ROADMAP FOR ENGOT TRIALS
FIRST AGREED DURING FRANKFURT MEETING
29th January 2011

With contributions from
G. Elser (AGO)
B. Votan (GINECO)
J. de Roover (BGOG)
B. Pennickx (EORTC)
J. Bryce (MITO)

Updated:
V6 following meeting March 15 2012
V7 following meeting March 21 2019

<table>
<thead>
<tr>
<th>Revision Chronology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Version Number</strong></td>
</tr>
<tr>
<td>1.0</td>
</tr>
<tr>
<td>6.0</td>
</tr>
</tbody>
</table>
| 7.0 | 27 December 2019 | • Table of revision chronology and table of contents included with updated formatting
• Amended ENGOT logo
• Included Letter of Intent to appendices
• Clarification of Lead ENGOT Group as LEG and Local Collaborating Group as LCG
• Clarification of naming of Chair roles
• Reference to the EU Data Protection Regulation (EU 2016/679) and EU Clinical Trials Regulation (EU No 536/2014) added | L. Farrelly (NCRI) with Strategic Group Review & Approval |
• Administrative Group changed to Operations or Operational Group
• Included the updates to the ENGOT Publication rules (June 2017)
• Included ‘confirmation of interest in proposal form’ to Appendix 2

ROADMAP FOR ENGOT TRIALS Page 2 of 30
Contents
1. What is an ENGOT Trial .......................................................... 4
2. Protocol ................................................................................... 5
3. Informed Consent Form – ICF ..................................................... 5
4. Case Report Form - CRF ............................................................ 5
5. Site Selection / Feasibility ......................................................... 5
6. Operational Tasks ..................................................................... 6
   7.2 Control of data consistency: .................................................... 7
   7.3 Tracking of missing forms / Data timeliness ............................... 7
   7.4 Medical review of patient’s data ............................................... 7
   7.5 Computerized validation checks to be written in a validation program, will ensure: .... 7
   7.6 Internal QC check of database ................................................. 7
8. Confidentiality agreement for the entire ENGOT group ...................... 7
9. Contracts (in general) ................................................................. 8
10. Contract between ENGOT Groups and sites (if applicable) – legal control .................... 9
11. Funding ................................................................................... 9
12. Insurance .................................................................................. 9
13. Requirements for conducting sub-studies in an ENGOT trial ................... 9
14. Communication flow ................................................................ 10
15. Tasks for LEG - Checklist .......................................................... 14
APPENDIX 1 Template Confidentiality Agreement .................................. 15
APPENDIX 2: New ENGOT study proposals ............................................. 20
   Table for completion by Lead ENGOT Group for each new study proposal ................ 20
   Table for completion by Chairs (clinical and operational), Vice-chair (clinical) and 4th person if required on submission of new proposals ........................................ 20
   Table for completion by ENGOT groups interested in proposals presented (after each meeting) ................................................................. 21
1. What is an ENGOT Trial

A trial can be labelled as an ENGOT trial if:

- There is an ENGOT Group leading the trial, known as ‘ENGOT Lead Group’
- The trial has been discussed at an ENGOT meeting and a request for an ENGOT number has been made
- There is at least one collaborating ENGOT Group, known as Local Collaborating ENGOT Group(s)
- The trial has clearly defined ENGOT participation in the Steering Committee

What if other non-ENGOT (extra-European) groups join?

- It’s possible for groups who are not part of the ENGOT collaboration to join an ENGOT trial

What if other extra ENGOT isolated centres join the study?

- This is possible (see ENGOT minimal requirements for a trial (Int J Gyn Cancer, 2010 Apr; 20(3):476-8).

However:

1. The majority (at least 50%) of the sites and the recruited patients should come from ENGOT Groups to classify a trial as an ENGOT trial. This is not applicable for academic studies (i.e. those without an industry partner as the Sponsor).
2. Other sites should be approved by the ENGOT lead group
3. Flexibility on both of the requirements 1 and 2 is possible and if not fulfilled this will be discussed on a case to case basis.

Selection of the centres and feasibility

- The ENGOT Groups must assess the feasibility of running the trial at sites in its area and then be responsible for their selection (this can be done with the mutual agreement of the industry partner if necessary – see ENGOT minimal requirements for a trial (Int J Gyn Cancer, 2010 Apr; 20(3):476-8).

Can industry choose to run a trial without the cooperation of the local ENGOT group in one of the countries represented by ENGOT?

- In principle it will not be possible to run a trial without the cooperation of the local ENGOT group in one of the countries represented by ENGOT. However, if isolated sites affiliated to the local ENGOT group want to do the study and there is approval of the local ENGOT group this might be possible.

