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EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

Cross-Border Access to Clinical Trials in the EU: Results from an Exploratory Study

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CDDF
Cancer Drug Development Forum
CDDF MULTI-STAKEHOLDER WORKSHOP

Patient Access and Engagement in Oncology Drug Development
19 - 20 September 2022

Disclaimer

Research funding: holder a scholarship PhD fundamental research, awarded by the Research Foundation Flanders (FWO), project number 11H3720N (2019-2023)

Study objectives

Analyse the current situation of cross-border access to clinical trials in the EU:

- Provide an **overview of stakeholders' real-life experience**
- **Identify** the **needs, challenges and potential for facilitation** of cross-border access

Methodology & Data collection

Literature review

Survey

Interviews

Literature review

No specific EU legislation

Directive 2011/24/EU
(so called *Cross-border healthcare directive*)

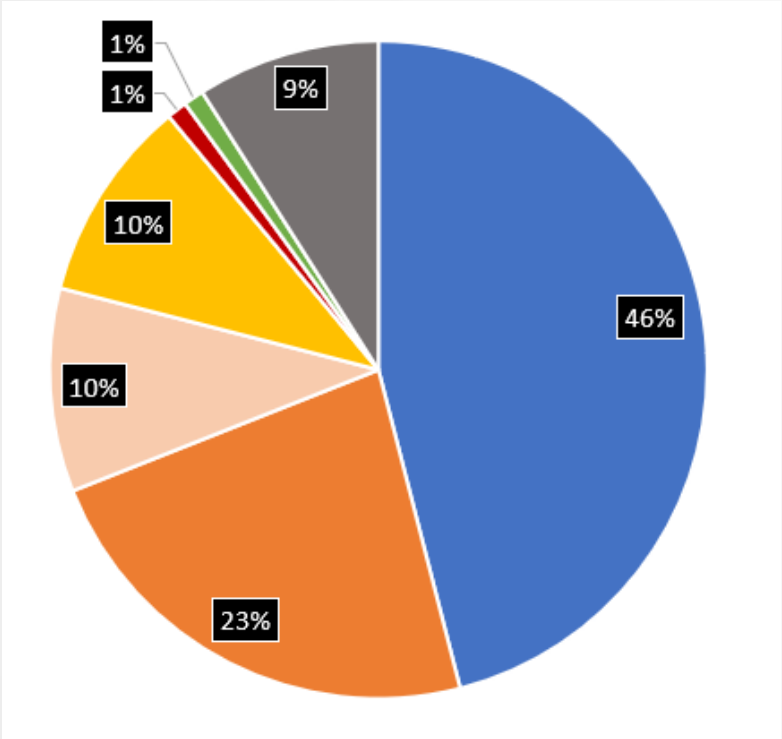
Clinical trials

NOT in SCOPE

Established the launch of the European Reference Networks (ERNs) system & National Contact Points

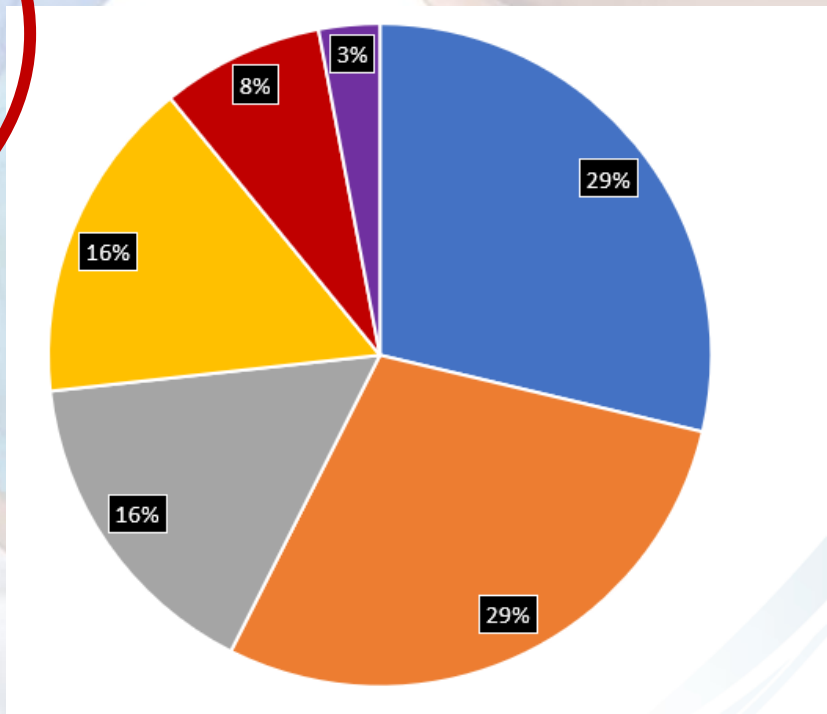
Demographics: Stakeholder representation

