

# Clinical Research Monitor Burnout - Root Causes, Corrective and Preventive Action

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**Abstract:** In clinical research settings, both psychological and physical well-being are components of individual health, and they are interdependent. Both elements should be considered while assessing well-being over the long run. Burnout and work-related stress are ongoing issues in industrialized nations. Early diagnosis and treatment of job-related stress symptoms might lessen individual suffering and enhance creativity and productivity at work. Clinical research monitors are responsible for various challenging activities, including recruiting patients, monitoring and evaluating patients, and data collection, among others. Despite initiatives such as role delineation and structural changes to streamline the complexity of this position, many research monitors continue to experience burnout due to the overwhelming and demanding nature of their job. This article aims to evaluate and define the trends of burnout in clinical research, identify personal and professional traits that are linked to burnout, and discuss the root cause, and corrective, and preventive actions of clinical research to monitor burnout. To prevent burnout, strategies such as time management, prioritization, self-care, and supportive work environments need to be implemented. Burnout has a considerable impact on contemporary culture and can affect socioeconomic status and job happiness. Therefore, it is crucial to address burnout in clinical research settings to promote the well-being of research monitors and improve the quality of research outcomes. The primary goals of this article are to assess and define burnout trends in clinical research, as well as to identify the personal traits, professional traits, excessive workload, area of competence, years of experience, and work fulfillment which are associated with burnout. Also provided corrective and preventive measures.

**Keywords:** Clinical Research, Burnout, Human Multi-Tasking, Workload Stress

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## 1. Introduction

Research is renowned for its challenging and fulfilling intellectual atmosphere. Research-related stresses, however, have been recognized by multiple studies as influencing the mental and emotional health of those employed in this profession. Due to the rigorous nature of their work, the persistent lack of employees, the high expectations for quality work and cost containment, and other factors, clinical research monitors in particular confront major hurdles. These elements can cause burnout and stress at work. This study tries to assess, characterize, and identify personal and professional characteristics linked with burnout in clinical research. The essay will also examine the underlying reasons for clinical research to monitor burnout and offer corrective and proactive measures to lessen its effects. The findings of

this research are intended to inform policymakers, mental health professionals, and social media users themselves about the potential risks associated with social media use and to identify strategies to mitigate these risks. By understanding the impact of social media on mental health, we can work to create healthier and more positive online environments that support mental well-being.

## 2. Clinical Research Monitor Burnout

Although, the research work settings are highly rewarding and stimulating environments several research-related stressful elements have been documented in the renowned literature. Previous studies in clinical research settings have demonstrated the fact that burnout and work-related stress are strongly associated with highly demanding attitudes placed

towards the research workers specifically in the places where the influence of the worker is minimal. Besides this, with extreme underlying demand for quality work and cost containment, clinical research occupations are exposed to the chronic shortage of working staff members and expectations [1]. Research monitors are emphasized to do more with less. Clinical research monitors may experience professional burnout and stress for a variety of reasons, which may either worsen or improve over time. Clinical research monitors are responsible for recruiting, Identifying, and enrolling patients; monitoring and evaluating patients during active treatment and follow-up; data collection and subservience (completion of the report forms) at investigative sites are just a few of the challenging clinical trial activities that must be coordinated, organized and managed properly. Some institutions have taken additional role-delineation and structural initiatives to create specialty roles like regulatory specialist, clinical trial nursing ladder, and positions of data manager (data collection purpose only) to streamline the complex role of clinical research monitor.

This is done in recognition of the challenges and complexity of this position. However, a lot of research monitors continue to handle everything, and they are still exposed to the potential stress brought on by a job that is widely overwhelming and defined [2]. Recent literature has examined these topics. Earlier initiatives concentrated on descriptive studies in three linked fields, including medical research infrastructure, strategic planning, and role definition at the investigative sites. Several studies have identified the difficulties clinical research locations and Clinical research monitors face in terms of task load and risk for burnout, but they have also raised doubts. Nobody has explicitly mentioned clinical research monitoring burnout and professional pleasure [3]. The main goals of this article are to evaluate and define the trends of burnout in clinical research and to identify the personal traits (such as age, family status, & personal traits) and professional traits (such as presumed heavy workload, area of expertise, years of experience, type of research managed, and work satisfaction) that are linked to burnout in this specimen. Burnout is a syndrome of emotional and mental tiredness at work that has gained recent attention. It has a considerable impact on contemporary culture, especially in Western civilizations and Japan. Work serves as more than just a means of subsistence; it also contributes significantly to one's social standing and provides a sense of purpose in life, particularly for those who have rejected conventional strategies as the answer to their existential issues. Despite its importance, money never prevents nor cures burnout, unless it is viewed as the only standard of achievement [4].

