency query, created by author.

This type of incentive management is based on rewarding the employees. We are considering this as performance-related pay rather than profit-related pay, and this kind of incentive is beneficial and associated with job satisfaction, organization commitment and trust in management, while some studies show that profit-oriented incentives do not have the same effect.[9]

During the analysis of interviews, it was evident that a straightforward and well-communicated incentive management program was in place. Employees are informed about it and understand the various incentive measures. This transparency and understanding are crucial in ensuring that the incentive management program is effective. Beyond basic needs, additional benefits for the internal team, such as educational opportunities, can enhance engagement and commitment to the team and company goals. Those measures cover compensation, recognition, and reward types. Indirect connection is visible, as the reward and recognition incentives are connected with efficiency of the clinical research (project) delivery, which is highly connected with patients engagement. Therefore, as one of the management implications in terms of patient engagement, we are considering it essential to implement reward systems for the employees who successfully engage patients in clinical trials. According to the literature, this should be monitored and quantified to understand the desired levels.[8] From the other hand we noticed empowerment in terms of fostering a culture that values patient-centric approaches and recognizes contributions to patient engagement. This was visible via ERG4:

> By concentrating or focusing on patient centricity as an example and you know, put positions in place and show that experts came on board to train further the team on this how to put it more to focus.

Therefore, by showing that department is modelled to focus on this activity and working towards achieving higher focus to the patient centricity model is demonstrating organizational empowerment with underpopulated settings. Also, by having such department, communication is directly affecting that employees are more informed and lectured about the goals to be achieved (patient engagement/centricity) which is further empowering them through access to information and gained new organizational knowledge. Also, through this, company goals can be easily achieved. However, patients as Non-Contributing Organisational members should also be considered as part of incentive management in the industry. However, incentive management as a term cannot be considered in its entirety with the OE model when it comes to patients. A specific case here is made because of the industry specifics, including regulatory constraints and rigorousness of clinical trials, where, in some cases, direct incentives to the patients/consumers could be considered a bias. Also, by knowing that effective incentive management leads to increased organizational viability through increased perception Prestby et al and by having a premise on the high level of organizational viability due to the nature of work, we were

predicting that evidence of both incentive management and viability will be shown to a great extent in the analysis.[9] Specifics of the business due to regulatory affection are limiting factors in different phases of clinical research where incentives might not be considered ethical. However, there is a program in place that replaces incentive management to avoid bias and support the patients in clinical research (especially in the early phases of clinical research and ultra-rare disease indications). This program is usually connected with reimbursement of the expenses and monetary and non-monetary support that is done through a particular external organization (eg, concierge organization) while keeping patient data blinded and, by this, succeeding to support the patient on its journey within the clinical trial and from the other hand allowing CRO to avoid bias and any direct affection to the patient stay in clinical research.

Figure 4 presents a showcase of how incentive management influences organization members within the flow of clinical research capturing the interactions between organisational structures.

Further, it was noted during analysis that patient support on the journey is crucial, as mentioned by ERG1:

> I think this is crucial when talking about patient support. We have limitations on supporting patient organisations and their participation in clinical trials. However, our performance as employees, our initiatives, and our approach in dealing with these duties in our company are key to supporting the conduction of trials.

While ERG 11 provided the following:

> Incentives are crucial for employees, patients, and investigational sites alike. If we expect dedication and focus, we must meet their needs within the regulatory framework.

To clarify how those incentives for the patient work, ERG 3 said:

> For instance, we arrange patient visits and organise transportation, such as taxis, to ensure convenience and comfort through partner organisations. These incentives may increase direct costs initially, but they improve patient compliance, reduce dropout rates, and increase willingness to participate. This, in turn, enhances enrollment rates and shortens study timelines, ultimately lowering overall project costs for sponsors.

