



Paediatric Cross-Border Clinical Trials: Enpr-EMA Working Group

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SJD Sant Joan de Déu
Fundació de Recerca

Patient Engagement
in Research Area

Enpr-EMA
European network of paediatric research
at the European Medicines Agency



The challenge...



Mother tongue and country of residence are used as eligibility criteria in clinical trials.

This practice is unethical, especially when there is a potential benefit of participating in a clinical study.

Exclusion criteria:

Parents or children with poor understanding of the English language.

Inclusion criteria:

The legally acceptable representative(s) and patients 15-17 years must be able to understand and speak local language

Exclusion criteria:

Neither parent competent in Norwegian language

Exclusion criteria:

Parents unable to speak and read Dutch/English language.

Exclusion criteria:

Insufficient knowledge of the Dutch language.



Inclusion criteria:

English as a first language.

Inclusion criteria:

Parents or the legal guardian able to read and write in the local language.

Exclusion criteria:

French language not spoken by parents.

Primary Objective

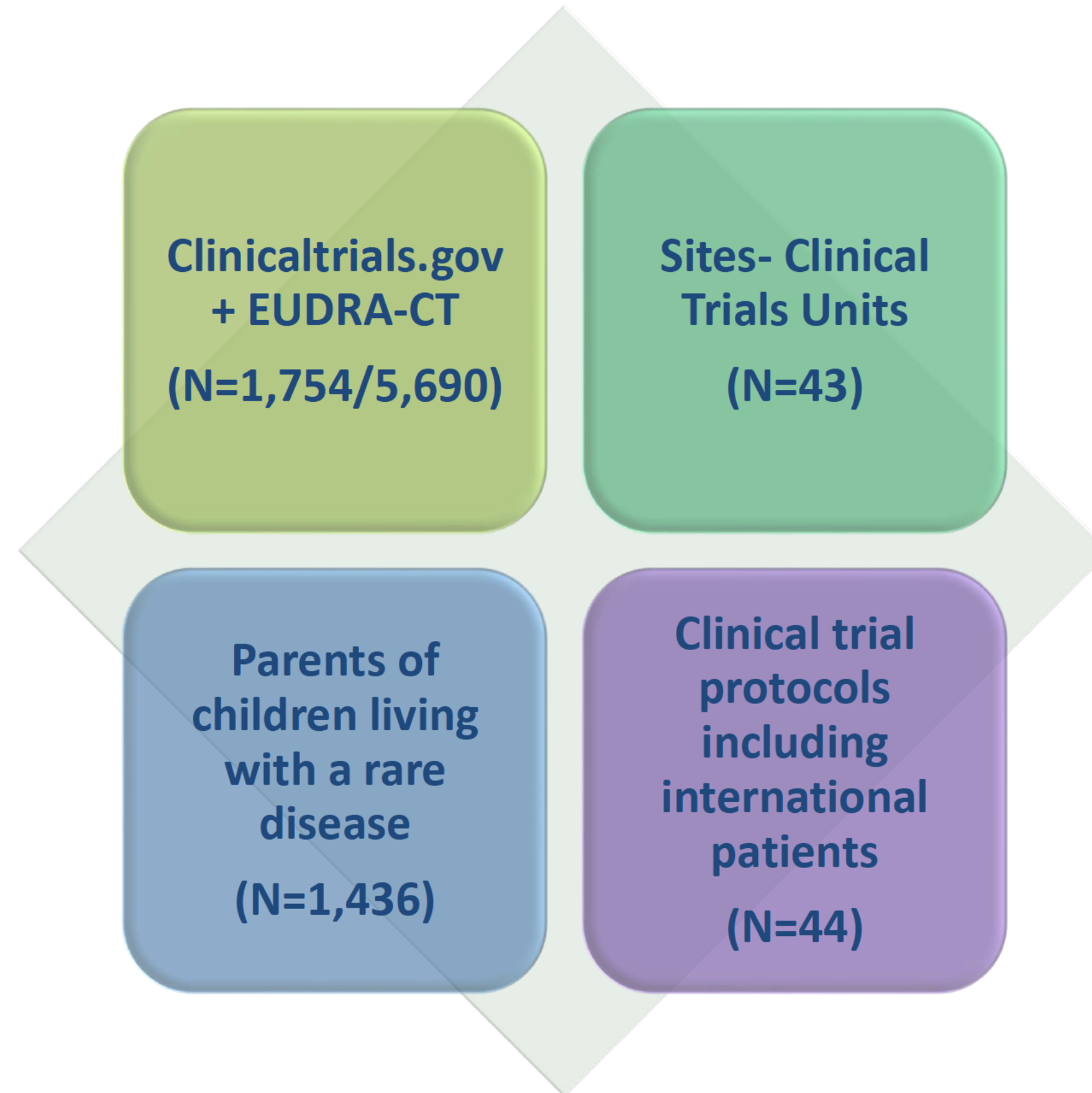


To provide recommendations that will facilitate the inclusion of paediatric patients in a clinical trial conducted in a language other than the patient's mother tongue, and in a different country than the country of residence, especially when there is a potential benefit to the child.