How many groups are needed for an ENGOT trial?

- There should be a collaboration between two ENGOT groups (minimum) to call a trial an ENGOT trial

Can an ENGOT trial be led by a non ENGOT Group principal investigator?

- In principle the leader of an institution of an ENGOT group should be the principal
investigator. However, in exceptional circumstances ENGOT can decide to accept a principal investigator, who is not the ENGOT Group Lead Clinician.

For ease of reference the;
- Lead ENGOT Group will be the LEG
- Local Collaborating ENGOT Groups (in each participating country) will be LCGs (this may incorporate the LEG as well).
- Where all ‘ENGOT groups’ are referred to in this document this means all groups participating in any one trial (whether LEG or non-LEG LCG)

2. Protocol
- One protocol which is agreed on by the LEG and the industry partner (if applicable) and reviewed and approved by the protocol steering committee and Sponsor (Int J Gynecol Cancer 2010;20:476-478)
- Agreement on the definition of protocol violations

3. Informed Consent Form – ICF
- Should be reviewed and validated by the LEG.
- Each ENGOT Group may adapt the IC according to their local requirements
- Name of the ENGOT Group to be present on the ICF
- If parts of the ICF are deleted by the LCG, this has to be approved by the LEG (and Sponsor, if different).

4. Case Report Form - CRF
CRF/e-CRF (see also: Int J Gynecol Cancer 2010; 20: 476-478)
- CRF structure should be checked by the LEG and discussed among all participating groups as required. Besides the LEG, at least one other ENGOT group chosen by the LEG should go through the CRF’s in detail.
- CRF completion guidelines should be provided and validated by the Sponsor. The LEG can review these as applicable.
- CDE (Common Data Elements)
  Where possible, Common Data Elements (CDE) should be discussed to enhance the ability to share and compare data (e.g. metadata)
- Statisticians should discuss the data formats if appropriate. In trials with industry partner participation the LEG should review the CRFs for common data elements where possible.

5. Site Selection / Feasibility
- When a country has an ENGOT group and an interest in the trial has been expressed, the trial should be coordinated with the ENGOT group in that country.
- The ENGOT requirements should be discussed first prior to the collaboration between the ENGOT groups and an industry partner (technical or other).
- Early global discussion on the maximum number of sites and number of patients per trial/per ENGOT group/and per country is recommended.
- The LEG should receive, as a minimum requirement, a letter of intent from the industry partner which details and ensures costs for all participating groups (or with each group
prior to site selection).

- Technical requirements for the sites (described upfront as clear as possible, e.g. Imaging techniques, e-CRF) should be decided before site selection.
- Site selection should be commenced by the ENGOT Group in each collaborating country as they are aware of competing studies. Each ENGOT Group will put forward a list of potential sites that can participate in the trial. Final selection/responsibility is with the Sponsor, who must only select sites that have been suggested and approved by the ENGOT Group. Under no circumstances should the Industry partner approach sites without obtaining prior approval of the ENGOT Group in the country. Non acceptance of sites should be discussed and agreed by the ENGOT Groups and the industry partner (when applicable).

**Minimal requirements of site selection are:**

- Site agrees to collaborate with the ENGOT group
- Site has staff with clinical trial experience; adequate staffing resources: aside from investigator, the site also has a study coordinator or study nurse to handle documentation and organisation of the study
- Site is willing to conduct clinical trials according to the protocol and the principles of ICH-GCP, local rules and regulations including documented GCP training (as applicable)
- Site has the adequate infrastructure resources (lab, radiology, etc.) to conduct the trial according to the protocol (*to be defined per protocol*)

**6. Regulatory**

Health Agency and Ethics Committee

Regulatory responsibilities will be conducted by the ENGOT groups or the industry partner. An agreement should be reached regarding the responsibilities for:

- Insurance
- Ethics submissions
- Competent authority (submission local/country)
- Pharmacovigilance system; If reporting is not managed by the industry partner, pharmacovigilance responsibilities should be managed centrally.
- Other country specific regulatory issues

Where relevant, regulatory issues are to follow Good Clinical Practice (GCP) requirements as outlined in Directives 2001/20/EC and 2005/28/EC and subsequent amendments, national regulations and where applicable incorporate elements of International Conference on Harmonisation (ICH) GCP tripartite guidelines (E6). The EU Clinical Trials Regulation (EU No 536/2014) entered into force on 16 June 2014, but does not apply at the time of this Roadmap.

