



TEDDY Scientific Activities and Tools

Mariagrazia Felisi

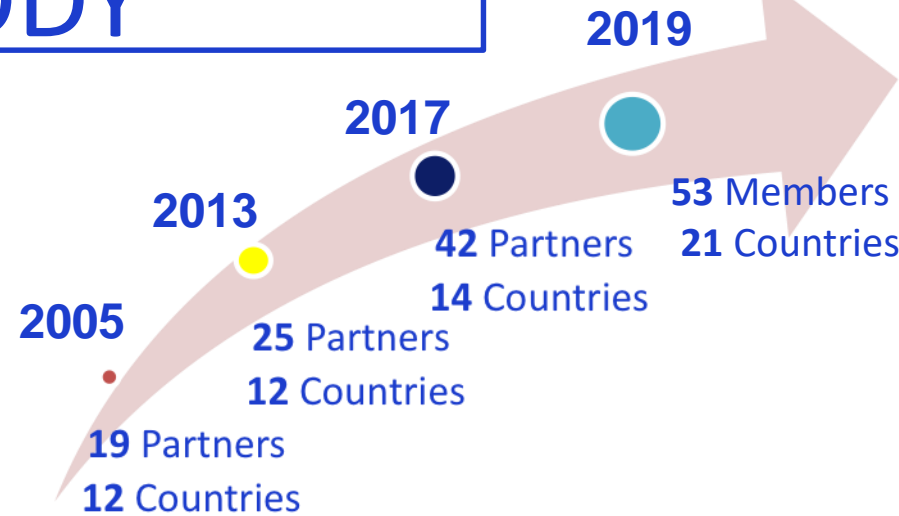
European Network of Excellence for Paediatric Clinical Research

Outline

- *TEDDY Network activities overview*
- *Scientific Coordination Committee (SCC) activities*
- *Participation to EnprEMA*
- *Working Groups results*
- *TEDDY tools*
 1. *ICH-GCP e-learning course*
 2. *European Paediatric Medicine Database (EPMD)*

What is TEDDY

- ...is an independent multidisciplinary, multinational **Network** aimed at facilitating the performance of good quality paediatric research.
- ...encompasses about **50 partners** from 20 EU and non-EU countries



TEDDY demonstrated a great **Networking capacities** involving European and non-European research centers

TEDDY members



INSTYTUT

"POMNIK - CENTRUM ZDROWIA DZIECKA"



GIANNI BENZI

PHARMACOLOGICAL RESEARCH
FOUNDATION



THE UNIVERSITY
of LIVERPOOL



ROMANIAN
Angel Appeal



Comunidad de Madrid

Espace Ethique Méditerranéen

Universitätsklinikum
Erlangen



UNSW
SYDNEY



Cairo University



Hospital Universitario
12 de Octubre



Fundació
Sant Joan
de Déu



QENDRA SPITALORE UNIVERSITARE
"NËNË TEREZA"



Childhood
Cancer
International



Institute of Physiology
Academy of Sciences
of the Czech Republic



REPUBLIC OF CYPRUS
MINISTRY OF HEALTH
OF THE REPUBLIC OF CYPRUS



Radboud University



Institut national
de la santé et de la recherche médicale



Technion
Israel Institute of Technology



HELLENIC REPUBLIC
National and Kapodistrian
University of Athens



University Medical Center
Utrecht

TEDDY is now 14 years old

2005-
2010



1st in Europe Network of Excellence to promote Paediatric Research and Paediatric Medicines development

2014-
2016

European Network of Excellence for Paediatric Clinical Research
Cat.1 (ex cat.4) Member of Enpr-EMA

Partners
Agreement



2017-
2019

Legal Status



A Network with a legal status to be fully represented in the European paediatric research framework

TEDDY from the past to the future

MAIN TOPICS

- ❑ *Life Science and Innovative tools*
- ❑ *Clinical research*
- ❑ *Ethics and regulatory*
- ❑ *Drug uses in children and pharmacovigilance*
- ❑ *Education and knowledge dissemination*

... and AMBITION

Be aligned with the PAEDIATRIC INITIATIVE(S) in EU

Be part of the European Paediatric Research Community

TEDDY Network BODIES

The Scientific Coordination Committee (SCC)

