Working Group : Young Persons Advisory Groups

From the Working Group to the Network

Chair: **Pamela Dicks** (NHS-NRS Children's Research Network)

Co-Chair: Jenny Preston (NIHR-Children's)

Membership: Joana Claverol and **Begonya Nafria** (Hospital St. Joan de Déu) **Segolene Gaillard** (RIPPS) Nathalie Bere (EMA) Irmgard Eichler (EnprEMA)

EnprEMA June 7th 2018

...2017 announced formation of eYPAGnet

- Why we need to involve CYP
- Why we need eYPAGnet
- Update on development of eYPAGnet
- What we have achieved
- Next steps

WHY involve CYP?

Give young people a voice!

- ✓ Respecting their rights
- ✓ Gate-keeping respecting their needs
- ✓ Platform for meaningful engagement
- ✓ Improve patient acceptability of trials
- ✓ Improve patient understanding of participation by improving communication tools
- ✓ Contribute to study/better medicines for children

What is a YPAG?

- ✓ 11 to 18 years old
- ✓ Common interest in children's medicine, health research and the development of new drugs
- ✓ Receive training in drug discovery, development of new medicines clinical trials and ethics
- ✓ Comment on design of clinical trials and patient visits
- ✓ Comment on the language, design and age appropriateness of patient documentation, apps and diaries
- ✓ Provide advice on social media, innovations and websites

How do they review protocol or documentation?

Facilitator

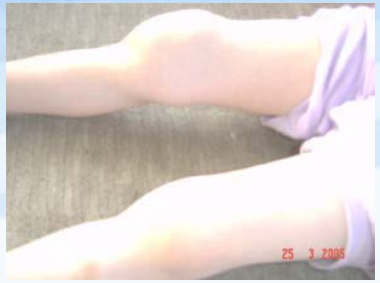
- Provide background to the condition-
- Current treatments available
- Life style
- Age of participants
- Work in small groups to review patient documentation
- Discussion facilitated and opinions encouraged
- Feedback to larger group
- Responses summarised and fed back to investigator

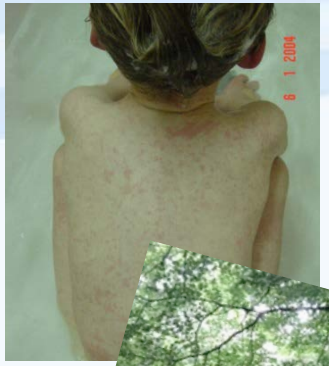
Investigator

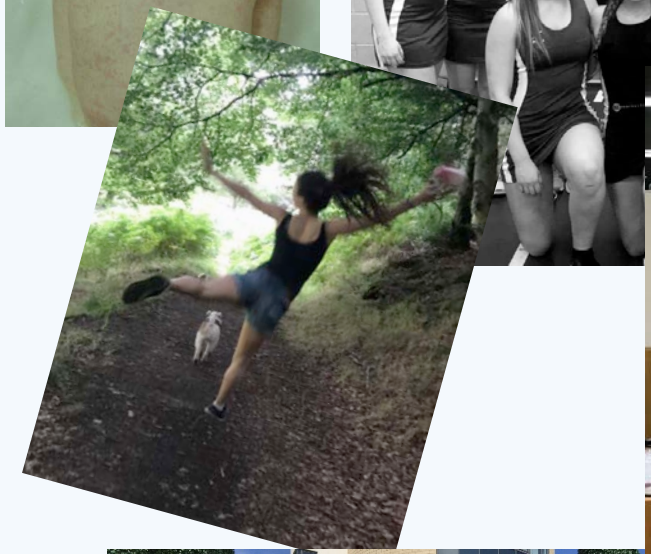
- Open questions
- Don't have preconceived ideas
- Be ready to be challenged
- Consider their opinions properly
- If there is a misunderstanding review your presentation of the information
- Report back to group changes made
- Beware of surveys

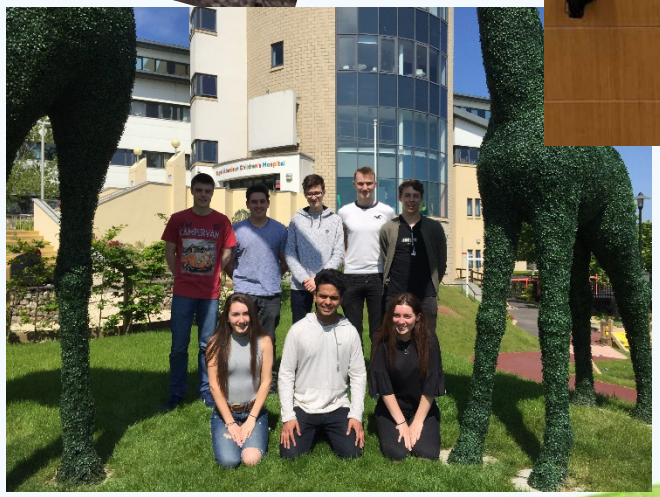
Our young advocates…

Patients- Young People or Academic?









