GCP ENHEDEN
AALBORG OG AARHUS UNIVERSITETSHOSPITALER

IS ACADEMIA READY FOR THE REGULATION?

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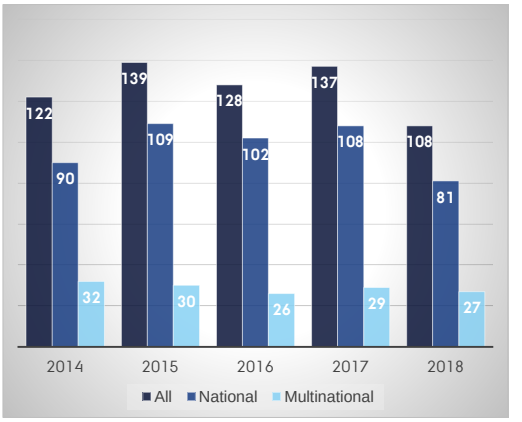
NON-COMMERCIAL TRIALS IN DENMARK

Clinical Trial Regulation

Increased efficiency of trials in Europe

- The Clinical Trials Information System
- Improved collaboration between and within Member States

Greatest benefit for multinational trials and sponsor-initiated trials



Non-commercial trials in DK
Årsrapport 2018 Kliniske forsøg med lægemidler

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IS ACADEMIA READY FOR THE REGULATION?

From my point of view the short answer is **"NO"**

27.5.2014 EN Official Journal of the European Union L 158/1

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(Legislative acts)

REGULATIONS

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) In a clinical trial the rights, safety, dignity and well-being of subjects should be protected and the data generated should be reliable and robust. The interests of the subjects should always take priority over all other interests.

(2) In order to allow for independent control as to whether these principles are adhered to, a clinical trial should be subject to prior authorisation.

(3) The existing definition of a clinical trial as contained in Directive 2001/20/EC of the European Parliament and of the Council (3) should be clarified. For that purpose, the concept of clinical trial should be more precisely defined by introducing the broader concept of 'clinical study' of which the clinical trial is a category. That category should be defined on the basis of specific criteria. This approach takes due account of international guidelines,

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THE CLINICAL TRIALS INFORMATION SYSTEM (CTIS)

Single entry point for:

Submission of applications and substantial modifications

Communication sponsor/member states

Assessments

Submission of notifications

Reporting of results

Considerations of the academia:

- **User-friendliness,** tests from 2016-2018
- Organisation
  - Sponsor with support
  - Super users at research departments or hospitals
  - Support function
- Deadlines

Call of the academia:

- Access to practice in CTIS
- "Support" access to CTIS, guidance by telephone

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CLINICAL TRIAL MASTER FILE (TMF)

- The sponsor and the investigator shall keep a clinical trial master file
- Essential documents related to the clinical trial
- Archived for at least 25 years after the end of the clinical trial.

Considerations of the academia:

- From 5 to 25 years?
- Trials with medicinal products compared to other health science research
- Level/Organisation
  - Research department or hospital
- How?
  - Physical TMF
  - Availability of electronic TMF that fulfil all requirements

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THE SUMMARY OF RESULTS AND SUMMARY FOR LAYPERSONS

A summary of results and summary for laypersons should be reported via the Clinical Trials Information System (CTIS)

Considerations of the academia:

- To day: a summery of results should be reported into the EudraCT-database
- About 10% of trials from the University Hospitals in Denmark have been reported in due time
- Survey from Aarhus University: process is too complicated and time consuming (Fedders and Kjær 2019)
- User-friendliness of the CTIS
- Need for support?

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OTHER ISSUES

Safety reporting

- SUSARs and annual safety reporting: a module of the Eudravigilance database
- Interaction Eudravigilance database/CTIS?
- Reported by Member State?

Monitoring

Fees

- Reduced fees for non-commercial clinical trials?

Transitional period

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Regulation, whereas 81

As regards Directive 2001/20/EC, experience also shows that a large proportion of clinical trials are conducted by non-commercial sponsors. Non-commercial sponsors frequently rely on funding which comes partly or entirely from public funds or charities. In order to maximise the valuable contribution of such non-commercial sponsors and to further stimulate their research but without compromising the quality of clinical trials, measures should be taken by Member States to encourage clinical trials conducted by those sponsors.

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HEAD OF DEPARTMENT

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