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 EU-X-CT initiative, a pan-European public-private partnership, aims to facilitate cross-border access to clinical trials. The Public Stakeholder's Forum, held on April 12, 2024, in Brussels, brought together diverse stakeholders to review the regulatory, ethical, social security, liability insurance, and organizational conditions impacting cross-border clinical trial participation. This report provides key insights from the meeting. The full meeting report is available at https://eu-x-ct.eu/.

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ACKNOWLEDGEMENTS

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

INITIATIVE LEADERSHIP

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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**

WHERE ARE WE TODAY

SUMMARY OF SESSION 1

Introduction to EU-X-CT

EU-X-CT co-chairs Ingrid Klingmann and Susan Bhatti welcomed all participants on behalf of the chairing organisations – EFGCP and EFPIA –to the first public stakeholders' meeting of the EU-X-CT initiative.

Sabine Kläger welcomed the participants on behalf of the academic community, and Lisbeth Snede welcomed the participants on behalf of the patient community.

They emphasised the need to make Europe more attractive for clinical trials by enabling better cross-border access and the concrete action needed in the next couple of months to ensure the initiative's success.

PERSONAL EXPERIENCES

Violeta Astratinei shared her experience looking for treatment for her sister in Romania (who had melanoma) and working as a patient advocate. Her narrative underscored the difficulties and burdens, including financial, logistical, and mental challenges, faced by patients seeking cross-border access to clinical trials. She noted that proactive, well-connected patients are sometimes able to access these trials, but this is neither sustainable nor equitable.

> "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, a Paediatric Oncologist at the Prinses Máxima Centrum voor kinderoncologie BV, and Frederik, the father of a paediatric patient, shared their experience with a cross-border trial. Logistic challenges and cultural differences, as well as post-study medical care caused practical problems.

ROUND TABLE AND KEYNOTE

The round table and keynote discussions highlighted the current challenges in cross-border access to clinical trials. Key issues included identifying hospitals that run trials, and dealing with lack of basic cost coverage by insurance companies, who are unwilling to support cross-border participation due to undefined financial coverage conditions in most countries. Websites such as https://clinicaltrials.gov/ and www.clinicaltrialsregister.eu/ could help when looking for a trial, but are difficult for patients to use. The necessity of patient-facing infomation material in the patient's language, ethical concerns about patient burden and difficulties of data sharing across borders and healthcare systems were also discussed.

In the Keynote Speech Elmar Nimmesgern (European Commission DG R&I) emphasised the complexity of harmonizing legislation among diverse EU member states, and also European investments in clinical research. An area where cross-border collaboration makes sense is rare diseases, including paediatric oncology.

THE EU-X-CT GAP ANALYSIS

Survey Results

Three surveys were conducted to gather information on legal, regulatory, ethical, financial, and operational aspects of cross-border clinical trials. Key learnings are summarised below:

