



MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

m agencia española de
medicamentos y
productos sanitarios



European Network of Excellence
for Paediatric Clinical Research

AUTHORISED PAEDIATRIC CLINICAL TRIALS IN SPAIN



**Maria Jesus Fernandez Cortizo,
(AEMPS, PDCO)**

In collaboration with:
Teresa Llácer Delicado (AEMPS)

Acknowledgements:
Clinical Trial Unit (AEMPS)

The views expressed are personal and do not necessarily represent the point of view of the AEMPS, nor those of the Paediatric Committee (PDCO) of the EMA.



Activities and proposals from TEDDY Spain partners. Madrid, marzo 2019.



□ Analysis of clinical trials (CT) with medicinal products including the paediatric population that have been authorised in 2017 and 2018 in our country.

- AEMPS CT database (ECMI, Ensayos Clínicos con Medicamentos en Investigación)
- Spanish Registry of Clinical Trials ("REec") in which clinical trials are uploaded once authorised by AEMPS. Offers the most updated information.
<https://reec.aemps.es/reec/public/web.html>
- AEMPS 2017 Annual Report
<https://www.aemps.gob.es/home.html>

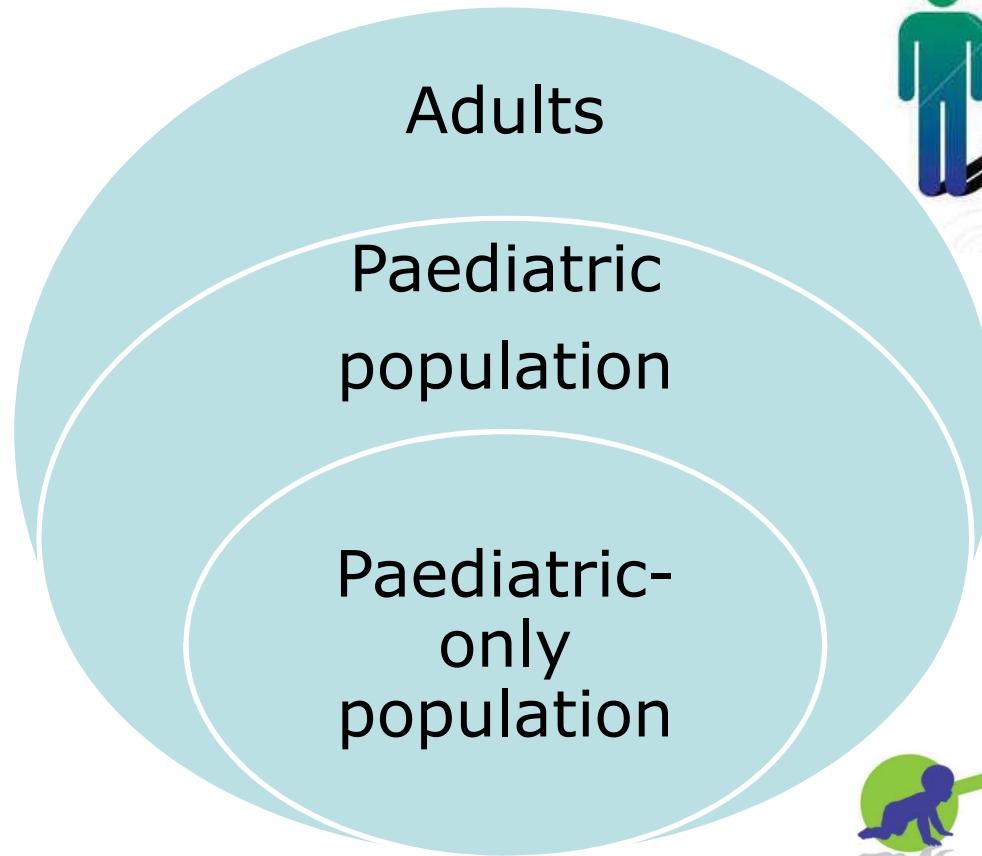
Limitations:

