CLINICAL TRIAL AMBASSADOR

Clinical Trial Ambassador ***eMagazine***

Report by Ien Fransen on the EU-X-CT Public Stakeholders forum

Brussel Crowne Plaza, 12 April 2024

Conference: EU-X-CT Public Stakeholders forum

Making cross-Border Access to Clinical Trials a Reality

Telling the audience about the CTAs

First let me express my gratitude to Ingeborg to be able to participate in this meeting. It was very inspiring and heartwarming to join this well-organized event and meet people who want to make a change for the best interest of patients.

Who organized this conference?
The EU-X-CT is a multistakeholder initiative jointly led by EFGCP (European Forum for Good Clinical Practice and EFPIA (European Federation of Pharmaceutical Industries and Associations).
In order to shed light on the barriers to cross-border participation in clinical trials in Europe and to develop recommendations for enabling better access, the EU-X-CT initiative has launched several surveys.

EFGCP is the European Forum for Good Clinical Practice. EFGCP is a non-profit organisation established by and for those interested in the development of medicines and medical technologies.

Introduction Stake holders Forum:
The pan-European public-private EU-X-CT Initiative aims at facilitating cross-border access to clinical trials in concrete terms. This initiative collects information on the regulatory, ethical, healthcare system and organizational conditions for the involved stakeholders, experience and best practices in all European countries. Information regarding legal, regulatory and ethical as well as practical aspects on conditions and

options for cross-border access to clinical trials is collected. The EU-X-CT gap analysis will be the basis for the panel and open forum discussions to come to conclusions about the most efficient European and national strategies and activities for improvement in the near and mid-term future.

Current experience with cross-border trial participation

In Romania patients who want to go cross-border cannot afford it because it is much too expensive or they are excluded from clinical trials for other reasons.

Others have problems due to the language barrier. In some instances a clinical trial is available but the informed consent is not available in translated form for their language.

A father talked about his experience with his child. He had to set up a makeshift bed in his car because an ambulance was too expensive for him. They had to wait three weeks for the insurance company to approve the treatment, but his child didn't have that much time. It was difficult for the father to find a clinical trial for his child.

That´s where we come in. I mentioned that there are already 54 Clinical Trial Ambassadors (CTAs) in Europe. One of the forum members, Janek Kapper from Estonia is one of these CTAs.

Janek and me

Overcoming borders will make Europe a more attractive place for clinical trials

Elmar Nimmesgern, Policy Officer Health Research at the European Commission reminded us that innovation cost a lot of time. The European commission already spent 500 million euros on clinical trials and 100 million euros on Covid intervention. The commission will work on an easy way to get the patients files in doctors' offices across borders.

He gave an overview about what has happened in the last 25 years and with the final words of his speech made clear that "There is still room for improvement".

The issues of cross-border access to clinical trials in Europe – Susan Bhatti Merck BV

The EU-X-CT gap analysis. In a multi-stakeholder survey 92% of 450 respondents said "yes" to cross-border clinical trials. Cross-border trial access is generally not prohibited.

It seems that a formal national legal/regulatory/ethical framework does not exist.

What are the laws in the European countries? Some countries have ethics committees and one needs their approval to go cross-border.

Who pays for it?
Currently there is no cooperation between the European health care insurance and EU-X-CT. However, EU-X-CT made it clear that they had already tried to initiate this cooperation and will not give up.

Conclusion:
Cross-border access to clinical trials is possible and necessary but in order to be successful it has to work for all parties involved.
Recurrent questions like who's responsible for covering the costs as well as the burden of administration and the translation into different languages are issues that need to be solved.

Where are the assessment gaps?
In the open forum discussion it was mentioned that there are all kinds of different laws in the European countries which need to be standardised.
Patients need to be guided in and to another country so that they do not feel lost. Hence, there are more challenges than insurance and language.

How can other EU initiatives benefit from improved cross-border access to clinical trials?
There are a number of EU-funded projects on rare disease therapy development and on personalized medicine development like PCM4EU and PRIME-ROSE that have the organisation of clinical trials in their work-plan. They all are in danger of not being able to complete patient recruitment within the strictly defined project time frame. They all would benefit from enabling patients from abroad to join their trials.

Enabling cross-border access to Clinical Trial
Bettina Ryll gave an example of cross border initiatives like PRIME-ROSE: Precision Cancer Medicine Repurposing System Using Pragmatic Clinical Trials funded by the European Union.

The way forward: How to make progress in cross-border access to clinical trials?
Recommendations given at the event:
1. Minimal ethical standards for cross-border trial participation.
2. Harmonized liability insurance conditions for foreign patients when liability issues occur after the patient's stay at the site across the countries.
3. Recommendations for sponsors on creating or preparing for participation of patients abroad.
4. Recommendations for sites on preparing for participation of patients from abroad.
5. Recommendations for national healthcare systems and health insurance on coverage of costs of the sites and of the patients for abroad participation in such trials.
6. Create an overview of options to find clinical trials and collect/present patient journeys on the EU-X-CT website.