Efficient Patient Recruitment is the Ultimate Key to Success in Clinical Development

Trials often struggle when recruiting and retaining patients, which can lead to high failure rates. Ursula Türcke at FGK Clinical Research explains to *ICT* what factors could be causing this struggle, and how they might be overcome

***ICT*: Why is efficient and effective patient recruitment such an important part of organising clinical research?**

Ursula Türcke: The goal of each clinical development is to demonstrate the safety and efficacy of a product, as well as an increase in the quality of life for patients after the optimal dose has been determined. To achieve this, different patient populations must be treated in different phases in a double-blind manner and ideally against placebo within the framework of clinical studies. CROs can contribute a great deal to the success of a clinical trial by helping the sponsor in planning and execution – deploying their know-how, contacts, processes, infrastructure, electronic systems, and, last but not least, their specialist staff.

All of these factors ensure professional and efficient support for a sponsor. However, CROs themselves cannot provide access to study subjects, without which nothing runs in clinical trials.

For this crucial step of efficient patient recruitment, one needs appropriately qualified and equipped study centres and physicians who treat patients with the target indication and who can select and inform them about the study, and obtain their informed consents. For example, the sponsor may have developed a product that has shown promising results in preclinical tests. Or, the CRO may have set up a regulatory-approved study by creating a clear study protocol on time, submitting meaningful essential documents to regulatory authorities and ethics committees, programming a user-friendly eCRF and integrating necessary laboratory partners. In short, providing the study infrastructure according to the joint planning, and yet, such a study would already be inevitably doomed to fail if the centres do not enroll patients in the planned recruitment period.

After all, running a clinical trial with all the components involved costs a lot of money. Every month of prolongation due to inefficient patient recruitment costs more.

What are the reasons study sites don't include patients?

The main reason is often a lack of personnel. Participation in a clinical trial is very labour-intensive for study centres. Patients must be selected, treated, and cared for, and all data must be documented in accordance with GCP. Even if the head of the institution has the scientific interest to conduct the study, this does not mean that the site staff,

who have to do most of the study work, have the time and energy to do so. Often, clinical studies have to be run alongside routine clinical work, and regular care of patients simply has priority.

Another important reason is that study investigators are often not involved early enough in the study planning. If problems such as a overly-complicated study protocol, or strict inclusion and exclusion criteria, are not communicated, discussed, and fixed at an early phase of a study, this can significantly hinder effective patient recruitment.

Certainly, another reason for low patient recruitment is fear or caution. Who wants to be the first to administer a completely new product to a human being for the first time? Concern diminishes as clinical development progresses, but in the early stages, with limited knowledge about a product's safety and efficacy, the hurdle for use in humans is high.

A fourth, and often underestimated reason, is that the physicians involved are not convinced about the product under investigation. In this case, they are often too polite to express this clearly towards the sponsor. They agree to participate in the study because they are qualified in the medical profession and also have access to the desired patients, but they do not include any patients – simply because they are not convinced that the product can help their patients. Consequently, even when telling their patients about the possibility to enter the study, they may not seem very convincing or equipped to help those patients, fearing ineffectiveness of treatment or side effects.

So, in summary, time in planning and for execution, courage, and the will to drive scientific development in an unbiased way are the most important requirements for physicians to include patients in clinical trials.

How can recruitment be supported?

First, the CRO can clarify – in intensive, personal contacts – whether the study centre in general has access to the target patient population, fulfills the corresponding formal requirements, and is really willing to participate in the clinical study. Ideally, the CRO submits certain advertising and educational texts during regulatory submissions, which the centres can then use from the start. The CRO monitors, who supervise, train, support, and control the study teams on-site and during the study duration, should arrange the cooperation in such a way that the study team members can work efficiently and receive the best support possible: this conserves the resources on-site.

What about patient concerns?

In addition to the fear of the study medication – which can only be alleviated by good information and support from the study centre – it can be too difficult for seriously ill patients to attend numerous study appointments and long examinations at the centre. Therefore, above all, the CRO should contribute, advise, and set up the study in a way that minimises the burden of study procedures on patients. In all activities, one should always keep the patient and, if necessary, accompanying persons, in mind. Thus, it may also be worth

considering decentralised study elements like phone, telemedicine visits, or homecare visits, if possible. This can help prevent high drop-out rates, which could cause a meaningful result to falter.

What additional measures can be taken?

Other measures to support patient recruitment include the use of targeted advertising measures via various channels (internet, print, social media etc.) in combination with external providers that can pre-select potential study patients and assign them to suitable study centres.

Taking over the organisation of travel to and from the study sites for patient visits, assuming travel costs and expense allowances for patients, and, if necessary, accompanying persons for the on-site study visits can also help. If possible, certain studies can also be organised as home visits by home care nurses, reducing the burden on patients and site staff. These services are often provided by specialist service providers and often involve significant additional costs.

What advice do you have for a sponsor when it comes to recruitment planning?

We advise customers to speak directly and openly with potential study centres as early as possible, and to make it clear to them that successful development can only be achieved with massive support from the study centres. The whole study team on site should be convinced of the potential of the product, or benefit of this clinical development, and in return, of course, be rewarded for their efforts.

Here we advise not only to pay for the individual study-specific examinations, but also to consider the effort for documentation, possible training, the monitoring visits, and the communication with all participants. Active participation in a clinical study is very much work and must, of course, be remunerated appropriately. In addition to the financial aspects and the involvement of the entire study team on site as early as possible, we also advise prior consultation regarding support measures. In our experience, this should be discussed individually with each centre in advance. Each centre has different needs and ideas in this regard, and we believe that any measure implemented can only be successful if all those involved have been included in the planning, and are prepared to accept the offers made. Only in a balanced interaction of all parties involved can a clinical trial be carried out successfully, and within the previously-defined financial- and time-frame.

We are firmly convinced that efficient trial conduct is only possible if everyone involved contributes their professional expertise in the best possible way. Then, cooperation on an equal footing is achievable. And once recruitment has been successfully completed, the data can be analysed and the sponsor can move on to the next step – or not – because there is no guarantee of success in clinical research, even if everyone involved has done everything perfectly right.

Ursula Türcke, MSc, Senior Director Clinical Operations at **FGK Clinical Research GmbH** in Munich, Germany, has more than 20 years of experience in all operational aspects of conducting national and international clinical trials with pharmaceutical products and medical devices including non-interventional studies.

She has actively supervised more than 500 national and international clinical research projects in various indications. Ursula is supervising all regulatory, project management, and monitoring activities at FGK as well.