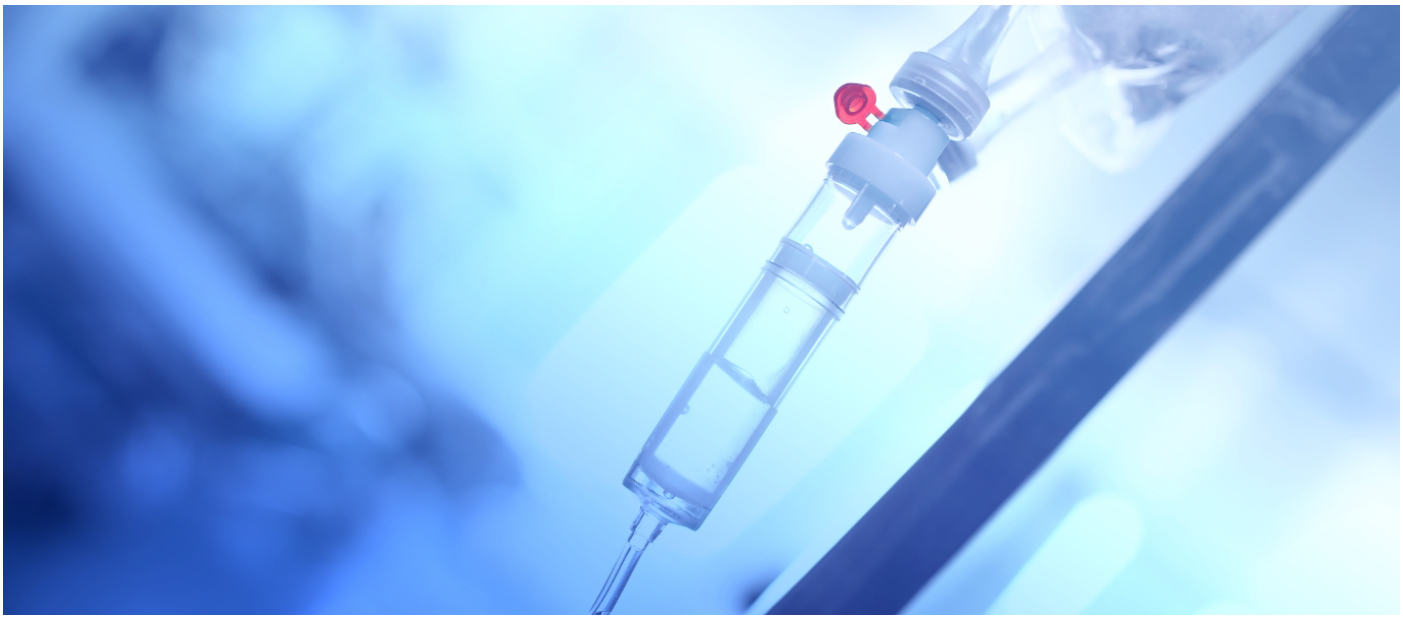
1. **Legal, Regulatory and Ethical Aspects**
   - Cross-border clinical trial participation is generally feasible from a regulatory prespective
   - Ethics Committee (EC) requirements are key, such as the need for patient-facing materials to be in a language understood by the patient
   - Accessing cross-border trials varys greatly across countries and there is a lack of reliable information or guidance

2. **Financial Aspects**
   - Liability insurance issues and healthcare costs not covered by the trial budget are major concerns
   - Financial support structures for cross-border trials need clarification and improvement

3. **Operational Aspects**
   - Challenges in identifying hosting hospitals and investigators willing to enable cross-border patient participation
   - Logistical issues related to patient travel and data transfer across borders

FUTURE DIRECTIONS

SUMMARY OF SESSION 2



CROSS-BORDER ACCESS INITIATIVES

Projects like PCM4EU and PRIME-ROSE have also looked at cross-border access to support precision medicine trials. Joanna Sprague shared useful examples and tips for cross-border enrolment of paediatric patients with a rare disease, which showed the importance of detailed preparation, clear information, and for everyone involved to work together closely to be successful.

THE WAY FORWARD

Panelists debated strategies for making progress in cross-border access to clinical trials. They explored how EU-X-CT could achieve its urgent goals and ensure sustainability. Discussions focused on the importance of providing information and guidance, insurance frameworks, and stakeholder collaboration to facilitate smoother cross-border trial processes.

CONCLUSIONS AND NEXT STEPS

Ingrid Klingmann and Susan Bhatti concluded the forum by emphasizing the need for continuous collaboration among stakeholders to address the identified gaps and challenges. The next steps include further efforts on awareness raising, ongoing information collection on national conditions for cross-border trial participation, and development of multi-stakeholder agreed recommendations on key conflicting aspects like ethical requirements, financial coverage and operational hurdles to ensure equitable access to cross-border clinical trials.

The next Steps are summarized in the following 6 points:

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

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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.

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