ICAN
International Children's Advisory Network

eYPAGnet
European Young Persons' Advisory Group Network

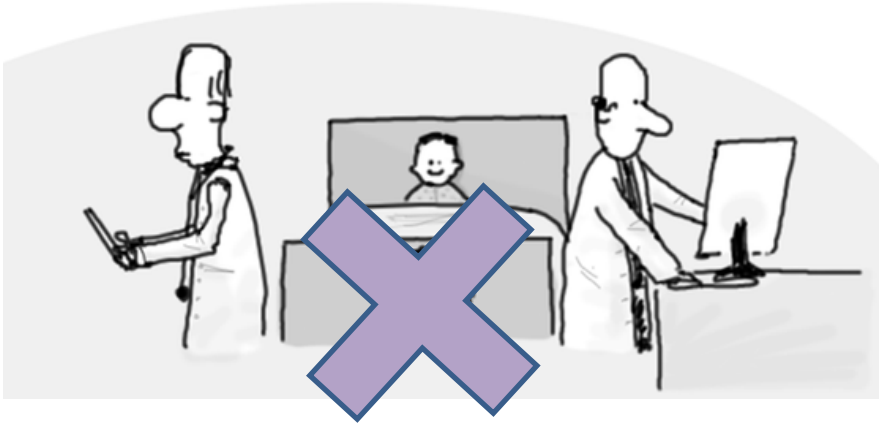
Interaction and cooperation between the EU and US on global paediatric research

Young persons' perspective: ICAN's experience

Health problems affect the entire population, only from a global vision can research advance

Stakeholders involved…

- Regulators: FDA and EMA
- Pharma Companies: worldwide pediatric clinical trials
- Academia and health care research centers: cross collaboration without borders
- Patients' organizations & YPAG: global network



FDA-EMA seeking alignment

EMA and FDA reinforce collaboration on patient engagement

News

22/06/2016

EMA and FDA reinforce collaboration on patient engagement

New working group established to exchange best practices

The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) have set up a new 'cluster' on patient engagement. The cluster will provide a forum to share experiences and best practices on the way the two agencies involve patients in development, evaluation and post-authorisation activities related to medicines.

FDA-EMA seeking alignment

- **New cluster between EMA and FDA** to:
  - Exchange information on how they engage and involve patients in their work
  - Define priorities and goals to scale up future engagement with patients
- **Areas of discussion** will include:
  - processes for selecting and preparing patients to take part in the agencies' activities,
  - how to ensure that patients are independent and representative
  - how to report on the impact of patient involvement
  - How to engage and include the young patients' participation

International Children's Advisory Network

- **Worldwide consortium**
- To provide a **voice for children** and families in health, medicine, research, and innovation through synergy, communication and collaboration
- Our goal is to educate the world about **children's involvement** in the development of **research and clinical trials**
- Opportunities to **provide their feedback** and input into studies and products intended for children
- **Single point of contact**

ICAN: a Growing Network

Europe

- KIDS Barcelona
- KIDS France
- YPAG Birmingham
- YPAG Bristol
- YPAG Liverpool
- YPAG London
- YPAG Nottingham
- YPG Scotland

North America

- KidsCan
- KIDS Central Ohio
- KIDS Connecticut
- KIDS Florida
- KIDS Georgia
- KIDS Houston
- KIDS Illinois
- KIDS Kansas City
- KIDS Michigan
- KIDS Childhood Cancer

Asia Pacific

- Sydney
- Japan

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www.icanresearch.org

Shared experiences US-EU: ICAN Summit

An invaluable opportunity to **learn** from one another and **network** with professionals from across the globe, while allowing the scientific community to **engage** with children and young people and learn about the value and the significant importance of the influence of children and young people on research, medicine, and innovation.

2015 Washington DC

2016 Barcelona

Shared experiences US-EU: ICAN Summit

One example: a health literacy approach to developing assent templates for pediatric studies

US-EU English native groups

Background

- Research on informed consent has shown that **many clinical trial participants do not fully understand what they are agreeing to when signing informed consent** documents.
- Creating assent forms and processes that are **comprehensible for children** is even more challenging.
- As this demographic has significant **limitations regarding literacy and health literacy.**

Goal

- One assent template for younger children ages 7–11.
- The second assent template for older children ages 12–16.

