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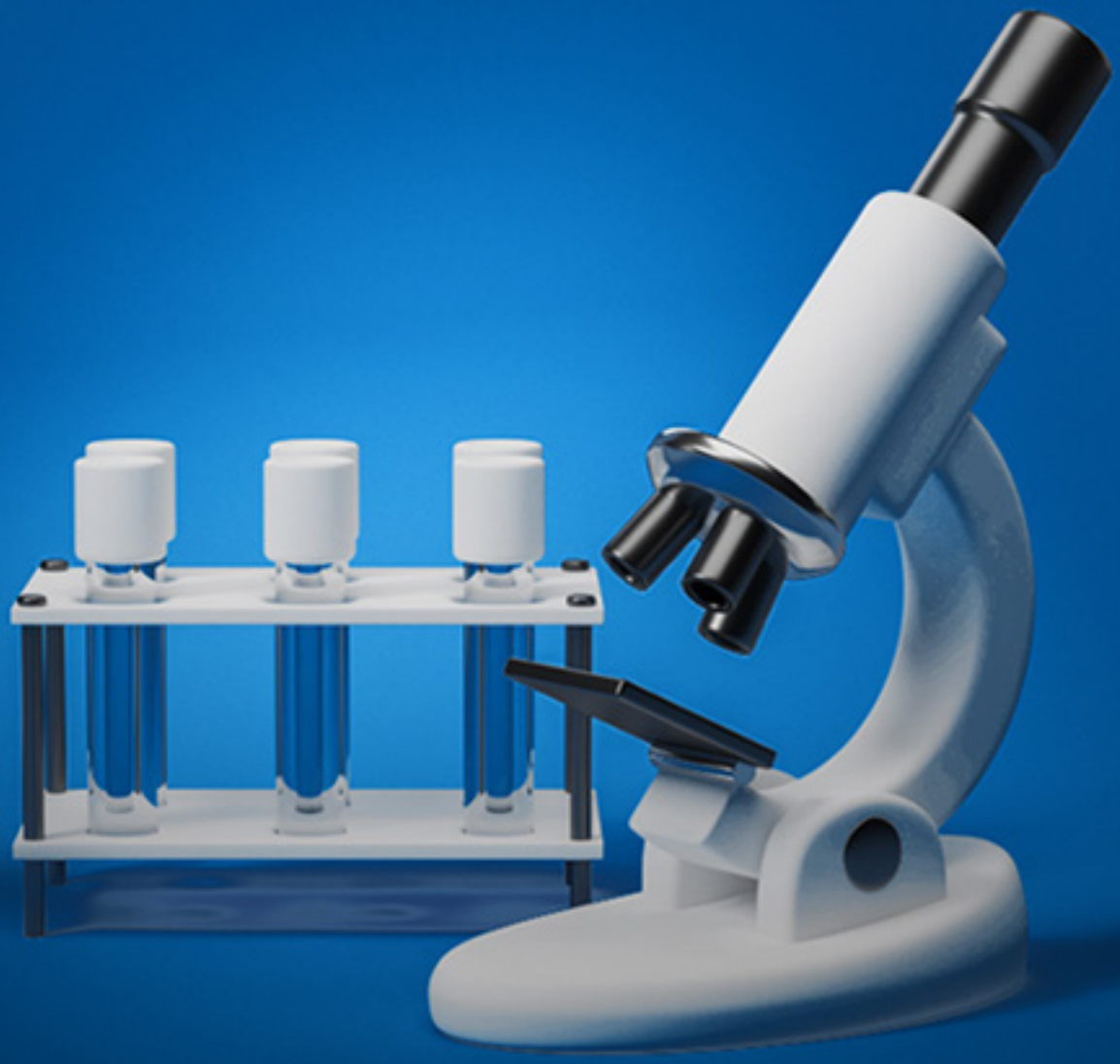
The Current State of Clinical Trial Staffing and Sustainable Staffing Strategies



Clinical trials are the continuation of research that begins in a laboratory. Researchers study the effects of treatments in cell lines and animals before investigating them in humans. Clinical trials require a team effort from many personnel and can be burdensome, expensive, and time-consuming for sponsors, staff, and participants. This guide explores the importance of staffing and patient recruitment for successful clinical trials, associated challenges, key considerations and strategies, and changes following the COVID-19 pandemic.

