Language Discrimination and Cross-border Access to Paediatric Clinical Trials WG

Chair: Begonya Nafria

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European network of paediatric research at the European Medicines Agency

Working Group Members

Prof. Dr. Gilles Vassal
Oncologist
(France)

Dr. Ricardo Fernandes
CT NH Network Chair
(Portugal)

Dr. Pamela Dicks
CT Network Manager
(United Kingdom)

Segolene Gaillard
CT Network Manager
(France)

Dr. Martine Dehlinger-Kremer
Industry expert
(Germany)

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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.

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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.

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Data Collection 2023-24

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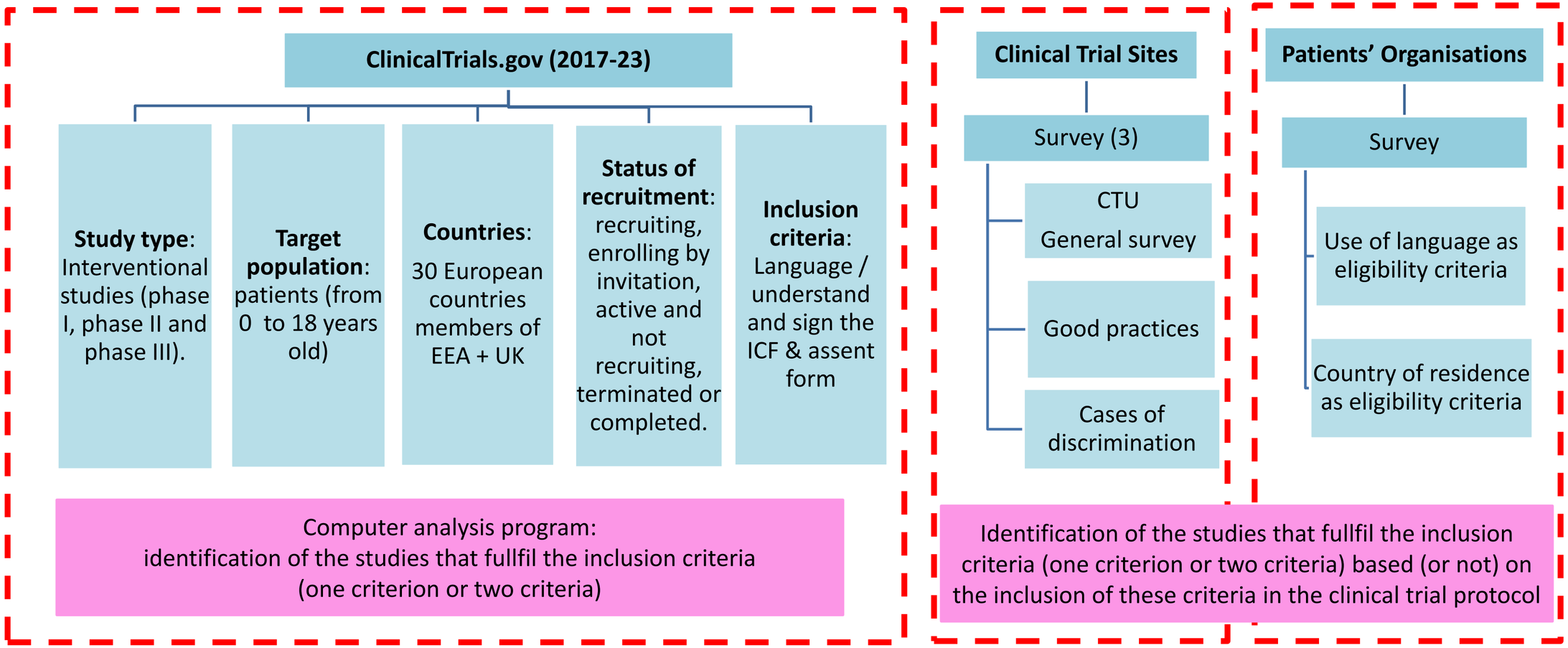
Data sources