Data Collection

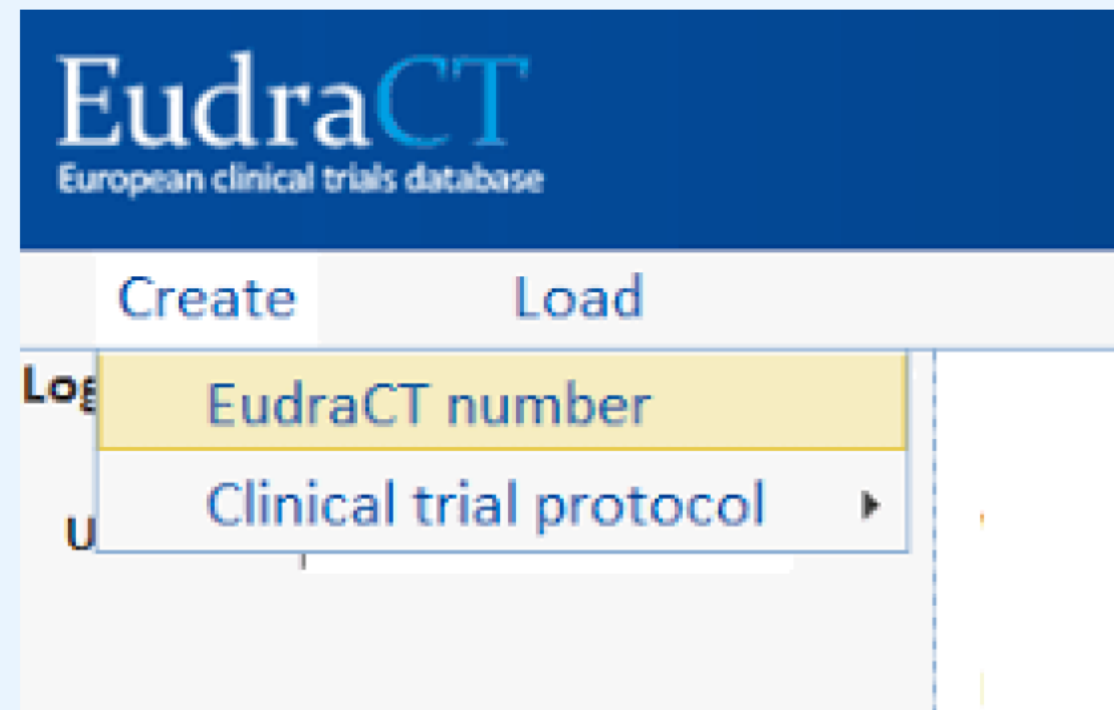
Data sources



Clinicaltrials.gov

EUDRA-CT

33 %



5,290
Studies



Data NOT published.