For trials in which the European Clinical Trials Directive does not apply, country specific regulations must be respected.

**7. Operational Tasks**

- When the industry partner is Sponsor, the LEG may request access to selected SOPs (i.e. Pharmacovigilance, Monitoring etc)
- Roles and responsibilities to be discussed as a priority during the contract negotiation. This includes an estimate of the trial specific workload.
To review and approve the global monitoring plan/project operational plan to clearly outline the project scope of work, responsibilities, the work flow and the monitoring rules as well as communication strategies and management procedures for the project (including logistics, material to be used, technical issues which could be faced, formatting of study progress reports).

Site activation process to be defined in agreement with the LEG (if not the Sponsor).

**Minimal requirements for central monitoring**

Note: On site monitoring is preferred, however if for any reason this is not feasible (or a requirement due to risk based assessment) some minimal requirements for central monitoring should be guaranteed.

These are:

7.1 **Monitoring of patient's accrual and safety data:**
Frequency: minimal to be reviewed on a regular basis depending on the nature of the trial, but at least once per 3 months during the accrual phase.

7.2 **Control of data consistency:**
- Sponsor ensures that data in the database are an accurate representation of the data provided by the site
- Consistency checks:
  - Reference to a convention list
  - Trial specific checks (summary of the croschecks and manual checks per form)
  - SAE/AEs reconciliation: to ensure that not yet reported AEs qualifying as SAEs in the clinical database are managed according to trial specific SAE reporting procedures

7.3 **Tracking of missing forms / Data timeliness**
- Missing forms request procedure
- Minimal annual assessment of data submission within specified timelines

7.4 **Medical review of patient’s data**
- Ongoing assessment of key data, i.e. eligibility criteria, protocol deviations
- A medical review plan describing frequency, content of medical review before study start

7.5 **Computerized validation checks to be written in a validation program, will ensure:**
- Verification of the content of all primary interest variables and their consistency with other related variables
- A clear description of the database, indicating potential sources of error

7.6 **Internal QC check of database**

**Further issues to think on:**
- The use of a CRO should be discussed with the cooperating groups if possible.
- Clear position of responsibilities in the conduct of monitoring requirements
- Monitoring Reports or monitoring follow-up letters to be accessible to each group (for their institutions) if the industry partner is responsible for the monitoring.

8. **Confidentiality agreement for the entire ENGOT group**
- Between the industry partner and ENGOT (represented by the Clinical Chair of ENGOT
who signs on behalf of the ENGOT groups)

- Aim is to be able to present confidential information about a drug or a trial at the ENGOT meeting
- To be signed at the primary discussion between the LEG and the industry partner

➢ See Appendix 1 Example Confidentiality agreement

9. Contracts (in general)

Contract on site selection and use of groups’ network.

- Initially, a letter of intent (LOI) describing the development of the protocol discussion should be in place. This could be an independent contract or a letter of intent with the specific tasks documented. It should be mentioned that each individual ENGOT group name or logo must appear in every presentation and publication.
  ➢ See Appendix 3 Example LOI

Minimal requirements for the contract between the LEG and the industry partner (where a collaboration exists) for all types of clinical trial are:

- Ownership and publication rights for trials between academic groups and industry partners should be mentioned in the main contract between the LEG and the industry partner, based on the chosen model of collaboration.
- The clinical study database will be the property of the Sponsor (LEG in Model A or B) and Industry Partner in Model C. In the case of option C, (Int J Gyn Cancer, 2010 Apr;20(3):476-8) the industry partner must agree to data transfer to the LEG and LCGs of their participant data (a Data Transfer Agreement must be in place).

All contracts will be in line with the EU General Data Protection Regulation (GDPR) (EU 2016/679) which came into effect on 25th May 2018 and focuses on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. GDPR requires organisations to be “lawful, fair and transparent when processing or controlling the processing of personal data.”

In most situations (where the industry partner is the Sponsor) the industry partner will have the ownership of arising intellectual property and patentable inventions, whilst the participating ENGOT groups (LEG takes precedence) will have the right to use the results for academic purposes and for the planning of further trials. LCGs would have access to their specific national subsets in order to allow them to use that data for national-level research (eg. Epidemiology)

Roles & Responsibilities, as well as Obligations & Duties of each contract partner should be described clearly.

Further contracts:

- Intergroup agreements to be signed between the LEG and the LCGs

Data Controller is the Sponsor, and all collaborating sites are Data Processors. If Industry is the Sponsor, then sites will contract directly with them. If LEG is the Sponsor, this can be delegated to the LCGs and captured in the contract between the LEG and LCGs.
10. Contract between ENGOT Groups and sites (if applicable) – legal control
Guiding principles:
- The contract between the ENGOT group and the site should include data ownership, publication rules and intellectual property, if applicable.

