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Need for a European Trial Data Base
Introductory Remarks

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Subject Trial Data Base

Why ?

- Prevention from double participation
- Adherence to blocking periods of different trials

What is the intention ?

- Reduction of risks for subjects
- Improvement of the quality of data
- Clear liability conditions for sponsor, investigator, and subjects

But: Drug abuse and other types of non-compliance shall not be subject of the checks

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Subject Trial Data Base

Risks for the subjects

- Double participation: Uncontrolled interactions
- Overlapping blocking periods
  - Blood loss not compensated
  - Preceding drugs not completely eliminated
  - Ongoing AEs
  - Continuing effects
- General risk of denial of liability by insurer

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Subject Trial Data Base

Quality of the data

- Ambiguous affiliation of efficacy outcome to treatment
- Ambiguous relationship of AEs to study medication
- Risk of erroneous SUSAR classification

Additional risk for sponsor and investigator: Unclear liabilities !

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Subject Trial Data Base

For Whom ?

- Healthy subjects: subject's fraud !
- Patients in Phase II/III/IV: investigator's fraud !

But: Only in very rare cases (isolated location of the study centre and highly restricted pool) a generalised trial data base is not necessary!

This is not applicable for most of the study centres!

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Subject Trial Data Base

Why not only national solutions

- In most of the European countries there are phase-I study centres located near borders, which recruit healthy subjects also from neighbouring countries (European Union but also Switzerland and Eastern European countries)
- National solutions may be sufficient for clinical trials phase II to III, but only if enrolment of foreign patients is strictly prohibited !

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Subject Trial Data Base

Open questions to be discussed

- Is there an independent institution acceptable as responsible body for all types of centres?
- How to guarantee completeness of information?
- How to keep costs in acceptable limits?
- How to protect subject's data during submission?
- How to realise the subject's right of error detection and correction of data?
- How to observe confidentiality for sponsor and investigator?