Clinical trial sites



43

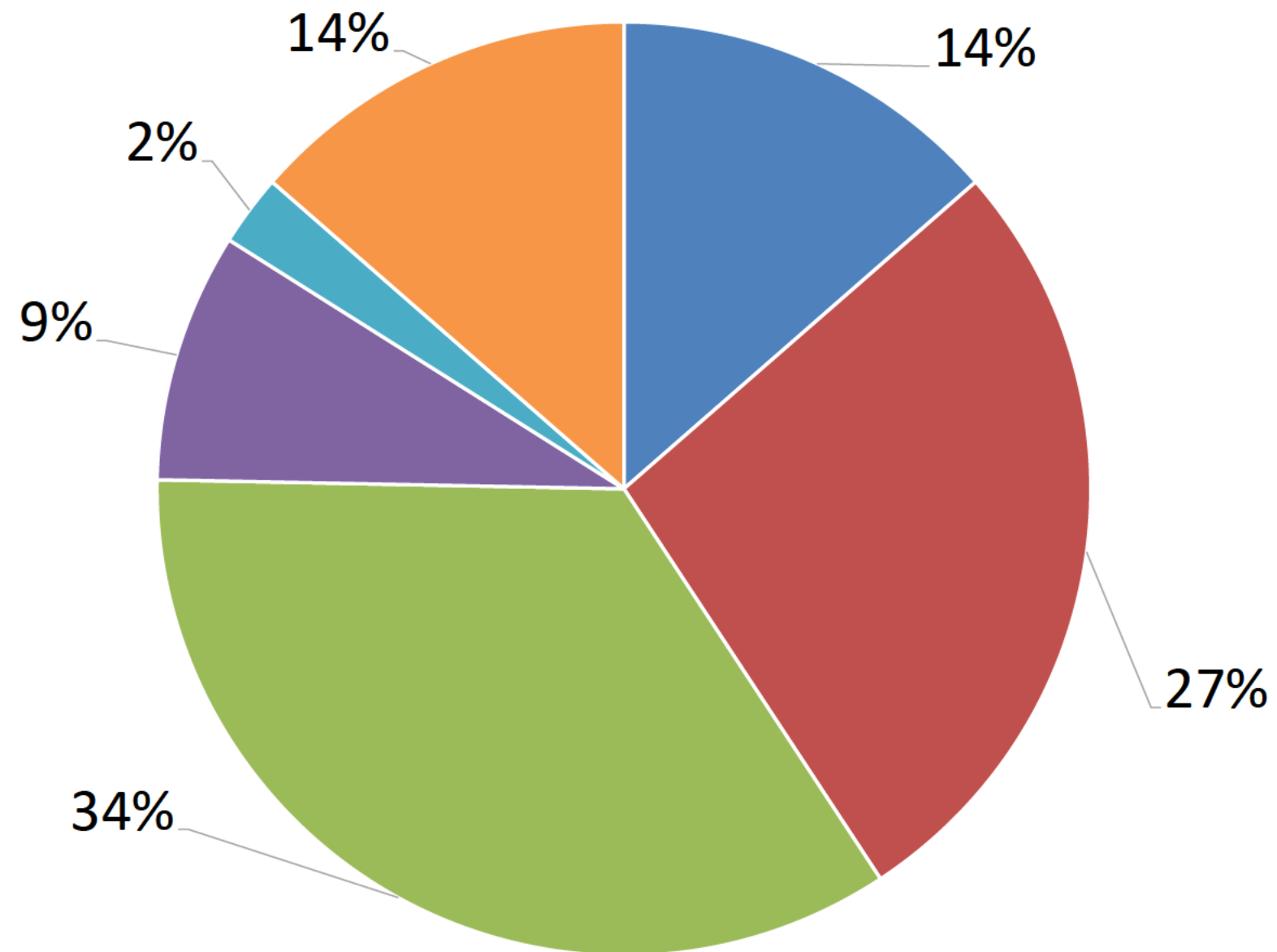
Sites

Country	N=
Albania	1
Austria	1
Belgium	2
Czech Republic	1
Denmark	1
Finland	1
France	4
Germany	4
Greece	1
Italy	10
Luxemburg	1
Netherlands	2
Norway	1
Poland	1
Portugal	2
Slovakia	1
Spain	9

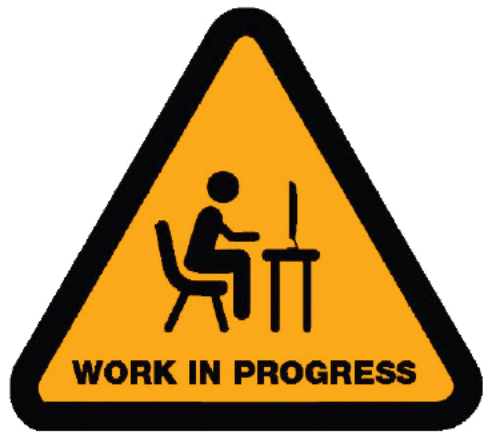


Clinical trial sites

Distribution of international patients by continent



Africa Asia Europe
North America Oceania South America



Data NOT published.

