



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Results from the questionnaire to PDCO members

- *Involvement of children, adolescents, parents/carers or legal representatives in the PDCO activities*
- *Strengthening the participation of members representing patients' organisations in the PDCO*

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Introduction

Recommendations from concept paper on the involvement of children and young people at the PDCO (2012) *:

- Define a framework of interactions between EMA, PDCO, children and/or adolescents and patients' organisations;
- Define the expectations and role of children and adolescents to support PDCO activities;
- Develop clear criteria on which situations need the consultation of children, adolescents and patients' organisations.

6th annual Enpr-EMA workshop (June 2014):

- Topic on involvement of children and young people in clinical research: it is important to engage children at every feasible stage of the research activities.



Structure of questionnaire

- 1. Involvement of children/adolescents in the activities of PDCO**
- 2. Involvement of parents/carers or legal representatives in the activities of PDCO**
- 3. Strengthening the participation of members representing patients' organisations in the activities of PDCO**

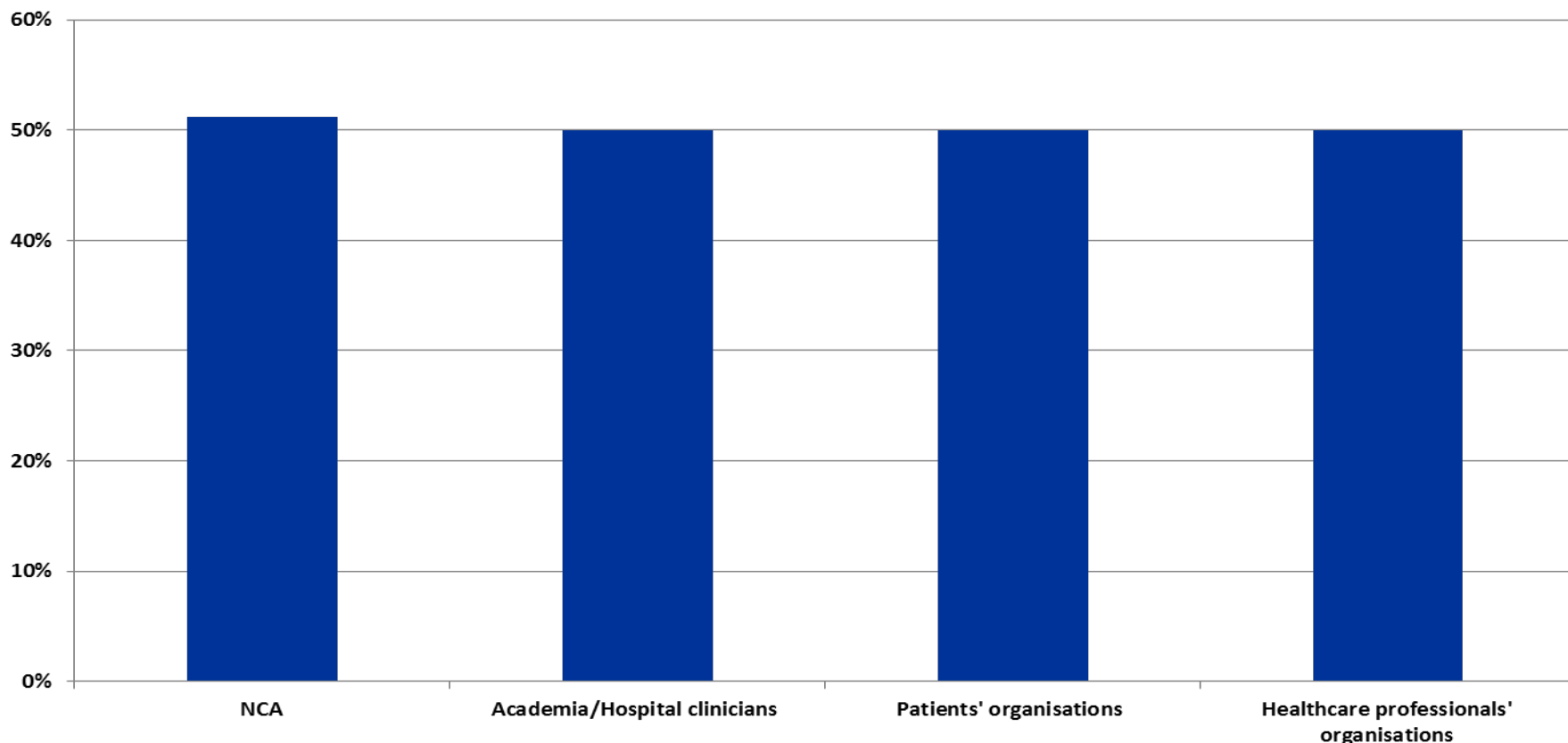


Results



Response rate

In total 35 of 69 members (51%) responded to the questionnaire. Within every category there was a 50% response rate.



