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PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

European Patients' Rights & Cross-Border Healthcare

HOW TO ENSURE TREATMENTS AND THE RESPECT OF PATIENTS' TIME ACROSS EUROPE?
Focus on timely access to innovative medicines after the European Commission approval

Bruxelles, 28 June 2017

Citizens' and patients' perspective: what about children?

Lucia Ruggieri

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Consorzio per Valutazioni Biologiche e Farmacologiche

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

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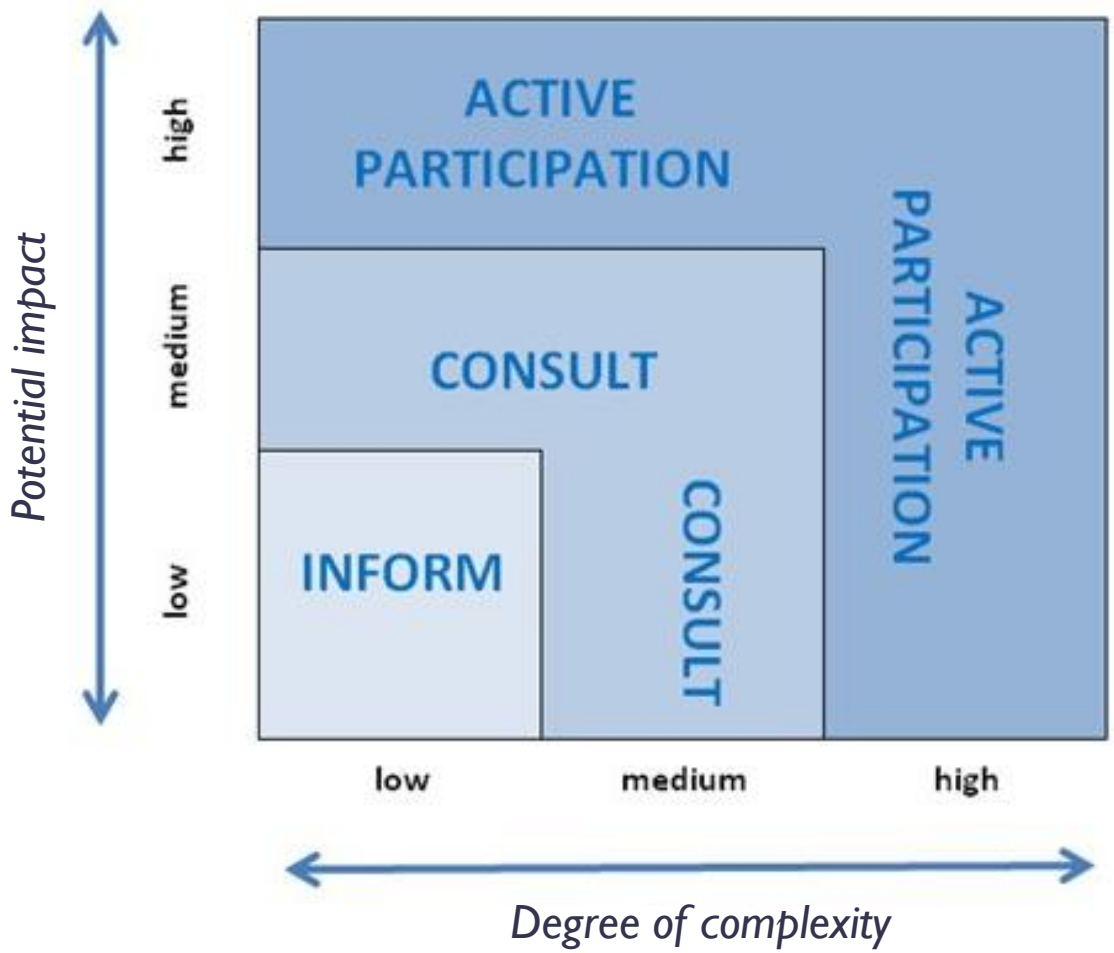
Patients' participation in medicines research and development



Empowered Patient model

Who?

