

Teddy Network of Excellence

Lessons learned on scientific-ethical issues from the TEDDY survey among European ECs

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Background



Network of Excellence founded by



- With the WP7 entirely dedicated to Ethics
- Continues to develop activities in the field of Ethics and Methodology



Survey on ethical and legal frameworks existing in Europe for CTs in paediatrics

- Objective:
to analyse measures enforced by Member States to implement the Clinical Trials Directive and all the other European norms relevant for clinical research in paediatrics
- Responses from **27** European Countries
- Results:
Many differences in the protection of children involved in clinical research exist across Europe

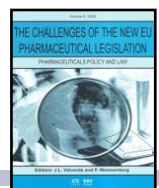


Journal International de Bioéthique

3/2008:17-48

Pharmaceutical Policy and Law Journal

11/2009:1-9



Participation in public consultation on the “European Ethical recommendations ”

INTEGRATION
principles contained in relevant
international/European
ethical/legal sources, consistent
with the
INTERNATIONAL HUMAN
RIGHTS LAW



Final 2008

ETHICAL CONSIDERATIONS FOR CLINICAL TRIALS ON MEDICINAL PRODUCTS CONDUCTED WITH THE PAEDIATRIC POPULATION

Recommendations of the ad hoc group for the development of implementing
guidelines for Directive 2001/20/EC relating to good clinical practice in the
conduct of clinical trials on medicinal products for human use

KEYWORDS	Ethics, Clinical trial, Child, Neonate, Minor, Adolescent, Directive, Consent, Ethics Committee, Assent
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“Survey on the Involvement of Ethics Committees in paediatric research in Europe”

Objectives:

- To identify ECs operating in Europe
- To identify ECs entitled to review paediatric protocols, according to national legislation
- To evaluate how paediatric expertise is guaranteed in ECs
- To assess ECs awareness of the new European paediatric regulatory framework
- To monitor and assess the impact of the new European paediatric regulatory framework on Ethics Committees activities
- To identify future initiatives to increase ECs involvement in paediatric research

Inventory of Ethics Committees Methodology



1007 / 29

ECs/countries

Contact information of

832/ 28

ECs/countries

COUNTRY	No. of ECs	Inhabitants (millions)	No. ECs / 1.000.000 inh.
Bulgaria	103	7.6	13.55
Iceland	3	0.3	10.00
Finland	25	5.3	4.72
Italy	270	60	4.50
Belgium	38	10.7	3.55
Austria	27	8.3	3.25
Spain	143	45.8	3.12
Ireland	13	4.5	2.89
Slovakia	13	5.4	2.41
UK	143	61.7	2.32
Latvia	5	2.3	2.17
Luxembourg	1	0.5	2.00
Malta	1	0.5	2.00
The Netherlands	32	16.4	1.95
Denmark	9	5.5	1.64
Estonia	2	1.3	1.54
Norway	7	4.7	1.49
Poland	54	38.1	1.42
Cyprus	1	0.8	1.25
Czech Republic	9	10.5	0.86
Sweden	7	9.2	0.76
Germany	54	82	0.66
France	40	64.3	0.62
Lithuania	2	3.3	0.61
Slovenia	1	2	0.50
Hungary	1	10	0.10
Portugal	1	10.6	0.09
Greece	1	11.2	0.09
Romania	1	21.5	0.05
TOTAL	1007	504.3	2.00

Survey on Ethics Committees Methodology

❑ Electronic Questionnaire

(12 questions, mandatory/optional + filter question on ECs competence)

✓ Two main sections:

- ECs awareness and knowledge of the current regulatory framework in paediatrics and its impact on their activities;
- ECs interest and involvement in paediatric research

✓ Preliminary version shared with the chair and some Members of the PDCO

Acta paediatrica 6.7.2011

Altavilla A, Manfredi C, Baiardi P, Dehlinger-Kremer M,
Galletti P, Alemany Pozuelo A, Chaplin J, Ceci A.



