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Darina HrdliÄ•kovÃ¡, chairwoman of the Association of Contract Research Organizations in the Czech Republic (ACRO-CZ), gives an overview of her new priorities and mission since taking over the position in 2018, and how dedicated she is to showcase the strengths of the Czech healthcare system and the advantages of the Czech Republic as a clinical trials destination. Whilst explaining the undergoing projects of ACRO-CZ, HrdliÄ•kovÃ¡ also exposes her concerns about the struggle to find sponsors for clinical research in the country.

Since we last met you back in 2016, you were appointed as Chairwoman of ACRO-CZ. What have been the main milestones achieved in your new role?

Long before my role as Chairwoman, my first milestone was the creation of ACRO-CZ in 2005. I have been on the steering committee since the beginning and contributing to all ACRO-CZ missions since its founding.

My role became more important when the association joined the European Clinical Research Organizations Federation (EUCROF) and I became the representative of EUCROF in the Czech Republic. Later on, in 2010, I became the board secretary of EUCROF and the relationship and cooperation between ACRO-CZ and EUCROF increased. This relationship reached its peak in 2016 when EUCROF organized its third Conference on Clinical Research here at the Prague Congress Center. Back then, I was chairing both the organizing committee and the program committee; it was my first time chairing two committees in parallel, which allowed me to create a better exchange of information and efficient cooperation.

Despite having to fight to find sponsors, participants, and good speakers, as there are many similar and well-established conferences organized in Europe, the conference in Prague was a great success also thanks to the commitment of ACRO-CZ organizing committee members. The event also presented an amazing opportunity to shine a spotlight on the Czech Republic. We prepared a booth where we showcased a poster summarizing the advantages of doing clinical research in the country. As the initiative garnered much attention, we will present another poster for the EUCROF conference in February 2020 in Amsterdam!

What do you see as the advantages and benefits of conducting clinical trials in the Czech Republic that you will showcase at this conference?

First, the Czech Republic boasts a well-organized healthcare system, a positive legacy of the socialist era. I am old enough to have experienced working as a physician before the Velvet Revolution, and I think many healthcare systems could learn from the pre-revolution healthcare system. Of course, finances were limited at the time, but then again it is the case everywhere. However, healthcare was very well organized and accessible to all patients. Each healthcare structure, such as public hospitals or group of state-owned outpatient clinics, had a catchment area. This meant that patients living in Prague 4 would have the right to be treated in the Prague 4 hospital and could not be denied access to treatment there. It was similar for specialized care clinics. This kind of healthcare setting makes it easier to find and enrol patients in clinical trials. For instance, a Czech physician would refer a patient to a clinical trial if the person cannot be treated by a general practitioner and must go to a specialized centre. I think the referral system might be the best way to enrol patients.

Specialized centres are another important element in the Czech healthcare system. Most of them were built after the Velvet Revolution for patients with a specific diagnosis, offering better treatment options, such as biological therapy, compared to small hospitals. Specialized centres make studies easier because patients and the infrastructure are there.

How does the Czech Republic compare to other European Countries when it comes to the clinical trial approval process and startup timelines?

In my opinion, the regulatory authority, the State Institute for Drug Control (SUKL), is strict but fair. There is no delay in approvals, all of them are given within the 60 days guideline. The SUKL is also very open to discussion and cooperation. Moreover, the SUKL is quite strict in comparison to other European regulators because its priority is to protect patients. It would not give approval without good pharmaceutical data. I feel extremely grateful and thankful towards SUKL because it puts patientsâ?? safety first.

What do you think could be done to attract more trials to the Czech Republic?

Over the decade, the number of clinical trials approved by SUKL has been in a slow downward trajectory, going from a peak of 313 in 2012 to 275 in 2018. As of November 2019, the SUKL has approved 194 trials. The reason for the decline possibly lies in the fact that pharmaceutical companies prefer to conduct trials in larger markets such as France, Germany and Spain where volumes and prices are more attractive in order to be able to introduce their innovative therapies sooner. By conducting clinical trials in these countries, physicians can get acquainted with these medications. In the Czech Republic, while prices for innovative drugs might not be low for health insurance companies and patients, they are low compared to Germany for instance. With such high price pressures, sponsors have no incentive to conduct clinical trials here.

Secondly, the cost of clinical trials is increasing unnecessarily. This is the case everywhere, of course. Although costly and complex processes exist for the protection of the patients as well as of the sponsors, they can sometimes be counterproductive as they slow down clinical trials and make it more complicated to enrol the patients. The sponsors then may decide for the smaller size of trials with fewer countries. For instance, Czechs and Slovaks used to live under the same nation and understand each other, and many Slovaks live in the country. However, in order to enrol in a trial, Slovaks need to be considered as foreign patients and go through a whole process stating that they understand the language and the norms.

