25 November 2011
EMA/923100/2011

Ethical considerations for paediatric trials - how can Ethics Committees (ECs) in the European Member States and the Paediatric Committee (PDCO) at the European Medicines Agency work together?

A European workshop at the EMA* on ethical aspects of the design and conduct of clinical trials with the paediatric population for medicine development, 29 - 30 November 2011, Room 3A

Agenda

29 November 2011, Tuesday, 08:00

- Registration open
- Please plan for about 30 minutes to complete security and registration

29 November 2011, Tuesday 09:00 – 09:45

Session 1: Introduction and meeting purpose (Chair: Daniel Brasseur)

#	Time	Agenda	Speaker	Min
--	09:00-09:05	Welcome		5
1	09:05-09:20	Role of the PDCO in the European regulatory system	Daniel Brasseur	15
2	09:20-09:35	Legal-regulatory framework for the assessment of paediatric trials in Europe and feed back on EMA meeting on third country clinical trials	Agnès Saint Raymond	15
3	09:35-09:45	Discussion		10

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29 November 2011, Tuesday 09:45 – 12:30

Session 2: How are paediatric trial proposals evaluated? (Chair: Petra Knupfer)

#	Time	Agenda	Speaker	Min
4	09:45-10:05	Lessons learned on scientific-ethical issues from the TEDDY survey among European ECs	Annagrazia Altavilla	15 + 5 disc.
--	10:05-10:30	Coffee break		15
5	10:30-11:15	Ethical assessment of paediatric trials: examples of issues with risk assessment	Inez de Beaufort	45
6	11:15-11:45	Evaluation of Paediatric Investigation Plans (PIPs) and of ethical aspects of the design of paediatric trials proposed in PIPs	Marek Migdal	30
7	11:45-12:30	Discussion: What are the issues? Given different roles and responsibilities, how can we collaborate on paediatric trials?	PDCO, ECs, EMA	45

Lunch break 12:30-14:00

29 November 2011, 14:00 – 17:15

Session 3: Methodology and ethical aspects of paediatric trials (Chair: Marek Migdal)

#	Time	Agenda	Speaker	Min
8	14:00-14:45	Ethical principles and practices in paediatric trials: emerging issues	Bartha Maria Knoppers	35 + 10 disc.
9	14:45-15:05	Methodological issues in paediatric trial design	Norbert Benda	15 + 5 disc.
10	15:05-15:30	Trials with neonates: desirable scientific approaches, their ethical issues and potential solutions	Dick Tibboel	20 + 5 disc.
--	15:30-15:45	Coffee break		15
11	15:45-16:15	Specific issues that Ethics Committees (ECs) face with paediatric trials	Petra Knupfer	30
11 b	16:15-16:30	Ethical issues of paediatric trials: a EUCROF survey	Martine Dehlinger-Kremer	15
12	16:30-17:15	Panel discussion: Agnès Saint Raymond, Petra Knupfer, Christoph Male, Albert Allen, further ECs, Brigitte Blöchl-Daum	See left	45

Evening:

For the participants interested, EMA is happy to contact a local restaurant / bar for an informal get together, but unfortunately EMA is unable to cover the costs.

30 November 2011, Wednesday, 09:00 – 12:30

Session 4: Looking to the future (Chair: Bartha Maria Knoppers)

#	Time	Agenda	Speaker	Min
13	09:00-09:15	Results of the EMA survey among European ECs	Ralf Herold	15
14	09:15-10:45	Work in subgroups (to be refined): 1. Approaches to the assessment of risks before the paediatric trial 2. Trials with neonates 3. Addressing vulnerability of children in details of trial design, e.g., monitoring risk, stopping rules 4. Different approaches of PDCO and ECs for assessing the relationship of benefit and risks / harms before the trial Each subgroup to make suggestions on: • How in PIPs (e.g., summary report) can EMA/PDCO help the ECs? • How could ECs help EMA/PDCO? • How could children be involved?	Moderator: 1. TBD 2. Ralph Bax 3. TBD 4. TBD	90
--	10:45-11:00	Coffee break		15
15	11:00-12:30	Reporting back to plenary meeting integrated with Panel discussion: Inez de Beaufort, Petra Knupfer, ECs, EMA		90

Lunch break 12:30-14:00

30 November 2011, Wednesday, 14:00 – 15:30

Session 5: Collecting and defining the outcome of the meeting (Chair: Tim Chambers)

#	Time	Agenda	Speaker	Min
18	14:00-14:15	Identifying meeting outcomes	Tim Chambers	15
19	14:15-15:15	Plenary discussion: • What do ECs want to see in a PIP? • What do ECs want to see in current guidance? • Would ECs want assistance and if yes, where and how? • Practical steps for information exchange	Panel: Petra Knupfer, Inez de Beaufort, Marek Migdal, Peter Helms, ECs, EMA	60
20	15:15-15:25	Summary	Tim Chambers	10
20	15:25-15:30	Closing remarks	Daniel Brasseur	10