



RESPECT
patient needs




Clinical Trials Networks

How can the patient or parent play an active part?


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RESPECT Dissemination Meeting
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 - ▶ Consultation among Paediatric CT Networks
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Clinical Trials Network definitions

- ▶ *Network*: virtual structure defined by a formal agreement between individuals, organisations or structures sharing and collaborating towards the same objectives, goals and quality standards
- ▶ *CT Network*: network focused on the development of medicinal products
- ▶ *Paediatric CT Network*: network with specific expertise in the performance of studies in the paediatric population

How many types of Paediatric CT Networks have been identified?

- ▶ National networks, generally benefiting from public funding
- ▶ European networks publicly funded (e.g. TEDDY)
- ▶ 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.

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Consultation among Paediatric CT Networks

- ▶ **AIM:**
 - To better understand how Paediatric CT Networks encourage patients' participation in their clinical research

- ▶ **METHODOLOGY:**
 - Questionnaire
 - Does your Network allow families or patient organisations any input in the design of clinical trials?
 - What is your Network's recruitment process?
 - Does your Network gather and provide feedback from/to families after trial completion?
 - Does your Network have any examples of best practice in their organisation or suggestions for improved focus on the child's experience of a clinical trial?
 - 13 Paediatric CT Networks selected from inventory carried out by EMA

Consultation among Paediatric CT Networks

Participating Networks

- ▶ BPCRN – Belgian Paediatric Clinical Research Network
 - ▶ CICP – French Network of Paediatric Clinical Investigations Centers
 - ▶ ECFS Clinical Trial Network – European Clinical Trials Network for Cystic Fibrosis
 - ▶ FINPEDMED – Finnish Investigators Network for Paediatric Medicines
 - ▶ MCRN – NIHR Medicines for Children Research Network
 - ▶ PENTA – Paediatric European Network for the treatment of AIDS
 - ▶ PRINTO – Paediatric Rheumatology International Trials Organisation
 - ▶ CVBF–TEDDY – Consorzio per Valutazioni Biologiche e Farmacologiche
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Consultation among Paediatric CT Networks

Overview of replies

	Direct involvement	Recruitment	Feedback	Best practise
BPCRN	No	<ul style="list-style-type: none"> • Network's Databank • Physicians' direct contact 	No feedback	-
CICP		<ul style="list-style-type: none"> • Network's involved centres • Contact with specialists • Involvement of patients organisation 	Occasionally (only general results)	-
ECFS	Yes	<ul style="list-style-type: none"> • Individual investigators 	General feedback on trial outcome	-
FINPEDMED		<ul style="list-style-type: none"> • Network's involved centres • Contact with specialists • Involvement of patients organisation 	Encouraged, but depends on type of trial and sponsor	Templates and picture cards www.finpedmed.com
MCRN	Yes	<ul style="list-style-type: none"> • Doctors 	Encouraged (newsletters, web links, etc.)	MCRN young person's advisory group Topic specific focus groups Youth groups
PENTA		<ul style="list-style-type: none"> • Network's involved centres • Contact with specialists • Involvement of patients organisation 	Newsletters Website	Youth groups
PRINTO		<ul style="list-style-type: none"> • Network's involved centres • Contact with specialists • Involvement of patients organisation 	No feedback	-
CVBF-TEDDY	Depends study	<ul style="list-style-type: none"> • Network's involved centres • Contact with specialists • Involvement of patients organisation 	Encouraged, but not always attainable	Informative packages for children (videos, picture cards) Recommendations for children and parents


PO representative in Executive Committee

Comprehensive patient and public involvement strategy achieved through forums


Parents representatives in Steering Committee

Type of study and disease influences involvement


Consultation outcomes

- ▶ Direct involvement of patients and patients' organisation not usually in current practice
 - ▶ Necessary to increase awareness on the subject
 - ▶ Might be useful to circulate recommendations targeted to families and patients to encourage their aware participation in clinical trials
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Review of public stakeholders involvement in CT Networks