- ***Annagrazia Altavilla*** – Espace Ethique Méditerranée- Marseille
- ***Adriana Ceci*** – G. Benzi Pharmacologic Research Foundation – Valenzano
- ***Giovanni Migliaccio*** – Consorzio Val. Biologiche e Farmacologiche – Bari
- ***Oscar della Pasqua*** – University College London
- ***Francesca Rocchi*** – Ospedale Pediatrico Bambino Gesù – Roma
- ***Saskia de Wildt*** – Radboud University

Scientific Secretariat
Angelica Intini

The Strategic Planning Board (SPB)

- ***Carlo Giaquinto*** – Penta Foundation – Padova
- ***Maria Mellado*** – Univesidad Autónoma de Madrid
- ***Marek Migdal*** – Children's Memorial Health Institute – Warsaw
- ***M. Sturkenboom*** – University Medical Center Utrecht
- ***Mark Turner*** – University of Liverpool
- ***Ian Wong*** – University College London

Networking Manager
Mariangela Lupo

Legal Representative and Administrator
Donato Bonifazi

SCC role

ART. 13 of Statute

The Scientific Coordination Committee (SCC) is set up **to coordinate the scientific activities of the Network TEDDY** and it is composed of at least 3 members appointed by the General Assembly.

The Committee aims to:

- **monitor all the scientific aspects of the Network,**
- **share knowledge and experience among the associated,**
- **monitor and review the progress of scientific activities,**
- **ensure that relevant scientific objectives are achieved.**

The Committee has the power to decide on:

- **the approval of scientific products and**
- **the updating of the scientific work plans**

SCC Meetings and outcomes

Outcomes

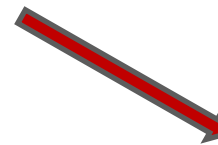
Meetings

- TC#1: 6 Jun 2018
 - TC#2: 4 Jul 2018
 - TC#3: 24 Sep 2018
 - TC#4: 14 Nov 2018
 - TC#5: 14 Feb 2019
- SCC Charter release
 - Discussion on WG plans of action and the involvement in public consultations of TEDDY interest
 - Revision of publications in which TEDDY is involved
 - Revision of dissemination material such as newsletter, news, etc
 - Endorsement for participation in new projects (COST and RESTORE)
 - Definition of agenda for General Assembly and key questions to be addressed during the round table

TEDDY entitled to be part of EnprEMA



European Medicines Agency



London, 15 January 2008
Doc. Ref. EMEA/MB/543523/2007

The Network of Paediatric Networks at the EMEA Implementing Strategy

4. Existing paediatric networks

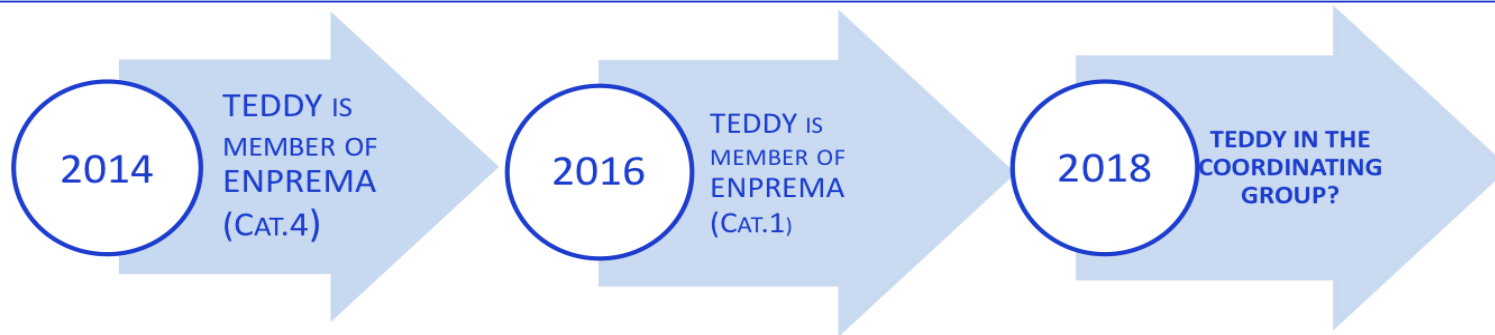
In parallel to the meetings held at the EMEA in 2005 and 2006, an informal inventory has identified that many different paediatric networks, investigators and centres with specific expertise^{#1} exist in the Community, or are under construction. The relevant networks are those with an interest in the development of medicinal products. They can be identified as:

