PINK SHEET
CITELINE REGULATORY

18 Apr 2024 | **News**

EU Stakeholders Devise Six-Point Plan To Improve Cross-Border Clinical Trials

by Eliza Slawther

Sponsors need guidance on ethics requirements and clarity around national regulations to conduct cross-border clinical trials in the EU, a multi-stakeholder forum says.

Stakeholders from the EU health care sector, including pharmaceutical industry representatives and patient organizations, convened on 12 April at a workshop to discuss the challenges faced in enabling cross-border patient access to clinical trials in the EU.

During the event, which was held by the EU Cross-border Trials Initiative (EU-X-CT) in a hybrid format in Brussels, Belgium and online, many speakers and attendees raised concerns about access barriers such as a lack of financial aid for patients looking to join clinical trials in EU countries other than their country of residence.

Challenges faced by trial sponsors were also explored during the event, with several speakers highlighting regulatory ambiguity when it came to setting up clinical studies in one EU country and recruiting patients from another.

EU-X-CT was set up in early 2023 by the European Forum for Good Clinical Practice (EFGCP) and the pharmaceutical R&D-based industry federation EFPIA to generate recommendations to enable cross-border access to clinical trials for patients in the EU. (Also see "*Patient*

Key Takeaways

- Pharmaceutical industry representatives have called for more clarity around national regulatory requirements when conducting cross-border clinical trials in the EU.
- The EU-X-CT initiative, which was established to help find solutions to these

PINK SHEET
CITELINE REGULATORY

Groups Back EU Cross-Border Clinical Trials Access Initiative" - Pink Sheet, 16 Mar, 2023.).

A six-point plan was drawn up by the event hosts towards the end of the meeting, based on these discussions. Susan Bhatti, director of EU global regulatory and scientific policy at Merck BV in the Netherlands, said the plan would ensure that "we are not in the situation where for every cross-border trial, the wheel is reinvented."

answers, has recommended working with ethics committees and developing guidance for sponsors as part of an action plan to increase the use of cross-border trials.

- Patients also need help with costs beyond those covered by the trial sponsor, which should be the role of health insurance companies and payers, some industry stakeholders have said.

The first point on the plan would be for the EU-X-CT initiative and other relevant stakeholders to "work together" with MedEthicsEU, a special group under the umbrella of the European Commission, to "work out what the minimal ethics committee requirements would be for cross-border access."

"We've seen that many of the national requirements are actually coming from ethics committees, but they are not identical, even within one country, so perhaps one of the first steps is to try to speak with ethics committees in the different European countries and say to them, 'can we agree on some requirements that everybody thinks are pragmatic?'," said Bhatti, who is also chair of EFPIA's clinical research expert group.

The second point of the action plan was to "come up with some recommendations for sponsors of cross-border trials," for instance around how their clinical trial protocol should address the cross-border nature of the trial, how clinical trial sites should be prepared, and how a sponsor could contact an ethics committee ahead of time.

"Preparation seems to be everything when it comes to a sponsor wanting to set up a trial with cross-border access," Bhatti said, adding that recommendations "would be extremely helpful for all of us in industry, for contract research organizations, but also investigators and academic sponsors."

Regulatory Requirements

Regulatory considerations were the third point on the EU-X-CT action plan, based on the concerns voiced by attendees of the workshop. Bhatti noted that there was a large "level of uncertainty" around the national regulations governing clinical trials.

"It would be super helpful if we did get feedback from the national agencies on whether there is

anything in their national legislation that we didn't pick up around cross-border access, and what the views are from the national regulators about this," she said. She added that the EU-X-CT would be looking for "pragmatic feedback" rather than a list of risks that would prevent cross-border access to trials from becoming more widespread.

Bhatti's co-host Ingrid Klingmann, chair of the board of the EFGCP, said that another point of action within the regulatory category would be to "get an agreed statement" from the EU's Clinical Trials Coordination Group (CTCG) that explains there is nothing in principle within EU legislation that would require a patient to gain approval to enter a cross-border clinical trial, but that there might be additional local laws that required some kind of approval.

"I think we should be very clear and should be able to create that clarity, that there is not really a need for legal approval at the European level," Klingmann said.

Empowering Patients

The fifth action point listed by Bhatti related to the need to "empower patients," a recurring theme during the workshop. Several speakers from patient organizations emphasized the financial hardships faced by EU patients in accessing cross-border trials, given that flights and accommodation are not always covered by the trial sponsor.

Bhatti stressed the need for patients to be made aware of cross-border clinical trials and the ways in which they can access them. She acknowledged that during the workshop, one attendee tabled the possibility of utilizing a network of "clinical trial ambassadors" from patient organizations who "know how to talk to patients."

"This is definitely not where industry excels," she said, explaining that engaging with patients in a way that is understandable for them would require the expertise of ambassadors who are skilled in this type of communication.

Klingmann added that there should be more signposting for patients to help link them up with clinical trial organizers abroad, and noted that since the COVID-19 pandemic, patient interest in clinical trials has increased – something that could be used to the advantage of trial organizers.

Payers & Insurers

The final action point related to connecting with health insurance organizations and payers,something that Bhatti described as "the elephant in the room."

She said that working with health insurance companies and payers was a "huge issue" in the context of cross-border clinical trials, based on surveys of stakeholders conducted by the EU-X-CT.

“It’s turned out to be very, very difficult to actually contact them and get traction, but we won’t give up,” Bhatti said, adding that the cost of joining a trial was often a limiting factor for patients.

While sponsors of commercial clinical trials could cover some of the costs involved, Bhatti noted that there were costs outside the trial setting that drug sponsors would not be able to help patients with.