
eYPAGnet
European Young Person's Advisory Groups Network

WHO are we

Begonya Nafria

Joana Claverol

Coordinator - Treasurer

Jennifer Preston

Coordinating Team

Pam Dicks- Segollene Gaillard

European YPAG network

- Recognised by EnprEMA (May 2017) – Category 4
- Presented in the International Children's Advisory Network (ICAN) in Orlando (July 2017)
- Formed by 9 teams from:
    - Barcelona (1) – Sant Joan de Déu Children's Hospital
    - England (5) – NIHR Generation R
    - France (1) - Hospices Civils de Lyon
    - Scotland (1) - Scottish Children's Research Network

WHY eYPAGnet External reasons

- **Specific environment** to regulate the development of new treatments in Europe. Different from FDA or others.
- EMA has established a set of **principles for the involvement of young patients** in their activities.
- Aplication in the call for projects for the **Pan-European Paediatric Clinical Trials Network** (IMI2).
- Increase the collaboration amongst European YPAGs: most of **paediatric clinical trials are international**.
- **Involve young patients along all the life cycle of medicines**. This is the right approach to develop **patient centered research**.

WHY eYPAGnet Internal reasons

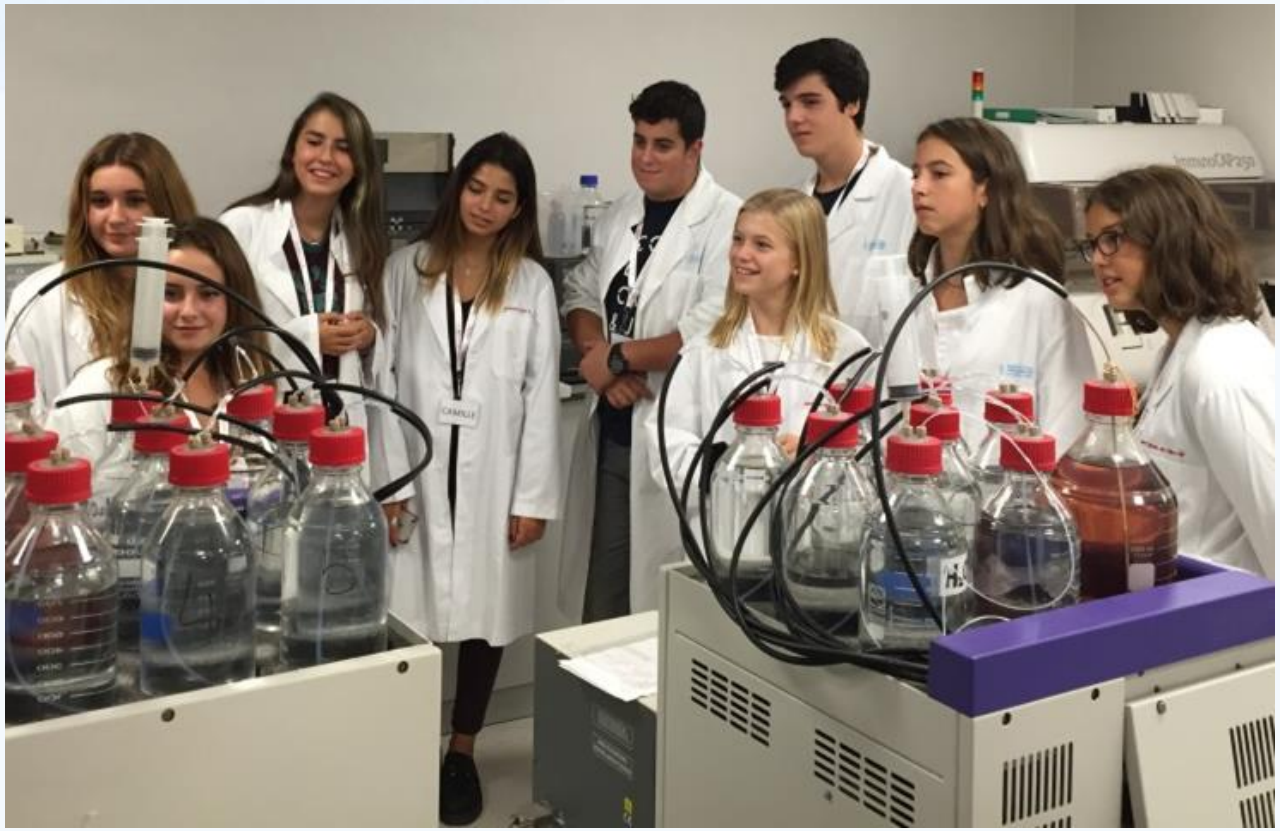
- Improve **collaboration with different stakeholders**.
- **Gather examples of best practice** and **promote research** in the field of young patient advocacy.
- Consolidate the **European curriculum** of capacity-building and empowerment **training programs for young patients**.
- **Europe's ICAN SPC** to promote and lead the creation of new chapters, at European level that can be connected globally, and to coordinate common projects among EU and US & Canada.
- Create a common portfolio of YPAG services addressed to the stakeholders: **Guidelines**.