- ✓ CT that are rejected
- ✓ CT prematurely ended or those which never start



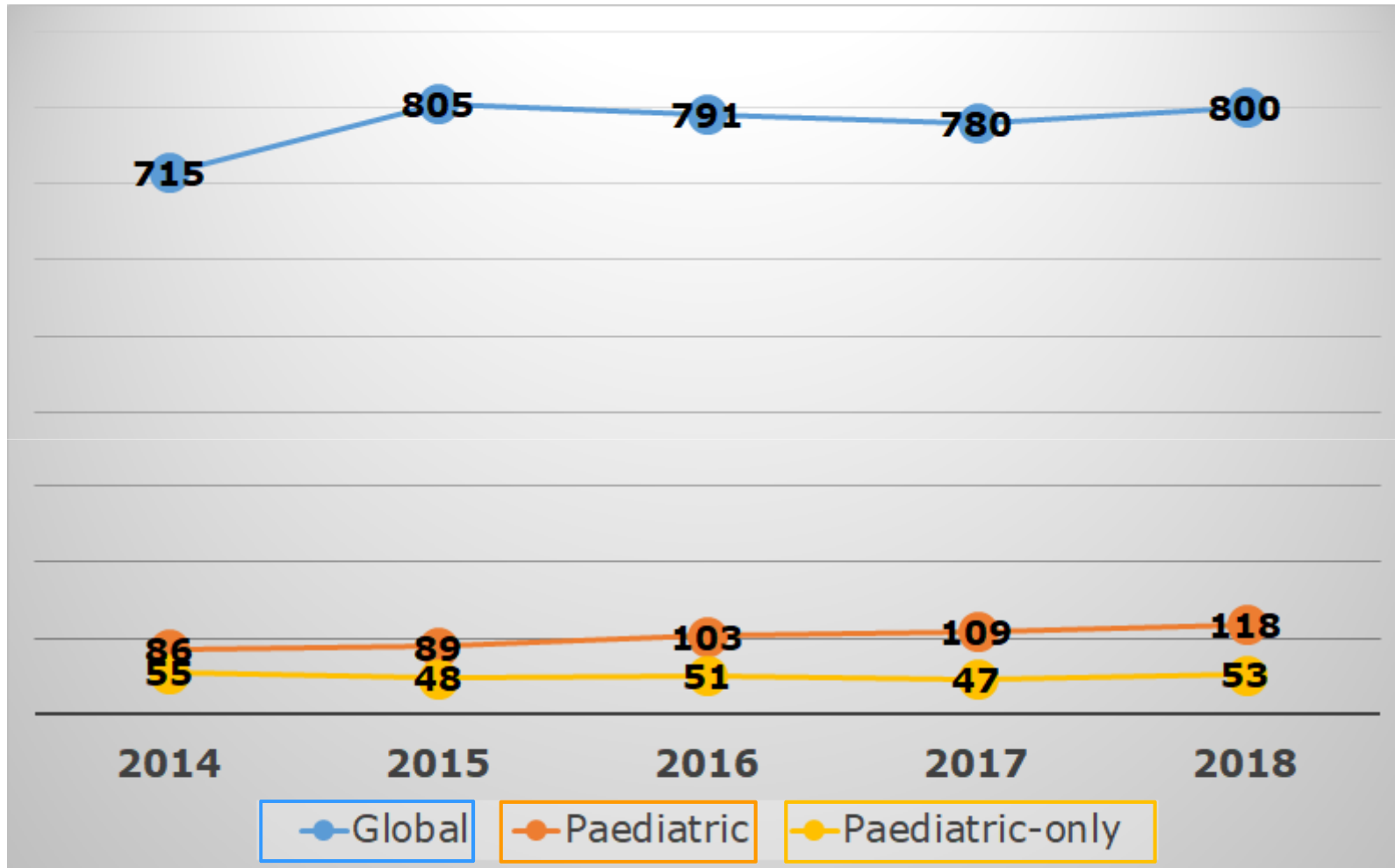
PAEDIATRIC CT

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AUTHORISED CT (n)





AEMPS 2017 Annual report

Percentage of authorised CT per AGE GROUPS

TABLA	Porcentaje de ensayos clínicos por la edad				
ENSAYOS CLÍNICOS POR EDADES	2013	2014	2015	2016	2017
Adults	90%	91%	92%	93%	92,9%
Elderly	69%	72%	73%	74%	72,3%
Paediatric population	13%	13%	12%	13%	14%

