Dr. György Blaskó – Former President and Chairman, HECRIN, Hungary

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Dr. György Blaskó, former President and Chairman of the Hungarian European Clinical Research Infrastructure Network, explains the role of the research network, the impact it has on the Hungarian clinical research environment, and the areas of improvement moving forward.

Can introduce yourself and the activities of the European Clinical Research Infrastructure Network (ECRIN)?

I am a clinical pharmacologist with several medical degrees and my field of speciality is blood coagulation and thrombosis. 20 years were spent in the post-graduate Medical University, and several years within governmental hospitals' pharmaceutical unit conducting bioequivalence studies. Thereafter, I moved to the industry side as medical director for 12 years in Sanofi, before taking the office of Head of Pharmaceutical Management at the University of Debrecen. This career path allowed for close interaction with all facets of drug development: from a researcher, writing protocols, and as an authority with the Clinical Pharmacology Ethical Committee (KFEB).

ECRIN was founded in 2006 and is a non-profit intergovernmental organisation that supports the conduct of multinational clinical trials in Europe. 10 years ago, the aim was to incorporate Hungary

in a wider network of clinical trials, to facilitate and help the investigator-initiated trials. Currently, these represent 42% of all trials conducted in Europe, and the remainder of them are sponsored by pharmaceutical companies. These types of trials are not performed in my country because of the current system. Any governmental unit including factories, hospitals, institutions, or research hubs must transfer their profit into the central budget. Inadvertently, to create protocols, conduct studies, clinical research or trials a proposal must be submitted to receive funds and this process can span over years. Under the current law, only the Parliament can change this system and the participation with ECRIN helps circumvent this issue.

ECRIN is an international network that contains hubs in certain countries country and have a local European correspondent. This person communicates and delegates between the hubs as well as the Clinical Trial Institutes, which conduct the trials. There is a scientific committee that oversees the proposals and if the protocols meet the requirements, through funding programs such as H2020 or the Innovative Medicine Initiative (IMI), the initiating country can apply for European grants. ECRIN will also support researchers in finding the appropriate entities in the various countries that are committed to the same topic. If a Spanish surgeon is conducting a study on a new medical device, ECRIN will find the appropriate hospital or university that utilizes the same tool. The originator of the study will receive all the funds and they will allocate it according to the participating countries.

What have been the most recent activities of HECRIN you can highlight?

Our first priority as HECRIN is to continue the building-up of the domestic clinical network by including all medical universities, county leader hospitals and national institutions, leading pediatatric hospitals (PEDCRIN) and cooperation with a euro-conform large data center. Additionally, we elaborate on common educational materials for the participants of trials. HECRIN also elaborated new concepts for the CTUs, joined the ERASMUS competition alongwith the Irish, French, Portuguese, and other nationality of universities, and joined the COST competition. We set up mutual purchasing systems for scientific instruments. Finally, the most important role of HECRIN is creating a roadmap program of innovation of the Hungarian government.

What was the impact of Hungary joining ECRIN on the clinical research environment?

When ECRIN was established its priorities were quality assurance and identifying certified clinical centres in the countries to connect partners with more ease. In turn, the local affiliative body—HECRIN—assumed an educative role to train nurses and doctors to be specialized in clinical trials. The aim was to embrace the opportunities the network offered and implement changes where appropriate to be more attractive as a potential partner within the network. The system that we have put in place, allows doctors to pursue an M.D. in clinical pharmacology, which is compulsory in Phase 1 and 2 studies. The studies that are conducted with ECRIN are equal to those performed by pharmaceutical companies in terms of quality and performance.

How do patients get access to these trials?

In-, ambulant or out-patients will get recruited by hospital doctors who are working in that area. It is therefore important to have transparent protocols and have strong pharmacovigilance capabilities to guarantee the safety of the patients. Thanks to clinical trials, 14-15,000 patients are treated yearly in Hungary, in the hopes to cure diseases for which previous treatments have failed. Domestic centralized health care and the presence of a single central ethics committee opinion all contribute to the success of clinical trials in Hungary. Currently, Hungary ranks first in Europe in terms of the proportion of clinical trials relative to the population.

What do you perceive as areas that need improvement?

In terms of quality control and clinical certification we are compliant with ECRIN. However, pharmacovigilance remains a field which requires more harmonization with the guidelines of other European countries. Pharmacovigilance is a key public health activity to safeguard and maximise the safety of medicines. Its mission is to continuously monitor the benefit-risk balance of medicines throughout their complete life cycle and is reliant on supporting infrastructure and capabilities in order to be effective. Historical data, patient registration, health literacy, access and drug records are areas that help support pharmacovigilance. Even though, Hungary follows the GDPR guideline, more time is required until the healthcare system is standardized.

What is your message to innovative pharmaceutical companies?

Be patient! Shortening deadlines only increases the chances of failure. Without proper protocols or summaries, the evaluation process will take longer. There is a responsibility tied to the assessment and that is maintaining the health of the patients. Certain institutions are not interested in the efficacy of a drug, but rather the availability of new products on the market. However, this is not the stance of HECRIN or the Clinical Pharmacological Ethics Committee: safety is the number one priority.

What would your final message be about Hungary?

Regarding ECRIN, we need to find a way to increase investigator-initiated trials originating from Hungary. If companies fully support a trial this represents HUF 50 billion a year in terms of business. If Hungary manages to get some of this business, this would be a big step in the right direction. However, this requires governmental regulations to change, so that more institutions or hospitals can initiate trials on their own.

We have outstanding doctors here in Hungary, but the healthcare system rests on the shoulders of few professionals. There are shortages of manpower in every aspect of the healthcare system, and this puts a lot of strain on medical practitioners. As a result, gynaecologists, obstetricians, and intensive care unit responders on average have a shorter lifespan of 10 years due to the stress. At the same time, there is a brain drain in Hungary. Benefits and infrastructure need to be improved, in order to motivate medical professionals to enter and stay in the healthcare system.

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