Session 3 – Holistic Approach to Paediatric Research
Clinical Trial Assessor perspective

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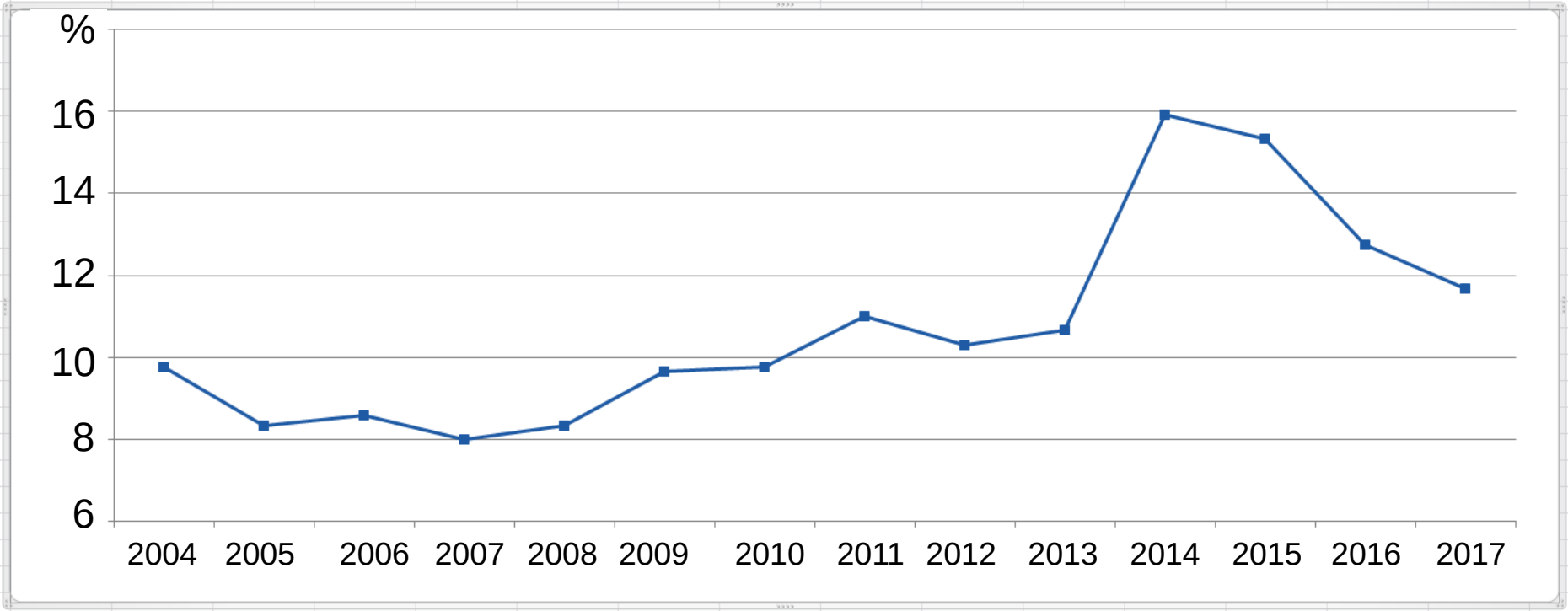
European network of paediatric research at the EMA (Enpr-EMA)
London, June 7 2018