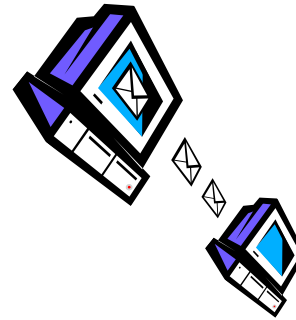
RESULTS

154

ECs Participants

139/22

**ECs in charge of
reviewing paediatric
protocols/Countries**

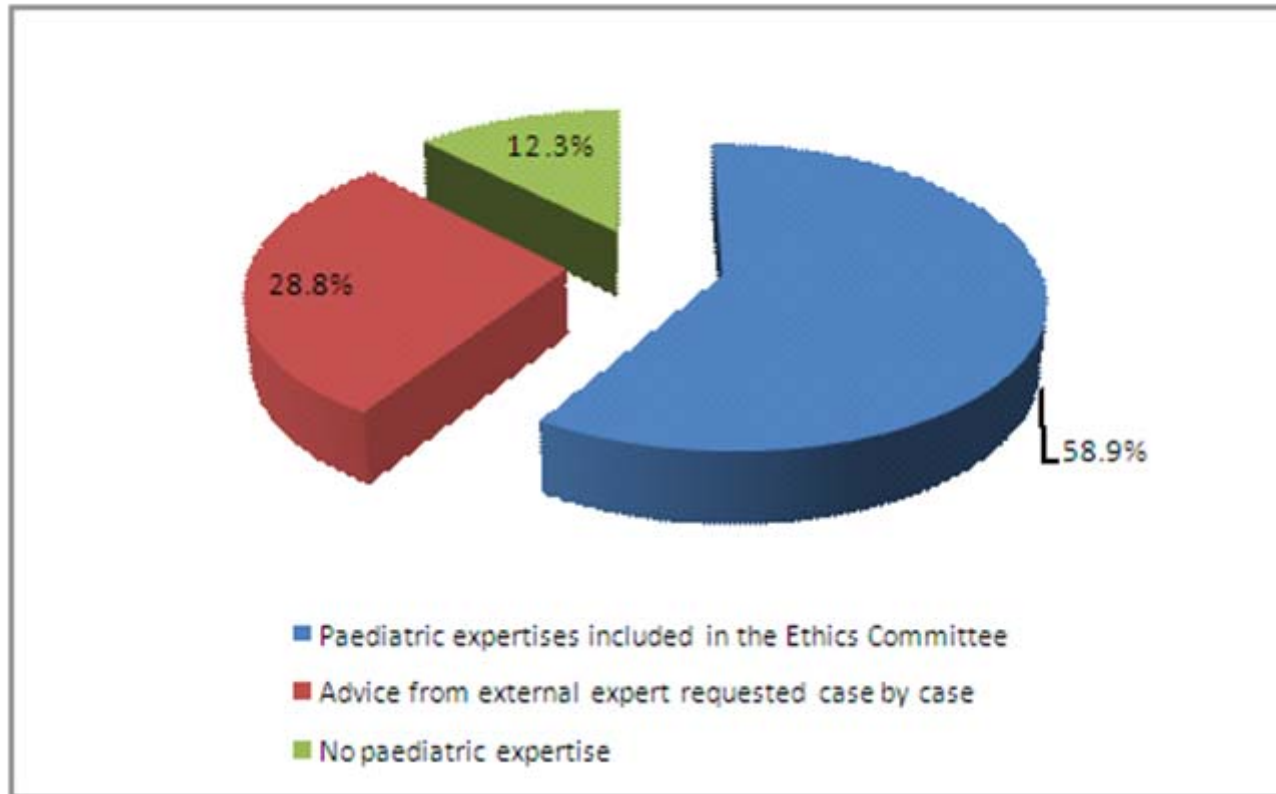


RESULTS

Data Analysis