Unique pool of data based on the ClinicalTrials.gov identification code

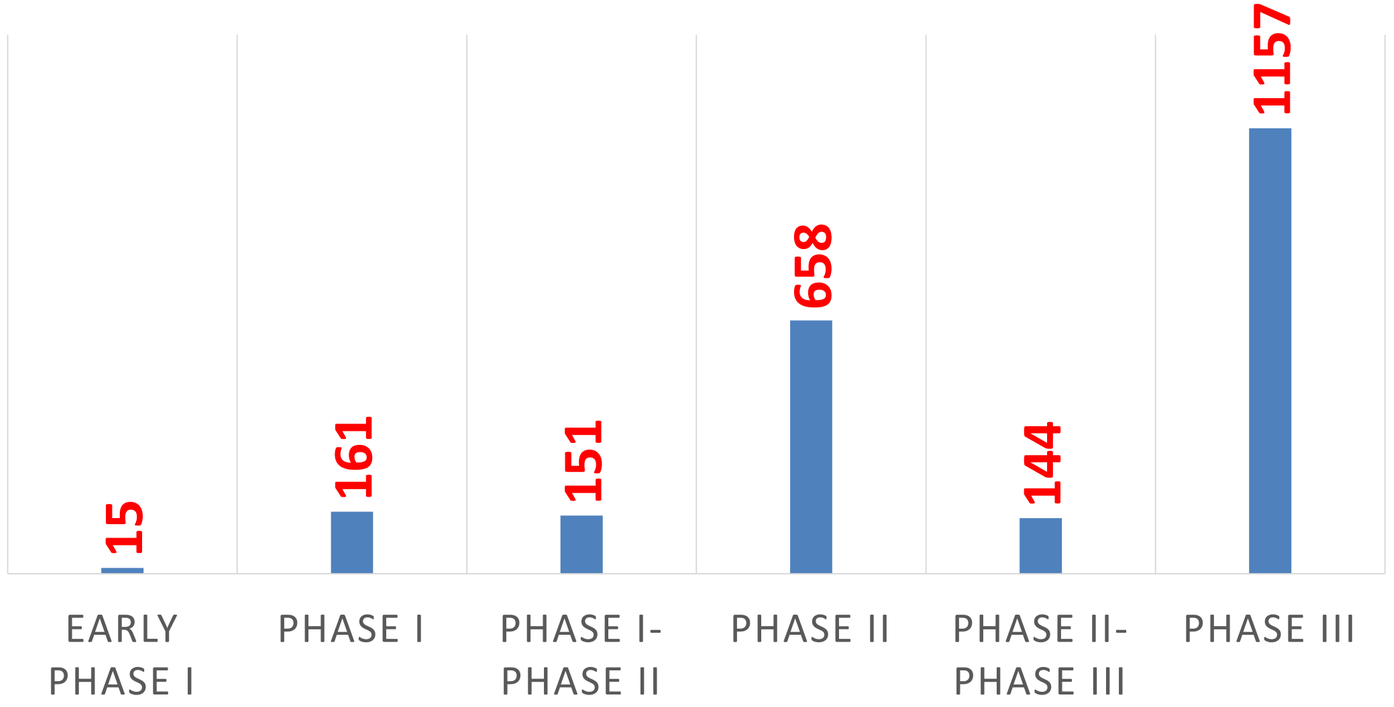
Clinicaltrials.gov Computer Data Analysis

2,286

Studies

Target population: from birth to 18 years old

Period of analysis 01-01-2017 to 31-12-2023



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Data collected until the 30th of September, 2024

Exclusion criteria:

Parents or children with poor understanding of the English language.

Exclusion criteria:

Insufficient knowledge of the Dutch language.

Inclusion criteria:

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

Inclusion criteria:

English as a first language.

Exclusion criteria:

Neither parent competent in Norwegian language

Inclusion criteria:

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

Exclusion criteria:

Parents unable to speak and read Dutch/English language.

Exclusion criteria:

French language not spoken by parents.

