

Young Person's Advisory Groups enhancing clinical trials

Begonya Nafria

Sant Joan de Déu Children's Hospital (Spain)

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Our mission

Contribute to the process to ensure the **paediatric patient-centricity** of any medicine or medical devices addressed to the children and young people.

Facilitate the **involvement** of young people and families with an **ethical approach** that will guarantee their rights in the health field.



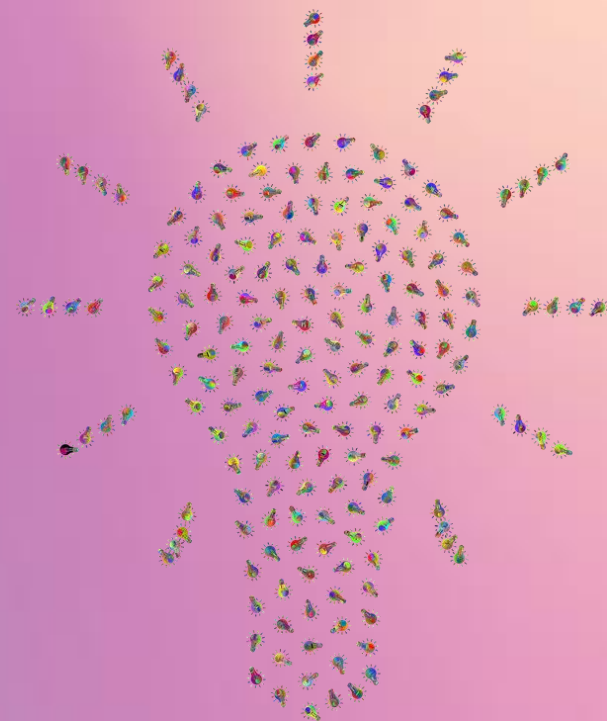
The 4 Qs

✓ WHY?

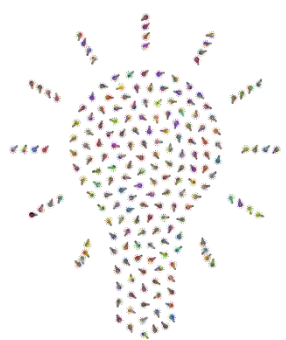
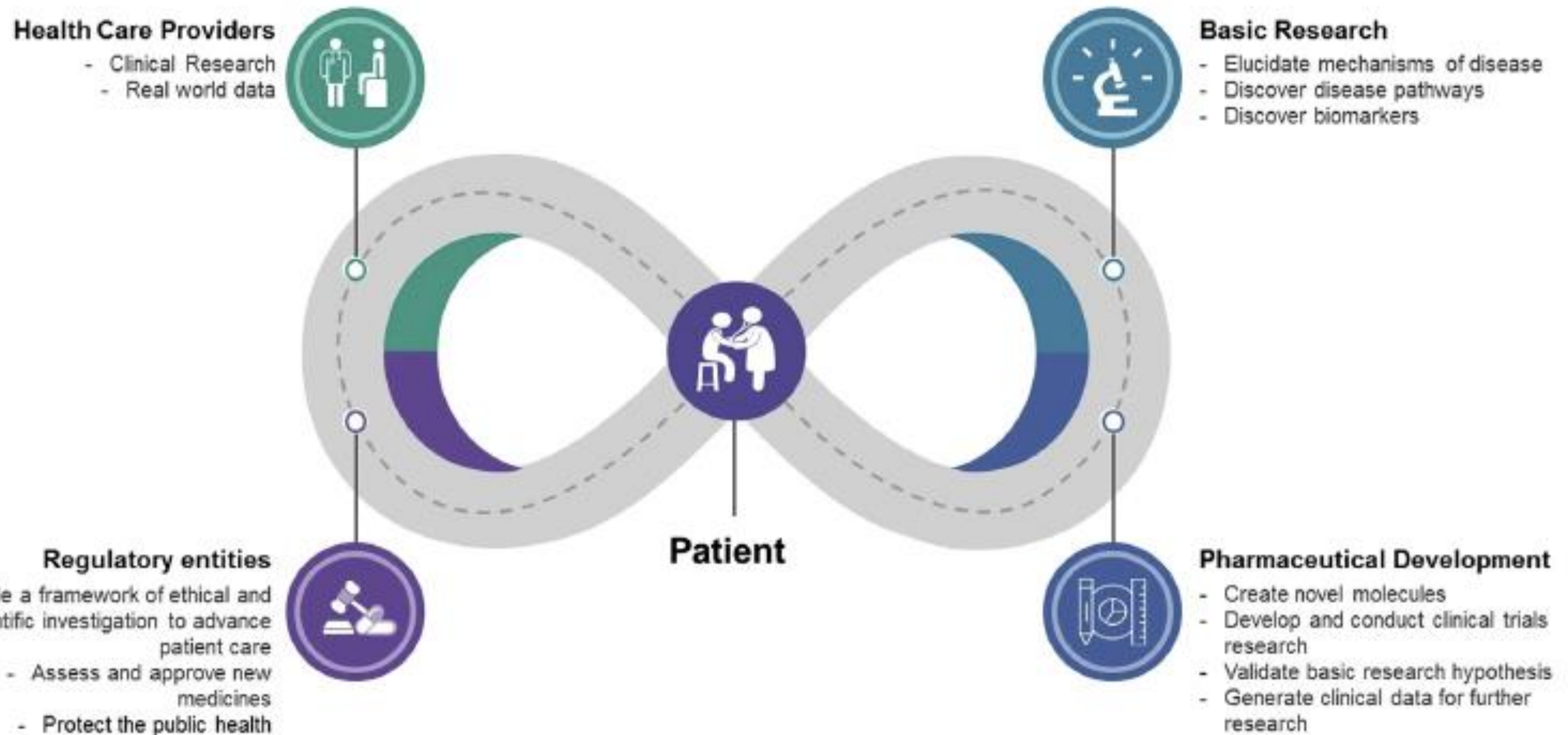
✓ WHO?