By this it is visible that the incentives to patients, are very affirmatively affecting the engagement of the patients, but also have positive financial implications. At first, direct costs are higher as the costs for the patient should be provided to

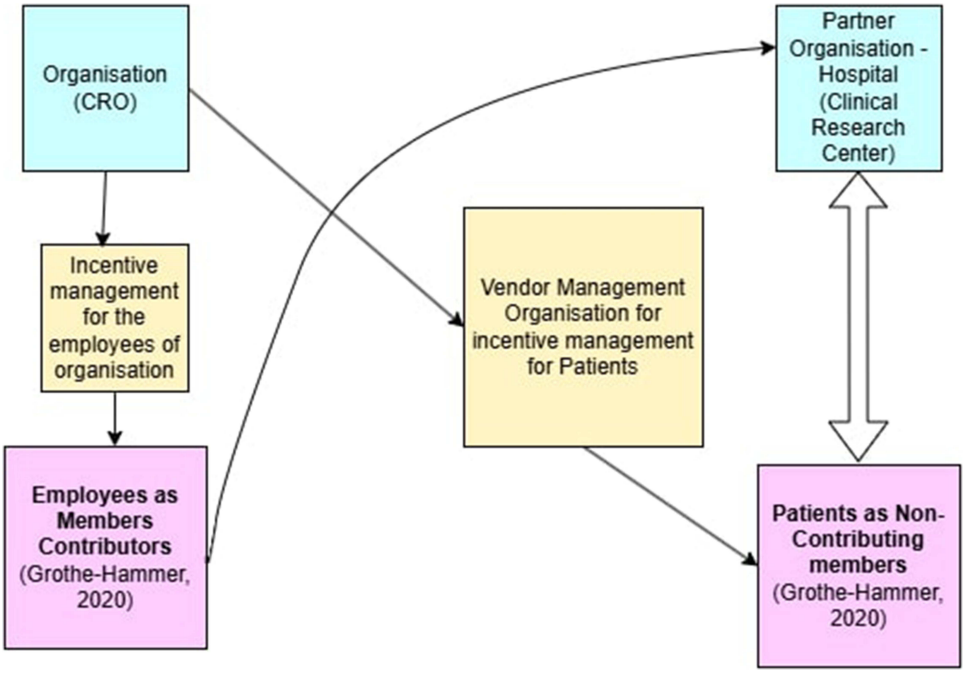

Figure 4 Showcase of incentive management affecting organisation members in the flow of the clinical research, created by author.

https://doi.org/10.2147/OAJCT.S515689

reduce the burden, but in the long run, by increasing engagement, it is noted that financial gain for the organisation is higher, caused by the higher patient retention and reduction in dropout rate which in the end keeps patient in the study longer. Therefore adequate incentive management driven by contributing organisational members (employees as decision makers) is affirmatively affecting non contributing organisational members (patients) if directed to them.

Another aspect we noted during the analysis is that incentive management and diversity of non contributing organisational members (patients) are connected on the example of our case study. Namely, ERG5 mentioned:

> Patient engagement is also about diversity as we need to cover all bases. One approach is ensuring there are no costs that patients cannot be reimbursed for. This includes travel, food, and accommodation, potentially even covering caregivers if needed.

It is noted that without having such incentive management for patients, it would actually affect the diversity in a way that patients who are socially marginalised could not potentially follow the treatment because of the additional costs that are produced. Therefore, by reducing the out-of-pocket expenses for patient incentive management, patients are not affected by barriers related to affordability, and access to treatments is crucial for participation. Here, we could also consider diversity management in terms of internal organisation (for contributing members) and achieving diversity in the clinical research population (non contributing members) to address adequate social response. This construct is relevant as, according to Patrick-Lake B, in 2018, it was noted that organisational diversity creates ambiguity about how to optimise relationships and effectively incorporate the patient perspective into clinical trials, raising questions such as who should be engaged, when, and to what extent. Engagement also entails complexities, including navigating conflicts of interest and avoiding undue promotion of investigational products, posing challenges for regulators, patient organisations, and sponsors. Recent initiatives, such as the FDA's Patient-Focused Drug Development program, have provided opportunities for increased patient involvement through diversity in the development of medical products.

One of the critical segments of incentive management (as shown by Prestby et al, 1990) could include the opportunities for social interaction with neighbours in his study. In our case, we are focused on the communities and other patients with whom patients might have the opportunity to meet, socialise and exchange opinions (non contributing members interaction with non contributing members and non members). This is one of the fundamental aspects, as education of the patients on their condition is essential for overall understanding of their engagement in the process.[18] As per ERG 6:

> Well, incentive management also might include opportunities for patients to connect with others facing similar diseases, access to specialised physicians, and engagement with patient advocacy groups. This fosters greater understanding of their condition and available treatments.