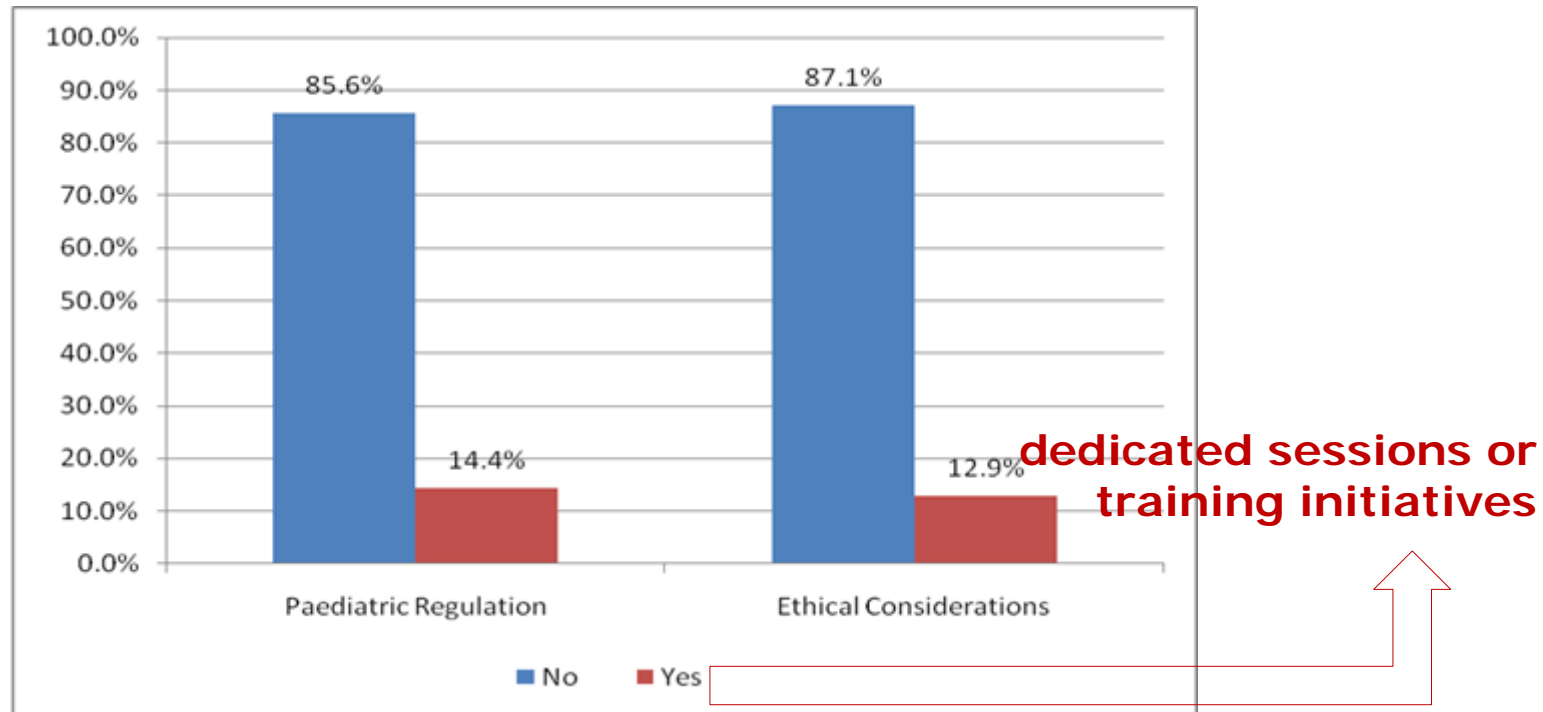
- Results expressed as frequencies and percentages
- Subgroups stratified in old EU Member States (EU-15) and new Member States
- Norway and Iceland included in the EU-15 group

