Can we improve cross-border access to clinical trials?

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CDDF
MULTI-STAKEHOLDER
WORKSHOP

Patient Access and Engagement in
Oncology Drug Development

19 - 20 September 2022

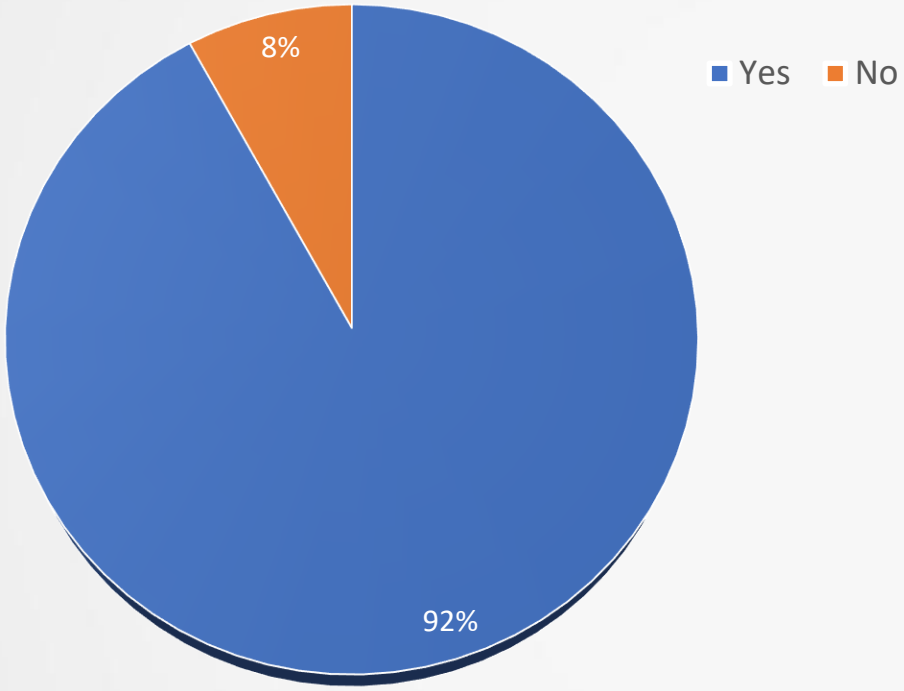
Disclaimer

The presentation is based on the information collected and the conclusions drawn in the frame of the „Cross-border access to trials“ research project, supported by EFPIA with an unrestricted grant and performed by a research consortium consisting of EFGCP, KU Leuven, Patvocates, and EORTC.

The plans for the new initiative are jointly proposed by EFGCP and EFPIA.

Do we need cross-border access to clinical trials?

Exploratory Study:



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

Can we improve cross-border access to clinical trials?

Options:

Harmonised EU framework ✗

No option as the review of Directive 2011/24/EC on cross-border access to healthcare will not foresee to include the conditions for clinical trials (response from EU Commission)

Changes to clinical trial system ✗

No option as this is much too complex but a number of other initiatives are ongoing that collectively will have a positive effect on cross-border access to clinical trials

Finding out about concrete options and solutions in all European countries ✓

Easy and comprehensive access to the concrete information and recommendations ✓

Can we improve cross-border access to clinical trials?

A call for action:

Multi-stakeholder Roadmap to cross-border access to clinical trials:

”EU Cross-Border Trials” or ”EU-X-CT”

Objectives:

- Bring together a broad pan-European stakeholder group to enable and support the initiative
- Create a registry of relevant national information from all European countries and offer it free of charge on a dedicated, independent website, and make this known to patients, patient organisations, sites and treating physicians
- Prepare jointly elaborated recommendations for the involved stakeholders

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EU Cross-Border Trials or EU-X-CT

Essential participants in the initiative:

- Patient advocates and patient organisations
- Academic institutions involved in clinical trial infrastructures
- Not for profit organisations
- Pharmaceutical and medical device industry/companies
- CROs
- Medical societies (physicians, pharmacists, HTA networks, ERNs, etc.)
- Trial matching organisations

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EU Cross-Border Trials or EU-X-CT

Proposed topics for the registry:

- National healthcare systems' abroad costs' reimbursement conditions
- National healthcare systems' conditions for follow-on treatment availability and its financial coverage
- National trial liability coverage requirements for trial participants from abroad
- National contact points for support (for patients and treating physicians)
- Description of practical challenges of investigator sites for investigators enrolling patients from abroad
- Description of practical challenges for patients wanting to join a trial abroad
- Best practice examples

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Recommendations for improving cross-border access relevant for:

