

Interactive Workshop: Addressing Barriers to Cross Border Access in Clinical Research



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Our 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 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**, launched in January 2022 by EFGCP and EFPIA, addresses this by creating a multi-stakeholder platform to remove barriers and enable cross-border participation.

What is EU-X-CT?



EU-X-CT stands for "EU Cross-Border Clinical Trials," a collaborative effort involving patient organizations, academics, industry, ethics committees, and more. It systematically gathers information on requirements, options, and obstacles for cross-border trials within and outside the EU.

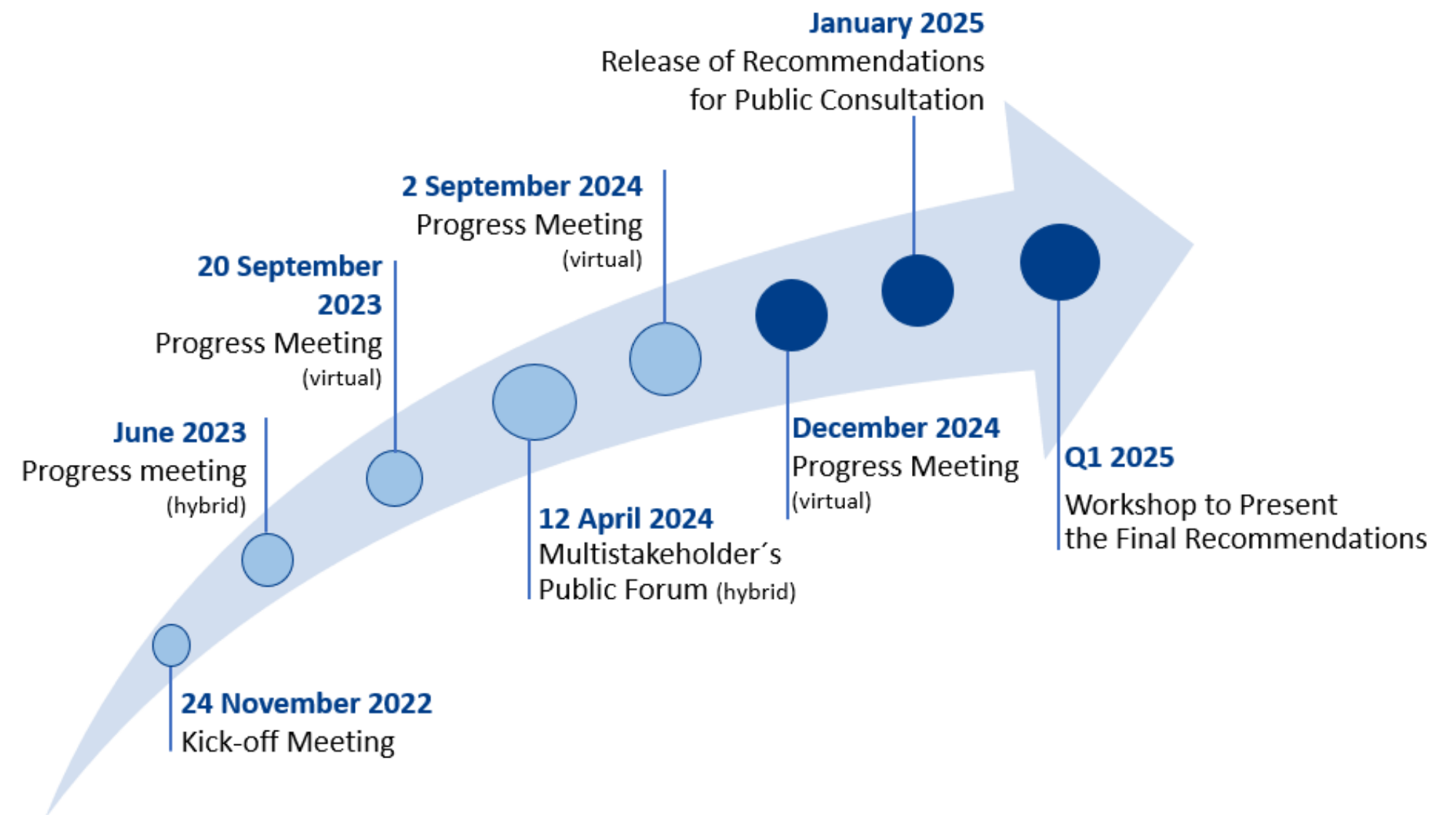


The goal: Help patients access innovative treatments like Advanced Therapy Medicinal Products when trials aren't available in their home country.