The expert patient:

The expert patient is an educated patient, at Eu level, on the drug development process, that is experienced and able to work in synergy with other patients, focused on specific diseases. The common interest is that the patients' voice is recognised, respected and considered as reference point . In this perspective, training and knowledge are milestones for patients' active participation and for their collaboration.

Paola Kruger, EUPATI Expert Patient,
Quotidiano Sanità, April 2017

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Patients' participation in medicines research and development: some examples

How?

- Identification of research priorities
- Participation in Advisory and Steering Groups
- Co-management of research projects
- Documents review
- Participation in results draft and communication
- Training (specific workshops/initiatives)
- Evaluation surveys

What?

- Transparency and dissemination of information
- Information on the product, including 'EPAR'
- Pharmacovigilance (ENCePP)
- Interaction with the European Medicines Agency and its scientific committees → 2014: creation of the Department of Patients and Healthcare Professionals at EMA

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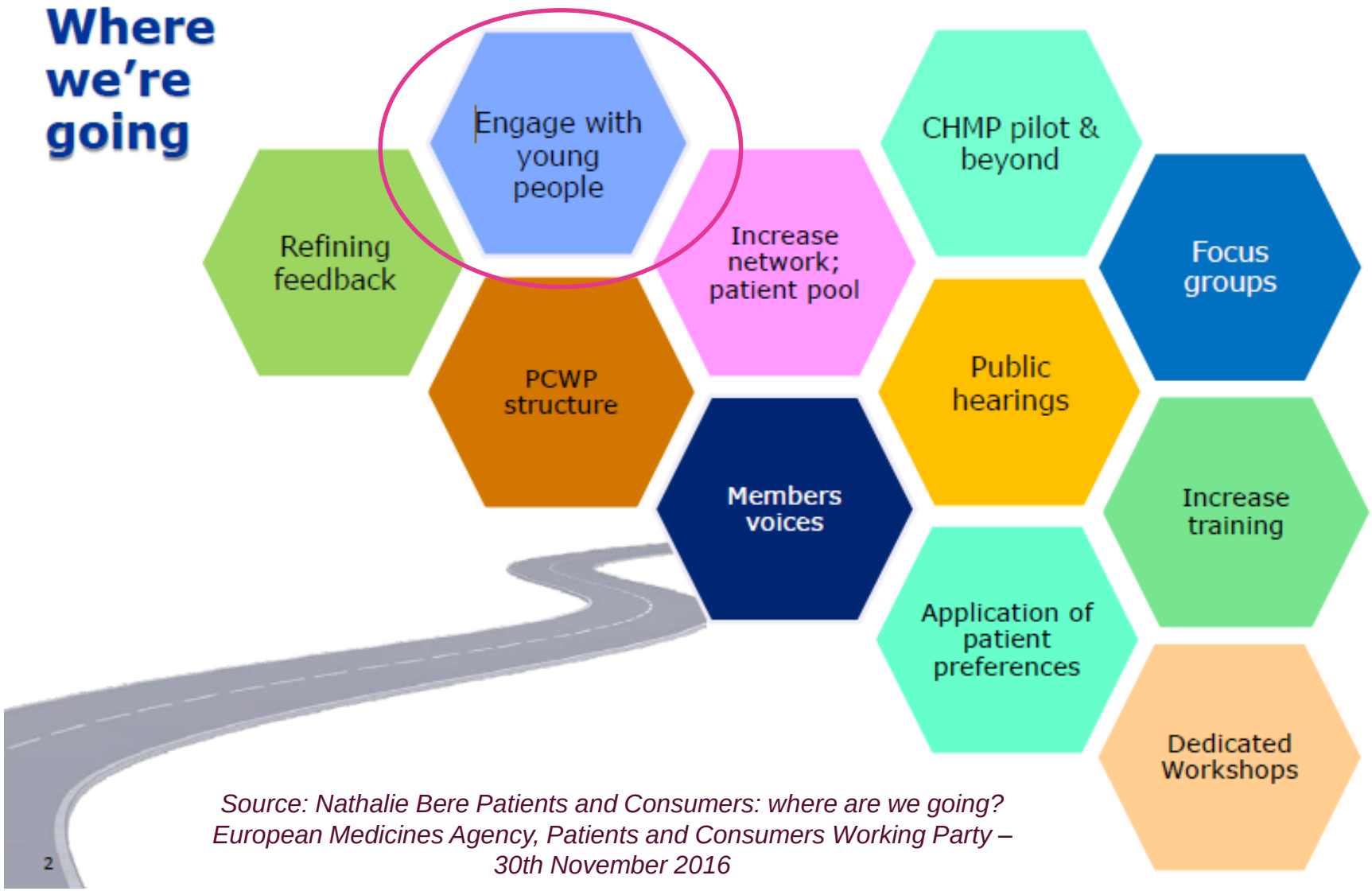
EMA Patients and Consumers working party



