Interview with Michele Garot, Vice President, BeCRO

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What was the motivation behind the establishment of BeCRO and why was it only established in 2010 given the strength of Belgiumâ??s clinical trials industry?

Philippe van der Hofstadt: Prior to establishing BeCRO, several of our members were already participants of other associations that also included pharmaceutical companies and academia, among others. However, in 2005 EUCROF, the European CRO Federation was established and we, as an industry, were determined to become members of that organization. In order to do so, we were required to establish an association that is purely composed of contract research organizations (CROâ??s), which triggered the founding of BeCRO in 2010.

BeCRO was initially founded by 19 member companies and has now grown to include 32 active members. This represents more than a third of the 83 CROâ??s we identified in the country in 2011.

Can you outline BeCROâ??s mission and objective towards your members and the industry and also highlight some of the associationâ??s most notable achievements and milestones since it was founded in 2010?

PvdH: Our primary objectives are obviously to represent our members and their achievements towards stakeholders (i.e. the pharmaceutical and biotech companies) and also towards the relevant authorities, where we intend to be the premium representatives of the industry. In addition to this, we aim to provide our members with a platform in which they have the opportunity to discuss and exchange ideas and provide a forum for training and interaction. Moreover, as one of the main stakeholders in the clinical research environment, we are initiating discussions with patient associations.

Beyond the Belgian context, we are also actively participating in various working groups (Clinical Trial Legislation, Early Phase, Late Phase and Communications working group) through EUCROF. In addition, we are currently organizing the first international EUCROF conference to be held in 2013 which relates the clinical trials in the EU compared to the global scene. Furthermore, considering our proximity to the European Commission, we have had the privilege to represent EUCROF several times at commission assemblies with stakeholders.

As an integral figure in the industry, what is your assessment of the Belgian clinical trials industry?

Michele Garot: We have enjoyed quite a strong competitive position in Belgium for a number of reasons. Under the current clinical trial directive, the time required to gain approvals for clinical

research is much shorter compared to elsewhere in Europe and the world (less than 2 weeks for phase I). Moreover, due to historical reasons, Belgium is particularly strong in early phase clinical trials and hosts the highest number of phase I trials in Europe in absolute terms. In this respect, this has considerably helped placing Belgium on the map and has attracted a wide range of sponsors.

In addition to this, Belgium is a leading destination for clinical trials owing to its world renowned local medical expertise of clinical trial staff and competent authorities, its distinguished network of academic institutions, its quality of trial execution and its adherence to Good Clinical Practiceâ??s (GCP). Furthermore Belgium is praised for the good synergies between the medical, academic, and bio-pharmaceutical research companies which creates a favourable climate for R&D and innovation. Indeed, Belgium has previously received credit for developing five of the 100 essential medicines identified by the World Health Organization (WHO). It therefore comes as no surprise that Belgium hosts one of the highest numbers of clinical trials sites in the world, per capita.

Although Belgiumâ??s legislation remains conducive to academic trials, the number of non-commercial trials is rather low compared to other EU member states. How would you explain this discrepancy and what could be done to improve the situation?

MG: It is difficult to say with complete certainty what the root cause of this discrepancy is. Somewhat ironically, the local authorities have enacted a number of financial incentives designed to stimulate academic trials. However, it is clear that the academic institutions may have limited access to resources, in the broadest sense of the word, including not only financial resources but also in terms of data management, biostats, nurses, etcâ?¦ In addition to this, I think the EU directive on clinical trials might have had a contributing effect to this discrepancy, since it has brought about increased costs and administrative complexities. Certainly, this effect is not limited to Belgium alone, but the EU as a whole, however, it is perhaps slightly more pronounced here owing to the small size of the country.

Nevertheless, as we speak, these institutions are actively attempting to reverse this trend. Specifically, there are a number of academic hospitals that decided to set a unique foundation on which they will be able to optimize their resources.

PvdH: Perhaps another potential explanation for this divergence is rooted in the competitiveness of the universities. Although we are currently observing increased levels of collaboration among universities, this was not quite the case in the past. Hence, it is not unlikely that if they were more open to each other in the past, that might have influenced the situation since they could have conducted more academic trials in collaboration with each other than alone.

