



EU-X-CT

- BORDERS SHOULD NO LONGER BE BARRIERS- Multi-stakeholder Initiative EFGCP and EFPIA co-led

Name of the Initiative

“EU Cross-Border Clinical Trials” or “EU-X-CT”

Duration

Nov 2022 – Jan 2025

Why EU-X-CT?

The EU-X-CT initiative has been established to help enable cross-border access to trials for patients when there is no option for them to join a clinical trial in their own country. To support this, EFGCP and EFPIA have set up a multistakeholder collaboration platform of **patient organisations, academic researchers and institutions, research networks, CROs and pharmaceutical companies**. Our aim is to **systematically collect likely sparse information on the requirements, options and obstacles to cross-border participation in clinical trials from all European countries** both in- and outside of the European Union. Based on a gap analysis, EU-X-CT will then **develop multistakeholder recommendations** for different aspects of cross-border access to clinical trials and **provide all collected information for each country on a publicly available website**.

Background

Participation in a clinical trial is an important element of healthcare, especially for patients with life-threatening and/or rare diseases and paediatric patients, for whom a medicinal product under investigation might be their only therapeutic option. Clinical trials that investigate rare diseases or involve innovative new treatments are often only feasible in well-equipped hospitals with specialized resources, and these exist only in a limited number of European countries. European patients need access to trials in other European countries when they are not available in their home country. In October 2020 a paper¹ was published in Frontiers in Medicine on Cross-Border Access to Clinical Trials

¹ Lalova T, Padeanu C, Negrouk A et al. Cross-Border Access to Clinical Trials in the EU: Exploratory Study on Needs and Reality. Front. Med. 2020; 7:585722. doi: 10.3389/fmed.2020.585722

in the EU: Exploratory Study on Needs and Reality ([Lalova et al 2020](#)). The paper contains the results of an exploratory study, jointly conducted in 2019 by the European Forum for Good Clinical Practice (EFGCP), KU Leuven, the European Organization for Research and Treatment of Cancer (EORTC) and Patvocates to investigate the current state of cross-border access to clinical trials in Europe. The research project was initiated by the EFPIA Oncology Platform.

A key outcome was the fact that no overall legal EU framework defines the conditions for accessing clinical trials in another EU country. The EU Directive² on the application of patients' rights in cross-border healthcare (2011/24/EU) aims to facilitate access to safe, high-quality cross-border healthcare and to promote healthcare-related cooperation between EU and EEA (Iceland, Liechtenstein, and Norway) member states, however, this Directive does not mention the access conditions for clinical trials. The exploratory study revealed that cross-border participation in clinical trials only occurs rarely despite a high need expressed by study respondents. There was consensus on the urgent need for reliable and accessible information regarding practical aspects of joining a trial abroad including healthcare cost coverage, as well as for multistakeholder, multinational recommendations on options and sharing of existing best practices on cross-border access to clinical trials.

Unfortunately, the EU Commission thus far does not seem open to revising the 2011 Cross-Border Directive with regard to access to clinical trials. Thus, patients, investigators and trial sponsors are forced to find individual solutions for some of the actual hurdles that patients and investigators experience in the country where the trial is being run as well as in the country where the patient is located, e.g., the logistical and financial burden on patients, investigators and treating physicians; financial coverage of the costs by healthcare systems and insurance; legal, ethical and regulatory requirements, organisation of an adequate follow-on treatment in the country of residence of the trial participant; trial insurance liability issues for participating patients from countries where the trial is not running.

Initiative Objectives

- ✓ **Enabling cross-border access to clinical trials to be a reality for patients: “Borders are no longer barriers!”**
- ✓ **Creation of a registry of information on an independent, freely accessible website that is open to the public**
 - Legal/regulatory/ethics framework already available in European countries;
 - National healthcare systems' cost reimbursement conditions;
 - Trial liability information;
 - Patients' experiences, views, needs, expectations (anonymised);
 - Investigators' experience, views, needs, expectations (anonymised);
 - Best practice examples.

² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN>

- ✓ **Connecting with existing and upcoming initiatives/projects to raise awareness, collect information, and disseminate recommendations to support the implementation of solutions generated in EU-X-CT.**
- ✓ **Development of recommendations for improving cross-border access relevant for:**
 - National policy makers
 - EU policy makers
 - Regulators and Ethics Committees
 - Patient organisations
 - Medical societies
 - Investigators and clinical study groups
 - EFPIA and national pharma associations
 - Industry & academic sponsors
 - European Research Networks (ERNs)
 - Relevant National Contact Points

EU-X-CT Membership and organisation

As of May 2023, the EU-X-CT Initiative has **50 members** from **18 European countries**.

Core Management Team (CMT)

Representatives from patients/patient organisations, academia, industry, contract research organisations (CROs) and medical societies are members of the CMT. They coordinate, contribute, and/or lead Task Forces (TFs) to ensure seamless communication and coordination between the three TFs.

Task Forces (TFs)

Each TF has two co-leads, from different kinds of organisations (e.g., patient organisation & industry or academia). The TFs' work plan is organised according to the main questions the initiative is addressing:

Task Force 1 – Legal/Regulatory/Ethics

Is cross-border trial participation allowed in a country and does the patient's home country allow them to join a trial in another country?

Task Force 2 – Financial

Who is going to pay for it? (i.e., trial sponsor, healthcare provider, insurance etc.)

Task Force 3 – People/Operational

How do we concretely enable it? (i.e., practical implications for patients, study sites, sponsors)

In the first phase, TFs are currently collecting and mapping information about the current European countries' conditions and requirements for cross-border trials. This information will be used to populate the EU-X-CT public website. After a gap analysis and multistakeholder discussion about achievable improvement options, EU-X-CT will prepare recommendations for the different stakeholders in the second phase of the Initiative.

Roadmap

As agreed at the Kick-off meeting on November 24, 2022, EU-X-CT members are meeting twice a year at progress meetings and public workshops.



The agreed recommendations will be prepared throughout 2024, for final presentation to the public in early 2025. The website launch is planned in 2023.

EU-X-CT Governance and Funding

The CMT oversees the financial aspects, coordinates efforts to obtain support and reviews the achieved results. EFPIA is supporting EU-X-CT with a small unrestricted grant, however, other participating members and external organisations are invited to provide financial support for the initiative to cover additional costs e.g. for setting up workshops (including participation/travel of patients and academics at the in-person meetings and the final event), IT expenses for the development of a sustainable project website etc.

EFGCP and EFPIA already have successful experience collaborating for the benefit of patients, e.g., in the Good Lay Summary Practice (GLSP) Initiative, which delivered recommendations adopted by the European Commission and included in EudraLex Volume 10 - Clinical trials guidelines³.

Contact

If you are interested in supporting and/or joining our EU-X-CT Initiative, please do not hesitate to contact representatives of the EU-X-CT Initiative leadership:

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More information: [EU-X-CT Web page](#)

³ https://health.ec.europa.eu/system/files/2021-10/glsp_en_0.pdf