✓ WHEN?

✓ HOW?



✓ WHY?



The 4 Qs

✓ WHY?

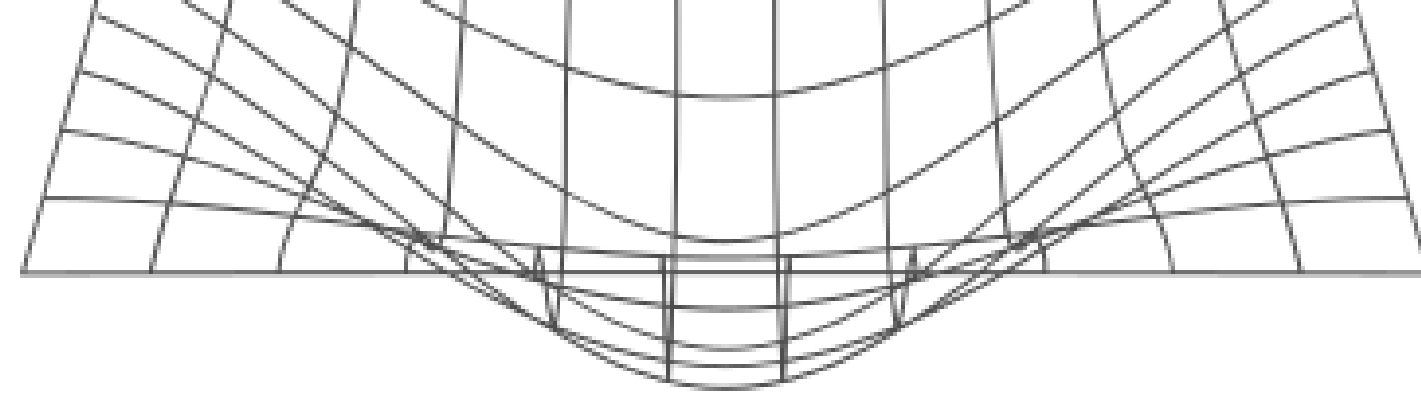
✓ WHO?

✓ WHEN?

✓ HOW?

- Young patients
- Parents
- Young Person's Advisory Groups
- National and international perspective





KIDS BARCELONA

KIDS
BARCELONA

Kids Barcelona ▾ Clinical trials ▾ News and agenda Schools

Kids Barcelona
Young person's advisory group

[LEARN THE INITIATIVE](#)



Clinical trials



What is a clinical trial?

From 8 to 12 years old



Why are clinical trials needed?

From 13 to 18 years old



Why are clinical trials necessary in children?

