

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

Chair: Begonya Nafria



Important information

- This presentation includes provisional data related to the interim analysis performed with the information collected until the 30th of September.
- The analysis is not conclusive. More data will be collected in the upcoming months.
- The data or any information of this presentation cannot be used, shared or published without the permission of the chair of the Enpr-EMA working group.



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 of residence, especially when there is a potential benefit to the child.**

These recommendations will be included in a multi-stakeholder consensus guideline.

Clinicaltrials.gov Computer Data Analysis

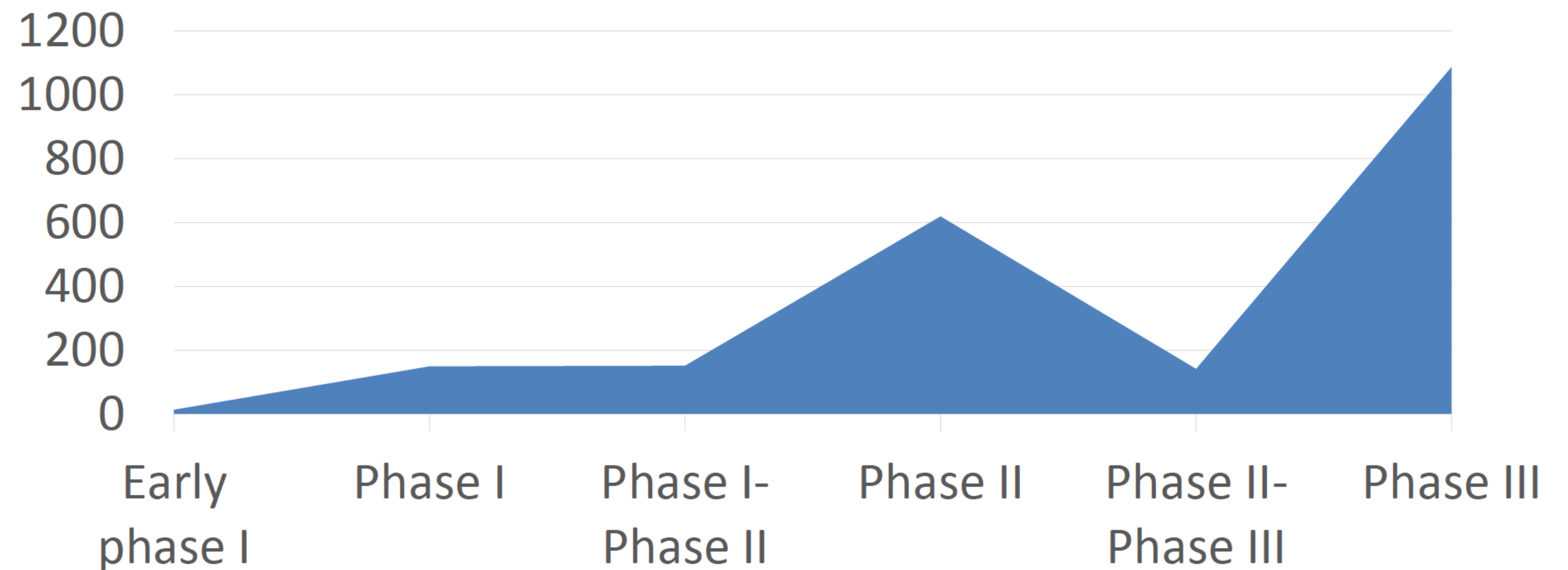
2,160

Studies



Target population: from birth to 18 years old (N= 842,382)

Period of analysis 01-01-2017 to 31-12-2022



Clinical trial sites questionnaire

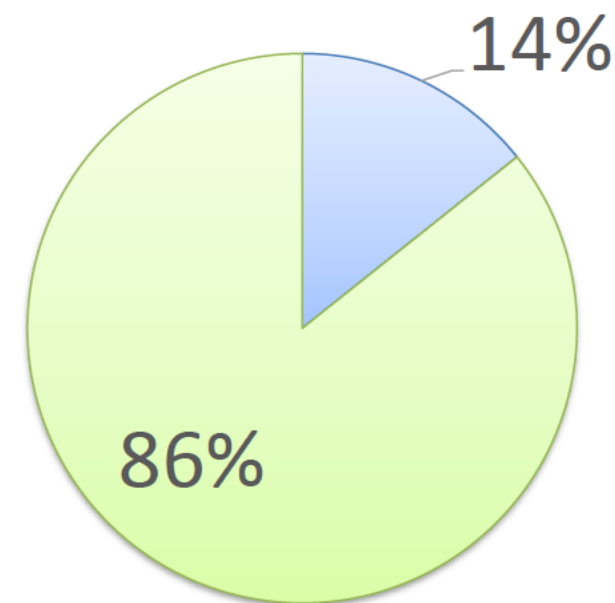
21

Sites

Country	N
Belgium	1
Denmark	1
France	2
Germany	2
Greece	1
Norway	1
Italy	6
Spain	7