Clinical Trials and Their Importance

Clinical trials are prospective research studies in which a behavioral, medical, or surgical intervention is tested on humans to determine its safety and effectiveness. Interventions can include novel treatments or prevention strategies, such as medications, medical devices, vaccines, or diets. Clinical trials are essential to:

- **Evaluate the safety and effectiveness of new treatments compared to those currently available.**
- **Identify strategies to improve current treatments or patients' quality of life.**
- **Test new ways to identify, diagnose, or manage disease symptoms or treatment side effects**
- **Determine if the side effects of interventions are within acceptable limits and if the benefits outweigh the side effects.**
- **Explore prevention strategies in healthy individuals at increased risk of developing diseases**
- **Improve care for future patients.**
- **Advance medical knowledge.**
- **Make progress against diseases.**
- **Help eradicate diseases that were once incurable, such as polio.**

Importance of Staffing and Patient Recruitment for Successful Clinical Trials

Participation in clinical trials originates from physicians enrolling their patients. Participants receive free healthcare services, comprehensive diagnostic evaluation, advanced medical treatments, continuous monitoring, counseling, and education. Patients and healthy volunteers of various ages and backgrounds can contribute to the development of therapies and disease prevention strategies, especially if none exist or current methods are ineffective.

Clinical Trials Staff and Responsibilities

Some of the most common personnel involved in clinical trials include:

Principal Investigator

The principal investigator (PI) is a licensed physician with overall responsibility for the trial. They develop the study concept and budget, prepare the clinical trial protocol (CTP) detailing the methodology, and submit documents for approval to the institutional review board (IRB). They oversee all aspects of the trial, including participant recruitment, informed consent, ethical and regulatory compliance, data collection, documentation, analysis, interpretation, and publication.

Clinical Research Coordinator

The clinical research coordinator manages multiple activities. They coordinate day-to-day tasks, manage timelines, schedule visits, interview participants, and assist in recruiting and screening patients. They ensure all participants understand study requirements and provide consent to participate.

Clinical Research Associates

Clinical research associates (CRAs) are an important link between staff, sponsors, and patients. They identify and set up sites, develop and archive protocols, create data collection surveys and forms, and train staff to implement the CTPs. They ensure data accuracy and compliance with ethical and regulatory standards, monitor trial progress across sites, and provide regular updates to the team.

Data Manager

The data manager collects information by developing case report forms, entering records in a database, and cleaning data to ensure optimum quality. Together with the PI, they determine key figures to track, provide documentation to regulatory and monitoring agencies, and draft summaries for analysis.

Regulatory Affairs Specialist

The regulatory affairs specialist reviews patient recruitment materials before dissemination, ensures compliance with regulations, and manages documentation and submissions to authorities. They advise on policies and procedures, interpret guidelines, and evaluate regulations and laws to determine the impact on trials.

Biostatistician

Biostatisticians design the study, calculate sample size, define endpoints, ensure proper randomization, and prepare the statistical analysis plan. They analyze data, interpret results, draw conclusions, and create tables and figures for reports.

Drug Safety Officer

The drug safety officer evaluates and monitors the efficacy, safety, and quality of medications. They detect and manage adverse effects and determine the risk-benefit ratio of the investigation product.

Medical Monitor

The medical monitor is a physician and the sponsor's spokesperson. They examine protocols, evaluate safety, and advise staff on ways to assess safety events. They ensure that manufacturing practices, standard operating procedures (SOPs), and regulatory measures align with standard requirements.