From 8 to 12 years old

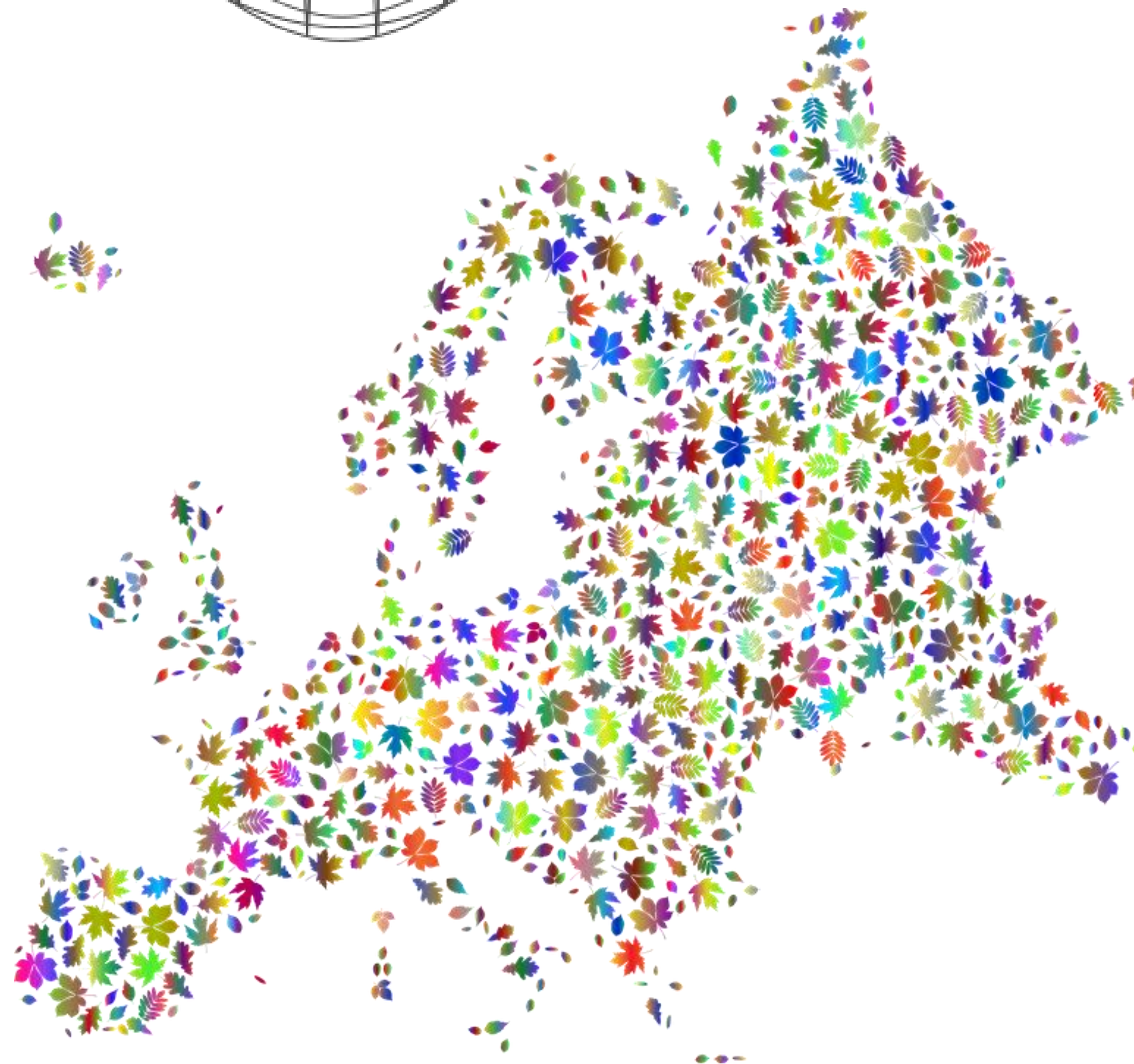
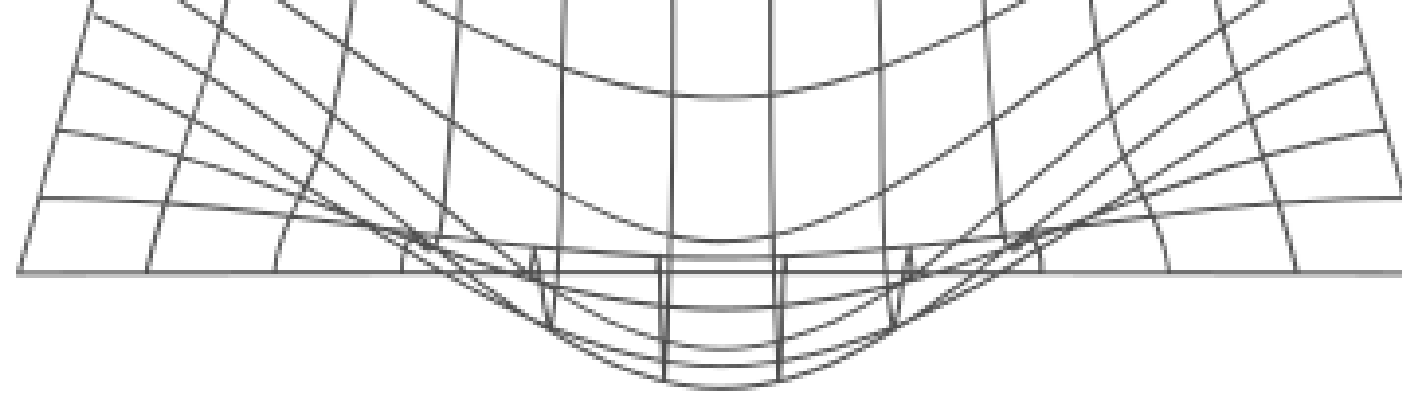


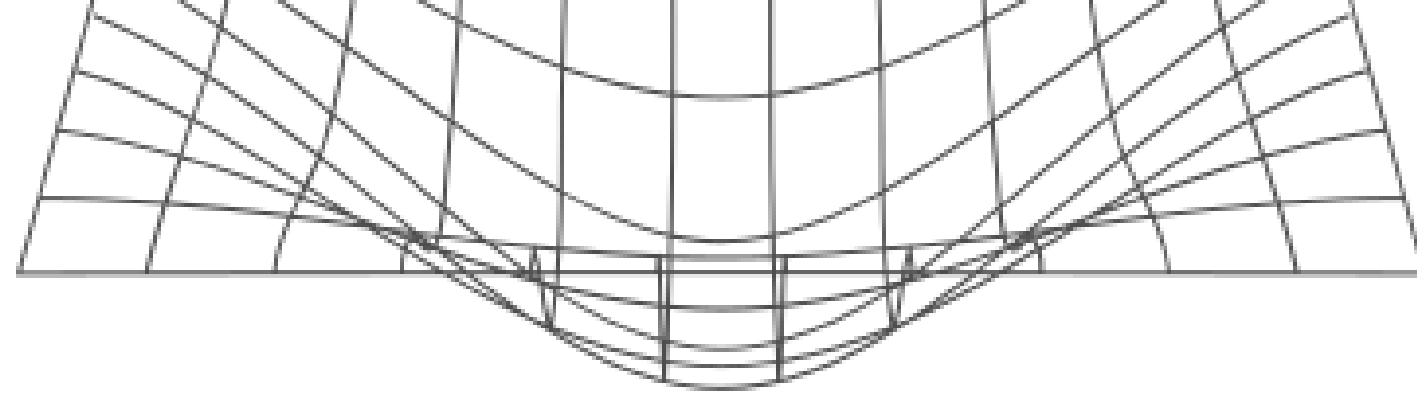
Where can you find information about current clinical trials?

