Young People and patient Involvement

Jennifer Preston, Senior Patient Involvement Lead, University of Liverpool

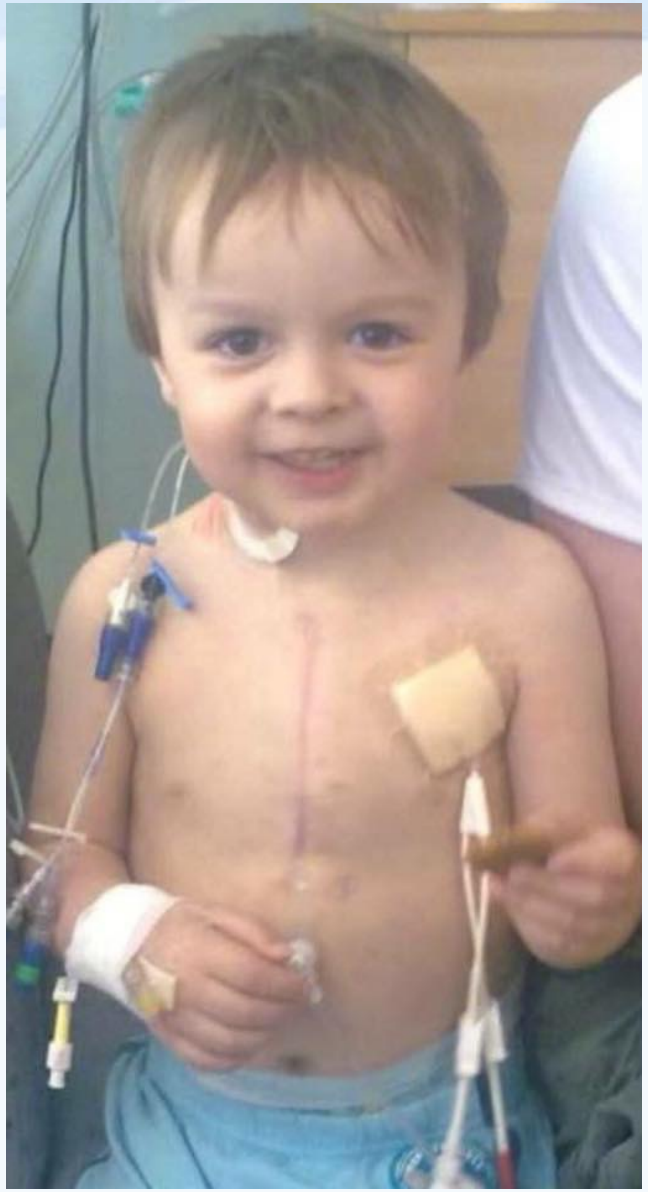
EnprEMA Annual Meeting
June 7th 2018

Overview

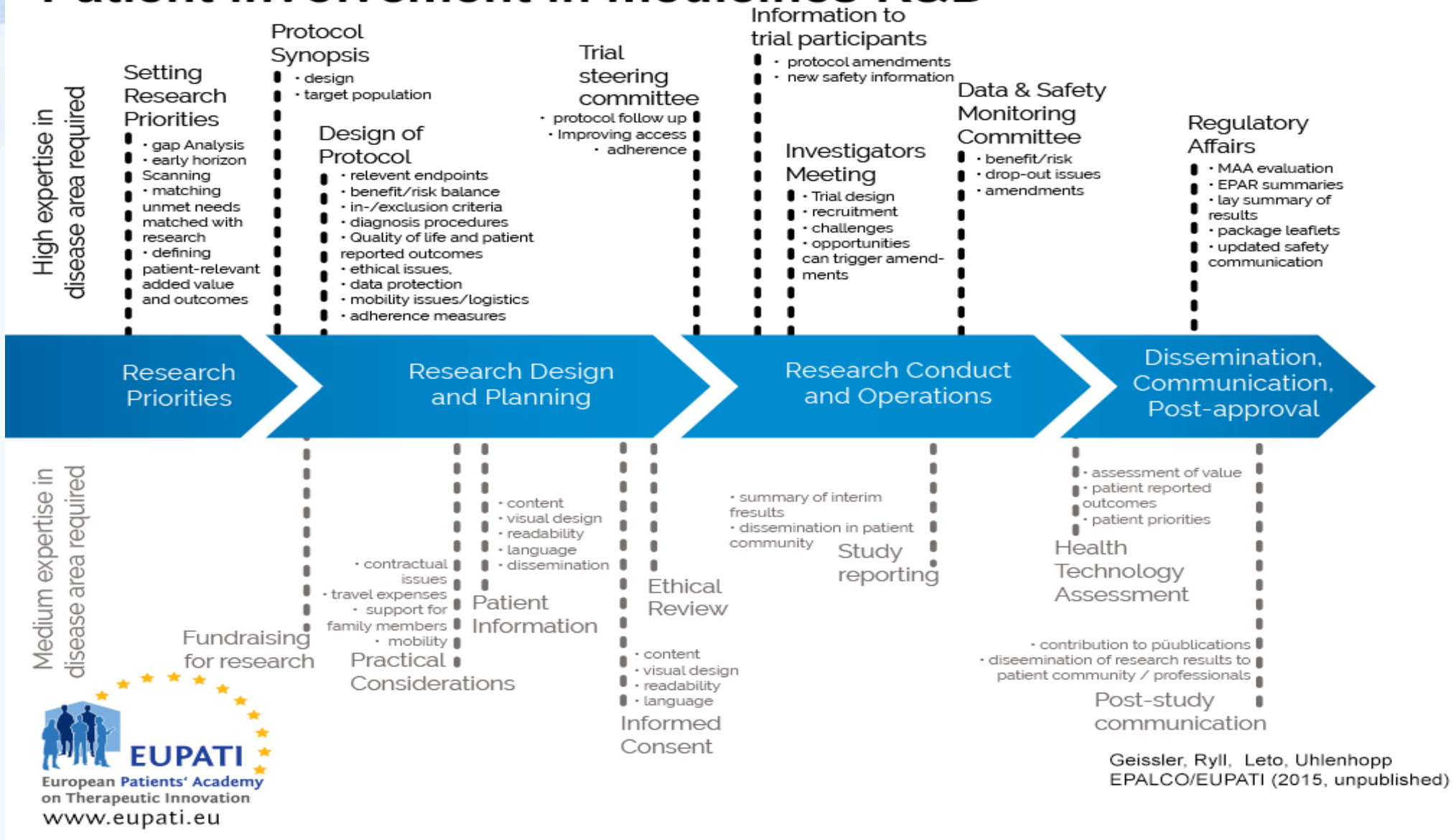
- Luke
- Patient involvement in medicines development
- Children's Rights
- Giving young people a voice
- Impact
- The future

Luke's Story

- Born with CHD