- National and EU policy makers
- Regulators and ethics committees
- Pharmaceutical and medical device industry associations, industry and academic sponsors
- Trial liability insurance companies
- (University) hospitals, investigators and clinical study groups
- Patients and patient organisations
- Medical societies and treating physicians
- European Research Networks (ERNs)

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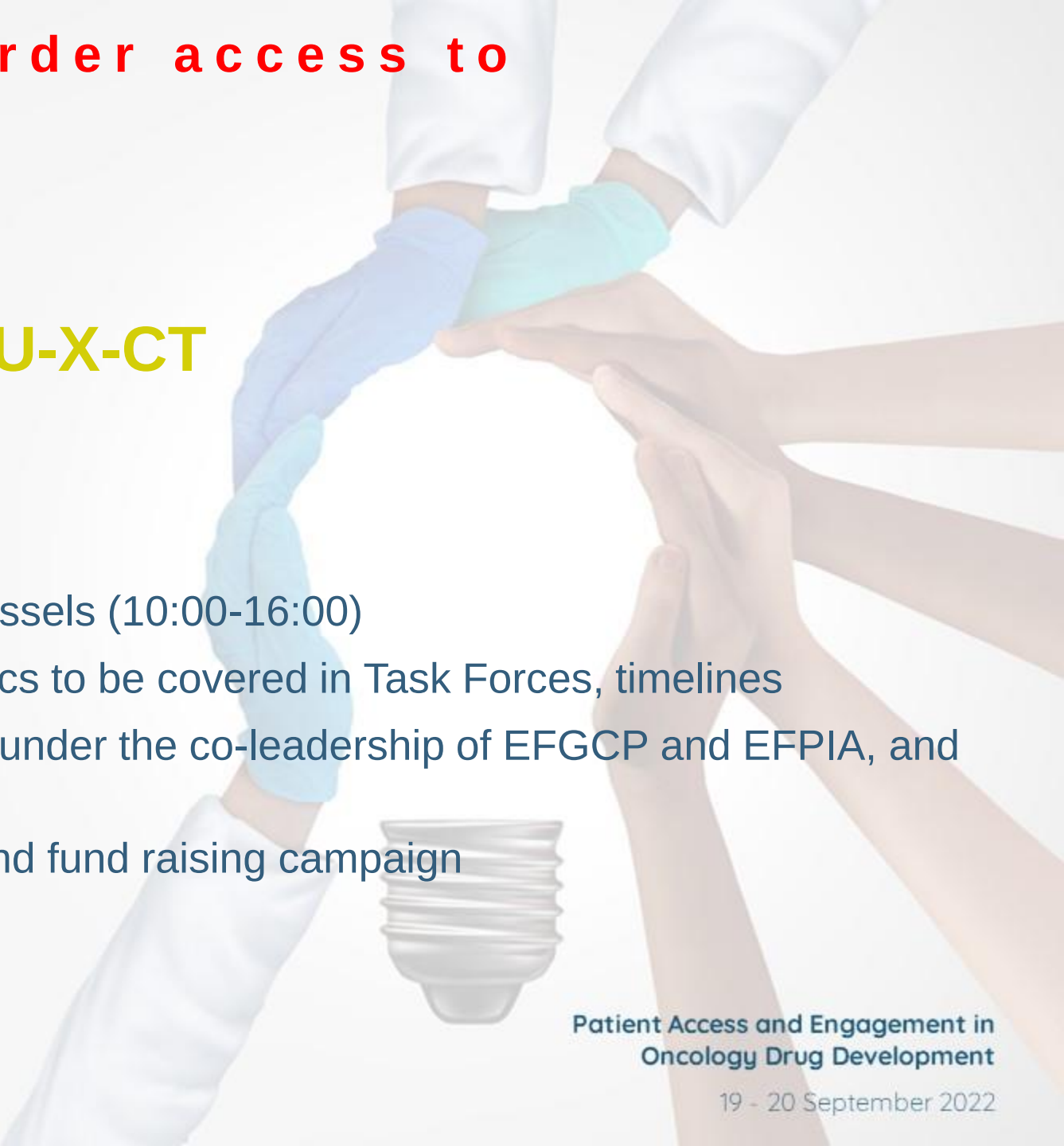
How to make it happen:

- Raise awareness broadly and invite to join
- Kick-off meeting on 24 November 2022 in Brussels (10:00-16:00)
- Definition and decision on the Work Plan: topics to be covered in Task Forces, timelines
- Appointment of the Core Management Team, under the co-leadership of EFGCP and EFPIA, and decision on the management process
- Elaboration and decision on the awareness and fund raising campaign



Please consider joining EU-X-CT
We need you and your support!

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