MEDICAL UNIVERSITY OF VIENNA

Protection of subjects and informed consent - the clinical trials regulation and the inclusion of minors and pregnant and breastfeeding women in research on medicinal products

Andrea Heckenberg

Ethics Committee

Medical University of Vienna

ethics committee
Medical University of Vienna

Informed consent form

CT Directive 2001

‘informed consent’: decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative

CT Regulation 2014

Article 29 - Informed consent

…written information given to the subject and/or the legal representative for the purposes of obtaining his or her informed consent shall be kept concise, clear, relevant, and understandable to a lay person.

Inclusion of minors in clinical trials

Protection, but not exclusion

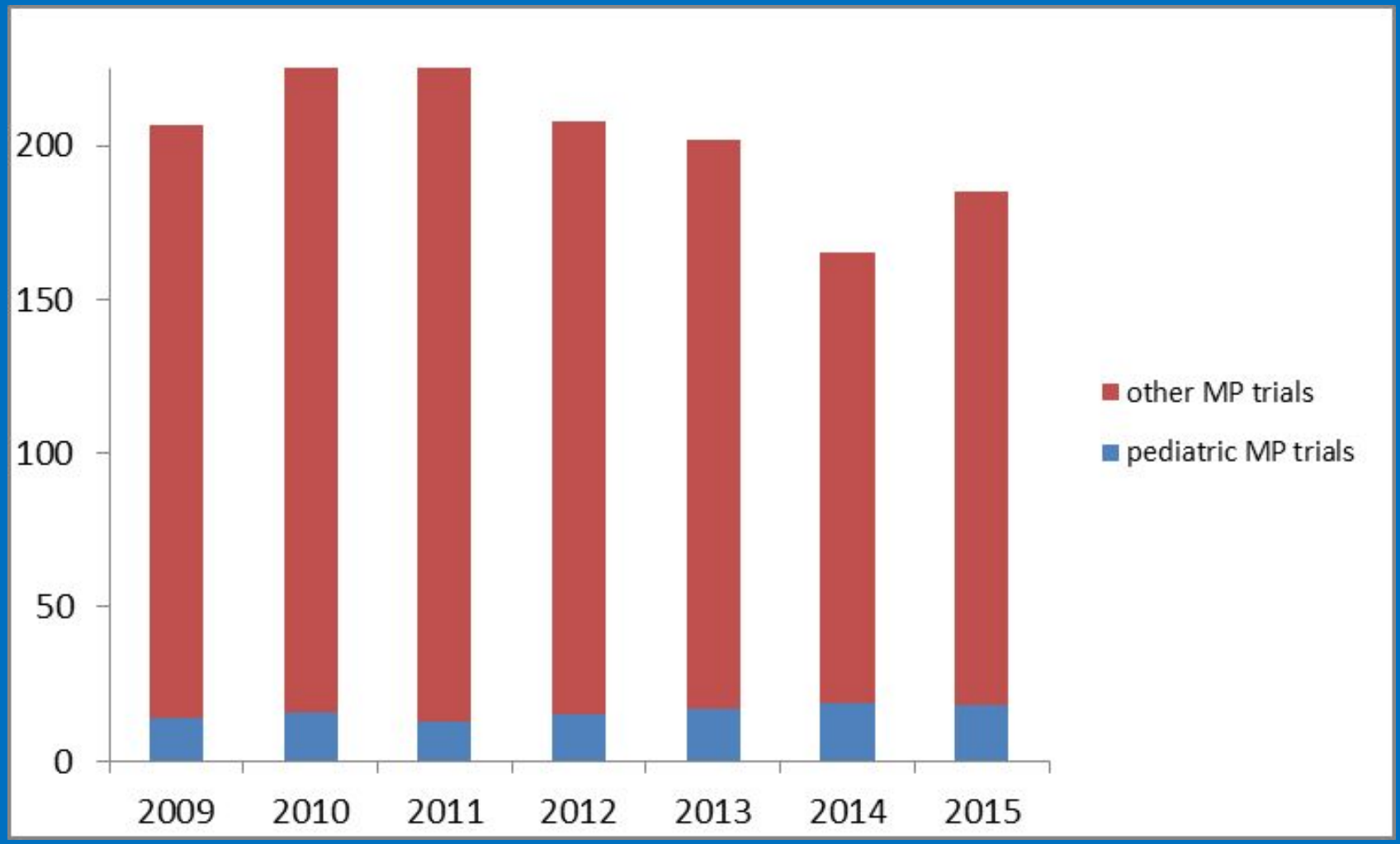
CT Directive 2001

Children represent a vulnerable population with developmental, physiological and psychological differences from adults, which make age- and development- related research important for their benefit.

