



Approved document Belgrade October 9th 2009

Guidelines for Authorship for Trials run within ENGOT

1. General.

- a. Authorships and Co-authorships are not granted by individual institutions but by groups or consortia of study centers.
- b. All calculations regarding the number and position of co-authorships will be based on numbers of recruited patients by group.
- c. Each group is completely free and independent to fill in individual names according to its number and position of co-authorships (the group even may appoint persons not having recruited patients by themselves).
- d. The following “rules” should guarantee participation and benefits for all groups involved and share as much attractive positions among the groups as possible.

2. Fixed authorship positions.

- a. All co-authorship positions depend on recruitment of groups except one authorship position of the International Principal Coordinator (appointed by leading group) and one for the statistician of the study (usually 4th position).
- b. International Principal Coordinator is first author or senior author depending on the occasion unless he grants this to anyone else.
- c. Co-authorship positions of a potential industrial sponsor (not a study group) could be foreseen on a case by case basis, however, this should be stated in the agreement upfront and would be rather the exception than the rule.

3. Number of authors per group

- a. Each group receives their first guaranteed authorship position when the group has recruited 4% of the total number of patients.
- b. The 2nd position will be achieved when the group recruited 8% of the total number of patients.
- c. The 3rd position will be achieved when the group recruited 12% of the total number of patients.
- d. The 4th position will be achieved when the group recruited 16% of the total number of patients by the respective group, and from then on by every 5% instead of 4% to avoid overrepresentation of very strong groups.

The percent numbers are a general guideline and might be adapted to each specific protocol and will depend on the population size of the study and the number of participating groups (e.g. 5 and 6% instead of 4 and 5 % etc.)

4. Position of the authors



Approved document Belgrade October 9th 2009

The specific place of the group's representative is defined by the overall recruitment by the group; e.g. if group A has the highest recruitment number, group B the 2nd highest recruitment number, group C the 3rd highest, and group D the lowest, 2nd author would be appointed by group A, 3rd author by group B etc.

Example: Study of 1000 patients

Group A : 220 pts. = 5 authorship positions

Group B : 210 pts. = 5 authorship positions

Group C: 120 pts = 3 authorship positions

Group D: 65 pts = 1 position

Group E: 40 pts = 1 position

Result:

International Principal Coordinator (appointed by leading group), A1, B1, statistician, C1, D, E, A2, B2, C2, A3, B3, C3, A4, B4, B5, A5 (A5 = senior author by strongest recruiting group)

5. Additional publications of subgroup data or sub-projects:

- a. Each participating group should receive a dataset of patients recruited by the respective study group after final analysis.
- b. Separate analyses by one participating group on their included patients should not include primary or secondary endpoints and the International Principal Coordinator and Intergroup study leading committee (Steering committee) should be informed on each project.
- c. Further subgroup analysis of the whole population should be prospectively discussed among the groups and agreed.
- d. First author should be of the group performing the analysis.
- e. Other groups should be mentioned and have co-authorship positions similar to the rules for primary and main publication.
- f. International Principal Investigator is usually senior author.
- g. All sub-publications or meta-analyses can only be published after the full manuscript of the study has been published.
- h. Full paper on general analyses of secondary endpoints (eg quality of life, prognostic factors etc.) should be shared among the groups with first author by group A, then 2nd general paper first author by group B etc.



Approved document Belgrade October 9th 2009

- i. Smaller groups (who did not recruit the necessary 4% of the total number of patients) might be co-author of one of the secondary publications.

6. Presentations:

- a. The study should be presented as often as possible to give as many groups as possible the opportunity to present.
- b. Local and national presentations should be done by the national group as first author (with mentioning all other groups, International Principal Investigator usually senior author).
- c. International presentations may be scheduled according to available data e.g.

- 1. safety and compliance and interim analysis whole cohort
Presenter/first author: group A*
- 2. safety, compliance and full details about recruitment, response, dose density etc.
Group B*
- 3. first presentation of primary endpoint
International Principal Investigator*
- 4. first presentation of secondary endpoint QoL
Group C*
- 5. first presentation of secondary endpoint overall survival
Group A*
- 6. first presentation of prognostic factors and subgroup analysis
Group B*
- etc. other presentations by other groups*

General remarks:

- 1. All specific modifications for every Intergroup trial should be specified before study start and amended to the general principles in written mode as appendix to the intergroup agreements. Each consortium is free to amend and modify these general rules.
- 2. If possible, all centres who have actively recruited in the trial should be mentioned as co-authors in the appendix.