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Everybody needs to know how important phase I studies are in clinical research. Without them, there would be no new drugs or vaccines

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With two in-house Clinical Research Units (PCRUs), Pfizer uniquely keeps its phase I research within the company. As Medical/Scientific advisor at the Brussels PCRU and with a history of more than 20 years there, Dr

Isabelle Huyghe shares the workings of the PCRU, explains how study participants are recruited, and underlines the importance of diversity in phase I clinical trials.

Can you start by explaining what the PCRU is and what its responsibilities are?

PCRU stands for Pfizer Clinical Research Unit, which is a unit focused on phase I studies. Phase I is the first step up after preclinical studies, and before giving medication to actual patients. Most phase I trials are conducted with healthy participants because we need to find out the level of absorption, distribution, metabolization and elimination of a drug without the interaction of other medications or diseases. It is also the first time that the potential side effects of a medicine are recorded.

The goal of phase I is to find the correct dose to give to patients, a dose that has to be high enough to produce efficacy, but low enough to minimise potential adverse events. That is the key point of clinical research in phase I. You can never go onto phase II or launch a new medication or vaccine without it.

At Pfizer, we have two phase I clinical research centres, one in Brussels, Belgium, and the other in New Haven, Connecticut. We also have a satellite unit in Hasselt where people who come from further away can get initial screening without having to travel to Brussels. It is quite unique for a company to have its own clinical research units for phase I studies.

Because we have these units within Pfizer, we are involved very early on in clinical research and thanks to our 30 years of experience in phase I studies, we collaborate with clinicians to build the most appropriate studies with adequate participants, so as to be as efficient as possible.

You have been with the PCRU for more than 20 years. What is the scope of your role today and how has it evolved?

I started in the PCRU as a clinical physician and was responsible for monitoring the safety of clinical studies. I also followed a training in pharmacological medicine and became Principal Investigator, which means that I am now accountable for all the safety and scientific aspects of a specific study.

Five years ago, I took the position of Medical and Scientific Advisor for the early development clinical trials. I am a member of the Clinical Protocol Study Design Committees that discusses new clinical studies to ensure the safety of participants and review the key medical and scientific goals of studies. My objective is to make sure that every study can provide added value and to ensure its safety and ethical aspects.

You mentioned that Pfizer has another PCRU in New Haven. In light of Pfizer's broad pipeline, do the two centres have different therapeutic focus areas and how are these areas divided?

We are one unit in two locations. We have the same clinical operation procedures and the same medical devices. If needed, we have the capability to work on the same studies and can share the workload between the two PCRUs, even though we usually stick to one location and distribute therapeutic areas between the two. It also depends on the local legislation.

With your decades of experience in phase I studies how have you seen research evolve at Pfizer?

Phase I has always been a passion because the work we do now will help patients in the future. Moreover, Pfizer's varied pipeline makes this work remarkably interesting. For example, we currently participate in both infectious diseases and oncology clinical studies. As the PCRU is located near the new Jules Bordet Institute, which is specialized in the treatment of cancer, we can collaborate for phase I studies in that therapeutic area.

How does the PCRU recruit participants in its phase I studies as they are not patients, but healthy participants?

Most of the studies in phase I are conducted with healthy participants, but that depends on the compound. For example, for some oncology compounds, we might need actual patients. In the database we have built up over time we have more than 8,000 healthy participants and 3,000 patients. We are recruiting new participants through different channels, including brochures in pharmacies, newspaper ads, social media, or, most importantly, through word of mouth. About 40 percent of our participants come to us that way. We have done some surveys in the PCRU asking participants if they would like to come back and 99 percent are willing to participate again.

Before participating in a clinical study, participants receive all the information about the study, the medication, and the process. Then they sign an informed consent document. During the selection process, they will go through an electrocardiogram, a blood pressure assessment as well as blood and urine tests.

Some people might participate for the money, but others do it out of altruism. Some people join our clinical studies because there is someone in their family, or a friend who is ill and they want to help.

Are PCRU' s participants drawn from Belgium or does your recruitment span across Europe?

We have participants coming from Belgium of course, but also from the UK, the Netherlands, Germany, France, Spain – everywhere in Europe, as well as from Japan and China.

There has been quite a lot of discussion about clinical trial diversity and testing medicines on a broader spectrum of the population. How much does diversity come into

play in your work?

We are aiming for inclusive recruitment, meaning that anyone can be accepted into a study, except if mentioned otherwise in the protocol. We try to have diverse participants (and not be limited to Caucasians between 18 and 45). Participants in our database could be considered as representative of the entire population. For specific clinical studies we might need certain populations, though, like elderly patients, for instance.

After such a lengthy career in phase I studies, what motivates you most about your work?

The most important motivation is to see the medicines I have worked on become available to patients. I am a physician, and my goal is to help patients, even though in a different way to General Practitioners (which I used to be when I started my career). I am contributing to their future treatment.

I like this position because we are in direct contact with participants. I manage all safety aspects during a clinical study and review clinical data, and I have a view on the future treatments that will hopefully one day make their way to patients.

On behalf of the PCRU, do you have any closing remarks you would like to share with our international audience?

Everybody needs to know how important phase I studies are in clinical research. Without them, there would be no new drugs or vaccines. 80 percent of the adverse events found in the package leaflet for a medicine come from the data recorded in phase I because we follow participants very closely and record all their reactions.

I would also like to thank all the participants who help us to develop new medicines and appeal to new participants from Belgium and other countries to come and participate in future clinical studies.

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