EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Encouraging paediatric clinical research in the EU

04 March 2015

HCPWP & PCWP joint meeting

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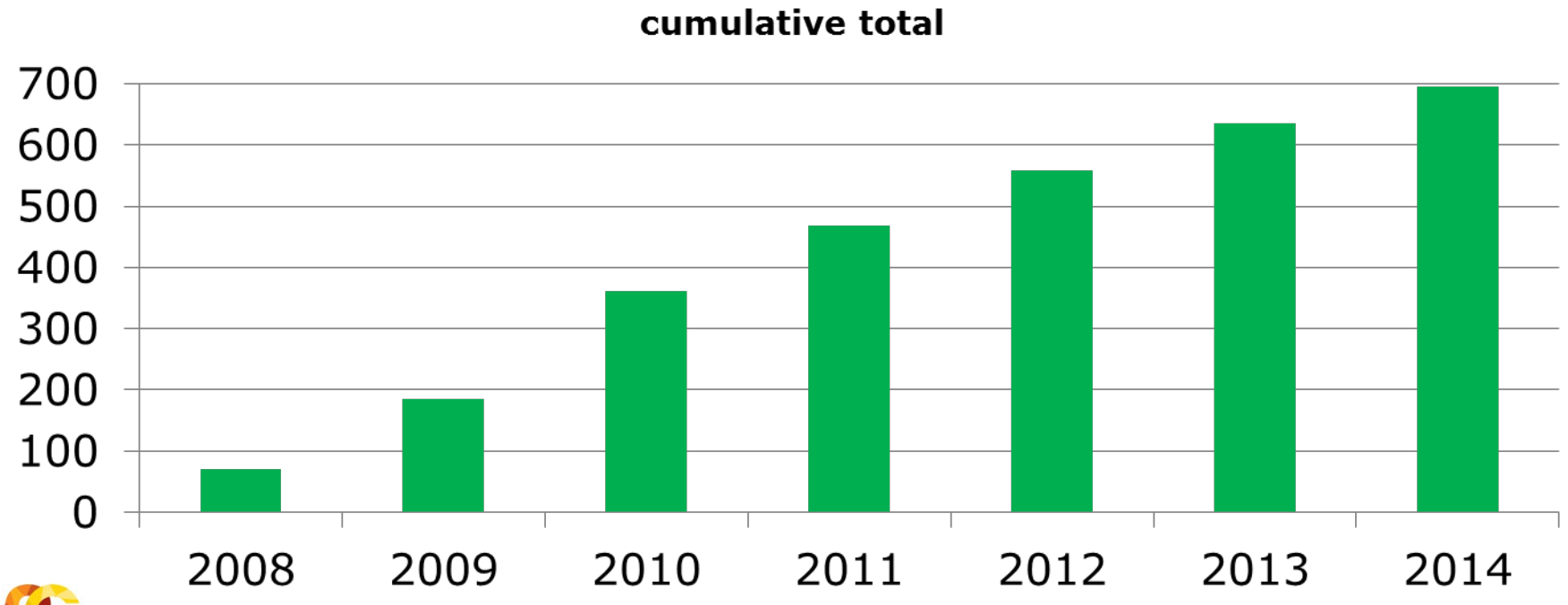
Paediatric Medicines Office

An agency of the European Union

Clinical Trials in children: the good news

The number of ongoing agreed Paediatric Investigation Plans (PIPs) is steadily increasing

A PIP is a development plan aimed at ensuring that the quality, efficacy and safety data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children



Number of agreed PIPs minus the completed ones (full compliance check)

More paediatric clinical trial authorisations!