Quality Assurance Specialist

Quality assurance specialists ensure trial data adhere to protocols and comply with regulations and SOPs. They review screened participants to determine eligibility before randomization and data for quality control. They conduct regular audits to maintain accuracy in data collection and management.

Study Physicians

Study physicians are medical doctors who provide treatment and care to participants according to the CTP. They monitor, evaluate, and document participant responses and treatment side effects. Together with the PI and research nurses, they identify and discuss trends in participants' responses to study treatment.

Research Nurses

Research nurses explain the study methodology to participants, administer medications, monitor side effects, and report observations to physicians. They assist in informed consent, data collection, management and analysis, quality assurance, and audits.

Considerations for Staffing Needs

Staffing needs can vary based on the study size and complexity, location(s), timeline and duration, budget, required expertise and qualifications, and regulatory requirements.

Study Size and Complexity

Enrolling an adequate number of participants is essential to obtain reliable data and results, draw accurate conclusions, and extrapolate findings to the wider population. Large, complex, and multicenter trials may require more staff.

Study Location(s)

Study location(s) can include hospitals, clinics, and government, nonprofit, or private sites. They should have all essential capabilities to conduct trials, particularly the required number of staff, patient pool, and adequate space for studies, drugs, devices, documents, and equipment.

Study Timeline and Duration

The study timeline and duration depend on the trial type and phase and can span months to years. Correctly estimating the required number of sites, timelines, and duration can result in complete trials, sufficient data, and study success.

Study Budget

Clinical trials cost millions of dollars. Funding will only be granted if the proposed budget is reasonable. Funding is primarily allocated based on the number of participants, number of procedures, and study type, size, location(s), and duration. Other considerations include startup fees, patient care, personnel salaries, data collection, and site costs. Although budgets, including administrative costs, can be negotiated with sponsors, pricing is competitive.

Required Expertise and Qualifications

All staff should possess the requisite credentials necessary for their specific roles. PIs, medical monitors, and physicians should be licensed medical doctors. Research nurses should also be licensed. Other staff should possess advanced medical, health, or science degrees. Senior staff should preferably be experienced in clinical research.

Regulatory Requirements

Regulatory requirements include obtaining necessary approvals from IRBs, government, and health authorities on the use of human participants and regulated products.

The Importance of Staffing in Clinical Trials

Adequate staffing can ensure smooth trial operations, efficient data collection, accurate analysis of results, and appropriate drawing of conclusions.

Benefits of Well-Staffed Clinical Trials

Some benefits of having well-staffed trials include:

- **Increased efficiency in service delivery**
- **Manageable workloads**
- **Energized and motivated staff**
- **Diligent compliance with regulatory measures**
- **Proper implementation of the CTP**
- **Higher quality of care for patients**
- **Improved safety and outcomes**
- **Increased participant satisfaction**
- **Better staff retention**
- **Cost savings**

Although expensive, hiring experienced staff is cost-effective.

Challenges Faced in Clinical Trial Staffing

Several challenges are associated with staffing for trials, namely a shortage of qualified personnel, high staff turnover rates, difficulty finding staff with appropriate language skills and cultural competence, and limited availability of specialized staff.

Shortage of Qualified Personnel

There is a serious shortage of qualified and trained staff to conduct and manage trials, particularly PIs, CRAs, coordinators, and site monitors. Academic institutions, in particular, are struggling to fill vacant positions. Many experienced personnel are in the advanced stages of their careers or have abandoned the profession altogether, especially after the pandemic. As a result, newer staff need more training and direction.

High Staff Turnover Rates

High staff turnover rates have been observed, particularly among CRAs. Common reasons include exhaustion, stress, burnout, lack of career advancement opportunities, and reevaluation of priorities. On-site staff often experience overwhelming workloads and long working hours to accommodate diverse schedules and meet timelines. Those working closely with patients fear the increased risk of developing illnesses. Many find traveling cumbersome.

