

Investigator perspective for non-interventional studies

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Ideal world

- Investigator remains successful magician
- Quick and easy research is possible
- No worries about regulatory approvals
- No lengthy informed consent documents
- No external monitoring on data
- No bureaucracy and control over control
- No problems with publishing when no ethics committee approval is required
- No data validation procedures prior to analyzing data
- Etc, etc., etc.

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Reality

- No clear distinction between interventional and non-interventional research for:
 - Regulatory requirements (Yes/No Ethics Committee approval)
 - GCP requirements for monitoring and data management
 - Risk management with respect to safety reporting
- Editor of Scientific Journal requiring Ethics Committee approval (IRB) for non-interventional research

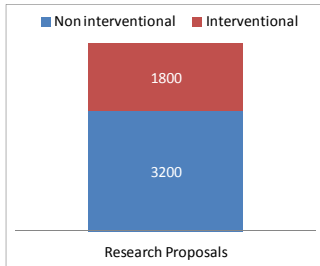
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Challenges

- Define regulatory requirements for non-interventional research in humans
 - Cave: new pharmacovigilance guideline for drugs
- Requirements should be restricted to essential questions like:
 - Relevance research proposal (medical – ethical aspects)
 - Quality of the organization
 - Feasibility of the project
 - Implementation and valorisation

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Perspective from the Netherlands



- Pilot project running in N=12 University and/or hospital settings to assess 10 research proposals for:
 - Criteria: yes or no interventional study
 - Criteria: relevance, quality, feasibility, valorisation
 - Assessment instrument

Future

- One research law applicable for all research in humans with lean and mean (quick and easy) assessment for non-interventional research on:
 - Medical, scientific and ethical aspect concerning relevance of the research proposal
 - Quality of the organisation (qualifications of researchers and project management skills, GCP requirements customized for the project)
 - Feasibility of the research
 - Implementation and valorisation
- One stop shop approach for assessment