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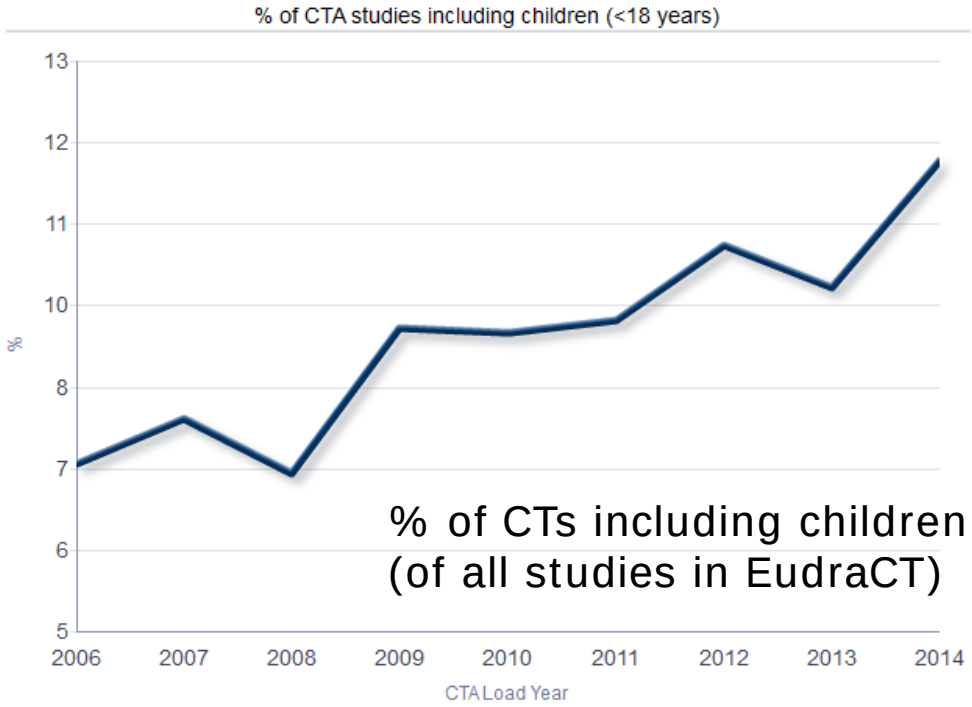
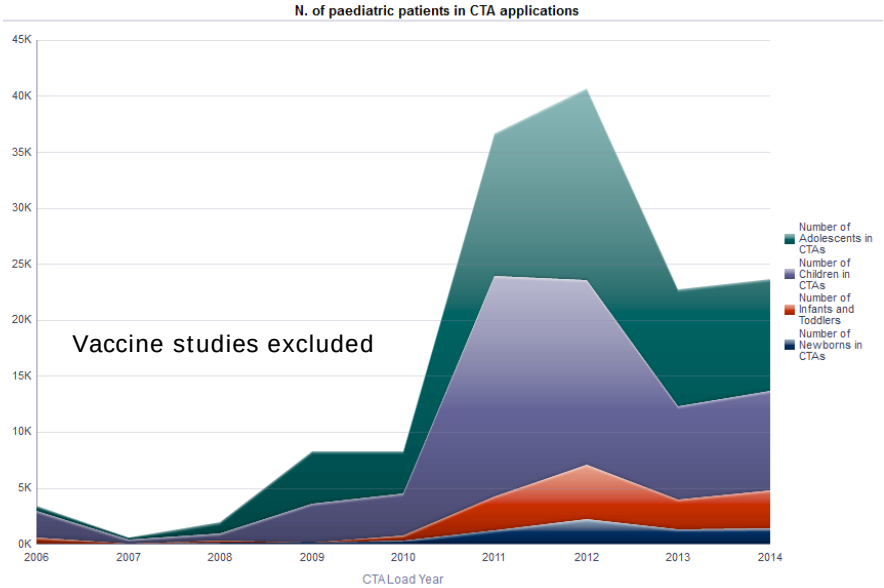


Data from:

EudraCT

However these are studies that have been **authorised**, it does not necessarily mean that they will be **completed**!



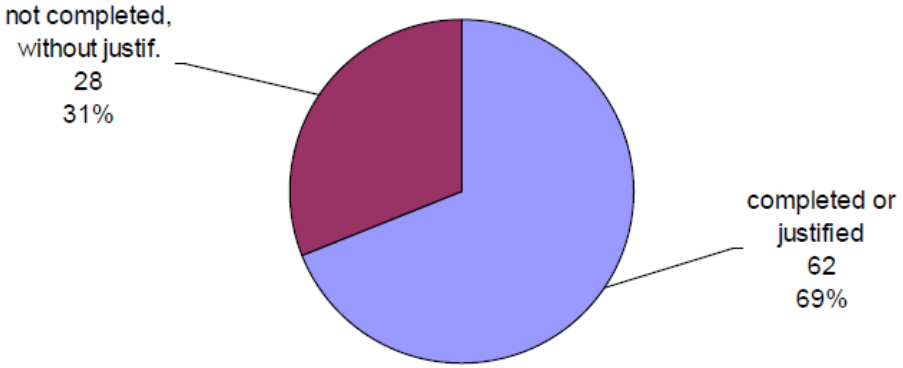
Number of children **planned to be included** in CT is increasing