Data collected until the 30th of September, 2024

Clinical trial sites questionnaire

29

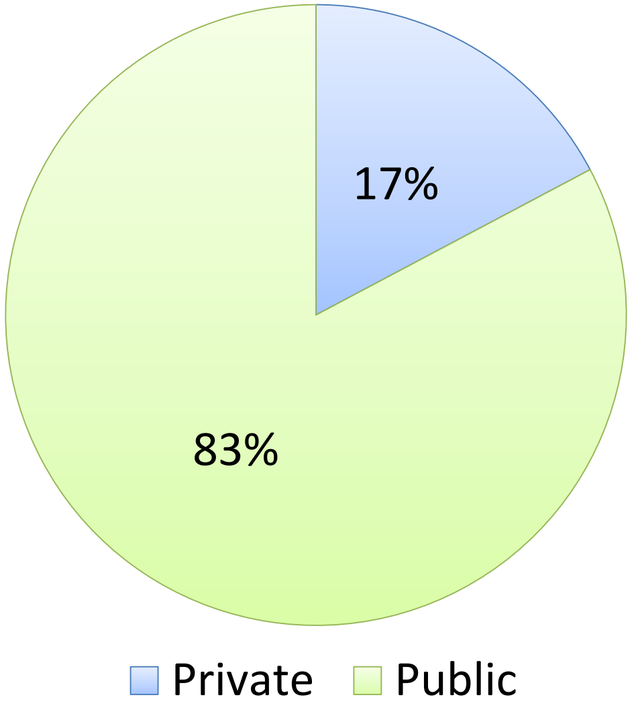
Sites

+ 6 sites
from the UK (1),
Ireland (1),
The Netherlands (2),
France (1) and
Luxemburg (1)

Country	N
Belgium	2
Denmark	1
Finland	1
France	3
Germany	3
Greece	1
Italy	7
The Netherlands	1
Norway	1
Poland	1
Portugal	1
Spain	5

Data collected until the 30th of September, 2024

Clinical trial sites questionnaire



2.04%

Screened patients from European countries

2.31%

Screened patients from non-European countries

Morocco, China, Senegal, Armenia, Ecuador, Syria, Venezuela, Peru, Kuwait, Saudi Arabia, North Africa, Ukraine, Russia, Moldova, Pakistan, Serbia, Argentina, Cambodia, Chile, Ivory Coast, Egypt, Ghana, Iran, Iraq, Kenya, Kyrgyzstan, Lebanon, Nigeria, Georgia, Belarus, Kosovo, Turkey, Afghanistan, Kyrgyzstan, Equatorial Guinea, The Philippines, Brazil, Paraguay…

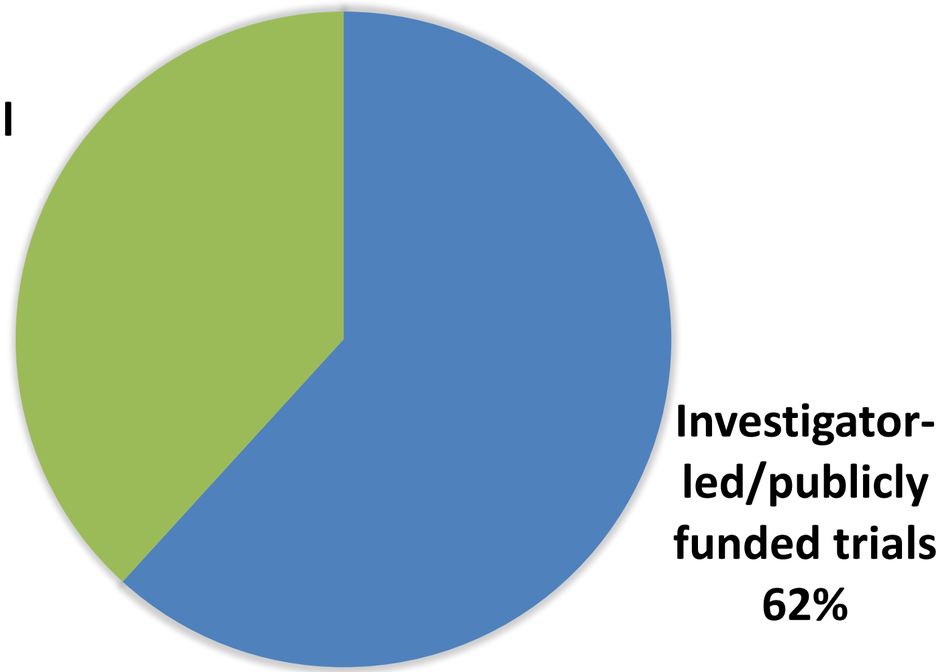
Data collected until the 30th of September, 2024