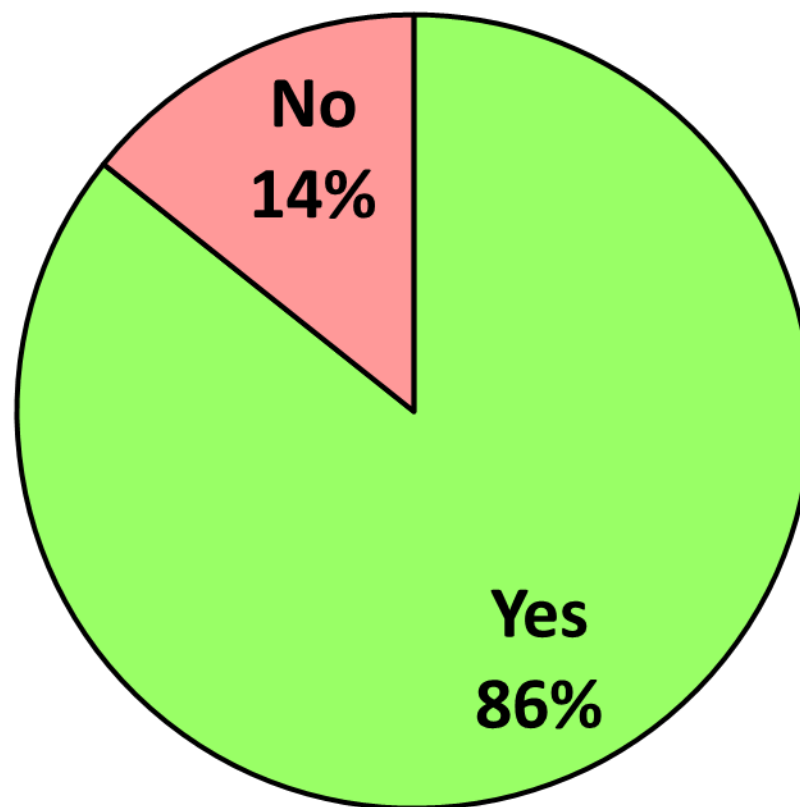
Response rate (%) of PDCO members representing each category (National Competent Authorities (NCA), or Academia/Hospital, or Patient's Organisations, or Healthcare Professionals Organisations)



Involvement of children in the activities of the PDCO



Do you see a **benefit** to involve children and/or adolescents in the activities of the PDCO?





Members' comments on involvement of children

Some expressed concerns

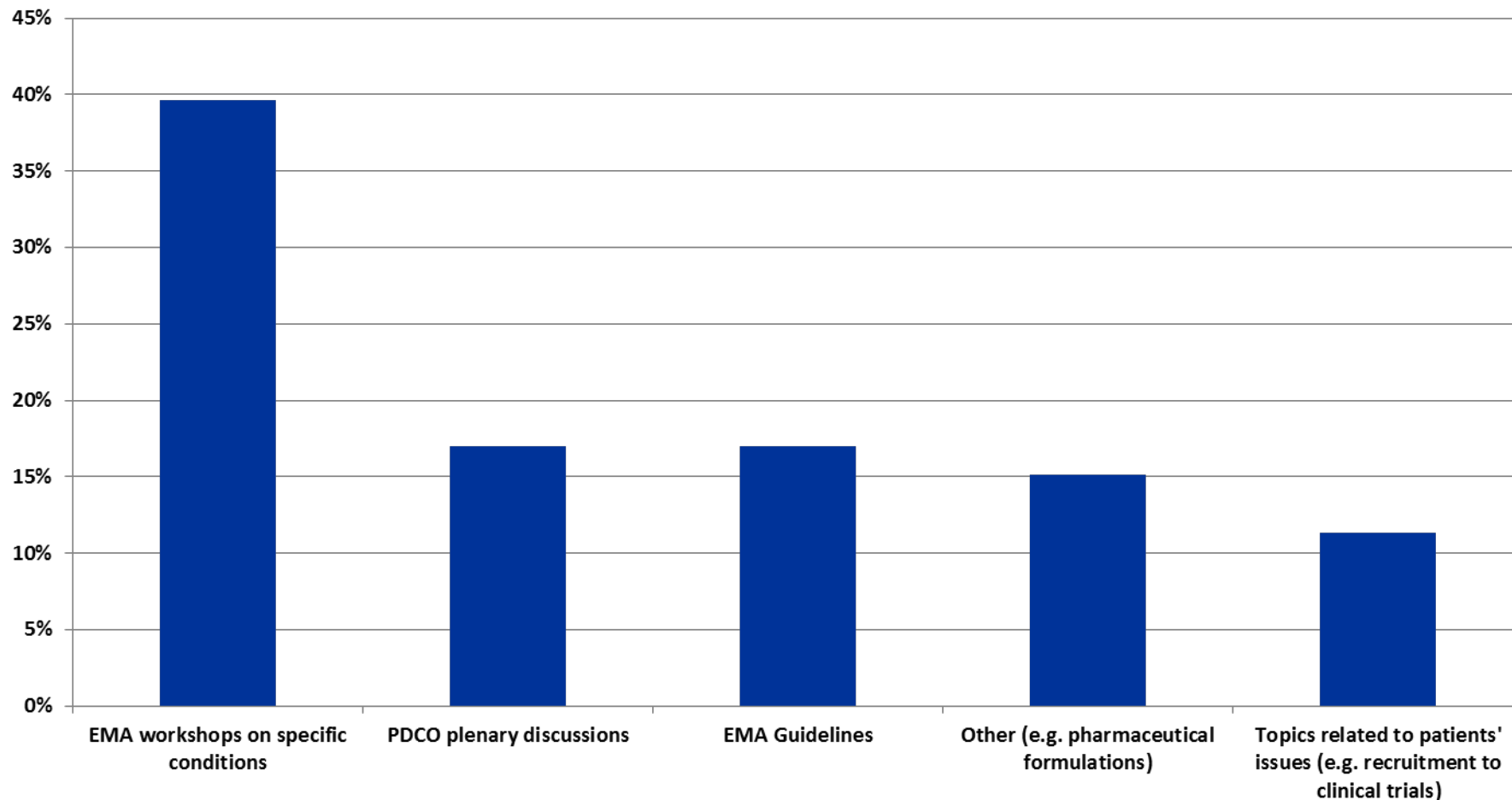
- *"Not the right innovation"*
- *"It is the role of patients' organisations, not children"*
- *"For practical reasons, this is **too difficult**"*
- *"Children are **not interested and don't know about the PDCO**"*
- *"Not a good idea to involve them directly during plenary meeting discussions as they may feel **intimidated**"*