Type of site

Private Public



3.10%

Screened patients
from European
countries

3.72%

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, Cyprus



Data collected until the 30th of September, 2023

Good practice questionnaire

81

Studies

22.2 %

Industry studies

95.5 %

Rare disease studies

80.9 %

Patients stayed
overnight in the
country

Country	N
Denmark	50
Germany	1
Greece	1
Italy	7
Spain	22

77.8 %

Investigator-
led/publicly funded
trials



Data collected until the 30th of September, 2023

Cases of discrimination

8

Studies

Country	N
Czech Republic	1
Italy	4
Spain	3

- 50% of the studies were related to childhood cancer.
- Patients excluded were from European and non-European countries

Data collected until the 30th of September, 2023

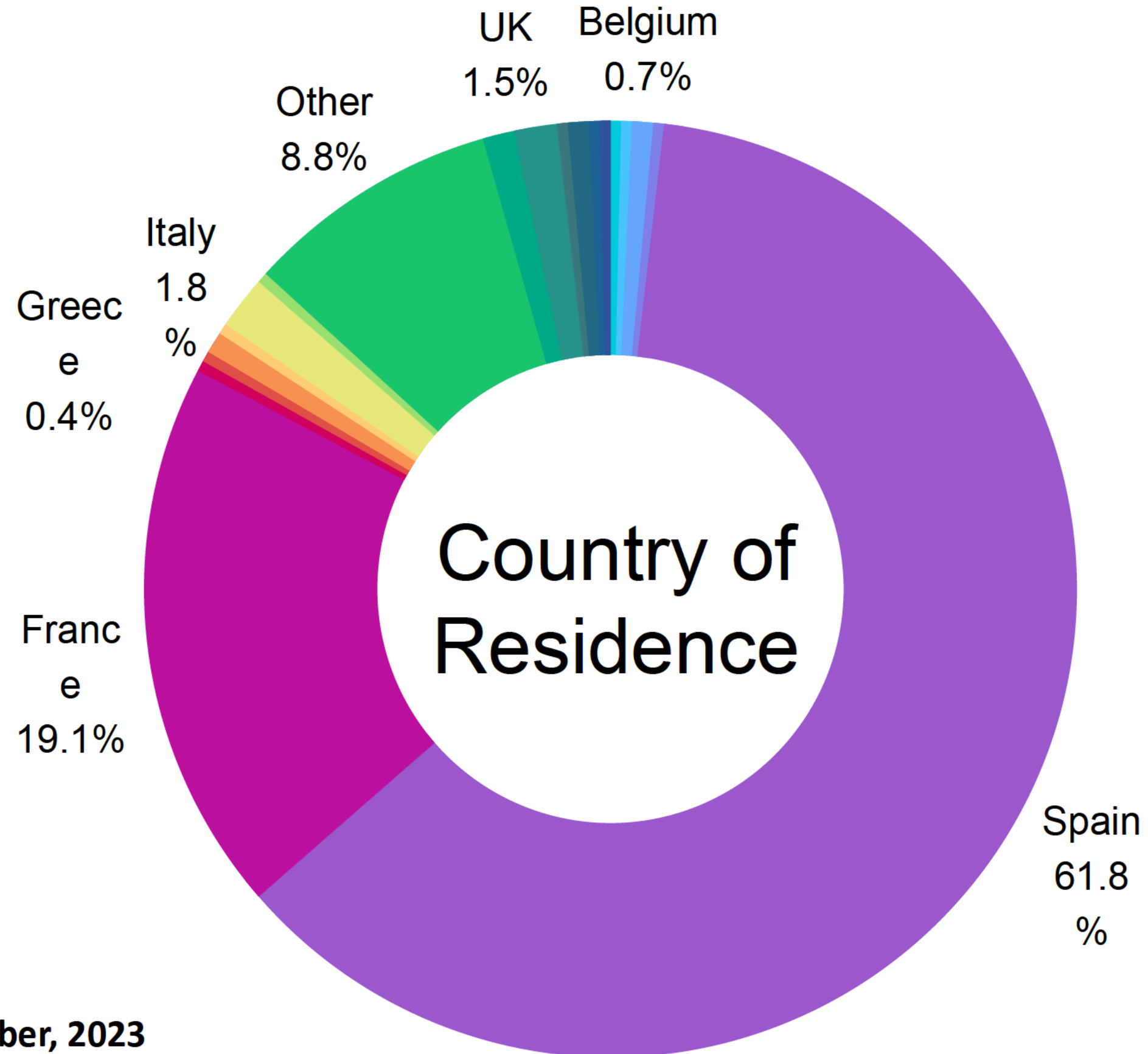


Parents' questionnaire

272

Answers

Who replied	N
Mother	215
Father	47
Young adult patient	6
Other relative	4



Data collected until the 30th of September, 2023

Co-creation with parents

Paediatric Cross-Border Clinical Trials



Begonya Nafria
PhD Candidate

Working together to ensure the