Good practices questionnaire

104

Studies

Country	N
Belgium	1
Denmark	50
Germany	1
Greece	1
Italy	13
Luxemburg	2
Spain	36



Data collected until the 30th of September, 2024

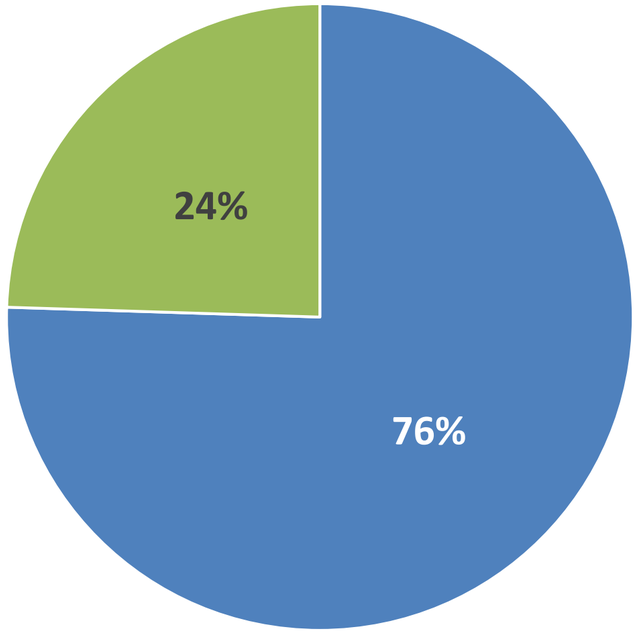
Good practices questionnaire

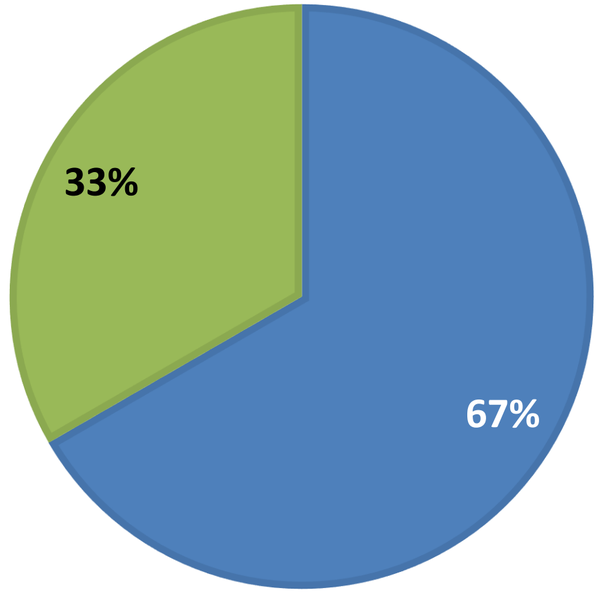
99 %

Rare disease studies

60 %

Patients stayed overnight in the country





Data collected until the 30th of September, 2024

Cases of discrimination

17

Studies

Country	N
Czech Republic	1
Italy	11
Spain	5

- 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

Data collected until the 30th of September, 2024

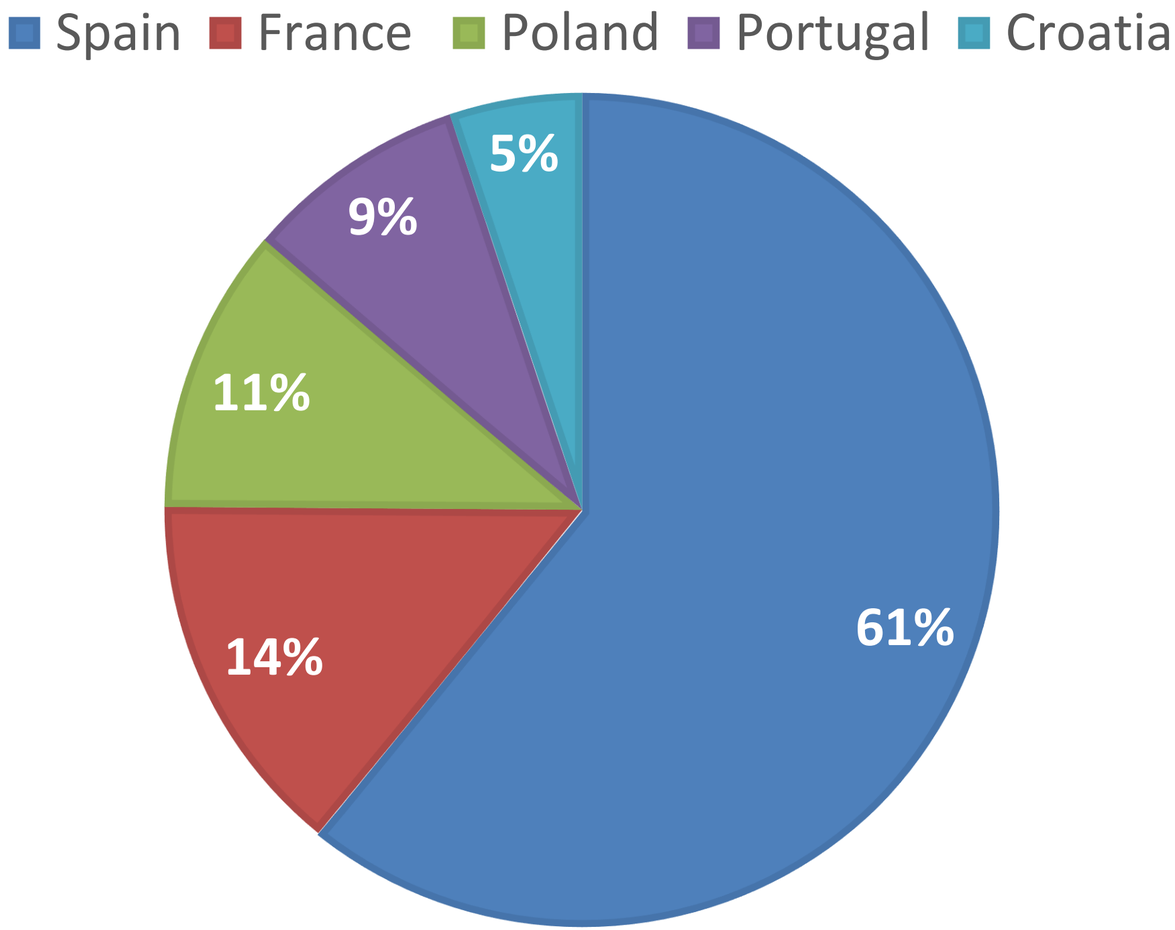
Parents' Questionnaire

Parents' questionnaire

1110

Answers

Who replied	N	%
Mother	906	81,62%
Father	159	14,32%
Young adult patient	16	1,44%
Other relative	29	2,61%