- national networks, generally benefiting from public funding (at present 7 national networks have been identified),
- European networks publicly funded, such as TEDDY (Task Force in Europe for Drug Development of the Young) which is funded through the 6th Framework Programme,
- paediatric 'sub-speciality' networks at European level and beyond, which group centres working in the same therapeutic area (e.g. HIV infection, rheumatology),
- age-related networks (e.g. neonatal networks),
- activity or structure-related networks (e.g. community-practitioners networks, hospital-based dedicated clinical-research centres linked by a common structure, pharmacovigilance networks)
- networks including paediatric centres but not dedicated solely to paediatric research.

The inventory will be expanded and developed.



TEDDY activities



- TEDDY has been invited to participate to the **tenth annual workshop (2018) of Enpr-EMA and Coordinating Group meeting**, held in London on June 7th and 8th
- It has also received the invitation to participate to the ***Enpr-EMA Coordinating Group meeting with networks members*** in 2018 October 22nd

- **TEDDY is working on many EnprEMA activities** WGs 3, 4, 5 Network consultation process & guideline, Ethics, Clinical trial preparedness, Training).

TEDDY WGs

- A practical way to exchange expertise within the Network and to engage interested stakeholders
- An instrument to react and interface with relevant actors in the arena: Paediatric Networks/Initiatives, EMA, EC, EnprEMA, etc.
- An educational tool for young researchers involved in TEDDY activities

People participating in the WGs

1. Altavilla Annagrazia, France
2. Bartoloni Franco, Italy
3. Bonifazi Fedele, Italy
4. Cabanas Fernando, Spain
5. Chiaruttini Giulia, Italy
6. Conte Rosa, Italy,
7. Cullufe Ornela, Albania
8. Enache Cristina, Spain
9. Felisi Mariagrazia, Italy
10. Filannino Doriana, Italy
11. Gazarian Madlen, Australia
12. Giannuzzi Viviana, Italy
13. Godo Anila, Albania
14. Intini Angelica, Italy
15. Jacqz-Aigrain Evelyne, France
16. Kalambayi Fidelie, Romania
17. Kleanthous Marina, Cyprus
18. Kreka Manika, Albania
19. Lagler Florian, Austria
20. Landi Annalisa, Italy
21. Lederer Carsten, Cyprus
22. Lupo Mariangela, Italy
23. Manfredi Cristina, Italy
24. Mangiarini Laura, Italy
25. Martín Torres Federico, Spain
26. Migliaccio Giovanni, Italy
27. Musaray Keyla, Italy
28. Nafria Begonya, Spain
29. Nardone Alessandra, Italy
30. Neubert Antje, Germany
31. Pellicer Adelina, Spain
32. Phylactides Marios, Cyprus
33. Pignataro Valeria, Italy
34. Preston Jenny, UK
35. Ruggieri Lucia, Italy
36. Sainz Talia, Spain
37. Sammons Helen, UK
38. Stuchlik Ales, Czech Republic
39. Tempesta Bianca, Italy
40. Trasorras Cristina Serén, Spain
41. Trigos Arjona Eugenia, Spain
42. Turner Mark, UK

TEDDY WGs

1. Off-label use in paediatrics
2. Health Data
3. Active engagement of children and adolescents
4. Advanced Therapies in paediatrics
5. Ethical issues in paediatric research
6. Paediatric clinical studies methodologies and procedures
7. Regulatory & Pharmacovigilance

TEDDY TOOLS

Available on the website:

<https://www.teddynetwork.net/>




- 1. ICH-Good Clinical Practice (GCP) Training Course*
- 2. European Paediatric Medicine Database (EPMD)*

ICH-GCP e-learning course

It is an e-learning training course aimed at providing a guide for all individuals that are involved in clinical research and clinical trials and they need to acquire GCP recognized certification.



 European Medicines Agency

July 2002
CPMP/ICH/135/95

ICH Topic E 6 (R1)
Guideline for Good Clinical Practice

Step 5

NOTE FOR GUIDANCE ON GOOD CLINICAL PRACTICE
(CPMP/ICH/135/95)

TRANSMISSION TO CPMP	July 1996
FINAL APPROVAL BY CPMP	July 1996
DATE FOR COMING INTO OPERATION	January 1997
POST STEP ERRATA (linguistic minor corrections)	July 2002

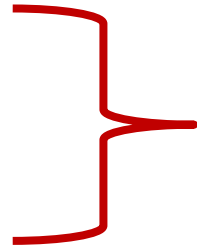
The course is based on the international E6 ICH Good Clinical Practice (R2), revised in 2016

This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma, as necessary to enable mutual recognition of GCP training among trial sponsors.