WHERE are we

Founder team

Team in process

What is the role of a YPAG



Learn about health and clinical research in monthly meetings to educate young advocates

Support and **work** in partnership with researchers in the design and delivery of health research

Provide input and **collaborate** with key stakeholders to promote young people's involvement in research (EMA, national agencies, pharma companies, etc.)

Delivery of paediatric Clinical Trials

Trials opened and completed on time

Recruitment of patients to agreed target

Retention of patients to completion

Trials meet the needs of patients

Issues to increase recruitment/retention with CYP

- ✓ School work –time commitment
- ✓ Conflict between consent and privacy
- ✓ Family dynamics
- ✓ Pregnancy testing
- ✓ Contraception
- ✓ Alcohol/smoking/recreational drugs/legal highs –honesty
- ✓ Self image concerns (side effects)
- ✓ Peers- publicity

- ✓ Technology-texts, apps, wearable, social media
- ✓ Un-blinding via social media
- ✓ Transfer to adult service
- ✓ Contact: relocation to University/college
- ✓ Upfront costs -travel
- ✓ Side effects such as tiredness, apathy, depression
- ✓ Exam pressure

If we include CYP in the design of studies, we can resolve these issues…

Let’s do research for patients with patients!

Methodology: review protocol or documentation

Facilitator role

- ✓ Provide background to the condition
- ✓ Current treatments available
- ✓ Life style
- ✓ Work in small groups
- ✓ Discussion facilitated and opinions encouraged
- ✓ Feedback to larger group
- ✓ Responses summarised and fed back to investigator

Investigator role

- ✓ Open questions
- ✓ Don’t have preconceived ideas
- ✓ Be ready to be challenged
- ✓ Consider their opinions properly
- ✓ If there is a misunderstanding review your presentation of the information
- ✓ Report back to group about changes made
- ✓ Beware of surveys

What is a clinical trial?

It is the study with patients of a drug, diagnosis technique or medical device with the aim of analysing its security and safety.

Statistical data has shown that over 50 % of the drugs that are prescribed for children have only been studied with adults. In this context, and with the challenge of assuring the highest level of security of these drugs, the **EMA** (European Medicines Agency) establishes as a mandatory requirement the submission of a **Paediatric Investigation Plan** (PIP) for the study of their administration in children before their authorization.

Depending on the country, young patients under 18 years old who are going to participate in a clinical trial have to sign the **assent document** to be able to participate in the trial. A similar document has to be signed by the parents.

