EUCT

Making cross-border access to clinical trials a reality

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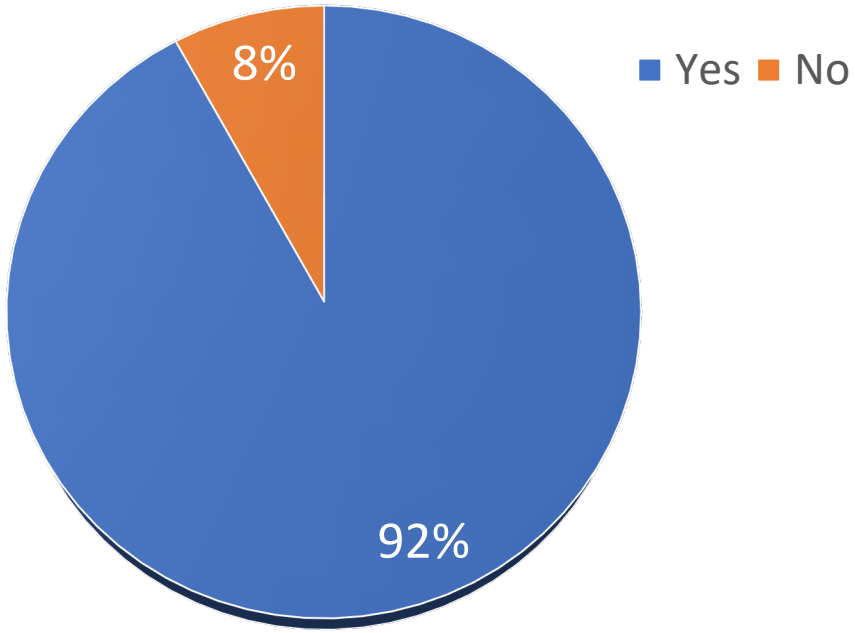
ACT-EU Multi-stakeholder Platform Advisory Group
18 September 2025
Virtual Meeting

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)

Do we need cross-border access to clinical trials?

Barriers in the Exploratory Study:

- Finding a suitable trial
- Costs coverage
- Language barrier
- Lack of information
- Organisational challenges
- Travel distance
- Vulnerability
- Cultural barriers

Barriers identified overall in EU-X-CT:

- Cross-border trials are not explicitly forbidden in any country
- **Cross-border access is currently managed on a case-by-case basis**
- **‘Who pays for what’ is THE most critical issue**
- **Language barriers might impact patient’s ability to understand risks**
- **Decentralized trial elements**

EU-X-CT survey

People & operational aspects

Feedback from patients & patient organizations:

>280 responses
9 with cross-border experience, 6 of those in Europe

Difficulty in accessing trials due to financial constraints	Instances where patients are required to pay substantial **amounts out of pocket upfront** to participate, even when insurance coverage is available
Challenges related to logistics and administrative processes	Obtaining necessary **forms for health coverage** and registration for medical attention in public hospitals, which can be cumbersome and time-consuming
Uncertainties in legal and insurance aspects	**Processes not clear** for cross-border participants
Difficulty in obtaining answers to any open questions	Leading to a **cautious approach** to cross-border participation

How could ACT-EU support cross-border access to clinical trials?

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IMP Shipment to Participant's Home Country

Clarify and harmonise the IMP and AMP import conditions to the participant's home country:

- IMP unauthorised in the site's and in the participant's home country
- IMP authorised in the site's but not in the participant's home country
- AMP authorised in the site's but not in the participant's home country
- Who can ship these IMPs and AMPs: the site, a vendor, the sponsor?
- To whom can these IMPs and AMPs be shipped: participant's home, a hospital pharmacy, a local pharmacy, treating physician, local flying nurse who administers the IMP?

Trans-national Liability Insurance Certificates

Clarify and harmonise the requirements for liability insurance certificates when the clinical trial foresees cross-border trial participation:

- For damage occurring when the participant is in the site's country
- For damage occurring while the participant is still in the trial but resides in his home country
- For damage occurring when the participant has completed trial participation and is back home

ACT-EU Workshop on Increasing Recruitment

Organise a multi-stakeholder workshop to discuss options for increasing recruitment in the EU:

- Comprehensive match-making infrastructure for patients/treating physician and sites
- Borderless EU for patients' cross-border access to clinical trials
- IT infrastructure for safe and easy medical data and records sharing between treating physician, investigator, patients
- Clarifying and harmonising national healthcare providers' cost coverage rules
- Increasing awareness of patients, patient organisations and treating physicians about benefits of joining a clinical trial – wherever it takes place
- Etc.

How could EMA support cross-border access to clinical trials?

