



Enpr-EMA Annual Meeting

October 9th, 2023

Promoting children participation in decision making process:

- ❃ iCAN- The International Children Advisory Network
- ❃ Case study from TEDDY KIDS

Donato Bonifazi

TEDDY Network Board Membes

iCAN Advisory Board Member

European Network of Excellence for Paediatric Research

www.teddynetwork.net - info@teddynetwork.net

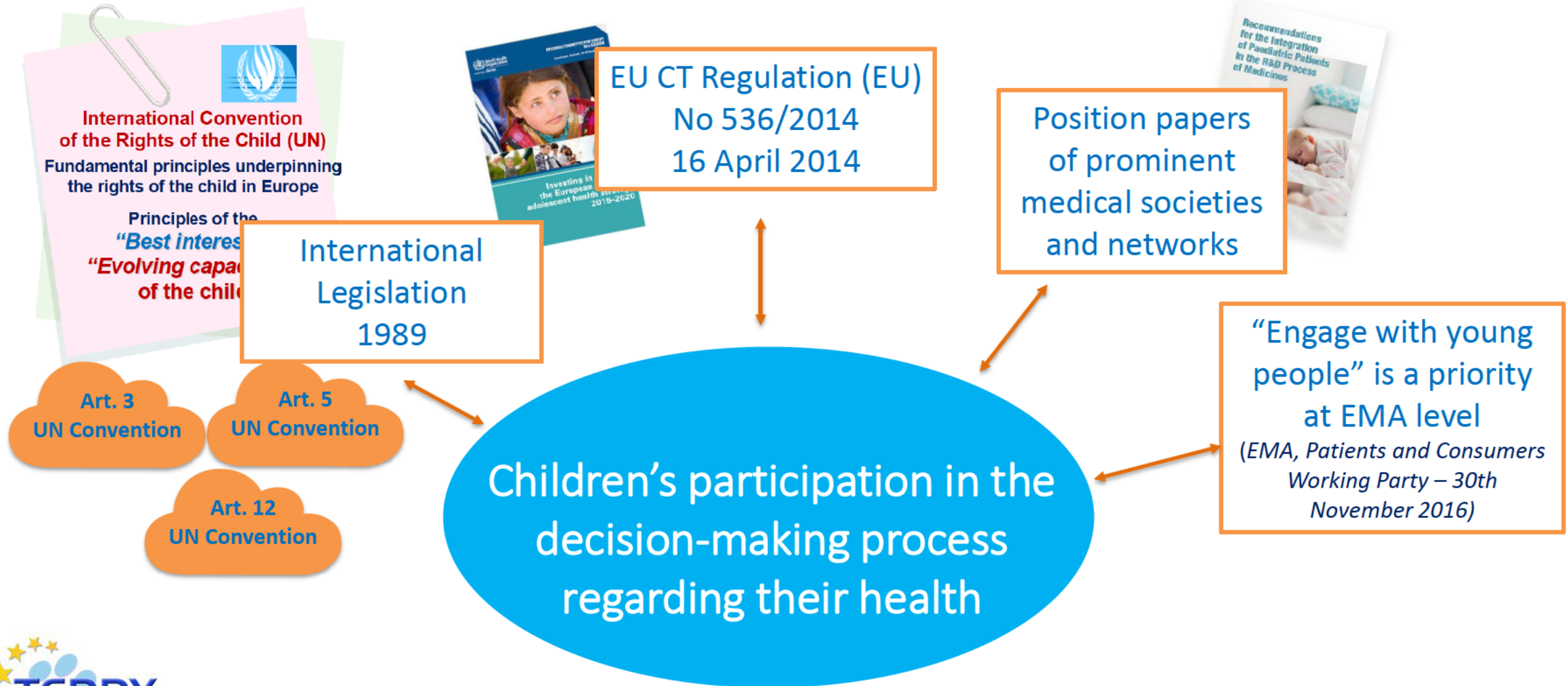
Ethical basis «*The right to be heard*»

Article 12 UN Convention on the Rights of the Child (UNCRC)

1. State Parties shall ensure that the child who is capable of forming his or her views **the right to express those views freely in all matters affecting the child**, the views of the child being given due weight in accordance **with age and maturity of the child**
2. For this purpose, **the child shall be provided the opportunity to be heard** in all matters affecting the child, through appropriate bodies or mechanisms, in accordance with the procedural rules of national laws.