[1] Conroy S et al. Br Med J. 2000;320:79–82

Resources of interest

Tool-box of Eupati
www.eupati.eu

International Children's Advisory Network (ICAN)
www.icanresearch.org

Spanish Agency of Medicines and Medical Devices
www.aemps.gob.es

Search engine of clinical trials of the European Commission
www.clinicaltrialsregister.eu

Clinical Trials (U.S. National Institutes of Health)
http://clinicaltrials.gov

Health research: making the right decision for me.
(Nuffield Bioethics – YouTube)

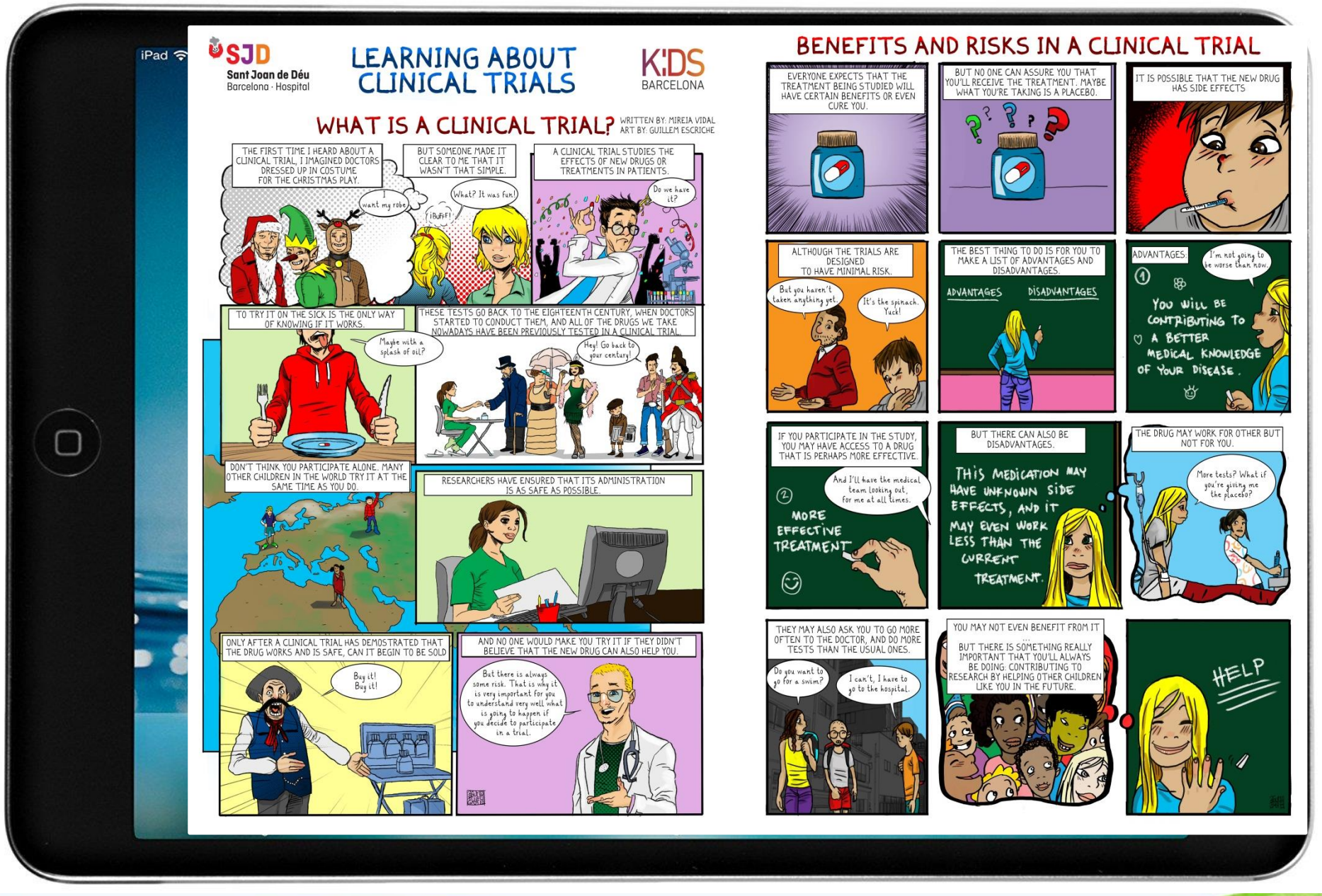
Kids Barcelona: young person's advisory group
(YouTube- Hospital Sant Joan de Déu)

