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Staffing Strategies for Sponsors During Each Phase of the Clinical Research Life Cycle

Clinical research is the cornerstone of developing safe and effective new drugs and therapies. Despite the industry's robust growth, projected to reach $69.8 billion by 2027[1], a significant challenge persists: finding qualified personnel for clinical trials. High turnover rates among clinical research associates, reaching 32% in the United States[2], underscore this pressing issue. To address this staffing shortage, this guide offers effective strategies tailored to support each phase of the clinical research life cycle.

Preclinical Phase

The preclinical phase involves robust research into the proposed treatment with a focus on laboratory and animal studies. During this initial phase of the clinical research life cycle, researchers evaluate preliminary efficacy, toxicity, safety, and pharmacokinetic data. The preclinical phase is critical for determining whether the drug is safe enough for human trials.

Key Staffing Needs

The preclinical phase requires specialized staff, such as:

- Pharmacologists
- Toxicologists
- Regulatory experts
- Animal technicians

Expertise in good laboratory practice and detailed knowledge of regulatory documentation is essential. It's also important to hire experienced regulatory affairs professionals, though this can be a daunting task with an average of 35 jobs posted per experienced professional in this field.[3] Working with a life sciences staffing agency such as Medix can help streamline the process of finding the right talent.

Staffing Strategies

It's best to assemble a cross-functional team from the earliest phase of the research process to streamline the transition to subsequent clinical phases. Sponsors must source niche talent specific to the needs of the trial with ample experience in preclinical research and regulatory compliance.

Phase I: First-In-Human Trials

In Phase I of a clinical trial, humans receive the drug for the first time. Phase I typically involves just 20 to 80 people.[4] During this phase, researchers focus on safety, tolerability, pharmacokinetics, and pharmacodynamics to determine the appropriate dosage range and potential side effects of the medication.

Key Staffing Needs

Phase I requires a team consisting of:

- Clinical research associates
- Medical monitors
- Medical personnel
- Clinical staff
- Biometrics staff

The first-in-human clinical trials create a high-stakes environment that requires highly experienced personnel. Unfortunately, these skilled employees are often difficult to find. The healthcare industry is experiencing its highest resignation rate ever, nearing 3%.[5] In 2021 and 2022, clinical trial sites reported an 80% to 100% turnover in regulatory staff.[5] These trial sites also reported losing 50% of their experienced research team.[5] Sponsors face the challenge of **finding experienced team members** who can lead trials and perhaps mentor newcomers to the field, who pick up the slack from the great exodus from healthcare.

Staffing Strategies

It's important to recruit personnel with specific experience in early-phase trials to ensure robust safety measures and monitoring. Sponsors can assemble a blended staff consisting of full-time employees and contract workers to maintain phase flexibility.

Throttle Outsourcing Everything to a CRO

The first phase of research is the most critical! Establishing a comprehensive safety profile demands substantial data and resources. CROs, while valuable, often split their focus among numerous clients, which may not provide the dedicated attention your study needs. Given the relatively small patient enrollment and the limited number of sites involved, it might seem acceptable to outsource clinical management. However, consider hiring internal data managers and biostatisticians to ensure seamless data collection, analysis, and overall integrity. This approach will help safeguard your study's quality and reliability from the outset.

Phase II: Efficacy and Dose-Response Studies

Phase II introduces the drug to a larger group that typically consists of 100 to 300 participants.[4] Though researchers continue to monitor safety, the focus shifts more toward the effectiveness of the medication. In Phase II, researchers attempt to identify the optimal dose.

Key Staffing Needs

Phase II requires experienced project managers who can handle the increased number of participants and complex trial protocols. These managers must also skillfully manage a diverse team. Hiring needs for Phase II include:

- Biostatisticians
- Clinical project managers
- Clinical data managers
- Site augmented staff

Staffing Strategies

In Phase II of a clinical trial, managers can leverage the functionality of technology and data management tools to enhance trial efficiency. As the trial expands, the entire team must scale up to accommodate its growing needs. Effective communication channels are critical to properly disseminate information between different functional areas.

Provide Resourcing to Your Sites

The challenges of recruitment often start to emerge during Phase II. At this stage, activating multiple sites and recruiting a significant number of patients becomes crucial. There may be instances where a site lacks the necessary resources or struggles to meet expectations after activation. As the sponsor or CRO, you can support site performance by providing dedicated, site-based resources to enhance productivity and ensure the study's success.

Phase III: Large-Scale Efficacy Trials

Phase III confirms the effectiveness of the drug by testing it on a population of approximately 300 to 3,000 individuals.[4] These studies take place across multiple test sites and may include global participation for ample diversity in the test subjects. Studies often continue for several years to evaluate the long-term effects of the medication. Phase III confirms efficacy, monitors side effects, and provides the data for regulatory approval.

Key Staffing Needs

Phase III's large-scale efficacy trials require skilled management personnel to handle the complexities of scaling the study to include multisite and multinational trials. During this phase, there's a high demand for:

- Clinical data managers
- Site coordinators
- Regulatory affairs specialists
- Clinical research associates

Staffing Strategies

Phase III involves large-scale operations that are most efficient with a mix of full-time and contract staff. Global coordination strategies are necessary to manage this dispersed workforce effectively. Managers should emphasize the use of electronic data capture systems to streamline data collection and analysis.

Study Specific Contractors

Volume, volume, volume. As you near the finish line, this surge in workload can overwhelm even the most prepared sponsors. Extra support may become essential, and contractors can be invaluable at this stage. Whether it's additional hands in regulatory, data management, or clinical operations, partnering with a quality staffing vendor such as Medix can help you maintain momentum and ensure nothing falls through the cracks just as you're reaching your goal.

Phase IV: Postmarket Surveillance and Long-Term Monitoring

Phase IV occurs after drug approval and evaluates the drug in real-world settings. Postmarket surveillance projects monitor the drug's long-term effects to identify any adverse reactions. The data gathered during this phase is the basis for evaluating new indications or revealing long-term outcomes for the drug.

Key Staffing Needs

Postmarket surveillance requires continuous monitoring and ongoing studies to ensure compliance with regulatory standards. In this phase, the team should include:

- Epidemiologists
- Medical science liaisons
- Pharmacovigilance experts
- Regulatory affairs specialists

Staffing Strategies

In Phase IV, sponsors should develop long-term staffing solutions to ensure consistency throughout the postmarket surveillance process. It's important to build a network of experts who can quickly address emerging safety concerns and manage ongoing data collection.

Cross-Phase Staffing Considerations

Whenever possible, it's best to build cross-functional teams that understand the entire life cycle of the product. Sponsors should strive for a flexible workforce that provides a vast pool of talent capable of moving between different phases. This helps ensure smooth transitions, continuity in staffing, and efficient knowledge transfer.

Expert Staffing Solutions for Your Clinical Research

A strategic partnership with a life sciences staffing agency, such as Medix, can help sponsors overcome the **staffing challenges associated with clinical trials** and streamline the process of finding the right personnel. Medix provides tailored solutions that can meet the evolving needs of each phase of clinical trials. By maintaining a diverse talent pool of industry experts, Medix ensures easy access to the skilled personnel you need when you need them. Contact us to learn more about our **expert staffing solutions** and how our talent pool can help accelerate drug development and ensure successful trial outcomes for your organization.

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