Interview: Bujor-Eugen Almasan – President, Association of the Companies Coordinating Clinical Trials in Romania (ACCSCR)

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The president of the association representing clinical research organisations speaks out about Romania's attractiveness as a destination country in an era of clinical research globalisation. He further sheds ideas on fostering greater in-country R&D activity and outlines his personal vision for developing the association.

How did the association come into fruition and how has it evolved since its inception?

The association was founded in 2009 in association with Johnson & Johnson, PPD, Kendle, Quintiles, Pharma Support, Inc, Icon, Parexel and GSK. In 2010, our association grew and Premier Research and Covance also joined the team. Together we helped start a scientific symposium that we conduct every couple of years. To date, we have hosted three. The scientific symposiums have a large number of attendants and we invite representatives from the pharmaceutical industry and stakeholders from the Central Ethics Committee, the Romanian Association of International Manufacturers and the Romanian Regulatory Authority. Also included are key opinion leaders and members of the Romanian Association of Patients. This symposium allows for pharmaceutical stakeholders in Romania to network, have a platform to share ideas and have debates about how the industry should be regulated. Moreover, this is an opportunity for key opinion leaders to think creatively and promote growth within the Romanian pharmaceutical industry.

What have clinical trials done to promote growth within the Romanian pharmaceutical industry?

In Romania, the research and development sector is one that has grown substantially since 1997 and led to clinical trials because of the amount of experienced medical doctors and healthcare professionals we possess, the large population size when compared to other European nations and because patients generally follow doctor's orders which allows researchers to gather more accurate results.

What policies have been instituted that affect the pharmaceutical industry, specifically clinical trials, since Romania joined the European Union in 2007?

When Romania joined the European Union (EU), the Romanian regulatory authorities, such as the National Agency of Drugs and Medical Devices, succeeded in changing the policies very quickly, especially compared to Bulgaria. These new directives changed the way business was done here and the way in which companies were able to conduct clinical trials within the EU. The European Medicines Agency gave specific guidelines about how industry practices were to be carried out. However, the average number of days to get the approval in order to conduct clinical trials has gone up every single year. In my opinion, this sort of bureaucracy stunts growth and prevents companies from wanting to invest in Romanian clinical trials. According to local legislation, which is in line with EU legislation, it should be 60 days.

This has decreased the attractiveness of the business in Romania and if this continues Romania will continue to loose its competitive advantage. The relative proportion of trials conducted in Central Eastern Europe-European Union (CEE-EU) indicated a gradual decline of approximately 5 percent per year while Western Europe and North America continue to be top destinations for clinical trials. The decline of clinical trials in CEE-EU is an important indicator for all stakeholders, including regulators, sponsors, contract research organizations (CRO) and principal investigators. Obviously we need to do all that we can to reverse this trend. What Romania needs is more consistency in order to ensure continued investment in the market. With that said, once Romania does get investment from clinical trials it excels in medical areas covering a large area of medical practices, such as oncology, neurology, mental health conditions (i.e., schizophrenia) and diabetes. Some data indicates that Romania ranks one of the first nations worldwide in treatment of the patients during clinical trials, which is testament to the quality work we conduct in our respective facilities.

Where do you see Romania's positioning in Central Eastern Europe comparatively with regards to clinical trials?

As a clinical trial location, Romania has to compete quite strongly against other nations in the region. With regards to ranking, Romania should be in second place after Poland in CEE, but unfortunately countries such as the Czech Republic and Hungary, which have much smaller populations, are all to often ahead of Romania due to the stronger legislation these nations possess that promotes quicker approval to conduct clinical trials.

Many of the studies we perform here are phase 3 and for the CROs it is phase 2 and 4. The number of phase 1 trials performed is limited because it requires special authorization to perform. In actual fact, all locations that conduct clinical trials in Romania must have proper certification, which creates an extra hurdle for investors. This certification is the only one of its kind in the European Union. This regulation run by the Romanian Regulatory Authority has resulted in Romania falling behind the Czech Republic and Hungary where these requirements are non-existent.

What potential benefits can an increase in clinical trials mean for the Romanian pharmaceutical market?

Easing up policies for investors to flock into Romania and conduct clinical trials can translate into many positive things for the general market and economy. For example, the market would have the opportunity to introduce new and innovative products that would benefit the client/patient and potentially bring in more revenue from future products that can be introduced and sold. Clinical trials is an avenue by which new products can be introduced to the market and we are missing out on the opportunity to allow local doctors and researchers to participate on innovation and creation of new pharmaceutical products.

From a financial perspective, clinical trials can also relieve the debt incurred by the healthcare system. This is particularly pertinent when the overall healthcare system appears to be somewhat unsustainable. The most important thing is the customer/patient’s needs and our healthcare system is unable to provide certain medications because the state budget does not permit. The price to launch new medication in the market has also increased from 1.4 billion USD to around 2.2 billion USD in recent years.

The EU is supposed to launch new policies in 2016 which will change how clinical trials are monitored which will save approximately 800 million Euros per year. These new policies regarding data entry will allow for fewer regulations, which in turn will encourage investment into the Romanian pharmaceutical market. I am hopeful that positive changes are coming.

What are your goals and ambitions regarding the association?

There are many aspirations I have for the association as a whole, but one of the main objectives I have is to reinforce our relationship with the Romanian Association of Patients. In the United States the CROs have a very good relationship with their association of patients—I want the same to apply here. This is a priority because it allows a more streamline method for clinical trials to occur and allows the patient to have quicker access to treatment. I also hope to have conversations with other key opinion leaders, such as PIs and create a similar association for them or have them join our association to create a better collaboration with other stakeholders. I believe that by completely restructuring the clinical monitoring by 2018 we can improve the Romanian medical system and help patients.

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