Some advantages

- *"Very good to have an established working group to **refer questions to if PDCO needs to**"*
- *"To identify their disease burden, **their experience of current treatment**, and how new treatments would create additional benefits"*
- *"To identify the acceptance of certain measures to be taken during the clinical trial"*
- *"Different groups of children depending on the topic discussed"*



For which **specific situations** would you see a benefit to involve children and/or adolescents in the activities of the PDCO?





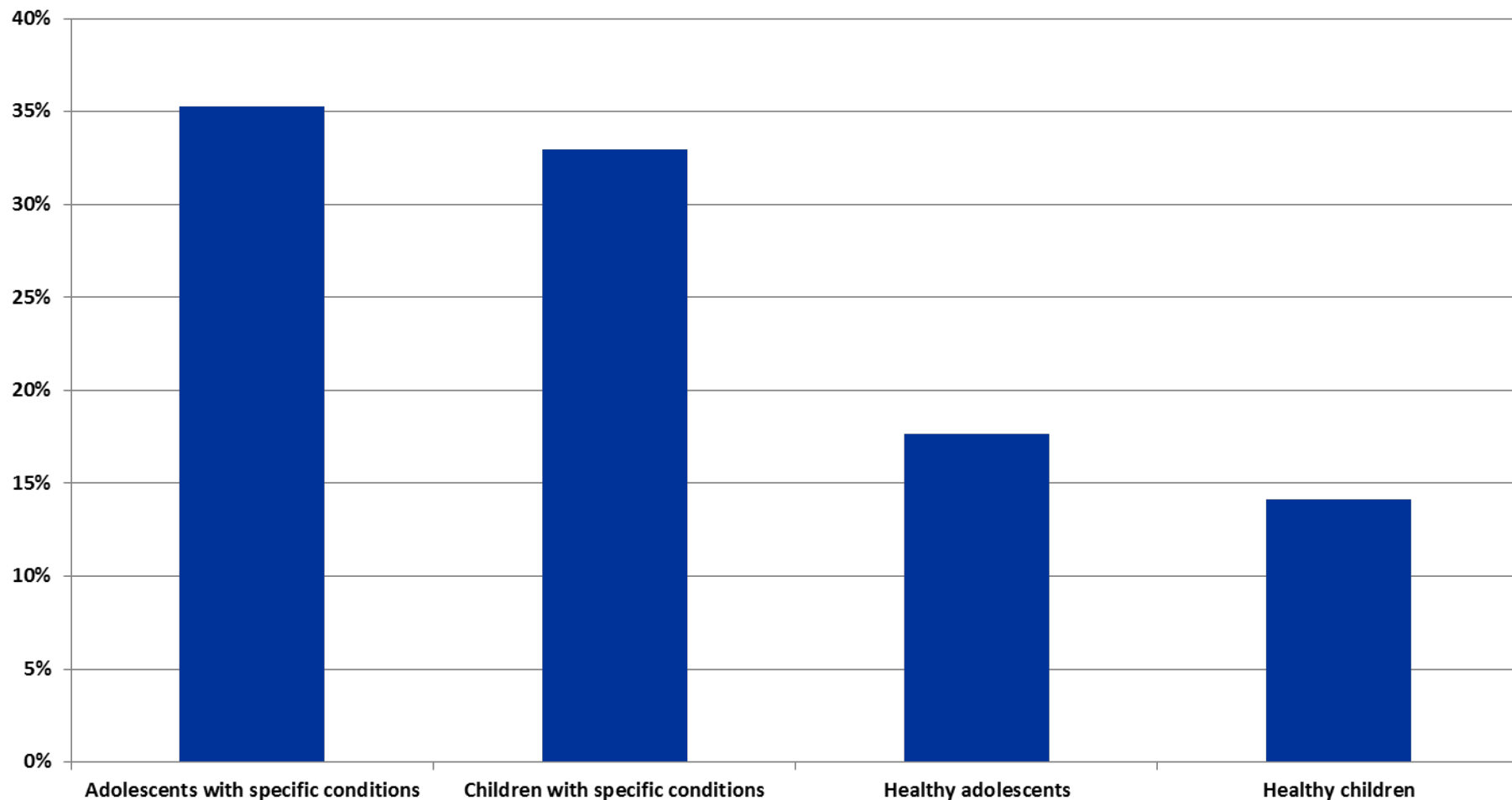
Relevant added comments linked to the involvement of children