- ▶ Enpr-EMA was established by the European Paediatric Regulation and officially set up in March 2011 at the EMA
 - ▶ Aim: to foster high-quality ethical research on quality, safety and efficacy of medicines to be used in children
 - ▶ Six criteria to be fulfilled:
 - Criterion 1: Research experience and ability
 - Criterion 2: Network organisation and processes
 - Criterion 3: Scientific competencies and capacity to provide expert advice
 - Criterion 4: Quality management
 - Criterion 5: Training and educational capacity to build competences
 - Criterion 6: Public involvement
 - ▶ 32 Networks submitted self-assessment reports:
 - 18 now official Enpr-EMA members
 - 1 currently undergoing clarification
 - 13 not qualifying for membership
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Review of public stakeholders involvement in CT Networks

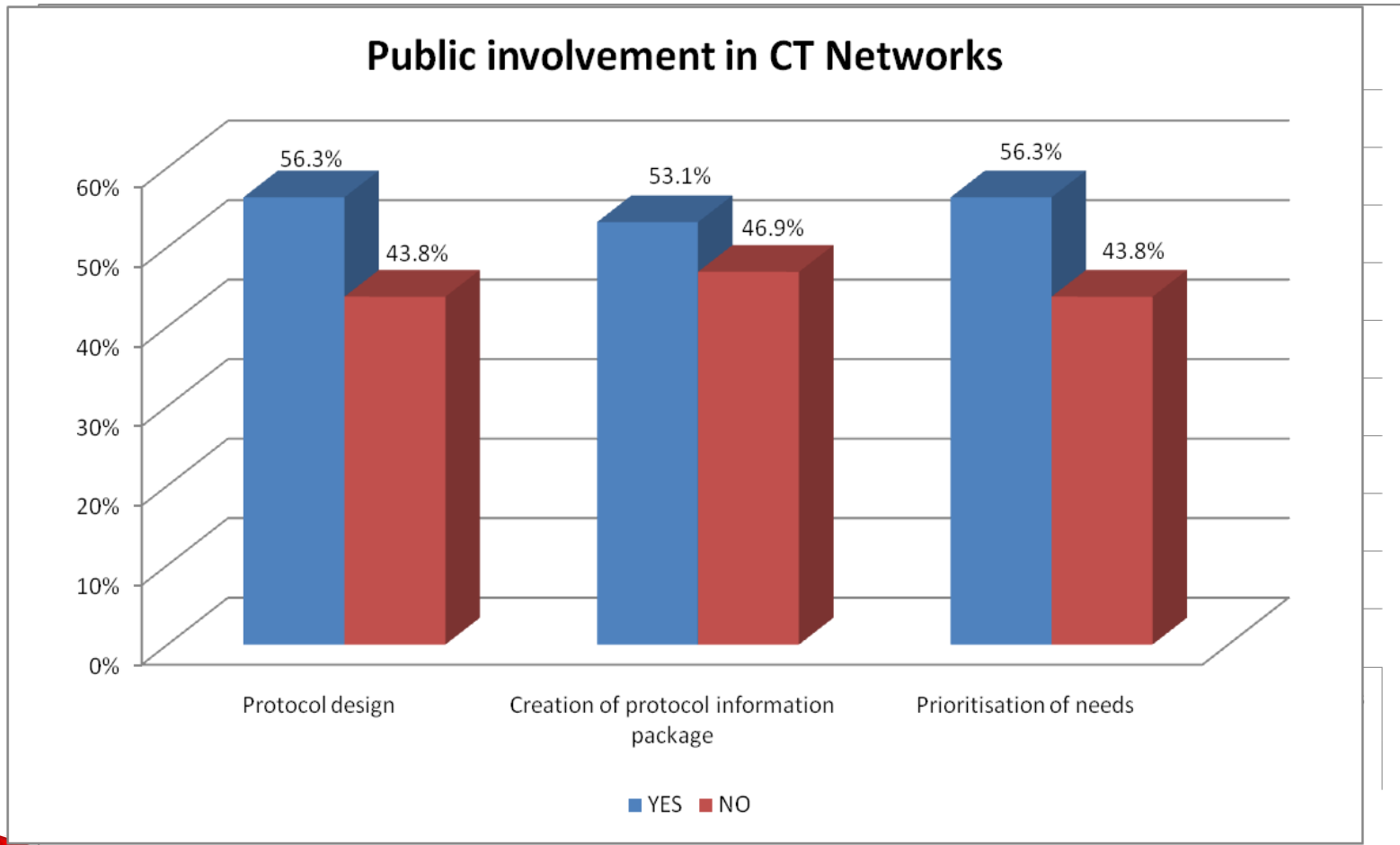
▶ AIM:

- To find best practice examples of patient/parent or patient organisation involvement

▶ METHODOLOGY

- 6.1 Involvement of patients, parents or their organisations in the protocol design
- 6.2 Involvement of patients, parents or their organisations in creating the protocol information package
- 6.3 Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children

Review of public stakeholders involvement in CT Networks Results



Review conclusions

- ▶ Public involvement also required by European Authorities
 - Qualifying criterion for membership in Enpr-EMA
 - POs representatives included in EMA Committees and working groups
- ▶ Giving patients possibility of direct input in prioritisation of needs, CT design and execution will motivate their participation in clinical research
- ▶ Closer cooperation enriches understanding of medical condition and outcomes
- ▶ Examples of patients involvement in CT Networks: PENTA, MCRN, ECFS

INVOLVEMENT OF PATIENTS WORKS!

Examples of public involvement

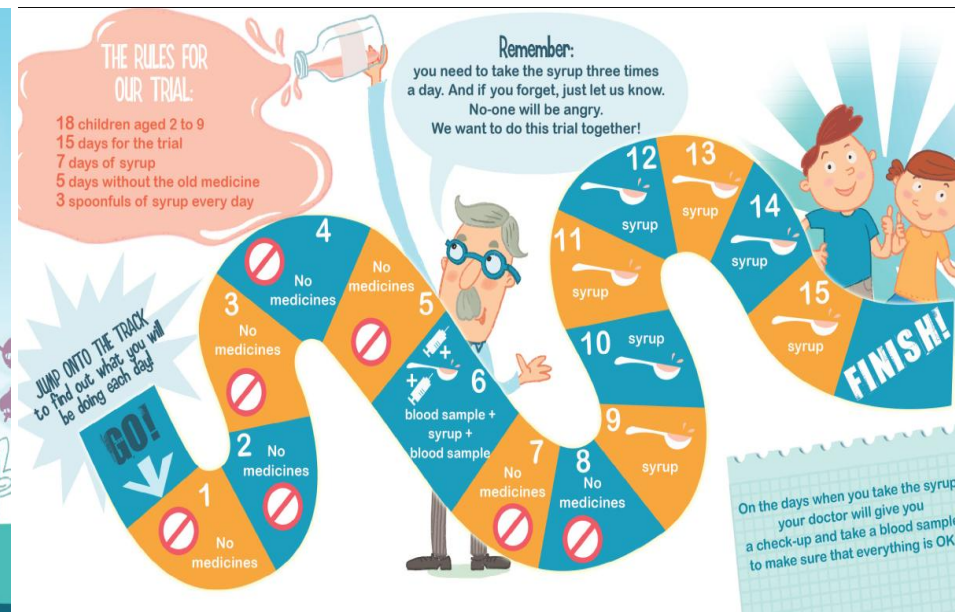
- ▶ **EUNETHYDIS: the European Network for Hyperkinetic Disorders**
 - Parent organizations provided information in gaining national support for improved clinical services and lobbying for increased funding for both pharmacological and non-pharmacological clinical trials in ADHD
- ▶ **I-BFM-SG: International BFM Study Group**
 - In some studies (e.g. ALL-Rez), parent organizations are able to provide funding

Examples of public involvement

- ▶ **MICYRN: Mother Infant Child Youth Research Network – Réseau de Recherche en Santé des Enfants et des Mères**
 - Patient/disease organizations provide funding to scientifically-competitive, peer-reviewed studies
 - Examples: cancer, diabetes, cystic fibrosis, arthritis, immunology, rare diseases, genetics, heart & stroke
- ▶ **PRINTO : Pediatric Rheumatology International Trials Organisation**
 - Patients' and parents' organisations identified through specific EU funded project, allowing creation of a website for families available in more than 50 languages (www.pediatric-rheumatology.printo.it)

Examples of public involvement

- ▶ **CVBF–TEDDY: Consorzio per Valutazioni Biologiche e Farmacologiche**
 - Informative packages for children developed as videos and picture cards



THANK YOU!

