Pros and Cons of the new Clinical Trials Regulation

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Table of content

European Organization for Research and Treatment of Cancer (EORTC)

- Private and not for profit organization created in 1962
- Main mission: promote and conduct research to improve cancer care
- Core activity: conduct clinical trials
  - International
  - Multidisciplinary
  - Develop new treatments
  - Define new standards of care
  - Large academic trials
  - Integrated & correlative translational research and biobanking

Henri Tagnon, Co-founder of EORTC

EORTC position on CTR

EU directive 2001/20/EC

Clinical Trial Regulation

MAIN POSITIVE ACHEIVEMENTS

- Single portal – to be developed by EMA – as the mean for communication between all parties involved
- All inclusive (CA+EC) coordinated assessment, its implementation would be under supervision of CTAG (group composed of MSs contacts + commission);
- Low-intervention trials: refers to the OECD guidelines
- Centralization of safety reporting at EMA
- Fees (inspection & submission): MSs may put in place
- Transparency and data sharing
- One time consent for future research on data is possible
- Delegated acts – delegated acts (to Commission)

National implementation

- 2nd chance for "missed opportunities":
  - Better risk adaptation
  - Patient involvement
  - Timelines (at least for single nation trials & amendments)
  - Indemnification mechanism
    -> can national scheme be put in place at least for academia?
- To be further detailed:
  - Review panel (nature and processes)
  - Local feasibility assessment (R&D in UK, RvB in the NL etc…)
  - Use (if any) of national portals
  - Waiver /reduction for fees for non-for profit organisations

Still to be delivered on EU level

- Functional user friendly portal up to highest technical standards & exact regulation implementation time
- Revision of EU directive 2005/28/EC
- Development of implementing acts and documents
  - Data sharing
  - GMP requirements
  - Inspections
  - FAQ to be produced [*EORTC suggestion*]

Zoom on potential challenges

Paperwork and timelines

- Paperwork required for submission
  - Description of financial arrangements (Annex I 69-71)
  - Disclosure of interests (Annex I 66)
  - Suitability of facilities (Annex I 67)
- Timelines for reply by sponsor: 12 days
- Archiving of trial master file: 25 years (after EoT)

Patient indemnification

- Not much changes to the current situation
  - Expensive
  - Available insurance products do not always provide full coverage
    - Expected damages
    - Other exclusion clauses

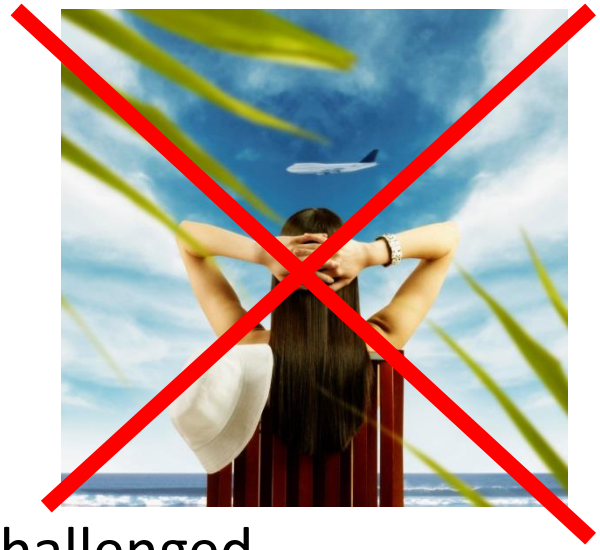
Low-intervention trials can be covered by national health insurance ☺
(if decided so by member states)
Currently in most of EU countries clinical trials are specifically excluded ☹

Site compensation

- From:
  the obligation for the sponsor to provide IMP for free
- To:
  costs of IMPs, auxiliary medication and protocol specific procedures shall not be borne by patients
  Currently in most of EU countries clinical trials are specifically excluded from health system coverage (even if they are standard of care) ☹

Take home messages

No time to rest!



- EU portal development is key
- More documents expected from EMA and/or EU Commission
- National implementation needs to be challenged

Academic research will need to adapt -> EVOLUTION

Is this adaptation going right way?

Academia needs to coordinate efforts to:

- Evaluate the potential impact of CT Regulation
- Review the role of academic organizations in driving research in Europe
- To identify topics where joint actions would be desirable.