eYPAGnet

**+ 30
YPAGs
across
Europe**

- Belgium
- Czech Republic
- Denmark
- Finland
- France
- Ireland
- Italy
- Netherlands
- Poland
- Portugal
- Spain
- UK





Ad hoc groups of patients and parents:



- All therapeutic areas in paediatrics and pregnant women
- Some therapeutic areas in adults
- Involving patients from different regions of the world

The 4 Qs

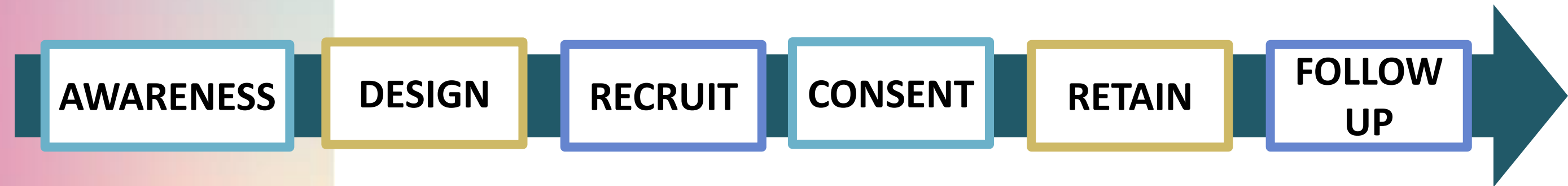
WHY INVOLVE CHILDREN AND YOUNG PEOPLE?

✓ WHY?

✓ WHO?

✓ WHEN?

✓ HOW?



UNMET MEDICAL
NEEDS

REVIEW OF PROTOCOLS

TRIAL STEERING COMMITTEE
DATA & SAFETY MONITORING COMMITTEE

*“Adapt the clinical trial to the patients,
no the patients to the clinical trial”*

✓ WHEN?

Co-design of protocols. Why is important involving patients?



OOPS!

- 57% of protocols can have at least one substantial amendment.
- 45% of these amendments were deemed “avoidable”.
- Phase II and III protocols: mean of 2.2 and 2.3 global amendments.
- Global amendments means longer recruitment time.

Think in terms of patient experience...



Recommendations in terms of feasibility, study visits, schedules of procedures



Involve patients allows think beyond the disease factors:
patient experience



Put the patient in the heart of your project

Benefits of
involving
paediatric
patients

ROE

✓ WHEN?

Co-design of protocols. Why is important involving patients?



**Clinical Trials
Regulation**

#EUPharmaStrategy
#HealthUnion

 European
Commission

- **Assessment of clinical trial applications**
- Article 9.3 *"...At least one layperson shall participate in the assessment..."*
- **Trial design** as described in the **protocol**
- Annex I, Application dossier, Protocol 17 (e) *"...where patients were involved in the design of the clinical trial, a description of their involvement..."*

✓ WHEN?

Lay summaries: patients involvement is required.

European Regulation EU N° 536/2014

- Article 37 requires trial sponsors to submit a “lay summary” that is understandable to laypersons.
- The LS must be submitted to CTIS via the EU Portal no later than 12 months from the protocol-defined end of the clinical trial:
 - 6 months for paediatric studies, and up to 30 months
 - for non-therapeutic Phase 1 trials.

The 4 Qs

✓ WHY?