Source: Nathalie Bere Patients and Consumers: where are we going? European Medicines Agency, Patients and Consumers Working Party – 30th November 2016

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Are children entitled to enter this process?

International Convention of the Rights of the Child (UN)

Fundamental principles underpinning the rights of the child in Europe

principles of the

"Best interests"

"Evolving capacities"

of the child

"States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services." (Art. 24)

"The child who is capable of forming his or her own 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 the age and maturity of the child." (Art. 12)

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Paediatric patients' participation in medicines research and development

1. understanding by the patient of his/her role
2. acquisition by patients of sufficient knowledge to be able to engage with their healthcare provider
3. patient skills
4. presence of a facilitating environment

ASPECTS TO CONSIDER IN PAEDIATRICS:

- Children awareness about their status
- Information and knowledge on disease-related aspects
- Individual maturation level
- Adequate language and means of communication, dedicated initiatives
- Parents' wills

Angelmar R, Bermann BP. Patient empowerment and efficient health outcomes. Financing sustainable healthcare in Europe. 2007 :139–162.; http://www.sustainhealthcare.org/The_Cox_Report.pdf

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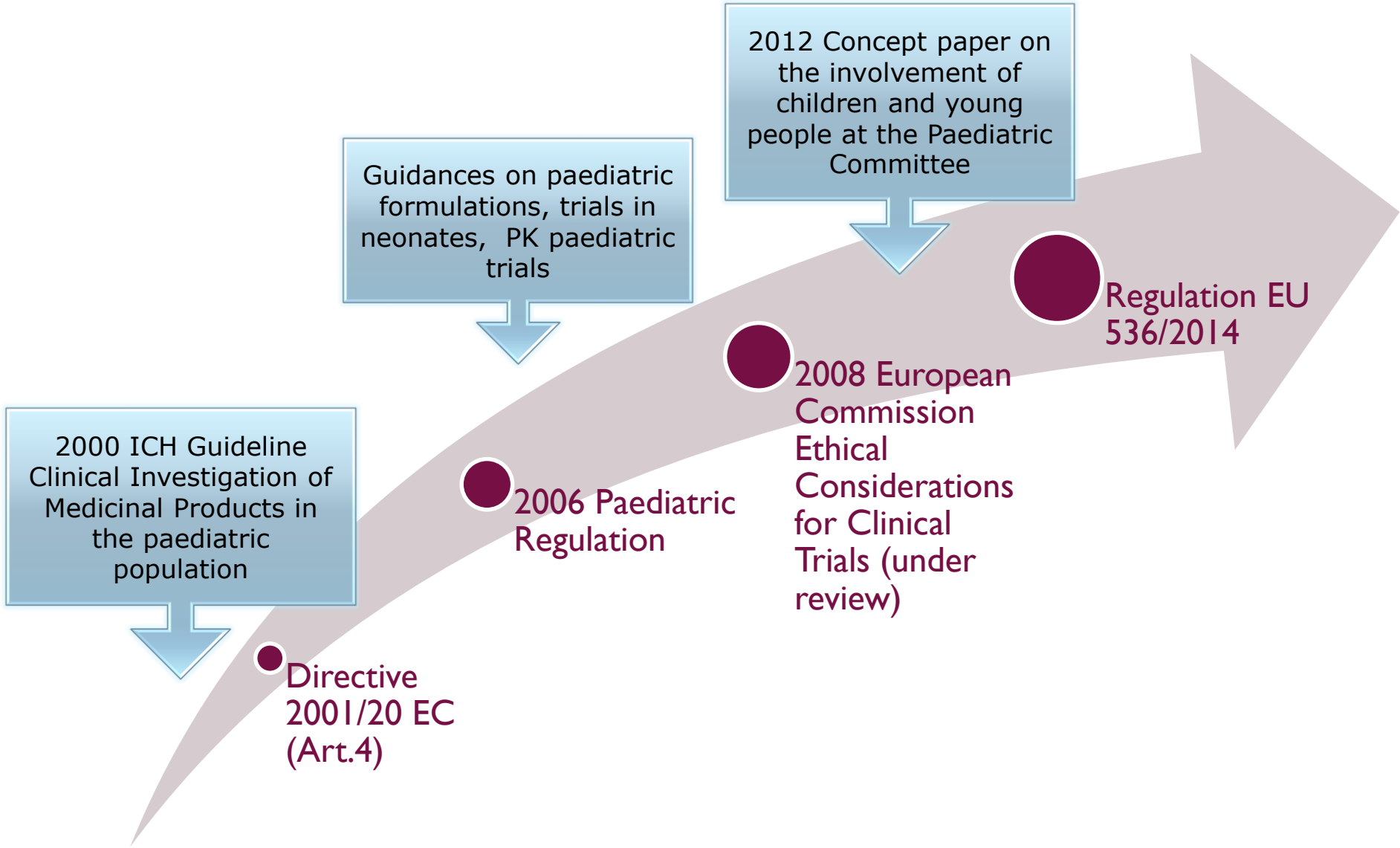
Children in medicines research and development – subjects or actors?



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Children in medicines research and development – subjects or actors?

Young Persons Advisory Groups

ICAN
International Children's Advisory Network

Organization composed of youths actively participating as partners, advising researchers and their teams on a full range of activities in various research projects and initiatives

eYPAGnet
European Young Persons' Advisory Group Network

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