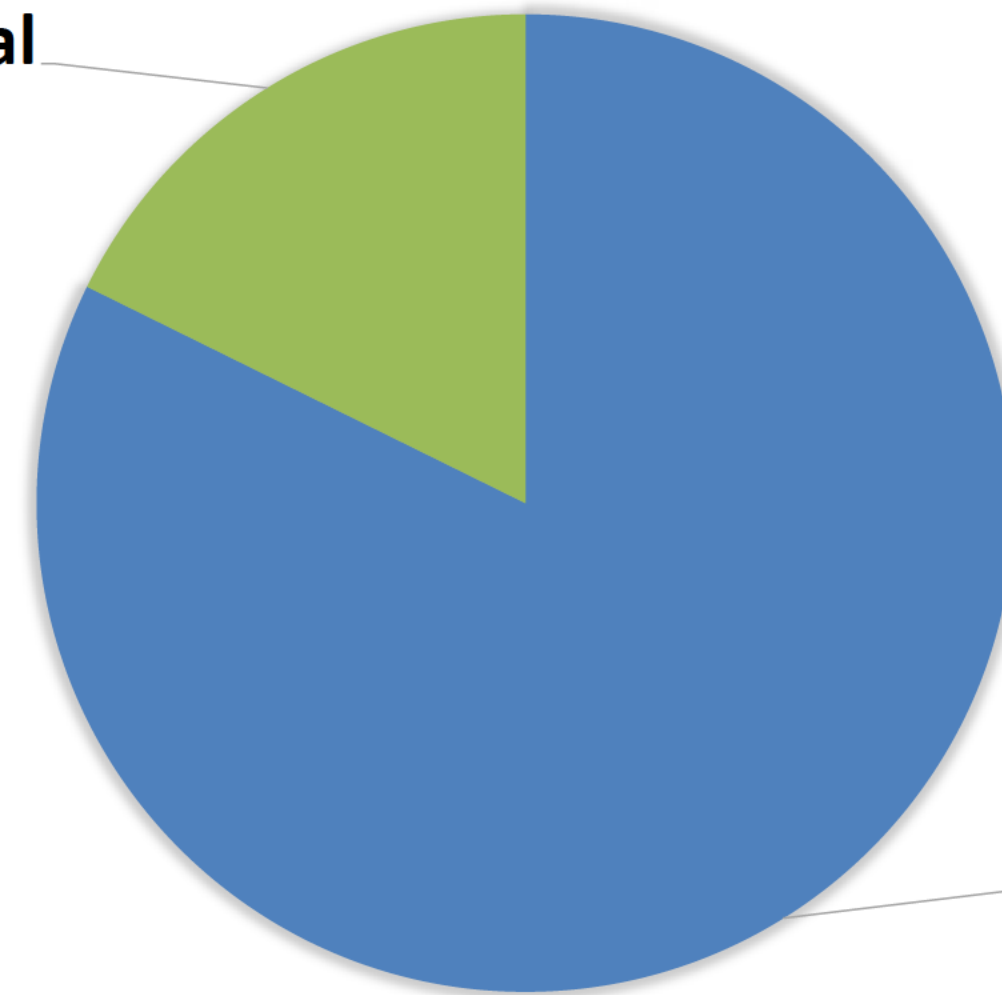
Good practices questionnaire

113

Studies

Country of the site	N=
Denmark	50
Spain	36
Italy	21
Belgium	1
Czech Republic	1
Germany	1
Greece	1
Poland	1
Sweeden	1
Total	113

Commercial
studies
18%



Investigator-
led/publicly
funded trials
82%



Data NOT published.

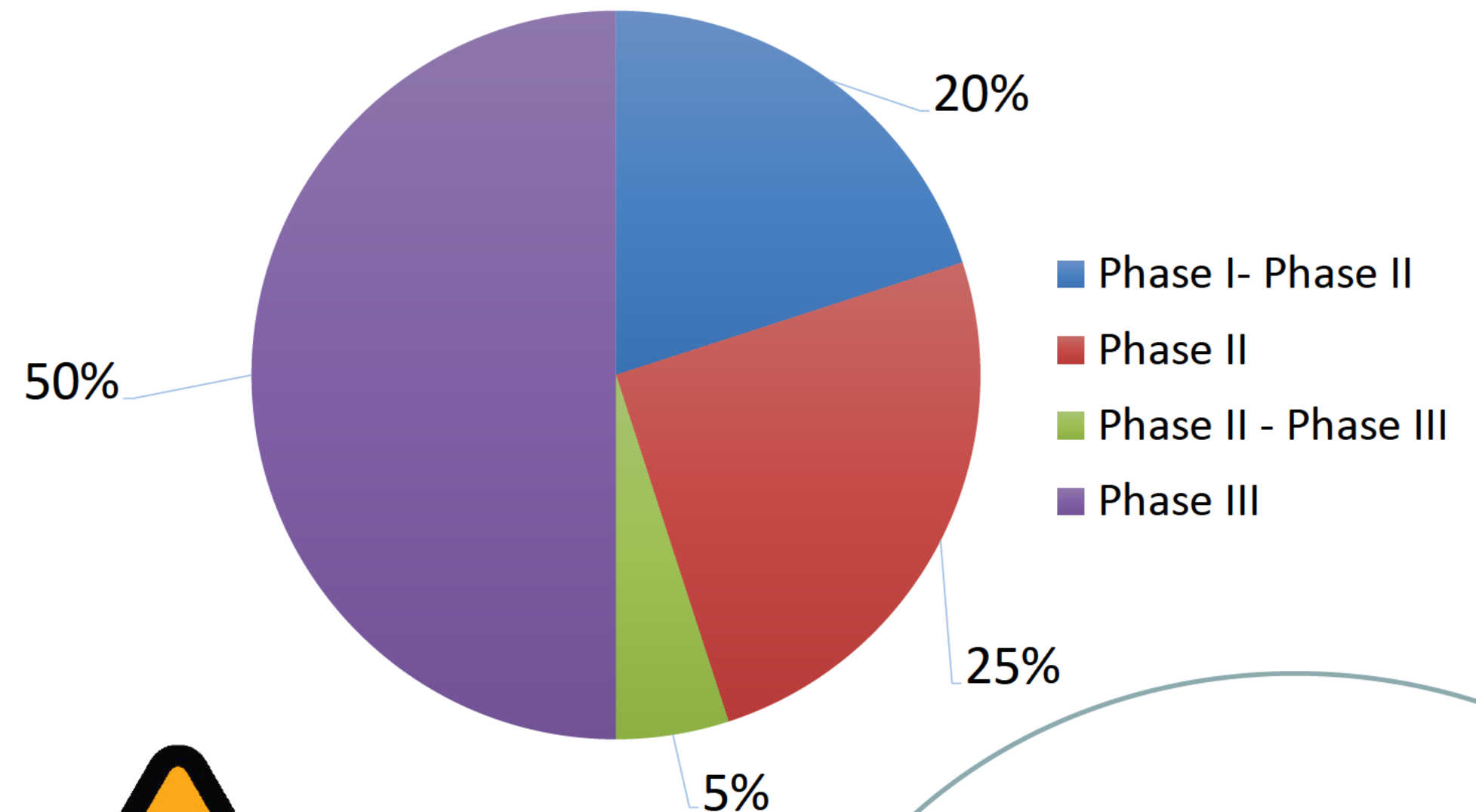
Cases of discrimination

20

Studies

Country	N
Czech Republic	1
Italy	12
Spain	6
Sweden	1

Distribution of cases of discrimination by study phase



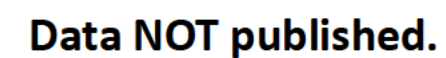
Data NOT published.

