REPORT SUMMARY

EU-X-CT PUBLIC STAKEHOLDERS' FORUM

MAKING CROSS-BORDER ACCESS TO CLINICAL TRIALS A REALITY

WEBSITE

EU-X-CT C/O EFGCP
https://eu-x-ct.eu/

eu-x-ct

INTRODUCTION

The work of EU-X-CT is trying to make it easier for patients to join a clinical trial in a foreign country. At a meeting in Brussels on April 12, 2024, many different experts and patient groups discussed the big obstacles and possible solutions for cross-border access to clinical trials.

The full report can be found at www.eu-x-ct.eu: **LINK**.
Presentations made at the event can be found here: **LINK**.

CONTENT TABLE

Table of Content

ACKNOWLEDGEMENTS

THE EU-X-CT THANKS ITS CONTRIBUTORS FOR THEIR CONTINUED SUPPORT

INITIATIVE LEADERSHIP

EFCCP

efpia

WITH THE SUPPORT OF

GOLD

Roche

SILVER

Johnson&Johnson

BRONZE

Pfizer

12 APRIL, 2024
SCHEDULE

09:00 **Registrations & Welcome Networking Coffee**

SESSION 1: WHERE ARE WE TODAY?

10:00 **Welcome and Introduction to EU-X-CT**

Welcome from EFGCP and EFPIA
Ingrid Klingmann, *Pharmaplex, EFGCP*
Susan Bhatti, *Merck BV, Chair CREG (EFPIA)*

Welcome from the academia members
Jacques Demotes Mainard, *ECRIN*

Welcome from the patient members
Lisbeth Snede, *Patients Unite*

10:20 **Round table: Current experience with cross-border trial participation**

Moderator:
Lisbeth Oxholm Snede, *Patients Unite*

Panelists*:*
Michel Zwaan, *Prinses Máxima Centrum voor kinderoncologie BV*
Violeta Astratinei, *Melanoma Patient Network Europe*

10:50 **Keynote: Overcoming borders will make Europe a more attractive place for clinical trials**

Elmar Nimmesgern, *European Commission DG R&I*

Q&A

11:20 **The issues of cross-border access to clinical trials in Europe: The EU-X-CT gap analysis**

Moderation and Introduction:
Susan Bhatti, *Merck BV*

Presentations by Task Force leads:
Maren Koban, *Merck Healthcare KGaA*
Lisbeth Snede, *Patient Unite*
Maja Pizevska, *Berlin Institute of Health at Charité (BIH)*

Q&A

12:20 **Panel and Open Forum Discussion:**
- Is this picture accurate and comprehensive?
- Where are the assessment gaps?
- What other EU initiatives would benefit from improved cross-border access to clinical trials?

Moderator:
Solange Corriol-Rohou, *AstraZeneca*

Panelists*:*
Elmar Nimmesgern, *European Commission DG R&I*
Emilie Prazakova, *Roche*
Janek Kapper, *Estonian Inflammatory Bowel Disease*
Marianne Lunzer, *AGES, CTCG co-chair*
Michel Zwaan, *Prinses Máxima Centrum voor kinderoncologie BV*
Monique Al, *CCMO, CTCG co-chair, MedEthicsEU co-chair*

13:00 **Lunch**

SCHEDULE

SESSION 2: WHERE DO WE WANT TO GO?

14:00 **Enabling cross-border access to Clinical Trial**

Moderator:
Sabine Kläger, *ECRIN*

PCM4EU and PRIME-ROSE - cross-border access to pragmatic precision medicine trials
Bettina Ryll, *Stockholm School of Economics Institute for Research and Melanoma Patient Network Europe*

Industry experience with Cross-Border Enrolment in Rare Diseases
Joanna Sprague, *ICON*

Q&A

14:30 **The way forward: How do we make progress in cross-border access to Clinical Trials?**

Moderator:
Bettina Ryll, *Stockholm School of Economics Institute for Research and Melanoma Patient Network Europe*

Panelists:
Begonya Nafria Escalera, *Hospital San Juan de Déu, eYPAGnet*
Elmar Nimmesgern, *European Commission DG R&I*
Jacques Demotes Mainard, *ECRIN*
Marianne Lunzer, *AGES, CTCG co-chair*
Monique Al, *CCMO, CTCG co-chair, MedEthicsEU co-chair*
Susan Bhatti, *Merck BV*