This type of incentive management, which is shown as highly empowering, addresses multiple patients' needs and strives for them to be more engaged, meaning also individually empowered. Another interesting point is connected with the incentive management and regulatory framework. As per previous research, it was noted that the OE model showing how an organisation affects public policy/practice via extraorganisational empowerment. At the same time, it does not include how organisations react to the demands of institutions and how organisations can create new institutions that are in the organisation's best interest.[8] Also, based on this observation, the OE model lacks a connection with organisational theories. In addition, Franscescato and Aber (2015) argued that organisational theory should be used to build OE.[19]

ERG8 mentioned the following:

> In our approach, while we avoid the term "incentive" due to regulatory constraints, we focus on alleviating patient burdens. Access to novel therapies through trials is a primary incentive, offering patients early access they might not otherwise receive. For phase one trials with healthy volunteers, we reimburse them for their time, which is a straightforward incentive. Beyond monetary compensation, leveraging patient advocacy organisations is important. These groups provide trusted information and support and enhance patient trust and enrollment.

Many terms were used during the interviews to direct us to the rigorous regulatory framework, which in this industry also represents constraints in a certain way. We will address this in later sections connected with external organisational factors. However, here we also wanted to mention that patient support needs might be affected by those limitations as per ERG1:

> The necessity to support patient organisations based on the regulatory constraints and their participation in clinical trials drives the implementation of incentive management. In contrast, limitations in support can hinder the effectiveness and efficiency of clinical trials.

Another limitation is visible through the type of clinical research funding, where incentive management for the patients as non contributing members is limited by the size of the budget predefined for the study by the Sponsor:

> …approach to patient support is constrained by client budgets. We typically bear these costs if there are specific overruns. While we propose strategies like concierge services, Healthcare at Home, and travel reimbursements to ease patient burdens, final decisions are often beyond our control. Despite budget limitations, investing in patient support can enhance recruitment, retention, and study timelines, ultimately reducing overall study costs.

Following the analysis of this segment, we are focusing on the limitations of incentive management as an OE component in facilitating patient engagement. Therefore, we have noted that besides the indirect connection of the goal to be achieved and incentives for the organisation members, limitations are connected with the measurement of the impact of the goal to be achieved, its quantification and direct implication to the organisation members in order to strive for its achievement. On the other hand, by focusing on specific departments with global organisation outreach connected with the goal of achieving a higher patient-centricity model, organisational empowerment is visible, and we have explained the rationale already in the previous text. Another limiting factor is related to regulatory constraints, which should be further explored by connection with the organisational theory, especially considering the complexity of the phenomena and the fact that organisational theories also have practical applications in many different areas within organisations, as well in the organisational environment.[20–22] One of the incentive programs focuses on reimbursing patient expenses and providing monetary and non-monetary support via third party organisations as response to regulatory pressures that discourage direct incentives. The reliance on external organisations to manage patient support underscores a boundary on the CRO's ability to influence all aspects of the trial process directly. While this separation is necessary to maintain ethical standards and avoid bias, it limits the CRO's control and oversight, complicating the trial's management and illustrating the complex interplay between regulatory pressures and organisational autonomy. We are considering the approach justified to protect the anonymity of the treated subjects and prevent any impact on the research data, but we are also showcasing the situation in which organisations are innovating in external environment due to regulatory implications. Here further research within Institutional theory would helps us understand how regulatory frameworks shape and limit organisational behaviour. Therefore, while programs designed to support patients in clinical trials address critical ethical concerns and mitigate financial burdens, they also reveal inherent limitations in organisational empowerment through the lens of institutional (regulatory) constraints. The necessity of external management for these support functions ensures objectivity and compliance but restricts the CRO's direct involvement. This dynamic underscores the significant impact of regulatory institutions on organisational behaviour and highlights the challenges organisations face in balancing regulatory compliance with effective clinical research management. Clinical Research Organisations (CROs) face significant limitations in organisational empowerment due to the constraints imposed by sponsors' budgets. The funding for clinical research often comes with predefined budgets, and these financial parameters directly impact the ability to manage consumer incentives effectively. Since patient support mechanisms, such as incentive management, are crucial for the success of clinical trials, limited budgets can severely constrain the CRO's ability to implement these strategies. This limitation highlights a critical dependency on sponsors' financial allocations, impeding the CRO's operational flexibility and overall empowerment. One of the main challenges CROs encounter is that their approach to patient support is heavily dictated by the budgets set by their clients, the sponsors. While CROs can recommend and devise strategies to facilitate patient participation, such as concierge services, Healthcare at Home programs, and travel reimbursements, the ultimate decision on these expenditures lies with the sponsor. Unless specific budget overruns require the CRO to cover costs temporarily, these support mechanisms are typically outside the CRO's financial purview. This dependency restricts the CRO's capacity to implement patient-centric initiatives essential for successful clinical trials.