children's rights in clinical research

Co-creation workshop with parents
1st of May 6 pm CET



Paediatric Cross-Border Clinical Trials



Begonya Nafria
PhD Candidate

Working together to ensure the
children's rights in clinical research

Co-creation workshop with parents
15th of May 6 pm CET



Ensayos Clínicos Pediátricos Transfronterizos



Begonya Nafria
Estudiante de
Doctorado

Trabajando juntos para garantizar los
derechos del niño en la investigación clínica

Taller de co-creación con padres
8 de mayo 18 h CET



Webinars with Patient Organisations

IMPORTANT ANNOUNCEMENT FOR PATIENTS ORGANIZATIONS

Webinar

**Paediatric Cross-Border
Clinical Trials in Europe**

11th of September, 6 pm CET

Registration:



ANUNCIO IMPORTANTE PARA ASOCIACIONES DE PACIENTES

Webinar

**Ensayos clínicos pediátricos
transfronterizos en Europa**

11 de septiembre a las 19 h CET

Registro:



ANNONCE IMPORTANT POUR LES ASSOCIATIONS DE PATIENTS

Webinaire

**Essais pédiatriques
transfrontaliers en Europe**

25 septembre à 18H CET

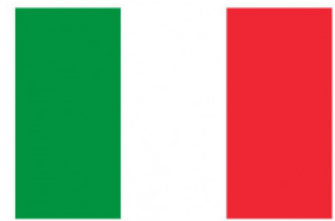
Inscriptions:



Speaker: Segollene Gaillard
Senior expert in Patient
Engagement in Research

Hospices Civils de Lyon

Parents' questionnaire



6
European
Languages
accessible

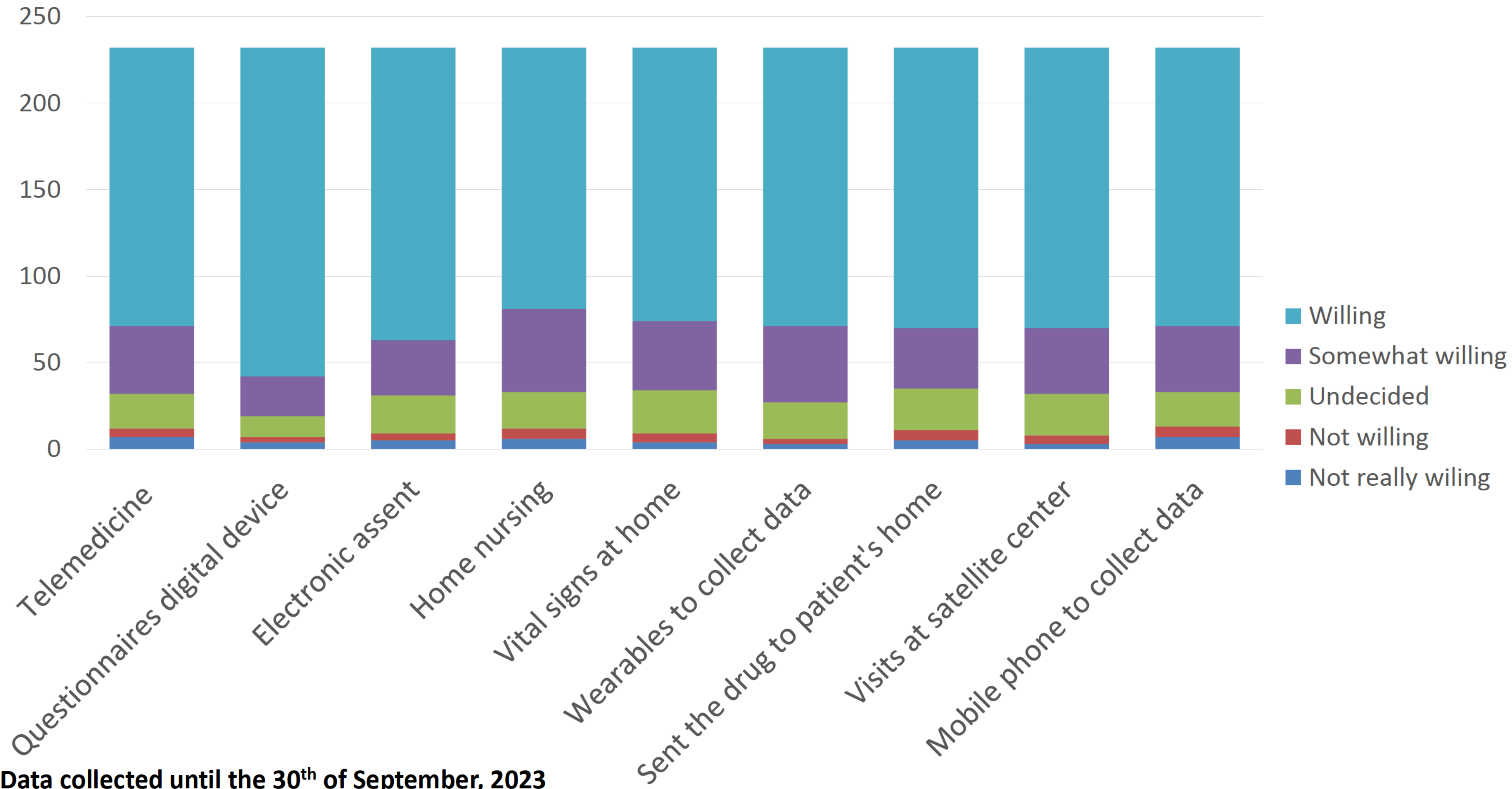
9
translations to be
implemented

9
translations
work in progress

- Czech
- Croatian
- Greek
- Danish
- Dutch
- Finnish
- Hungarian
- Romanian
- Serbian

