



**TEDDY Network General Assembly**

***March 29<sup>th</sup>, 2019***

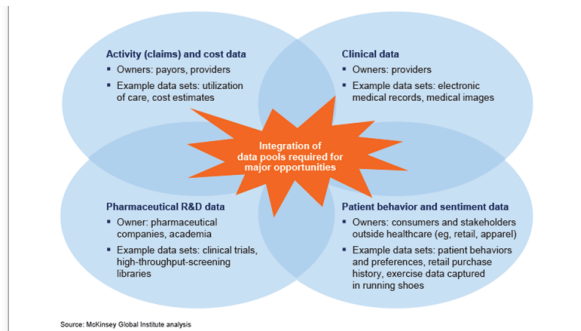
**Ministry of Health, Madrid - Spain**

# **WG Health Data Plan of Action**

**European Network of Excellence for Paediatric Clinical Research**

# Why this Working Group?

## THE IMPORTANCE OF HEALTH DATA



*Health data – and electronic health records (EHRs) – are widely viewed as a potential treasure trove for medical research*

## AND WHEN A LARGE POPULATION IS NOT AVAILABLE ?

### Paediatric patients represent a 'small population'

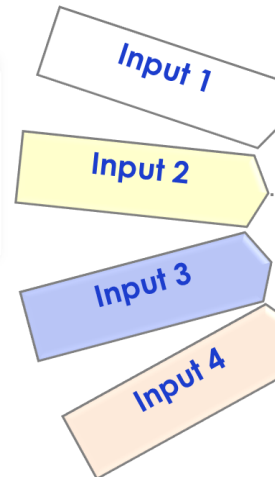
- ✓ Recruitment challenges
- ✓ Geographical dispersion
- ✓ No active control available
- ✓ Adequate statistical power needed
- ✓ Surrogate and validated endpoints needed
- ✓ Sample size to be minimised



**Trials are more difficult, take longer and cost more**

**Large population for CTs and other studies are needed**

Studies involving "small populations" are typically multi-centre and multi-national



**1° step TO SEARCH FOR PAEDIATRIC DATABASES**

- Reports and statistics on use
- Overview on developmental status
- Market reports
- Regulatory information
- Efficacy and safety of the drugs
- Information on PK/PD
- ...

# AGENDA

➤ *ACTIVITIES CARRIED OUT in 2018*

➤ *PROPOSED ACTIVITIES*

# ACTIVITIES in 2018

*TEDDY participation to the **European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)** – WG3 on Inventory of EU data sources and methodological approaches for multi-source studies*

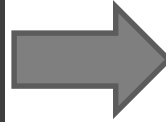


Contribution to the concept paper:

*“Different strategies to conduct multi-database studies for drug surveillance in real world setting: a reflection on the European model”*

# ACTIVITIES in 2018

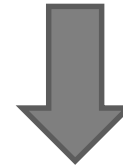
ENCePP WG3 MANDATE: Systematic review of multidatabase studies aimed ultimately at identifying key elements to be considered to judge the potential value of multiDB studies



Concept paper drafted



Comments and revisions received from WG Health Data members



Concept paper ready to be submitted



***Acknowledgments to the contribution provided by TEDDY WG health data will be included in the publication!***

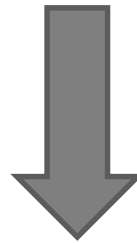
# PROPOSED ACTIVITIES

- *Participation to ENCePP WG3 activities*
  - *Draft of a position paper*
- *Participation to public consultations*



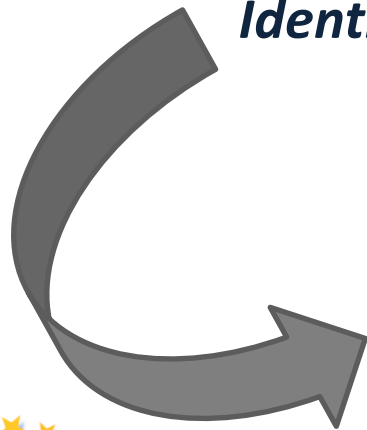
# Participation to ENCePP WG3 activities

**ENCEPP activity** → review of the studies in the EU PAS register  
with a special emphasis on multiple database studies and their contribution to  
regulatory actions



- Paediatric studies  
- Studies investigating drugs  
with a paediatric relevance

*Identification of the number of studies to be revised by  
TEDDY WG health data*