Members' comments:

- “Need for **clearly defined questions** for the children who are participating”.
- “Make the children **active participants and not ‘subjects’** in clinical trials”.
- “Established groups of children that PDCO can ask trials-specific questions”.
- “Topic-driven focus groups rather than on specific products or procedures. Topics should focus on the burden of therapy, rather than the burden of the disease, which we have no direct control over”.



What should be the target paediatric population?





How often should children or adolescents be involved?

Trend response: *On a **limited basis** and on specific questions.*

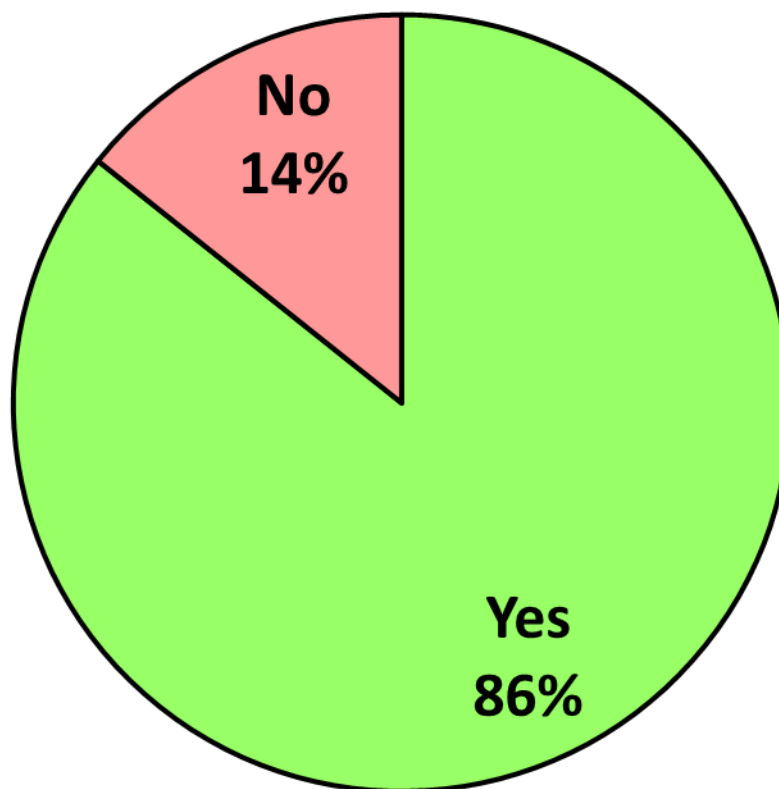
- *“Approximately **twice yearly** according to **school holiday time**”*
- *“Children and young people have a lot to give to the PDCO”*
- *“Prepare the meeting with the National representative”*



Involvement of parents along with children in the activities of the PDCO

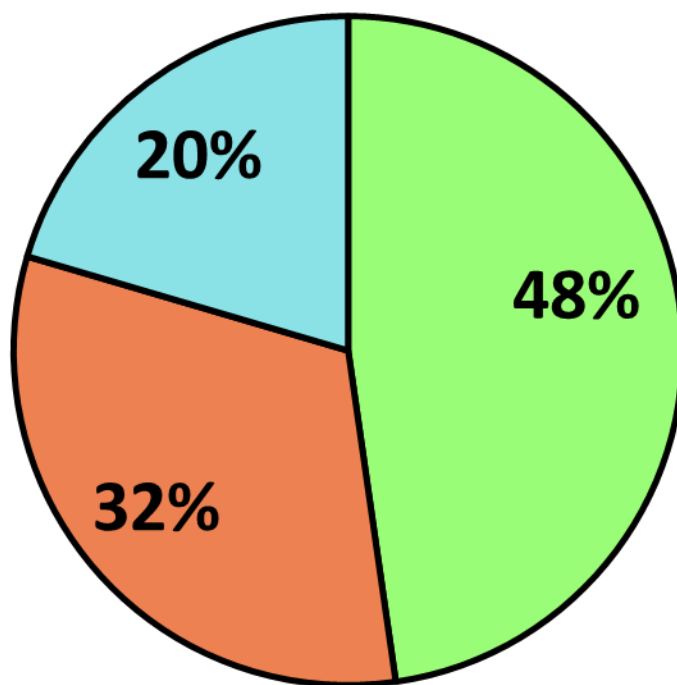


Do you see a need to involve, along with children and/or adolescents, **parents, carers or legal representatives in the activities of the PDCO?**





What would be the most appropriate way to involve children and/or adolescents (and parents/carers/legal representatives)?