Structure of the course

The course is structured in 3 parts:

- Introduction
- Module 1
- Module 2



Duration: 3 hours

Each part is constituted by a PowerPoint presentation supported by audio comments.

Additional material (textbooks, publications, and guidelines) related to the course is made available to participants..



Course objectives

- understand the basics of Good Clinical Practice (GCP) and the current legal regulations and guidelines;
- describe the main responsibilities of the involved parties;
- get familiar with the essential trial-related documents (e.g. informed consent form, investigator's brochure, protocol).



Course Contents

4.	INVESTIGATOR	12
4.1	Investigator's Qualifications and Agreements.....	12
4.2	Adequate Resources	12
4.3	Medical Care of Trial Subjects.....	13
4.4	Communication with IRB/IEC.....	13
4.5	Compliance with Protocol	13
4.6	Investigational Product(s).....	14
4.7	Randomization Procedures and Unblinding.....	15
4.8	Informed Consent of Trial Subjects.....	15
4.9	Records and Reports.....	18
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Module 1

Course contents



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Module 2

Access to the course

The course is available online on a dedicated e-learning platform (www.gcptraining.cvbf.net) and all materials can be viewed via web or saved by the user on the computer.

To begin and access the course, the user should register himself/herself by filling in the registration form available at the “**ACCESS TO THE COURSE**” page to create his/her account.

DESCRIPTION OF THE COURSE	ACCESS TO THE COURSE
	
Event	ICH-GOOD CLINICAL PRACTICE (GCP) TRAINING COURSE
First name	<input type="text"/>
Last name	<input type="text"/>
Date of birth	<input type="text"/> DD-MM-YYYY
Organisation	<input type="text"/>
Study Role / Job title	<input type="text"/>
Email	<input type="text"/>
Telephone	<input type="text"/> (facoltative)
Mobile	<input type="text"/> (facoltative)

Once the user has already registered himself/herself and created the account, he/she can log in at the LOGIN page to access the course material.

Certificate

Once the first module is completed, the user needs to pass a test to access the second module. At the end of the second module, the user will have the second and last test. The tests are a quadruple choice test with only one exact answer and are aimed to evaluate the acquired knowledge/competence..

If the tests are successfully completed with at least the 80% of corrected answers, a certificate of GCP training will be released.