Difficulty Finding Staff with Appropriate Language Skills and Cultural Competence

The drastic mismatch between supply and demand for staff has also led to difficulties in finding qualified, specialized personnel with appropriate language skills and cultural competence. Standard approaches to recruitment could be more effective.

Limited Availability of Specialized Staff

There is limited availability of specialized staff, particularly PIs and CRAs. Many PIs are reluctant to conduct trials due to administrative, financial, ethical, and regulatory hurdles and lack of institutional support.

Key Factors in Staffing Clinical Trials

Many organizations prefer to source staff regionally to avoid delays. Key factors to consider when staffing trials include recruiting qualified personnel, ensuring staff can adapt to changing circumstances and protocols, finding people with diverse backgrounds and skill sets, conducting staff training and development, and implementing engagement and retention programs.

Recruiting Qualified Staff

Recruiting qualified and experienced staff is necessary for operating trials smoothly, developing skill sets in junior personnel, honing good clinical practices, and creating a positive impression among patients. Qualified staff can be identified and recruited through career and job sites, social media, networking events, and staffing agencies. Databases can be useful for recording candidates' details to build a constant pipeline of staff for current and future assignments. Resource management platforms can be used to source, train, and deploy **new talent** and potentially mitigate staff shortages.

Ensuring Staff Adapt to Changing Circumstances and Protocols

Staff who are flexible and alter their strategies to adapt to changing circumstances and protocols drive the most successful patient recruitment efforts. Hiring dual-role staff to provide patient care and perform research activities can equip them to handle unexpected protocol deviations. At times, participating physicians must be available to attend investigator meetings and conduct physical examinations and patient assessments beyond regular working hours. Staff in charge of patient recruitment must be available to call patients at night and on weekends.

Benefits of Staff with Diverse Backgrounds and Skill Sets

Staff with diverse backgrounds and skill sets can:

- **Develop into subject matter experts.**
- **Provide trial navigation services to underserved patients.**
- **Connect patients with culturally sensitive education materials and support resources.**
- **Engage and partner with community-based organizations and minority groups to recruit patients.**
- **Advocate the importance of trial participation in specific locations.**
- **Help overcome mistrust among patients seeking to participate in trials.**

Importance of Training and Development Programs for Staff

Training and development programs are necessary for better quality of services, smooth operations, consistent results, and improved outcomes. Establishing formal training programs for new staff is crucial, as they may need to gain the necessary experience. Implementing a comprehensive curriculum with instructor-led training and workshops, a hands-on experience, and mock or simulation visits is ideal. Providing individually-tailored skills development, coaching, and mentoring are crucial for developing the necessary technical expertise and soft skills in staff.

An understanding of the basics of clinical research is required, in addition to medical education and clinical experience, to prepare staff to conduct trials. In a clinical trial, analysis (evaluating interventions) and care delivery (treating patients) are performed differently. Hence, staff must understand various trial designs, prevailing laws and frameworks of trial operations, and relevant technologies.

Besides completing basic research training requirements, research nurses and CRAs should be provided with real-world lessons and urged to pursue specialty certification in clinical research, as they are generally not trained to conduct trials. All staff should know about the trial and special requirements associated with the study medication. Upskilling staff to develop proficiency in technological solutions is crucial to improve overall efficiency in discharging services.

Staff Engagement and Retention

Trial staff are in high demand, and this demand is expected to grow further. Some ways to ensure staff engagement and retention include:

- **Fostering teamwork**
- **Holding regular meetings to discuss updates, concerns, and progress**
- **Recognizing accomplishments**
- **Assigning mentors to train staff to balance work, study, and domestic obligations**
- **Establishing professional development and cross-training activities**
- **Encouraging staff to complete certifications to take on newer or advanced roles, avoiding redundancy**
- **Supporting staff to pursue nonlinear career pathways by investing in their education**
- **Reimbursing tuition costs**
- **Developing an internal promotion system**
- **Redesigning roles and work across multiple fronts**

Patient Recruitment for Clinical Trials

The most critical and arduous aspect of clinical trials is recruiting the required number of patients. Under-enrollment can affect the scientific validity of the study, raise ethical concerns, and cause premature termination, wasting time, resources, and money.