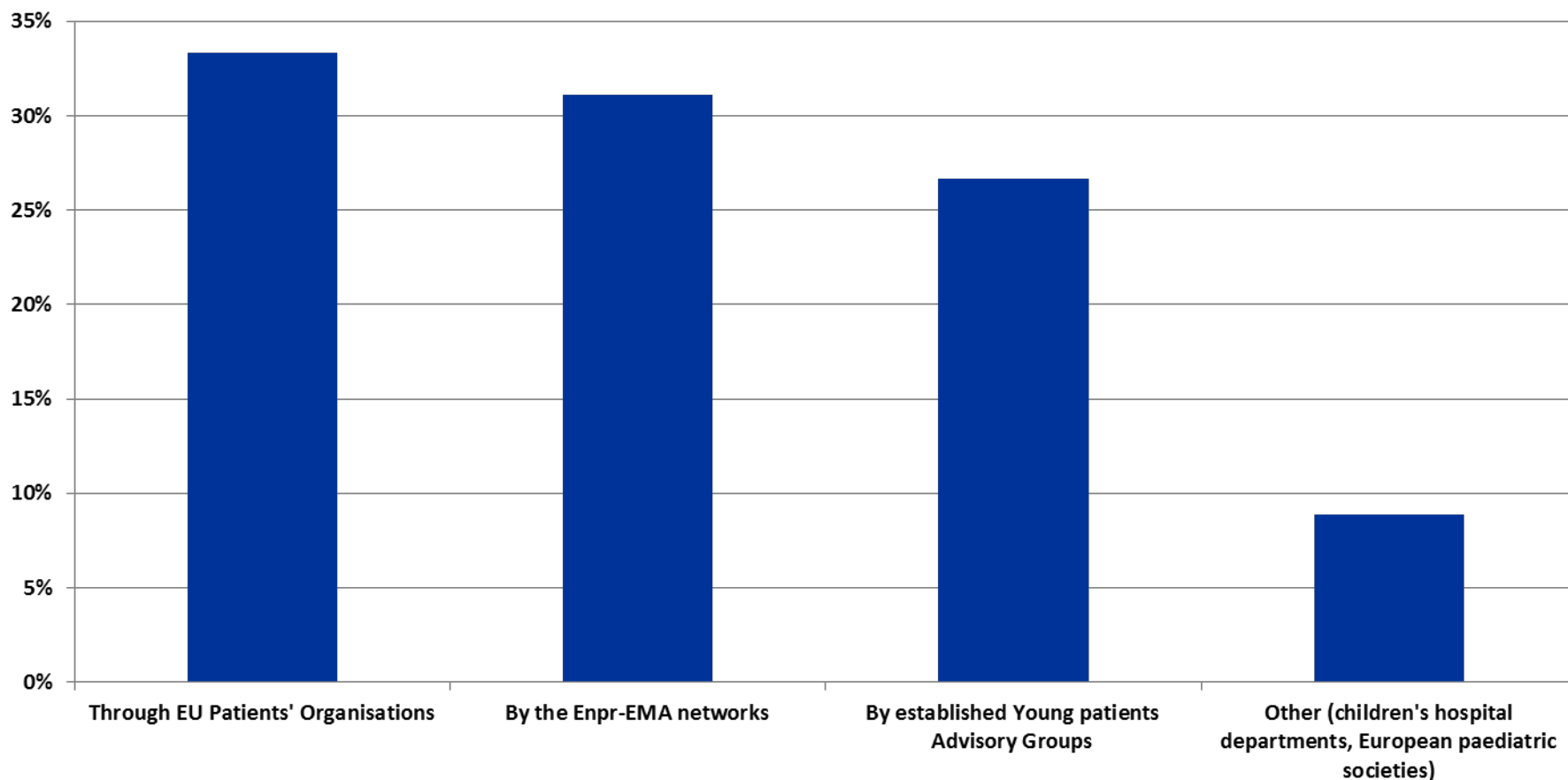


- Direct participation in the PDCO plenary meetings (in person or via TC) 48%
- Written comments and/or oral discussion on specific topics between PDCO plenary meetings 32%
- Other (focus groups, workshops, social media) 20%



How could the access to children and/or adolescents (and parents/carers/legal representatives) be facilitated in each Member State?