RESULTS: Paediatric expertise



Paediatric expertise usually represented by a paediatrician

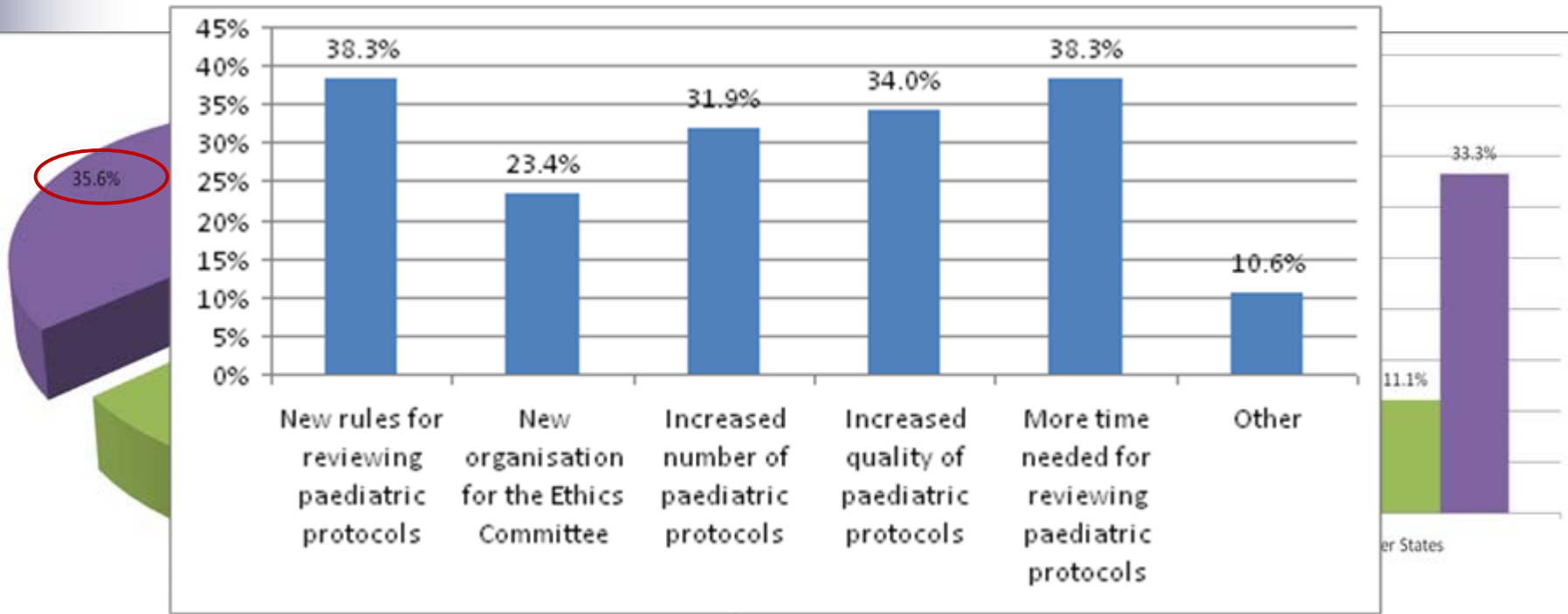
RESULTS: ECs awareness of the new regulatory framework



- 70% EU-15 (Belgium, Denmark, Germany, Italy, Norway, Portugal, Spain, Sweden)
- 30% new MS (Czech Republic, Latvia, Poland, Slovakia)