Survey n=396

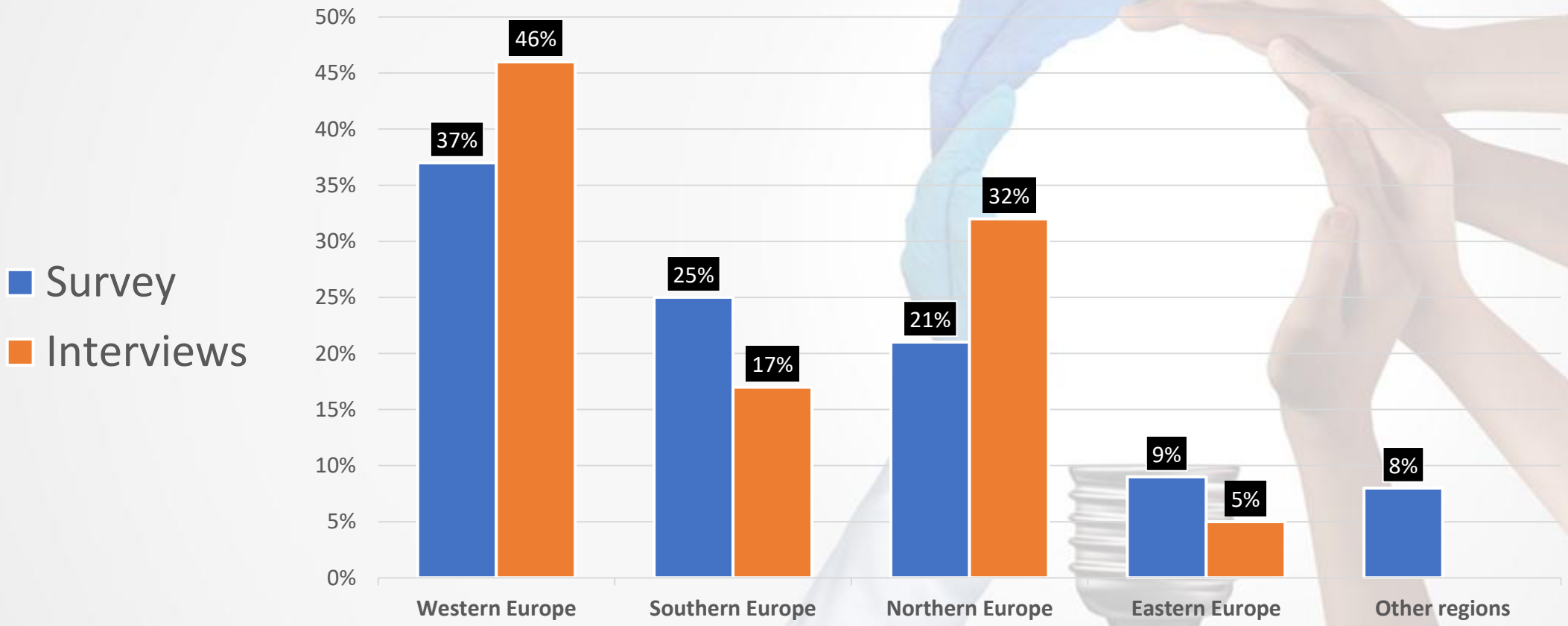


- Investigators
- Patient organisations representatives
- Individual patients/carers
- Sponsors (commercial & academic)
- Ethics committees
- Regulators
- Policy experts
- National contact points
- Others

Interviews n=38



Demographics: Country representation



Topics explored

- ❑ **Experience** with cross-border access to clinical trials
- ❑ **Frequency, increase, or decrease** in cross-border access to clinical trials
- ❑ **Motivations**
- ❑ **European countries attractive** for patients to seek participation
- ❑ **European countries of origin** of patients seeking participation
- ❑ **Challenges** to participate
- ❑ **Responsibility** for logistics & cost coverage
- ❑ **Cross-border access: needed or not?**
- ❑ **Limitations?**
- ❑ **Facilitation of cross-border access**: existing initiatives & proposals for the future

Experience

Interviews

- "close to zero"
- "maybe three, four, five patients…"
- "less than 1%"

BUT ALSO:

"Once somebody realises that there is a freedom of movement, there's very little that can keep them back. (…) you cannot put the spirit back into the bottle. People will move, and especially if their life and if their health depends on it. "

(Patient representative)

Motivations

Interviews

Access to treatment, *understood as:*

- **Rare diseases:** if no treatment existed before
- When **all available lines of therapy** have been **exhausted**
- When the **treatment is not reimbursed** by the healthcare system in the patient's home country
- When the study uses **specific technology that is not yet available** in patient's home country

Challenges

- Costs coverage
- Language barrier
- Lack of information
- Procedural challenges
- Travel distance
- Vulnerability
- Cultural barriers

Challenges

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Challenges

Lack of information: 3 key aspects

Information **about ongoing trials** (eligibility criteria, sites, appropriate system for patient referral…)

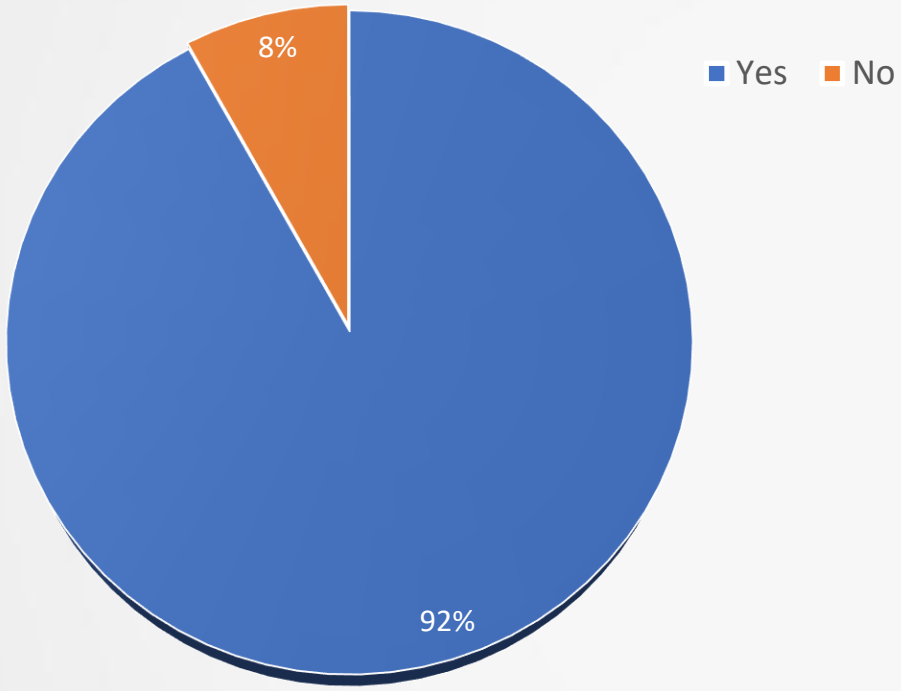
Information **about the value of clinical research** in general

Information **about best practices** when joining a clinical trial abroad (legislation, regulation…)

Existing initiatives

- Nordic Network for Early Cancer Trials (Nordic NECT)
- Bi-lateral agreements for collaboration of university hospitals
- Multidisciplinary national tumour boards/expert panels (Denmark, Norway)
- A joint Nordic electronic information portal on ethics committee approvals *(in progress)*

Do we need cross-border access?



⇒ There is a **strong need to improve the system**

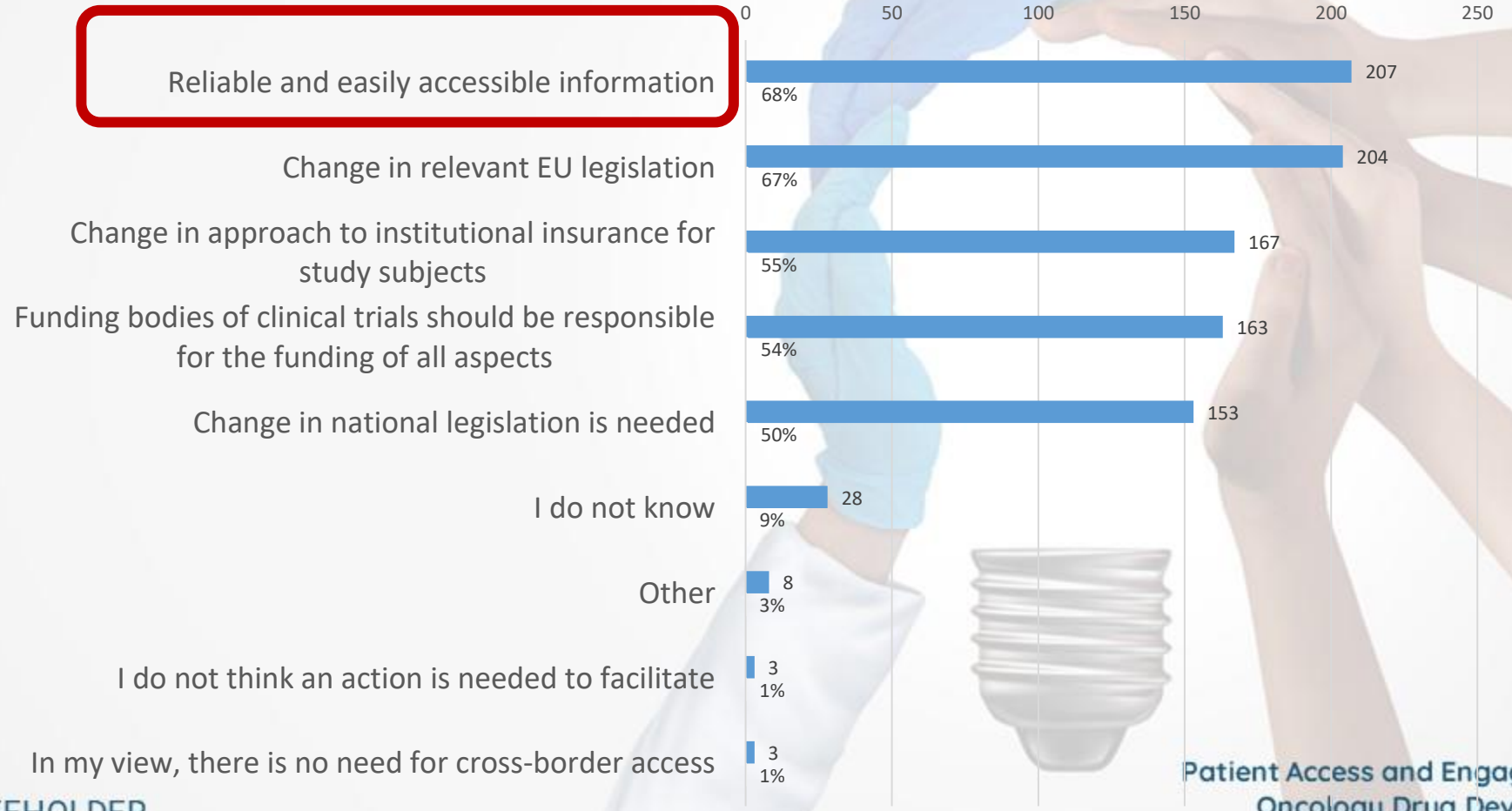
However:

We also need to keep the broader view in mind:

- Cross-border access is **only a part of the solution**
- **There is a also a need to bring clinical trials closer to the patient = need for simplification of the EU clinical trials framework**

Proposals for future actions? (1)

Survey



Proposals for future actions (2)

Directly addressing CB access

Interviews

Indirectly addressing CB access

- Multi-stakeholder guidelines
- Optimising how information is disseminated
- Bi-lateral agreements
- Stronger role for the ERNs
- Amending the Cross-border healthcare directive

- Remote/decentralised clinical trials
- Harmonisation of the EU clinical trials framework
- Common ethics approval framework in the EU

What is next?