Methods

- **Writing** the original Child Assent Templates (Lilly)
- **Assessing** the original Child Assent Templates
- **Revising** the documents (within perceived IRB constraints) for improved health literacy (HRA and Lilly)
- **Assessing** the revised documents via:
  - Usability tests (qualitative scripted and structured interviews) of 6 healthy children to identify areas of confusion (HRA)
  - Focus group feedback from **3 youth advisory groups** (iCAN)
- **Revising** the document based on usability tests and youth advisory group feedback (HRA and Lilly)
- **Assessing** the final documents using the SAM (HRA)
- **Providing recommendations** for improving Child Assent Templates from a health literacy perspective (HRA)

Results: older child

OLDER CHILD ASSENT FORM

Study Alias:	XXX-XX-XXXX	Age Covered:	XX to XX Years

[Instructions: Update the study alias and the ages covered by the assent above. It is acceptable to add the sponsor and/or investigator name to the table above. Add study alias and version date to footer. Delete first page.]

Information and Assent Form for Minors

You might not know what some of these words mean. Please ask the study doctor or the study staff to explain any words or information that do not make sense to you. You may take home a copy of this assent form to think about or discuss with family or friends before making your decision.

Will you be a part of this research study?

We are asking you and about [number of subjects] other children to be in our research study. This study will help us learn more about a study drug called [insert name of study drug]. [insert name of study drug] that is being tested to find out if it helps children who have a medical condition called [insert name of condition]. The study drug is also being tested to find out what other effects, sometimes called "side effects," this drug might have for the children who take it.

Children who have [insert name of condition] often have [description of symptoms]. We are asking you to be a part of this study because your doctor has determined you have [insert name of condition].

In order to be a part of this study, you and your parent (or legal guardian) must listen to someone from your doctor's office explain the information about this study, and you should ask any questions that you have. Then, in order for you to start the study, your parent or your legal guardian must agree, in writing, that you will take part. Also, if you agree to take part, you must sign this form at the end to show that you want to be in the study. If you decide to take part in this study, and then change your mind, you may choose to stop at any time.

Do you need to be in this study to be treated?

Being in this study is your choice and the choice of your parent or guardian. You do not have to be in this study to be treated for your medical condition. There are other ways of treating your condition that your doctor can tell you about.

The Verina Research Study

This booklet will tell you about a research study on Verina, a medicine to treat your condition. You and your parents might decide to be part of this study. This booklet will help you decide.

Why should I read this booklet?

This booklet explains what a study is, and what it will be like to be in the study. If you want to take part, you can sign the form at the end of this booklet or just say yes. Your parents will also sign a form that says they consent to you being in the study.

You can change your mind.

If you choose to be in this study, you can always change your mind later. This means you can stop being in the study at any time. You do not have to be in the study at all if you do not want to.

What will this research study do?

This study will help us learn more about a medicine called Verina. We are testing this medicine to find out if it helps children who have cancer. We also want to find out if this medicine causes any unwanted reactions. Unwanted reactions are usually called side effects.

Who will this study help?

Will it help me?

Taking part in the study could make you feel better. It also could make you feel worse, or the same.

Will it help other kids?

The study might help other young people. If this study shows that the study medicine works and is safe to use, then more children may be able to take it.

Ask questions.

Before you decide, you can ask us anything you want. For example, if there is a word you do not know, you can ask what it means. You can also ask about how you might feel during the study.

Older template

New template

Results: younger child

The doctor has told you that you are sick and you have an illness called XXXX.

We are asking if you will let us look at you to see if this medicine called XXXX will help you.

We want to learn more about this medicine. We also want to know if it can help other children with XXXXX too.

Children with XXXX (**Instructions:** Insert a simple explanation of the disease issues; an example for ADHD, "*a hard time sitting still and doing their school work.*")

Script

Both doctors then told Hannah and Michael the same thing. They said:

"You don't have to say yes. And no one, including your parents, will be upset if you say no. And if you do say yes, you can stop at any time.

So do you want to be in the study? If so, you can sign your name or just say yes."

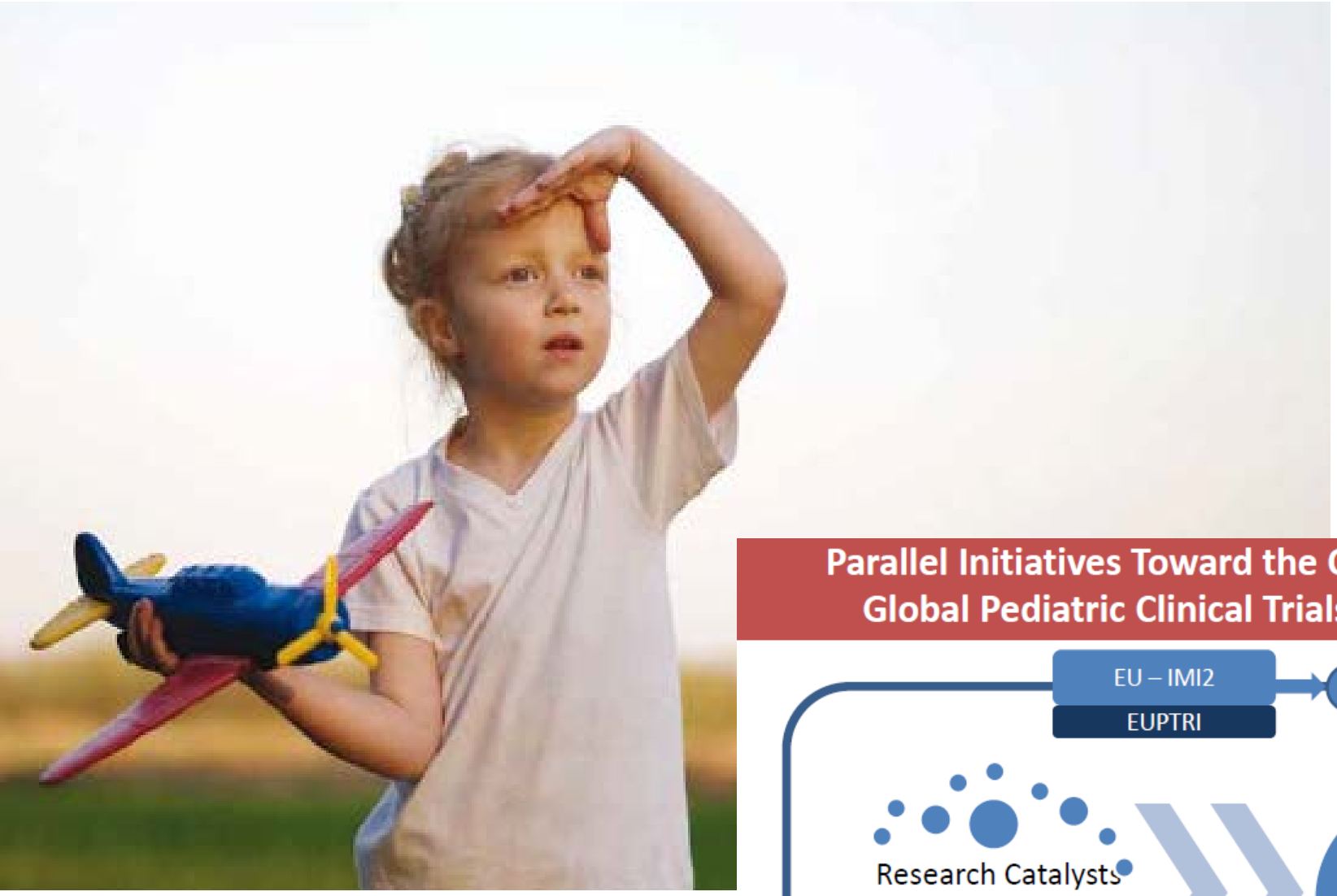
You can swipe the screen now.

11

EU characteristics

- 24 official languages
- Specific Regulation at EU level and in the 28 member countries
- European projects with funds limited to EU
- Different stakeholders: different framework
- Need for a EU point of contact

European Young Person's advisory Group-eYPAGnet
https://www.icanresearch.org/chapters/eypagnet/



Parallel Initiatives Toward the Creation of a Global Pediatric Clinical Trials Network