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Short article

Clinical Trials Recruitment Challenges

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Abstract

Recruitment is a challenging phase of clinical trials due to its relevance to research success. Failure in reaching recruitment goals might implicate in trials early termination, loss of statistical power and financial wastes. For the well-trained research centers there are several key points that might be addressed as recruitment challenges: first, finding new trials in the site therapeutic area and getting proper approval at local Institutional Review Board; secondly, having a self-sustainable research institution that can hire and train high qualified staff, and lastly, getting and retaining the potential patient the consent in participating. Mistrust, communication, and cultural barriers are common reasons why patients decided not to enroll. On the other hand, altruism, access to better care and closer clinical monitoring are common motives to consent. Understanding reasons why patients decide to participate or not in clinical trials can reduce the evident gap between registered trials and studies with posted results. The objective of this work is to discuss the recruitment challenges; it's reasons and implications as well as share our barriers and strategies.

Recruitment Challenges

Achieving the recruitment goals in a clinical trial plays a critical role for the investigators and sponsors once the success of the trials is directly dependent on proper enrollment. Not recruiting the desired number of patients within the established timelines leads to trials delays that can result in early trial termination, loss of statistical power and inability to draw conclusions [1]. These grim outcomes have ethical implications once participants were exposed to a risk that cannot lead to scientific knowledge [1]. An impaired recruitment also results in time, funds and resources wasted both for the patient and for the research team which can harm investigators and institutions credibility and drive to further frustration and burnout of those who take the recruitment responsibility [1,2].

The key challenge is to recruit as many eligible patients as possible, in a minimum time without losing the trial momentum, which means attending the eligibility criteria within the protocol design, getting Institutional Review Board (IRB) approval and following the trial schedules. Those steps are different within the investigation centers geographic location once IRB's have different ethical dilemmas worldwide meaning individual timelines and specific requirements for the green light. There is a geographic contrast in registered trials amount over the globe, and it's a fact that the higher are the registered number of studies the higher are going to be the recruiting opportunities [3]. Our experience as a center based in Brazil shows that it's common to undergo delays in protocol and amendments approvals in oppose to other countries based research centers. This fact begets reduced time to achieve the recruitment goals and further small enrollment numbers.

The amount of recruiting studies is also related to research centers categorization by therapeutic area. This center specialization might narrow trials possibilities and result in hurry and anxiety to meet the recruitment goals. To overtake this barrier, the use of a patient database can improve the recruitment rates by refining screening time and lower screen failure. We see patients that are potential candidates for clinical trials, pro bono, once a year or twice a year. In that way, we create a robust and selective database with demographic data, BMI, vital signs and lab tests. Whenever there is a new study the database is a very useful tool for fast and efficient recruitment.

However, in the very best research site, there are eligible patients that decline to sign the consent form. Jo-anne Hughson and colleagues [4] reviewed the issue of recruiting culturally and linguistically diverse (CALD) older people and found that mistrust, communication barriers, and cultural barriers are the three most important issues for this population enrollment. Mistrust holds for distrust in mainstream society, the scientific community, and research institutions [4]. Communication and cultural barriers go from the complex forms and too much time with informed consent procedures [4]. The overcome of the quoted barriers can highly benefit from a prepared and qualified staff with an endeavor to build trust and establish a stable relationship with the participants.

Julie Brintnall-Karabelas and colleagues [5], evaluated by self-report reasons why individuals chose not to participate in a mental health research. The first reject cause was due to protocol issues' (36%), which comprises the length of inpatient studies and disinterest in placebo-control studies[5]. The protocol issues worsen in CALD patients, a group that represents a significant portion of diabetics with the goodwill for participating in clinical trials at our practice, including these group in the trials is only possible by staff teamwork, which means full attention to the patient needs and concerns. The feedback from those patients often includes the great staff care and the access to qualified medical care as a determinant for their enrollment.

This insight agrees with commonly cited reasons why patients take part in the trials. Usually goes from an altruism wit to the understanding that research participants may receive better care with closer clinical monitoring, may have earlier access to experimental treatments and technology and may have an improved health outcome. Those feelings need to be pondered with the fact that occasionally participating in a study can consume personal time and money to get to the research center, to wait for the study procedures and to complete required forms, in particular for those with physical fragilities and visual and hearing deficits. In Brazil, patients cannot be paid to participate in clinical trials, and that makes the access to a specialized and qualified medical care the greatest benefit for the research patients, and it, however, many times does not surpass the personal time and money required to attend a trial.