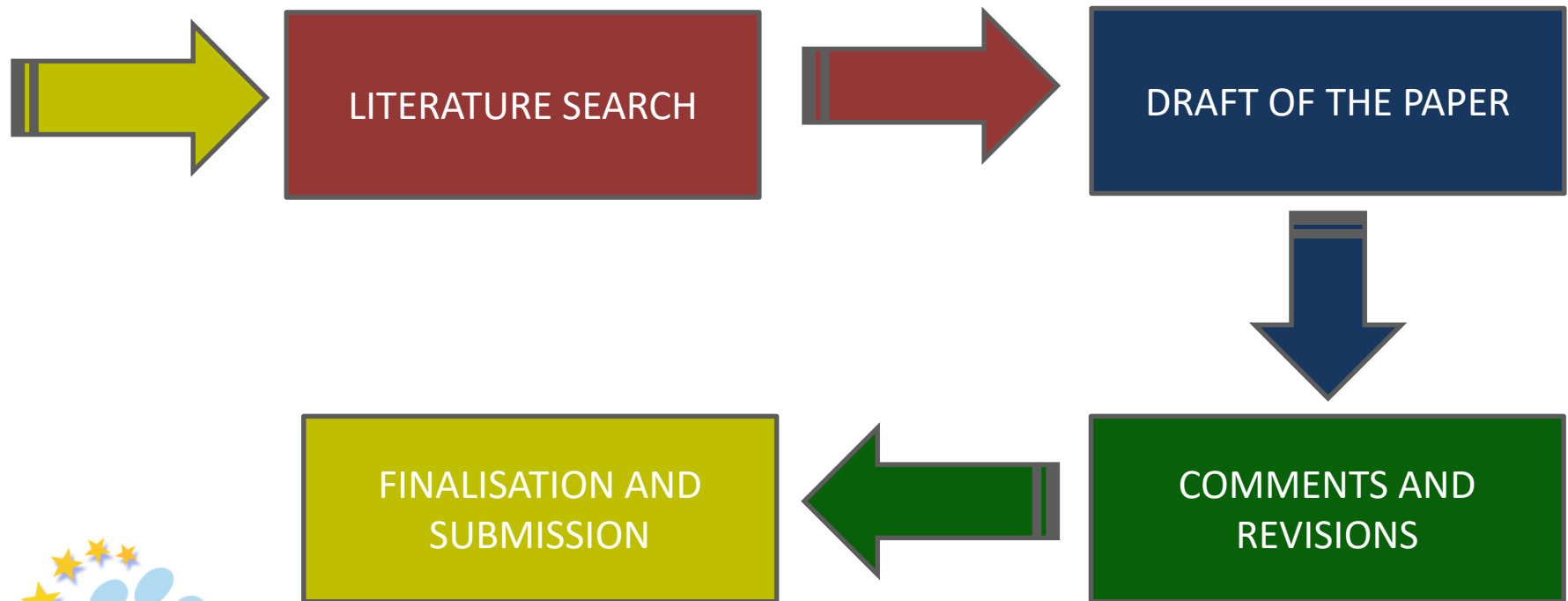


**DETAILS ON TEDDY CONTRIBUTION TO BE PROVIDED TO  
ENCEPP WG3 AFTER THE GA!**

# Draft of a position paper

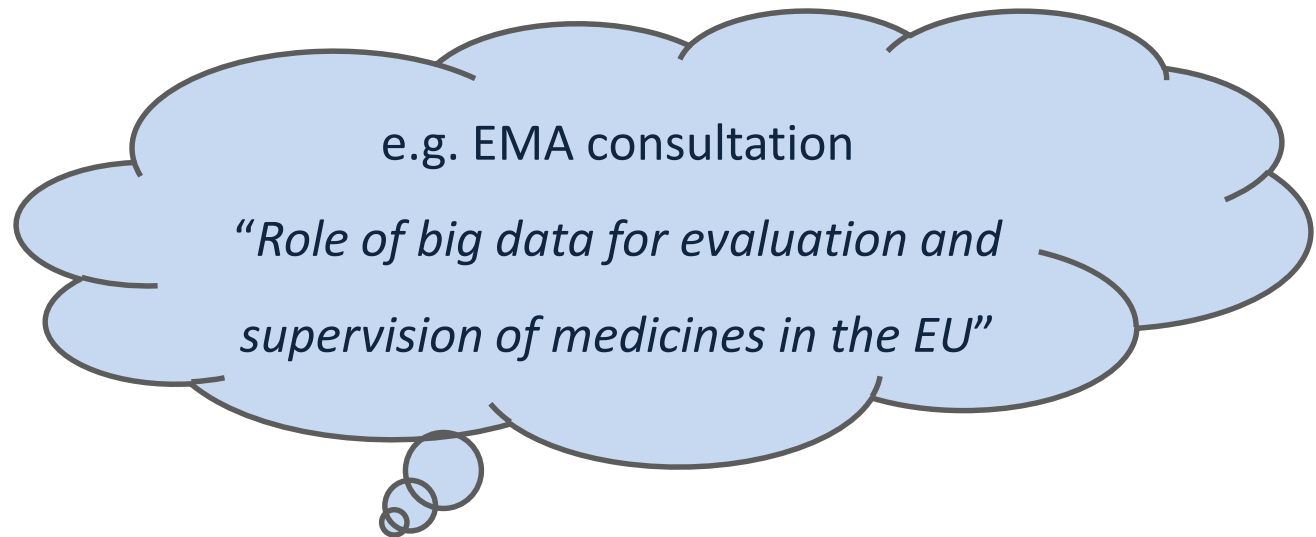
...within 1  
year!

Position paper discussing paediatric peculiarities in  
processing data from children....





# Participation to public consultations



Participation to consultations on the topics of health data  
and health paediatric data issued by EMA, European Commission  
and other relevant stakeholders

# TEDDY Working Group members

- ***Fedele Bonifazi***
- *Franco Bartoloni*
- *Letizia Carrara*
- *Oscar Della Pasqua*
- *Mariagrazia Felisi*
- *Madlen Gazarian*
- *Anila Godo*
- *Annalisa Landi*
- *Manuela Lopez-Azorín*
- *Kejla Musaraj*
- *Valeria Pignataro*
- *Miriam Sturkenboom*
- *Ian Wong*



NEW MEMBERS ARE WELCOME!

VOLUNTEER



THANK YOU