"I remained on etanercept for 7 years, requiring joint injections along the way. I even managed a 6-month break from all meds around age 8. I switched onto infliximab infusions along with the methotrexate injections, this combination didn't seem as effective to my arthritis. I am now on Tocilizimab injections having recently changed from the 3 weekly toc infusions."
Anna Sherriffs Age 17

Why? - Performance of networks, CRF's, CRO's and industry!

Trials opened and completed on time

Recruitment of patients to agreed target

Retention of patients to completion

Trials meet the needs of patients

WHY a European network?

WHY a European network?

- EMA is a **specific environment** within Europe to regulate the development of new treatments.

- EMA has established a **framework to involve the young patients** in their activities.

- Increase the collaboration among European YPAG: **all the paediatric clinical trials are international.**

What are benefits to current YPAG's to join us?

- Increase **collaboration with different stakeholders.**
- Gather examples of **best practices** and **promote research** in the field of young patients advocacy.
- Share **tools and educational materials.**
- **Support new groups** and build capacity within Europe.

WHAT have we achieved?

WHAT we promised 2017-2018

Strategy paper:

Terms of Reference

Membership

Website

Training in Clinical Research

Publicity and meetings

Business model for sustainability

Terms of reference. The eYPAGnet will:

- ✓ be responsible for developing an engagement strategy to support, signpost and promote collaboration with all the YPAGs and and patient organisations
- ✓ collate and disseminate information about relevant activities to the eYPAGnet (congresses, webinars, etc.)
- ✓ build an evidence base, in Europe, on the impact of the involvement of CYP in research.
- ✓ standardise a common curriculum to train CYP around Europe.

Membership

Application Process

- Open at end-of July 2018
- Require to demonstrate meet minimum criteria:
  - Group of CYP > 8 members, between 10-18 years
  - Experience of coordinator – knowledge of clinical trials in paediatrics
  - Meetings of >3 hours 8 times per year
  - Agree to deliver common curriculum and achieve minimum standards of understanding
  - Category full member-or in development

Standard Operating Procedures

Communication

- Internal communication: steering committee, advisory board
- External communication: website, social media, traditional ways

Management

- Internal and external management processes

Financial management

- Documents: contracts, estimates…
- Fees being defined

Website

www.eyapgnet.org

- Provide information
- Receive requests for scientific advice
- Collate responses from the YPAG members of the network
- Support specific requests e.g. focused on a specific disease
- Obtain feedback from researchers about the impact of YPAG involvement.

Will be launched in July!

Training in Clinical Research

- Catalogue of existing tools
- Unify a common curriculum for the European environment.
- Blended learning
  - Face to face meetings, webinar
- Training of "mentors".

Publicity and meetings

- National
- European
- International

- ✓ Workshop 10 years of the Paediatric Regulation. March 2017. EMA London
- ✓ Anonymization data workshop EMA – 30th of November (London)
- ✓ Ethics Working Group of EnprEMA- Consultation about assent templates
- ✓ Presentation of eYPAGnet in the PCDO session- January 2018
- ✓ Clinical Trials Preparedness- Working Group
- ✓ Ethics Working Group of EnprEMA – Participation in a meeting in January of 2018
- ✓ Paediatric Clinical Trials Congress. London. March 2018

Business model for sustainability

In progress!

- Portfolio of services
- Fees for the different services addressed to different stakeholders
- Pilot of fees and services with industry
- Work towards financial sustainability of the Network

SINGLE POINT of CONTACT –

FOR INVOLVEMENT of YPAG's IN EUROPE

FOR EYPAGnet COORDINATION WITH ICAN

One stop shop model

Framework of the education activities in the field of young patient engagement in C4C

- Prioritisation of research needs / unmet medical needs
- Contribution to protocol design (elegibility criteria, secondary endpoints, PROMs…)
- Assistance in design of assent/consent documents, patient information sheet, etc.
- Adherence measures
- Advise on study recruitment
- Ethical issues
- Data protection
- Innovation tools for the patient assent process and information

- Scientific advice in PDCO and Working Parties
- Testimonies in hearings
- Single Contact Point to support the Patient Engagement Department of EMA

- Lay summaries
- EPAR summaries

Pre-study → Development plan → Study start-up → Study conduct → Analysis & dissemination → EMA review and approval → Post-authorization

NATIONAL STUDIES

INTERNATIONAL STUDIES

eYPAGnet

SPONSORS | INVESTIGATORS | REGULATORS | ETHICS COMMITEES

NATIONAL HUBS

C4C

Single Contact Point for Patient Engagement – FSJD

YPAG 1 | YPAG 2 | YPAG 3 | YPAG 4 | YPAG 5 | YPAG X

F2F meetings (1-1,5 months)
Standardized methodology

Feedback consultation provided to stakeholders

Consolidated feedback report (2-3 months)

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Please follow us on Twitter @eYPAGnet