

A CenterWatch Publication

## Profile: Phase I/Exploratory Development Contract Research Organization

### FOCUS Clinical Drug Development, Neuss, Germany

An interview with Maikel Raghoobar, Ph.D., director of clinical pharmacology and business development

*Interview conducted at the DIA EuroMeeting in Berlin*

#### Tell me about the background of FOCUS Clinical Drug Development.

At the time of the merger between SmithKline and Beecham, the new company, SmithKlineBeecham, decided to divest its clinical pharmacology units. FOCUS was originally one of these units. The global head of clinical pharmacology of SmithKlineBeecham at that time was Dr. Wolfgang Greb, who made a management buyout and started a clinical research organization in 1992 at the same location in Neuss. Most of our staff had been working at SmithKline Beecham and are still working at FOCUS as a service provider to sponsors on phase I/II studies.

#### What differentiates FOCUS Clinical Drug Development from other phase I CROs?

In the 1990s, Dr. Greb developed certain paradigms to see how he could improve our clinical pharmacology expertise. He focused on first-in-man studies and studies with biologicals, peptides, monoclonal antibodies and vaccines, which other CROs were reluctant to do because of the lack of experience. In 1997, Dr. Greb took the initiative to conduct ethno-

bridging studies. He was one of the first clinical pharmacologists and CEOs of a CRO who decided to do these studies. The reason is that Düsseldorf has the largest population of Japanese living outside Japan. He differentiated FOCUS in how he designed the bridging study, recruited Japanese volunteers, and conducted the informed consents. He recognized that there were cultural differences and that he needed to build a team that would be able to manage these types of studies. Dr. Greb did it exactly right from the first time because he hired Japanese staff, and, notably, most of the staff are still with us.

When we were running these studies, we received so many requests from our sponsors that we began to recruit Japanese volunteers living outside Düsseldorf. Nowadays, we are recruiting Japanese volunteers from UK, France, Germany, Austria, the Netherlands and several other European countries. Our recruitment team based in Neuss, Germany, is not only a recruitment team but also a travel agency. We have built up a pool of 800 Japanese males and females who are participating in our studies, and they are based in European countries. The largest portion comes from Germany, France is number two and UK is number three. In Europe, next to some companies in London and

**Year founded:** 1992

**Employees:** 120

**Unit locations:** Neuss/Düsseldorf, Germany; Moscow, Russia; Belgrade, Serbia

**Beds:** Neuss, 128; Moscow, 8; Belgrade, as needed

**Active projects:** 50+

**Contact:** Dr. Maikel Raghoobar

**Tel:** +49-2131-155-307

**Email:** [businessdevelopment@focus-cdd.de](mailto:businessdevelopment@focus-cdd.de)

**Web site:** [www.focus-cdd.de](http://www.focus-cdd.de)

Paris, we are a large provider of ethno-bridging studies in Japanese subjects.

Based on our success in ethno-bridging studies in Japanese subjects, sponsors asked us to do ethno-bridging studies in other Asian subjects and in subjects from other regions. So, since 2008, we have done ethno-bridging studies for sponsors in Japanese, Chinese and black Africans. We also have a request for a study that we will start later this year to recruit Hispanics.

Our third core strength is based on scientific interests. We do a lot of studies with biologicals, peptides, monoclonal antibodies and vaccines based on our preclinical and clinical immunology experience. Another differentiating factor is that many sponsors come to us when they have a very complicated study design. This is what FOCUS is known for in the marketplace. We look at the whole process, so when the

**CWWeekly** (ISSN 1528-5731)

To subscribe to *CWWeekly* or other CenterWatch publications, contact our customer service department.  
Tel (800) 765-9647 Fax (800) 850-1232  
P.O. Box 105109, Atlanta, GA 30348-9891



## PFC Phase I/Exploratory Development (continued from page 1)

sponsor comes we are able to discuss everything with them and try to help the sponsor improve their study design.