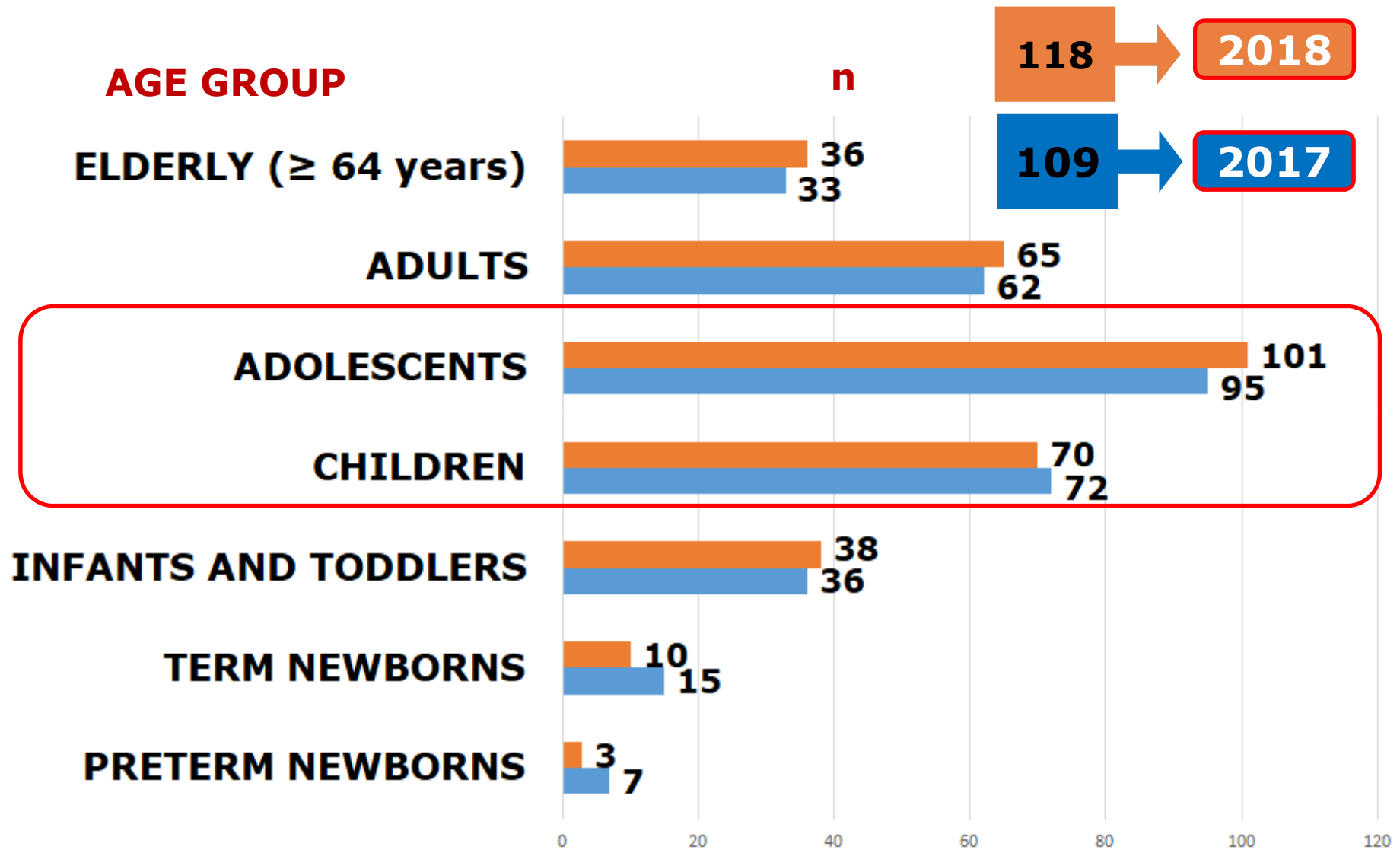
Age categories collected as indicated in the CT application