Clinical trials in children:

(some of) the difficulties

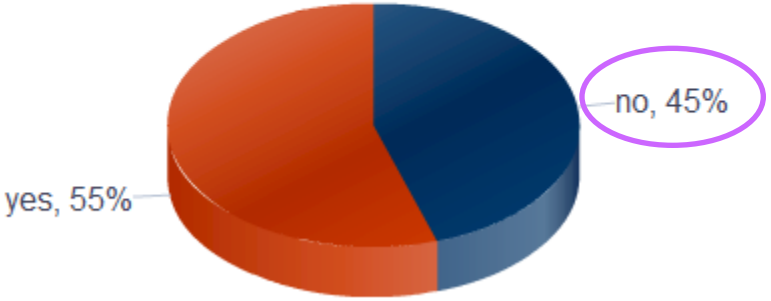
Delays in PIP progression and completion

PIPs scheduled to be completed by June 2013



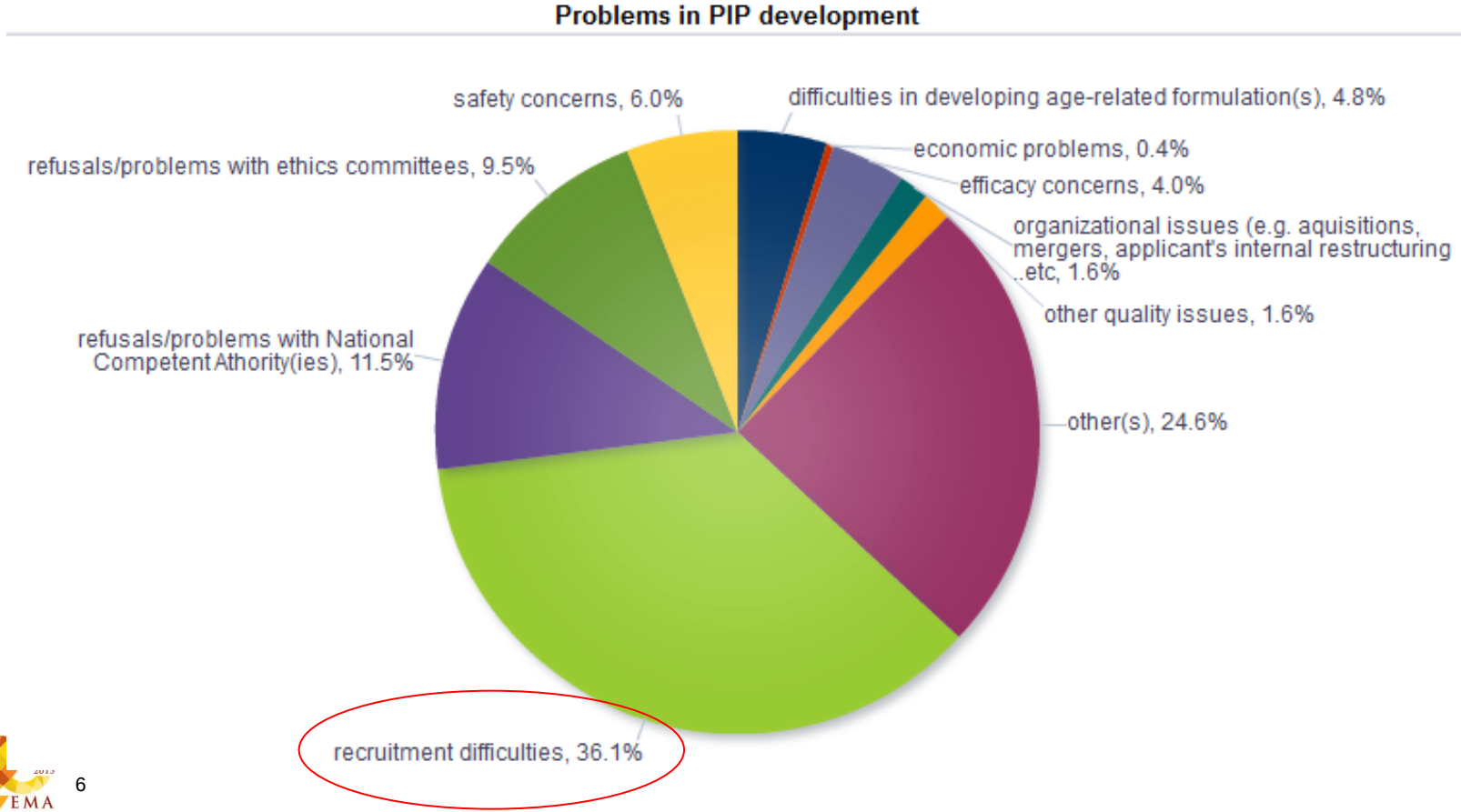
Year 2013

PIP progressing as planned?



Data from EMA annual reports to the EC

Problems reported in Annual Reports



Ongoing and planned initiatives at Enpr-EMA

Enpr-EMA

- **European Network of Paediatric Research at the European Medicines Agency** http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000303.jsp
- Set up according to **Art. 44** of Paediatric Regulation 1901/2006
- **Network** of research networks, investigators, centres with recognised expertise in performing clinical studies in the paediatric population
- **Mission:** to facilitate studies in order to increase the availability of medicinal products authorised for use in the paediatric population
- **45 registered Enpr-EMA networks**
- Acting as a **platform** to allow dialogue among all stakeholders, i.e. industry, academia, patients, HCPs, with the aim of sharing good practices but also to avoid duplication of activities and studies

Communication on improved framework for clinical trials

Ad-Hoc WG (dialogue and interactions with Ethics Committees):

- Identified **global and national hurdles** in attaining Ethics approval for multicentre trials across countries / **Variation** in informed recruitment and consent regulations (variation re age for providing assent and consent and parental requirements for providing consent i.e. 1 parent versus 2 parent signatures)
- **Table** which contains, per EU country, collected data on **national Ethics requirements for designing trial protocols** (consent/assent and language requirements, specifications/documents for Ethics submission and national Ethics contact points). To be published in a scientific journal and then on Enpr-EMA webpages

Engaging with Learned Societies

- E.g. with **European Academy of Paediatrics** (E.A.P) / Prof A.Hadjipanayis, observer member of Enpr-EMA CG

- **EAPS Barcelona 2014**:
