



Recruiting subjects for early-stage drug trials: a behind-thescenes look

At CHDR, both the number and intensity of studies have increased in recent years, and recruiting sufficient numbers of healthy volunteers and patients can be quite a challenge, particularly given the current high standards regarding medical ethics. However, by applying novel strategies, CHDR's Recruitment Department rises to the challenge.

A closer look at CHDR's recruitment strategy

Upholding strict ethical guidelines

CHDR maintains high ethical standards and complies with all Dutch, European, and international laws regarding experiments with human subjects. This means that we generally cannot begin to actively recruit subjects for a specific study until the study protocol has been approved by the Medical Ethics Committee. The study protocol includes the strategy that will be used to recruit subjects, and subjects must not be recruited by a promise of financial compensation. Instead, subjects are generally recruited by appealing to their altruism (for example, their desire to help move medical science forward). In addition. subjects can only participate in a drug trial once every three months. All of these requirements are in place to protect the subjects; however, they also increase the challenges associated with recruiting enough subjects for a study. For example, there is often little time between the moment the protocol is approved and the start of the study. Therefore, CHDR's Recruitment Department is dedicated to finding creative solutions, thereby ensuring that the study can begin on time.

A continuous web presence

To maximise the visibility of our presence on the World Wide Web, CHDR's recruitment website (www. proefpersoon.nl) is among the top three hits returned by search engines. This website is an invaluable tool for reaching individuals interested in participating in a drug trial, as well as providing information regarding the latest studies.

Sponsoring events to increase brand awareness among a wide variety of demographics

University students are an important pool of potential test subjects, as they often have extra free time and a strong sense of social awareness – and of course, most students are easily motivated by financial compensation. CHDR is highly visible within the student population by sponsoring events and by maintaining an active presence on university campuses. At the same time, CHDR also sponsors other events in the community to attract other demographics. For example, to attract participants for studies in the field of geriatrics,

CHDR is often present at trade fairs frequented by senior citizens. These are just a few of the many approaches CHDR uses to help make CHDR a household name among study participants.

The Database: the key to CHDR's recruitment success

The cornerstone of CHDR's Recruitment Department is its unique database containing the contact information and other details for more than 60,000 participants. Many of the individuals in the database are students, but the database also contains the names of a wide range of participants, including retirees. Most of the names in the database come from previous studies at CHDR, and the database is continuously updated to help ensure that it only contains individuals with the time and willingness to participate in a study.

Highlights

- CHDR maintains a large, up-to-date database of active study participants, including both healthy volunteers and patients.
- CHDR also reaches out to potential study participants by sponsoring public events such as sporting events and concerts, particularly events attended primarily by university students.
- An addition recruitment strategy is our website (www.proefpersoon.nl) and banner ads that link to this website.
- CHDR recruits many of its specific patients through direct contact, as well as through patient organisations and physicians.
- Many participants in a trial return to CHDR for additional studies.

'CHDR's recruiters can usually find enough patients, thanks to our creative and diverse recruitment strategies.'





Finding healthy volunteers

As soon as the Medical Ethics
Committee gives a new protocol
the green light, recruiters contact
potential subjects by phone and/or
email. This approach is often sufficient
to reach the number of subjects
required to complete the study. As a
basic rule of thumb, four individuals
must be recruited for each subject
needed in the study, as approximately
half of all who reply either fail to show
up for screening or fail to complete
the study, and half of those who do
show up for screening are ultimately
excluded for medical or other reasons.

Sometimes, when we cannot recruit enough volunteers, CHDR's recruiters have to 'dig deeper', placing ads in local newspapers and posting online ads on Facebook and in the form of website banner ads. Although these channels often reach many more possible subjects, experience has taught us that these respondents often fail to show up if they have no previous experience with CHDR; therefore, these channels can have limited value.

In the next stage of the recruitment process, volunteers who respond are contacted personally by a recruiter, who provides them with important additional information regarding the study. If the respondent is still interested, he or she is invited to CHDR for an informational meeting, where participants are given all the information they need in order to make a clear, informed decision regarding whether they wish to participate. Subjects who provide written informed consent are then invited for medical screening (in some cases, the informational meeting and medical screening can be combined in a single visit). Medical screening can also be used to teach subjects to perform specific tests, for example if the study will include CHDR's NeuroCart® and/or PainCart®.

