

Take home messages...



What is fair research (for children)

Questions anyone involved in research should ask.

1. Is there justifiable purpose?
2. Is the study built on what is known already?
3. Will the study provide meaningful information (information of value)?
4. Will the method provide valid information (that we can trust)?
5. Is the research team equipped to complete the study?
6. Does the research incorporate public, patient and participant views?
7. Is selection fair? (inclusion / exclusion)
8. Are participants recruited fairly?
9. Is there fair balance of benefits and harms for all with an interest ?
- 10. Are participants offered a fair choice (informed consent)?**
11. Is personal data handled appropriately (confidentiality)?
12. Are there fair payment and recompense for injury?
13. Once finished do participants receive acknowledgment and appropriate care?
14. Will the project be registered and results placed in the public domain?

Patient Engagement at EMA

- European network of paediatric research at EMA (Enpr-EMA)
-> expertise in performing paediatric clinical trials
- Patient representatives are involved in the work of Enpr-EMA, and different Committees (PDCO, PRAC, CAT, COMP)
- Patients, consumers and carers are involved in a wide range of EMA activities:
 - Eligible EMA patient organisations
 - Individual experts – sign the EMA expert database:
<https://fmapps.emea.europa.eu/stakeholders/signup.php>

Take home messages...

1. **Make sure the involvement of children and young people in the drug development process is feasible.**
2. **PPI needs to be an integrated part of the process from the beginning**
3. **Design, execution and evaluation of every PPI activity is essential.**
4. **Share your experiences of PPI (good and bad) so everyone can learn 'how' to effectively involve patients and families in the research process**
5. **Showing the added value of PPI (in terms of outcomes/financially) is important for implementing points 2 and 3 below.**

Promote a new research paradigm educating patients



Home

The Project ▾

Network ▾

Academy

PoV Studies

Patients ▾

News ▾

Contact

Q Search

Educational Resources Library

Home / Educational Resources Library



This Toolkit is intended as a living repository of educational materials to provide patients participating in clinical trials, their families and new YPAGs (Young Person Advisory Groups) with information to get started in patient and public involvement in the development of medicines.

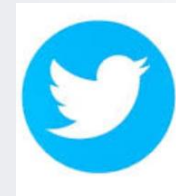
In this section, patients and their families will find materials that will help them understand what a clinical trial is, what happens in a clinical trial, what ethical and legal implications entail and what role patients' (and their families) can play in the development of a clinical trial.

Click the panel below to access the complete educational resource bank.



c4c resources

- c4c Educational resources:
<https://conect4children.org/educational-resources-library/>
- c4c database for patient representatives:
<https://conect4children.org/patient-and-public-involvement/>
- LinkedIn:
<https://www.linkedin.com/company/conect4children>
- Twitter:
https://twitter.com/c4c_network
@c4c_network



Final poll

After this workshop, I plan to take action by....

Write your answer in the chat box

THANK YOU!



innovative
medicines
initiative



PPI team

Jennifer Preston (Senior Patient and Public Involvement Manager, University of Liverpool)

Pamela Dicks (Network Manager, Scottish Children's Research Network, ScotCRN)

Begonya Nafria (Patient Engagement in Research Area Coordinator, FSJD)

Nuria Noel (Patient Engagement in Research Area, FSJD)

Joana Claverol (Clinical Research Unit Manager, FSJD)

Eric Vermeulen (Policy Officer Research, VSOP)

Mariette Driessens (Policy Officer Research, VSOP)

Aisling Walsh (Senior Project Manager, EFCNI)

Loïc Notelet (Trial Operations Program Manager, Sanofi)

Segolene Gaillard (Project manager - Methodology adviser – Paediatrics, Hospices Civils de Lyon)

Katherine Cheng (Senior Director, Paediatric Drug Development, Janssen)

Maria Cavaller (Patient Engagement Junior Manager, EURORDIS)

Gulcin Gumus (Research and Policy Project Manager, EURORDIS)

#conect4children



Congratulations to all of you!



Congratulations to all of you!