Despite these budgetary constraints, investing in patient support services can significantly enhance recruitment and retention rates, positively impacting study timelines. Effective patient support reduces dropout rates and ensures better compliance with study protocols, which, in turn, streamlines the entire clinical trial process. This can lead to faster data

collection, reduced need for additional recruitment, and overall cost savings. However, when the sponsor's budget does not allow for adequate patient support, the CRO's ability to influence these positive outcomes is limited, undermining the potential benefits that could be reduced. Therefore, the financial limitations set by sponsors create a significant barrier to organisational empowerment for CROs and affect organisational legitimacy. These constraints limit the CRO's ability to manage and support patient incentives, which are crucial for the success of clinical trials. Nevertheless, emphasising the long-term cost savings and efficiency gains from investing in patient support might encourage sponsors to allocate more resources in this area, potentially mitigating some of the limitations CROs face. Therefore, we are commenting that incentive management, in this case for the non contributing members is affecting organisational legitimacy and, by that, also affecting organisational viability (referred to as how an organisation creates and maintains legitimacy) which is a constraint to further OE of the organisation. As one of the resolutions to this limitation, we are considering the increase and distribution of organisational learning impacting negotiation with the Clients, where the financial constraints would less affect non contributing members and by that the goals to be achieved. Also, by increasing organisational learning, there is an increase in viability affecting organisational legitimacy.[8]

Another finding revealed during our analysis is the relationship between incentive management and diversity. As highlighted in the interviews, ensuring comprehensive coverage of patient-related expenses—such as travel, food, and accommodation—is crucial for maintaining diversity in clinical trials. Without adequate reimbursement and support, socially marginalised patients may face financial barriers that hinder their participation in treatment. Thus, effective incentive management mitigates these barriers and promotes inclusivity, making it easier for a diverse patient population to engage in clinical research. This approach aligns with broader diversity management principles, emphasising the importance of incorporating varied patient perspectives into trials to address social disparities and enhance research outcomes. Patrick- Lake B. (2018) highlights that organisational diversity can introduce complexities in optimising patient engagement and managing potential conflicts of interest, emphasising the importance of strategic approaches and regulatory frameworks like the FDA's Patient-Focused Drug Development program.[22] On the other hand, diversity in management plays a crucial role in fostering a sense of community and improving access to information, indirectly enhancing professional empowerment.[6,23] In our context, incentive management supports the diversity of patients as non contributing members of the clinical research ecosystem by reducing social barriers, enabling broader participation, and fostering greater engagement among diverse participants. In addressing diversity, we noted cultural barriers as very important to overcome.

Additionally, our analysis underscores the significance of social interaction and patient education in incentive management. This form of incentive management addresses multiple patient needs by fostering a supportive community and increasing their understanding of their conditions and treatment options. By enabling patients to engage with others and access vital resources, incentive management empowers them individually and contributes to their overall commitment to the clinical research process. This approach exemplifies how comprehensive incentive management can play a pivotal role in enhancing patient involvement and addressing the diverse needs of the research population.

Several limitations of incentive management as an organisational empowerment (OE) component in patient engagement were noted. A primary concern is the challenge of measuring and quantifying the impact of incentives on achieving organisational goals. Although incentives can indirectly motivate organisational members, their direct implications and effectiveness in reaching specific goals remain complex. This limitation is further compounded by the need for a focused department to enhance patient centricity, demonstrating organisational empowerment. However, more than this focus is needed to fully address the broader challenges posed by regulatory constraints and their implications for the OE model, as these constraints can limit the application and effectiveness of incentive management.

Based on those and other findings noted, we are considering that membership role function shift is required for enhancing patient engagement in way to have patients more involved in decision making process. Currently, regulators are also advising more involvement, and in reality this is possible to the certain extent through use of the "patients experts" and patient groups primarily. However, patients involvement in the majority of the processes remains limited and from this reason they were considered as Non contributing organisational members in this research. Based on the findings we are considering importance of paradigm shift from patients as Non contributing members towards Contributing organisational members. This shift might be based on the shaded progress (gradual) among the levels of

contribution between the contributing and non contributing function rather then direct switch to contributing function due to complexity of the processes, but also due to high level of asymmetry of information.