TEACHER AND TUTOR



Viviana
Giannuzzi

SCIENTIFIC DIRECTOR



Mariagrazia
Felisi

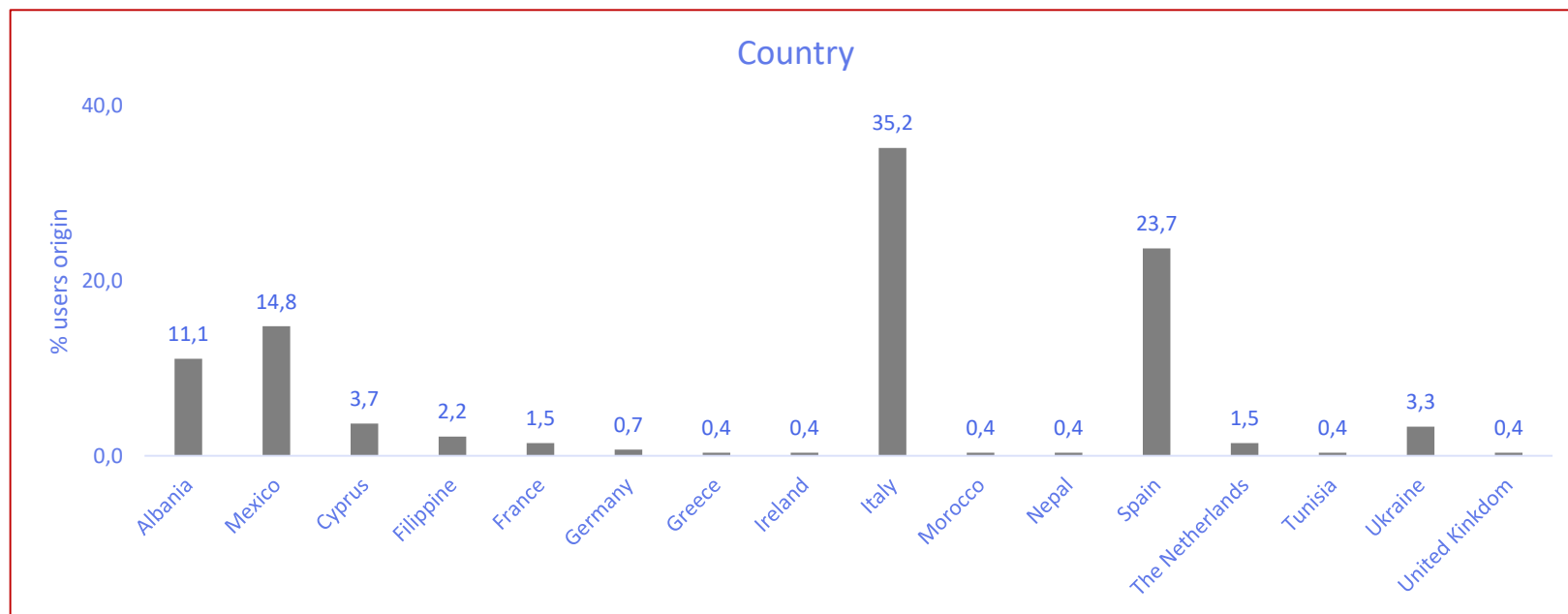
COURSE COORDINATOR



Donato
Bonifazi

Currently...

More than 600 users



European Paediatric Medicines database (EPMD)

[Home](#) [Network](#) [Activities](#) [Working groups](#) [Join the Network](#) [YPAG](#) [Media](#) [Meetings](#) [Q](#)



European Paediatric Medicines Database – EPMD

In line with European initiatives, in 2007 TEDDY set up the European source of information.

The data stored in this database is the basis for examining the 's Through this tool TEDDY supports the transparency of the information innovative drug treatments and provides health professionals, p concerning the rational use of paediatric medicines.

For all paediatric medicines registered in Europe under the EMA Therapeutic Chemical (ATC) code – first-level, paediatric indicat

To date the database contains a total of 411 medicinal products

Moreover, from 2015, a report is prepared at the end of each year

- 2015 – Periodic report on drugs approved for children under the EU Centralised Procedure
- 2016 – Periodic report on drugs approved for children under the EU Centralised Procedure
- 2017 – Periodic report on drugs approved for children under the EU Centralised Procedure
- 2018 – Periodic report on drugs approved for children under the EU Centralised Procedure

The European Paediatric Medicines Database – EPMD is available [here](#).

NETWORK

European Network of Excellence
for Paediatric Clinical Research

A database containing information on paediatric drugs authorised by the European Medicine Agency (EMA) under the centralised procedure. It is aimed to create a harmonised, integrated and reliable European source of information on paediatric medicines in Europe.

Available on-line

EPMD: medicines information available

- Tradename
- Active substance
- Marketing authorization date
- ATC code
- Indication/paediatric indication
- Orphan MP
- Withdrawn or suspended
- Paediatric Age
- Priority list
- Other use in paediatrics
- Variation
- Conditional Approval
- Exceptional Circumstance
- Generic/Biosimilar/Vaccine/
- Additional Monitoring
- Safety items

To be made available online

EPMD: paediatric studies information

Information about the studies conducted in the paediatric population leading to a centralised Marketing Authorisation (MA) for a medicinal product with a paediatric indication have been collected.

- Study title as stated in EPAR
- Study Code
- Type of study (based on scope)
- Type of study (based on statistical approach)
- Codification
- N. of paediatric patients
- N. of total patients
- Randomization (Yes/No)
- Blindness
- Controlled study
- Type of control
- Competitor details
- Age of patients
- Innovative study design
- Modeling & simulation
- Extrapolation

To be updated

EPMD available on-line



Active substance search - Search Filter

Active substance	<input type="text" value="DEFERIPRONE"/>	Medicinal Product	<input type="text"/>	ATC Code	<input type="text"/>
Orphan status	<input type="text" value="-"/>	Main condition	<input type="text"/>		
Results limit	<input type="text"/>				