Finding patients

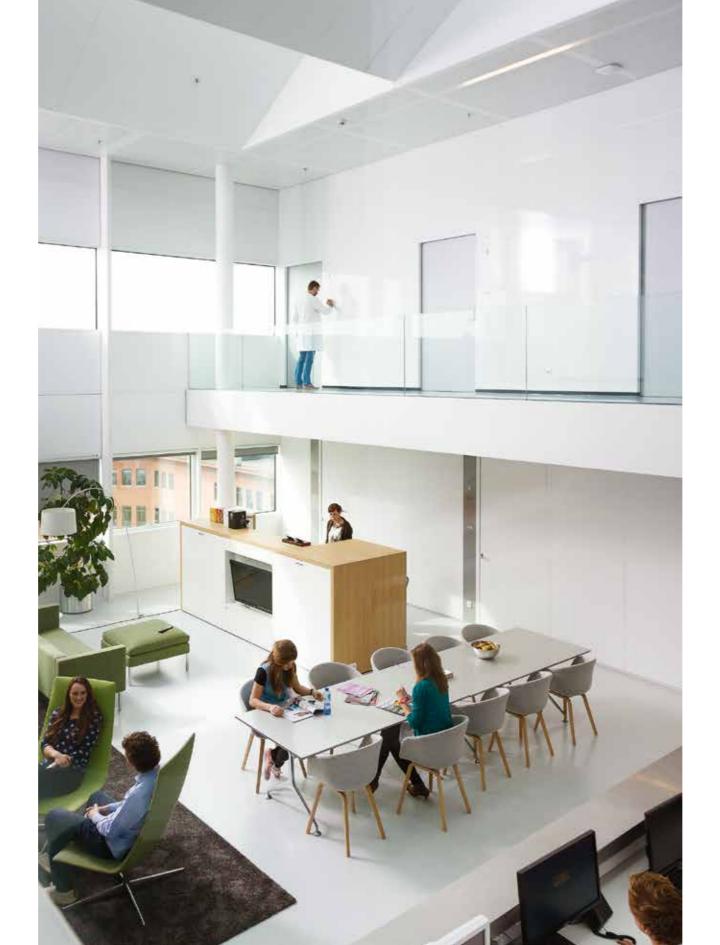
CHDR increasingly performs studies using patients with specific diseases or other medical conditions. Although recruiting patients is generally more challenging than recruiting healthy subjects, CHDR's recruiters can usually find enough patients, thanks in part to our creative and diverse recruitment strategies. For example, recruiters maintain strong contact with various patient organisations. In the Netherlands, most patient advocacy groups are keenly interested in participating in innovative scientific research, especially given that these groups represent the end-users of that research - the patients themselves. To reach these patient groups, CHDR places advertisements in their newsletters and on their websites, and they also send alerts to specific patient groups. Ads can be placed in other media outlets as well, depending on the specific patient population needed for a study. In addition to these direct forms of recruitment, patients are often referred to CHDR by CHDR's vast network of clinicians in a variety of fields. Together, these strategies help ensure that each study conducted at CHDR has a sufficient number of suitable patients.



Ready-for-ResearchTM

To help make the recruiting process easier and smoother for both researchers and subjects, CHDR developed the Ready-for-Research program. Rather than recruiting patients for a given clinical study on an as-needed basis, CHDR has established a well-defined pool of patients who are ready and willing to participate in new trials. In the Ready-for-Research program, patients who have specific conditions and are interested in participation in a drug study are pre-screened at CHDR using specific protocols that have been approved by an ethics committee. Depending on their specific medical condition and disease stage, patients can return to CHDR on a regular basis (for example, annually or semi-annually) for re-screening in order to assess their condition, general health, and other possible factors that may affect their ability to participate in an upcoming study. By maintaining an up-to-date Ready-for-Research database, CHDR has immediate access to a large cohort of specific patients as soon as a sponsor wishes to study a new drug in patients with this specific condition.

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Continuously learning, continuously improving

Recruiting healthy volunteers and patients to participate in early-stage clinical drug trials is no simple task. Indeed, to keep up with CHDR's growth and the ever-changing needs of our sponsors, our recruiters must continuously adapt their strategies. In turn, our recruiters provide valuable input to the project leaders who write the protocols, including exclusion and inclusion criteria and other relevant factors. And everyone at CHDR who comes in contact with our subjects - from the receptionists to the researchers to the nursing staff – plays an important role the recruitment process. There is one clear rule when recruiting subjects: the best advertising comes from subjects who enjoyed their experience.



Why choose CHDR?

The Centre for Human Drug Research specialises in early-phase clinical drug research. CHDR's overall mission is to improve the drug development process by collecting as much information as possible regarding the candidate drug in the early phases of development. This information helps sponsors make informed decisions regarding the course of clinical development for their product.

Why choose CHDR?

Research at CHDR covers a wide range of fields, including the central nervous system (CNS) and pain, the cardiovascular system, haemostasis, immunology, and dermatology. In addition, CHDR is at the forefront in developing novel biomarkers and methods for measuring drug-related effects in all of these research areas.

Pharmacology matters

Whether studying a new cognitive-enhancing drug, a next-generation painkiller, or a new monoclonal antibody designed to treat rheumatoid arthritis, the goal is to determine how the compound's effects correlate with both the dose and blood concentration at any given moment. In addition, understanding which biological systems are activated is an essential first step towards quantifying this relationship. At CHDR, our focus on pharmacology is reflected clearly in what we call question-based drug development.

Question-based drug development

CHDR actively uses question-based drug development - or QBD - as a more rational approach to drug development compared to conventional approaches. QBD can be best described as a series of questions that are addressed throughout the process. These questions often seem simple enough, but failing to answer even one question - or even addressing the questions in the wrong order - can have dire consequences. Thus, using this approach can potentially save companies millions of dollars by helping predict a catastrophic issue early in the development process, before the more expensive latter stages (for example, large-scale clinical trials or the marketing phase).

From a general perspective, the most important questions are:

- 1. Does the biologically active compound and/or active metabolite(s) reach the intended site of action?
- 2. Does the compound cause its intended pharmacological and/or functional effect(s)?
- 3. Does the compound cause any unintended pharmacological and/or functional effect(s)?
- 4. Does the compound have a beneficial effect or the disease and/or clinical pathophysiology?
- 5. What is the compound's therapeutic window?
- 6. How does any variability with respect to the drug response in the target population affect the product's development?



Contact

To learn about CHDR's full range of services, contact us today.



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