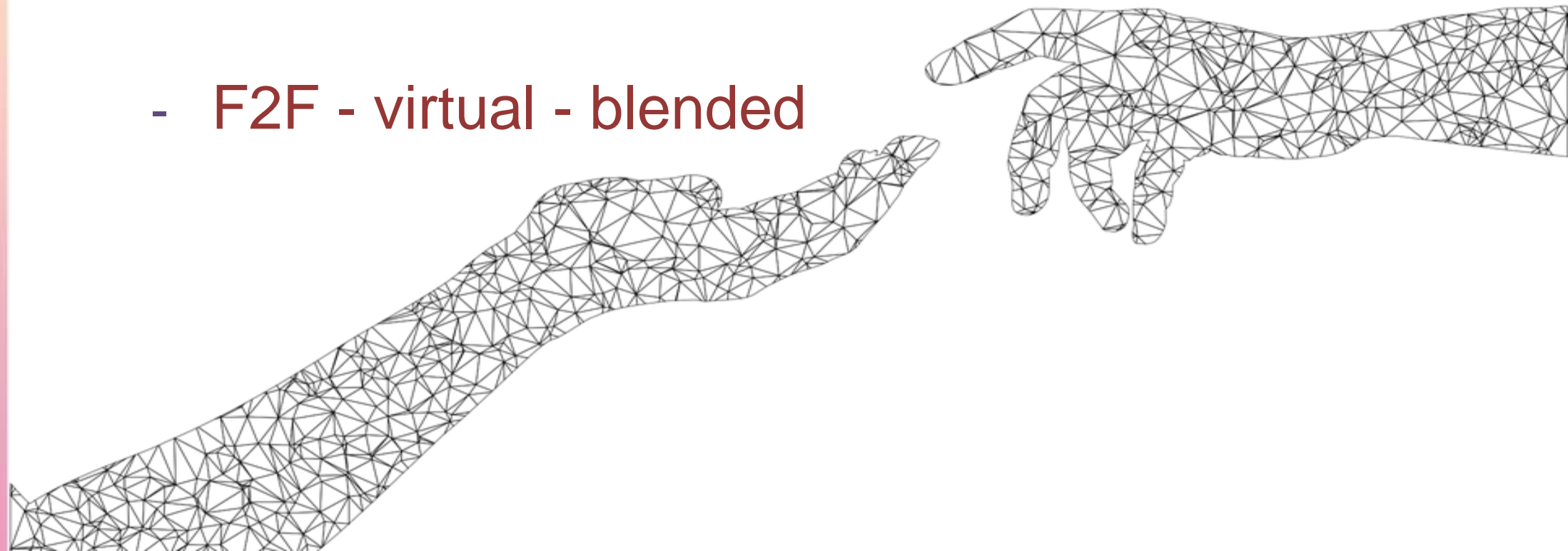
✓ WHO?

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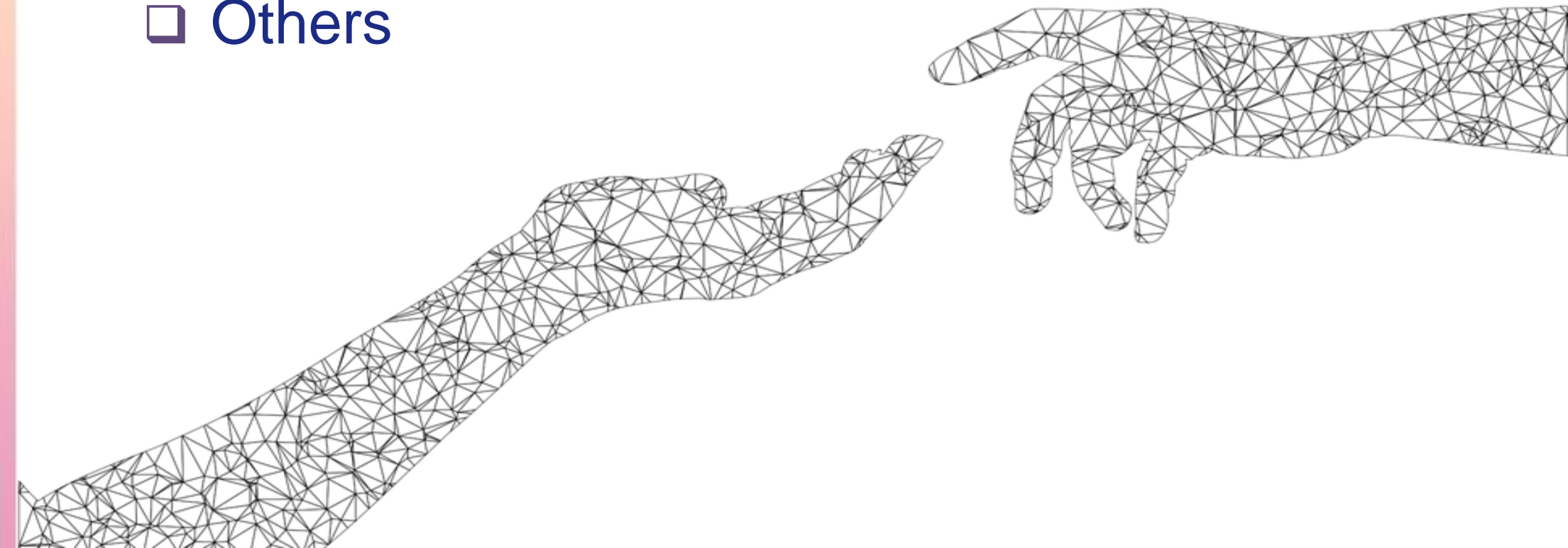
- Focus group
- Questionnaires
- Interviews
- Patient journey
- Advisory boards
- Steering committees
- Simulation

- F2F - virtual - blended



Patients' information and education resources

- Assent form for paediatric patients
- Consent form
- Patient Diary
- Patients training in clinical trials
- Others



More examples

More examples



The screenshot shows the website for 'conect 4children', a collaborative network for European clinical trials for children. The navigation menu includes Home, The Project, Network, Academy, PoV Studies, Patients, News, and Contact. A search bar is located on the right. The main content area features a large image of a young girl with a blue tongue, with the text: 'Better medicines for babies, children and young people through a pan-European clinical trial network'.

conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN
CLINICAL TRIALS FOR CHILDREN

[Home](#) | [The Project](#) | [Network](#) | [Academy](#) | [PoV Studies](#) | [Patients](#) | [News](#) | [Contact](#) |

**Better medicines for babies, children
and young people through
a pan-European clinical trial network**

More examples



The **Young Person Advisory Group** (YPAG), Kids Barcelona, of Sant Joan de Déu Hospital (Barcelona-Spain) has written some guidelines with a collection of recommendations to be considered by the sponsors of the clinical trials (drug companies, researchers, etc.) and for the ethics committees of the research centres, with the aim that the informed **consent document** (or assent document in the case of paediatric patients) be fully adapted to the children's necessities of information.

The **participation** of a child in a clinical trial must be **voluntary**, and for this reason his/her consent is necessary from a certain age.

This is an altruistic act that contributes to the advancement of science in the treatment of a specific disease.

It must also be ensured that the child or young patient knows his/her rights, what will happen during participation in the study and the important contribution of clinical trials for medical science.

Recommendations on the content

- Concise content.
- Use easy to understand vocabulary.
- Include a general explanation of what a clinical trial is.
- Easy understandable explanation of the possible side effects of the drug under study.
- Include a glossary with definitions of the most difficult words to understand.
- Detail the basic contact data of:
 - Principal investigator (PI)
 - Hospital responsible
- Describe what to do in case of emergency, who to connect, how to proceed.
- Audio-visual resources, such as a video or cartoon can make it easier to understand the purpose of the study.

Recommendations on the format

- Length from 2 to 5 pages.
- Font size: between 12 and 14 points.
- Always address the child in the second person singular.
- Do not use the term "subject".
- Use the term "patient" or "boy / girl"
- Use colour, drawings, photos or infographics to facilitate the understanding of the information.

CLINICAL TRIAL GUIDE

A CLINICAL TRIAL GUIDE which can be easily used by children, that can be carried, may facilitate their participation:

- Include a calendar
- A space for taking notes
- A glossary with scientific terms
- With more visual than written content

These recommendations have the approval of the Ethics and Research Committee of Hospital Sant Joan de Déu.



agencia española de
medicamentos y
productos sanitarios

More examples

SJD Sant Joan de Déu
Barcelona - Hospital

LEARNING ABOUT CLINICAL TRIALS

KIDS BARCELONA

WHAT IS A CLINICAL TRIAL? WRITTEN BY MIREIA VIDAL
ART BY GUILLEM ESCRIBÉ

THE FIRST TIME I HEARD ABOUT A CLINICAL TRIAL, I IMAGINED DOCTORS DRESSED UP IN COSTUME FOR THE CHRISTMAS PLAY.

BUT SOMEONE MADE IT CLEAR TO ME THAT IT WASN'T THAT SIMPLE.

A CLINICAL TRIAL STUDIES THE EFFECTS OF NEW DRUGS OR TREATMENTS IN PATIENTS.

TO TRY IT ON THE SICK IS THE ONLY WAY OF KNOWING IF IT WORKS.

THESE TESTS GO BACK TO THE EIGHTEEN TH CENTURY, WHEN DOCTORS STARTED TO CONDUCT THEM, AND ALL OF THE DRUGS WE TAKE NOWADAYS HAVE BEEN PREVIOUSLY TESTED IN A CLINICAL TRIAL.

DON'T THINK YOU PARTICIPATE ALONE. MANY OTHER CHILDREN IN THE WORLD TRY IT AT THE SAME TIME AS YOU DO.

RESEARCHERS HAVE ENSURED THAT ITS ADMINISTRATION IS AS SAFE AS POSSIBLE.

ONLY AFTER A CLINICAL TRIAL HAS DEMONSTRATED THAT THE DRUG WORKS AND IS SAFE, CAN IT BEGIN TO BE SOLD.

AND NO ONE WOULD MAKE YOU TRY IT IF THEY DIDN'T BELIEVE THAT THE NEW DRUG CAN ALSO HELP YOU.

But you haven't taken anything yet.

Maybe with a splash of oil?

It's the spinach. Yuck.

Heyl! Go back to your century!

Buy it! Buy it!

But there is always some risk. That is why it is very important for you to understand very well what is going to happen if you decide to participate in a trial.

BENEFITS AND RISKS IN A CLINICAL TRIAL

EVERYONE EXPECTS THAT THE TREATMENT BEING STUDIED WILL HAVE CERTAIN BENEFITS OR EVEN CURE YOU.

BUT NO ONE CAN ASSURE YOU THAT YOU'LL RECEIVE THE TREATMENT, MAYBE WHAT YOU'RE TAKING IS A PLACEBO.

IT IS POSSIBLE THAT THE NEW DRUG HAS SIDE EFFECTS.

ALTHOUGH THE TRIALS ARE DESIGNED TO HAVE MINIMAL RISK.

THE BEST THING TO DO IS FOR YOU TO MAKE A LIST OF ADVANTAGES AND DISADVANTAGES.

ADVANTAGES: ① You will be contributing to a better medical knowledge of your disease.