Do you think the government could provide incentives to encourage clinical investigation?

I do not think the government will give incentives for referrals, at least not now. However, the government could provide support for the creation of clinical trial departments, not only in big university hospitals but also in smaller and local hospitals in order to make the administrative burden shift to study coordinators instead of physicians and nurses whose numbers are decreasing while the number of coordinators can be increased. Even if in certain cases, physicians want to conduct clinical trials by themselves; this is not well feasible in clinical centres. Clinical studies not only require handling tons of data, such as electronic Case Report Forms (CRF) but also managing communication with many vendors. It is the work of the study coordinator to communicate with and organize all these stakeholders. Without coordinators, the process is a lot more complicated.

Moreover, we are currently in a generational turnover. There are still physicians from the older generation who never learned to use computers at school. I belong to this generation. I only had my first computer when I began working as a physician. Obviously, we have learnt since then but there is still a gap with younger generations who have been exposed to these new technologies since their childhood. Older physicians in particular mostly need study coordinators for administrative support. On the other hand, it is still a challenge to educate these physicians about the fact that conducting a clinical trial on their own brings a large and unnecessary administrative burden, so they need a study coordinator.

One of the focus of our association is on education, not only towards physicians but for all healthcare professionals. For a period of time in the past, we have benefited from support via an educational grant from the European Union to organize lectures in cooperation with the Third Faculty of Medicine of Charles University. It was a very successful project, but unfortunately, this financial support did not continue. For ACRO-CZ, it was a step-down, we had to stop the activity as it was not feasible without funding. Under my chairmanship, we are putting a lot of effort into relaunching this activity, which will also give ACRO-CZ more visibility. Thus, we are partnering with the Association of Innovative Pharmaceutical Industry (AIFP) to create joint educational activities. Together, we organize training

sessions for investigators. The first round happened here in Prague, and then we will organize these pieces of training across the country. These courses are one of the important recent milestones of ACRO-CZ.

New technologies, such as digital monitoring, are creating efficiency and efficacy breakthroughs within the clinical research operations. Is the Czech healthcare system ready to embrace these technologies?

Unfortunately, the legal framework is missing for the healthcare system and SUKL to implement digital technologies.

Remote clinical trials, where patients rarely come to the clinic and receive treatment at home, are impossible to conduct in the Czech Republic because homecare is still underdeveloped and there is no certification and approval process. However, since patient logistics and transportation are well organized, and the Czech Republic is a small country, this does not represent such a challenge.

EUCROF is organizing the 5th European Conference on Clinical Research in Amsterdam. What makes you excited about this event, and how do you intend to portray the Czech Republic during this event?

As the chair of the organizing committee, I am extremely excited about the conference in Amsterdam! I would really like to make this conference a meeting point for CROs and pharmaceutical companies to discuss the hottest topics and trends and improve healthcare, treatments, and accessibility together. I am currently working hard on advertising the conference and our appealing program touching upon regulatory affairs, the top issues for clinical research, and the digitalization trend.

For the Czech Republic, as I said, we will showcase a new poster highlighting the quality of our healthcare system and our investigators who behave very fairly, are strictly following the protocol and produce high-quality data. Despite the size of our country, we are still at the top of the enrollment rates in our studies!

Finally, what would like to achieve in the upcoming years?

First, I would like to continue regulatory improvement. We have already been quite successful in this regard with the elaboration of the national contract template for clinical trials through collaboration with the AIFP. The first version of this contract with hospitals has already been implemented, and we are now working with the Ministry of Health to make it mandatory.

Secondly, I wish to intensify the promotion of clinical trials in the country. ACRO-CZ has already initiated a group travelling across the country visiting the management teams in major hospitals to persuade them to conduct more clinical trials by showing them the support we can offer and the advantages for them, such as access to free medications, new knowledge, publications, and so on.

Thirdly, a key focus of my chairmanship will be to involve patient organizations more. We are currently working on a new website, which we will launch in the near future, where CROs will be able to advertise ongoing clinical trials with the criteria for eligibility, details, contacts, and so on. The links

will redirect the user to the respective contact person for a consultation. Our website will be the source of information for patient organizations in particular. We will work with patient organizations so that their members are aware of clinical trials opportunities and they know where to apply.

Finally, I want to continue our training programs for investigators because the first step of a successful clinical trial is knowledge. This is vital in order for no patient to be left behind in the complicated systems used in clinical trials.

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