- Intrauterine
- Preterm newborns (<37 weeks GA)
- Term newborns (≥37 weeks GA)
- Infants and toddlers (28 days-23 months)
- Children (2-11 years)
- Adolescents (12-17 years)



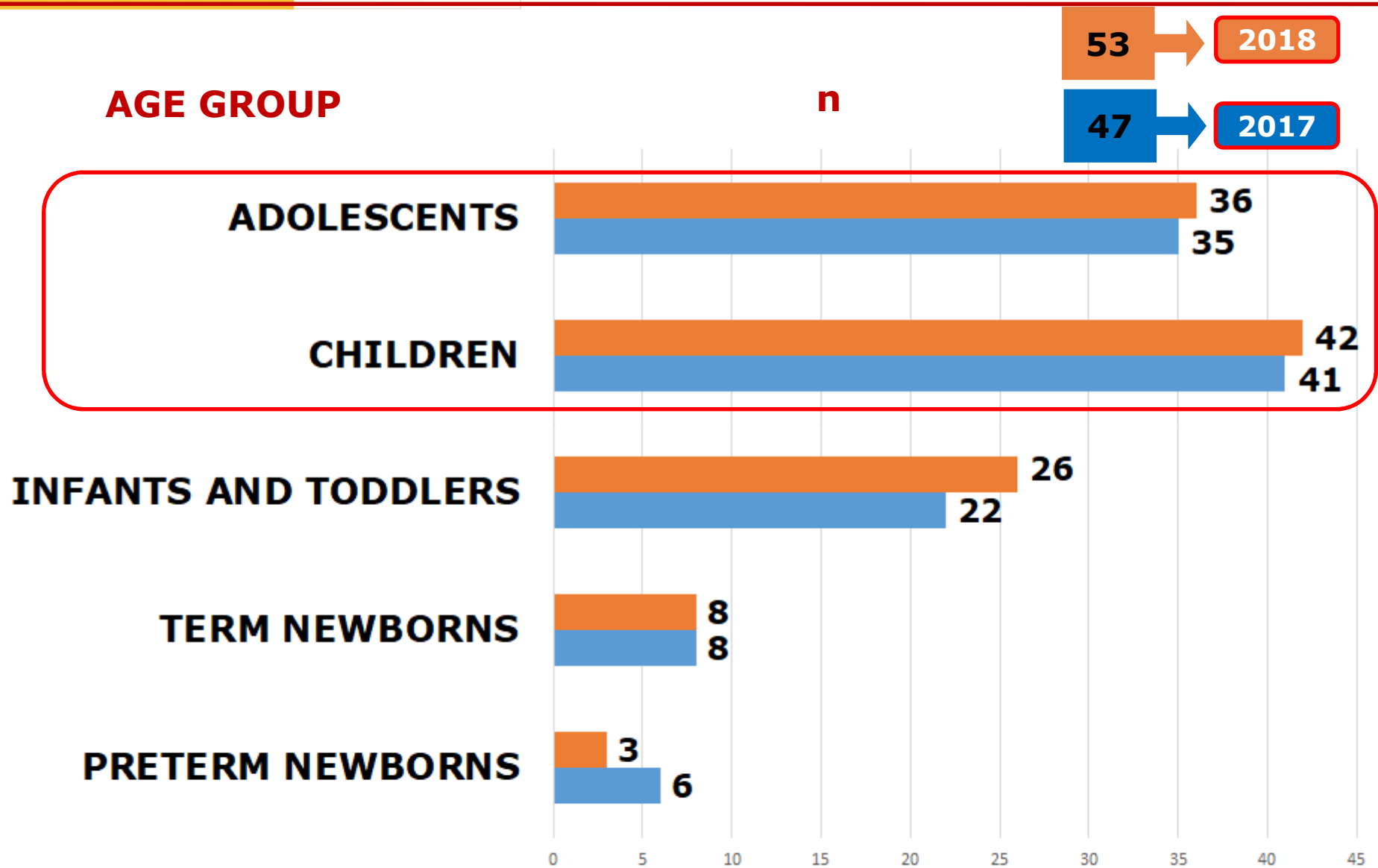


Paediatric CT per AGE GROUP (n)