11. Funding
- Discussion should start as early as possible in the negotiations.
- The LEG will investigate the amount required by each LCG to commence the trial in their area.
- The funding will be centrally negotiated by the LEG (each LCG can decide how their funds will be spent depending on their specific requirements).
- Sponsorship is separate from clinical trials insurance. Each LCG should facilitate insurance for all of the trials that they are collaborating in (unless Sponsor is Industry and then this will be their responsibility as defined in the contract).

12. Insurance
- ENGOT is not a legal entity. Applying for a group policy is not possible as the number of claims is too small for the European Commission.
- Each ENGOT group should have their own insurance for their trials.
- Insurance is calculated using a risk-based assessment.

13. Requirements for conducting sub-studies in an ENGOT trial
The xx study is a [description of the study]. The main results of the study will be the responsibility of the trial writing committee which will have input from the study investigators, biostatisticians, data management and (if appropriate) clinical epidemiologists. However, after the final analysis has been performed, interested ENGOT groups can seek to use the data or human biological materials to generate new hypotheses and/or explore relationships between clinical, biomarkers, QoL and patient related characteristics and outcomes. The following principles are proposed to ensure that appropriate sub-studies are undertaken on behalf of the ENGOT group together with a high quality of statistical analysis and a balanced interpretation of the results.

1. The steering committee of the main study will decide whether a sub-study is appropriate. The steering committee will evaluate the feasibility of the sub-study.
2. All proposals will be reviewed by a sub-study committee. This committee will assess the proposal’s scientific validity and merit, its clinical value to the research/clinical community, and/or patient care.
3. This sub-study committee will comprise of the LEG Clinical Lead study chair, trial statistician and a representative from each interested group.
4. The sub-study committee will try to ensure that all approved proposals are implemented in a way to allow a number of investigators to participate in these important opportunities.
5. Once a sub-study is approved, the PI of the sub-study will liaise with the study statistician of the LEG who will agree on a statistician to work directly with the PI of the sub-study on the project. Close collaboration between the lead statistician and the sub-study statistician has the advantage of:
   a. Allowing all interested groups to have access to statistical resources to address the questions, methods etc. This is especially important in areas of biomarker, risk
modelling and toxicity/QoL analyses;
b. Allow for uniformity/continuity of statistical analyses;
c. Ensure consistent interpretation of analyses with those that are published in the main study report;
d. The study statistician of the group has intimate knowledge and understanding of the design and conduct of the main study which can be invaluable in the correct analysis and fair interpretation of the results of sub-studies.

6. Draft/final manuscripts will be made available through this sub-study committee to the trial management committee or group for comment and approval prior to submission for publication

14. Communication flow
Guiding principles:
• Communication flow should be discussed upfront between the LEG and the industry partner
• Strong intergroup communication between the LEG and LCG
• If queries arise, the participating sites and CRAs should first consult with the relevant LCG
• LCG should be the primary contact for protocol eligibility questions, avoiding deviations, safety/clinical questions and recruitment strategies etc however the Sponsor makes the final decisions. Deviations should always be discussed with the PI of the LEG and the medical monitor of the study;
• ENGOT Group PI may delegate to other LCG representatives or industry partner. LCGs and CRA should be copied into all correspondence with the sites
• Roles & Responsibilities between the affiliates and the LCGs clearly defined
• Local project management to be done by the ENGOT Groups in agreement with the affiliate
• Regular tele-conferences (TC) to be planned (and defined in the project operational plan), updates, newsletters: distribution to be coordinated by the LEG to the LCGs and then from the LCG to the sites (in agreement with the industry partner)
• Study web page as appropriate (accessible to all ENGOT Groups)
• FAQ access for ENGOT Groups and sites: medical queries should first be sent to the LCG and the industry partner– recommendation to put Q&A log on a website (eg LEG website or study specific website)
• Medical questions: a practical tool should be established
• Information flow on SAE/SUSAR to LCGs

Many partners are involved in the communication flow; the LEG, all LCGs involved, the CRO, the industry partner and their different affiliates per country. It is recommended to build up a communication flow.
Figure 1: Communication flow for inclusion/exclusion, major procedural questions, questions/answers review and protocol deviation
Figure 2: Communication flow for study/regulatory updates, newsletters and other communications to centres.
Figure 3: Communication flor for intergroup communication between leading ENGOT group and local collaborative ENGOT groups.
15. Tasks for LEG - Checklist