- Open heart surgery at 2 weeks old, further two before the age of 3 and another at 8
- Tube fed his whole life



Patient involvement in medicines R&D



Geissler, Ryll, Leto, Uhlenhopp
EPALCO/EUPATI (2015, unpublished)

Patient Training

Guidance

Standards

Community

Publications

Toolbox

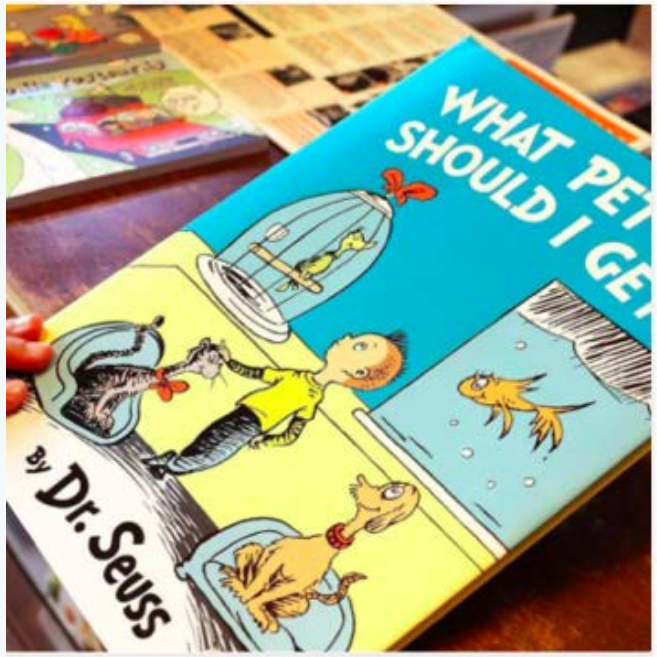
Article 12 - every child and young person has the right to express his or her views freely in all matters affecting them