DISADVANTAGES: ② THIS MEDICATION MAY HAVE UNKNOWN SIDE EFFECTS, AND IT MAY EVEN WORK LESS THAN THE CURRENT TREATMENT.

IF YOU PARTICIPATE IN THE STUDY, YOU MAY HAVE ACCESS TO A DRUG THAT IS PERHAPS MORE EFFECTIVE.

BUT THERE CAN ALSO BE DISADVANTAGES.

THE DRUG MAY WORK FOR OTHER BUT NOT FOR YOU.

AND I'LL HAVE THE MEDICAL TEAM LOOKING OUT FOR ME AT ALL TIMES.

THEY MAY ALSO ASK YOU TO GO MORE OFTEN TO THE DOCTOR, AND DO MORE TESTS THAN THE USUAL ONES.

YOU MAY NOT EVEN BENEFIT FROM IT.

Do you want to go for a swim?

I can't, I have to go to the hospital.

BUT THERE IS SOMETHING REALLY IMPORTANT THAT YOU'LL ALWAYS BE DOING: CONTRIBUTING TO RESEARCH BY HELPING OTHER CHILDREN LIKE YOU IN THE FUTURE.

HELP

More examples



ALBA
9 años

1 ★ 2 ★ 3 ★ 4 ★

76 BMP SpO2 98 % TEM 36 °C



More examples



More examples

YEAH
Youngsters EngAgement in Health

DESIGNING RESEARCH PROJECTS WITH CHILDREN AND YOUNG CITIZENS

QUALITY OF LIFE AND PROMS

CO-CREATING HEALTH PROTOCOLS WITH YOUNG CITIZENS

RESEARCH INFORMATION FOR YOUNG PATIENTS

eit Health

EIT Health is supported by the EIT, a body of the European Union

The infographic features a central horizontal molecular structure with various icons: a test tube with blue liquid, a DNA helix, a microscope, and a hand cursor. On the left, a scientist in a white coat stands next to a podium with a laptop. On the right, a group of four diverse young people are shown, one holding a smartphone. The background is a gradient of purple and blue with white stars.

More examples



[Development of the standards](#)

[Download the standards](#)

[The Team](#)

[Publications and presentations](#)

[Share your views](#)



Contact



**International rights-based
standards for children having health
care tests, treatments,
investigations or interventions**