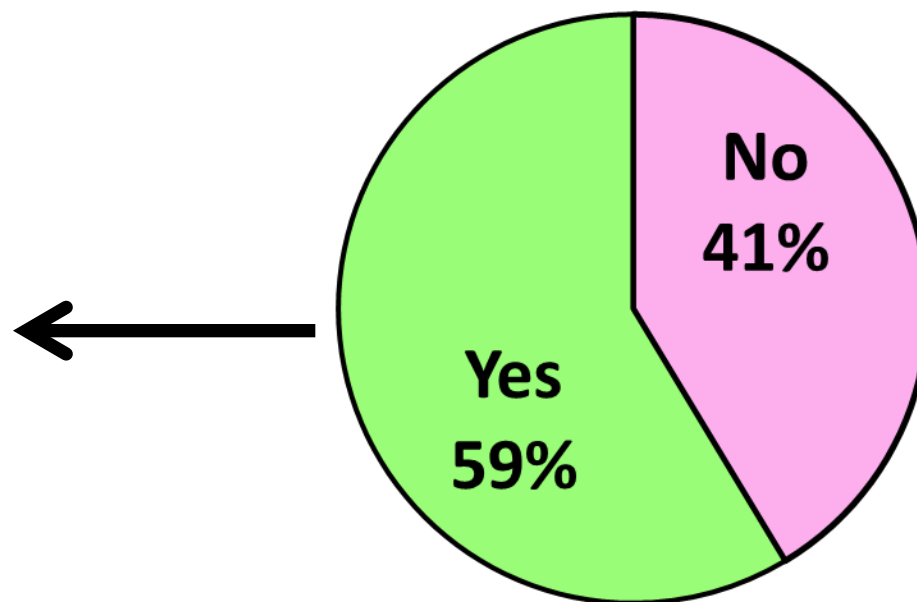
State?





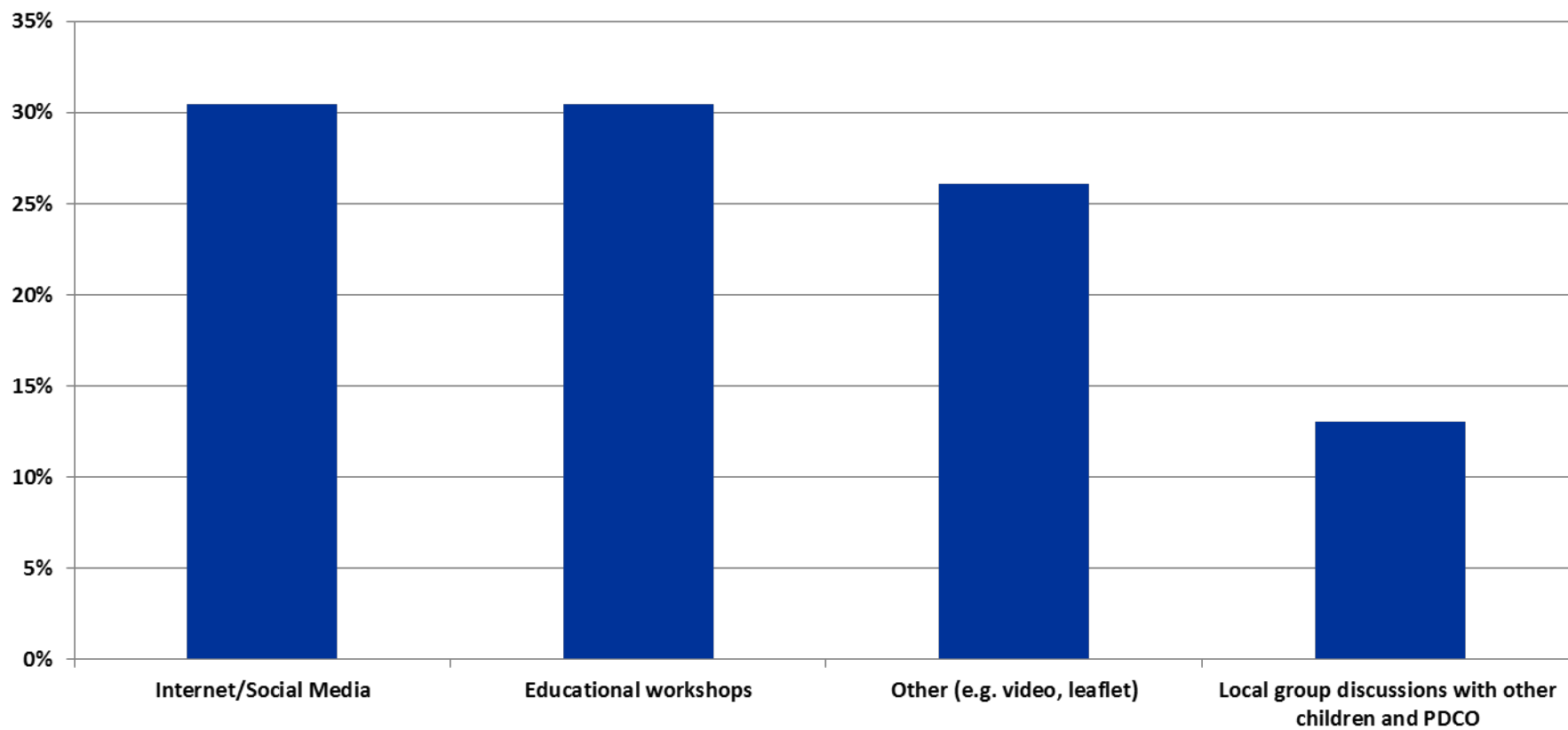
Do you/your organisation have **access to children** and or adolescents (and parents/carers/ legal representatives) potentially keen and suitable to be involved in the PDCO activities?