### **Tell me about the FOCUS phase I units located outside Germany.**

In 2003, we established a clinic in Moscow. We are not only a CRO with lots of experience but a CRO that is a pioneer. We established one of the first phase I units in Moscow. We are running studies in patients, which can vary from special population studies, such as renally impaired and hepatically impaired, but it can also be a drug-drug interaction study in certain patient populations. That is the first part of our business in Moscow, and the second part is that some sponsors, especially the smaller companies, ask us to do phase II studies for them. These enroll a few hundred patients. We are able to monitor them, find the sites for them and run the study for the sponsor.

At the end of 2007, we opened a phase I unit in Belgrade, Serbia, because of the patient opportunities. Our sponsors would like to start in an earlier phase with exploratory clinical development studies in patients. Our responsibility now is not only to do these studies but it is also to have our staff in Moscow and Belgrade trained in clinical pharmacology, in GCP [Good Clinical Practice] and our global SOPs [standard operating procedures]. In addition to that, we train them in exactly what to do to perform an exploratory development study. For six to eight weeks of the year, I am in Moscow, and for another six to eight weeks I am in Belgrade to train staff, meet new investigators and do feasibility studies.

### **What challenges do you face and how do you address them?**

One challenge is that in Russia and Serbia the regulatory approval timelines for phase I studies are

about three months, which is longer than in the U.S. and in Germany. So, what we have done is, in Moscow, we invited members of the ethics committees and pharmacological committees that are part of the regulatory review process in Russia to our site in Neuss, Germany. There, on the first day, I gave lectures about clinical pharmacology and drug development so that they understand when a sponsor comes with a specific study design why the sponsor would like to do it. Then the members of the committees asked questions. On the second day, we met with the ethical review committee from Düsseldorf that reviews on a weekly basis the studies that we are running in Germany so that they can exchange thoughts with another ethics committee. On the last day, we visited the BfArM, which is the German regulatory authority, where they exchanged thoughts also. As a pioneer, this is the way we like to establish the contact between Germany and Russia but moreover to educate the Russian regulatory authorities how they could review protocols from sponsors a little more quickly and why it's important to stick to timelines.

### **What changes have you observed in the clinical research industry?**

There is a trend to go to emerging markets, such as India and China, but FOCUS is approaching this trend in a different way. We have established an office in Dubai where we have people who previously worked in the pharma industry in India working for FOCUS now. They visit pharma companies in the area, including Arab-speaking Middle East countries and India. They ask companies to do studies in Germany because they have compounds that they have discovered in India, which they would like to study in a high-quality phase I study. The Dubai office offers project management and business development, and the German unit offers the clinical component. When those sponsors are happy with the first

studies, they come back to us and ask us to do a second study, not in our unit in Germany, but in a CRO in India, but they are not willing to outsource their own compound directly to that CRO. They ask us to do that because if we do it, we can outsource it with the FOCUS label, a quality label, and the FOCUS report format. The Indian government requires that some phase of the study be conducted in India. If they do everything outside India, then they have difficulty catching up later on. To avoid that, they ask us to run the study in India, but not with their name, the sponsor's name, but the name of FOCUS. We have visited some of these CROs and have qualified them. Those that are on the list can get a study from FOCUS. That is the second part of the business model. The last part is that some small biotech companies ask us to do a package of studies for them. That means we do the preclinical part—not in our unit because we are a clinical unit—but we outsource it. We are able to do that because we employ experts and have consultants who work closely with us. Then we do phase I in the unit(s) in Germany and the phase II studies can be done either in Moscow or Belgrade.

### **What are your plans for growth?**

We plan to have more novel technologies in our phase I units in Germany because that will be a market-attractive thing for sponsors when they are choosing between us and another CRO. In Germany, in addition to our 120-bed unit, we have eight beds in a hospital ward for higher risk compounds and biologicals, and we are in discussion with the hospital to find a larger ward because of sponsor requests. Finally, we intend to intensify our biomarker and immunology activities to bridge the preclinical development with the clinical drug development from phase 0/I through phase III.