Regulation (EC) No 1901/2006 of the European parliament and of the council of 12 December 2006 on medicinal products for paediatric use

This Regulation aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat the paediatric population are subject to ethical research of high quality and are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric populations.

Clinical trials on medicinal products submitted to the EC of Vienna Medical University



Inclusion of minors in clinical trials

Self-determination and autonomy

CT Directive 2001

A clinical trial on minors may be undertaken only if:

informed consent of the parents (legal representative) has been obtained - must represent the minor's presumed will

the minor has received information according to its capacity of understanding regarding the trial, risks and benefits

the explicit wish of a minor who is capable of forming an opinion and assessing this information is considered

CT Regulation 2014

Article 32 - Clinical trials on minors

1. A clinical trial on minors may be conducted only where

…the minors have received … information …in a way adapted to their age and mental maturity

…the explicit wish of a minor who is capable of forming an opinion and assessing the information … to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator

CT Regulation 2014

Article 32 - Clinical trials on minors

The minor shall take part in the consent procedure in a manner adapted to his or her age and mental maturity.

If during a clinical trial the minor reaches the age of legal competence to give informed consent as defined in the law of the Member State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical trial.

Inclusion of minors in clinical trials

Definition of benefit and risk

CT Directive 2001

Article 4 - Clinical trials on minors

A clinical trial on minors may be undertaken only if:

some direct benefit for the group of patients is obtained from the clinical trial

clinical trials have been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress have to be specially defined and constantly monitored

CT Regulation 2014

Article 32 - Clinical trials on minors

A clinical trial on minors may be conducted only if there are scientific grounds for expecting that participation in the clinical trial will produce:
(i) a direct benefit for the minor concerned outweighing the risks and burdens involved; or
(ii) some benefit for the population represented by the minor concerned and such a clinical trial will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition.

Inclusion of minors in clinical trials

Therapy optimization studies

CT Regulation 2014

‘Low-intervention clinical trial’

A clinical trial which fulfils all of the following conditions:

(a) the investigational medicinal products, excluding placebos, are authorised;

(b) according to the protocol of the clinical trial,
(i)the investigational medicinal products are used in accordance with the terms of the marketing authorisation;

or

or

(ii) the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and

(c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned;

Inclusion of pregnant and breastfeeding women in clinical trials

CT Regulation 2014

Specific expertise should be considered when assessing clinical trials involving subjects in emergency situations, minors, incapacitated subjects, pregnant and breastfeeding women and, where appropriate, other identified specific population groups, such as elderly people or people suffering from rare and ultra rare diseases.

CT Regulation 2014
Article 33 Clinical trials on pregnant or breastfeeding women

A clinical trial on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 28, the following conditions are met:

(a) the clinical trial has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved; or

(b) if such clinical trial has no direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, it can be conducted only if:

(i)a clinical trial of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;

(ii) the clinical trial contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction or other embryos, foetuses or children; and

(iii) the clinical trial poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth;

(c) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child; and

(d) no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial.

Conclusion

Important steps concerning informed consent and inclusion of minors and of pregnant and breastfeeding women in clinical trials have been undertaken in the CT Regulation 2014

Emphasis on quality of ICF

Increased recognition of autonomy and self-determination of minors taking part in a clinical trial

Better definition of benefit / risk conditions in clinical trials on minors

Low intervention trials: facilitation of therapy optimization studies (also in off-label use)

Inclusion of pregnant and breastfeeding women

MEDICAL UNIVERSITY OF VIENNA

Thank you
for your attention

ethics committee
Medical University of Vienna