Clinical trials sponsorship by academic and research institution: challenges and opportunities

Christine Mathieu - Katelijne De Nys
EDCTP, Antwerp, November 29th 2013

UZ Leuven | Herestraat 49 B - 3000 Leuven | www.uzleuven.be tel. +32 16 33 22 11 | UNIVERSITY HOSPITALS LEUVEN

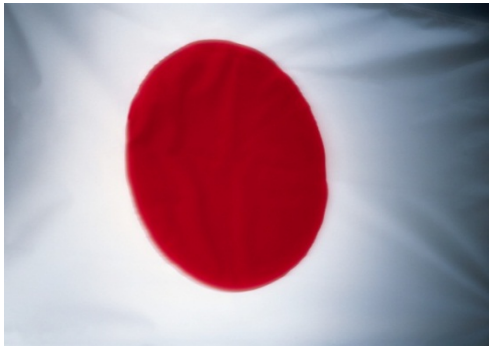
- History of the legislation in Europe
- ICH-GCP
- European Clinical Trial Directive
- Impact on daily practice
- European Clinical Trial Regulation
- Conclusion

History

- 1947 Nuremberg Code
- 1961 Thalidomide disaster
- 1964 Declaration of Helsinki
- 1997 ICH-GCP guidelines
- 2001 European Directive
- 2014 European Regulation?

ICH-GCP

- **ICH: I**nternational **C**onference on **H**armonization of technical requirements for registration of pharmaceuticals for human use
- US/Europe/Japan
- Authorities and industry
- Aim: set up of a consensus about efficacy – safety – quality requirements in registration files for new medicinal products
- Thoroughly implemented in every European Country, for national as well as international trials



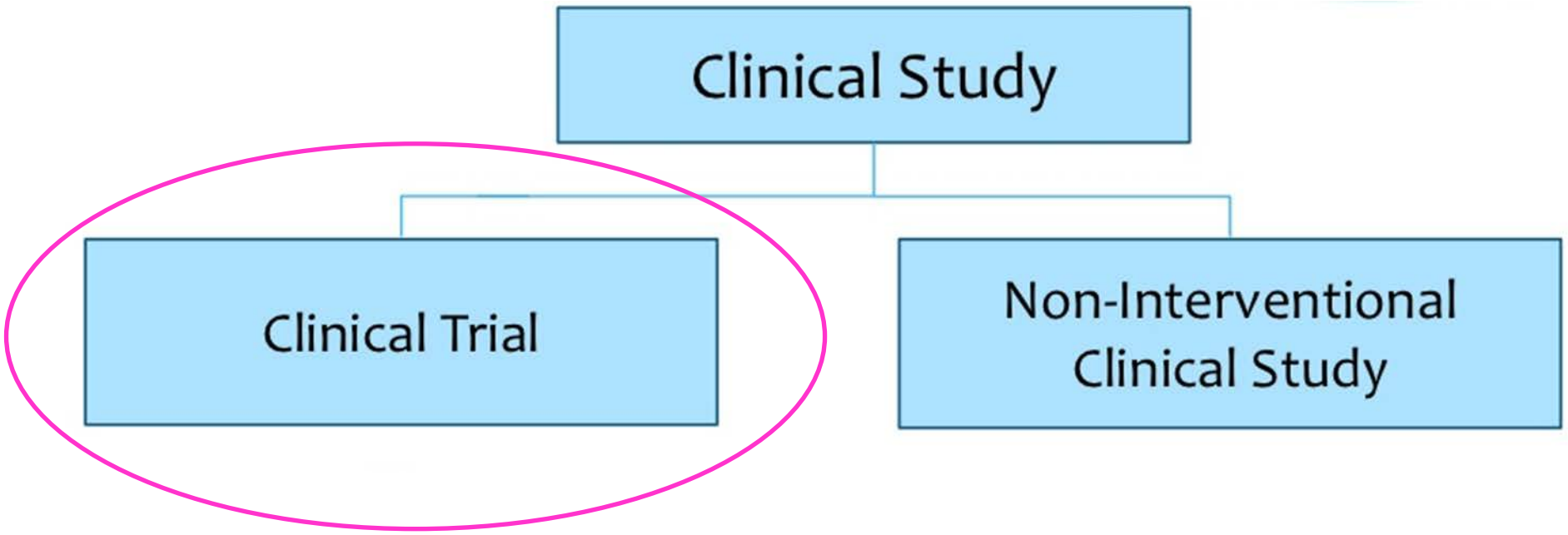
The European Directive 2001/20/EC (1)