Phase 1 Achievements

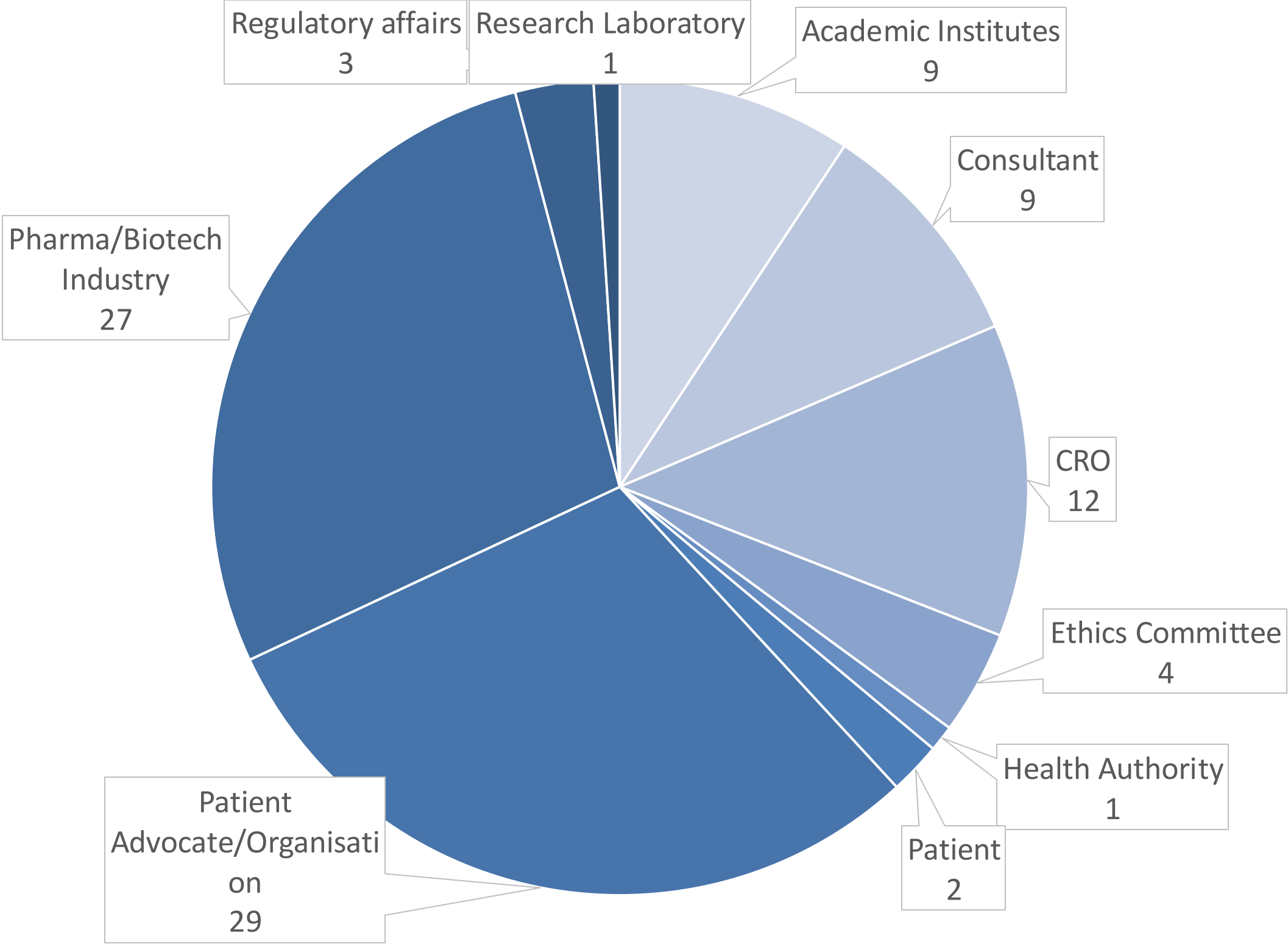
- In Phase 1, EU-X-CT collected data through surveys and interviews, leading to multi-stakeholder **recommendations** published in June 2025 after public consultation. These cover aspects like national requirements and patient guidance.
- A public website (EU-X-CT.eu) now provides country-specific information for professionals and patients, making it easier to explore cross-border options. This resource empowers individuals considering trials abroad.