The extremely high level of dedication is a significant aspect of employment as it relates to modern society. Many clinical research professionals, notably high-level individuals, get so personally invested in their job and organization that they attribute every achievement or failure to them. According to this theory, failure can be viewed as a painful experience that causes a person to lose their sense of purpose

in life and triggers a depressive illness. Work-related stress can also affect the socioeconomic status and job happiness. Contrary to stress originating from one's daily experience or environment, managing stress at work is challenging because there are typically few things that can be done to change the work environment. This is comparable to the idea of inner vs external influence, which has been proposed as a key element in the formation of coping. In actuality, job stress can occur without any particular large stressful occurrences. The collection of small, ordinary incidents may well cause significant stress. Burnout cannot be brought on by work stress alone. Professionals typically operate at high degrees if their job receives favorable feedback [4, 5]. In this article, I'll discuss the Root cause and corrective and preventive actions of clinical research monitor burnouts.

### 3. Root Cause

#### 3.1. Assigning Multiple Protocols [6, 7]

Imagine our brain functions like a computer with multiple tabs open at once. The laptop is functional, if perhaps a little slow. Tab switching requires a little more time. That's our brain, then. We switch between jobs more slowly the more tasks we have running at once. Imagine that we close some of the open tabs on our laptops. Suddenly, switching between tabs is quicker. We can feel as though multitasking is our only chance to manage the tremendous burden we deal with every day. But multitasking is a fact that cannot be denied. It makes it harder to execute each work quickly and effectively, which can make life more stressful overall. The phrase "multi-tasking" was first applied to the internal wiring and operation of computers, not to people. The phrase was used to explain how computers could move back and forth between various tasks or alternate between them. The phrase was eventually used out of context to refer to people's capacity to handle several jobs at once.

It is a proven fact through various research studies that multitasking and the assignment of multiple protocols in a clinical research setting have a direct relation with physical and mental burnout. In clinical research settings, overload burnout happens when a concerned person works longer and harder to succeed, frequently at the expense of his health and personal life. The majority of individuals are aware of this sort of burnout, which is also the most typical. Highly dedicated workers who feel forced to work at an unsustainable rate frequently experience overload burnout due to the assignment of multiple protocols simultaneously. They exhaust themselves both physically and mentally as a result of this. According to researchers, there are two ways to recover from overload burnout. First and foremost, it's crucial to strengthen your emotional regulation abilities, such as acknowledging and processing feelings and rephrasing self-defeating thoughts. Clinical research monitors may, for instance, rephrase the notion that must constantly work to succeed as "enjoying the life helps them become more successful." Resting is hardly a reward for achievement, after

all. It is necessary, especially for a clinical research monitor.

### **3.2. Assigning Multiple Sites to One CRA Simultaneously [8]**

Burnout is a complex syndrome caused by prolonged occupational stress that includes feelings of extreme weariness, interpersonal disengagement or cynicism, and a diminished sense of professional efficiency. The observed links between burnout and physician attrition, physical and mental health, and self-reported medical errors have drawn attention in the medical profession. Physician attrition brought on by burnout and decreased clinical hours cost the US healthcare system about \$4.6 billion annually. In nationwide research, nearly twice as many practicing doctors as the general public reported having at least one symptom of burnout. However, Burnout prevalence figures are not certain. The researchers have discovered that clinical research monitors who are frequently inundated with information from various sites are less able to pay attention, remember details, or switch between tasks than those who focus on a few at a time.

### **3.3. Managers Who Are Bosses Not Leaders [9]**

It is simple to understand why leadership is so important in dealing with the burnout of clinical research burnout. Leaders establish the culture and expectations. Additionally, bosses and managers drive their employees too frequently to cede too much of their sense of power. The boss is frequently given control over their work schedule, projects, deadlines, and decision-making processes. The CRA has less autonomy the more the supervisor micromanages and based on a wealth of studies, we are aware that autonomy, a feeling of control over someone's life and decisions is a fundamental requirement for all people. We need to be careful whenever we take anything away, even in small amounts.

### **3.4. Tight Timelines**

Clinical trials require tight deadline adherence from monitors to guarantee that the research proceeds as intended because they are time-sensitive. But doing so could lead to strain and exhaustion. The CRA has to work continuously with a short lunch or tea break and work for hours and hours. Even leaves are not granted for refreshments or outings i.e., he/she can mitigate his stress and mental fatigue.

### **3.5. Lack of Social Support**

When the job place is monotonous or chaotic, CRA has to isolate himself to mitigate the workload which leads to feeling stressed and uncomfortable and indulged in burnout condition.

Moreover, if could not get moral or social support or motivation he/she may lead to extreme consequences.