Legal context on children participation in decision-making process



Participation of children in decision-making processes regarding their health

The **involvement** of children is a **progressive process**, according to their evolving capacities, and implies **four levels of participation**:

1. being informed
2. expressing a view
3. influencing decisions
4. being the main decision-maker

Engaging with children to improve individual decision-making processes

ADVOCACY



ADVISORY



iCAN

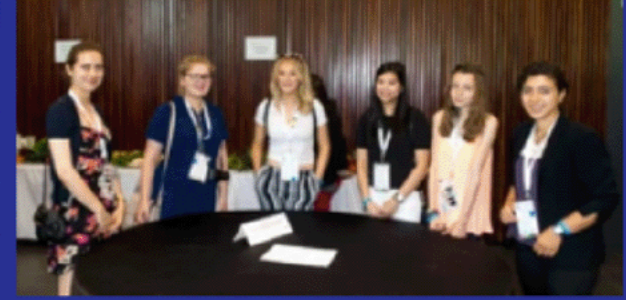
International Children's Advisory Network



www.iCAN.health

#iCANMakeADifference

The first International YPAGs Network -2014



iCAN Chapters members are children

Youth Members:

- Ages: 8-18, with some slightly younger or older kids
- Health: affected by complex medical conditions or not

Common Goals:

- Give voice to their concerns and needs
- Being heard by individuals, industry, government agencies
- Make a difference in Pediatric healthcare

<https://www.icanresearch.org/>

What is iCAN?



A non-profit organization dedicated to empowering every child, everywhere by working to improve pediatric health, medicine, research, and innovation by sharing children's voices



A dedicated platform for children and families to give input and feedback into study designs, treatment plans, and educational materials of our industry partners

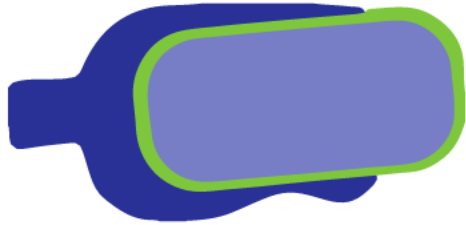


Made up of 34 member organizations working at the local and international level to empower youth voices globally



A worldwide organization that works with a wide network of community and industry partners as well as hospitals, high schools, researchers, and non-profits.

How Does iCAN work with Industry?



Collaborate with youth on innovation, science, research, and technology



Facilitate world-wide networking by sharing projects via social media, and other opportunities like the iCAN Summit



Give youth feedback during pre-clinical research using surveys and focus groups



Provide advice for pediatric healthcare issues by leaning on the expertise of iCAN's youth

Seal of Approval Program

iCAN is a resource available to any organization, company, or group that seeks that input of children and families for their projects and products. When you work with us, you know that **your product is iCAN approved and friendly to kids around the world.**



Kids review your material

You make any kid-recommended changes



Your product can proudly display the iCAN Seal of Approval*



Kid Reviewed. Kid Approved.

The iCAN Advocacy and Research Summit

Paediatric Rul

The summit acts as a spotlight and gathering place for research, science, medicine, and friendship

Kids all around the world from 4 different continents come to see how they are changing the world

NEXT Summit (2024) will be in EUROPE!

It will be in BARI!



Hot topics →

- Paediatric regulations
- Equal access to paediatric medicine

It will involve all KIDs and YPAGs in the world and will aim to implement new Groups in Europe



How Can You Start A Chapter?