EUPATI
European Patients' Academy on Therapeutic Innovation

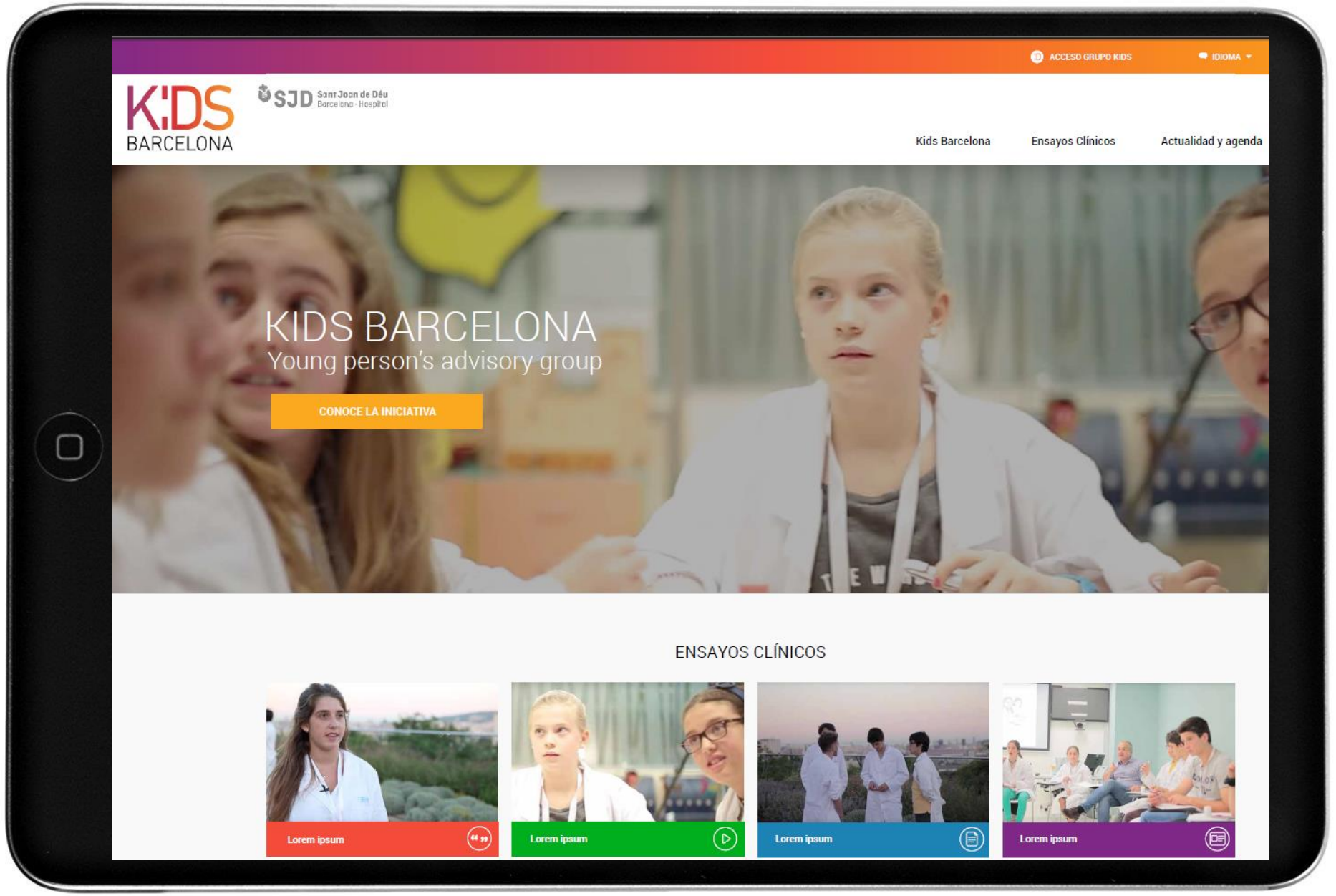
Informed consent document addressed to paediatric patients: the assent

