Denis Comet â?? President, AFCRO, France

> France is back. We, the French, might be harsh critics, but for the first time, I see the Ministry of Solidarities and Health taking concrete and simple steps to improve the competitiveness of France in clinical research.

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Dr. Denis Comet, President of AFCRO (the French Association of CROs), talks about the evolution of the clinical research environment in France and the new government actions aimed at speeding up the clinical trial process.

Didier Genot from France Biotech told us that France has lost competitiveness when it comes to clinical research and trials. More and more, companies are conducting their clinical trials in other countries such as Belgium and Spain. How would you say that the situation has evolved in recent years and what kind of market dynamics have you witnessed in the CRO field?

AFCRO is indeed a partner of France Biotech. The latter being the association of biotech companies in France, their area of focus is naturally on Phases 1 and 2. In these phases, the time needed to get the authorization is very important and the situation in the past year was not the best in France. According to French law, the Ethics Committee is randomly selected, so as to break any potential link between the principal research investigator and the committee, itself. This results in having ethics committees that have to deal with dossiers in domains they have never worked in, due to the fact that each committee does not represent a comprehensive pool of experts. This is problematic especially in Biotech, Medtech and in the first two phases of trials, as the ongoing investment is considerable and you need to get approval as soon as possible to get to the next step of the research process. Luckily, in the first semester of 2019, the situation could change: a new law proposed to the National Assembly and a new software package will help assemble more qualified committees. For example, if a committee does not include an expert in the specific relevant field, you will not be qualified on the list of possible ethics committee. The random access will remain but it will be limited to qualified ethical committees that could have a good knowledge of the protocol. This is fundamental, as research is getting more and more specific.

When was the random access of ethical committee enforced?

It was enforced quite recently, in October 2016. The lawâ??s approval happened quickly, so they did not have the time to develop the specific software for random access. They have been using an old software that was not originally designed for this purpose, a very simple tool that does not consider the expertise of each committee and in which a lot of information needs to be added manually.

How have these changes impacted the CRO scene?

They shortened the ethics committee review to 60 days, but committees are less professional in their approach. Luckily, as I mentioned, it is just temporary, as in 2019 the new software will evaluate other factors: the availability, the expertise of the committee, and so forth. The efficiency of the process will increase steeply, probably reaching a new record for our country. What will however not change in France is the fact that our ethics committees are non-professional, meaning working on a voluntary manner. Hence, while in other countries you might have a session every week or every day, in France it is much less frequent. It is a matter of choices, as in our case, committees are more representative of the national population.

How is the situation changing after the announcements made during the July 2018 Strategic Council for the Healthcare Industries (CSIS)?

The situation is changing, but it will take time. We hope that soon, France will be back in a very good position. This is also what CEOs of big pharma companies are taking away from the 8th edition of the CSIS. The big changes announced by the council are realistic, as they can be achieved through simple, concrete actions. For example, we have 39 ethical committees, and each committee has just one administrative manager responsible for receiving the dossier. If this person is ill or on vacation, there is no way of receiving the dossier, and this is simply unacceptable. I do not think it would be a lot of pressure on the governmentâ??s budget to add another responsible administrative figure in each committeeâ?¦ Similarly, the software I mentioned is not a big investment and it will have a significant impact in speeding up the clinical trial process. This is why the Minister of Solidarities and Health AgnÃ¨s Buzyn said, â??we know it is a simple but very concrete program.â?• Simple actions are needed. What is at stake is not only clinical research, but also patients, experts, the pharma industry, and the general image of France in Europe. Brexit presents the opportunity for us to be leaders like Germany, while countries in Eastern Europe are gaining a more and more important presence. We have to remember that this is a competition.

What other reforms are you expecting from the French government?

An important and unique step is the creation of the Health Data Hub, currently under construction, aimed at merging all the single health databases of the country. The French Authority on Data Privacy was one of the leaders in drafting the new EU General Data Protection Regulation (GDPR), and they created the new reference methodologies. With these administrative simplifications on clinical research, it is not necessary to ask for authorization before addressing a dossier. For example in France, it is possible to access the biggest database for CROs by simply stating the compliance with all requirements, without the need to request authorization from the National Commission for Informatics and Liberties. Now you can submit a dossier and have an answer in less than one month, whereas before, it could require one year.

This provides an advantage both for the first phases of clinical trials, and the post-marketing research. Indeed, in Phase 1&2, it provides a very precise way of finding the patients for the clinical study through an informatic query. The post-marketing studies will become more and more important in the future and require a high degree of control: it is necessary to know how frequently a patient took the product, the doses he or she took, the length of the treatment and the outcomes. In real life this information is entered by the physician and conditions are checked a-posteriori. However, when the government bodies ask about this kind of information, if you do not have access to the database, you have to do a large-scale, extremely expensive study. Often this requires millions of Euros and years of time. If you have a database, the solution is provided in a few minutes with no uncertainty. Moreover, studies right now need to be large, as to answer multiple questions it is necessary to divide the population in sub-groups. With databases, it is possible to have hybrid studies, wherein a study is mixed with a query. In the past it was necessary to have thousands of patients for methodology, while in the future you will have perfectly representative studies with just 500 patients, as you have access to the data of the full population. On top of that, it will be much more immediate as you will not have to pass through clinical research.

Another important provision aimed at making the clinical process more agile is the reform in the contractual aspects for the recruitment of patients. Before the situation was characterized by a lot of delays, in particular for the negotiation of the contract with the physician: not only was the contract different for each hospital, but there could also be variations from physician to physician. Now, similarly to the UK model, we have established a unique contract for the whole territory that is unmodifiable by law. First it was enforced in public hospitals, then it was extended to private and covering all. Now signing the contract requires on average just 15 days.

What are the consequences of this unique contract for CROs?

There is no reason for spending six months negotiating the contract line-by-line, physician-by-physician. Why should the cost of glycaemia in Lille be different from that in Marseille? The results were a harmonization of prices. While the prices of some high-quality private centers slightly decreased, the prices in public hospitals were upgraded, improving public revenues. Initially, some actors were not enthusiastic, but then they could not risk missing out in participating in high-impact studies: now the unique contract is well accepted. In this way, the delays in the recruitment of the first patient are greatly reduced.

What is your view for the future of CROs in France?

The outlook is positive. We have improved the communication concerning clinical research by reopening the website *notre-recherche-clinique.fr,* dedicated to informing patients and based on a strong collaboration with all bodies of clinical research. On top of that, the new generation of physicians will be very prepared in dealing with these online tools and patients are becoming more and more open to recruitment for trials. In the future, I could see ads for trial recruitment on social networks, with no false moralism, but pragmatism.

A few words to conclude for our international readers?

France is back. We, the French, might be harsh critics, but for the first time, I see the Ministry of Solidarities and Health taking concrete and simple steps to improve the competitiveness of France in clinical research. The spirit is to listen to problems and to fix them. We are hence in a good direction.

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