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Website

Cross-Border Access to Clinical Trials

For many patients with life-threatening or rare diseases, participating in a clinical trial abroad is sometimes the only option—but without an EU-wide legal framework or guidance, barriers remain high, and access out of reach.

EU-X-CT is a multi-stakeholder initiative aimed at systematically collecting information on the barriers to cross-border participation in clinical trials within Europe and developing recommendations for enabling better access.

The initiative is a concerted effort by volunteers from patient organisations, academics, research networks, industry, and not-for-profit organisations, led by EFGCP and EFPIA.

Watch the video to learn more: Click Here

EU-X-CT to Launch Final Recommendations at its Public Stakeholder Conference 2025

The **EU-X-CT Public Stakeholders' Conference: Making Cross-Border Access to Clinical Trials a Reality** has successfully taken place!

A **heartfelt thank you** to all delegates for attending The EU-X-CT Public Stakeholders' Conference! Thanks to everyone who actively contributed in the morning sessions, where we tackled key issues in facilitating cross-border trial access, and to those who shaped the forward-looking discussions in the afternoon sessions, exploring sustainability, impact, and usability.

It has been a day full of meaningful dialogue and collaboration. We appreciate your engagement and look forward to **continuing the conversation!** Stay tuned for the next steps:

The Conference Report The Patients Website And more...

New Tools Available

Recommendations Country Analysis Trial Preparator

News

Patients Trial Preparator: Launch 2025-08-05
The preliminary version of the Trial Preparator is available and covers an initial group of EU countries, more to come!

Country Analysis: Preliminary Version 2025-03-03
The preliminary version of the Country Analysis is available and covers an initial group of EU countries, more to come!

EU-X-CT Recommendations: Public Consultation 2025-02-03
The EU-X-CT Recommendations are available for Public Consultation for 5 weeks - Submit your review now!

EPF Joins EU-X-CT Cross-Border Clinical Trials Initiative as a Member 2024-10-31
EPF Joins EU-X-CT

Clarifying the cross-border trial access in Europe 2024-05-30
Interview with our CRO partner published by Clinical Trials Arena

Website:
https://www.eu-x-ct.eu/

Website: Patients/Caregivers Information

Dedicated to Patients & Caregivers

Same website but organised differently
Use of Lay Language
Translations for Narratives and Key Information

Patient Information Tool

Replaces the Country Analysis
Series of Questions leading to Tailor Made Information

Translations Status

26 Languages Planned
Amount of available Translation Reviewers: 6
Amount of Translation Reviewers Needed: 14
Patients Information Page:

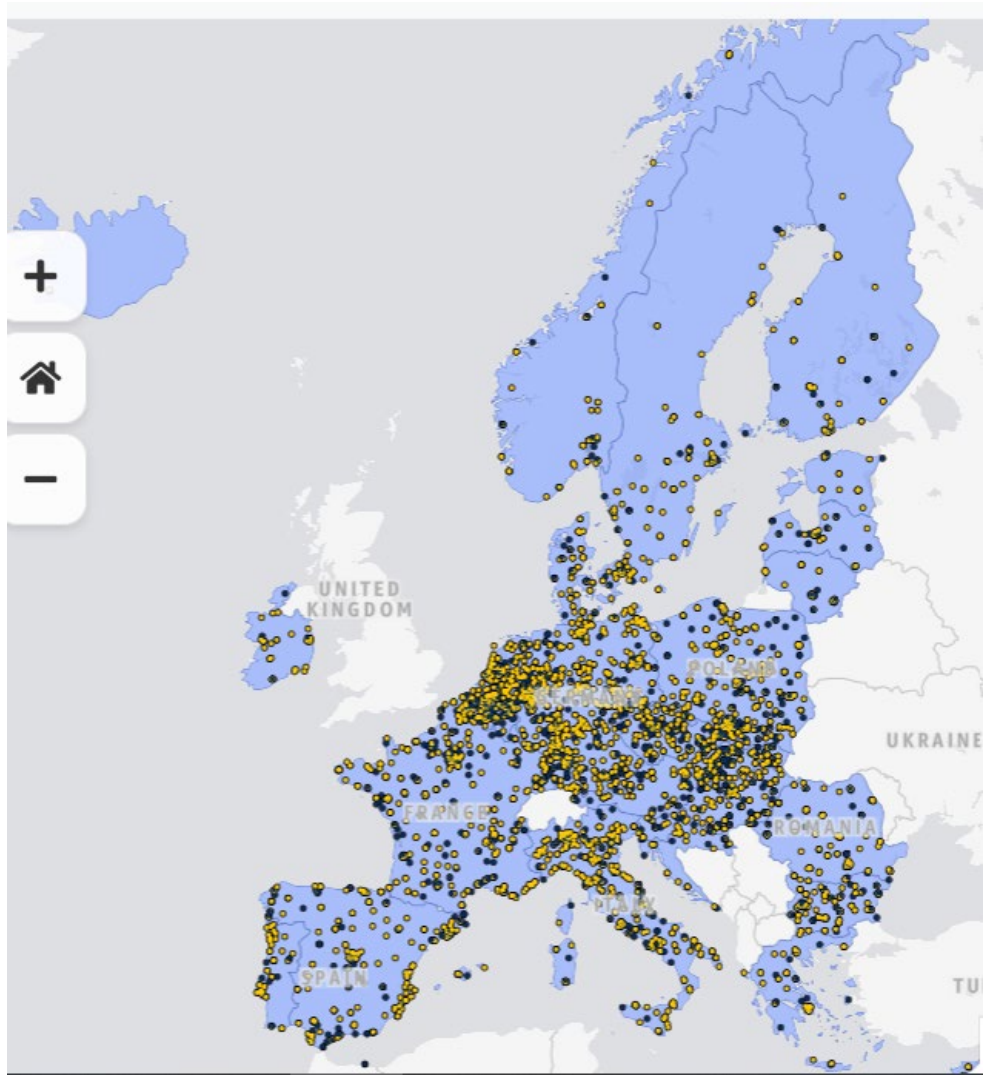
- 18 Languages available (soon on the Website)
- 8 Languages Pending

