Interview with Virginie Hivert

Transcription

So my name is Virginie Hivert, I'm working for EURORDIS, the European organisation for rare disease patients. I'm the Therapeutic Development Director, and so I'm a patient advocate and from background I'm trained as a pharmacist and I worked also as a researcher.

We're facilitating the engagement of patient in existing opportunity especially with the different stakeholders like with the European Medicine Agency. And we're also advocating to create new opportunities for patient engagement at different step of the development of a project. We have, are of the opinion that patient should be involved all along the life cycle of a project development, and that their input is really important especially at the beginning of a development, when you are planning to develop a project especially in the field of rare disease. Patient are key to identify their unmet medical needs, they're key to help collecting data for natural story studies. They're also key to define what will be the appropriate outcomes of clinical research, so which endpoint you would like to choose for developing your product. So, for that, they also have to be prepared and to know how to interact with the different stakeholders in these processes.

HOW DO YOU SUPPORT PEOPLE BECOME PATIENT EXPERTS?

So we have several capacity building programs, EURORDIS is part of EUPATI. We also have EURORDIS summer school. So, with all these different opportunities, what we are aiming is to allow patient to know how to play by the rules, which, how the different stakeholders, what is the environment in which they will have to give their inputs, because the more you know the environment outside, the more you have a meaningful impact. So that's really the idea to have the knowledge of the R&D processes and also more practical hands-on training on how our meeting is going on, how people are interacting and where patient can have the maximum of impact.

WHAT KIND OF IMPACT CAN PATIENT EXPERTS HAVE IN R&D PROCESSES?

From what I've observed, from patient participating in protocol assistance procedure in EMA committees, the regulators, the other stakeholders are always very keen to listen to what the patient have to say, and the patients are bringing the unique perspective of living with a disease, living with a rare disease. So all the other stakeholders are listening to them.

WHAT ARE SOME OF THE CHALLENGES THAT PATIENT EXPERTS CAN BE FACED WITH?

Another challenge for patients is, because there is multi stakeholders in the research and development field, they sometimes have to choose, so I think this choice can be difficult because when you have several opportunities, then you are confrontated *[sic]* to the issue of conflict of

interest which can be real or just perceived conflict of interest, but for a patient, it can be quite disturbing. So I think the question I get the most often are “What choice should I make? I’m contacted by pharmaceutical company, I think that would be interesting, but if I go then maybe I will not be able any more to go and take part of meetings, the EMA, with scientific advisor protocol assistance meetings.“

WHAT IS SO SPECIAL ABOUT INVOLVING PATIENT EXPERTS IN R&D?

What impress me the most is the energy from patient and their ability to combine their own skills with the training they received and to make it even more powerful. And in fact, I think the training is really a gate opener for them. It’s how to, I mean, enter in a new world that probably they were not aware of before. But it’s also cross-fertilising process because we all learn from each other, so it’s not only one way, it’s really two ways of learning. So that’s what I get from my experience so far. And we also need to adapt continuously to the change of the regulatory processes, to the new methods, and the evolution of the science and clinical research. So we also have to adapt the training and the way we organise and we facilitate the patient engagement.