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Can you give us an overview of what the regulatory landscape currently looks like in Brazil?

Eduardo: Yes, I think it is important to have a perspective of what has happened in Brazil in the last years. Regulations for clinical research started in 1996, the same year as the ICTCP. And our regulatory agency was created in 1999. Since then, there were very positive changes in terms of creating ethics' committees and a national body that regulates the ethic committee that we call CONEP that is The National Ethics' Committee in Research. Those bodies were very efficient in terms of creating a background, training people for reviewing clinical protocols, etc. Now I think they are victims of their own success. Because of the number of the studies that we have now, they don't have the necessary manpower and infrastructure to cope with this volume of work. So, right now we have quite a complicated system. Very efficient in terms of protecting the research subject, but also taking a long time to approve the studies. That is some place to grow in the next future.

Are you seeing the Ethics' Committees try to build up their structure or try to grow in order to address that problem? You mentioned that they are victims of their own success. Are they doing anything to change that?

Eduardo: Yes, they are doing a lot of things and they are working hard. As you know, everything that depends on government is a little bit slower than with the private companies, but they are really struggling to cope with the high volume of work that they have.

Do you think that high volume of work and complex regulatory landscape is preventing Brazil, to some extent, from its ability to do innovative drug development?

Eduardo: Oh, yes. Unfortunately, it is. Right now, we do not participate in 30-40% of the studies that are initially offered to Brazil because of the timelines. That also prevents a number of sites to be developed and to have more sites and more studies in Brazil.

Are there any initiatives that you are aware of in the industry to build up the site networks and clinical research sites available in Brazil at this time?

Eduardo: Yes, there are some networks of sites that are being formed in Brazil and I think that the event that we are going to have in August is also an important initiative in terms of putting the slides together and exchanging information and best practices. That will be very helpful to develop new sites.

Eduardo is referring to our Site Management full day Symposium that we are going to be featuring on the first day of the Conference. Obviously, successful clinical trials rely on a variety of factors and site management performance is an integral piece of the puzzle. So, what we'll be doing is bringing in nine different faculty leaders to interact with site professionals and sponsors, as well as CROs, and explore topics including global trial identification and selection, clinical trial feasibility, negotiation strategies with sponsors and CROs, clinical study start-ups, metrics for group site performance, risk management techniques to minimize risk and ensure regulatory compliance, how to prove data management and more. So, that is what Eduardo is referring to.

How are you seeing Brazil's regulatory timelines compared to others in Latin America?

Eduardo: Right now it takes around eight to nine months to approve a new study in Brazil and that's at least two to three months more than in other countries from Latin America.

How does that compare to other regions of the world? To Asia and to Europe?

Eduardo: In terms of Asia, I think that China is a place where the studies also take a long time to be approved. And that's always the example that we use in Brazil to say that we

do not delay that much. In terms of Europe and the US, we are far behind. We are at least four to six months behind.

So, regulatory timelines are a little longer in Brazil than in other parts of the world and in Latin America. But, what are some of the advantages of working in Brazil? Opportunities that maybe other people in the industry are not aware of?

Eduardo: I think that is very important because we do not have this volume out of nothing. So, there is a lot of good side and recruitment and retention of patients is very good; very positive. And also the way that sites work and flexibility and the interaction with people. It's very, very positive. So, I think that the companies that overcome this initial issue, they do have good results.

Are you seeing any collaboration currently underway between different regulatory agencies within Latin America to help improve regulatory timelines?

Eduardo: Right now the collaboration between regulatory agencies is restricted to the issues of registration of new product. They have not achieved the level of clinical research. So, we do not foresee significant changes in the next years in terms of collaborating one agency to the other or having a harmonization of requirements between the agencies, unfortunately.

So, standardization in regulatory procedures is still a little farther away?

Eduardo: It is. Unfortunately, that's true.

So, what can a sponsor company proactively do in order to achieve better regulatory timelines and work with regulatory agencies when conducting clinical trials in Brazil?

Eduardo: I think that the most important topic is to develop local expertise and establishing a direct contact with the regulators and understanding profoundly what the regulations are and what the meanings of them are. What the regulators want with this type of requirement – it's not only bureaucracy, but there's something that they want to protect that is the research subject in this. So, developing local expertise is the most important issue here.

And in terms of partnerships, are you seeing global pharmaceutical companies, such as Pfizer, expand their offices locally? Or how are you seeing global pharmaceutical companies develop more local expertise?

Eduardo: Right now, I think there is a strong competitiveness between the regions. As you know, global research is a global enterprise and Latin America now competes with Asia, Eastern Europe and other regions to have more studios. So, pharmaceutical companies are investing heavily in developing this local expertise and the CRO, as well. That's very important to create a critical mass to bring more studies to the area.

Do you have any tips for people from biotech, pharma, medical device companies or CROs who have never worked in the region, but are looking to do clinical research in Latin America?

Eduardo: I think one important question is to come with an open mind. Sometimes, especially American companies that are very heavily influenced by the way the FDA and the regulatory environment is in the US, they go to other regions and they say: "That's the way we operate in the US, so that's the way it should be". That doesn't work in Latin America. So, come with an open mind and understanding the regulations and comply with them. That will bring very interesting results for those companies.

Hear more from Eduardo Motti, Pfizer at
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