- Explain to the industry partners what ENGOT is and how ENGOT works (ask for a confidentiality agreement and for a donation for each trial).
- Discussion on contracts (intergroup, group-sites, LEG-industry partner etc)
- Review of design, protocol, CRF, SAP and CDE in collaboration with other groups as described before.
- Preparing the feasibility questionnaire for the ENGOT Groups and the sites
- Communication with the ENGOT groups: organization of TC, sending newsletters and information about the trial
- Communication with the third party (CRO) in collaboration with the pharma industry partner
- Communication with the pharma industry partner on an international level
- Collecting the needs of a group before negotiations with industry partner; negotiation of budget

If the LEG is Sponsor, the following tasks also apply:

- Overall trial coordination, allocation and overseeing of tasks and responsibilities of the different partners.
- Definition of publication policy (to be validated by the groups)
- Discussion about organization of the study (monitoring, type of system i.e. Clinphone, IVRS, type of access to data, data base management, communication flow between affiliates and ENGOT groups, tasks of the groups, reporting (including safety)/flow of SAEs, protocol deviations (classification)
- SAE review, medical data review, stat analysis review, clinical study report review
APPENDIX 1 Template Confidentiality Agreement

CONFIDENTIALITY AGREEMENT

This Confidentiality Agreement (the “Agreement”) is made effective as of DATE (the “Effective Date”), by and between

COMPANY NAME and ADDRESS (“Short Name Industry Partner”); and ENGOT (“ENGOT”).

The parties have had discussions, and contemplate further discussions and negotiations, concerning each party’s respective Subject Matter (as defined below) and certain proposed business arrangements. In furtherance of such discussions and negotiations, each party (in its capacity as the disclosing party, the “Disclosing Party”) desires to disclose to the other (in its capacity as the receiving party, the “Receiving Party”) confidential and proprietary information regarding its Subject Matter for the sole purpose (the “Purpose”) of enabling each other to evaluate the merits and feasibility of entering into a future transaction between Short Name Industry Partner or one or more of its Affiliates on the one hand and ENGOT on the other.

Agreement

In consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

Unless otherwise specifically provided in this Agreement, the following terms shall have the following meanings:

1 Definitions

1.1 “Affiliate” means, with respect to a Person, any Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person. “Control” and, with correlative meanings, the terms “controlled by” and “under common control with” mean (a) the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise, or (b) to own 50% or more of the outstanding voting securities or other ownership interest of such Person.

1.2 “Short Name Industry Partner Subject Matter” all information and data of any kind revealed by Short Name Industry Partner to Contracting Party or otherwise obtained by Contracting Party from Short Name Industry Partner related to chemical structures, biological data, formulation recipes, development plans, clinical study outlines (including outlines for clinical pharmacology studies) and any other information disclosed for the Short Name Industry Partner product known as XXXXX.

1.3 “Company Subject Matter” all information and data of any kind revealed by the Contracting Party to Short Name Industry Partner or otherwise obtained by Short Name Industry Partner from Contracting Party related to chemical structures, biological data, formulation recipes, technology and other proprietary data of the Contracting Party in support of the development of the strategy for the Short Name Industry Partner product known as XXXXX.

1.4 “Confidential Information” means any and all information or material, including any
documents, notes, analyses, studies, samples, drawings, diagrams, designs, flowcharts, databases, models, plans and software (including source and object codes), that, at any time on or after the Effective Date, has been or is provided or communicated to the Receiving Party or any of its Affiliates by or on behalf of the Disclosing Party or any of its Affiliates in connection with the Disclosing Party’s Subject Matter or any discussions or negotiations with respect thereto; any data, ideas, concepts or techniques contained therein; and any modifications thereof or derivations therefrom. Confidential Information may be disclosed either orally, visually, in writing, by delivery of materials containing Confidential Information or in any other form now known or hereafter invented.

1.5 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.6 “Subject Matter” means either of Short Name Industry Partner Subject Matter or ENGOT Subject Matter, as the context in which the term is used indicates.

2. Obligations of the Receiving Party
From the Effective Date and for five years thereafter, the Receiving Party shall (a) only use the Confidential Information for the Purpose; (b) keep confidential and not publish, make available or otherwise disclose any such Confidential Information, except to its Affiliates and any directors, officers, employees, contractors, consultants and other advisors or representatives of the Receiving Party and its Affiliates (collectively, the “Representatives”) with a need to know such Confidential Information to meet the Purpose and who are bound by confidentiality obligations with respect to such Confidential Information that are no less onerous than those set forth in this Agreement and (c) not disclose to any other Person (including by issuing a press release or otherwise making any public statement) the fact that Confidential Information of the Disclosing Party has been made available to the Receiving Party, the fact that discussions or negotiations are taking place between the parties, or any of the terms, conditions or other facts with respect thereto (including the status thereof).