15:30 **Break**

15:50 **Open Forum Discussion: How can EU-X-CT achieve the most urgent goals and how to make them sustainable?**

Moderators:
Ingrid Klingmann, *Pharmaplex, EFGCP* and **Susan Bhatti**, *Merck BV*

16:50 **Conclusions and next steps**

Ingrid Klingmann, *Pharmaplex, EFGCP*

17:00 **End of meeting**

CURRENT STATUS

SUMMARY OF SESSION 1

Introduction to EU-X-CT

The leaders of EU-X-CT, Ingrid Klingmann and Susan Bhatti, welcomed the participants and stressed the importance of making Europe more attractive for clinical trials. They called for clear actions to make cross-border access to clinical trials easier for all patients needing access to an innovative treatment, especially patients with life-threatening and rare diseases.

PERSONAL EXPERIENCES

Violeta Astratinei, a patient representative and care giver, shared her experiences when helping her sister in Romania to join a trial in another country when a melanoma was diagnosed. She described the financial, practical, and emotional difficulties in finding and joining a clinical trial in another country because no fitting trial was performed in Romania. She said that only well-connected patients with financial reserves sometimes manage to join a trials in another country, which is unfair.

> "If you have the financial means, then you can go with your money to Germany or Belgium and occasionally to Italy. But lately, some hospitals in Germany have started to ask for a deposit of 10,000 euros for trial participation."
>
> **— Violeta Astratinei**

Prof. Michel Zwaan, an investigator based in the Netherlands, and Frederik, the father of a young patient with a rare cancer living in Belgium, shared their experiences with such cross-border trial participation. They faced practical travel issues as well as cultural differences in hospital care, and talked about problems in medical care after the trial, when the patient was back home in Belgium

CHALLENGES IN ACCESS TO CROSS-BORDER TRIALS

Discussions showed that finding the hospitals where a trial is open and getting support from health insurance companies to cover the costs of cross-border participation are major hurdles. Websites like www.clinicaltrialsregister.eu or clinicaltrials.gov can help to find a potentially suitable trial but are difficult for patients to use. Providing trial information in a language the patient understands, reducing the burden on patients joining a trial so far away from home, and difficulties in health data sharing between the site and the patient's treating physician across a border were also key concerns. Elmar Nimmesgern from the European Commission spoke about the difficulties of harmonizing laws across EU countries and the importance of European investments in clinical research, especially for rare diseases like cancer in children.