Cases of language discrimination

- 70 % of the studies were related to rare conditions (not including childhood cancer).
- 70% of the clinical trials were commercial sponsored.
- Patients excluded were from European and non-European countries.
- Limited data.



Data NOT published.



Parents' questionnaire

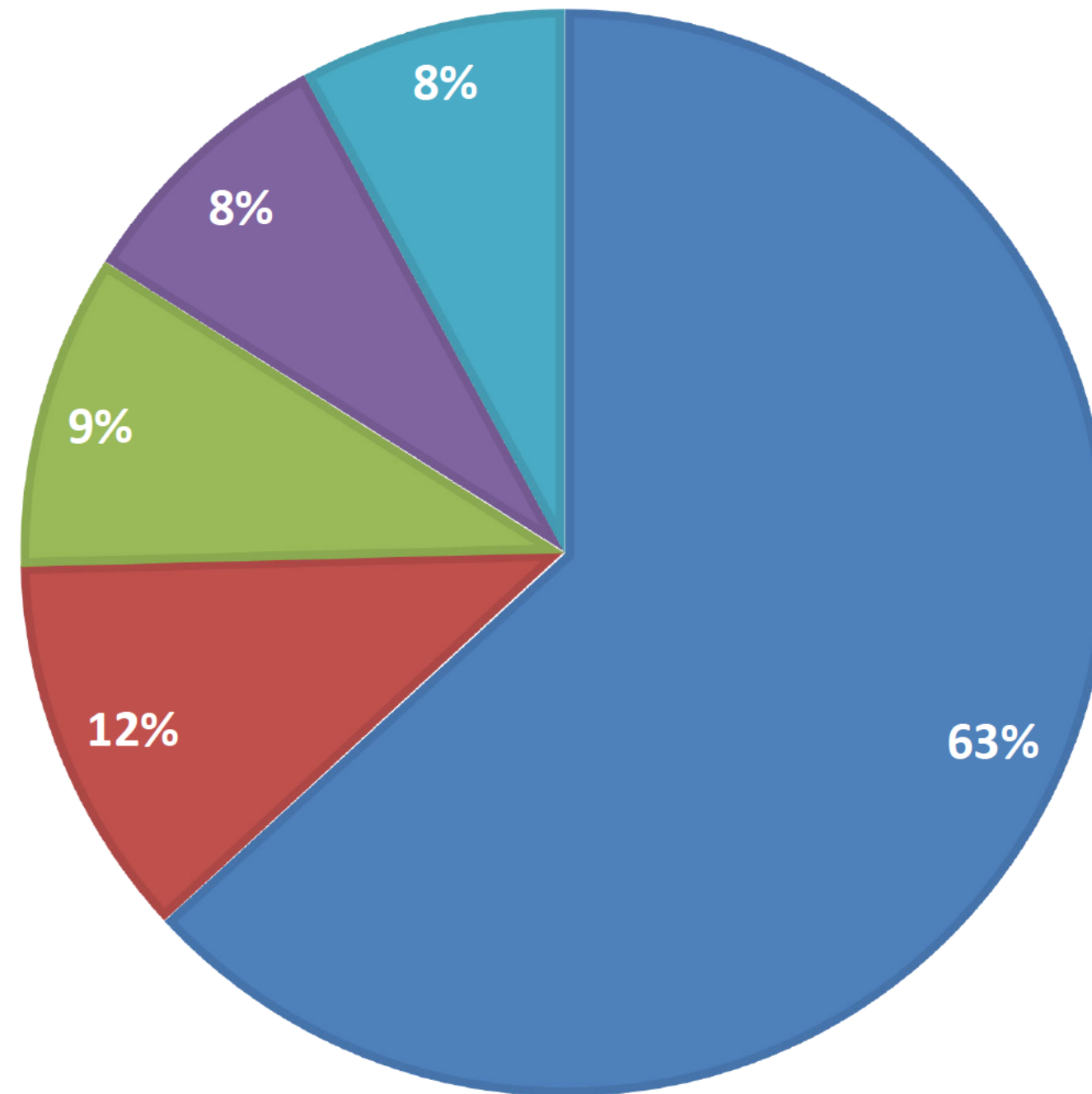
Spain France Slovenia Portugal Poland

1,436

Answers



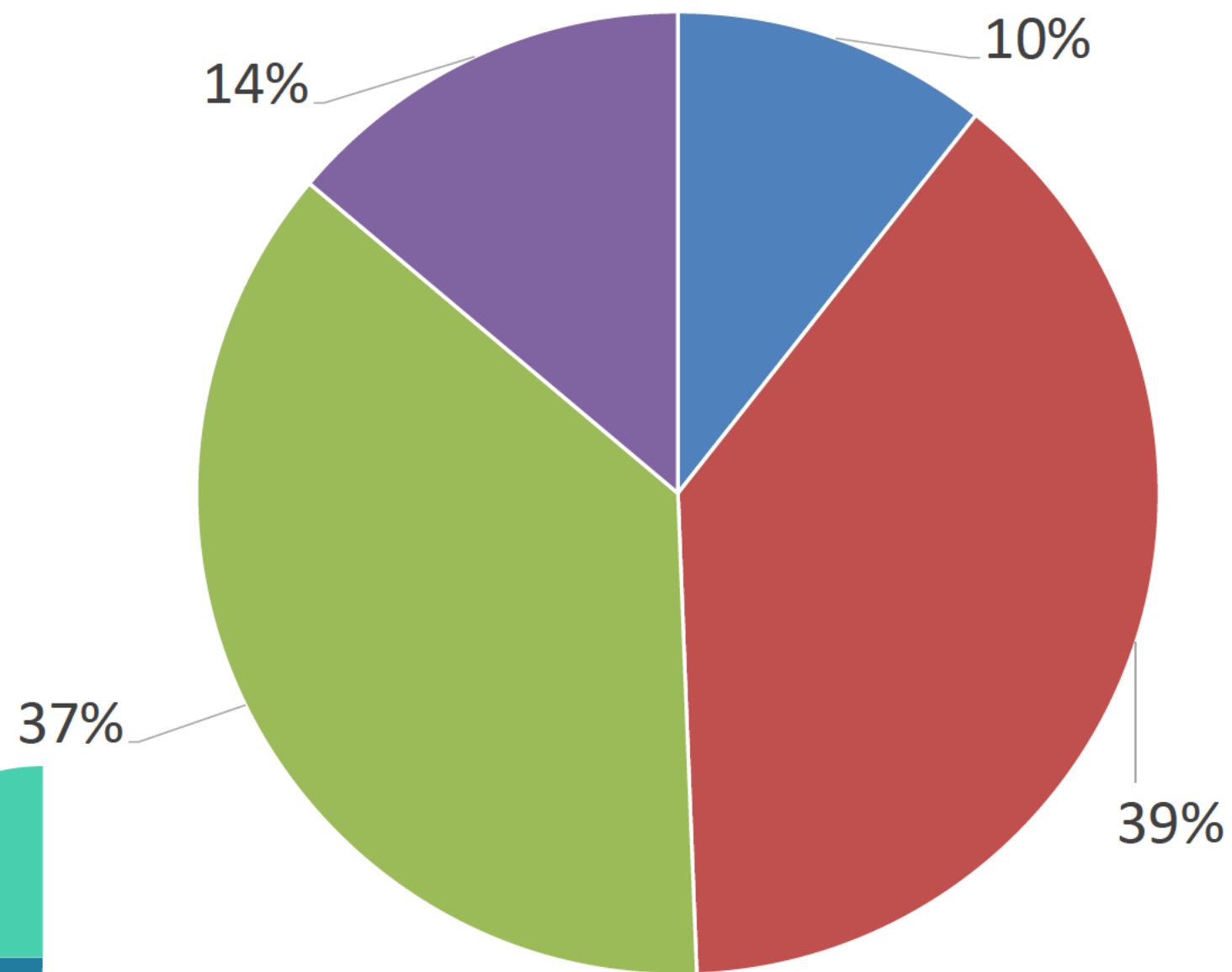
Data NOT published.