” You have the right to be involved in discussions about your healthcare and to be given information to enable you to do this”

Giving young people a voice

Assent & Consent Materials

- Information is too long (18+ pages in some cases for children 7 years old)
- Repetitive
- Too much jargon
- Too complex
- Too technical in parts
- Lacks colour
- Looks dull and uninviting
- Often patronising

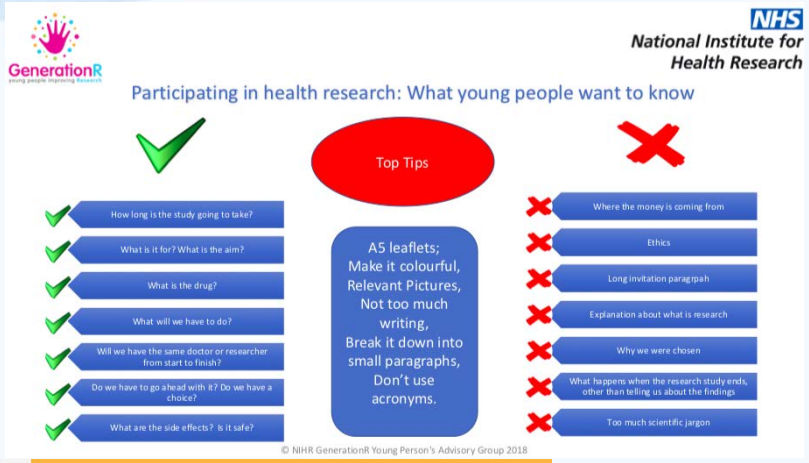


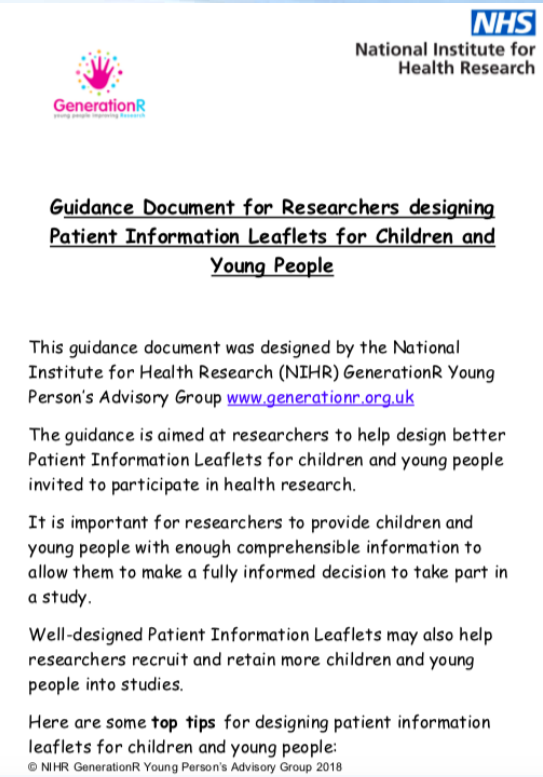
It's all 'Gobbledegook' – communicating health research to young people

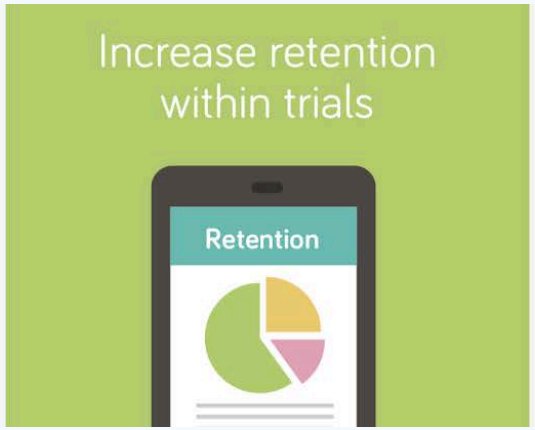
February 26, 2018

http://bit.ly/2BTKyQO

Developing guidance & tools







EnprEMA NETWORK

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Developing and evaluating multimedia information resources to improve engagement of children, adolescents and their parents with trials (TRECA study): Study Protocol for a series of linked randomised controlled trials. Trials
https://www.ncbi.nlm.nih.gov/pubmed/28595613

Lay writing: Strategies for improving assent forms for children and adolescent participation in health research