- Via hospital
- National or local patient organisations





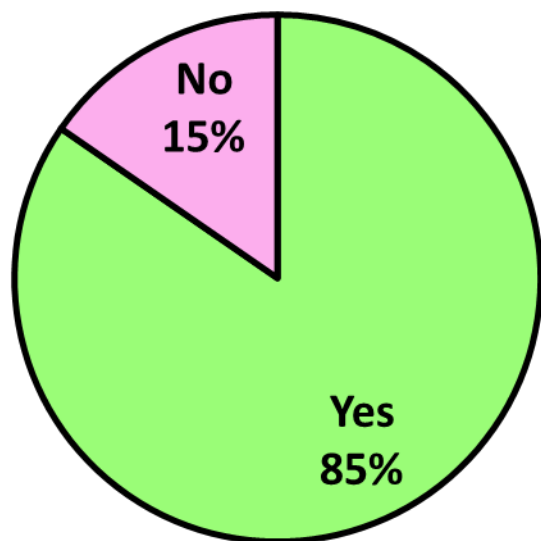
How could keen children and/or adolescents (and parents/carers/legal representatives) be **best trained /informed** so as to be prepared for their involvement in the PDCO activities?





Do you think it may be beneficial to set up a **small PDCO Working Group** whose primary role would be to further define the scope and specific objectives of the involvement of children and/or adolescents (and parents/carers/legal representatives) in the activities of the PDCO?

Beneficial Yes/No



→ **If yes, would you like to be a member of this group?**

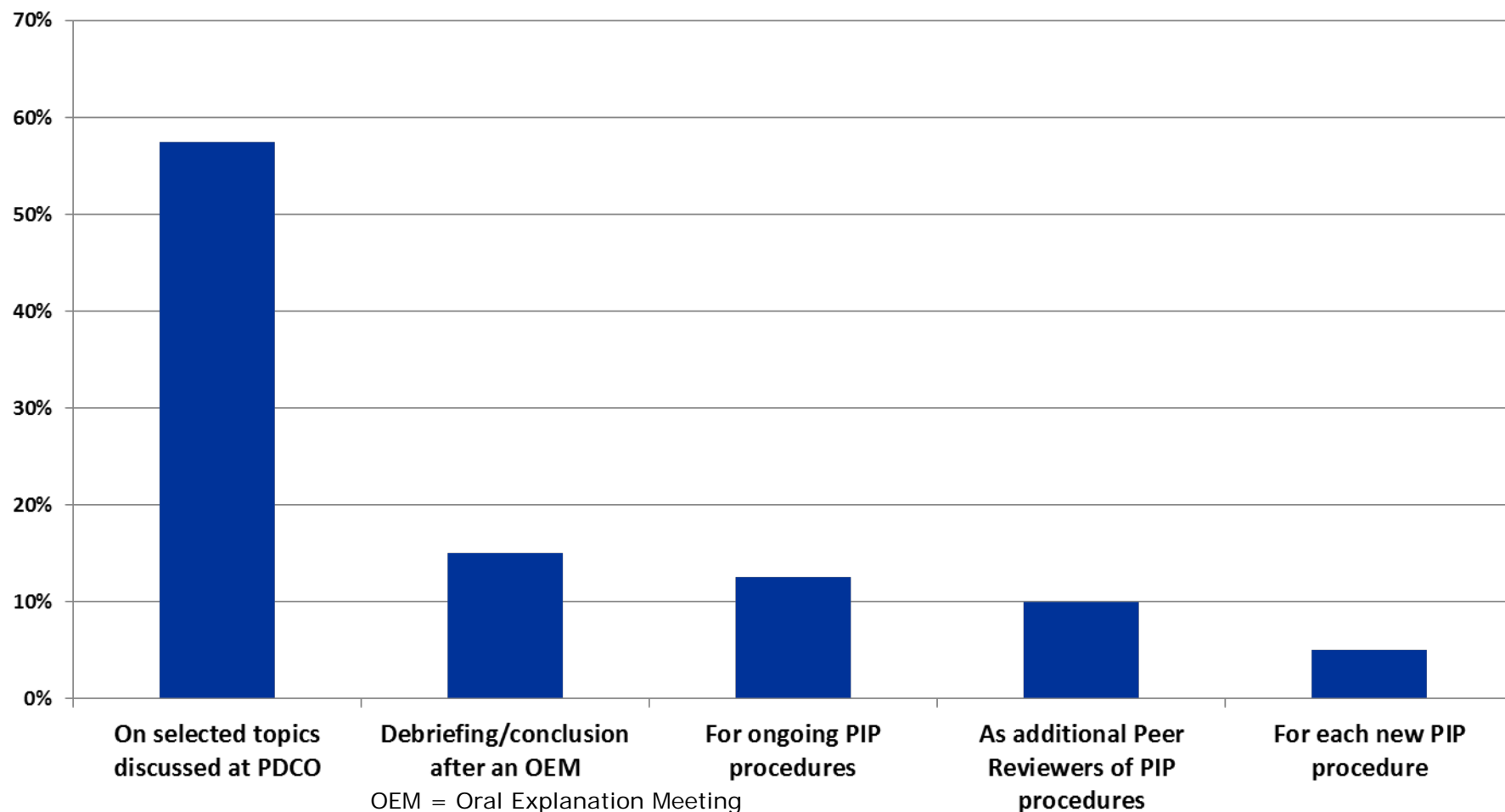
60% (13 responders) wish to become members of the WG



