Revision of the Clinical Trials Directive - Key issues and next steps

EURECNET Conference

Bratislava, 12-13 April 2012

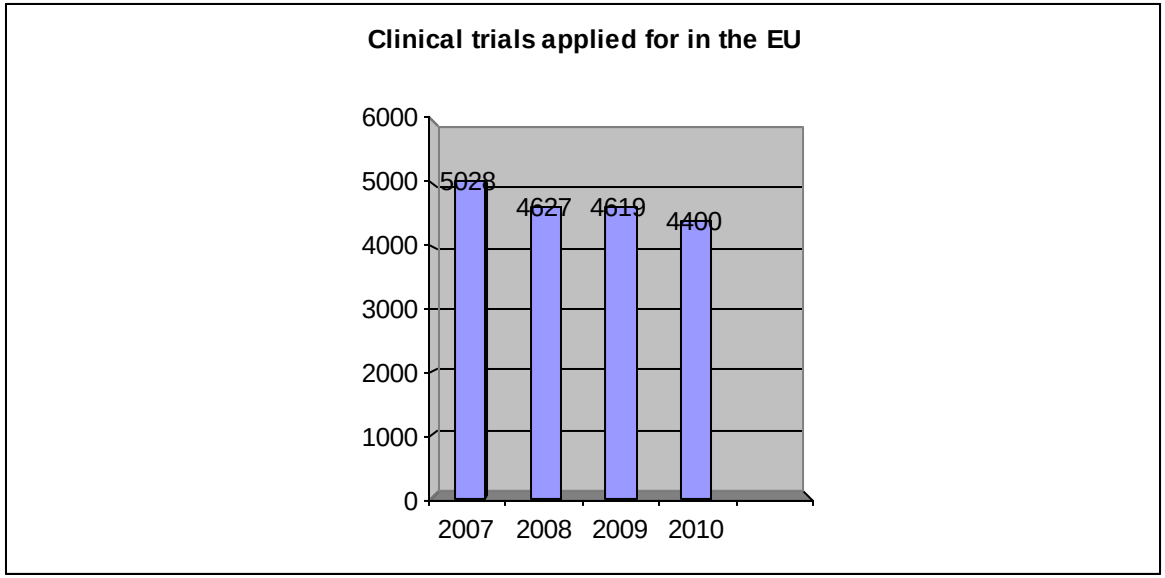
Fabio D'Atri

Unit D6 „Medicinal products – quality, safety and efficacy"

Directorate-General „Health and Consumers"

European Commission

Trends


Clinical trials applied for in the EU
6000
5000
4000
3000
2000
1000
0
5028
4627
4619
4400
2007
2008
2009
2010

Trends

- *Increase of delay of start of trial: 90%*
- *Increase of resource needs to handle authorisation process: 107%*
- *Increase in administrative costs: 98%*
- *Increase in costs for insurance fees: 800%*

State of play of the revision

- *Report on the direct and indirect impacts of the Clinical Trials Directive published in 2008*
- *2 public consultations (responses and summaries published on SANCO website)*
- *Various workshops and meetings with stakeholder.*

State of play

- *Impact assessment finalised*
- *Drafting phase*
- *Legislative proposal (a Regulation) by COM ➔ scheduled for mid-2012*

Key issues of the proposal

- *Submissions and assessments of clinical trials*
- *Adaptation of requirements to risks considerations*
- *Global aspects of clinical trials.*

Limitations

Ethical and local issues remains in the remit of MS competences

Jurisdictional limits towards 3rd countries

‘Deconstructing authorisation’

- *Submission (single EU-portal?)*
- *Assessment*
- *Decision*

Assessment

Until now only voluntary coordination in the assessement of multinational trials (VHP)

Assessment

In the future coordinated assessment of multinational trials, but:

- **How many Member States involved?**
- **Who coordinates?**
- **What areas are assessed jointly (scope)?**
- **What in case of disagreement?**
- **What to assess together?**
- **Who assesses what?**

Assessment

1. Compliance with the rules on manufacturing and importation?
2. Compliance with rules on tracking, storing, destruction, returning?
3. Compliance with the rules on labelling?
4. The anticipated therapeutic and public health benefits taking account of
   - the characteristics of and knowledge about the investigational medicinal products; and
   - the relevance of the clinical trial and the reliability and robustness of data generated in the clinical trial, taking account of statistical approaches, design of the trial and methodology (including sample size and randomisation, comparator and endpoints)?
5. The risks and inconveniences for the subject, taking account of
   - the characteristics of and knowledge about the investigational medicinal products and the 'non-investigational medicinal products';
   - the characteristics of the intervention compared to normal clinical practice;
   - the safety measures, including provisions for risk minimisation measures, monitoring, safety reporting, and the safety plan; and
   - the risk to subject health posed by the medical condition for which the investigational medicinal product is being investigated?
6. The completeness and adequateness of the investigator's brochure?
7. Compliance with the requirements for informed consent?
8. Compliance of the arrangements for rewarding or compensating investigators and subjects?
9. Compliance of the arrangements for recruitment of subjects?
10. Compliance with Directive 95/46/EC of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data?
11. Suitability of individuals?
12. Suitability of facilities?
13. Compliance with rules on insurance and indemnity?
14. Compliance with the applicable rules for the collection, storage and future use of biological samples of the subject?

The role of Ethics Committees

- **We will not touch at the role of EC**
- **This will remain national competence**
- **However, in multinational trials EC will will have to collaborate with other EC and/or NCA**

The role of Ethics Committees

- **What are your views on these possible interactions?**
- **What would be the major challeges of such a system?**

Risk-adaptatation

- *Adapting requirements to risk of the trials*
- *Screening the existing requirements*
- *To recall:*
  - **Regulation of clinical trials addresses two risks: subject safety & data robustness**
  - **Risk-adaptation means more detailed rules and/or more flexible rules depending of the type of trial.**

Global aspects of clinical trials

- *Global cooperation and capacity building*
- *Inspections*
- *Transparency*

However jurisdictional limits have to be considered.

Conclusion

- *Streamline, simplify and harmonise*
- *Overarching aim is subject rights, safety and data robustness*
- *Thorough preparation of proposal*
- *Final decision is with the co-legislators.*

Many thanks!

http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm