Support of Non-Commercial Clinical Trials by EU/EEA Member States

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CT Regulation 536/20104 and Non-Commercial CTs

Whereas (81)

"As regards Directive 2001/20/EC, experience also shows that a large proportion of clinical trials are conducted by non-commercial sponsors. Non-commercial sponsors frequently rely on funding which comes partly or entirely from public funds or charities.

In order to maximise the valuable contribution of such non-commercial sponsors and to further stimulate their research but without compromising the quality of clinical trials, measures should be taken by **Member States to encourage clinical trials conducted by those sponsors**".

Art. 78 (4) "**Inspections fees**, if any, **may be waived** for non-commercial sponsors".

Art. 86 "Member States may establish **reduced fees** for non-commercial clinical trials"

- **Results of a survey across CTCG's members:**

  19 of 30 Member States participated

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1 What is a Non-Commercial Clinical Trial?

About 70% (13 MSs) of the 19 responding MSs have a clear (legal) definition for ‘non-commercial’ CTs , 6 MSs do not

Definitions contain mostly

- **Purpose** of CT

  not for development or registration/marketing authorization, no financial interest

- **Sponsor** characteristics

  CT site, public institutions or entities, **academics** e.g. universities or hospitals, (national) scientific societies/organisations, protection of patients organisations, foundations, **non profit organisations**

- **Ownership exclusive**

  on design, planning, conduct, generated data and results , **decision on publication**

- **Financing**

  by public funds

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2 Specific Support Mechanism for Non-Commercial CTs

95 % (18/19) have **specific support** mechanism **for non-commercial CTs**

Mainly,

- **Fee reduction** to waiver : National Competent Authorities, Ethic Committees, Scientific Advice, Inspections
- **Information - Training**
- Support **regulatory** (NCA/EC), Support **CTIS**
- Identifying the research **network, funding**, or navigating the regulatory **infrastructure**
- Support **scientific** (protocol writing, design), GCP and **conduct**