RESULTS: Declared Impact of new regulatory framework on ECs activities

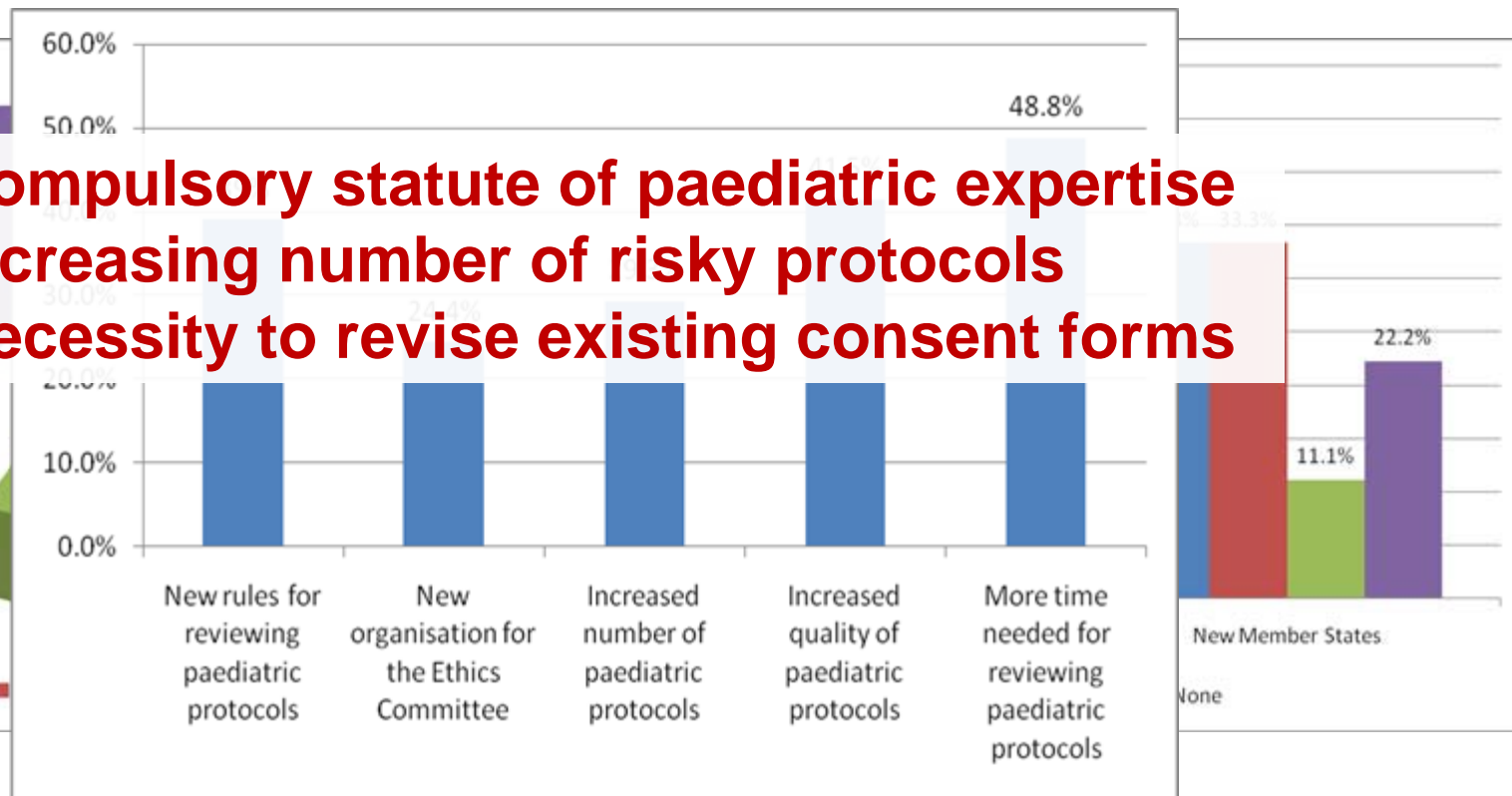
Paediatric Regulation



RESULTS: Declared Impact of new regulatory framework on ECs activities

European “Ethical considerations”

- Compulsory statute of paediatric expertise
- Increasing number of risky protocols
- Necessity to revise existing consent forms