Membership and Organisation



Membership by Stakeholders

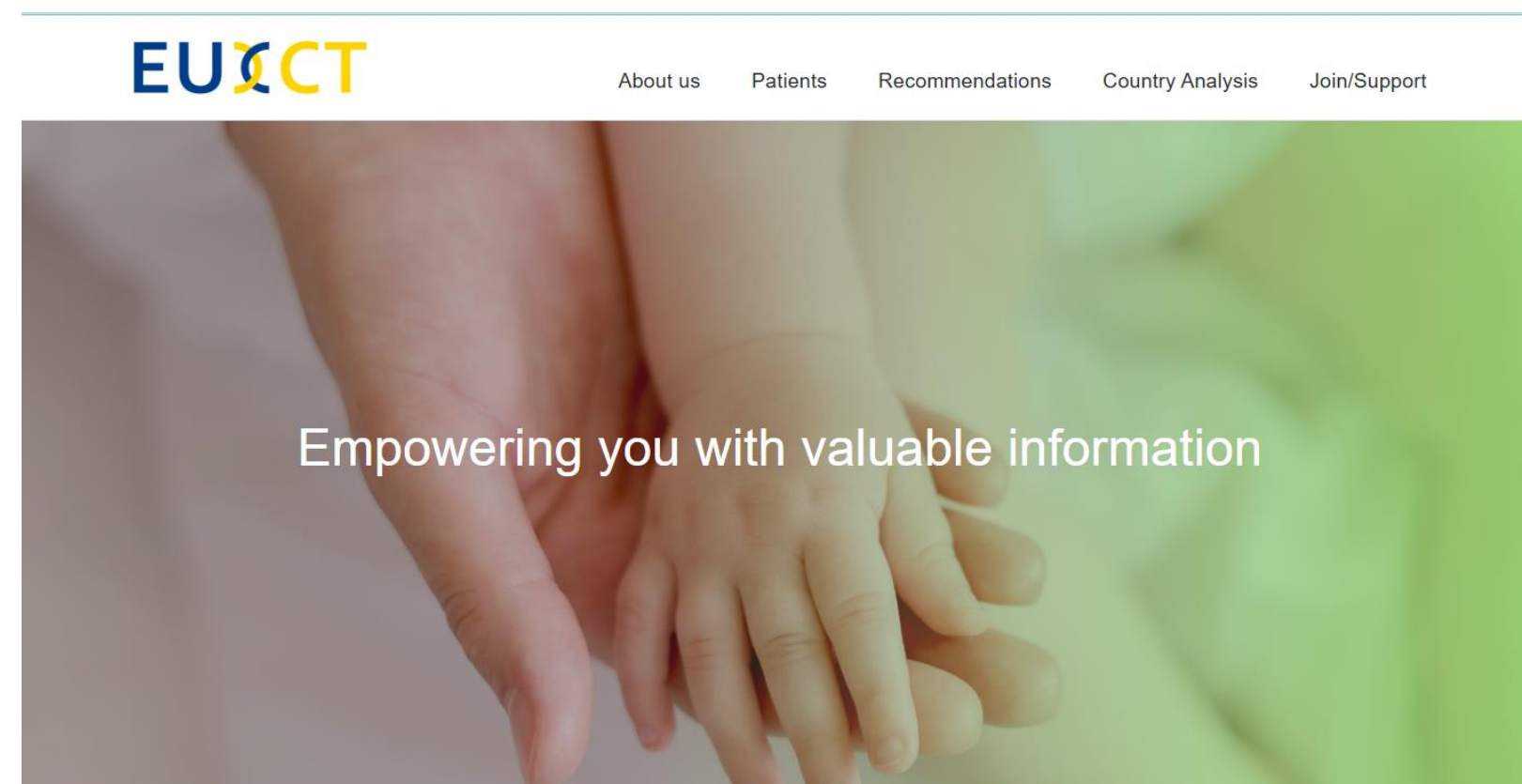


- As of January 2026, EU-X-CT boasts **139 members from 32 countries**, including patient advocates, academic institutions, pharma/biotech companies, CROs, regulators, and ethics committees.
- A **Core Management Team (CMT)** coordinates efforts, with representatives from patients, academia, industry, and medical societies ensuring diverse input. This structure fosters seamless collaboration across workstreams.



Phase 2 Objectives – Building on Success

- Phase 2 focuses on practical advancements, such as drafting a **Cross-Border Trial Plan template** and expanding website resources for patients and professionals. We're identifying legislative tools with policymakers to clarify patient rights and remove hurdles.
- Key priorities include creating a **permanent infrastructure** for access, engaging on costs (e.g., with insurers and hospitals), and organizing workshops on liability, ethics, and funding. Collaboration with EMA will improve public communication on trial sites ready for cross-border patients.



Workstreams and Action Teams



EU-X-CT – Phase II: Workplan 2026



Workstream 1:

Annexes to the Recommendations

Action Teams

- Cross-Border Trial Plan template
- Annex on cross-border access to trials in border regions
- Ad-hoc participation in cross-border trials
- Adapted informed consent forms
- Information for trial funders
- Academia and investigator-initiated trials

Workstream 2: Policy

Action Teams

- Regulatory Improvement: ACT-EU initiative EMA
- Regulatory Improvement: EU Commission initiatives – BioTech Act, EU life science strategy
- Sustainability: Collaborate with EU funding schemes, Collaborate with and ERA4Health/ERDERA/EP PerMed

Workstream 4: Communication

Action Teams

- Website & Communication
- Country Analysis for Professionals & Trial Preparator for Patients

- To deliver Phase 2, EU-X-CT has established workstreams led by diverse co-leads. These include developing trial plan templates and annexes, improving regulatory frameworks (e.g., with EMA and EU Commission), engaging national stakeholders on insurance and ethics, and enhancing the website for better patient information.

- Action teams address specifics like informed consent forms and investigator-initiated trials, ensuring comprehensive support.



Workstream 3: Stakeholders

Action Teams

- Health insurances, hospitals, ethics committees, liability insurances, national improvement initiatives
- Implementation of the Network of National Working Groups (NWGs)

Thank you!



Join us to strengthen patient access – contact the secretariat at eu-x-ct@efgcp.eu or visit eu-x-ct.eu. Together, we can make borders irrelevant for clinical trials.



Workshop:

How can you get your organisation ready to better support cross-border clinical trial participation?

Please work in your groups to propose 3 actions that could be implemented within your organisation.