Cross-border Access to Clinical Trials

EUCCT

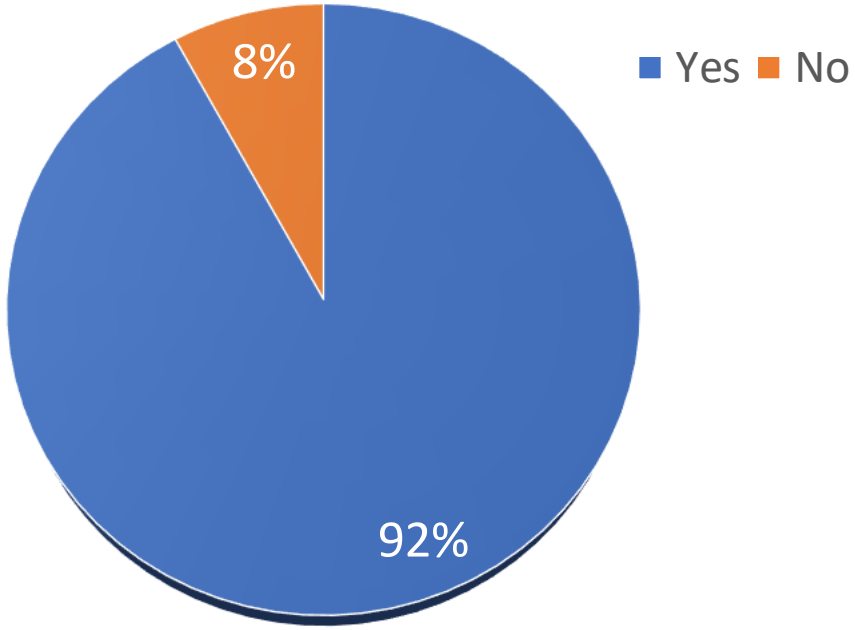
EFGCP

efpia

Why cross-border access to trials?

An exploratory study* in 396 stakeholders conducted in 2019/2020 showed a high need for cross-border access to clinical trials in Europe

Do we need cross-border access to trials?



Stakeholder representation in survey

Investigators	**46%**
Patient organisations	**23%**
Individual patients or carers	**10%**
Sponsors	10%
Ethics Committees	1%
Regulators	1%
Others	9%

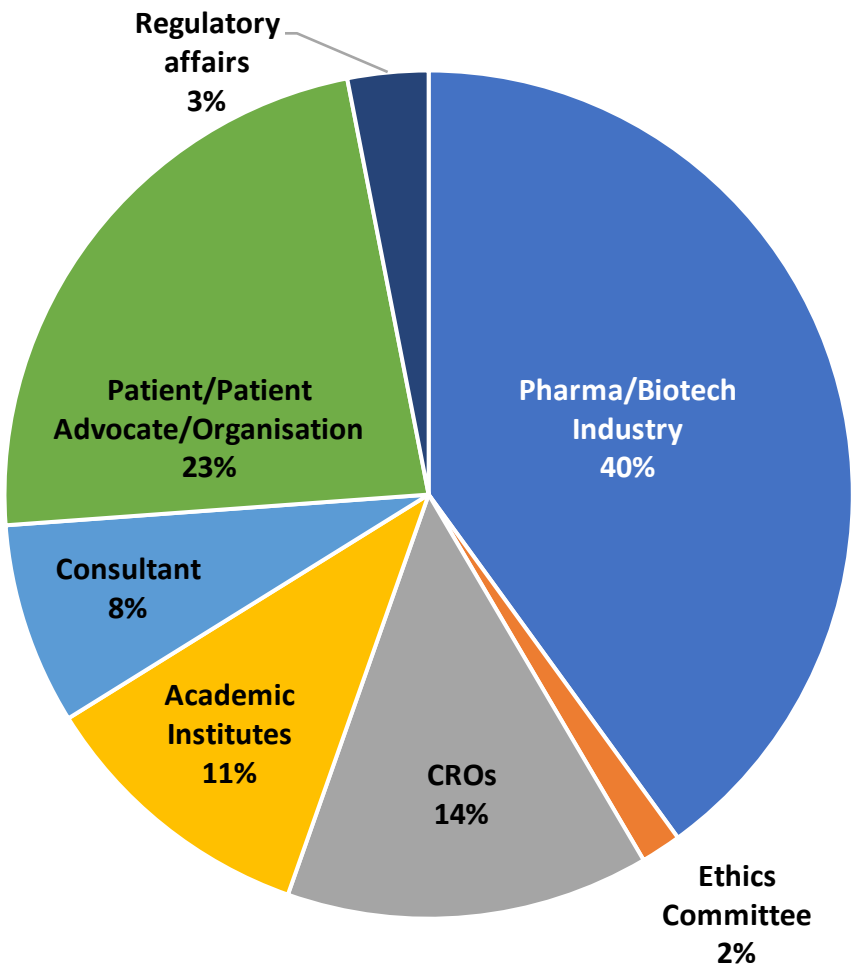
* Frontiers | Cross-Border Access to Clinical Trials in the EU: Exploratory Study on Needs and Reality (frontiersin.org)

EU-X-CT Mission

- Opportunities for patients to join a clinical trial in Europe differ greatly depending on the country they live in – **most trials are still done in West European countries**
- Clinical trials are an important element of healthcare, especially for **patients with life-threatening and/or rare diseases** where this might be the only therapeutic option.
- Joining in a clinical trial abroad is **theoretically possible,** but there is **no specific EU legislation or guidance to facilitate cross-border trial participation**

The EU-X-CT Initiative is aiming **to enable cross-border access to trials for patients** when there is no option for them to join a clinical trial in their own country

Membership & organization



Core Management Team
Co-led by EFGCP & EFPIA

3 Task Forces (TF)

TF1 Legal & Regulatory: National laws, regulations, ethics committee requirements

TF 2: Financial incl. patient liability coverage (healthcare systems/ insurance/payers

TF 3: People/Operational: Role of patient organisations, ERNs

65 members from **21 European countries** and the **United States**

What have our surveys shown?