Danielle Yuill[1], **Rachel Barron**[1], and **Jennifer Preston**[2]
1 GW Research Ltd, Cambridge, UK
2 NIHR Alder Hey Clinical Research Facility, Liverpool, UK

Correspondence to:
Danielle Yuill
Technical Writer
GW Research Ltd
Sovereign House
Vision Park
Histon
Cambridge, UK CB24 9BZ
+44 (0) 1223 266800
dyuill@gwpharm.com

Abstract

Writing for lay audiences is recognised as a difficult task for medical writers, whose specialised knowledge can often hinder effective lay communication. This task is even more challenging when preparing clinical trial information for a paediatric population. Involving advisory groups in the development of clinical trial materials improves their quality and ensures that they are fit for purpose. This article describes how medical writers can build successful partnerships with advisory groups in developing assent forms for children being approached to participate in clinical trials.

Research involving children has more complex considerations than research with adults. Although children are dependent on their parent(s)/legal guardian to provide written informed consent for their participation in clinical trials, they should be involved in the decision-making process if they have the capacity to assent.[1–4] Assent is, therefore, given by children with capacity, in addition to consent by the legal representative(s), and indicates their understanding of the trial procedures and willingness to participate.[2] In the European Union, while there is consensus regarding the need for assent forms to be adapted in accordance with the age and level of understanding of the children targeted for inclusion, there is discordance regarding the appropriate age of assent and the requirement of a child's signature to confirm their agreement to participate.[5] A medical writer tasked with developing assent form templates for use across multiple countries and multiple trials is, therefore, presented with challenges in negotiating national laws and local practices, as well as trying to ensure the use of appropriate language to aid a child's understanding of a clinical trial.

We advocate partnering with children's advisory groups to overcome some of the challenges of writing for paediatric populations; such partnering is a concept that is newly emerging in the pharmaceutical industry and often daunting for medical writers to undertake. This article describes the process of assessing the suitability of assent forms and how the support of advisory groups can aid medical writers in preparing clinical trial materials that are fit for purpose.

Where to start

As medical writers, how do we write assent forms to adequately inform children of differing levels of maturity about participation in clinical trials? How do we know that what we produce provides adequate information to enable a child to make a choice? The internet is an abundant source of information, and there are several examples of ethically approved informed assent forms, which medical writers could use to develop their own company-specific templates. Most of these examples, however, are outdated and do not describe the involvement of children and young people in their development.

> An important element of involving lay groups in clinical research is acknowledging the value of the reviewers' input.

We aimed to develop two new assent form templates for use in our paediatric clinical trials that provide sufficient information for children and young people to make informed decisions about participation.

Our original assent form templates (categorised as being suitable for younger children and older children) had been developed in 2013 when we conducted our first clinical trial in paediatric patients. On review in 2016, we determined that there was scope to improve the design and overall comprehensibility of the templates. Having prior experience with lay writing and the involvement of patient and public groups

GW pharmaceuticals

GenerationR
young people improving Research

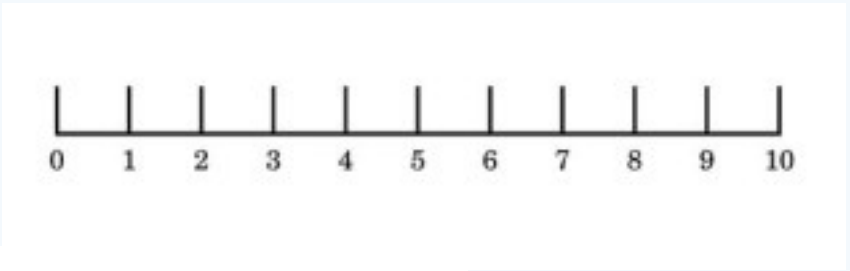
http://journal.emwa.org/vaccines-and-immunotherapies/lay-writing-strategies-for-improving-assent-forms/

Developing medicines that are acceptable to children

The European Medicine Agency (EMA) guidance states that patient acceptability must be an integral part of paediatric formulation development

https://jennyprestonblog.com/2017/09/02/improving-medicines-for-children-part-2-what-is-important-to-children-and-young-people/

Developing the tools



Feedback from researchers

"Generation R is a particularly valuable resource for any researchers involving young people…I was not aware of them prior to recommendations by the research ethics committee**. I will certainly hope to seek their support in future studies**"

