Hopes and fears for the single portal from a Pharma company conducting Phase I trials in Europe

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Why has the 2001 Clinical Trials Directive been replaced?

- Was criticised by patients, researchers and industry for its disproportionate regulatory requirements
- These restrictions contributed to a significant decline in the number of clinical trials in the EU – about 25 % in the last few years

Maximum 60 days for approval

Some changes introduced by the Regulation

- Authorisation procedure → one single assessment outcome

- Legal form : Regulation

Minimum 60 days for approval (range : 60 – 106 days)

What role will Ethics Committees have under the new rules?

Assessment of clinical trials application

- Responsibilities and detailed composition will be determined independently by each EU country

Hopes

New Regulation aims at :

- Restoring EU's competitiveness in clinical research and development of new and innovative treatments
- Bringing patient-oriented research back to Europe
- Simplifying processes and standardising approaches between Member States
- Making it easier to conduct multinational clinical trials in the EU

Hopes

- Scientific, technical and ethical aspects of the trial will use a **single, co-ordinated procedure**; each MS will continue to assess purely national aspects and informed consent procedures
- Regulation : ensures identical rules are used throughout the EU
- Controls in EU countries and 3rd countries to make sure same rules apply

Hopes

- Simplified safety reporting procedures
- Tacit approval system will permit Sponsors to proceed with starting a trial once timelines have passed

Fears

- Timelines get lengthened, especially for Phase 1 monocentric trials
- CT Regulation is only feasible if the EU Portal is fully functional
- Changes to how we interact with MSs (CAs + ECs)
- Transparency

Transparency ?

- Transparency on the conduct and results of clinical trials has several benefits, and the Regulation strengthens the rules accordingly
  - Avoids redundancy and duplication
  - Ensures that even clinical trials with unfavourable results are made public, thereby avoiding 'publication bias'
  - Gives patients the possibility to find out about on-going clinical trials in which they may wish to participate

Transparency ?

Industry calls for responsible data sharing that :

- Safeguard the privacy of patients
- Respect the integrity of national regulatory systems
- Maintain incentives for investment in biomedical research
- Sets a deferral period for the release of both information about the trial and summary results from Phase I trials conducted in Europe

Thank you !

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