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Children in medicines research and development – the TEDDY network experience

TEDDY
Task-force in Europe for Drug Development for the Young

European Network of Excellence for Paediatric Clinical Research,

born in the framework of the the 2003 FP6 LSH-2003-1.2.1.1 Medicines for children

Since 2010 TEDDY has revised its organisation and gathered research centres and groups willing to be engaged in developing clinical research

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

TEDDY today…

- …is **an independent multidisciplinary, multinational Network** aimed at facilitating the performance of good quality paediatric studies and research.
- …encompasses about **50 partners** from 18 Eu and non-Eu countries
- …is a **category 1 network member** of Enpr-EMA

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Children in medicines research and development – the TEDDY network experience

Participation in all the consultation and initiatives for official documents laws release/revision → from the 'paediatric initiative' to the group on off-label use

Involvement of patients and families in the preparation of clinical trials information packages:

- Education videos
- Age-appropriate leaflets and brochures
- Surveys for the evaluation of informative material
- Organisation of focus groups.

TEDDY Young Persons Advisory Group:

- Officially presented in June 2017 in Bari, at the University paediatric hospital "Giovanni XXIII"
- Objectives: Peer support for young patients; advocacy for children, patients and participants in clinical trials; advise young people on research; raising public awareness; fundraising.

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Children in medicines research and development – what is to be developed?

- Summary of Clinical Trial Results for Laypersons → missing any paediatric reference
- Support for initiatives requiring children active participation
- Specific methodology for the involvement of the paediatric population
- Identify fields of activity for which it is most relevant to have children's active participation
- Collaborative model children - families

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