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The revision of the Clinical Trials Directive – State of play and key issues

Workshop in the EP on
1 December 2011

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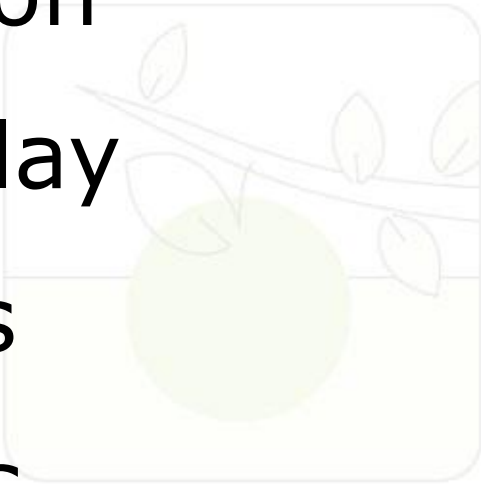
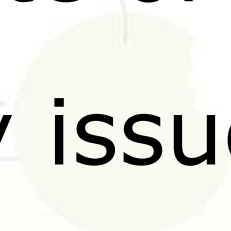
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- Introduction

- State of play

- Key issues

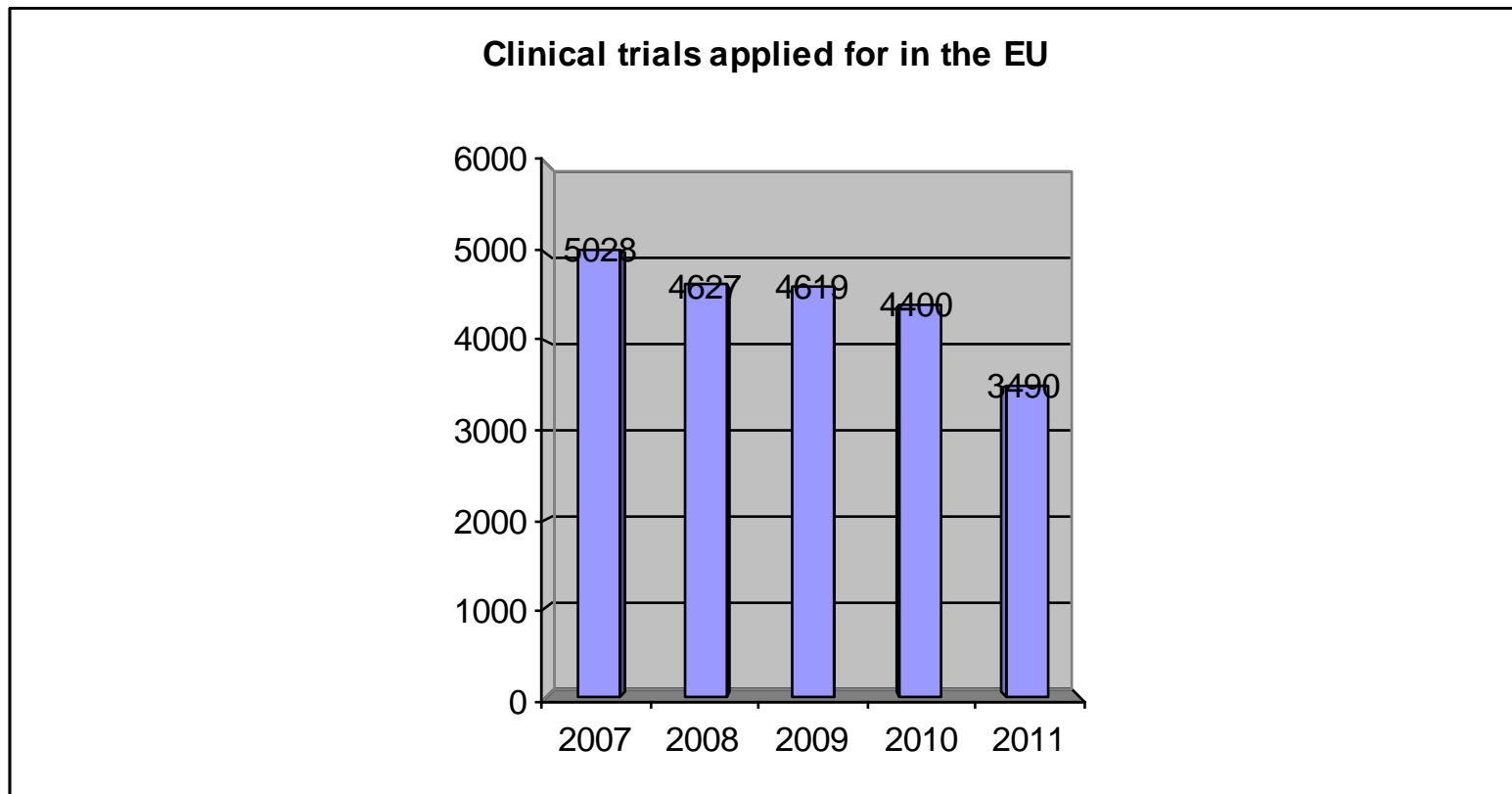
- Next steps





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Intro – a worrying decrease





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Revision of Directive - State of play

- 2 public consultations
- Responses and summaries are published on SANCO website



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Key issues (1)

- Separate submissions and assessments in multinational trials
- Adaptation to risk/practical requirements
- Global aspects of clinical trials
 - Alignment with global reg. trends
 - Challenges in supervision (jurisdictional limits!)



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Key issues (2) – possible options

- Single EU-portal
- „Coordinated assessment procedure“
- Risk-adapted regulation
- Clear rules on application dossier, safety reporting, etc.
- No change in scope



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Next steps

- Finalisation of impact assessment and legislative proposal
- Adoption of Impact assessment report and legislative proposal by COM → scheduled for mid-2012
- Then, submission to co-legislators



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Many thanks!



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