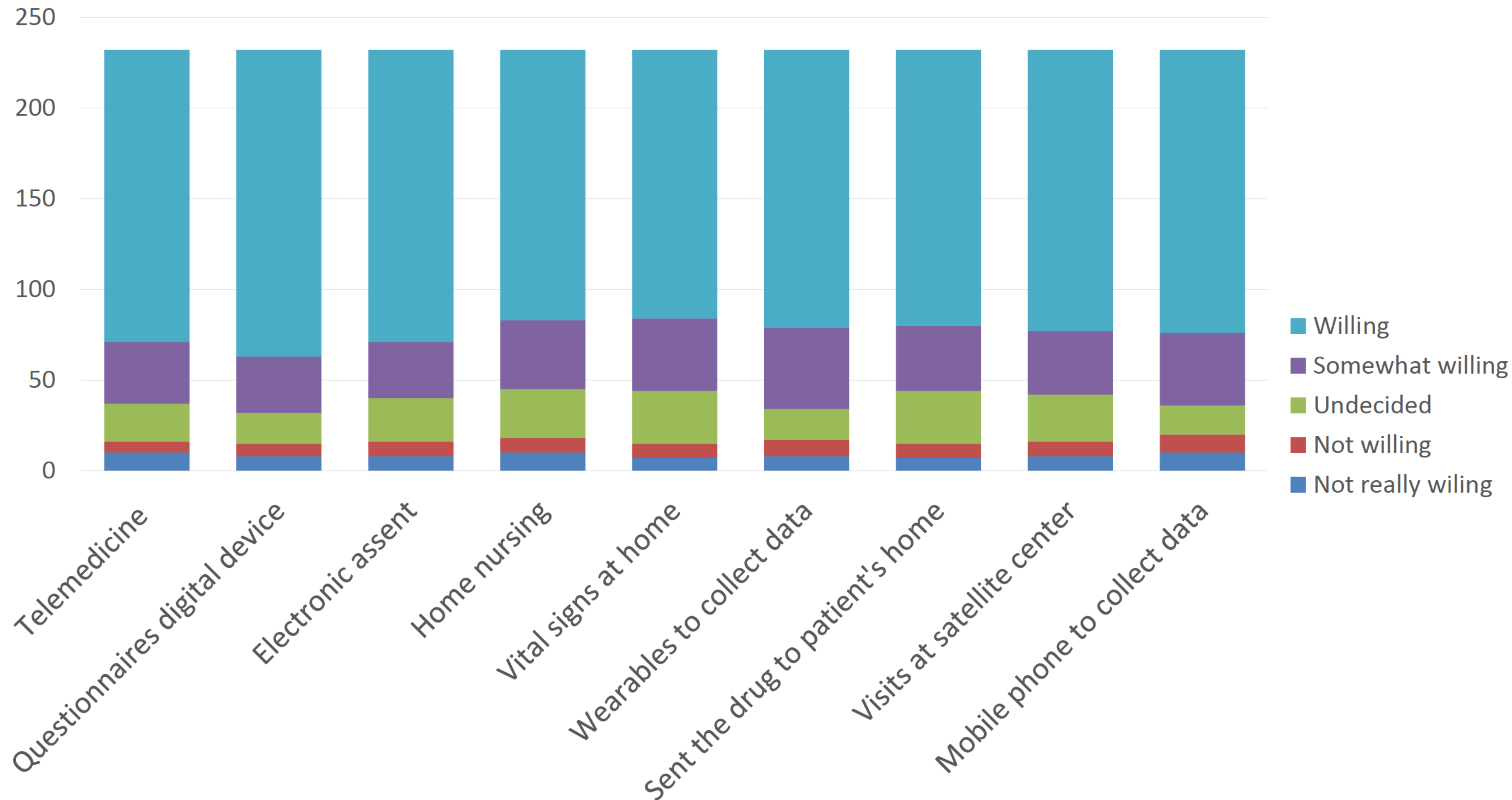
+ 50 volunteers

DCT options - clinical trial in the country of the patient



Data collected until the 30th of September, 2023

DCT options. Cross-border clinical trial



Data collected until the 30th of September, 2023



Future steps

- Site questionnaires + Parents' questionnaires:
 - Extension until December 30, 2023
- Working group to create a questionnaire for sponsors
- Legal framework of cross-border clinical trials (state of the art analysis)

WG members



Dr. Gilles Vassal
Oncologist
(France)



Dr. Ricardo Fernandes
CT NH Network Chair
(Portugal)



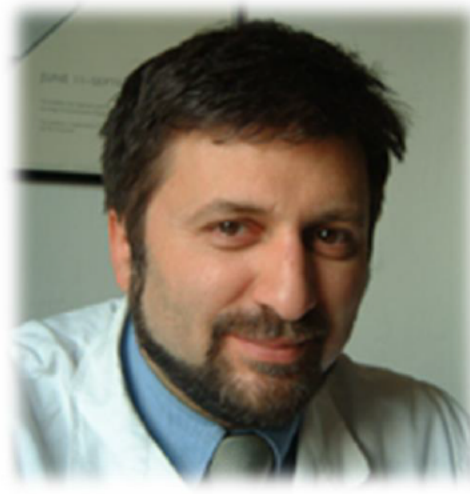
Dr. Pamela Dicks
CT Network Manager
(United Kingdom)



Segolene Gaillard
CT Network Manager
(France)



Dr. Martine Delingher
Industry expert
(Germany)



Dr. Luca Sangiorgi
ERN Coordinator
(Italy)

Advisory group members

- Anita Kienesberger, Chair of CCI Europe Committee
- Barbara Bierer, MD, Professor of Medicine (Pediatrics) at Harvard Medical School (USA)
- Jennifer Preston, expert in PPI, University of Liverpool (UK)
- Joana Claverol, Clinical Research Director, Sant Joan de Déu Children's Hospital (Spain)
- Lucy Bray, PhD. Professor in Child Health Literacy, Edge Hill University (UK)
- Magda Conway, Consultant: adolescent health, youth participation in research, HIV. Penta Foundation (UK)
- Thierry Lacaze, Neonatologist, Coordinator of the MICYRN (Canada)



https://bit.ly/cases_discrimination_CT



https://bit.ly/Survey_sites



https://bit.ly/Good_Practices_CT



https://bit.ly/Survey_Parents_CT



Thank you so much!

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