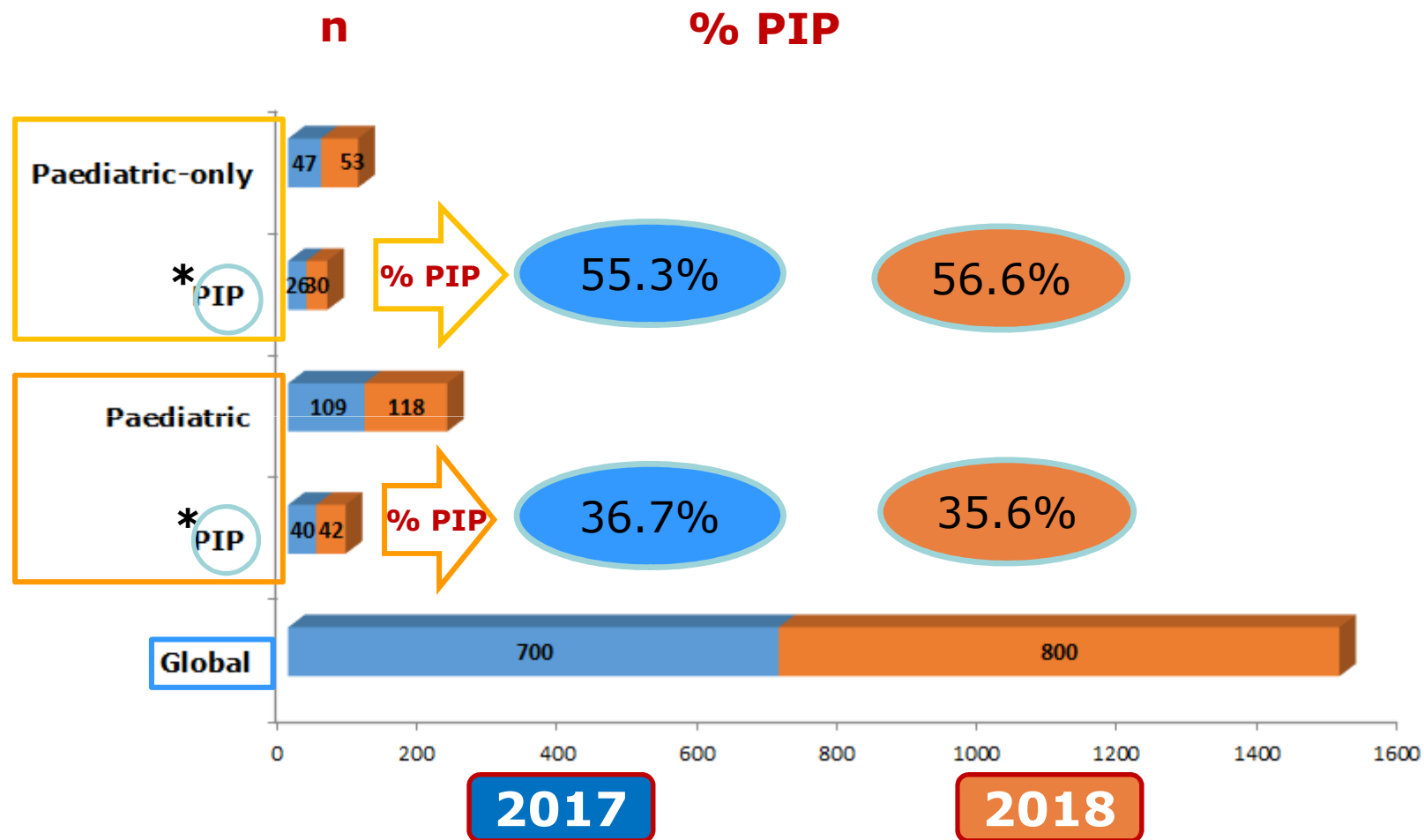


Paediatric-only CT per AGE GROUP (n)