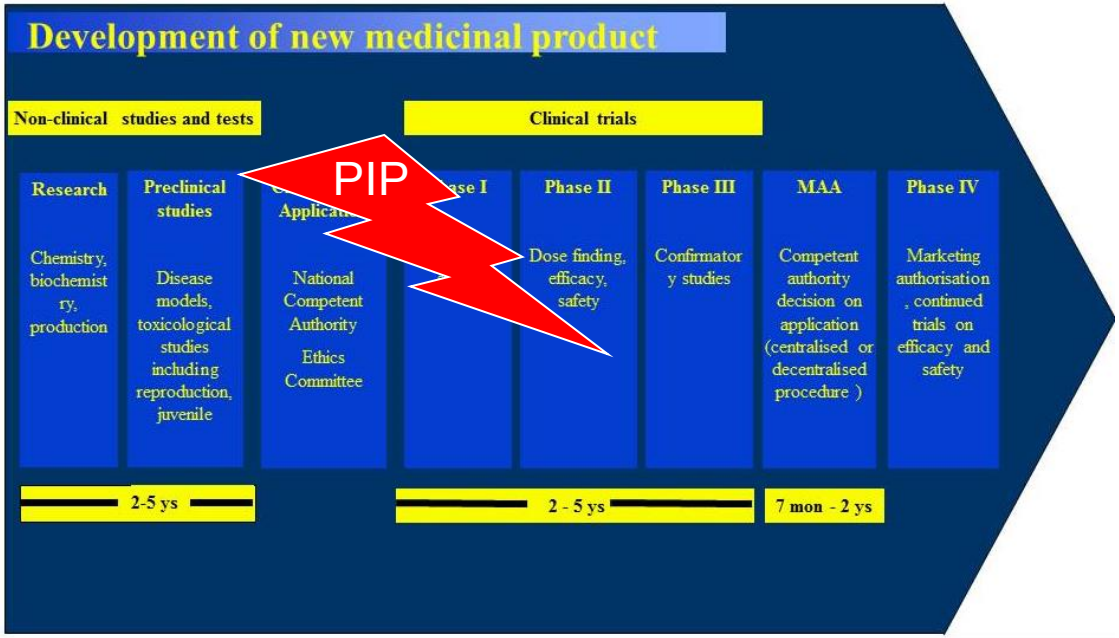
Clinical trial percentage involving minor subjects



Clinical Trial applications reported by sponsors to involve minors in at least one MS as a percentage of the total number of trials (not restricted to trials only involving paediatric population, *year reported when data generated in EudraCT* – risk for mistake if data not uploaded year of trial application submission).

Datawarehouse search 2018-03-19 in EudraCT database

When is timely application of PIP during development program related to individual clinical trial applications?



When, if complex clinical trial design not structured in traditional separate phases?

How do clinical trial applications (CTAs) interplay with an application for a paediatric investigation plan (PIP)?

	Scope	Decision/opinion /responsibility	Applicant	Possible contradiction PIP-CTA?
PIP	**Development program for an IMP** (trial results to be generated prior to market authorisation application)	**Centralised** in EU, PDCO	Market authorisation applicant	Application time after initial clinical trial(s) completed (phase I, II)
CTA	**Each clinical trial must have scientific grounds** (relevant, reliable and robust data) and **ethical basis** (integrity, rights, safety, dignity and well-being of subjects)	**Decentralised** in EU, clinical trial unit of National Competent Authority (NCA) and Ethics Committee	Sponsor of clinical trial - commercial (e.g. MAA applicant) or - non-commercial (e.g. new paediatric use for already marketed products)	Today no formal correlation PIP-CTA approval. Future clinical trial regulation – one single decision per Member State (NCA and EC) ”..taking opinion of PDCO on PIP into consideration..”

CTFG open for actions to increase contacts between assessors from different structures - PDCO, clinical trial units of NCAs and Ethics Committees

- Future **single decision National Competent Authority and Ethics Committee** on clinical trial applications per Member State when **Clinical Trial Regulation (CTR, EU No 536/2014)** replaces national laws on interventional clinical trials on safety and efficacy of medicinal products
  CTR will apply when Portal and Database built by EMA has reached full functionality

- CTFG (Clinical Trial Facilitation Group) open for **exchange on issues relating to pediatric trials** between PDCO delegates and assessors from clinical trial units of National Competent Authorities and colleagues from Ethics Committees

- CTFG plans a **EU training workshop of paediatric clinical assessors from national competent authorities trial units and ethics committees** (date and program to be decided) promoting exchange of scientific and ethical perspective of paediatric clinical trials and harmonisation paediatric clinical trial assessment within EU

Thanks for your attention – questions welcome!

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