There are a few simple steps to starting a chapter...

1. Identify an adult Team Leader and connect with the iCAN team.
2. Establish a partner/s organization/s
3. Determine the structure of the chapter
4. Create chapter by-laws
5. Complete the New Chapter form from iCAN

There is **NO**
cost to starting
a chapter!

What Do iCAN Chapters Do?

Every iCAN Chapter is an unique, dynamic organization housed within the global iCAN umbrella!

iCAN Chapters...

- Organize field trips
- Invite and learn from guest speakers
- Volunteer in community service activities
- Encourage leadership
- Participate in iCAN learning activities
- Foster a shared community



Giving voice to children

TEDDY **since 2017**, is part of the iCAN community and promotes **KIDS groups**.

KiDSBari **KiDS**Albania



Young patients and healthy youngers, aged from 12 to 18 years, and more, who work together to give voice to children in the decision-making process involving health, medicine, and research.

TEDDY kids are specifically educated and empowered about **fundamental children rights and biomedical research**.

Promote Children participation in decision-making process

The
TEDDY Kids

Strong motivation

Experts scientific
contribution

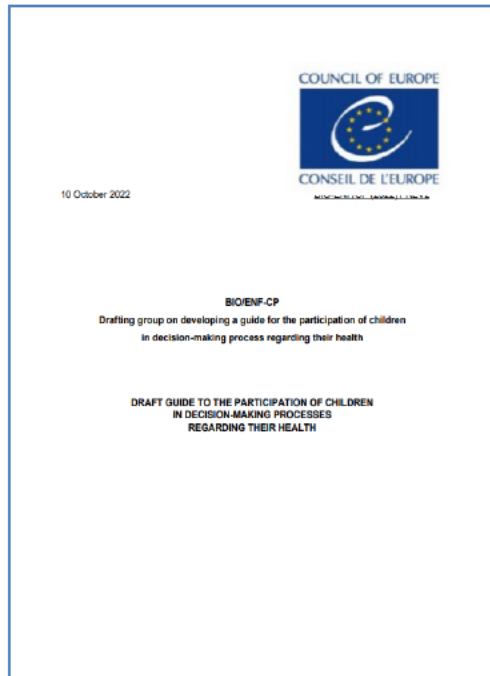
Attractive
(cartoon,

Involvement
external partners
and stakeholders

LET'S DISCUSS TOGETHER



Council of Europe Draft Guide to the participation of children in decision-making processes regarding their health



OBJECTIVES

- ▶ To highlight relevant **international frameworks and standards**
- ▶ To **provide examples of national legislation and good practices**
- ▶ To provide **guidance on how professionals can improve their practices** when involving children in individual decision-making processes affecting their health
- ▶ To identify other **measures** that healthcare and other relevant institutions may **apply to advance and facilitate involvement of children**

*Promoting children rights, needs, and resources, empowering children at every stage,
a Council of Europe initiative (2021-2022)*