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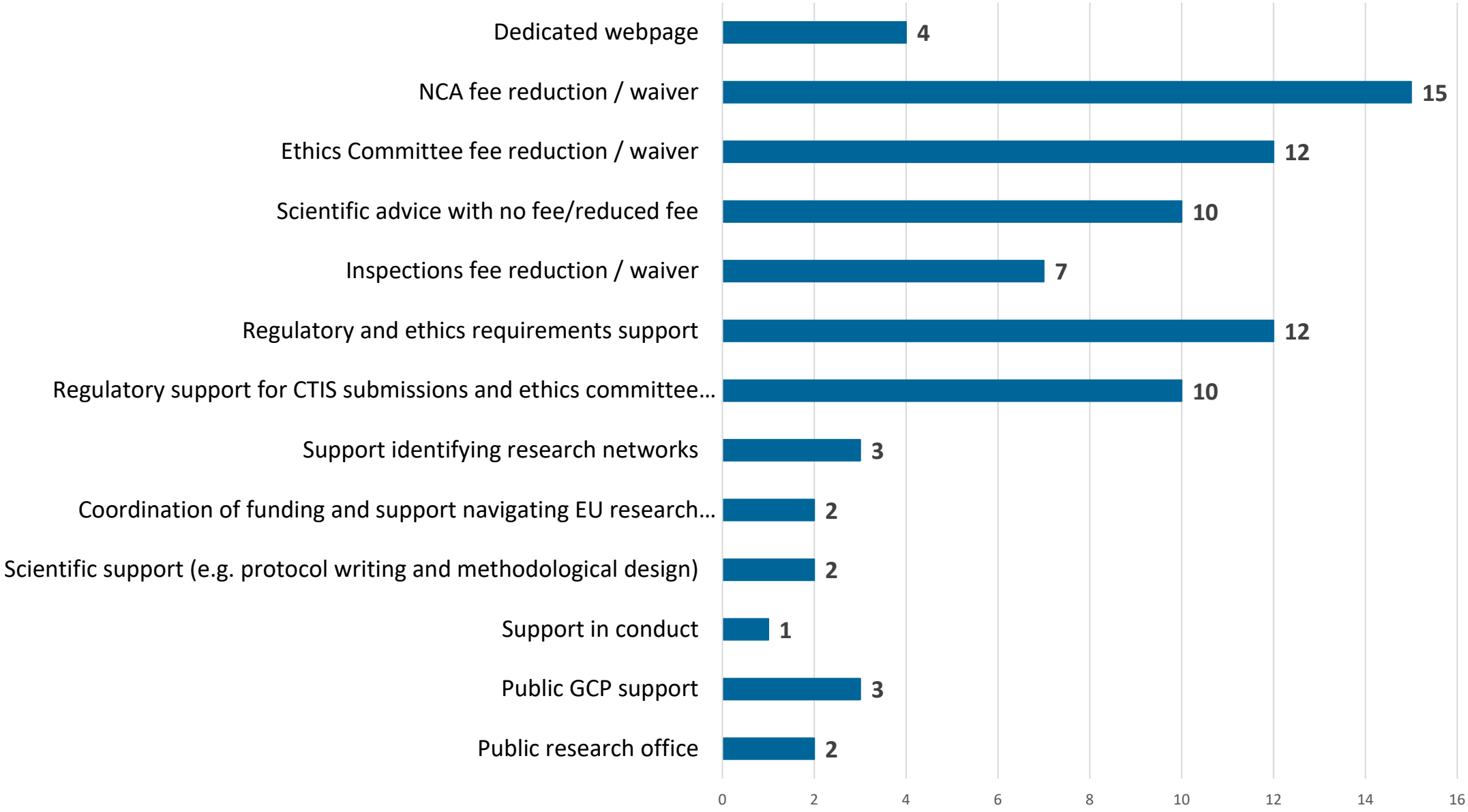
Support mechanisms for non-commercial CTs



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3. **Support** mechanisms applicable at **mono- and/or multinational level**?

- 58% (11MSs) support at **national and multinational** level
- 21% (4 MSs) level **depends** on type of support - some national, others multi- too
- 16% (3 MSs) at ***national*** level only
- Unknown in 1 MS, since responsibility at different organisation

4. **Funding to** support **Conduc**t of a **non-commercial CT**?

- 7 MSs fund conduct of national and multinational CTs
- 5 MSs fund conduct of national CTs only, including at national CT sites only
- No support to conduct a non-commercial CT is available in 6 Mss

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Funding to support **Conduct** of a **non-commercial CT - examples:**

AT	Under the remit of the **Ministry of Education, Science and Research** (not NCA) https://www.bmbwf.gv.at/Themen/Forschung/Forschung-in-Österreich/Forschungsförderungseinrichtungen.html
BE	Non-commercials have nothing to pay for trials submissions in CTIS, safety follow up and GCP inspections.
DE	**DFG** and **BMBF**
DK	It is possible to apply for fundings at **varios bodies** (public and non-public) in our MS, but not by the goverment itself.
ES	There are other organisms (for example Carlos III Health Institute) which helps on this matter, different from the Spanish Agency for Medicines.
FI	Public funding availabilities available through **various channels** (however not directly from medicines agency)
IE	HRB (https://www.hrb.ie/) operates a funding scheme called **Definitive Intervention and Feasibility Awards** (DIFA). This DIFA supports researchers and research teams to conduct high-quality definitive intervention trials and feasibility studies.
LV	**University** funds and other funds
NO	It is possible to apply for funding from the **National Reasearch Council** and the **Regional Health Areas**
PL	The **Medical Research Agency** (MRA) was founded in order to improve the use of potential for development of medical research and health sciences, particularly in the scope of non-commercial clinical research
SE	For example via the **Swedish Research Council**

Thanks for listening.

Questions?