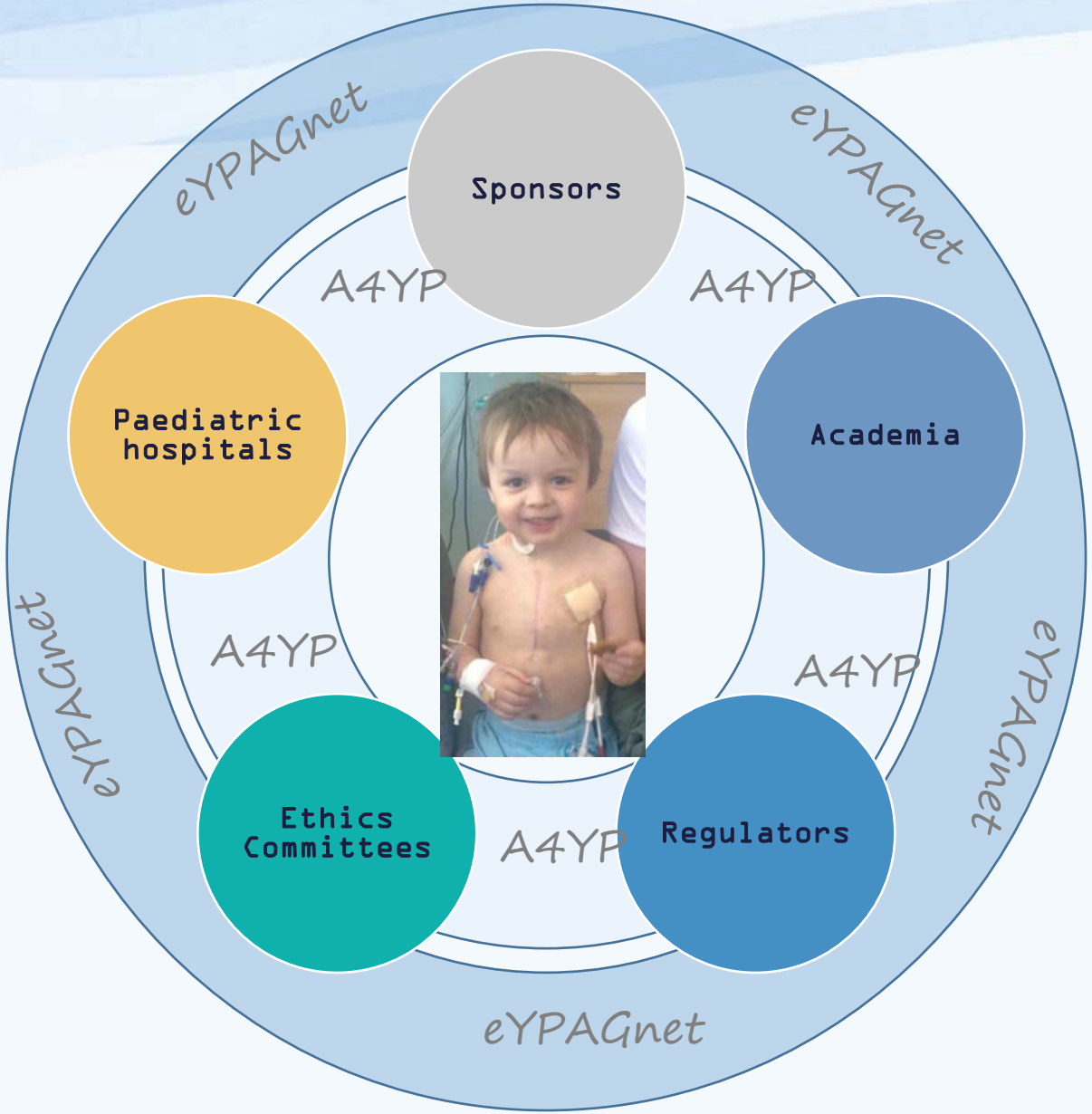
"The group were instrumental in ensuring that the **study outcomes were valid, important and meaningful** for young people and parents"