Guidelines for a design focused on the children

By KiDS Barcelona


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 ESCRICHE
THE FIRST TIME I HEARD ABOUT A CLINICAL TRIAL, I IMAGINED DOCTORS DRESSED UP IN COSTUME FOR THE CHRISTMAS PLAY.
I want my robe!
BUT SOMEONE MADE IT CLEAR TO ME THAT IT WASN'T THAT SIMPLE.
¡Buff!
What? It was fun!
A CLINICAL TRIAL STUDIES THE EFFECTS OF NEW DRUGS OR TREATMENTS IN PATIENTS.
Do we have it?
TO TRY IT ON THE SICK IS THE ONLY WAY OF KNOWING IF IT WORKS.
Maybe with a splash of oil?
THESE TESTS GO BACK TO THE EIGHTEENTH CENTURY, WHEN DOCTORS STARTED TO CONDUCT THEM, AND ALL OF THE DRUGS WE TAKE NOWADAYS HAVE BEEN PREVIOUSLY TESTED IN A CLINICAL TRIAL.
Hey! Go back to your century!
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 DEMOSTRATED THAT THE DRUG WORKS AND IS SAFE, CAN IT BEGIN TO BE SOLD
Buy it! Buy it!
AND NO ONE WOULD MAKE YOU TRY IT IF THEY DIDN'T BELIEVE THAT THE NEW DRUG CAN ALSO HELP YOU.
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.
But you haven't taken anything yet.
It's the spinach. Yuck!
THE BEST THING TO DO IS FOR YOU TO MAKE A LIST OF ADVANTAGES AND DISADVANTAGES.
ADVANTAGES
DISADVANTAGES
ADVANTAGES
I'm not going to be worse than now.
1
YOU WILL BE CONTRIBUTING TO A BETTER MEDICAL KNOWLEDGE OF YOUR DISEASE.
IF YOU PARTICIPATE IN THE STUDY, YOU MAY HAVE ACCESS TO A DRUG THAT IS PERHAPS MORE EFFECTIVE.
And I'll have the medical team looking out for me at all times.
2
MORE EFFECTIVE TREATMENT
BUT THERE CAN ALSO BE DISADVANTAGES.
THIS MEDICATION MAY HAVE UNKNOWN SIDE EFFECTS, AND IT MAY EVEN WORK LESS THAN THE CURRENT TREATMENT.
THE DRUG MAY WORK FOR OTHER BUT NOT FOR YOU.
More tests? What if you're giving me the placebo?
THEY MAY ALSO ASK YOU TO GO MORE OFTEN TO THE DOCTOR, AND DO MORE TESTS THAN THE USUAL ONES.
Do you want to go for a swim?
I can't, I have to go to the hospital.
YOU MAY NOT EVEN BENEFIT FROM IT
...
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


CLINICAL
TRIALS
EXPERIENCE
ALBA
9 años
1
2
3
4
76
BMP
SpO2
98
%
TEM
36
°C
1
FASE 1
SEGURIDAD
2
FASE 2
CANTIDAD
3
FASE 3
COMPARATIVA
4
FASE 4
SEGUIMIENTO