- 4Th of April, 2001
- Directive:
  - ✓ Used to bring different national laws into line with each other
  - ✓ Lays down certain end results that must be achieved in every Member State
  - ✓ National authorities have to adapt their laws to meet these goals, but are free to decide how to do so with the possibility to take into account differing national situations
  - ✓ harmonisation

The European Directive 2001/20/EC (2)

- Aim: Clarification and harmonisation of existing legislation and administrative procedures related to clinical trials
- Also: partly implementation of the principles of Good Clinical Practice (GCP) in a legally binding document
  - ✓ This process was proceeded in 2005 with the Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice regarding investigational medicinal products for human use
- Only for interventional clinical trials with a medicinal product
- Independent of the Sponsor: commercial and non-commercial
- Also for early phase trials with (healthy) volunteers

The European Directive 2001/20/EC (3): scope



European Directive 2001/20/EC

EUROPEAN COMMISSION

Impact on daily practice (1)

P. Breugel de oude
“Toren van Babel”

- European harmonisation has not been achieved
  - Different laws
  - Different scopes
  - Different insurance clauses
- Increase of costs
- Increase of administrative burden
- Non-commercial sponsors suffer even more

→ on European level important decrease in number in trials

Impact on daily practice (2)

- Different obligations regarding the necessity of insurance
- Different approach of academic observational studies (specifically for multicentric studies with Belgian “Sponsor”)
- Different approach of protection of privacy
- Different submissions + different evaluations/remarks in different MS
- Differences between EC’s (international, but even national)
- …

European Clinical Trial Regulation?
Why a Regulation?

- 24% of all clinical trials in EU are multi national
- 67% of all patients in trials are involved in multi national trials

EUROPEAN COMMISSION

Proposed key changes in the Regulation

- It’s a regulation!
- Single portal, single dossier
- Coordination of assessments in multi-national trials shifts from Sponsor to Competent Authorities
- Coordinated 2-parts assessment procedure amongst Member States
- Role of Ethics Committees?
- Single national decision (back to Sponsor) via EU Portal
- Risk based approach?
- Streamlined safety reporting
- New indemnification provisions
- Data free available

when?

- Timelines?
- Currently under debate in European Parliament and Council
  - Final version Q1 2014
  - Vote in March 2014?
  - Optinional application as off Q1 2016 (until Q1 2017)
  - Obligatory adoption Q1 2017 – Q1 2019
  - Elections May 2014…

Goals of the Regulation

- ...

- greater **collaboration on approval** – authorities in EU countries need to:
  - work together
  - be held to the same timeframe when approving clinical trials
  - ensure that clinical trials are thoroughly and expertly assessed.
- greater **openness** in clinical trials both within and outside the EU
- public access to the **results**, whether positive or negative.
- continue to protect **patients' rights and safety**
- ensure **reliable** data

Conclusion

- Advantage: common denominator = GCP
  - all european countries comply with ICH- GCP
  - Accepted in every contract (proposal)
- Challenges (partly in progress)
  - Different national legislation
  - High administrative burden for Sponsor
  - ,,,

New Regulation -> new common denominatior

-> will be both a challenge and an opportunity!

REFERENCES

- Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such product.
- CPMP/ICH/135/95: “Note for Guidance on Good Clinical Practice”.
- Declaration of Helsinki, Fortaleza, Brazil, October 2013 .
- Website links:
  - Eudralex: http://ec.europa.eu/health/documents/eudralex/index_en.htm
  - ICH: http://www.ich.org/cache/compo/276-254-1.html
  - Clinical trials registration: http://www.clinicaltrials.gov/
  - FAGG: http://www.fagg-afmps.be/nl/MENSELIJK_gebruik/
  - CTC UZ Leuven: http://www.uzleuven.be/clinical-trial-center/clinical-trial-center