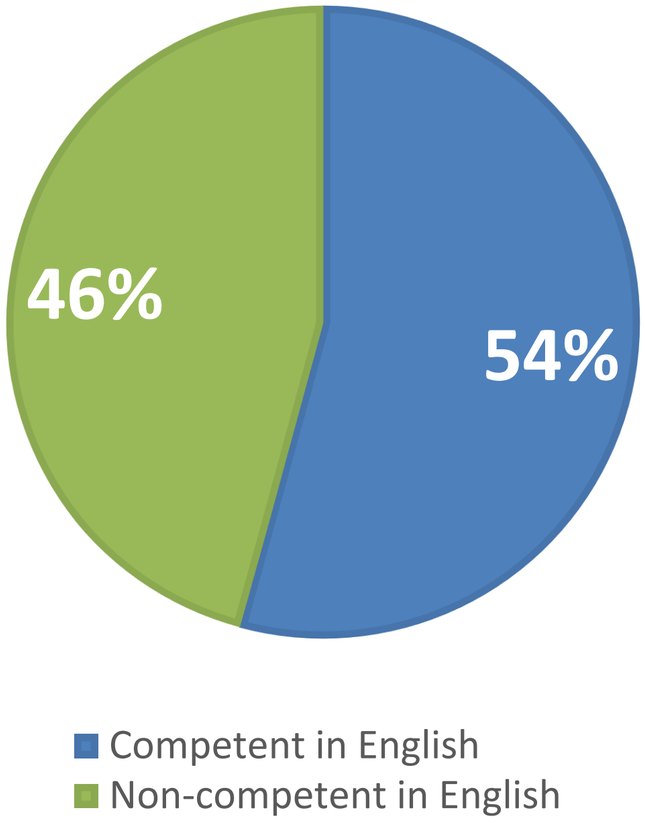


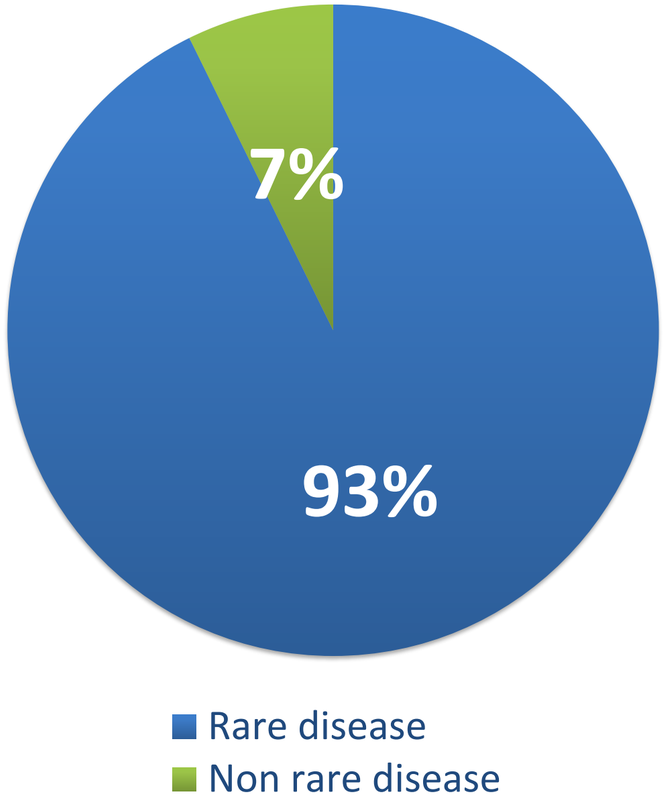
Data collected until the 30th of September, 2024