THE EU-X-CT GAP ANALYSIS

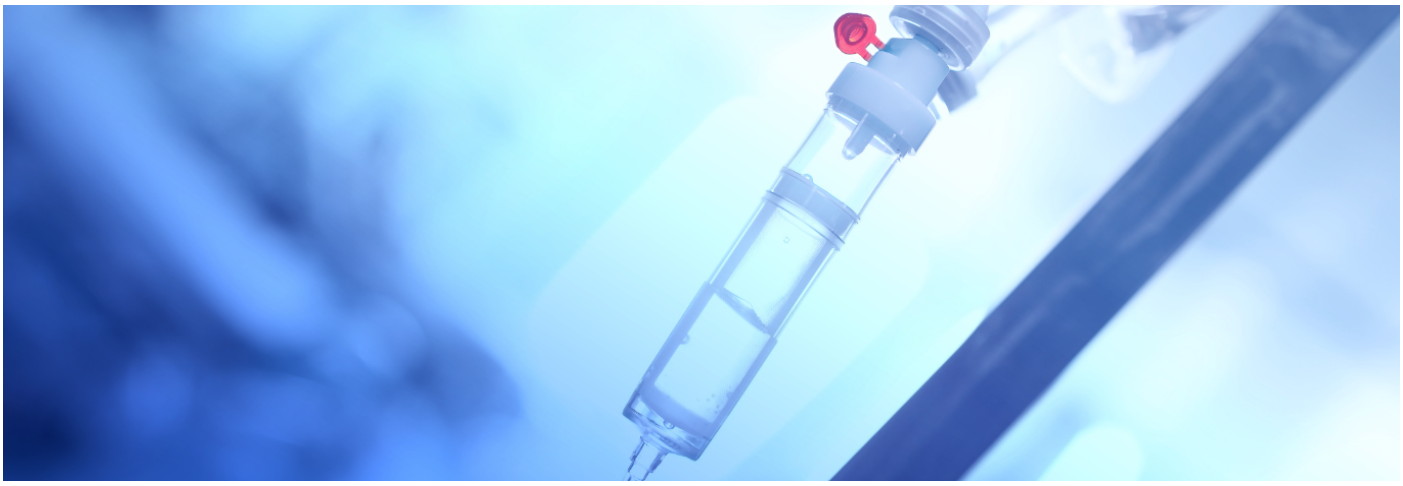
Survey Results

EU-X-CT sent out three surveys to many different experts to collect information on cross-border access to clinical trials:

1. **Legal, Regulatory and Ethical Aspects:**
   Cross-border access to trials is allowed but exact requirements vary across countries, such as how to provide information in a language the patient understands.
2. **Financial Aspects:**
   Insurance of trial risks and coverage of costs not included in the trial budget are major issues. Clearly defined financial support conditions for cross-border trials are needed.
3. **Operational Aspects:**
   Identifying hospitals where a trial can be joined by a patient living in another country and managing patient travel and medical data transfer are often challenging.

FUTURE DIRECTIONS

SUMMARY OF SESSION 2



SUCCESSFUL INITIATIVES

Projects funded by the European Commission like PCM4EU and PRIME-ROSE have also looked at cross-border access to support precision medicine trials. Joanna Sprague shared useful experiences, examples and tips for cross-border enrolment of children with a rare disease, which showed the importance of detailed preparation, clear information, and the need for collaboration in order to be successful.

STRATEGIES FOR IMPROVEMENT

The participants debated how to improve the conditions for cross-border trials.

They recommended:

- extended raising of awareness about this problem,
- more concrete collection of information on national legal, ethical, financial and operational conditions for patients and sites involved in cross-border trials,
- and to jointly develop recommendations with all involved stakeholders on how to overcome these issues.

CONCLUSIONS AND NEXT STEPS

Ingrid Klingmann and Susan Bhatti concluded the forum by emphasizing the need for all parties to work together on concrete improvement of trial participation in another country for all patients in need.

Recommended Concrete Next Steps are summarized below:

HOW CAN EU-X-CT ACHIEVE THE MOST URGENT GOALS AND HOW TO MAKE THEM SUSTAINABLE?

EU-X-CT co-chairs, Ingrid Klingmann and Susan Bhatti, presented a 6-point action plan based on the results of the EU-X-CT gap analysis and the multi-stakeholder discussions at the Public Forum

1. To work out the minimal ethics committee requirements for cross-border participation in clinical trials in collaboration with MedEthicsEU.
2. To develop a set of recommendations for industry and academic sponsors as well as CROs, on how to approach cross-border trials in their protocols, when to inform the relevant ethics committees about the planned conditions, and how to prepare and support sites for hosting patients from abroad.
3. To develop a set of recommendations for investigators and sites on aspects they need to clarify when wanting to host patients from abroad.
4. To reach out to payers and health insurance companies to get clarity on the cost coverage of cross-border trial participation.
5. To clarify with liability insurance companies how damages occurring to the patient in his/her home country could best be covered.
6. To raise awareness among patients and treating physicians about the option of cross-border participation in clinical trials. Establishing national contact points for patients was also suggested.

THANK YOU

All speakers and participants of the EU-X-CT Public Forum 2024

All EU-X-CT members and collaborators

EFGCP and EFPIA

EU-X-CT sponsors

EU-X-CT Public Forum Programme Committee

EFGCP Secretariat

Report written by Dr. Roshini Beenukumar (Medical Writer) based on notes taken during the meeting and recordings of the talks. Summaries reviewed by Dr. Susan Bhatti and Dr. Ingrid Klingmann.

EU-X-CT PUBLIC STAKEHOLDERS' FORUM

MAKING CROSS-BORDER ACCESS TO CLINICAL TRIALS A REALITY

Contact us

WEBSITE

EU-X-CT C/O EFGCP
https://eu-x-ct.eu/

eu-x-ct

Crowne Plaza Brussels Airport
Da Vincilaan 4, 1831 Diegem
Belgium