- BORDERS SHOULD NO LONGER BE BARRIERS-

The EU-X-CT Multi-stakeholder Initiative

EFGCP and EFPIA launched this Initiative to enable cross-border access to clinical trials for all patients in Europe

January 2023

Participation in a clinical trial is an important element of healthcare, especially for patients with life-threatening and/or rare diseases for whom a medicinal product under investigation might be the only therapeutic option. Clinical trials that investigate rare diseases or involve very innovative, complex new treatments are often only feasible in well-equipped hospitals with specialized resources that only exist in a limited number of countries and sites in Europe. Therefore, there is often a need for European patients to participate in trials that are being conducted in another European country.

In October 2020 a paper[1] was published in Frontiers in Medicine on Cross-Border Access to Clinical Trials 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) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), which together with the European Organization for Research and Treatment of Cancer (EORTC) and Patvocates formed a research consortium to investigate the current state of cross-border access to clinical trials in Europe.

There is no legal EU framework that defines the conditions for accessing clinical trials in another EU country. The Directive[2] 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, but this Directive does not mention the access conditions in clinical trials. The Exploratory Study revealed that cross-border participation in clinical trials only occurs very rarely despite a high need expressed by study respondents. There was consensus on the need for reliable and accessible information regarding practical aspects, as well as for multi-stakeholder, multi-national recommendations on existing options and best practice on

[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

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

cross-border access to clinical trials. These results are also echoed in some of the responses to the survey[3] performed by the EU Commission in early 2021 on Cross-border healthcare – evaluation of patients' rights. Unfortunately, the EU Commission does not seem open to revising the 2011 Cross-Border Directive with regard to access to clinical trials. Thus, patients, investigators and trial sponsors need 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., logistical and financial burden on patients; financial covering of the costs by healthcare systems and insurance; need for 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.

To support patient communities, investigators, and trial sponsors in enabling cross-border access to trials when appropriate, EFGCP and EFPIA have set up a multi-stakeholder consortium of patient organisations, academics, research networks and industry with the aim to systematically collect available information from all European countries, including EU non-member states and develop recommendations for enabling cross-border access to clinical trials. EFGCP and EFPIA have already a successful experience working together for the benefit of patients, e.g., in the Good Lay Summary Practice (GLSP[4]) Road Map Initiative which delivered recommendations which have been included in EudraLex Volume 10 since October 2021.

Further to a kick off meeting on November 24, involving some key stakeholders (i.e., industry, patients' representatives) the following was agreed:

➢ **Name of consortium:** "EU Cross-Border Trials" or "EU-X-CT" as a short form.

➢ **Consortium Objective**: Enabling cross-border access to clinical trials to be a reality for patients: "Borders are no longer barriers!"

➢ **Agreed Next steps:**

1. ***The consortium members agreed to set up a core management team (CMT) and 3 Task Forces (TF) to focus on*:**
    - Legal/Regulatory aspects;
    - Financial aspects;
    - People/Operational aspects.

    Representatives from patients/patient organisations, academia, industry, contract research organisations (CROs) and medical societies will be asked to sign up to contribute or lead these TFs. Each TF will have 2 co-leads, preferably from different types of organisations (e.g. patient organisation & industry or academia). The coordination of the TF will be the responsibility of the CMT which is led jointly by EFGCP and EFPIA. The TF leaders will also be members of the CMT to ensure seamless communication and coordination between the TFs.

    The main questions the initiative will have to address are:
    - Is cross-border trial participation allowed in a country and does the home country of the patient allow them to join a trial? (i.e., regulatory & legal aspects)
    - Who is going to pay for it? (i.e., trial sponsor, healthcare provider, insurance etc.)
    - How do we bring it about? (i.e., practical implications for patients, study sites, sponsors)

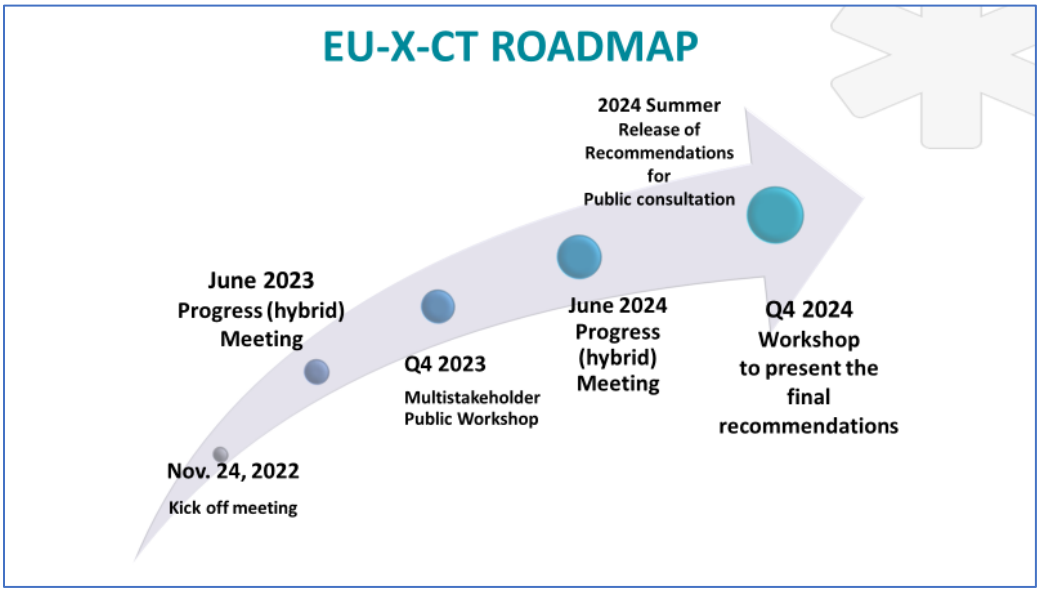
    The first step for the TF will be to collect and map information about the current EU countries position and requirements for cross-border trials. This information will be used to populate the EU-X-CT registry.
2. ***Creation of a registry of information on an independent website (under EFGCP) that is open to public***
    - Legal/regulatory framework in EU countries;
    - National healthcare systems' cost reimbursement conditions;

[3] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-border-healthcare-evaluation-of-patients%E2%80%99-rights_en

[4] https://glsp.network/

- Trial liability information;
- Patients' experiences, views, needs, expectations (anonymised);
- Investigators' experience, views, needs, expectations (anonymised);
- Best practice examples.

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



The agreed recommendations will be prepared throughout 2023 and 2024, for final presentation to the public in early 2025 together with the launch of the website.

EU-X-CT will be supported by EFPIA with an unrestricted grant. However, other participating organisations will be invited to also financially support the Initiative's work including the fee for the part-time project manager and EFGCP's organisational and IT contributions, for the participation/travel of patients and academics at the in-person meetings and at the final public discussion event, and/or for providing facilities and catering for the meetings. The CMT will oversee the financial needs, enable efforts for achieving support and review results achieved.

If you are interested in joining our EU-X-CT Roadmap Initiative, please do not hesitate to contact: ingrid.klingmann@efgcp.eu, susan.bhatti@merckgroup.com or silvia.garcia@efpia.eu