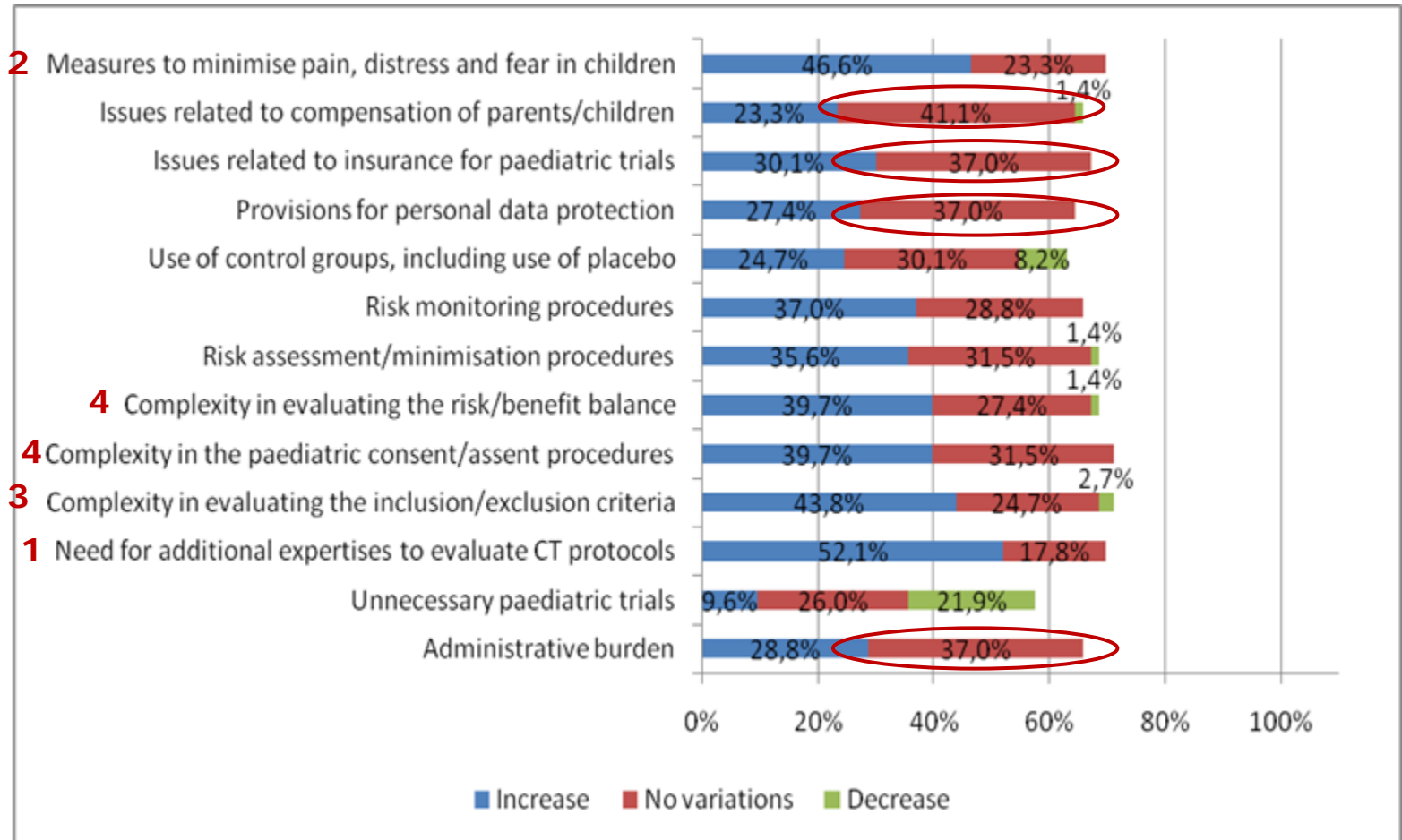
RESULTS: Impact of new regulatory framework on ECs activities

Other possible global effects, the increase of:

- ❑ number of medicines tailored for children
- ❑ well designed paediatric trials
- ❑ paediatric multicentre clinical studies
- ❑ lack of knowledge and studies regarding the risks and burdens really acceptable for children in different age group
- ❑ difficulty to adapt information to parents and children in accordance with new requirements

RESULTS:

Major issues to be dealt with

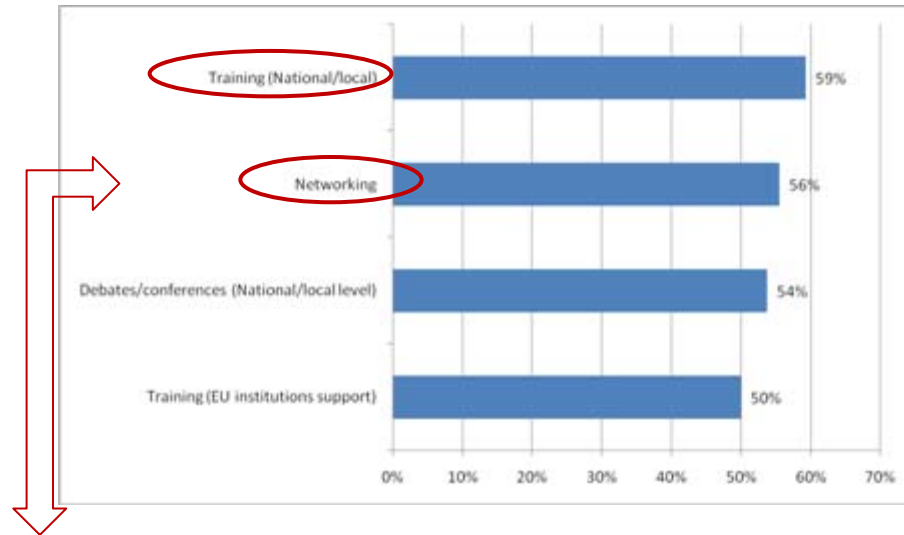


RESULTS: ECs involvement and interest in initiatives

Participation in paediatric initiatives

Only 30% participated 74% would like to participate

Types of initiative	%
Conferences	68%
Training	32%
Projects	23%
Debates	18%
Other	18%



63% EU-15 (Belgium, France, Germany, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, The Netherlands)

27% new Member States (Cyprus, Czech Republic, Estonia, Latvia, Malta, Poland)

Conclusions

Gap between the European and local level



- lack of knowledge of the European regulatory framework related to paediatric research
- lack of awareness of ethical issues specifically related to paediatric research
- lack of involvement of Ethics committees in paediatric research

Conclusions

- ❑ Need to favour the growing of competence and involvement of Ethics Committees in paediatric research as well as of the awareness of ethical aspects
- ❑ Need to promote the implementation of “European ethical recommendations” at local level

Conclusions

- ❑ Need to let parents/children to acquire competencies and awareness on critical issues related to clinical trials
- ❑ To empower the role of parents in decision process in order to favour children participation in clinical trials