Strengthening the participation of patients' organisations in the activities of the PDCO

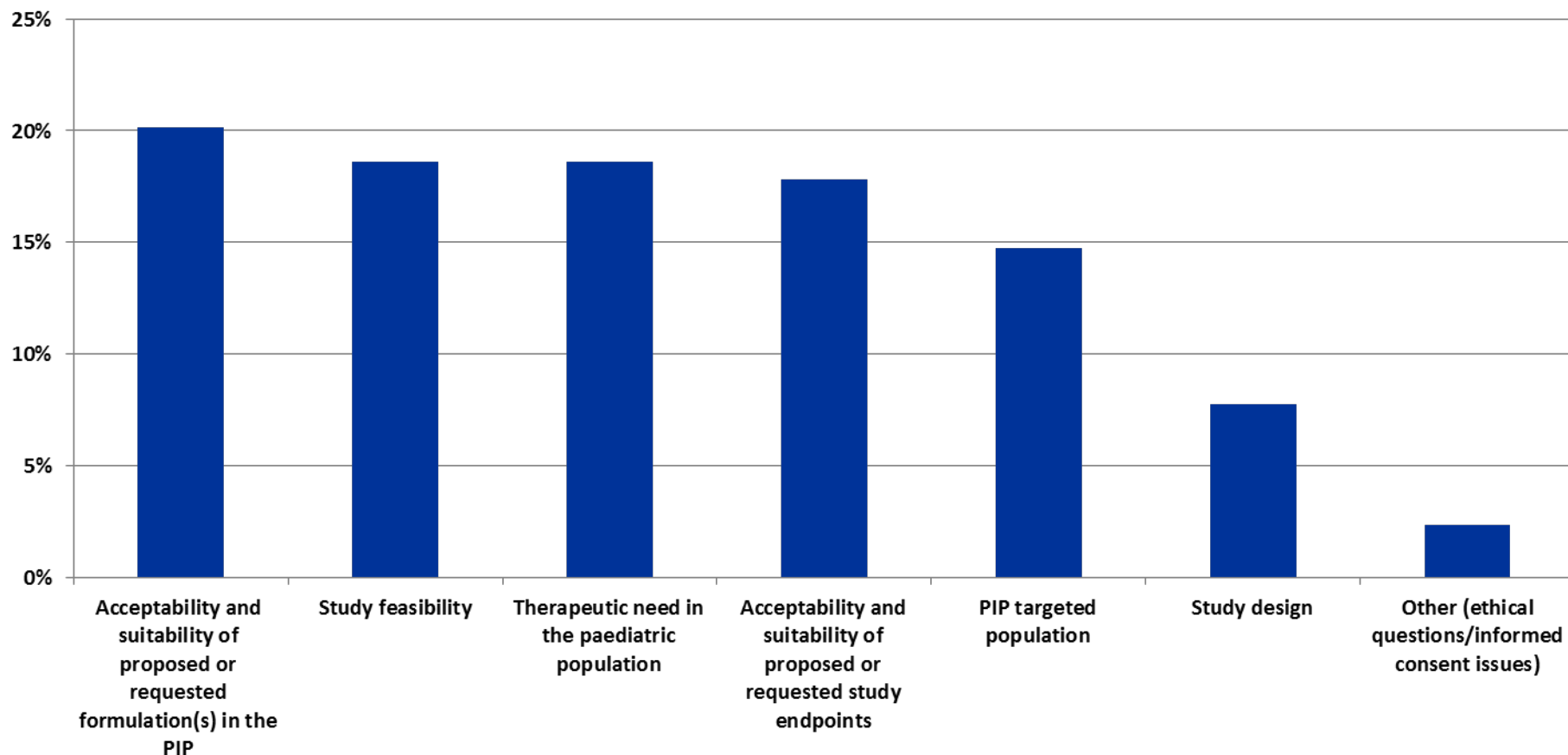


What do you think a **systematic feedback from patients' organisations** would be required for?





What would be the **issues** the members representing patients' organisations attending the PDCO could provide **systematic input on?**





Challenges for involving children and adolescents in the PDCO activities

- **Language barrier** (issue with non-English speaking children);
- Need for **adapted training** and adjusted terminology so that information can be easily understood by children and adolescents;
- Unknown access to pool of patients in some EU countries;
- Need to define **clear and specific questions** to children and adolescents;
- Travel to EMA if participation in person / Avoid missing school;
- Priority in terms of **therapeutic areas** to be looked at first (high variation in responses among PDCO members).



Next steps

- To set up a **small PDCO WG** to better define the scope and objectives of the involvement of children/adolescents and their parents/carers or legal representatives;
- To circulate **questionnaires** to children on views in taking medicines and views in taking part in clinical trials in Q1 2015;
- To raise awareness on the **need for clinical trials in children**, and develop better information and communication on clinical trials to increase children participation (? create a video or leaflet);
- To set up, via Enpr-EMA, a **virtual EU network/platform** of young people to input into the design and delivery of research in children.



Any questions ?