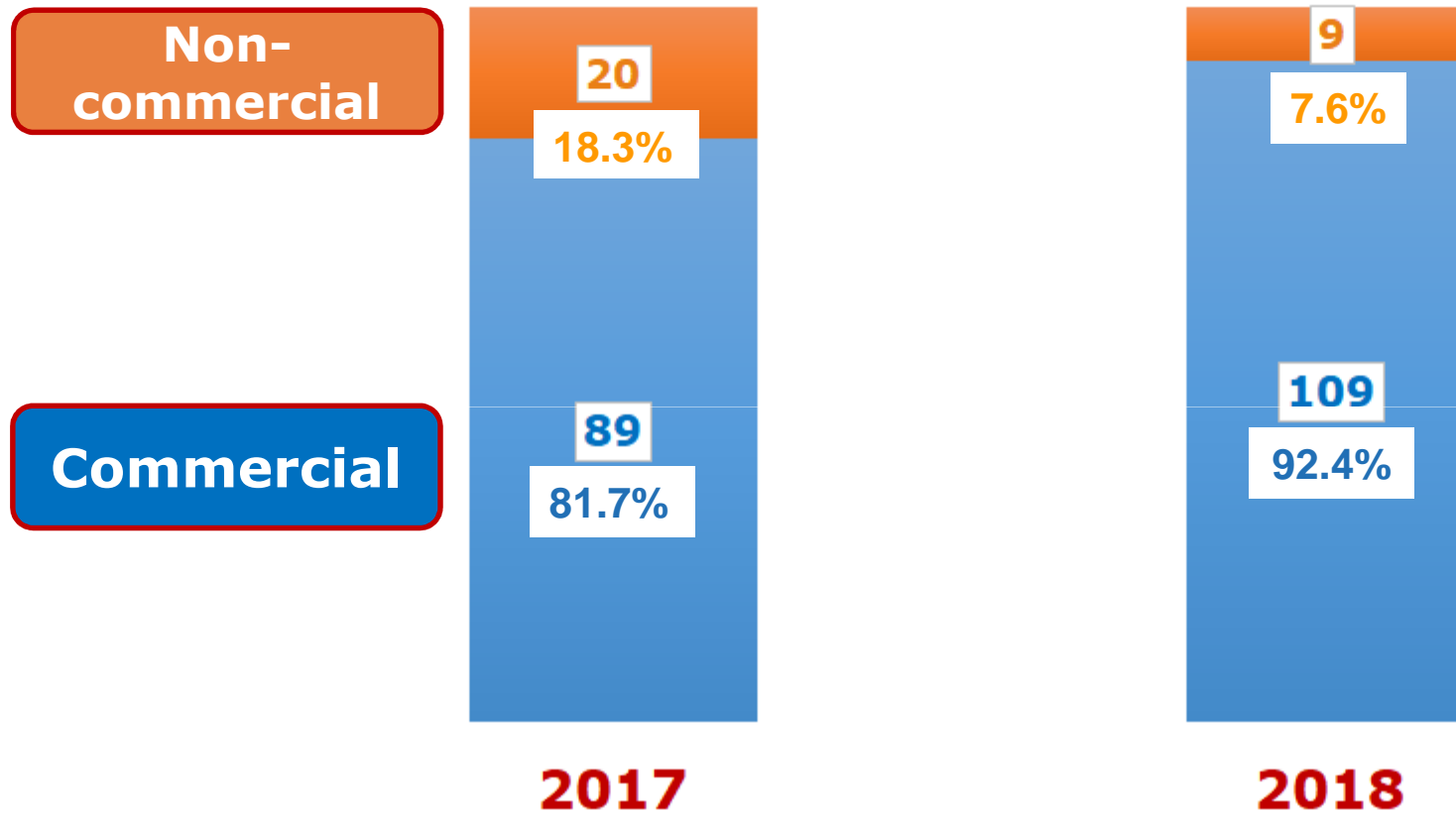
Paediatric CT included in a PIP (n,%)