Succeeding in all the exposed loses, it's meaning if the enrolled patient is the unwillingness in keep participating and attending to trials commitments. Research centers based in areas with a broken healthcare system as ours are challenged to adjust the protocol schedule to a different reality that it was designed. Protocol visits end up being the only medical appointment for the enrolled patient and sub-investigators needs more time than established with the patients and often more visits and more laboratory work than foreseen. To promote patient's retention, it is also part of our routine to add telephone calls and short message services (SMS) reminders.

The need for clinical trials is increasing worldwide due to new diseases and the development of new drugs for both new and old diseases. The number of registered studies had more than doubled in a period of six years: until May 30, 2016 there were 216,468 registered trials in a parallel with 101,158 studies registered in 2010 [6]. Figure 1 compares the registered studies with the registered studies with posted results since 2009.

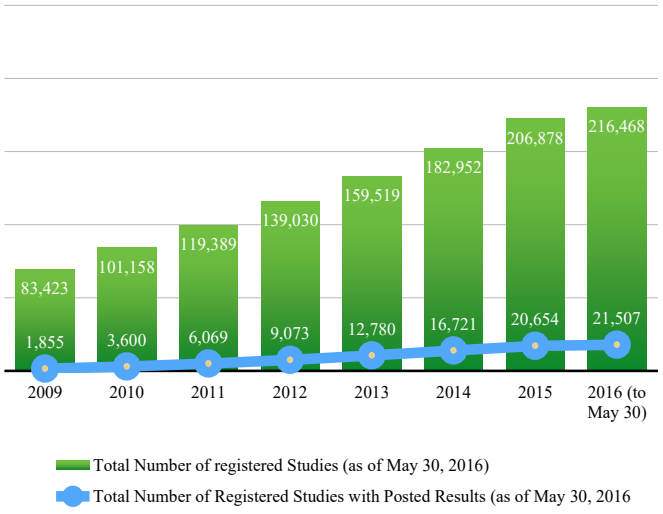

Figure 1. Total Number of Registered Studies and Total Number of Registered Studies with Posted Results (as of May 30, 2016)

The evident gap between registered studies and studies with published results has multifactorial reasons but for sure is also consequence not only of a low patient recruitment but also of an impaired patient retention.

Conclusion

The consequences of not achieving recruitment goals in clinical trials can be as worrisome as no validation of the trial by loss of the statistical power. Financial, time and credibility wastes for both the patient and the research team are also relevant outcomes of impaired recruiting. Due to the relevance of this study phase, it's important to share in literature success strategies of patient recruitment and retention.

It is a fact that IRB's are diverse, and that implicates in dissonant timelines for approvals and consequently dissonant studies availability per geographic region. To attend to the straight deadlines, our experience of a database has shown good results by highlighting potential patients within the eligibility criteria and smoothing the recruitment process.

High qualified staff and infrastructure at the research sites go beyond the suitable protocol following, it is also paramount to

patient's recruitment. Our experience has demonstrated that patients trust better when there is a good staff-patient relationship. However, promoting standard assistance often implicates in unforeseen financial costs and protocol adjustments, as extra visits and telephone contacts.

Although recruiting and retention are challenging, there are many missed opportunities for those who can benefit from clinical trials once research can give access to standard healthcare attention to underrepresented groups.

References

1. Elizabeth M, Jamie R. Barriers to Clinical Trial Recruitment and Possible Solutions : A Stakeholder Survey. Applied Clinical Trials. 2015:1-8.

2. Institute of Medicine. Public Engagement and Clinical Trials: New Models and Disruptive Technologies: Workshop Summary; 2012.

3. Map of All Studies on ClinicalTrials.gov.

4. Hughson JA, Woodward-Kron R, Parker A, Hajek J, Bresin A et al. A review of approaches to improve participation of culturally and linguistically diverse populations in clinical trials. Trials. 2016; 17(1): 263.

5. Karabelas JB, Sung S, Cadman ME, Squires C, Whorton K et al. Improving Recruitment in Clinical Trials: Why Eligible Participants Decline. J Empir Res Hum Res Ethics. 2011, 6(1): 69–74.

6. Trends , Charts , and Maps. 2016, 136: 2-5.