Landstinget i Kalmar län

Barn och kliniska prövningar

Falkenberg 17 maj 2012

Ellen Vinge

Varje dag lite bättre
– kraften hos många!

Historik

- 1947 Nürnbergkodexen: all humanforskning kräver informerat frivilligt samtycke (inget tvång förekommer och att försökspersonen har insikt i eventuella risker, är myndig och har förmåga att ge samtycke).
- 1964 The World Medical Association antog ”the Declaration of Helsinki – Ethical Principles for medical research involving human subjects”
- 1989 FNs barnkonvention
- 2002 i USA: The Best Pharmaceuticals for Children Act
- 2007 i EU: The Paediatric Regulation med huvudsakligt syfte att förbättra hälsan hos barn i Europa, utan att utsätta barn för onödiga studier, och utan att fördröja godkännandet av läkemedel för vuxna.

Ny lagstiftning om läkemedel för barn i EU:

EMA: Medicines for Children

- The European Paediatric Initiative

- ¨In the EU, 50% or more of medicines used in children have never been actually studied in this population, but only in adults, not necessarily in the same indication (or the same disease).¨

The Paediatric Regulation

- The Regulation came into force on 26 January **2007.** Its main impact was the establishment of the Paediatric Committee (PDCO)
- The Committee's main role is to determine the studies that companies must carry out on children as part of **paediatric investigation plans** (PIPs).
- All applications for marketing authorisation for new medicines that were not authorised in the EU before 26 January 2007 have to include the results of studies carried out in children of different ages.

Essential medicines for children

Essential medicines for children
Advocacy
Paediatric medicines Regulators' Network
Publications

Paediatric medicines Regulators' Network (PmRN)

There is a significant need for research and development of paediatric medicines. The lack of suitable paediatric medicines, paired with inconsistent regulatory frameworks, poses significant risks to a particularly vulnerable patient population.

As part of the WHO's Better Medicines for Children initiative a Paediatric medicines Regulator's Network (PmRN) has been set up with representatives from national medicines regulatory authorities (NMRAs) from all regions.

Objectives of the network

National medicines regulatory authorities are welcome to participate in the network. For further information, interested Member States are encouraged to contact: pmr_network@who.int

List of Members as of November 2011
pdf, 11kb

make medicines child size

Contact: pedmeds@who.int

Department of Essential Medicines and Health Products

20 Avenue Appia
CH-1211 Geneva 27

Editor's choice

Paediatric clinical trials guidance for

PmRN Newsletter No.2

PmRN Newsletter No.2 [pdf 131kb]

StaR Child Health:

Developing evidence-based guidance for the design, conduct and reporting of pediatric trials.

Nätverk grundat 2009 för att arbeta med bristen på, och bristerna i, kliniska prövningar på barn.

Priority topics *(från Hartling et al. Pediatrics 2012; 129:S112-117)*

1. Recruitment and informed consent: providing appropriate information for children and families eligible for inclusion in a trial
2. Containing the risk of bias
3. Data monitoring committees
4. Adequate sample sizes
5. Valid measurement of relevant and standardized outcomes

StaR Child Health - Priority topics, continued:

6. Appropriate age groups for pediatric trials
7. Age-specific dosages
8. Age-specific administration
9. Relevant comparators
10. Short-term and long-term participants´ safety
11. Global child health: ensuring relevance and appropriate representation of all children in research

Hartling, Wittmeyer, Caldwell, van der Lee, Klassen, Craig, Offringa and for the StaR Child Health Group. Pediatrics 2012; 129:S112-117