Parents’ questionnaire

48

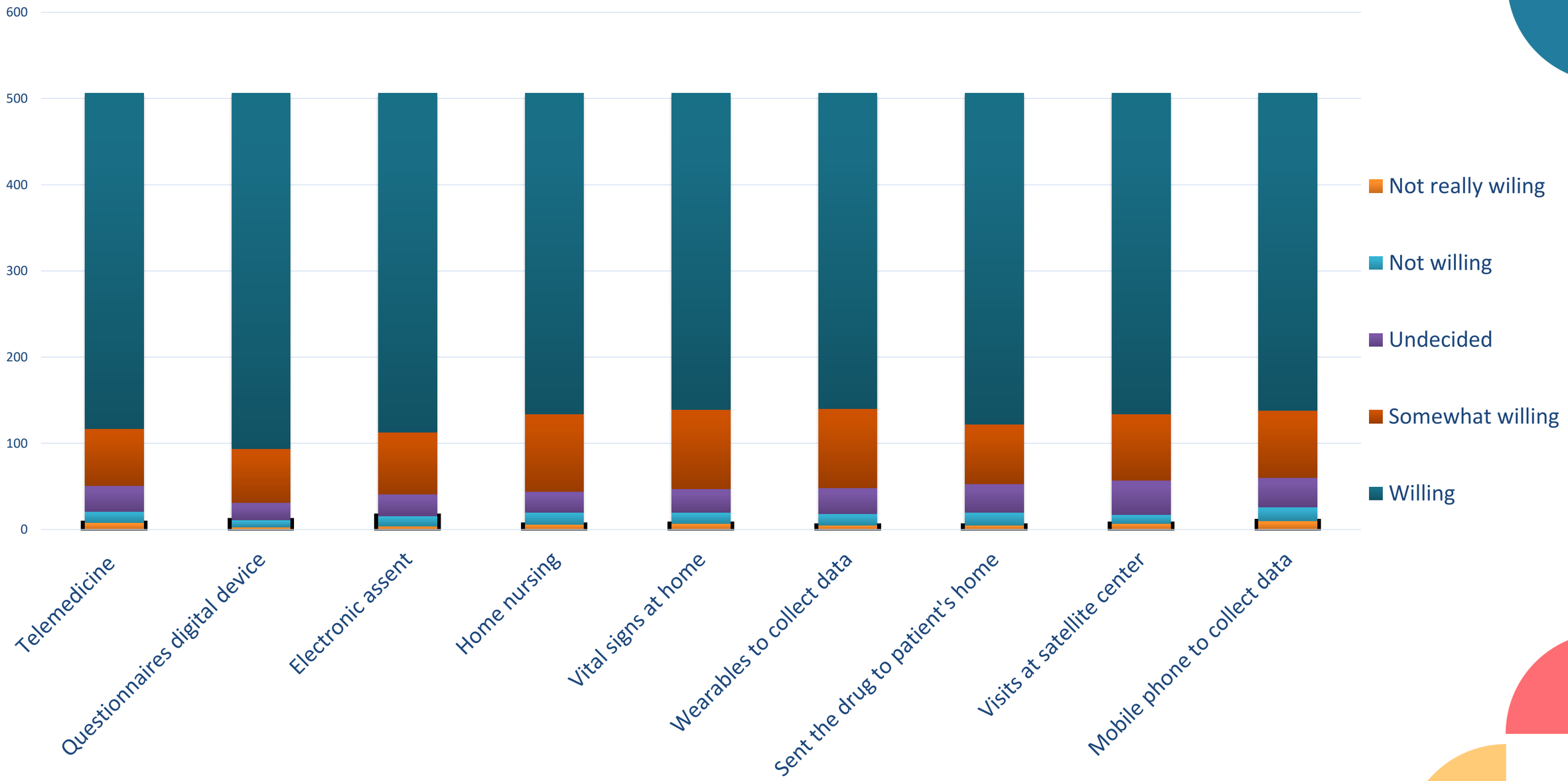
Patients excluded to participate in clinical trial abroad