Search result

Tot. records found: 1

Active Substance	ATC Code	Medicinal Product	Marketing Authorization Holder	Main Condition	Orphan Status	Details
DEFERIPRONE	V03AC02	FERRIPROX	Apotex Europe BV	beta-Thalassemia Iron Overload	no	

EPMD available on-line



TASK-FORCE IN EUROPE FOR DRUG DEVELOPMENT FOR THE YOUNG

[Back to search](#)

General info

Paediatric studies

Main Safety concerns

Related medicinal products

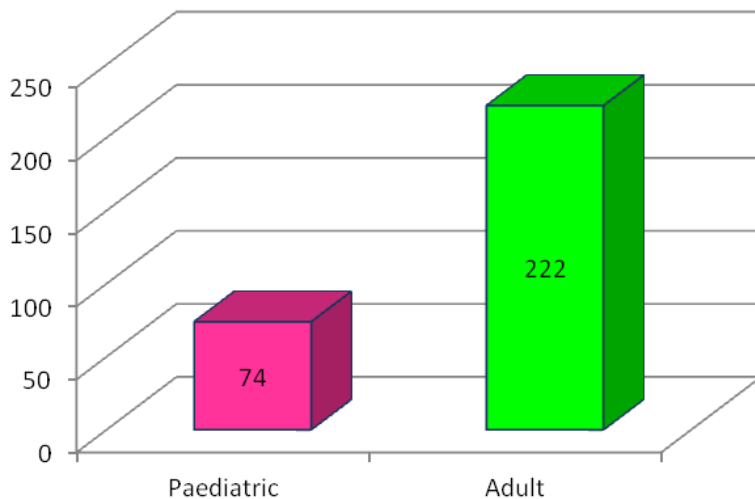
Generic name	DEFERIPRONE
ATC Code	<div>V - VARIOUS</div> <div>V03 - ALL OTHER THERAPEUTICS</div> <div>V03A - ALL OTHER THERAPEUTICS</div> <div>V03AC - Iron chelating agents</div> <div>V03AC02 - Deferiprone</div>
Main condition	beta-Thalassemia Iron Overload

EPMD: some results

In EU only ~ 30% of marketed drugs includes in their documentation (SmPC or PL) information on paediatric use.

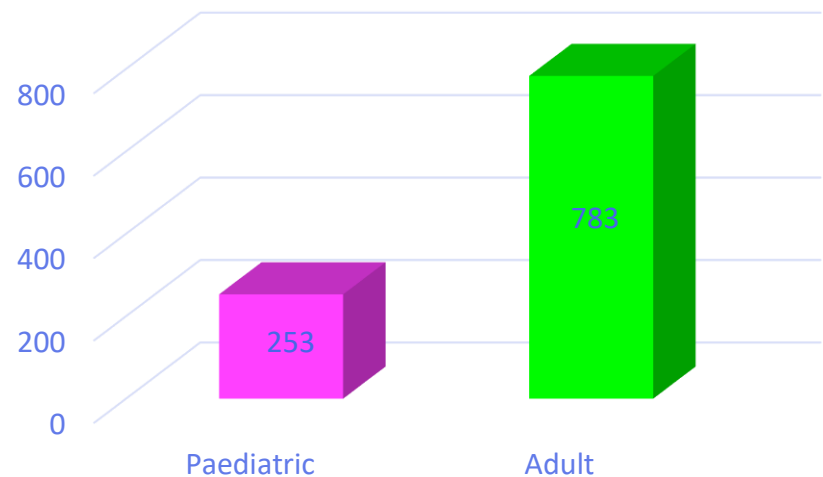
After 12 years from the entry into force of the Paediatric Regulation, the number of paediatric medicines has tripled, but they remain ~ 1/3 of all the centrally authorised medicines