## **4. Consequences of Job Burnout [15]**

Job burnout can have serious repercussions if ignored or

untreated, including:

1. excessive anxiety
2. Insomnia
3. Anger, sadness, or irritation
4. Fatigue
5. Diabetes type-2
6. Abuse of alcohol/other drugs
7. Heart Problems
8. Higher blood pressure
9. Availability to diseases

## **5. Corrective Actions**

### **5.1. Not Assigning More Than Two Protocols at a Time [7, 9]**

Adding structure to the day and paying attention to the purposeful transitions from one protocol to the next one will help the CRA avoid burnout by preventing the overflow of his job from the professional life. This may appear to be an impossible undertaking given that all the CRAs need to prioritize the requirements for mental and physical well-being at this time by reducing stress and optimizing pauses. If it becomes difficult for a clinical research associate to manage multiple protocols within the assigned timeline, then he/she must be confident enough to prefer his physical and mental health over other financial benefits. Working within the capacity is the best solution to deal with this burnout.

### **5.2. Site Assignment Should Be Discussed [8, 9]**

Forcefully imposed work significantly affects the physical, mental health, and overall productivity of a CRA. That's why it is very important to take care of the overall health of CRA by discussing all the aspects of the site before assigning it to any CRA. Otherwise, it can cause severe alcohol abuse, irresponsible behavior, isolation, and anger as personal and dissatisfaction from the job as professional consequences for a CRA.

### **5.3. Managers Should Be Reminded That Staff Retention Is Their Responsibility [10]**

Managers are what make a great company. They assist their team's long-term performance by fostering culture, communication, employee engagement, productivity, and morale. In a company's backbone, competent managers link workers to leaders and are in charge of inspiring everyone to work together for collective success. Managers are responsible for a lot, including goals, initiatives, communications, and team dynamics, in addition to growth and profit. Due to consistent pressure, they run a significant risk of making their employees burn out. By assisting them in striking a balance between their personal and work lives, we can enhance the CRA and managers' well-being. CRA will avoid burnout and have more time to concentrate on their work if new initiatives that provide extra time off, flexible working hours, child support, or project re-delegation are implemented.

## 6. Preventive Actions

### 6.1. Stop Micromanagement [11]

Understandably, leaders would resort to micromanaging while juggling the responsibilities of the job, the demands of the leadership team, and the requirement to sustain productivity. But it is completely a wrong approach.

Micromanaging should be avoided by:

- a) Recruiting the right people with the required skills.
- b) Having structured, informal, and consistent communication channels.
- c) Making the peers answerable.
- d) Not expecting perfection as mistakes are a significant factor of continuous learning.

### 6.2. Management Training Is Necessary to the Burnout [12]

A manager needs to have the team-leading ability for being able to take his team productively, especially in clinical research settings. For this, it is necessary to arrange induction management skill training before hiring any manager. Managers must learn how to connect with their subordinates to make them feel comfortable, how to effectively respond to their queries, organize work and sketch a working model for their team.

### 6.3. Early Detection of the Burnout State with the Support of Digital Devices [13]

Using modern technology identification of the burnout stage using a wearable gadget can be monitored using the Heart-Rate (HR), peripheral capillary oxygen saturation (SpO<sub>2</sub>), and Galvanic-Skin (GS) values are examined using data acquisition followed by local and remote optical wireless communication (OWC) technology, etc. And a fast estimation of the burnout state is obtained using an artificial neuronal network (ANN). Early identification of burnout assists individuals to improve their physical and mental well-being.

### 6.4. Foster a Supportive Workplace Culture

Employers may foster a positive workplace culture by fostering open communication, fostering chances for social contact, and acknowledging accomplishments. Motivation and a supportive environment not only enhance working capability but also improve mental health.

### 6.5. CRA Should Be Awarded for Excellence [14]

It is not mysterious or difficult to understand how pleasure affects a person's health. To support this, studies have shown that happiness promotes glowing optimism, a considerable decrease in stress, good blood pressure levels, and improved sleep habits. In other words, ensuring that your staff members are happy in every manner possible will support their mental health and ultimately help them avoid burnout. Now the question is, what can make CRAs happy? Well, the most important dimension of happiness is the recognition of

someone's effort and regard for it. Employee pleasure and delight can rise with reward and recognition reducing the likelihood of burnout.

## 7. Conclusion

In conclusion, the research findings suggest that incorporating mindfulness meditation practice into the daily routine of college students can have significant positive effects on their mental health and academic performance. The study showed that practicing mindfulness meditation led to a reduction in symptoms of anxiety and depression, as well as an increase in feelings of well-being and happiness.

Burnout among clinical research monitors is a significant problem that may have an impact on both their health and the effectiveness of their work. By controlling workload, offering training, encouraging work-life balance, creating a positive workplace culture, and keeping an eye on workload and stress levels, organizations may take action to solve this issue. Employers can guarantee that monitors can carry out their responsibilities efficiently and retain their well-being by addressing the underlying causes of burnout.

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