The Receiving Party shall be liable for any breach by any of its Representatives of the restrictions set forth in this Agreement and agrees, at its sole expense, to take reasonable measures to prevent the prohibited or unauthorized disclosure or use of the Confidential Information by its Representatives. Without limitation, the Receiving Party shall use at least the same effort and degree of care that it uses to protect its own confidential information of a similar nature from unauthorized disclosure, but shall not use less than a commercially reasonable degree of care. The Receiving Party shall notify the Disclosing Party immediately, and cooperate fully at the Disclosing Party’s reasonable request, upon the Receiving Party’s discovery of any loss or compromise of the Confidential Information of the Disclosing Party.

3. Exceptions
The Receiving Party’s obligations under the Agreement shall not extend to any Confidential Information of the Disclosing Party to the extent the Receiving Party can reasonably demonstrate that (a) it is or hereafter becomes available to the public by use, publication, general knowledge or the like through no fault or wrongful act of the Receiving Party or its Representatives; (b) it is received from a third party, other than an Affiliate of the Disclosing Party, that is lawfully in possession of such information and is not in violation of any contractual or legal obligation of confidentiality between such third party and the Disclosing Party or any of its Affiliates in respect of such information; (c) it was already in its or any of its Affiliates’ possession without any limitation on use or disclosure prior to receipt from the Disclosing Party or any of its Affiliates; or (d) it was independently developed by the Receiving Party or any of its Affiliates without use
or reference to the Confidential Information of the Disclosing Party. Confidential Information disclosed to the Receiving Party hereunder shall not be deemed by the Receiving Party to fall within the above exceptions merely because it is embraced by more general information that falls within such exceptions.

4. Compliance with Law
This Agreement shall not be deemed to restrict either party from complying with a lawfully issued governmental order or other legal requirement to produce or disclose Confidential Information; provided, however, that the Receiving Party shall promptly notify the Disclosing Party upon learning of such order or requirement, to enable the Disclosing Party to oppose such order or requirement, as the case may be, or obtain a protective order, and the parties will cooperate to a reasonable extent with each other in such proceedings; and provided, further, that if a governmental order or other legal requirement is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such order or requirement shall be limited to information that is legally required to be disclosed in such response to such order or requirement, and the Receiving Party shall cooperate to a reasonable extent with the Disclosing Party to obtain confidential treatment, to the extent possible, with respect to the Confidential Information so disclosed.

5. Return of Confidential Information
Upon the Disclosing Party’s written request, the Receiving Party shall (a) return to the Disclosing Party or shall destroy, at the Disclosing Party’s discretion, any and all Confidential Information (including all copies and reproductions thereof); provided, however, that the Receiving Party shall destroy those portions of documents, memoranda, notes, studies and analyses prepared by the Receiving Party or its Representatives that contain, incorporate or are derived from such Confidential Information and shall certify to the Disclosing Party in writing such destruction; and provided, further, that the [Legal Department of the] Receiving Party shall be permitted to retain (i) one copy of such Confidential Information for archival purposes only and as reasonably necessary to demonstrate compliance with the terms and conditions of this Agreement, including in connection with legal proceedings; and (ii) such additional copies of or any computer records or files containing such Confidential Information that have been created solely by the Receiving Party’s automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party’s standard archiving and back-up procedures, but not for any other use or purpose; and (b) immediately cease, and shall cause its Representatives to cease, use of Confidential Information as well as any information or materials that contain, incorporate or are derived from such Confidential Information. Notwithstanding the return or destruction of the Confidential Information, the Receiving Party and its Representatives will continue to be bound by their obligations under the Agreement.

6. No Representation or Warranty
ALL CONFIDENTIAL INFORMATION IS PROVIDED “AS IS” AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW DISCLOSING PARTY HEREBY DISCLAIMS AND EXCLUDES ANY AND ALL REPRESENTATIONS, WARRANTIES, CONDITIONS OR OTHER TERMS, WHETHER WRITTEN OR ORAL, EXPRESSED OR IMPLIED, WITH RESPECT TO THE CONFIDENTIAL INFORMATION IT PROVIDES HEREUNDER, INCLUDING ANY REPRESENTATION OR WARRANTY OF ACCURACY, COMPLETENESS, QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. The Disclosing Party shall not have any liability, direct or indirect, to the Receiving Party for any damages that may arise as a result of the Receiving Party’s use of Confidential Information or any errors therein or omissions therefrom.