Similarly, over the past decade, the number of clinical trials in Belgium has been growing, however more recently the country has been experiencing a small but real decline in the absolute number of CTâ??s. What is the root cause of this phenomenon and what is being done to counter act it?

MG: Different factors have contributed to this decline; the reduction in R&D investments by Pharma companies, the global economic downtown. Again, in this context, the current EU directive on clinical trials has likely negatively impacted the entire European market. The cost of setting up a trial in a given country is characterized to a large degree by a fixed set-up cost with extensive administrative burden, and with a variable component that is dependent on the number of sites, therefore making the involvement of smaller countries such as Belgium ineffective. In that respect, American or Asian companies seeking to establish clinical trial activity in Europe may have been slightly discouraged over time, leading to this recent drop in absolute figures.

The EU is currently proposing a new directive for clinical trials which is set to reduce these complexities and harmonize the industry across the entire EU. What impact will this have on the

local industry as well as your members?

MG: Indeed, the new regulation will simplify access to Europe thanks to a single procedure and hopefully boost the number of clinical trials carried within its member states. However, this does not particularly include Belgium unless we take the necessary measures and leverage the assets we have.

The new regulation will reduce the administrative burden to obtain authorization to conduct trials in each EU member-state. At the same time however, the new regulation will unfortunately make Belgiumâ??s fast track differentiating factor obsolete. Hence, in order to differentiate ourselves, we are aiming capitalizing on our specific expertise and reputation in early phase trials, vaccines, advanced therapies and oncology. By focusing on these core competencies, we expect to create many opportunities for growth for the local industry.

PvdH: Interestingly, these four areas of expertise also represent the FAMHPâ??s (the Federal Agency for Medicine and Health Products, or the agency) four pillars of expertise. For instance, the agency is frequently requested to speak at conferences on the subject of early phase trials and was in fact the first to publish guidelines on exploratory clinical trials (also called Phase 0 studies) in 2007. Also, we believe that the new clinical trial regulation may have a positive impact on the many biotech and academic investigators in Belgium by creating new business opportunities.

In terms of impact on the industry, we believe that local CROâ??s will need to adapt to the new regulations since we can expect them to be exposed to an increased amount of â??non-localâ?? requests which of course may require a different set of expertise or resources. In addition, CROâ??s must also differentiate themselves as the market will undoubtedly become more competitive. Finally, in order to reinforce their credibility, CROâ??s should also look to create synergies with other associations or stakeholders including research institutions and EU level working groups, for instance.

MG: Similarly, we are also discussing with a number of academic centers how to differentiate ourselves in terms of quality, efficiency and effectiveness. The goal is to create an environment which could allow for the rapid initiation of clinical studies, not only from an administrative perspective but also from a quick contractual setup; bringing the first patients in and conducting rapid clinical trials. This can be achieved through establishing a solid foundation for the studies and introducing a degree of standardization throughout various aspects of the process including ethics committee approvals, for instance. Ultimately, since the approval times for clinical trials will be harmonized in the EU, these efforts to standardize some processes will help Belgium differentiate itself by becoming operationally quicker. Likewise, in an attempt to speed up the patient recruitment process, we are also communicating with a number of patient associations in order to understand any concerns they may have about clinical research and educate them on its potential benefits. In this respect, we are hopeful that we will be able to put in place concrete actions that can get patients to become familiar with the activity to the point that they would dare to at least inquire and educate themselves of the practice and hopefully decide to participate.

Through these multi-axis communications with the agency, academic institutions and patient associations, we are proactively encouraging the differentiation of the Belgian clinical trials industry. In this respect, I believe that Belgiumâ??s small size can be viewed as an asset since it can be more agile, dynamic and responsive to the requirements of the industry as compared to other larger European countries.

Moreover, Belgium has been well reputed so far for its rapid approval processes and we are certainly very proud of this. In fact, I believe this will, to some degree, continue to serve as a

competitive advantage for us even after the new EU directive is enforced. After all, adapting to the new regulation timelines will undoubtedly prove to be challenging for a number of countries. Belgium has been a pioneer in this respect and will certainly face considerably less obstacles in adapting to the new timelines.

Although people in Belgium have a positive view of the practice of clinical trials, other populations tend to view the sector more apprehension. How has Belgium managed to foster such a good perspective of the industry?