*Information about PIP as indicated in the CT application

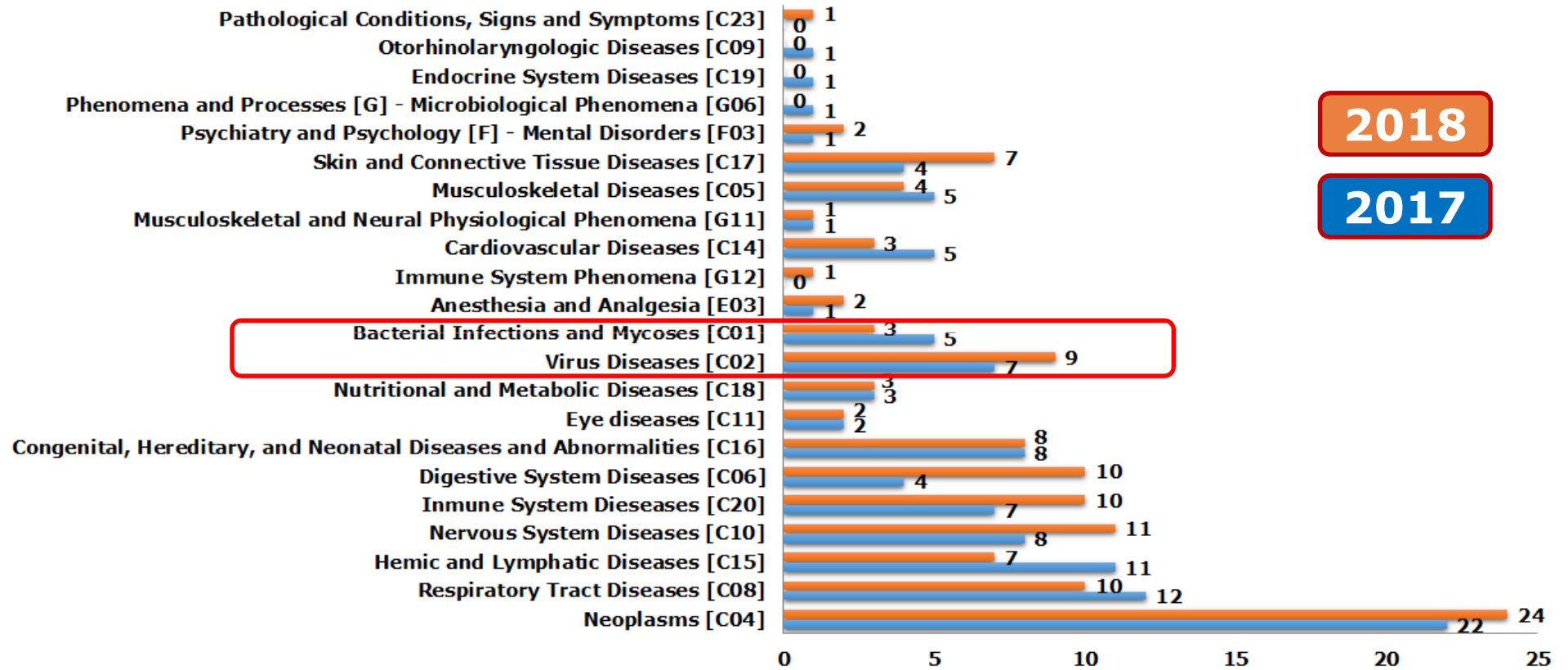


CT by type of SPONSOR (n, %)





CT per THERAPEUTIC AREA (MedDRA)



2018

2017



SITES INVOLVED per main TA

Oncology

- 35 sites in 10 AC (2018)
- 45 sites in 12 AC (2017)

Respiratory tract diseases

- 22 sites in 5 AC (2018)
- 44 sites in 5 AC (2017)

Haematology

- 10 sites in 5 AC (2018)
- 20 sites in 6 AC (2017)

Infectious diseases

56 sites in 9 AC (2018)
52 sites in 10 AC (2017)