Multi-stakeholder, multi-national discussions

↓

Guidelines

Research team

- **Dr. Ingrid Klingmann**, Chairman EFGCP, Project Lead
- **Members of different EFGCP Working Parties**

- **Teodora Lalova**, PhD researcher (FWO fellow), KU Leuven & EORTC
- **Prof. Dr. Isabelle Huys**, Department of Pharmaceutical and Pharmacological Sciences
- **Dr. Steffen Fieuws**, Leuven Biostatistics and Statistical Bioinformatics Centre

- **Dr. Denis Lacombe**, Director General
- **Anastassia Negrouk**

- **Jan Geissler**, CEO

- **ADVISORY COMMITTEE**: 6 representatives from patient organisations, investigators, sponsors, ethics committees

- **EFPIA Oncology Platform**: supported this study with an unrestricted grant

Thank you!

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Cross-Border Access to Clinical Trials in the EU: Exploratory Study on Needs and Reality

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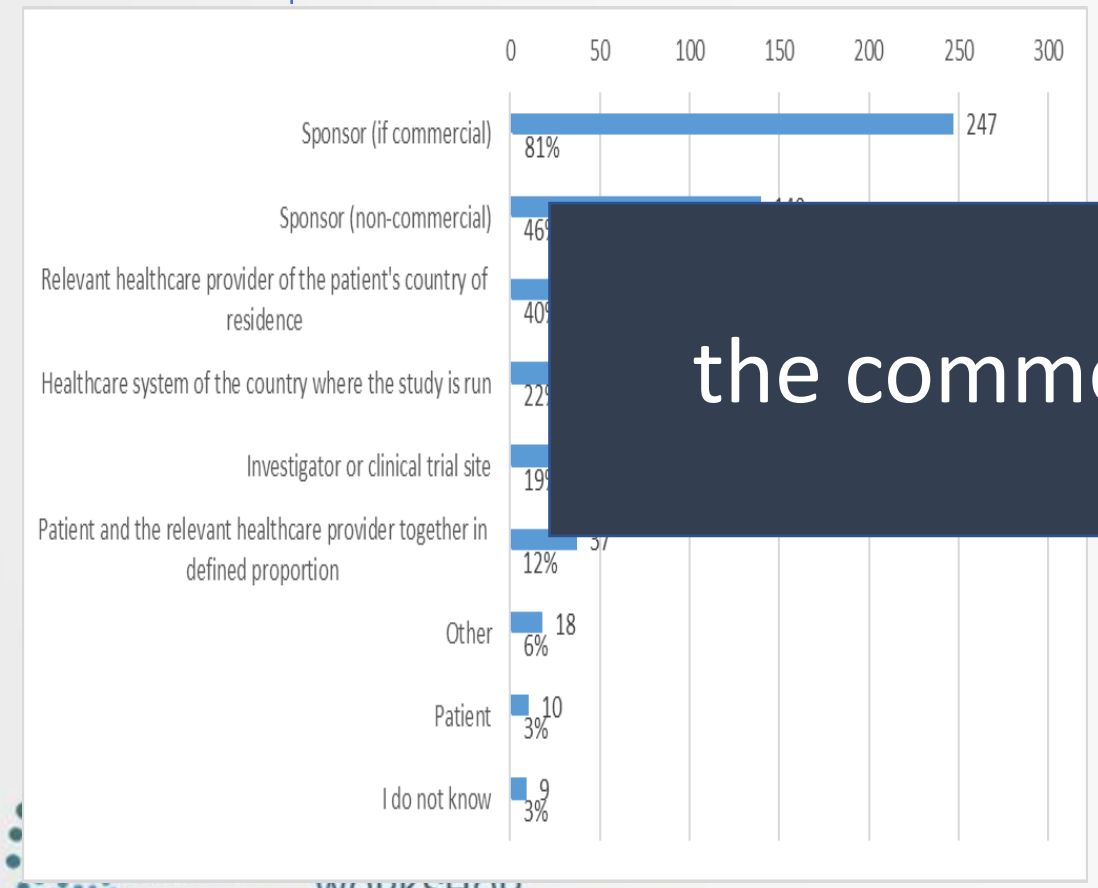
Find it here