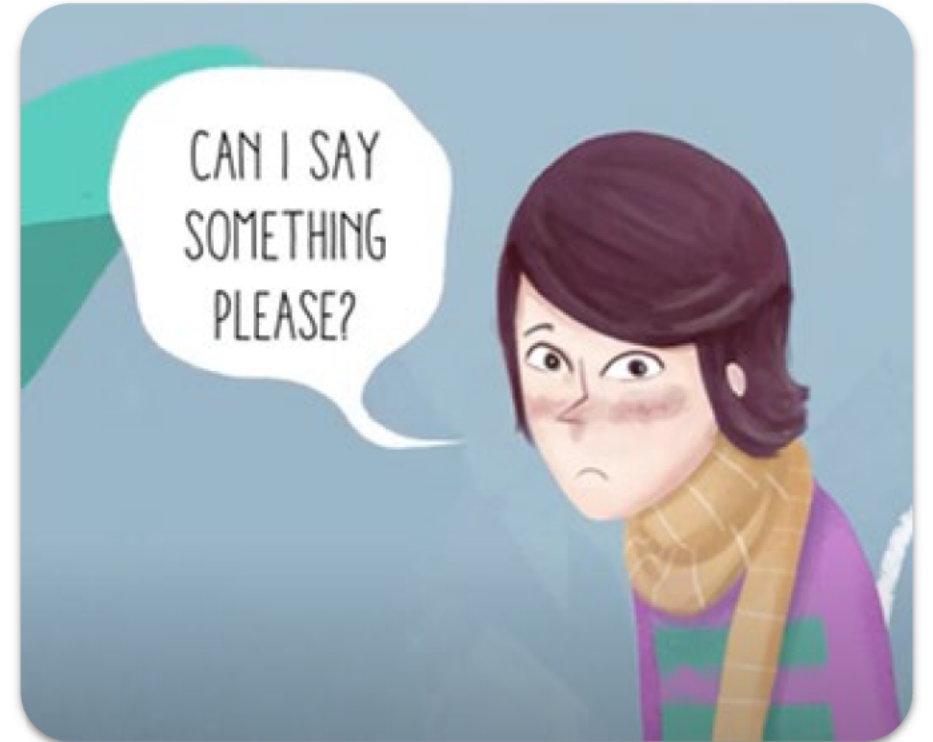
Children's participation in the decision-making process on matters regarding their health.

A Council of Europe video **made by children for children**

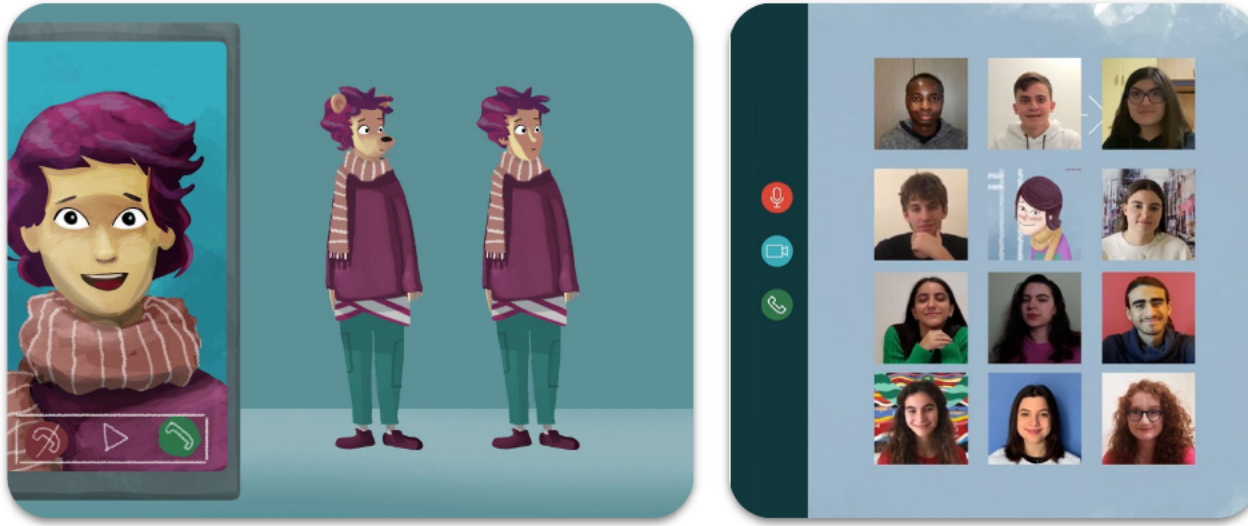
The Council of Europe (COE) asked the TEDDY Network to develop ***Have Your Say!***, a short **informative video** about children's participation.

