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ESF Workshop
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Health Research Strategic Needs in Europe

Pan European Clinical Trials. EU Clinical Trials Regulation

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OECD Global Science Forum (GSF) Working Group in Clinical Trials

- **OECD GSF** established a Working Group in 2010 to facilitate international cooperation in non-commercial clinical trials
  - Initiative from Germany and Spain
  - A need to approach the challenges for improved international collaboration in multicentric clinical trials, in particular in the field of non-commercial trials providing the essential basis for policymaking and guidelines
  - Working Group members nominated by GSF delegations, in total 35 members from 20 countries

OECD GSF Working Group Report

Current situation
Major gaps and challenges
Main recommendations:

Needs for

A: Regulatory harmonization

B: Risk-based approach

C: Education
Training
Infrastructure
Patient involvement

A. Regulatory harmonization

Recommendations

Create a common web-based repository about national laws and regulations for performing clinical trials

Initiate an international harmonization process of legal and administrative requirements for multinational trials

B. Risk-based approach

Recommendations

Introduce risk categories for clinical trials based on marketing-authorisation status of health product:

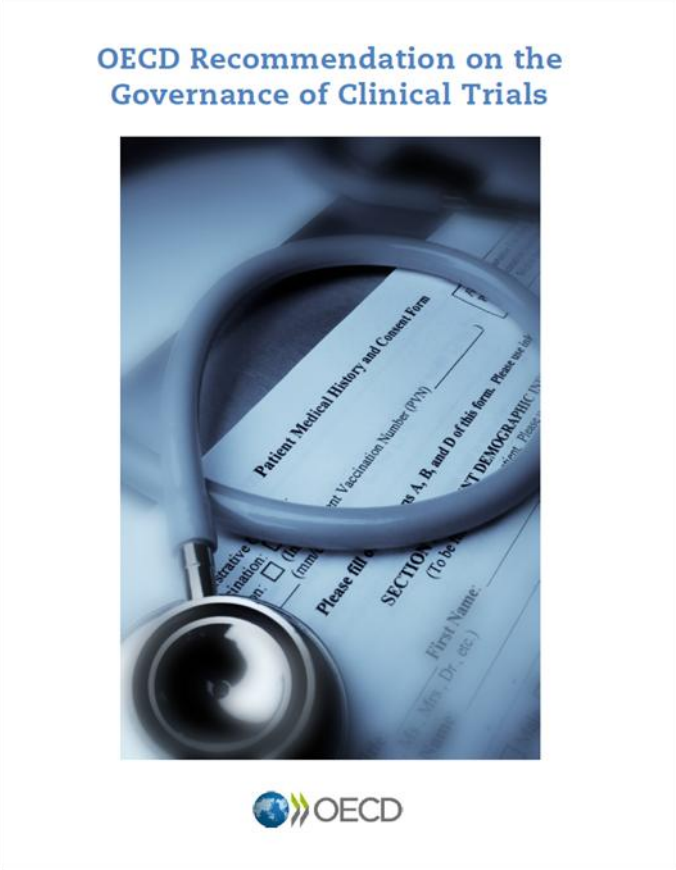
A. Health product used under an already licensed indication
B. New indication/population for a marketed product
C. New health product without marketing authorisation

B. Risk-based approach

Recommendations

Develop and validate a set of tools and guidelines on risk assessment, as well as a set of risk-adapted monitoring procedures to be used and applied for every protocol

OECD recommendation on the Governance of Clinical Trials



Adopted by OECD Council December 2012

A policy instrument defining a framework for better oversight over clinical trials

Recommends Members to adapt their national reguations to a risk-based approach

Invites non-Members to adhere to the recommendation

EU Clinical Trials Regulation

Differences in risk categories vs OECD

Clinical Trials

Corresponding to category C and part of category B in OECD terms

Low-intervention clinical trials

Corresponding to category A and part of category B in OECD terms

C. Education, training, infrastructure and patient involvement

Recommendations

1. Strengthen education and training – develop a concept of ***Global Core Competencies*** in Clinical Trials

2. Develop infrastructure and global networks

3. Increase patient involvement in Clinical Trials

Implementation project focused on key gap areas

Subprojects proposed with corresponding secretariats/subgroups:

1. Infrastructure and funding. ECRIN
2. Global Core Competencies. Australia
3. Ethics Committees. (tbc)
4. Patient involvement. NIH
5. Regulatory harmonization. EMA
6. Comparative Effectiveness Research. Norway

All groups will be based on international participation from relevant networks, institutions, organisations, societies, experts etc.

Pan European Clinical Trials

1. The key recommendations from the OECD GSF project are relevant for consideration and implementation in Europe in order to support the basis for Pan European Clinical Trials. Harmonization of risk categories.

2. A Pan European strategy should be integrated in a broader international cooperation according to the recommendations from OECD GSF

3. Take advantage of synergy potentials between different European networks and organisations; e.g. the novel HTA Network (HTAN) and Clinical Research Networks

Discussion

Pan European Clinical Trials

- How to support and develop infrastructure (at local, national and international level)
- Global Core Competencies (education and training)
- How to build efficient funding mechanisms?
- Scientific relevance, mechanisms for selection of research questions for clinical research?