

Cross-border access to clinical trials is a puzzle that Europe needs to solve

The current EU directive on patients' rights for cross-border healthcare guides how patients can travel for care in another country. But it does not account for the needs of cancer patients seeking access to clinical trials abroad. Today's challenges and opportunities for cross-border trials are summarised in a new study that was discussed at the ECCO 2019 European Cancer Summit.

Patients benefit from access to innovative medicines through clinical trials, and the EU single market should facilitate patient participation in trials in other countries. Results emerging from a recent study on cross-border clinical trials indicate that ease-of-access for clinic trials in another country is not there yet.

The study highlights that there is a current lack of EU legislation or guidelines to facilitate patients' participating in trials in other locations. But cross-border trials are happening, and the trend is growing in some regions. This lack of a European legal framework means that patients travelling to another country for trials face issues such as: a lack of clarity on protocols for follow-up when they return home, and how national insurance covers costs; and practical issues such as who is responsible for covering the cost travel, lodging and related logistics.

These obstacles to participating in trials in other countries suggest improvements to the legislative, administrative and regulatory frameworks around cross-border trial participation in Europe are still possible. Developing the new legislation will take time, and it is a puzzle that needs to be solved, said

KEY MESSAGE

Greater facilitation for cross-border clinical trials is possible through further legal and administrative clarification.

discussants. But despite the lack of a legal basis, there are bright spots that can guide practice in the meantime. A range of practical examples that show what is working today can serve as guidance until an EU directive or regulation is finalised.

The Nordics – Denmark, Finland, Norway, Sweden – have a network for sharing new trial results and information on access to new therapies. Slovakia's legislation specifies that their citizens participating in trials in other countries will be covered by national insurance at home, provided they inform medical authorities. In the Netherlands-Germany border regions, university hospitals cooperate on research, they exchange data and, for trials, work together to facilitate and simplify patients' access.

These issues are complex. But participants agreed that sharing these and other practical examples will help harmonise the situation for patients today. It was emphasised that the purpose of cross-border trials is not to encourage mass movements of patients between countries. Discussants said this is unlikely to happen in any case, as patients prefer treatment near home in a familiar environment. Cross-border trials add value to treatment in specific cases, such as rare diseases, where there are no local options left. At this point, the possibility to easily access new therapies in another country brings life-changing potential.

The study's research partners are now building on the results to prepare a call to action with guidelines for cross-border trials, hopefully moving toward EU legislation.

Spotlight session: Clinical trials across borders

Teodora Lalova, European Organisation for Research and Treatment of Cancer (EORTC): Overview of the study on issues and gaps related to cross-border access to clinical trials in Europe, by the European Forum for Good Clinical Practice (EFGCP), EORTC, KU Leuven and Patvocates, with support of the European Federation of Pharmaceutical Industries and Associations (EFPIA)

Panelist: Dr Ingrid Klingmann, European Forum for Good Clinical Practice (EFGCP)

Moderator: Jan Geissler, ECCO Patient Advisory Committee and CML Advocates Network



Teodora Lalova, European Organisation for Research and Treatment of Cancer (EORTC)