ACCESO GRUPO KIDS
IDIOMA
KIDS BARCELONA
SJD Sant Joan de Déu Barcelona - Hospital
Kids Barcelona
Ensayos Clínicos
Actualidad y agenda
KIDS BARCELONA
Young person's advisory group
CONOCE LA INICIATIVA
ENSAYOS CLÍNICOS
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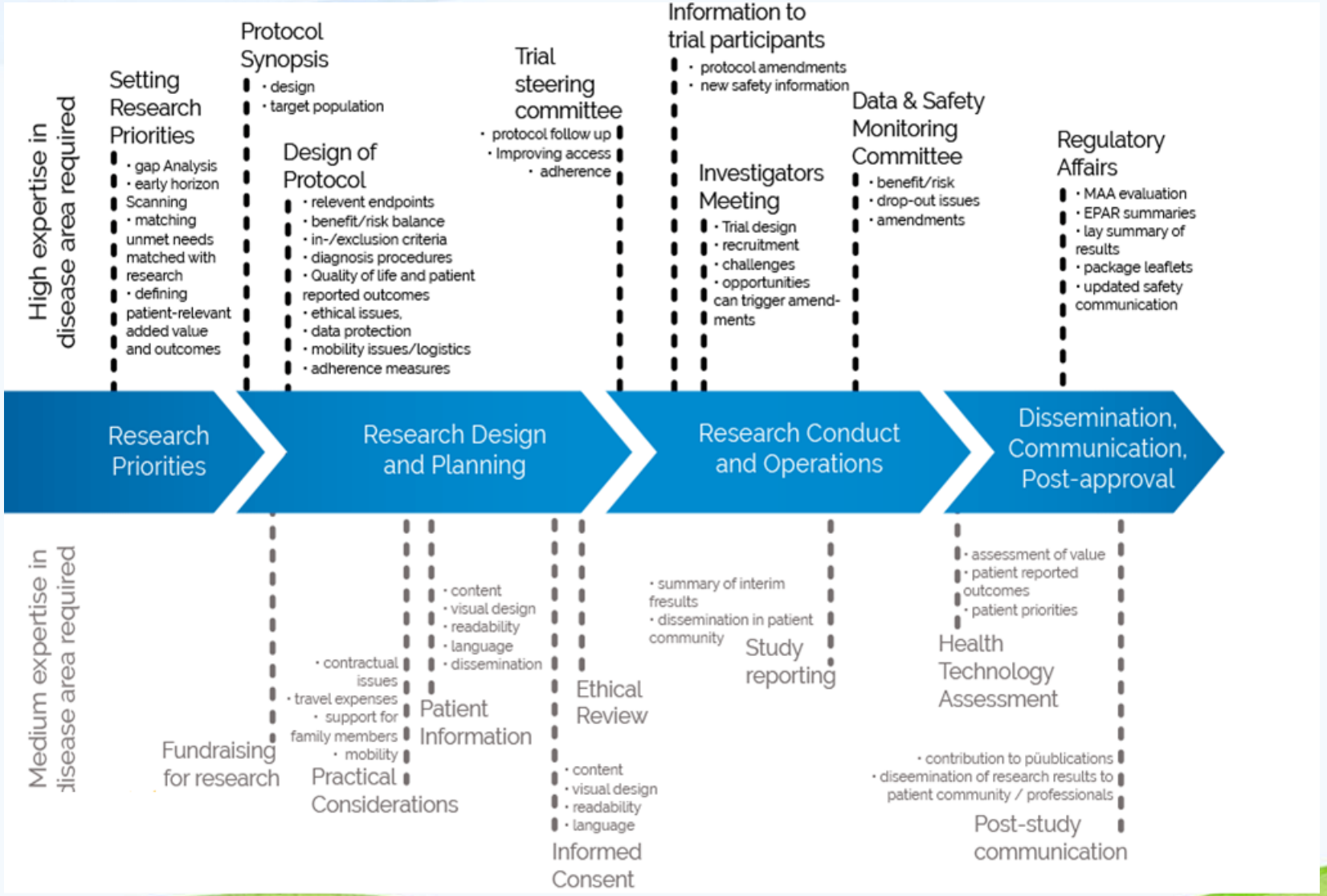
Adult patients involvement in clinical research…