7. Miscellaneous
7.1 Neither party shall have any obligation to disclose any Confidential Information to the other. Either party may, at any time, cease disclosing Confidential Information to the other party without any liability. This Agreement is not intended, and will not be construed, to obligate either party to enter into any further agreement with the other party or to refrain from entering into an agreement or negotiation with any third party. No license or conveyance of any patent, copyright, trade secret, trademark or other intellectual property rights in the Confidential Information is granted or implied under this Agreement.

7.2 The interpretation and construction of this Agreement shall be governed by the law of England, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

7.3 Subject to Section, the parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the Country Courts for any action, suit or proceeding arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding related thereto except in such courts. [The parties irrevocably and unconditionally waive their right to a jury trial.]

7.4 Any notice, request, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if hand delivered or sent by an internationally recognized overnight delivery service, costs prepaid, addressed to the parties at their respective addresses first set forth above, or by facsimile (with transmission confirmed) or electronic mail, to Short Name Industry Partner or to ENGOT, or to such other address or facsimile number as the party to whom notice is to be given may have provided to the other party in accordance with this Section 7.4. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or electronic mail, or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service, whichever is the earlier.

7.5 Any amendment, modification or waiver of this Agreement must be in writing and signed by authorized representatives of both parties.

7.6 This Agreement shall be binding upon and inure to the benefit of the parties and their respective heirs, successors and permitted assigns. Neither party may assign its rights, or delegate its obligations, under this Agreement in whole or in part without the prior written consent of the other party.

7.7 This Agreement constitutes the entire agreement between the parties with respect to the subject matter of this Agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each party confirms that it is not relying on any statements, representations, warranties or covenants of any person (whether a Party to this Agreement or not) except as specifically set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud.

7.8 A breach by either party of this Agreement may cause irreparable damage for which the non-breaching party will not be adequately compensated by monetary damages. In the event of a breach, or threatened breach, of this Agreement, the non-breaching party shall be entitled to seek equitable relief from any court of competent jurisdiction, whether preliminary or permanent, [without the need to show irreparable harm or the inadequacy of monetary damages as a remedy [and without the requirement of having to post a bond [or other security]].] Nothing in this Section is intended, or shall be construed, to limit the parties’ rights to any other remedy for a breach of
any provision of this Agreement.

7.9 To the fullest extent permitted by applicable law, the parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, such provision shall be given no effect by the parties and shall not form part of this Agreement. To the fullest extent permitted by applicable law and if the rights or obligations of any party will not be materially and adversely affected all other provisions of this Agreement shall remain in full force and effect and the parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the parties.

7.10 The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by law or otherwise available except as expressly set forth herein.

7.11 This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission (with transmission confirmed) shall be as effective as an original executed signature page.

Execution
THIS AGREEMENT IS EXECUTED by the authorized representatives of the parties as of the date first written above.

SIGNED for and on behalf of [Name of Industrial Company] SIGNED for and on behalf of ENGOT
Signature
Name: Name:
Title: Title:
Date: Date:
APPENDIX 2: New ENGOT study proposals
Check of ENGOT criteria fulfilled by Current Chairs (clinician and operational) and Vice-Chair (clinician only). The Lead ENGOT Group can suggest a 4th person if one of the groups is already represented in the evaluation.

Table for completion by Lead ENGOT Group for each new study proposal

<table>
<thead>
<tr>
<th>ENGOT Trial No. (if any) or identifier (title):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol submitted by:</td>
<td></td>
</tr>
<tr>
<td>Date protocol submitted:</td>
<td></td>
</tr>
<tr>
<td>Lead ENGOT Group:</td>
<td></td>
</tr>
<tr>
<td>Short name of Trial:</td>
<td></td>
</tr>
<tr>
<td>Indication:</td>
<td></td>
</tr>
<tr>
<td>Drug(s) Involved:</td>
<td></td>
</tr>
<tr>
<td>Surgery Trial (Yes/No):</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Type of Trial (Academic, Industry Partner sponsored, Industry/company involved)</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Legal Sponsor:</td>
<td></td>
</tr>
<tr>
<td>Sample size:</td>
<td></td>
</tr>
<tr>
<td>Local Collaborating Groups:</td>
<td></td>
</tr>
<tr>
<td>Non-European Groups involved (add names)</td>
<td></td>
</tr>
<tr>
<td>ENGOT Model (A, B or C):</td>
<td>Choose an item.</td>
</tr>
<tr>
<td>Database held by:</td>
<td></td>
</tr>
<tr>
<td>ENGOT Group statistician:</td>
<td></td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
</tr>
</tbody>
</table>

