EFPIA Point of View – Clinical Trial Regulation and Ethics Committees

Nordic Trial and Nordic Research Ethics Committees’ Joint Meeting
Oct. 9th 2014, Helsinki, Finland

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Objectives of Clinical Trial Regulation

- Enhance Efficiency in the Clinical Trial Regulation Process
- Boost EU’s competitiveness

Implementation of Regulation plays a crucial role!
Key Elements in Implementation – EFPIA Point of View

1) Timelines
2) Cooperation with Ethics Committees – More later
3) Cooperation of Ethics Committees and Health Authorities
4) Functionality of EU CT Portal and database
5) Transparency provisions
6) Opt-out mechanisms
7) Substantial modifications
8) Notifications
9) Safety reporting provisions
10) Review of experience with the legislation
# Cooperation with Ethics Committees – EFPIA Point of View

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<thead>
<tr>
<th>Industry Standpoint</th>
<th>Final Regulation</th>
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<tbody>
<tr>
<td>• Member States to further develop mutual recognition concepts (non-legislative action) via greater networking and collaboration between ethics committees</td>
<td>• No provisions on greater collaboration between ethics committees</td>
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<td>• Enhanced cooperation via introduction of EU-funded platform (“EUnEthics”)</td>
<td>• Commission leaves it to the Member State to obtain input from Competent Authorities and Ethics Committees</td>
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<td>• Ethics Committees recognised with a role in assessing CTAs</td>
<td>• A clinical trials application shall be refused if an ethics committee with national remit issued a negative opinion</td>
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Cooperation with Ethics Committees
– EFPIA Point of View

★ Greater collaboration between ethics committees:
  ★ Support in implementation/ promoting consistency
  ★ Improve the pace of approval of a trial
  ★ Provide the potential for networking and collaboration
  ★ Convergence of standards in the field

★ Streamlined approval process and collaboration with national authorities is a key!

★ EFPIA welcomes initiatives such Nordic Ethics Committee Collaboration! Many possibilities!
**EFPIA engaged in implementation phase:**

- **Annex VI provisions** – pushing for a change
- **EMA CT Portal and Database Development** – Collaboration with EMA
- Supporting National Trade Associations
  - position papers/webinars/surveys
Cooperation with Ethics Committees
Pharma Industry Finland (PIF) Point of View

* Nordic ECs trendsetters in evaluation process – How to get organized?
  * ICH composition
    * National/regional members but flexible meeting procedures, e.g. video meetings
  * Well defined working procedures and clear instructions
    * Nordic instructions and templates
  * Competent Authority to transfer/present PART I
  * Meetings once a week (also July)
  * Enough resources and competence at the EC secretariat
    * Defined coordinator for each study, e.g. finalize IC details

* Nordic Pharma Industry Associations eager to be part of developing feasible approach!
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