- BORDERS SHOULD NO LONGER BE BARRIERS -

The EU-X-CT Multi-stakeholder Initiative

EFGCP and EFPIA launch initiative to enable cross-border access to clinical trials for all patients in Europe

January 2023

To support patient communities, investigators, and trial sponsors in enabling cross-border access to clinical trials when appropriate, EFGCP and EFPIA have set up a multi-stakeholder consortium of patient organisations, academia, research networks and industry with the aim to develop recommendations to enable cross-border access to clinical trials for patients across the EU.

With no current European Framework to define the conditions for cross border clinical trials, the project will map out the current state of each Member State, detailing the logistical and financial support required as well as issues like accessing ongoing treatment for those patients involved. The project will be vital in bringing groundbreaking trials to patients in countries who previously had no access and could revolutionise treatment options for those with rare diseases.

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 these diseases are often only feasible in well-equipped hospitals with specialized resources that only exist in a limited number of countries and sites in Europe. For European patients, it often means participating in trials that are being conducted far away from where they live, and sometimes in another European country.

In October 2020, a paper[1] published in Frontiers in Medicine collecting the outcome of a stakeholder survey, revealed that cross-border participation in clinical trials only occurs very rarely despite a high need expressed by respondents. The stakeholder views captured in this paper were also confirmed by the results of a 2021 EU Commission survey and the publication of a report[2] on the implementation of Directive 2011/24/EU[3]on the application of patients' rights in cross border healthcare published in May 2022. However, this Directive does not define the conditions to access clinical trials in other EU Member States. The above demonstrates the need for recommendations and best practices to improve cross-border access to clinical trials in Europe.

[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://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-border-healthcare-evaluation-of-patients-rights_en

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

[4] https://glsp.network/

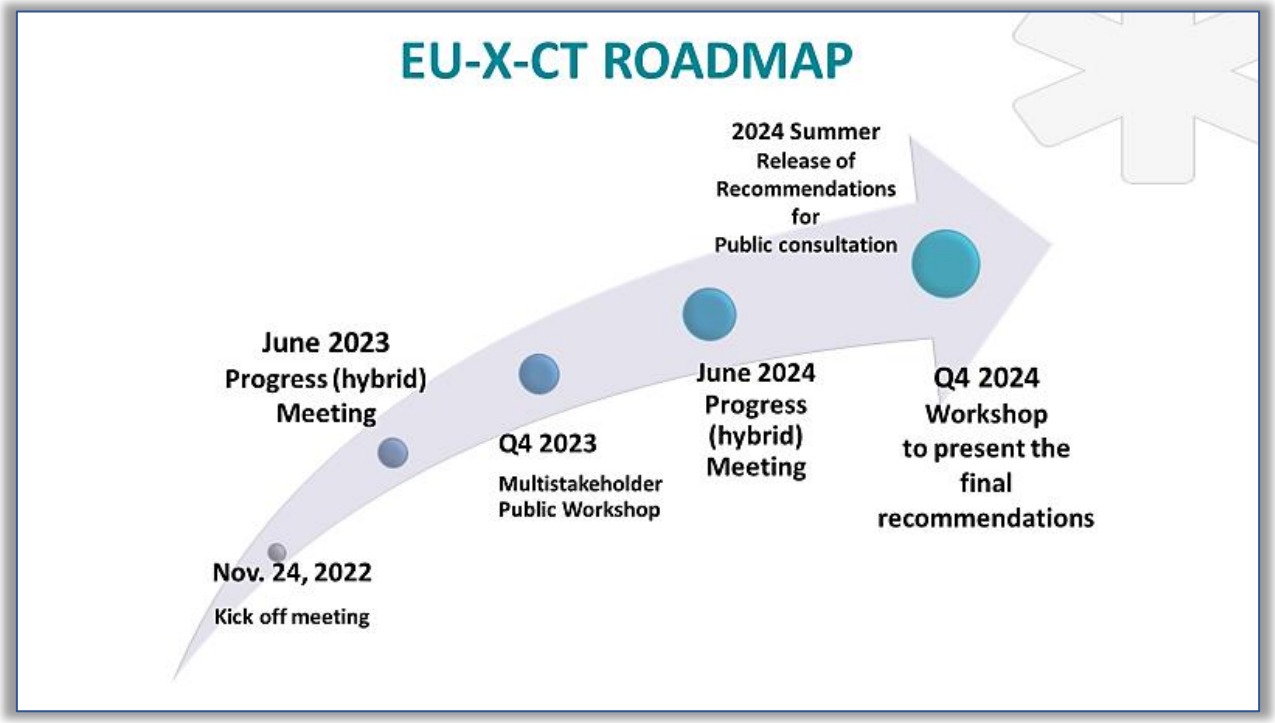
Building on the success of the Good Lay Summary Practice (GLSP[4]) Roadmap Initiative, EFGCP (European Forum for Good Clinical Practice) and EFPIA (European Federation of Pharmaceutical Industries and Associations) will further collaborate to establish a multistakeholder roadmap initiative, **the EU-X-CT**, with the aim to improve cross-border access to clinical trials for patients where "***Borders should no longer be barriers*****".**

An EU-X-CT multi-stakeholder consortium including patient organisations, academic institutions, research networks, not-for-profit organisation, CROs, pharmaceutical and biotech companies has been created to tackle European and national hurdles experienced by patients, their physicians and investigators when trying to join trials in another EU Member State. Considerable hurdles include logistical and financial burden on patients; financial covering of the costs by healthcare systems and insurance; trial insurance liability issues for trial participants from countries where the trial is not running; legal and regulatory hurdles; or national lack of information to access clinical trials.

The aim is to release recommendations for public consultation and to launch a website to share all the necessary information to facilitate cross-border access to clinical trials by patients in Europe by mid 2024**.** Final recommendations will be published in 2025.

EFPIA is supporting this initiative with an unrestricted grant.

If you are interested to join our EU-X-CT initiative, please do not hesitate to contact:
ingrid.klingmann@efgcp.eu or silvia.garcia@efpia.eu



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