  - **Enpr-EMA poster** addressed to clinicians to present ongoing/planned Enpr-EMA activities "*Enpr-EMA: a platform for disseminating good practices about paediatric medicines research across Europe and with international partners*"
  - *First **neonatology meeting**: preliminary discussion on the way forward to collaborate with Enpr-EMA networks/learned societies and PDCO Working Group on neonatology to offer a strong neonatology delivery network. Larger follow-up meeting to be hosted at the EMA on 17/03/2015 to bring together and closer neonatologists and regulators*

Engaging with Healthcare Professionals

Planned Ad-Hoc WG (GCP Training):

- Links with **TransCelerate** accredited GCP trainings: http://www.transceleratebiopharmainc.com/site-qualification-and-training-resources/
- Lack of GCP modules with specificities related to paediatric clinical trials: Enpr-EMA networks to share any known information re GCP trainings with paediatric clinical trial modules for dissemination among all networks

Engaging with patients

- One of Enpr-EMA **recognition criteria** to become member = engagement with paediatric patients/parents or their organisations (involvement in the trial protocol design, in PIL/ICF creation, in the prioritisation of needs for clinical trials in children)
- One member of the PCWP (Josie Drabwell) is a member of the Enpr-EMA CG
- **Planned initiatives:**
  - Ad-Hoc WG to establish a **virtual communication platform for YPAGs across Europe** and collaboration with **ICAN Research** (International Children's Advisory Network) – linking existing EU YPAGs with established North American ones into a Communicating International Network for worldwide involvement of young people in research
  - As part of GRiP, **online platform** which will provide some guidance on the establishment and operation of a YPAG (to be available in Summer 2015)

Proposed initiatives at national level

Potential initiatives to raise awareness on paediatric clinical trials at EU Member States

- **Educational materials**, **adverts** and **campaigns** via use of the Internet, social media, TV, radio
- **Information packages**: brochures, leaflets, videos for children
- **Training** at school
- Etc…