Or

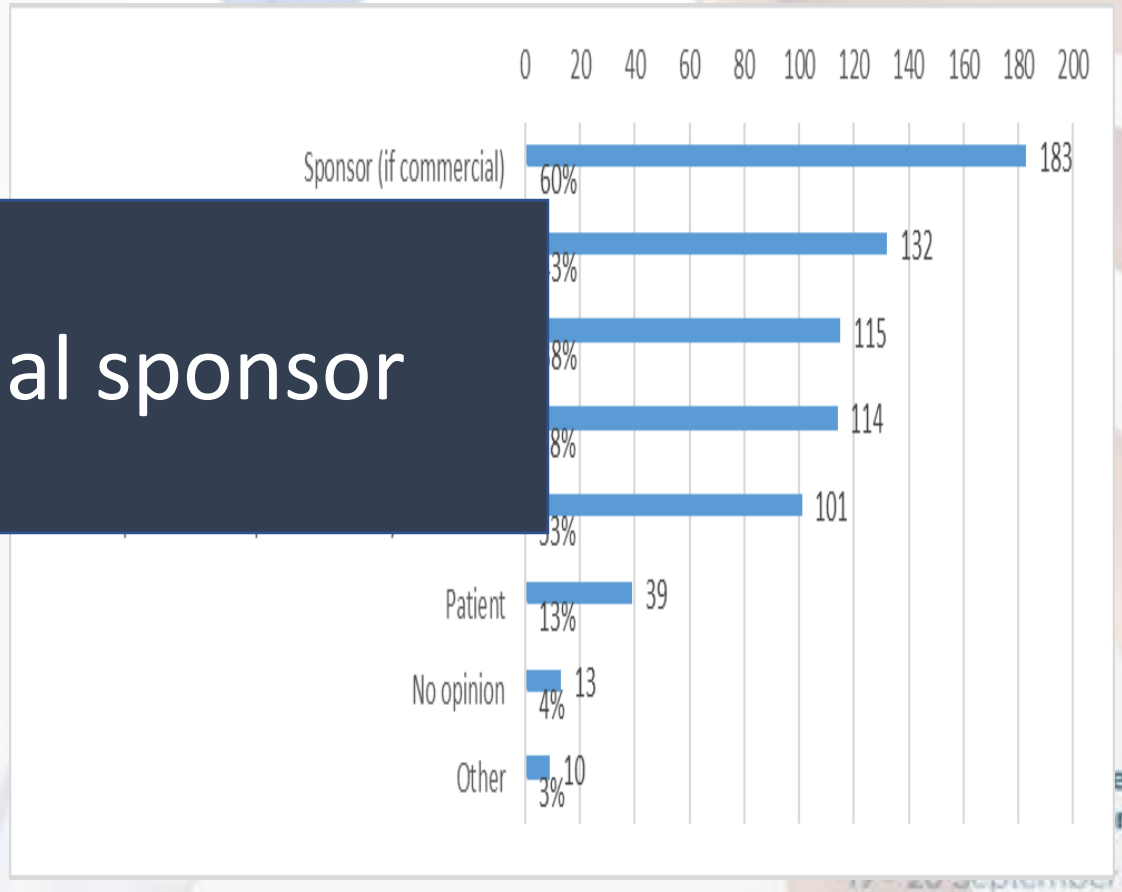
https://www.frontiersin.org/articles/10.3389/fmed.2020.585722/full

Responsibility (1)

Cost coverage | Survey | **Logistics**



the commercial sponsor



Responsibility (2)

Cost coverage

Interviews

Logistics

more nuanced…

Sponsor only
(regardless commercial or academic)

Different responsibility for commercial & academic

Joint model: Sponsor +

- Home country
- Host country
- EU

Joint model: Home +

- Host country
- Host + ERNs
- Other (e.g. CROs)

Home country only

Sponsor only
(regardless commercial or academic)

New EU organisation