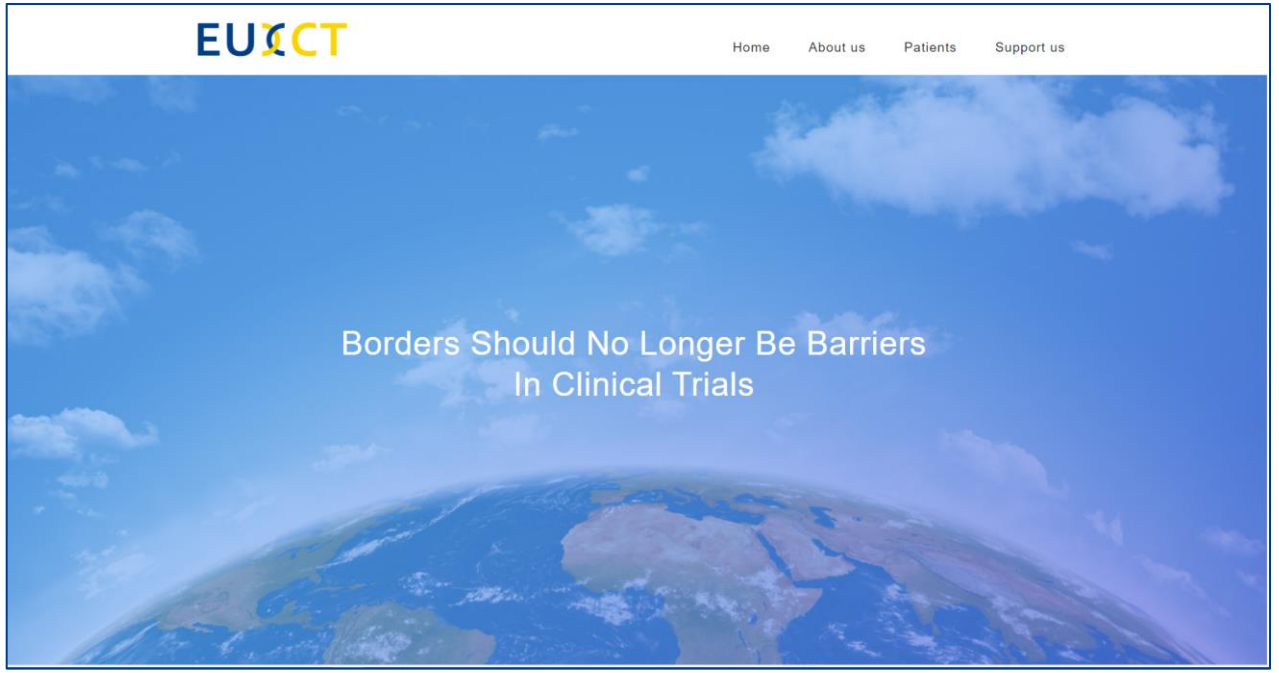
- Formal national legal/regulatory/ethical frameworks do not seem to exist for cross-border access to trials, but **cross-border trial access is generally not prohibited**
- Several countries (and the Heads of Medicines Agencies*) have issued national guidelines for cross-border access for patients from Ukraine to clinical trials in the EU
- **Additional information is mainly requested by Ethics Committees** - often **on a case-by-case basis** and specific requirements can vary even within a country
- **Patient facing information is often needed in the patient's own language** and there can be requirements for translation/ translators at sites and approval by Ethics Committees
- **Health insurance aspects and indemnity considerations are key,** but it is **very difficult to get information** beyond anecdotal experiences
- **Very limited experience amongst patients and patient organisations** with cross-border trial access – **sometimes it is good and sometimes "a nightmare"**

*CTCG recommendation to sponsors on managing the impact of the war in Ukraine on clinical trials

EU-X-CT Website

We have created an EU-X-CT website

- Independent, neutral
- Freely accessible
- Sharing information on conditions for cross-border access per country for
  - Patients and patient organisations
  - Treating physicians/ investigators
  - Sponsors
  - Healthcare systems/payers/insurers
- Will include relevant recommendations, guidelines when available
- Information on European and national events to discuss/improve the conditions for better cross-border access to trials



[EU-X-CT - Borders Should no Longer be Barriers]

Conclusions and next steps

Report from Public Forum

- A report will be published on the outcome of the EU-X-CT Public Forum held on 12th April in Q2 2024
- It will capture the main outcomes from the EU-X-CT surveys and the key discussions and conclusions from the stakeholders at the meeting

Report will be a starting point for drafting recommendations on cross-border access to trials

Co-create draft recomendations

- Based on our survey outcomes, discussions at the public forum and best practice examples shared by stakeholders, EU-X-CT will collaborate with all concerned stakeholders to co-create draft recommendations on cross-border access to clinical trials
- The draft recommendations will request feedback from targeted stakeholders – aim is by Q4 2024

Draft recommendations will be made available on the EU-X-CT website

Public consultation

- A public consultation will be initiated to collect wider feedback on the draft recommendations by Q1 2025
- Once the recommendations are final a 2nd public workshop will be held in Q2 2025 to prepare dissemination & implementation in the stakeholder communities
- The information on national conditions and options on the EU-X-CT website will be completed in Q2 2025.

Final recommendations and information on cross-border access to trials to be shared widely in patient and clinical trial communities

Thank you!

On behalf of EU-X-CT

New members are always welcome to join the initiative!

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