Importance of Patient Recruitment for Successful Trials

Efficient recruitment of evaluable patients is critical to ensure successful and timely completion of trials. Recruiting patients of different ages, genders, races, and ethnicities helps to extrapolate findings to a broader population and discover important safety information about the medication. For instance, many older adults have different health needs from those of younger people. They may also react differently to certain medications, have different side effects, and need different dosages to produce the intended result. Hence, enrolling older adults in trials can enable researchers to develop appropriate treatments for this specific age group.

Cost of Patients Dropping out of Clinical Trials

The actual cost of patients dropping out of clinical trials far exceeds recruitment costs. Across trials, about 30% of patients drop out, resulting in heavy financial losses for sponsors. The cost of recruiting a new patient to replace a dropout is usually higher than the initial cost. Dropouts can cause expensive delays and wasted time and resources, resulting in potential losses of up to $600,000 per day. Besides the financial aspect, dropouts can also lead to a loss of valuable data, insufficient results, and trial discontinuation.[1]

30% Drop Out

of clinical trials

$600,000 Loss

(potential) per day due to dropouts

Challenges in Patient Recruitment

Recruiting patients is the most challenging part of trials. It requires considerable planning, evaluation, and revision. Some trials may have additional inclusion criteria, which can make enrollment complicated. Patient enrollment is rarely completed on schedule, as it can be difficult to identify a strong pool of eligible patients in specific locations, particularly for rare diseases. Enrolling adequate numbers of elderly patients is also challenging due to frailty, disability, and comorbidities. Other factors include:

- **Lack of awareness of trials among patients**
- **Unfamiliarity with what clinical research entails**
- **Lack of education and knowledge about diseases**
- **Poor outreach in underserved communities**
- **Under-representation of ethnic, racial, and minority groups**
- **Accessibility issues (lack of transportation to recruitment centers)**
- **Communication issues**
- **Language barriers**
- **Fear of study procedures, treatment side effects, and poor compliance**
- **Lack of support from physicians and family members**
- **Scheduling conflicts**
- **Financial, social, and religious issues**
- **Negative media publicity**
- **Ethical considerations in the case of terminally ill or elderly patients**

Slower-than-expected patient recruitment can delay drug development, resulting in the loss of millions of dollars in revenue.[2-4]

Strategies for Successful Patient Recruitment

A critical requirement of trials is having a large patient population. Developing well-planned and effective patient recruitment strategies within the allotted budget and timelines can prevent low accrual. Investigators often face challenges in identifying efficient and cost-effective recruitment strategies. Some of the most successful patient recruitment methods include:

- **Maintaining lists of current studies on sponsor or public websites, including study purpose, eligibility criteria, site location(s), and contact details**
- **Scanning an institution's patient database or electronic medical records**
- **Contacting primary care physicians (PCPs) and obtaining patient referrals**
- **Sending mass mailings using personalized messages**
- **Developing specific and targeted media campaigns (television, radio, newspaper, email, and Internet advertisements)**
- **Using word of mouth**

Factors critical to successful patient recruitment include:

- **Definition of the target audience and ideal participant demographics based on protocol requirements and location**
- **An ability to draw patients from a large population**
- **Easy accessibility to the trial location and other logistical issues**
- **Staff who can respond to numerous calls about trial participation**
- **Introductory meetings with staff to discuss study goals**
- **Endorsement of the trial by PCPs**
- **Competency of staff in honestly assessing recruitment progress**
- **The ability of staff to rapidly shift from unsuccessful recruiting measures**

Broadening eligibility criteria, if clinically feasible, can help to recruit a wide variety of participants. Some trials extend recruitment periods by a few months to overcome stringent enrollment criteria and ensure that participants and their families fully understand the protocol and can complete the study requirements. Other trials establish multiple centers for recruitment to avoid significant delays. Patient incentives, such as free medication, counseling, access to staff, and travel reimbursement, are also beneficial.