The video is the result of a **participatory methodology** developed with TEDDY Kids, coming from Italy, France, Greece, and Albania.

A **full** collaboration from the choice of characters, to storyline, to giving voice to a young hero.



From real to cartoon to feel reality better



The experience of **sharing different cultures, geography and videocalls** inspired the kids to create the story based on their journey in producing the video, and to be themselves actors in the video with the 'patient' which was instead a cartoon.

The video has been presented on 2022 during the TEDDY Hearing within the CoE in Strasbourg



Paediatric expert training workshops

The initiative aims at providing young people living with rare diseases with the skills that would enable them to get involved in biomedical research and to play a role in decision making while contributing with their specific experiences.



Third paediatric expert patients training workshop

21th - 23rd June
Barcelona - Spain



From an Informed to an Expert patient having an higher impact on decisional process

Paediatric patients' voice shall be recognised, respected and considered as reference point

EJPRD Paediatric workshops



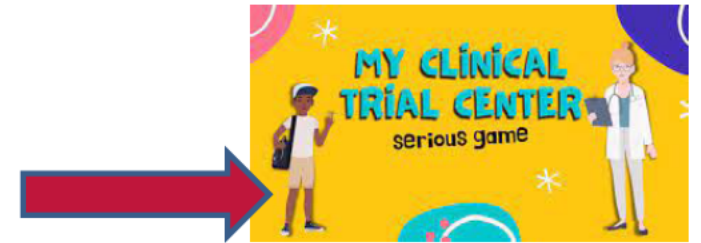
- **3-5 days workshops** including lecturer practical activities and case studies, discussions
- Participants: **aged** from 12 to 17 years, belonging to **10 countries** (Albania, Italy, Germany, Greece, France, Latvia, Spain, Switzerland, Germany, Neetherlands)
- Several chronic rare diseases represented
- Multidisciplinary Teachers and experts: from **European institutions and EU countries**

Training Course: interactive sessions, games, etc

➤ **Ice-breaker activity** to get young people to know each other

➤ **Child friendly tools:**

- **Serious game** entitled “My Clinical Trial Center” (available on both Android and iOS) created by TEDDY KIDS Bari and Albania. It is a **digital game** aimed at explaining what are clinical trials , how do they work.
- **Awareness campaign** : video developed by the TEDDY team and KIDS Bari for the Rare Disease Day
- **Kahoot activity** (Kahoot is a **free game-based learning platform**) to assess the participants knowledge.



➤ **Adapted methodology** : e.g. “colours methodology” applied to the analysis of ‘adults’ on informed consent to develop paediatric template.

➤ **Participative methodology** applied for developing child friendly materials: paediatric assent form for processing/sharing data.



MY CLINICAL TRIAL CENTER



PLAY TO LEARN!



KiDSAlbania and KiDSBari



Let's play!





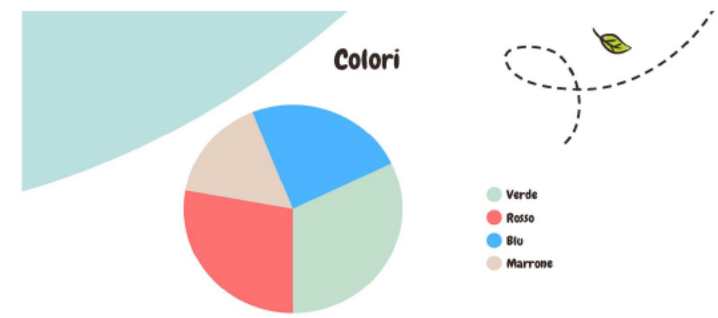
Target audience and contents

Addressed to children **8 years old or older**, the game offers to players the opportunity **to learn about clinical trials and their different stages**. Information given to the players includes: study protocol, informed consent and assent in children, trial phases, data collection, pharmacovigilance.

Kids **tested the trial version** of the video game to **improve the user experience** before the release, reporting **bugs or anomalies**, and any other **technical or language issues**.