Centrally-approved medicines up to 2003



Ceci A. and al, on behalf of TEDDY NoE, EJCP, 2006

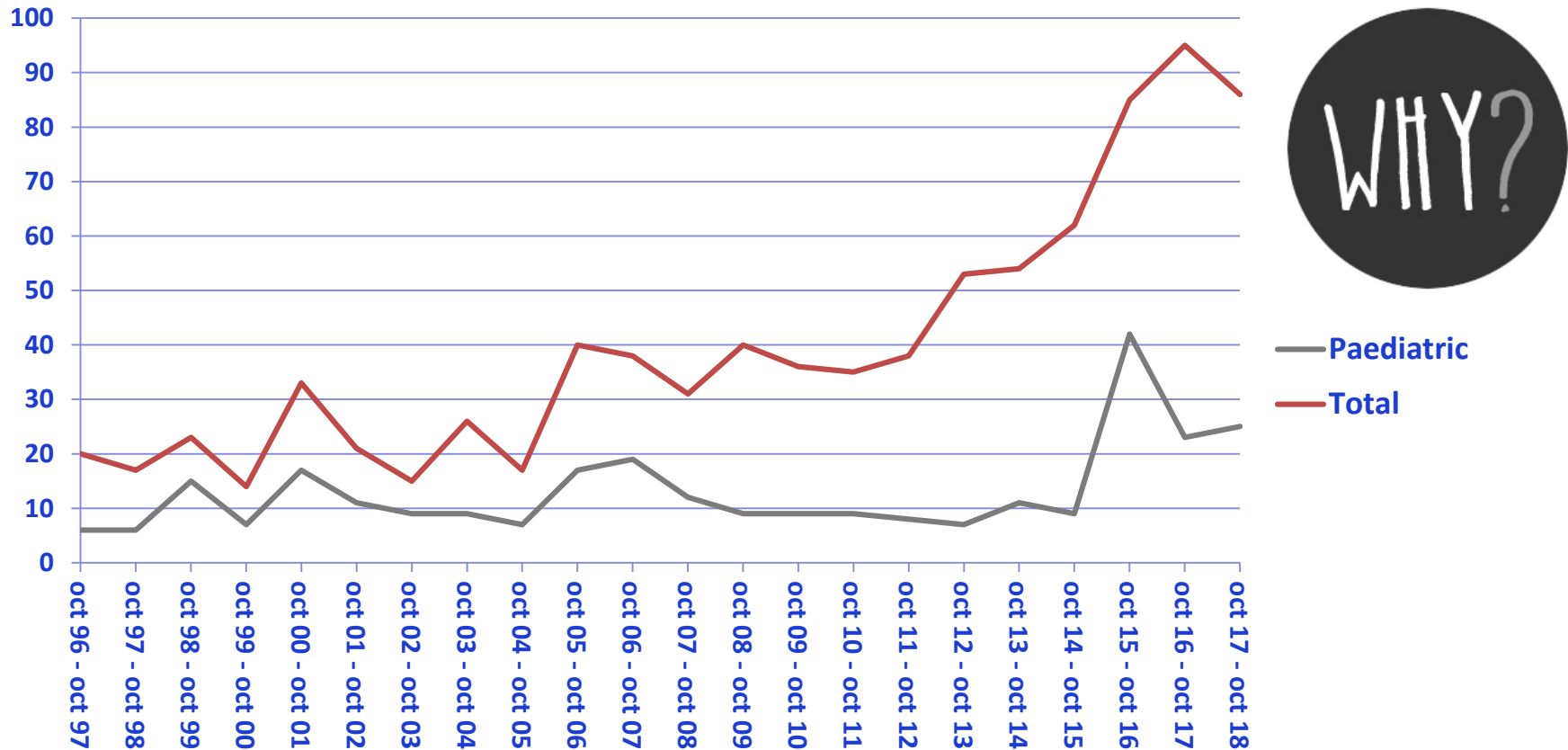
Medicines approved up to 2018



European Paediatric Medicines Database, update October 2018

Paediatric medicines in EU – trends by year

No clear trend: increase observed in the last years



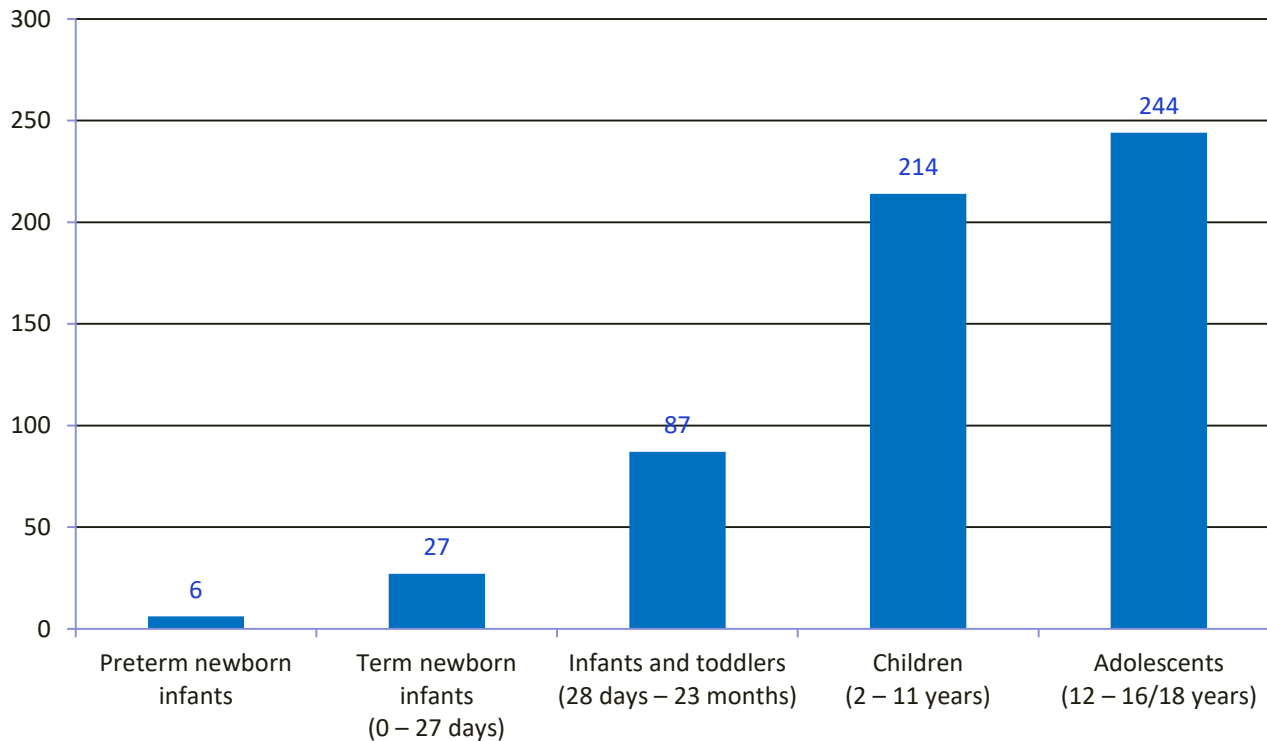
Paediatric medicines – distribution by ATC

	Paediatric/Total	
	N	%
A -Alimentary tract and metabolism	46/100	46
B - Blood and blood forming organs	28/62	45
C - Cardiovascular system	6/38	16
D - Dermatologicals	2/10	20
G - Genito-urinary system and sex hormones	2/32	6
H - Systemic hormonal preparations, excluding sex hormones and insulins	4/14	28
J - Anti-infectives for systemic use	71/145	49
L - Antineoplastic and immunomodulating agents	46/190	24
M - Musculo-skeletal system	3/23	13
N - Nervous system	17/64	26
P -Antiparasitic products, insecticides and repellents	1/1	100
R - Respiratory system	10/27	37
S - Sensory organs	5/24	20
V -Various	12/47	25
Not assigned yet	0/6	-
TOTAL	253/783	32%

In green the highest percentage

In yellow the lowest percentage

Paediatric medicines – distribution by age



It still persists a paucity of medicines approved for preterm and term newborns



Some conclusions

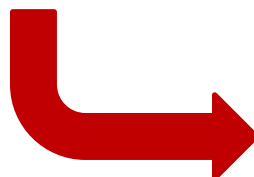
- After 12 years, the principal aim of the Paediatric Regulation is partially achieved
- Inequality between adults and children is still relevant
- Advantages should be better distributed among all the therapeutic categories and the paediatric ages
- There is the need to increase the efforts to not reduce the Paediatric Regulation's effects.

EPMD: useful information for...

- Conducting analysis of paediatric studies in order to acquire useful lessons for set up new studies.

Specialty areas: hematology, oncology, infectious diseases, respiratory diseases, intensive care, pain, endocrinology, rare diseases, neonatology

- Supporting the activities of the WG on off-label uses through an integration of the database with the drugs used off-label



Reports/Publications

Other activities

- Participation in projects (EPTRI-c4c-EJRPD)
- Scouting and applications of new projects
- Scientific publications
- Participation to EMA consultations

**THANKS FOR
THE ATTENTION!**