Conclusion

The clinical trial ecosystem is a multifaceted network crucial for effectively executing clinical trials involving various interconnected components and stakeholders. Researchers, clinicians, patients, regulatory bodies, sponsors, funders, ethics committees, and healthcare institutions are central to this ecosystem, collaborating to advance medical knowledge and improve patient care. Each entity plays a vital role with the surrounding community in ensuring the successful conduct of trials, from designing and managing studies to analysing results and implementing new treatments.

As we look toward the future of global health, both internal and external factors suggest that solutions might lie within clinical research. This research could pave the way for new drugs, therapeutic procedures, best practices, and medical devices that address pressing health challenges. Contemporary healthcare systems are grappling with issues such as equity, access to care, and varying costs of services. A shift toward a patient-centric model, which emphasises patient and organisational engagement, could drive significant progress in these areas.

Empowering patients is central to this approach, as it encourages them to take a more active role in their healthcare. This active involvement can lead to better adherence to treatment plans and, ultimately, improved health outcomes. Patient engagement transforms individuals from passive recipients of care into active partners in their health journey, fostering a sense of ownership and responsibility essential for achieving long-term health goals.

In parallel, Organizational Empowerment (OE) is critical in aligning organisational goals with patient-centricity principles. OE initiatives aim to empower patients and providers in healthcare, creating a more collaborative and effective care environment. Contract Research Organisations (CROs), instrumental in managing various aspects of clinical trials, are critical players in this process. By ensuring efficient and high-quality research, CROs contribute to a healthcare ecosystem where patients and providers are empowered to achieve better outcomes. Empowerment at individual and organisational levels is vital for enhancing the patient-centric model, which can address uncertainties and add value across the healthcare spectrum. Theories of empowerment, such as Peterson and Zimmerman's model, offer a framework for understanding how CROs can act as change agents within clinical research. By fostering empowerment within these organisations, we can further improve patient engagement and advance the overall effectiveness of healthcare systems. In this research, we have extended the Peterson and Zimmerman 2004 model with additional processes and outcomes based on the systematic literature search. We have incorporated those into a nomological network as a basis of the theoretical framework.

We acknowledged the ongoing debate regarding membership as a central concept in organisational theory and its shift towards a more nuanced understanding of the relationship between organisations and those associated with them. We contribute to this discourse by emphasising that any analysis of Organizational Empowerment (OE) must clearly define membership roles within the research scope, challenging the conventional assumption that membership is a self-evident category. Our approach applies the concept of organisational contributorship as the foundational premise for organisational existence, which was applied to our findings to explain participant roles and their interactions with OE components. This approach bridges organisational theories and OE, addressing an underexplored area in current research.

Our analysis of incentive management, which encourages participation through rewards and cost reductions, focused on enhancing empowerment within the company's employee-centric and innovative environment. Effective incentive strategies encompass financial and non-financial rewards, such as skill development opportunities, but their success hinges on understanding the motivations driving employees and external stakeholders. Tailoring these programs to align with cultural and technological factors can boost engagement, productivity, and organisational sustainability. By applying Grothe-Hammer's concept of contributorship over traditional membership, we better understand how individuals contribute to organisational goals. Interviews revealed that while the importance of incentive management is recognised, its practical application is complex. Internally, it primarily targets employees as critical contributors to decision-making, whereas externally, it involves patients who, despite limited decision-making power, significantly influence outcomes in Contract Research Organizations (CROs). The distinction between members and contributors is particularly significant in healthcare, where regulatory constraints limit patient influence, even as their input remains crucial to organisational decisions.

The organisation's commitment to patient-centricity reflects its dedication to empowerment in underrepresented settings. Creating specialised departments improves communication and aligns employees with patient engagement goals. The company progresses toward broader objectives by equipping staff with essential information and knowledge. However, integrating patients—classified as Non-Contributing Organizational Members—into incentive management is necessary despite clinical research's ethical and regulatory complexities. External services like concierge support offer ethical solutions that maintain confidentiality and ensure unbiased trial participation.

Our analysis underscores the link between incentive management and diversity in clinical trials. Addressing social and financial barriers is crucial for maintaining diverse participation and preventing marginalisation due to resource constraints. Effective incentive management supports diversity principles by including varied patient perspectives and enhancing research outcomes. Overcoming cultural barriers and regulatory challenges is vital for fostering inclusivity and optimising patient engagement in trials. This interplay highlights the need for strategic approaches to advance organisational empowerment in clinical research.

Disclosure

The author reports no conflicts of interest in this work.

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