Pediatric clinical trials require work at international level from basic to clinical research

WHAT are we going to do

Informed groups

Training in clinical research

Scientific meetings

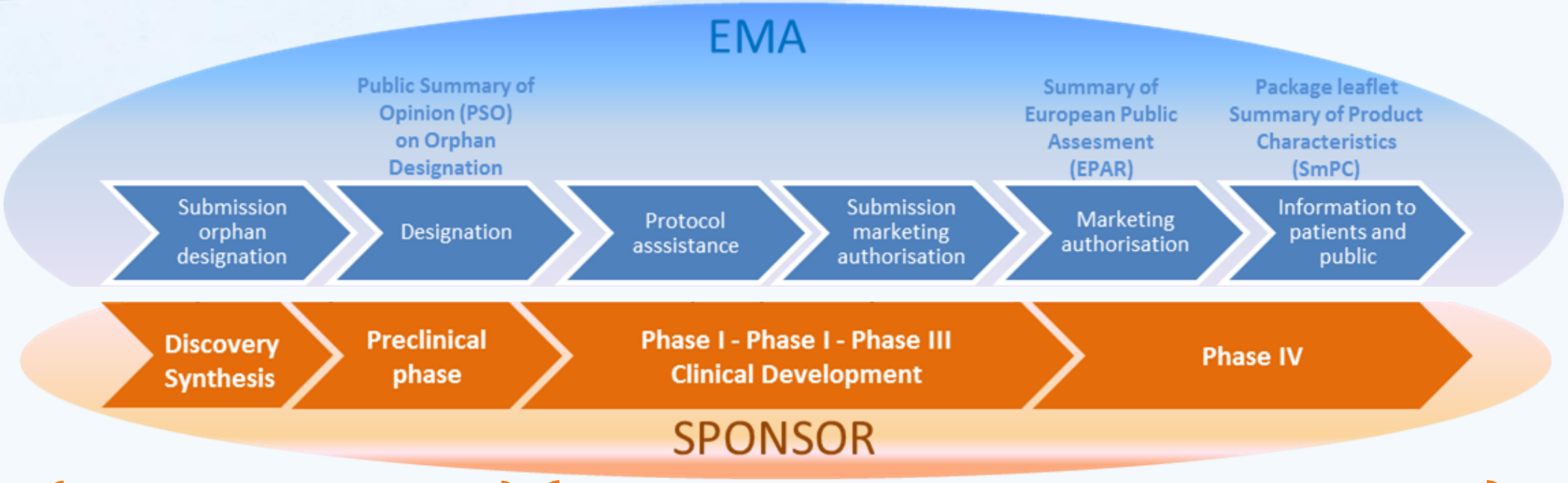
Single point of contact

Coordination at European level

Business model for sustainability

New landscape of peadiatric research in Europe … with CYP involvement

eYPAGnet



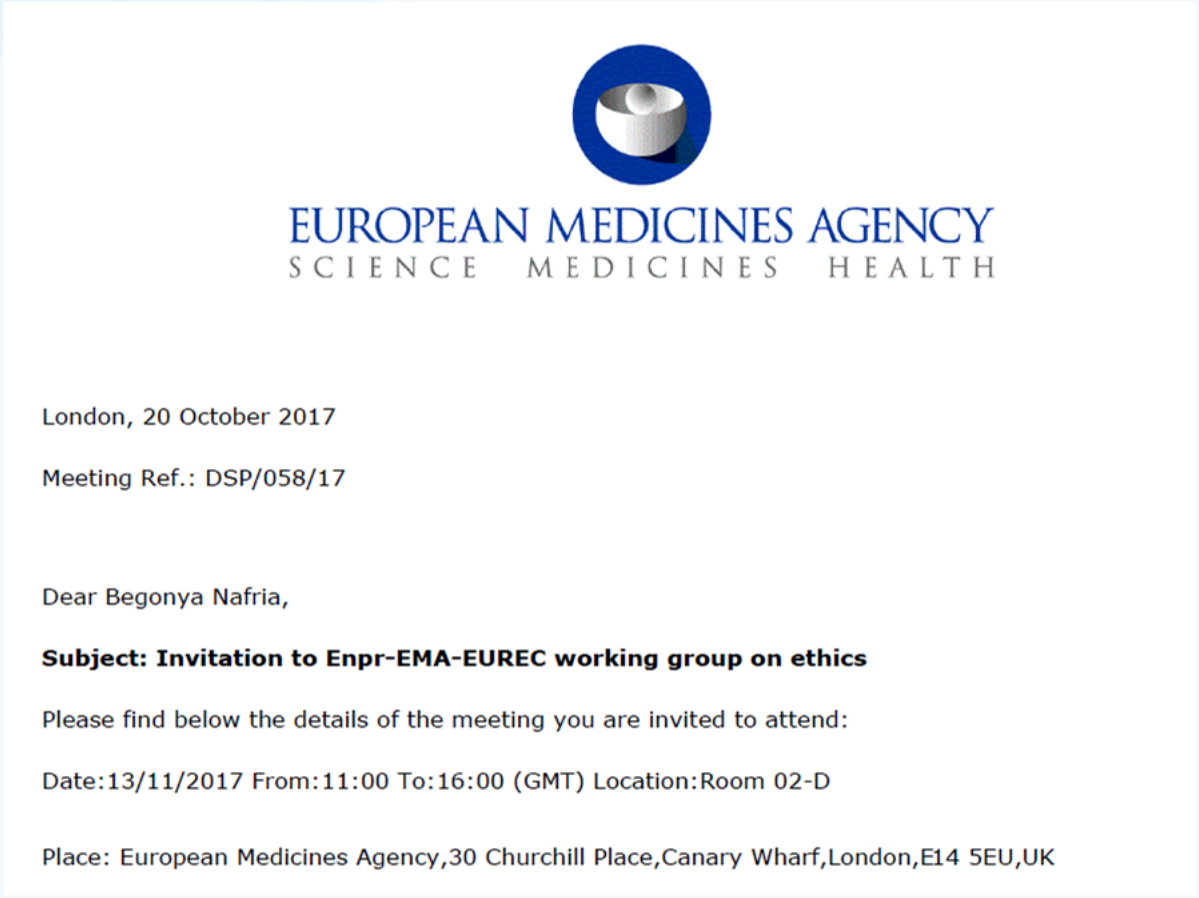
EPTRI

Future pan-European Paediatric Clinical Trials Network

PedCRIN

PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

Collaboration with EMA – 2017



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

London, 20 October 2017

Meeting Ref.: DSP/058/17

Dear Begonya Nafria,

Subject: Invitation to Enpr-EMA-EUREC working group on ethics

Please find below the details of the meeting you are invited to attend:

Date:13/11/2017 From:11:00 To:16:00 (GMT) Location:Room 02-D

Place: European Medicines Agency,30 Churchill Place,Canary Wharf,London,E14 5EU,UK

Participation in the Enpr-EMA-EUREC working group on ethics

ACTION POINTS:

Compile available guidance documents and prepare a template / material package about considerations on ethical aspects in paediatric research, including involvement of YPAGs that should be addressed by RECs.

Propose scope of and framework for organizing systematic involvement of YPAGs in ethics assessment of new CTs (non-official opinion), and at what time points – as early as possible (reference is the CTR Part I and II assessment which will close the timeframe)

Thank you for your attention!

Fight for your dreams and your dreams will fight for you

eypagnet@sjdhospitalbarcelona.org

Please follow us on Twitter @eYPAGnet