GenerationR
young people improving Research

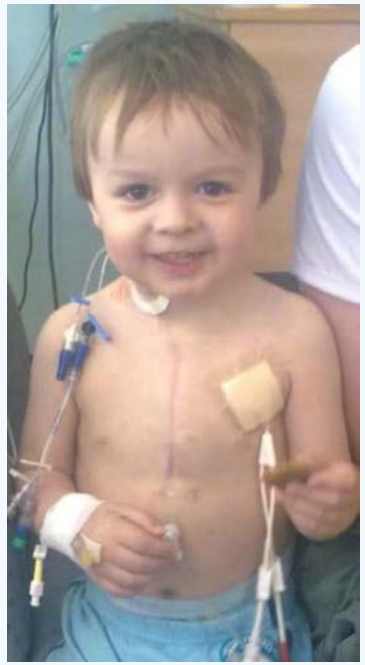
conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

eYPAGnet
European Young Persons' Advisory Group Network

iCAN
International Children's Advisory Network


eYPAGnet
eYPAGnet
eYPAGnet
eYPAGnet
eYPAGnet
Sponsors
A4YP
A4YP
Paediatric hospitals
Academia
A4YP
A4YP
Ethics Committees
A4YP
Regulators

What research means to Luke



“ What you children do today will impact on children who have not been born”

Newman, J., Callens, C., Tibbins, C., Madge, N. (2012). **Medicines for Children: reflecting on how young people improve research in this area.** The Active Involvement of Children and Young People in Health and Social Care Research. Routledge.

Caldwell, P., Dans, L., De Vries, M., **Newman, J.**, Offringa, M., Sammons, H., Spriggs, M., Tamble, P., Van't Hoff, W., Woolfall, K., Young, B,. (2012) **Ethical dilemmas in research with children: consent and recruitment**. Pediatrics 2012; 129

Modi., N, Vohra., J, **Preston.**, J, Elliott., C, Van't Hoff., W, Coad., J, Gibson., F, Partridge., L, Brierley., J, Larcher., V, Greenough., A for a Working Party of the Royal College of Paediatrics and Child Health. **Guidance on clinical research involving infants, children and young people: an update for researchers and research ethics committees.** (2014) Archives of Disease in Childhood, Vol 99 No 10.

Gamble., C, Dudley., L, Allam., A, Bell., P, Goodare., H, Hanley., B, **Preston., J,** Walker., A, Williamson., PR, Young,. Y. **Patient and public involvement in the early stages of clinical trial development: a systematic cohort investigation**. BMJ Open (2014).

Preston., J, Van't Hoff., W, Semple., G, Challinor., R. **Young People's Voices Improving Research**. Pharmaceutical Physician, Vol 25 issue 5.

Hannah Lythgoe, Victoria Price, Vanessa Poustie, Sabah Attar, Daniel Hawcutt, **Jenny Preston**, Michael W Beresford. **NIHR Clinical Research Networks: What they do and how they help paediatric research.** http://adc.bmj.com/content/early/2017/01/17/archdischild- 2016-311057.short

Bate ., J, Ranasingh ., N, Ling ., R, **Preston ., J,** Nightingale .,R, Denegri., S. **Research in Practice: Public and patient involvement in paediatric research**. January 2016. *Arch Dis Child Educ Pract Ed* doi:10.1136/archdischild-2015-309500.

Preston., J, Bagley., H, Challinor., R, Stones,.S. **Research together: the value of patient and family involvement**. Neonatal and Paediatric Prescribing Book (**In-Press**) Pharaceutical Press.

Gaillard S, Malik S, Preston J, Nafria B, Dicks P, Touil N, Mardirossian S, Claverol-Torres J, Kassaï B **Involving Children and Young People in Clinical Research through the forum of a European Young Persons' Advisory Group: Needs & Challenges**. Fundam Clin Pharmacol. 2018 Feb 19. doi: 10.1111/fcp.12360.

Nafria B, Claverol-Torres J **KIDS Barcelona: Young Person's Advisory Group Focused in Clinical Research and Innovation Projects.** Chapter of a book. In press

Preston J, Dicks P, Nafria B, Gaillard S. **The ethical principles underpinning the participation of young people in the development of paediatric clinical research** Chapter of a book. In press

Thank you for listening

Jenny Preston BA (Hons)
jennifer.preston@liverpool.ac.uk
https://jennyprestonblog.com
@GenrYPAGs @jen_preston1
https://www.linkedin.com/in/jenny-preston

eypagnet@sjdhospitalbarcelona.org

Please follow us on Twitter @eYPAGnet