

ENGOT

Requirements for trials between academic groups and pharmaceutical companies.

Approved version Belgrade October 9, 2009



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1. One **protocol** developed and agreed on by study group and industry partner and reviewed and approved by the later steering committee.
2. One **database agreed on by study group and industry partner.**
3. One **CRF**, preferentially website-based e-crf, agreed on by study group and industry partner.
4. Sponsor: the academic group or the industry.
5. **Monitoring:**
 - a. Preferentially done by the academic group, but monitoring by company (possibly through CRO in mutual agreement with the academic group) is allowed.
 - b. Central monitoring will be allowed over on-site monitoring, depending on the own group policies of quality control and quality audits, if allowed by the protocol. The financial budget available for such quality controls and legal requirements of the territories covered by each group needs to be taken into account.
6. **Data base property:**

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- a. **Legal ownership: sponsor.** The sponsor can be industry or study group (leading on behalf of all involved study groups)
- b. **contracts and organisational structures must assure:**
 - i. that sponsor (company *or* study group) gets all information needed for pharmacovigilance
 - ii. SAE 's should be regularly reviewed by the steering committee (composed of study group and industry company) and the IDMC.
 - iii. that neither the study group nor the company gets access to data regarding study endpoints before pre-defined time points for analysis (according to statistical plan)
 - iv. that both get the opportunity to follow any changes made in the database (cleaning, queries etc.)
 - v. that both get the same database, regularly updated and blinded for endpoints and treatment arm
 - vi. that no party provide access to the database to any third party
 - vii. scientific ownership by study group irrespective who is sponsor
- c. Data base **ownership:** Could be organized as:
 - I. OPTION A: data base (DB) itself at the academic group (1st choice).
 - i. quality assurance and certified database software;
 - ii. audits by company or company assigned auditors.
 - iii. Transfer of database for registration issues and analysis to the company
 - II. OPTION B: Database at CRO and CRO is contracted by the academic group (2nd choice).
 - i. quality assurance and certified database software;
 - ii. audits by company and by study group.
 - iii. Installation of SOPs for the respective protocol and information system for any violation to the sponsor.
 - iv. Transfer of the complete database to study group for scientific analysis and to company for registration purposes.
 - III. OPTION C: Database at CRO and CRO is contracted by the company (3rd choice)
 - i. quality assurance and certified data base software with 100% tracing of any access or changes made;
 - ii. audits by study group or study group assigned auditors.

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- iii. Installation of SOPs for the respective protocol and information system for any violation to the study group.
- iv. Transfer of complete database for further scientific evaluations to the study group after final analysis of pre-defined endpoints.

7. Statistical analysis and publication:

- a. Study group performs independent analysis of the complete DB for primary and secondary endpoints.
 - i. The DB may be used later for further meta-analyses or subgroup analyses of the study group or within an Intergroup consortium.
 - ii. The publication is the sole responsibility of the study group.
 - iii. The company may comment within a pre-defined period but cannot prohibit any publication.
- b. Intergroup trials:
 - i. Each participating group should receive a dataset of patients recruited by the respective study group after final analysis.
 - ii. Separate analyses by one participating group on their included patients should not include primary or secondary endpoints and the Intergroup study leading committee (Steering committee) and PI should be informed on each project.
 - iii. Further subgroup analysis of the whole population should be prospectively discussed among the groups and agreed.
- c. The company may perform all analysis necessary for registrational purposes or economic purposes.
 - i. The official study report must be agreed on by the leading study group
 - ii. the company is neither allowed to scientific publishing nor to transfer the DB to any third party for scientific publishing
- d. In the publication it should be mentioned that the trial was performed according to the principles of the current document and to which data base property model (paragraph 6.c. option A, B, or C).

8. Non-EU Countries

Institutions from non-EU countries can participate, and 2 models are possible:

1. a non-EU academic study group participates in the intergroup consortium
2. single non-EU centres may participate if they are adopted by one of the participating ENGOT study groups (these centres act as study group member

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centres) – or the company is the sponsor for these centres (these centres do not have the same rights as study groups in intergroup studies)

8. Independent Data Monitoring Committee:

- a. The IDMC is appointed by academic group in mutual agreement with industry partner. Company may suggest members but study group must not follow.
- b. Vice versa, company may not accept one member suggested by the study group if they could give rational reasons.

9. **SOPs:** have to be agreed on by study group and company. Preferentially based on SOP of the academic study group modified according to the needs of the protocol.