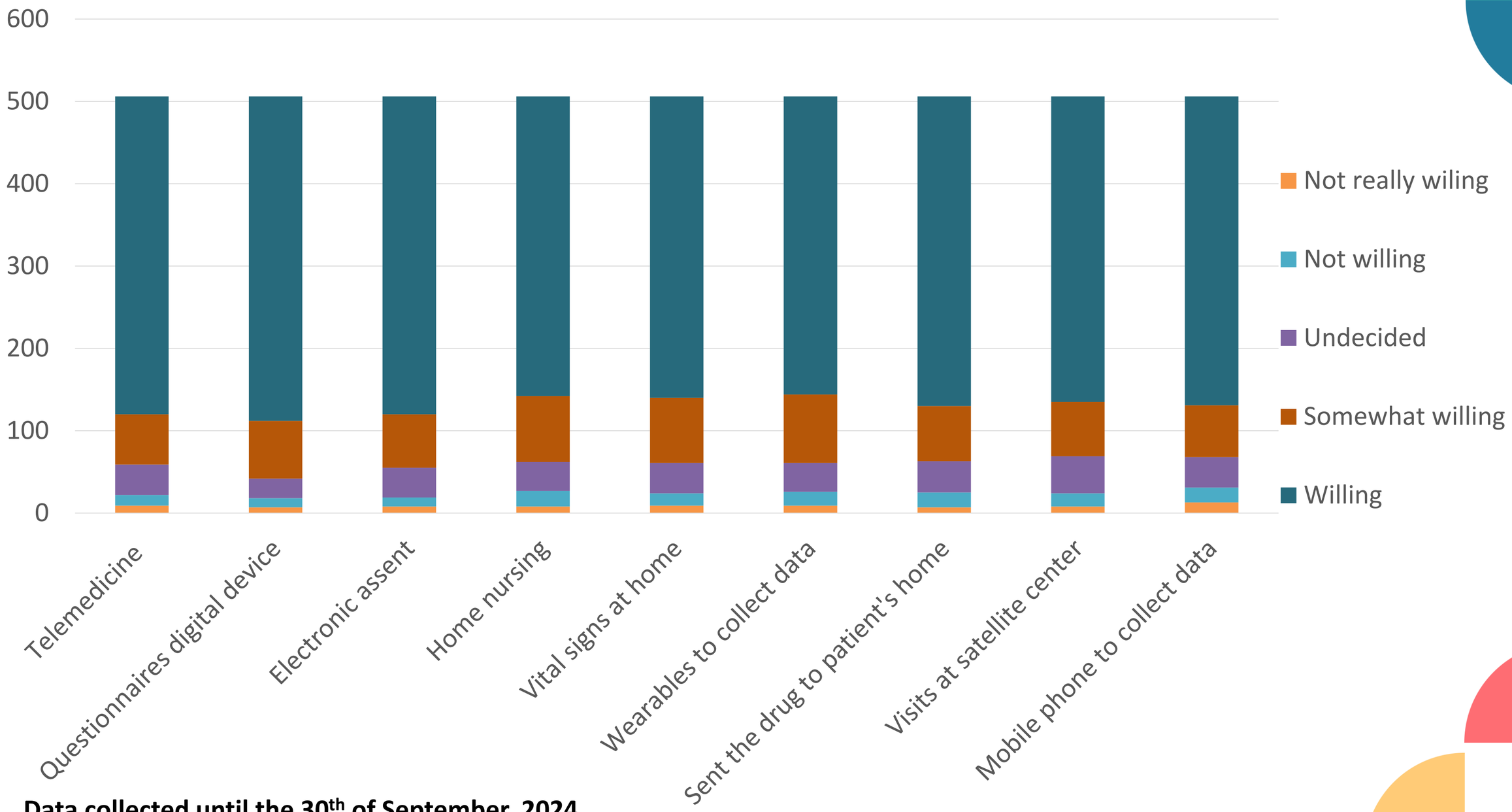
Data collected until the 30th of September, 2024

DCT options - clinical trial in the country of the patient



Data collected until the 30th of September, 2024

DCT options. Cross-border clinical trial



Data collected until the 30th of September, 2024

https://bit.ly/cases_discrimination_CT

https://bit.ly/Survey_sites

https://bit.ly/Good_Practices_CT

https://bit.ly/Survey_Parents_CT

Future steps

- **DATA ANALYSIS:**
  - Clinical trial sites
  - Parents' questionnaire
  - Clinicaltrials.gov
- **DATA COLLECTION:**
  - Questionnaire for industry sponsors
- **Interviews with researchers**
- **Interviews with parents**

Final outcome...

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

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"STOP DREAMING
AND START
DOING TOGETHER"

Thank you so much!

begonya.nafria@sjd.es