Update on the new clinical trial Regulation

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Disclaimer

The views and opinions expressed in the following slides are those of the presenter.

They should not be understood or quoted as being made on behalf of the European Commission.

Procedure

- **The Commission adopted the proposal on 17 July 2012;**
- **4 trilogues in December leading to an agreed text;**
- **COREPER agreement on 20 December 2013;**
- **ENVI vote 22 January 2014;**
- **EP plenary vote 10 March;**
- **Published on 27 May 2014 *Regulation (EC) 536/2014*;**
- **Application at the earliest 28 May 2016.**

Scope

- *Unchanged:*
  - **Interventional clinical trials with human medicinal products**
  - **New category of low intervention clinical trials with adapted requirements**
- *Not covered:*
  - **Non-interventional trials (observational…)**
  - **Trials without medicinal products (ex: devices, surgery…)**

Submission

- *Submission of the application via an EU portal*
- *All document to be submitted listed in the Annex to the Regulation (language of the documents decided by each MS)*

Authorisation procedure

3 steps:

- Validation
- Assessment
- Decision

Authorisation procedure - validation

- Reporting MS: chosen by MS (but sponsor may indicate one);
- Procedure to ensure that a reporting MS is always designated;
- Consultation between concerned MS;

Assessment

The Regulation defines issues that:

- *Have to be assessed jointly by MS (part I);*
- *Have to be assessed independently by each concerned MS (part II) – national/local issues.*

Assessment (part I)

The reporting MS interacts with the concerned MSs, collects their remarks and asks for clarifications to the sponsor.

The reporting MS in collaboration with the concerned MS drafts a report on part I.

Assessment (part II)

Each MS prepares independently a report on the issues covered by part II.

This assessment is carried out in parallel with the one of part I.

Decision

Each MS takes a single decision on the conduct of a CT on its territory.

The decision is composed of conclusions of the assessment of

Part I (possibilities for qualified opt-out)

and

Part II

Authorisation procedure - decision

- Refusal:
  - If part I negative,
  - if opt out used,
  - if assessment of part 2 negative,
  - if a “national” EC has issued a negative opinion.

- MS shall set up an appeal procedure.

- If trial not started within 2 years authorisation expires.

Assessors

- Independent from sponsor, investigators, trial site and person financing the trial.
- Specific expertise needed if “specific” groups of population involved (including rare/ultra rare diseases)

Ethics commitees

- Their role in the assessment and composition follows national rules.
- They will have to work within the given procedures and timelines.
- They have to take into account the views of lay persons (in particular patients/patients' organisations).
- In case of negative opinion by a "national "EC a trial cannot be authorised.

Protection of subjects

Specific provisions
- on minors
- on incapacitated subjects.

Protection of subjects

- Rules on CT on pregnant and breastfeeding women.

- National measures can be maintained for:
  - Soldiers;
  - Prisoners;
  - Person for which there is a judicial decision;
  - Persons in residential care institutions.

CT in emergency situations

- CT expected to produce a potential direct clinical relevant benefit for the subject;
- CT can only be conducted in emergency situations;
- Minimal risk and minimal burden in comparison with standard treatment.

EU Portal and database

- EU portal and database to be developed and managed by EMA
- Application of Regulation linked to the full functionality of portal and database (not before 2y. from publication).

EU Portal and database

- EU database publically accessible, except:
  - Personal data
  - CCI
  - Communications between MS
  - Ensure supervion of CT

- Data of application dossier not acceptable before a decision on the application is taken.

CT Results

- **Summary of results and layperson summary 1 year after the end of the trial (details in Annexes);**
- **CSR 30 days after MS granted, decision making process completed, withdrawal of application.**

THANK YOU FOR YOU ATTENTION !