

European Network of Gynaecological Oncological Trial Groups' Requirements for Trials Between Academic Groups and Pharmaceutical Companies

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The European Network of Gynaecological Oncological Trial Groups (ENGOT) is a research network of the European Society of Gynaecological Oncology and was founded in Berlin in October 2007. Currently, 17 European trial groups are members of the ENGOT (Appendix). As a network of European national or regional clinical trials groups, the ENGOT promotes clinical trials within Europe on patients with gynecological cancer. This coordination is not only particularly relevant for academic clinical trials, translational research, and research on rare diseases but also for clinical trials in cooperation with the industry desiring to perform multinational studies with academic groups in Europe.

The current statement does not define academic trials but is the result of a consensus between the 17 involved trial groups on the requirements for trials between academic groups and the industry. The document was developed in 2008 and discussed during the general assembly meeting of the ENGOT in January 2009. After this meeting, a consensus text was sent to all the ENGOT trial groups for comments and approval. These comments were incorporated in the consensus document and approved during the ENGOT meeting in October 2009. In November 2009, the consensus text

was discussed and approved during a meeting with the most important industrial partners. The ENGOT believes this model might be important for future research on gynecological cancer and, probably, also for clinical research of academic groups in cooperation with the industry in other diseases.

Requirements for trials between academic groups and the industry:

1. One protocol developed and agreed on by the lead study group and the industry partner and reviewed and approved by the trial steering committee.
2. The statistical analysis plan is agreed upon by the lead study group and the industry partner.
3. One database (DB) agreed on by the lead study group and the industry partner.
4. One case report form, preferentially a Web site–based electronic case report form, agreed by the lead study group and the industry partner.
5. Sponsor: the academic group or industry. The legal sponsor has the final responsibility according to the European Union directive.
6. Monitoring:
 - a. Preferentially done by the academic group, but monitoring by industry (possibly through a contract research organization [CRO] in mutual agreement with the academic group) is allowed.
 - b. Central monitoring may 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 need to be taken into account.

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7. Database property:
- a. Legal ownership: sponsor. The sponsor can be an industry or study group (leading on behalf of all involved study groups).
 - b. Contracts and organizational structures must assure:
 - i. that the sponsor (composed of study group and industry company) receives all the information needed for pharmacovigilance. The company will maintain the global safety reporting for the drug trial DB. This will contain only serious adverse events that may be unblinded only by patient safety personnel as required for regulatory reporting.
 - ii. serious adverse events should be regularly reviewed by the steering committee (composed of a study group and an industry company) and the independent data monitoring committee (IDMC).
 - iii. that neither the study group nor the industry has access to data regarding study end points before predefined time points for analysis (according to statistical plan).
 - iv. that both the study group and the industry have the opportunity to follow any changes made in the DB (cleaning, queries, etc).
 - v. that both the study group and the industry have reports and copies of the DB regularly updated and blinded for end points and treatment arm.
 - vi. that no party provides access to the DB to any third party unless after mutual agreement (eg, for the European Medicines Agency or the Federal Drug Agency reporting).
 - vii. the study group is responsible for the publication and use of the DB for educational and scientific purposes, irrespective of who is the sponsor. Intellectual property is governed according to the EMEA legislation.
 - viii. contracts with third parties (eg, for central imaging reviews) can be made by the sponsor in mutual agreement between the academic groups and the industry.
 - c. The database could be organized as follows:
 - I. Option A: The database itself at the academic group.
 - i. Quality assurance and certified DB software.
 - ii. Audits by company or company assigned auditors.
 - iii. Transfer of DB to the company for registration issues and analysis.
 - II. Option B: The database at the CRO; the CRO is contracted by the academic group. The choice of a CRO is made in mutual agreement between the academic groups and the industry.
 - i. Quality assurance and certified DB software.
 - ii. Audits by the company and by the study group.
 - iii. Installation of standard operating procedures (SOPs) for the respective protocol and information system for any violation to the sponsor.
 - iv. Transfer of the complete DB to the study group for scientific analysis and to the company for registration purposes.
 - III. Option C: Database at the CRO; the CRO is contracted by the company. The choice of a CRO is made in mutual agreement between the academic groups and the industry.
 - i. Quality assurance and certified DB software with 100% tracing of any access or changes made.
 - ii. Audits by the study group or study group–assigned auditors.
 - iii. Installation of SOPs for the respective protocol and information system for any violation to the study group.
 - iv. Transfer of complete DB for further scientific evaluations to the study group after final analysis of predefined end points.
8. Statistical analysis and publication:
- a. A study group is responsible for the independent analysis of the complete DB for primary and secondary end points.
 - 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 predefined period but cannot prohibit any publication.
 - b. Intergroup trials:
 - i. Each participating group should receive a data set 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 end points, and the intergroup study leading committee (steering committee) and the principal investigator 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 the analyses necessary for regulatory or economic purposes.
 - d. The official study report must be agreed on by the leading study group.
 - e. The company is neither allowed to scientific publishing nor to transfer the DB to any third party for scientific publishing, unless after mutual agreement.
 - f. In the publication, it should be mentioned that the trial was performed according to the principles of the current document and to which DB property model (paragraph 7.c option A, B, or C).
8. Non-European Countries
- Institutions from non-European countries can participate, and 2 models are possible:
1. A non-European academic study group participates in the intergroup consortium.

2. Single non-European centers may participate if they are adopted by one of the participating ENGOT study groups (these centers act as study group member centers) or the company is the sponsor for these centers (these centers do not have the same rights as study groups in intergroup studies).
9. The IDMC:
 - a. The IDMC is appointed by the academic group in mutual agreement with the industry partner.
 - b. Similarly, the industry partner may object against a member suggested by the study group, if they could give rational reasons.
 10. Standard operating procedures have to be agreed on by the study group and the company, preferentially based on the SOP of the academic study group modified according to the needs of the protocol, but SOPs of the industry may be acceptable.

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APPENDIX

Trial groups of the ENGOT (alphabetically listed)

Arbeitsgemeinschaft für Gynäkologische Onkologie (AGO)
 Austrian Arbeitsgemeinschaft für Gynäkologische Onkologie (A-AGO)
 Belgian Gynaecological Oncology Group (BGOG)
 Danish Gynaecological Cancer Group (DGCG)
 Dutch Gynaecological Oncology Group (DGOG)
 European Organisation for Research and Treatment of Cancer—Gynaecological Cancer Group (EORTC-GCG)
 Grupo Español de Investigación en Cáncer de Ovario (GEICO)

Groupe d'Investigateurs Nationaux pour les Etudes des Cancers de l'Ovaire (GINECO)
 Hellenic Cooperative Oncology Group (HECOG)
 All Ireland Cooperative Oncology Research Group (ICORG)
 Mario Negri Gynecologic Oncology group (MANGO)
 Multicenter Italian Trials in Ovarian Cancer and Gynaecological Malignancies Group (MITO)
 National Cancer Research Institute (NCRI)
 Nord-Ostdeutsche Gesellschaft für Gynäkologische Onkologie (NOGGO)
 Nordic Society of Gynaecological Oncology (NSGO)
 Scottish Gynaecological Clinical Trials Group (SGCTG)
 Turkish Gynaecological Oncology Group (TGOG)