Next Step: 3 Narratives to be translated

CTIS: Clinical Trial Map

Flag sites that are prepared to host cross-border trial participants

- EU-X-CT could work out the qualifying criteria and develop a template for sites' self-assessment
- Outcome to be ticked (yes – no) by the sponsor as an element of the site information



What EU-X-CT is doing next

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Work on Annexes to

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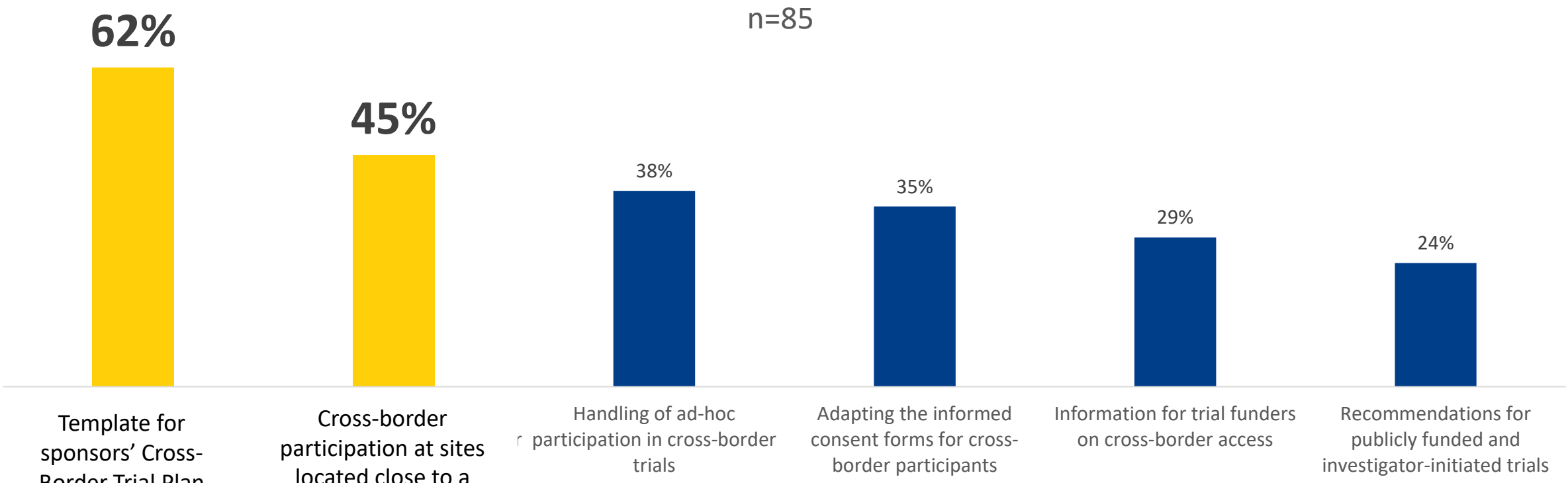
Requested Annexes to the EU-X-CT Recommendations

Feedback from participants of the Multi-stakeholder Conference on 24 June 2025 (65 participants on-site, 132 participants on-line) on priorities for development of annexes to the recommendations at the EU-X-CT Public Stakeholder Conference



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Thank you!

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