The new European Regulation on clinical trials (n°536/2014)

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Introduction

- In December 2017, the new European regulation on clinical trials EC 536/2014 will enter into force and will replace the current Directive 2001/20/EC on clinical trials.
- The new regulatory framework
  - ✓Aims to create an environment that is favorable to conducting clinical trials in the European Union (EU) and applies the highest standards of safety for patients.
  - ✓Ensures that the rules for conducting clinical trials are consistent and harmonized throughout the EU, and allows for administrative simplification

Full text EC 536/2014 http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

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Scope

- The new regulatory framework
  - ✓Applies to **all** clinical **trials** conducted in Europe, independent of:
    - *Type of sponsor*: academic and commercial
    - *Type of study*: early and late phase
    - *Number of sites or countries involved*: mono and multi-center / mono and multi-country
  - ✓Does not apply to non-interventional studies

New procedure for clinical trial applications (CTA): highlights

- The new regulatory framework
  - ✓Will ensure the simplification and harmonisation of the submission and evaluation procedure for a clinical trial application
    - *One single application* for all member states concerned by the study via a *European portal*
    - One of these member states centrally assesses the dossier and provides single opinion to sponsor and other member states within *harmonised defined timelines* (duration for initial application is between 60-106 days including clock stop) with *principle of tacit approval*
      - Interaction between ethics committee and competent authorities at national level
      - Interaction between member states

New procedure for clinical trial applications (CTA): highlights

- The new regulatory framework
  - ✓Each member state must organise itself at national level to ensure coordinated review of the application by the authorities and ethics committees and be able to provide one single decision at national level
- Assessment
  - *Part I*: central assessment by reporting member state in collaboration with other concerned member states
    - Knowledge about investigational medicinal product, relevance of clinical trial, reliability of data, completness of investigator brochure, compliance with GMP
  - *Part II:* national assessment by each Member state
    - Aspects of the dossier related to informed consent form, compensation to investigators & subjects, recruitment arrangements, privacy directive, suitability investigator & investigating site, damage compensation

New procedure for clinical trial applications (CTA)

Part I

Portal → validation (10 days) → assessment (50 days) → Portal

- Assessment report by RMS — 26 days
- Coordinated review by CMS — 12 days
- Consolidation — 7 days
- Notification by CMS — 5 days

10 days for sponsor to submit additional info
5 days for review

12 days for sponsor to submit additional info
12 days for coordinated review, 7 days for consolidation

Part II

Portal → validation → assessment → Portal

- Assessment report by CMS — 45 days
- Notification — 5 days

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