Parents' questionnaire

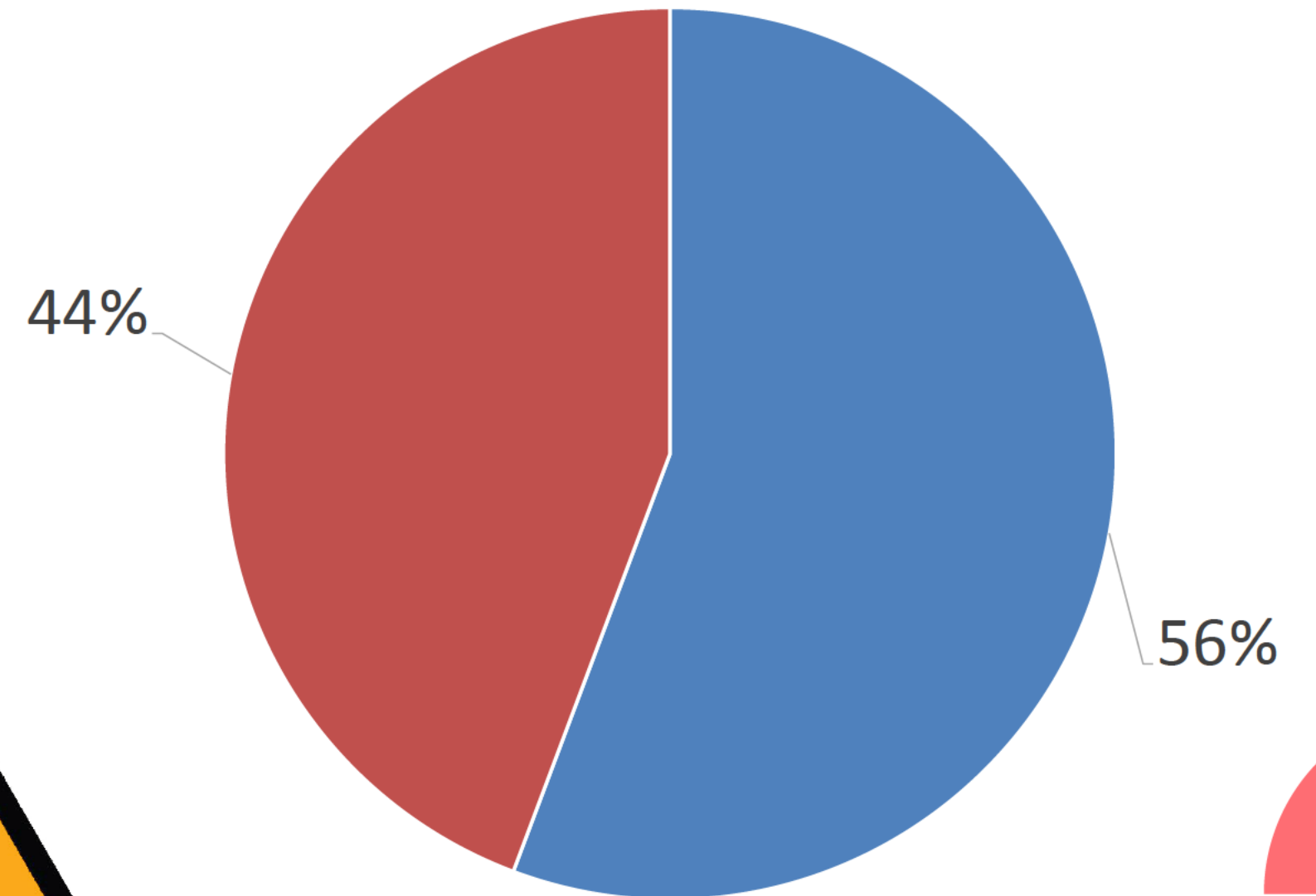
Level of English

■ Beginner ■ Intermediate ■ Advance ■ Native



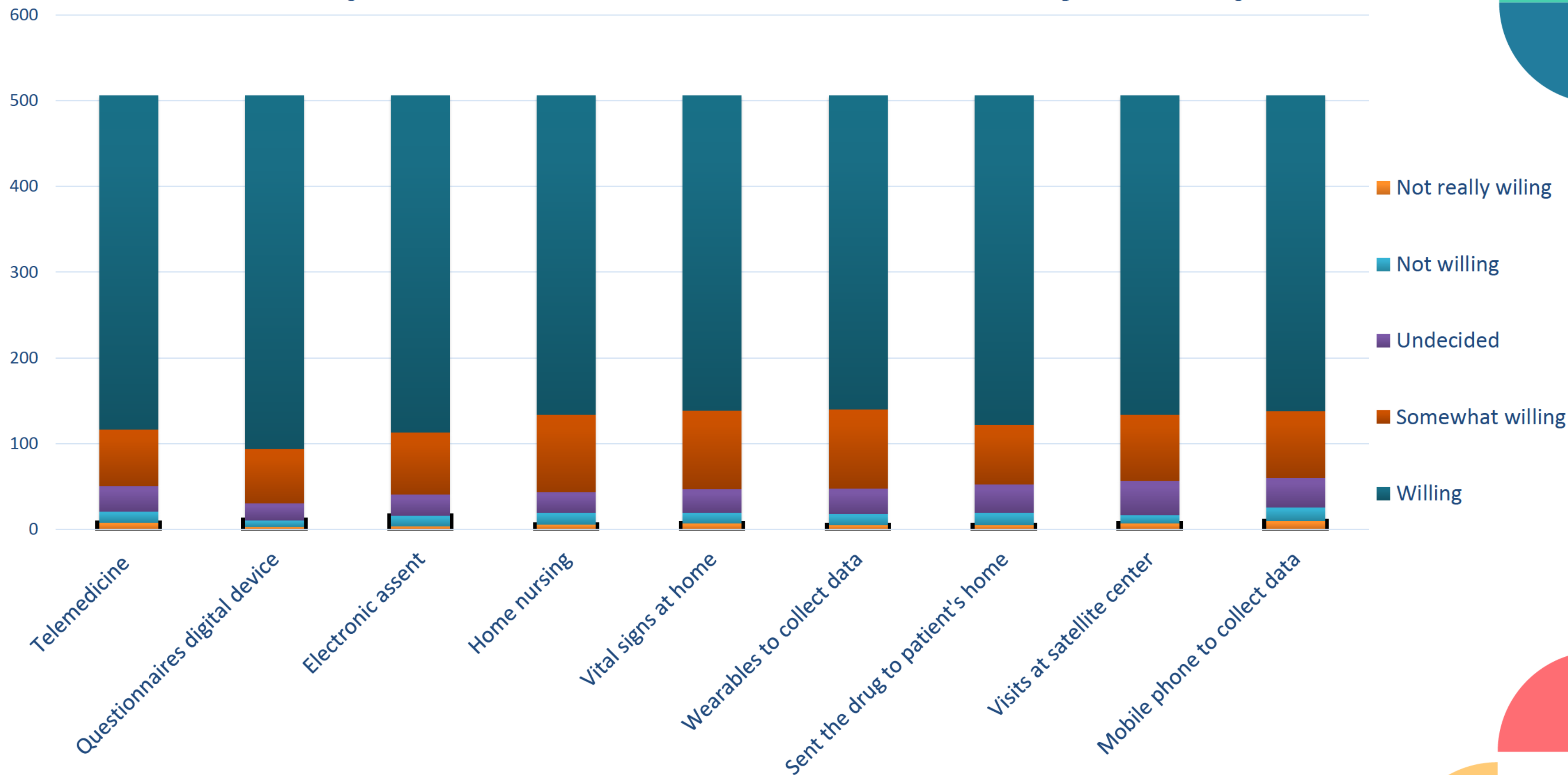
Parents able to communicate in English

■ Yes ■ No



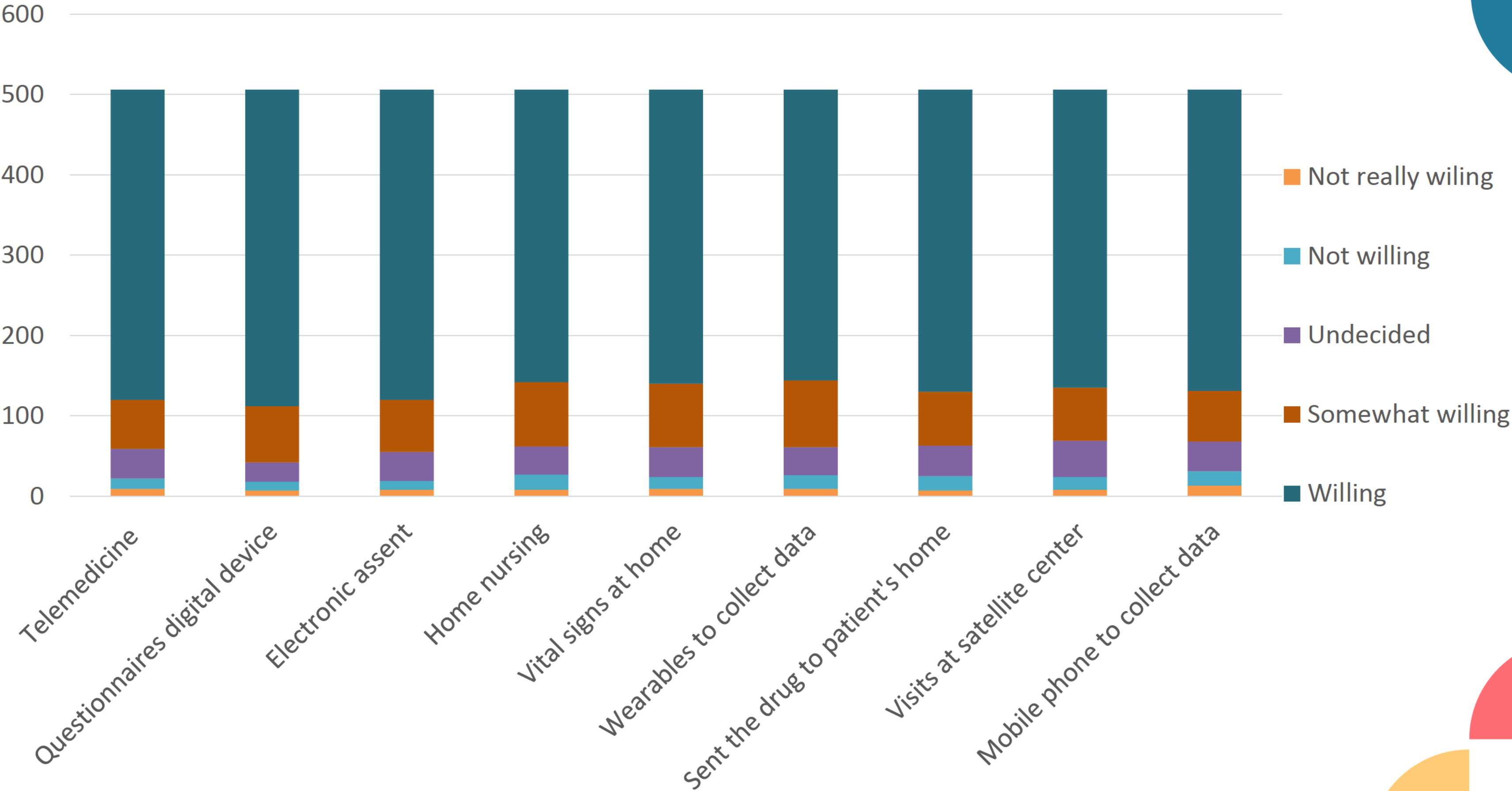
Data NOT published.

DCT options - clinical trial in the country of the patient



Data NOT published

DCT options. Cross-border clinical trial



Data NOT published

Next steps...

4

Manuscripts submitted to scientific journals

2

Manuscripts (*working progress*)

5,960
Studies

EUDRA-CT data analysis

44
Studies

Sponsors' questionnaire

Timeline ...

1

Feb-26

Guidance: paediatric cross-border clinical trials avoiding language discrimination (draft).
(Open) Public consultation

2

June-26

(Close) Public consultation

2

Set-26

Guidance: paediatric cross-border clinical trials avoiding language discrimination (FV).

WG members



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Dr. Ricardo Fernandes
CT NH Network Chair
(Portugal)



Dr. Pamela Dicks
CT Network Manager
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**"STOP DREAMING
AND START
DOING TOGETHER"**



Thank you so much!

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