AC: Autonomous Community



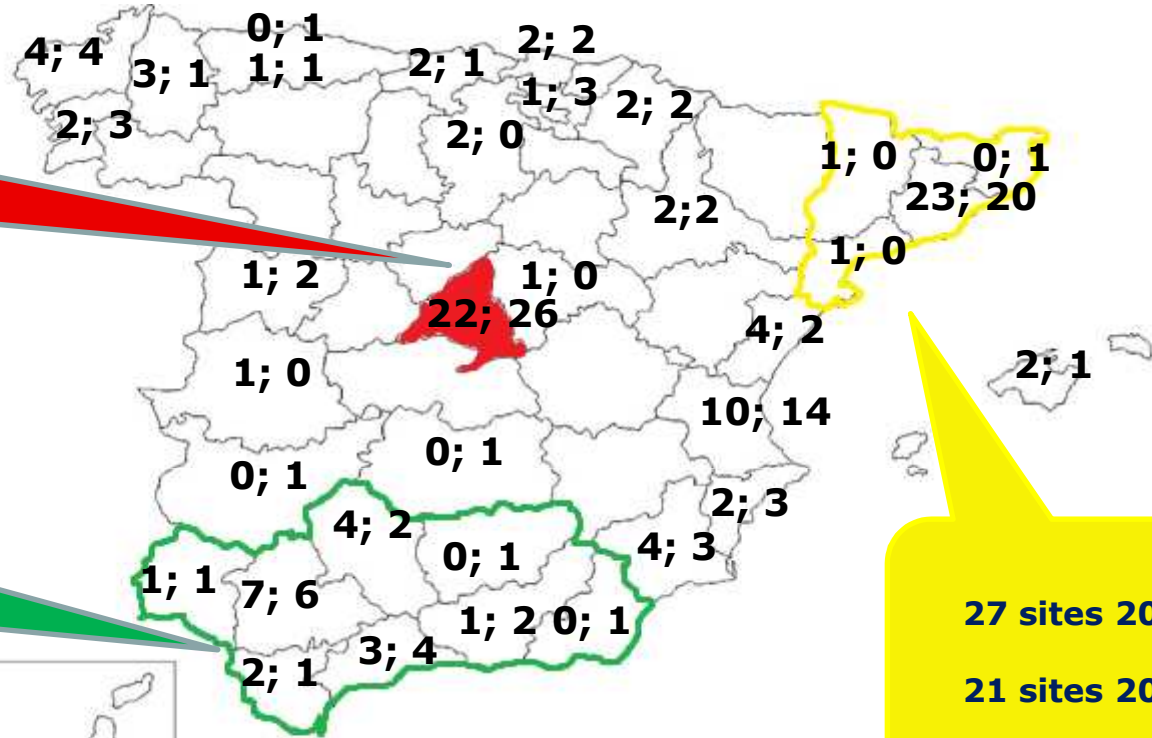
Sites and locations involved in paediatric CT

22 sites 2017
26 sites 2018

21 sites 2017
18 sites 2018

1; 1)
1; 1

27 sites 2017
21 sites 2018



Total number of sites involved in CT enrolling paediatric population: 113



CONCLUSIONS

1

The percentage of CT that include paediatric population remains below 15% of the global number authorised. Most of them are mixed trials (enrolling paediatric and adult subjects).

2

The **age groups mostly included** in the CT authorised in Spain were **adolescents and children.**

3

The **main therapeutic areas** investigated in paediatric CT were oncology, respiratory tract diseases, haematology, neurology and infectious diseases.





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EU



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency and European Commission (DG Health and Food Safety) action plan on paediatrics

2. Strengthening of cooperation of decision makers

Action	Objectives	Status (July 2018)	Deadline	
1	Establish framework for exchange of information between the EMA/PDCO and the <u>Clinical Trial Facilitation Group (CTFG)</u> as well as ethics committees	To <u>improve dialogue between EMA/PDCO and clinical trial assessors</u> and facilitate mutual understanding of the interplay between assessment of PIPs and of clinical trials.	In progress.	12/2020



Activities and proposals from TEDDY Spain partners. Madrid, marzo 2019





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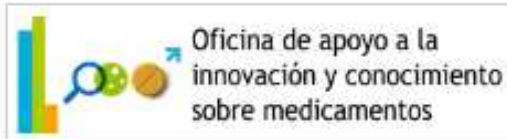
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AEMPS



**Information about all authorized CT
with medicinal products**

<https://reec.aemps.es/reec/public/web.html>



**Office for support of Innovation and
knowledge of medicinal products**

innov_spain@aemps.es



Independent Clinical Research Support Office

<https://www.aemps.gob.es/investigacionClinica/medicamentos/oficinApoyo.htm>



Activities and proposals from TEDDY Spain partners. Madrid, marzo 2019