Playing is serious business

The game represents an important **gamification tool** that can be used to **engage children and paediatric patients**, by combining elements and principles of games with motivational theories.



Participatory design

This serious game represents an example of **children's engagement**. Kids has been involved in the development through a **participatory design approach**.



Kids talk about the game



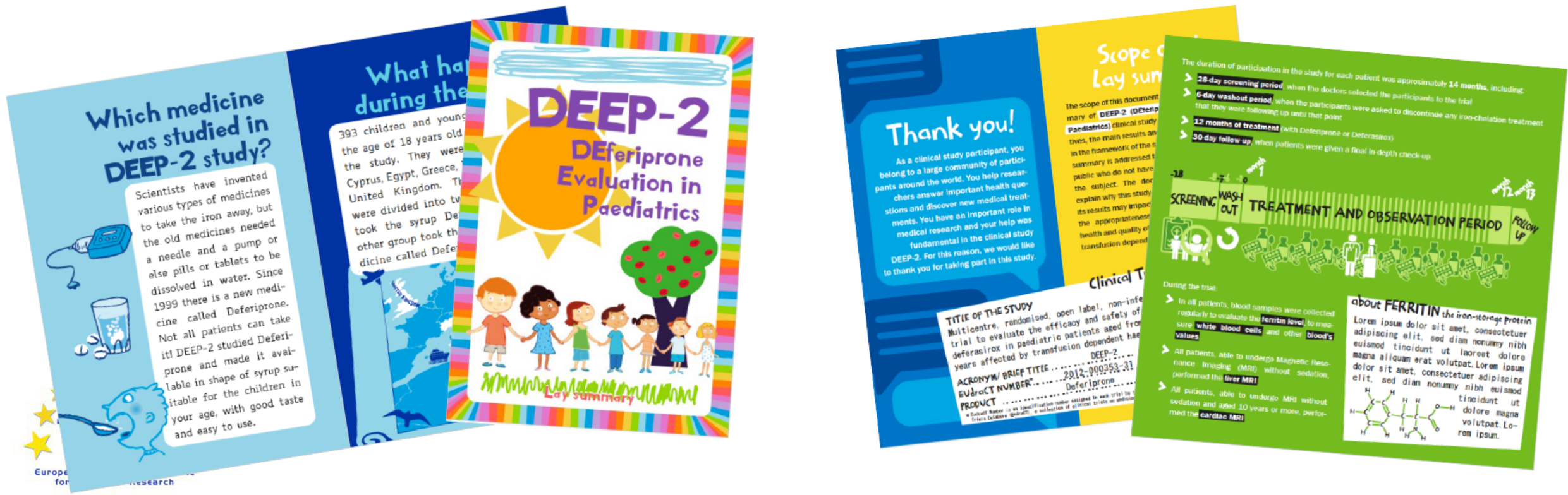
https://www.youtube.com/watch?v=d2o9U2H_hgM&t=202s

DEEP-2 Clinical study Lay summary

Lay summary of the **DEEP-2 clinical study**, developed with the **expert contribution** of the TEDDY Kids, in collaboration with CVBF, sponsor of the study and coordinator of the DEEP Project.



DEFERIPRONE
EVALUATION IN
PAEDIATRICS



Conclusions

- ❁ Participation of children in decision-making processes regarding their health is an evolving process worldwide
- ❁ Young people and Children are the new actors on the scene able to accelerate and qualify the process
- ❁ The involvement of the Governments and Health Authorities may make the difference in term of support and sustainability
- ❁ In EUROPE, EnprEMA may have a crucial role and the today initiative is a fundamental step in this direct

May the YPAGs and KIDS direct participation to EnprEMA be envisaged?



Thank You, from iCAN



Donato Bonifazi
Advisory Board Member

dbonifazi@teddynetwork.net

www.icanresearch.org