PvdH: Through our communications with patient associations over the past two years, we have come to realize that patients who have access to commercial treatments are not that keen on clinical research. On the other hand, patients with life threatening or rare diseases as well as patients who lack available treatments are obviously much more sensitive and open to clinical research.

Can you provide us with some instances in which BeCRO is actively educating patients on the benefits of clinical research?

MG: We are actually communicating with a patient association in particular where we intend to provide them with a clear and complete depiction of what clinical trials actually constitute and how they can be potentially beneficial to them. In addition to this, we are also highlighting the fact that we, as the CRO industry, have no vested interested in any specific molecules being tested since that seems to be an areas of concern for some patients.

Broadly speaking, our aim in this context is not bring about a direct benefit for any particular member of BeCRO, but rather to offer a sort of generic solution for the industry as a whole. In other words, we want to be a source for solutions, by having a unique, simple and transparent structure that is void of any private direct interests. So far, as Mr Van der Hofstadt, mentioned, we have now been in discussion with several patient associations over the past two years and are only now beginning to see the first concrete requests. Needless to say, we are very excited about this development and are looking forward to future advancements.

Evidently BeCRO is a strong supporter of collaborations as illustrated by the partnerships it maintains with various organizations such as EUCROF. Can you tell us more about these initiatives and what benefits they are expected to generate for both your members and the industry at large?

PvdH: BeCRO is indeed very active in its attempts to consolidate its network in the field of clinical research. As an example, I am heading an early phase working group that we initiated in February of this year which has 16 members from different countries. Over the past eight months, we have identified three key areas which require our attention. One is that some existing clinical volunteers are in fact over volunteering and crossing borders to participate in different trials. At the moment, within the EU, there are national systems that indicate whether patients are participating in other clinical studies. However, there is no such international system.

In this context, we have already been able to put into place and begin testing a system that can make these verifications on a cross border basis. More specifically, we have one center that is already active in this respect in Belgium with another soon to follow, as well as two in the UK, the Netherlands and Germany, each. Of course, this is an international initiative working at the European level where we aim to stop volunteers from simultaneously participating in cross border trials.

The ultimate goal of this initiative is to demonstrate to the relevant stakeholders that although there are such control systems in place on a national level, there is also a strong need for a similar international system. Moreover, we aim to exhibit how the current pilot system is in fact more user-friendly and does not require any additional data entries for instance. Again, this can serve to

differentiate Europe from other destinations for clinical trials.

Another aspect we are preoccupied with within that working group relates to quality. That is, when you look at the varying regulations for phase I units within Europe, we see some countries which require certification before commencement while others do not. Hence, we are now assessing the potential to establish a certification program. To that end, we have now drafted a certification manual which we will submit to the European board of EUCROF and will subsequently liaise directly with the European authorities following their approval.

What is on the agenda of the BeCRO over the short term? And what reforms would you like to precipitate in the market?

PvdH: Firstly, we intend to reinforce the role of CROâ??s as crucial stakeholders for clinical research, not only in Belgium, but across its borders as well. Similarly, as an association, we aim to attract an international perspective to Belgium to help the local stakeholders identify where our efforts should be focused in order to maintain our leading position.

In addition to this, although I am not quite certain if this is characteristic of Belgians, but many of us seem to want to work on our own. However, considering that we have a lot of expertise, we should consider finding strengths and synergies by joining together; as the saying goes â??Lâ??union fait la forceâ?• (or, unity is strength). That is, as Mrs Garot, mentioned, there are many associations or organizations that are working in their individual fields, but from an individual perspective. In that respect, since 2010 we have aimed to overcome their reluctance to work in tandem. Indeed, we have started a number of cooperationâ??s with other associations to work together on specific projects and bring them forward.

If we can demonstrate this on a European level, as we are currently doing (Belgium is leading three of the ten EUCROF task forces at the moment), then we can demonstrate to the Belgian stakeholders that we can certainly achieve far more together than we can individually. This perhaps represents the main aim of BeCRO.

Finally, on a general note, I believe that Belgium is a highly ambitious country that will do everything necessary, along with its stakeholders, to maintain its unique position in the field of clinical research. In this respect, we are completely convinced about what Belgium is able to offer in an international environment and will continue to do so into the future.

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