Patient involvement: quantitative approach

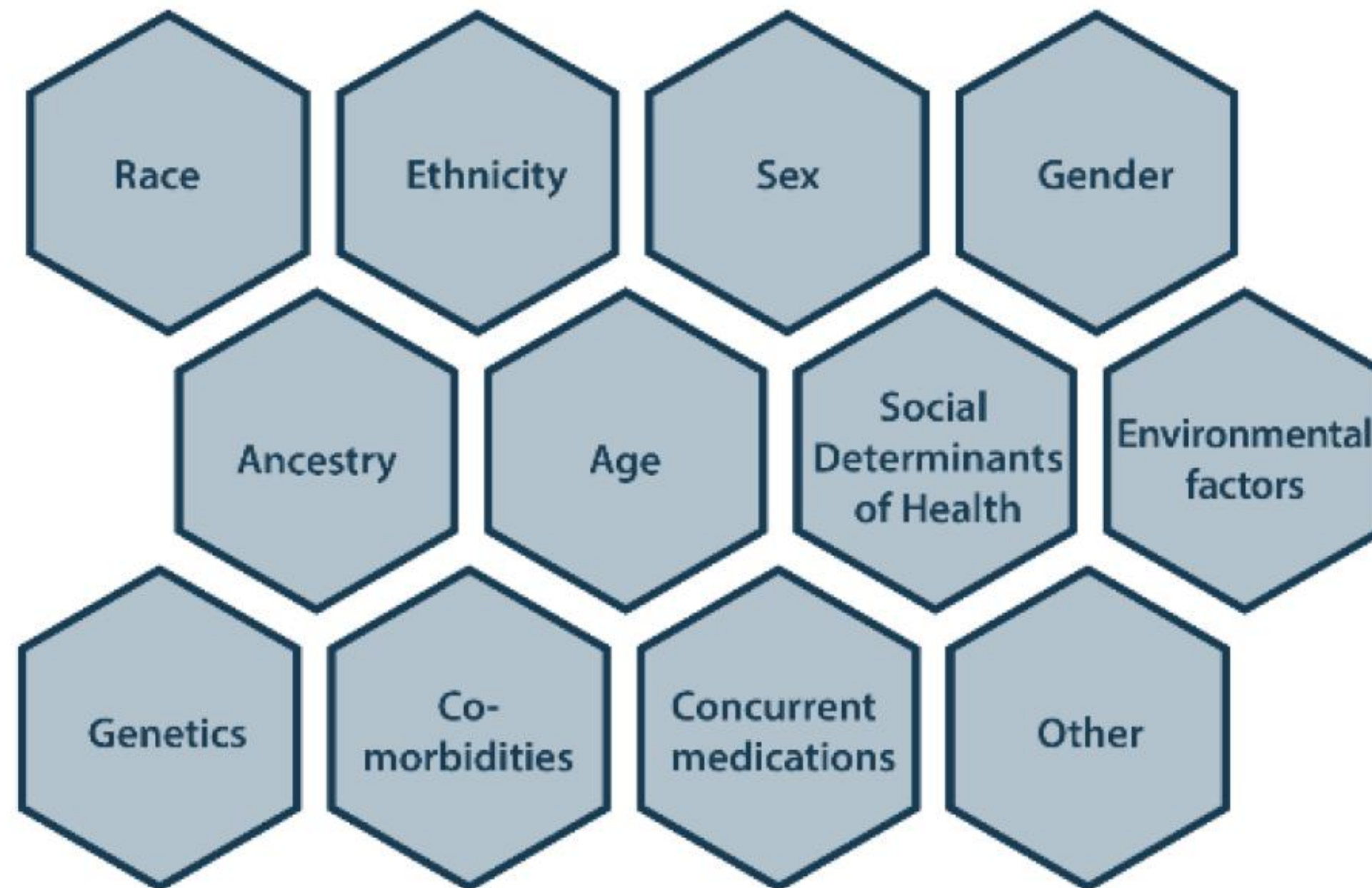


ENPV (Expected Net Present Value)

Benefits of involving paediatric patients

ROI

Importance of diversity



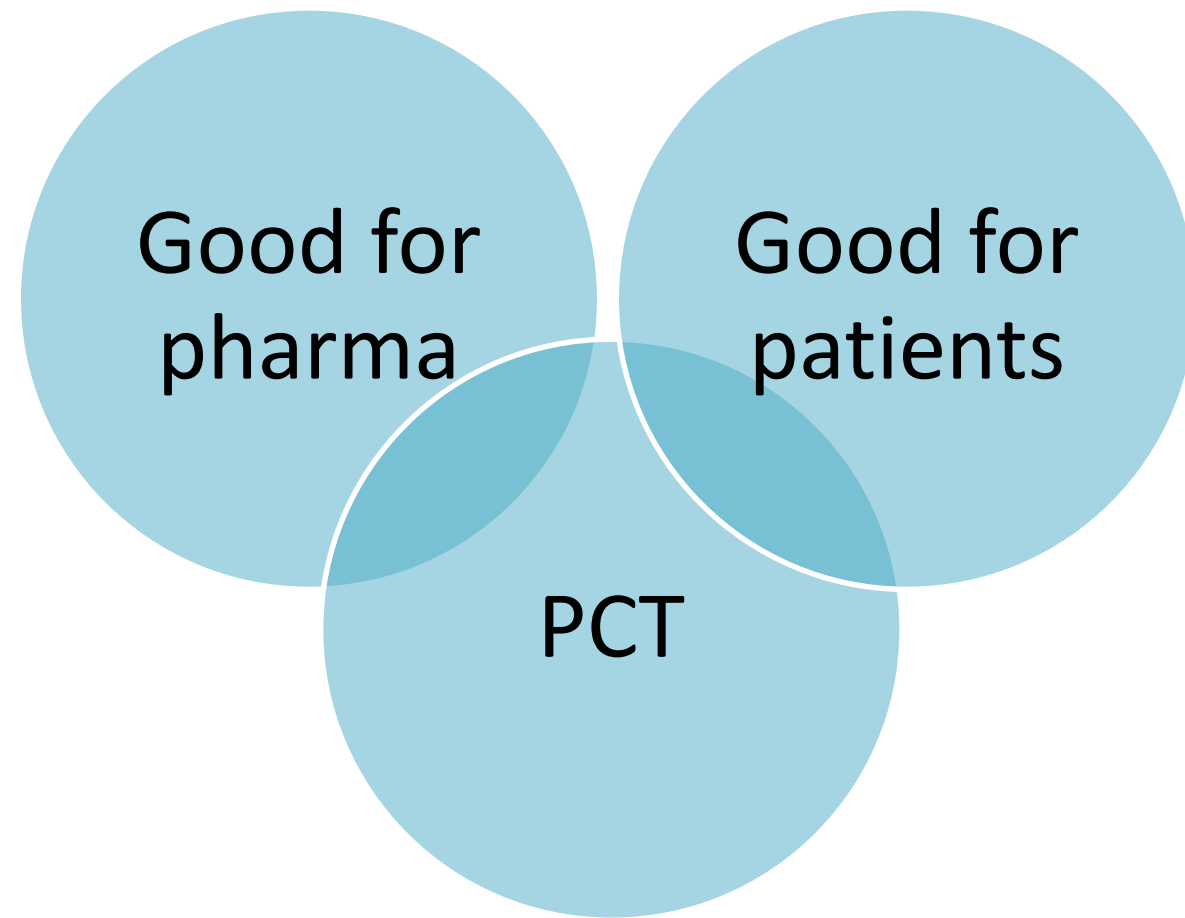
Rigth to Science and Research



Children and young people have the right to **freely express their views** (CRC art. 12), the right to the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health (including **research**).

Convention of the Rights of the Child-
1989 – United Nations

Real value of patients involvement



We spend a lot of time designing the bridge, but not enough time thinking about the people who are crossing it”.

Dr. Singh, Director of System Design at the Earth Institute

Nothing for the patients, without us!

begonya.nafria@sjd.es