Recommendations for parents and children



Age appropriate information/assent forms for children

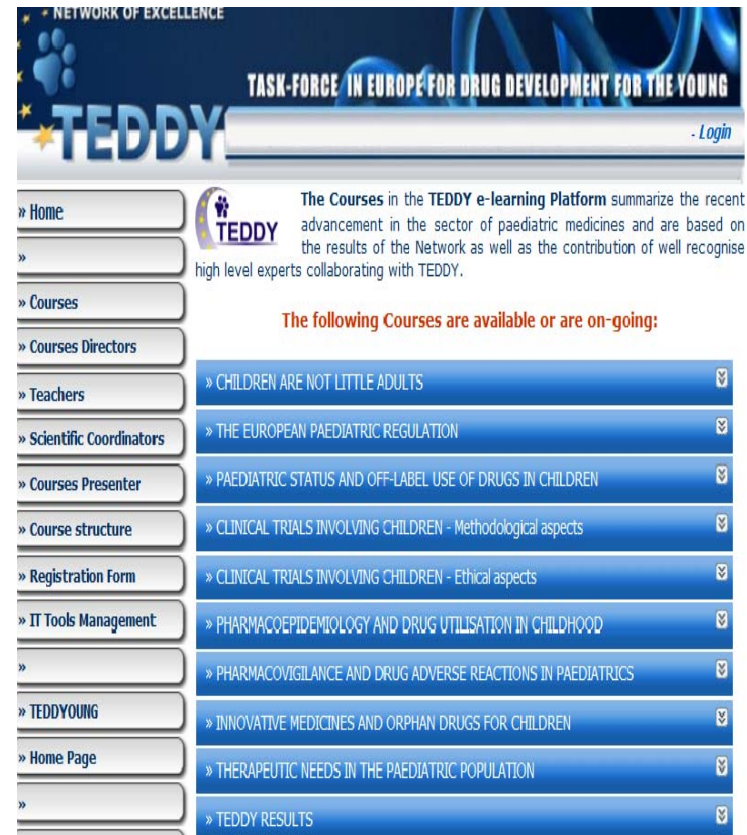


Conclusions

- ❑ Need to favour initiatives (e.g. debates, training...) aiming at the integration of Ethics Committees interested in paediatric research

E-learning platform

<http://www.teddylearning.org/>



NETWORK OF EXCELLENCE
TASK-FORCE IN EUROPE FOR DRUG DEVELOPMENT FOR THE YOUNG
TEDDY - Login

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» TEDDYOUNG
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The Courses in the TEDDY e-learning Platform summarize the recent advancement in the sector of paediatric medicines and are based on the results of the Network as well as the contribution of well recognise high level experts collaborating with TEDDY.

The following Courses are available or are on-going:

- » CHILDREN ARE NOT LITTLE ADULTS
- » THE EUROPEAN PAEDIATRIC REGULATION
- » PAEDIATRIC STATUS AND OFF-LABEL USE OF DRUGS IN CHILDREN
- » CLINICAL TRIALS INVOLVING CHILDREN - Methodological aspects
- » CLINICAL TRIALS INVOLVING CHILDREN - Ethical aspects
- » PHARMACOEPIDEMIOLOGY AND DRUG UTILISATION IN CHILDHOOD
- » PHARMACOVIGILANCE AND DRUG ADVERSE REACTIONS IN PAEDIATRICS
- » INNOVATIVE MEDICINES AND ORPHAN DRUGS FOR CHILDREN
- » THERAPEUTIC NEEDS IN THE PAEDIATRIC POPULATION
- » TEDDY RESULTS

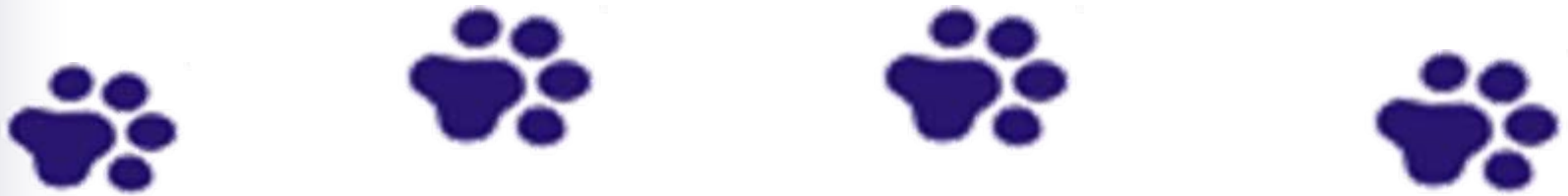
Conclusions

- ❑ Need of more collaboration between PDCO/EMA and Ethics Committees



NETWORKING among Ethics Committees across Europe

Essential tool to enhance collaboration and sharing experiences



Thank you

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