Special efforts must be undertaken to overcome cognitive and literacy issues during outreach in underserved communities. Letters to patients can be complicated and ineffective, unlike face-to-face conversations with their PCPs. Children may be able to express their desire to participate depending on their age and study complexity.

How COVID-19 Affected Clinical Trials

The COVID-19 pandemic highlighted many shortcomings in the clinical trial industry, namely staff shortages and recruitment challenges.

Disruption to Clinical Trials Due to COVID-19

The COVID-19 pandemic disrupted trial operations. Several important trials were halted, delayed, suspended, or discontinued due to restrictions on travel and in-person visits. The resulting staff shortage negatively impacted:

- **Patient recruitment (delayed, interrupted, or slowed down)**
- **Screening procedures**
- **Data collection**
- **IRB processes**
- **Financial and legal review**
- **Audit activities**
- **Accrual to trials**
- **Data transfer to sponsors**
- **Sponsor visits**
- **Regulatory activities**
- **Trial durations (extended)**
- **Sites (closed)**
- **Protocols (deviated)**

Initiation of new, non-critical trials was temporarily halted as clinicians tended to COVID-19 patients. Up to 90% of trials suspended patient enrollment.[5-7]

Post-COVID-19 Changes in Clinical Trial Operations

Post-COVID-19 changes in trial operations include a shift to remote patient monitoring, the use of virtual trial technologies, and adaptation to regulatory changes.

Shift to Remote Patient Monitoring

Leveraging remote technologies, such as telemedicine, Internet connectivity, mobile apps, social media, and wearable biomedical devices, can mitigate financial and geographic barriers for patients and staff. Both can participate from a comfortable location without traveling. Site staff can use software to record and store data and documents and give sponsors access to remote monitoring. Staff can even recruit, screen, and obtain consent remotely, utilize at-home laboratory services, and send medications to patients. Decentralized trials provide flexibility to the industry and patients.

Use of Virtual Trial Technologies

Virtual technologies and digitization can significantly impact trial operations. Integrated systems can obviate repetitive data entry into multiple databases and systems and increase overall efficiency. For instance, if sites have a trial management system that integrates with their electronic master file, data can be entered into one system and accessed on another. Using technology to evaluate trial feasibility can save time. Recruiting staff with remote work experience and technical knowledge can even lower billing rates.

Adaptation to Regulatory Changes

During the pandemic, remote regulatory assessments were used to examine records, assess compliance with regulatory guidelines, and gain compliance insight. They were valuable in identifying deficient practices, verifying corrective actions following inspections, and mitigating risk. They can overcome travel and logistical barriers, reduce resource expenditure, and expedite regulatory approvals.

Finding the Right Solution for Sustainable Staffing

Staffing shortages affect every aspect of clinical trials. Post-COVID-19, there has been a steep decline in the number of physicians, CRAs, and other staff available to conduct and manage trials. Reasons for attrition include inflexible working conditions, burnout, desire for better pay and opportunities, lack of promotion, low morale, and trial complexity. Hence, there is an urgent need to develop initiatives to recruit, train, and retain staff.

Continuing education is necessary to ensure all staff are adequately trained and familiar with the latest approaches, requirements, and technologies in conducting trials. Using integrated systems rather than several different technological solutions can increase overall efficiency, enable remote trial monitoring, and prevent unnecessary site visits. Ensuring staff are more flexible and adaptable in scheduling visits and handling unexpected events can enable successful trial completion.

Patient recruitment is an integral aspect of clinical trials; however, there are several challenges, including logistical obstacles, perceived ineffectiveness of trial interventions, time constraints, lack of awareness, and poor outreach. Providing flexible options, results of past trials, and removing traditional barriers to access can enable diverse populations to participate in life-saving clinical research, which can help to draw more reliable conclusions about the efficacy, safety, and applicability of interventions.

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