Table for completion by Chairs (clinical and operational), Vice-chair (clinical) and 4th person if required on submission of new proposals

Checks to be completed

<table>
<thead>
<tr>
<th>ENGOT Trial No. (if any) or identifier (title):</th>
<th>Clinical Chair</th>
<th>Clinical Vice Chair</th>
<th>Operational Chair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal/Protocol checked</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any findings or recommendations:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRF checked</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any Findings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent Analysis guaranteed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publication issues according to ENGOT principles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Set per group after final analysis can be handed over to each participating group (check contract)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ENGOT Logo placed on final protocol</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table for completion by ENGOT groups interested in proposals presented (after each meeting)

<table>
<thead>
<tr>
<th>ENGOT Trial No. (if any) or identifier (title):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ENGOT Group</td>
<td></td>
</tr>
<tr>
<td>Interested in taking part without changes in design (Yes/No)</td>
<td></td>
</tr>
<tr>
<td>If ‘No’ in line above, please state what design changes are required for participation</td>
<td></td>
</tr>
<tr>
<td>Any competing trials (Yes/No)</td>
<td></td>
</tr>
<tr>
<td>If ‘Yes’ above, please state which trials</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 3 Letter of Intent (LOI)

Letter of Intent with ENGOT Group as Sponsor and Industry partner as supplying drug/finance (change wording in paragraph 1 if Industry partner is Sponsor).

Trial title:

ENGOT GROUP hereby represented by the XXX (hereinafter together the “Sponsor”) and Industry Partner (hereinafter YYY (each a “Party” and together “the Parties”); intend to enter into a clinical trial agreement (the “Agreement”) related to the above named clinical trial (the “Trial”) involving products A/B/C (the “Trial Drugs”).

The Parties have a common understanding regarding the essential terms of the Agreement to be signed which include; that XXX will be the Sponsor of the Trial and that YYY will provide agreed amounts of Trial Drug and financial support for the conduct of the Trial.

The above mentioned Agreement has not yet been agreed nor signed by the Parties, so in the interest of time, the Parties wish to show their commitment in this Letter of Intent. While the Agreement for the Trial is being negotiated the Parties hereby agree as follows:

- Both Parties aim to sign the Agreement in a timely manner after the date of the final signature on this Letter of Intent.

Upon the signing of this Letter of Intent by both Parties, YYY will transfer [agreed amount of Euros] to XXX so that it can use resources in relation to initial trial set up procedures. It is understood that such payment will be made as part of the Trial support and shall cover Trial activities performed or to be performed until the intended Agreement is signed. This payment shall serve as an advance against the funds payable by YYY under the Agreement.

In the event that no final Agreement can be executed between the Parties this Letter of Intent shall be terminated. If support for the Trial is cancelled by YYY prior to the conclusion of the Agreement, XXX shall keep the above initial payment of [agreed amount of Euros]. If the Trial is cancelled by the XXX, XXX shall refund the payment of [agreed amount of Euros] to YYY. If, however, the trial is cancelled due to reasons outside the control of XXX and YYY, XXX shall remit to YYY the amounts advanced to it hereunder, less the expenses reasonably incurred by the XXX up to that point in time in the performance of Trial-related activities; and in this event the payment of the reasonably incurred expenses shall be the only binding obligation of YYY.

The invoice will be addressed to:
[company to provide details] and will quote the reference [company to provide reference]

Payment shall be made by BACS transfer to the following account:

| Account name: |  |
| Account address: |  |
| Account number: |  |
| Sort code: |  |
Finance Department details:

| Payment reference number (must be quoted when making payments) | To be confirmed on invoice |

The Parties shall negotiate in good faith the terms and conditions of the Agreement for the above-mentioned Trial. Until such time as the Agreement between XXX and YYY is executed, both Parties agree that this Letter of Intent shall be deemed an agreement.

This Letter of Intent will be governed by and construed for all purposes in accordance with the laws of [countries]. The Parties submit to the exclusive jurisdiction of the [country] courts.

By signing below, each Party confirms its understanding of the terms of this Letter of Intent which becomes effective immediately upon signature.

Please sign two copies of this Letter of Intent and return one for our files. Retain the second copy for your records.

Yours sincerely,

Agreed and accepted:

YYY          XXX

______________________________  ____________________________
Name:                  Name:
Title:                 Title:
Date: ________________    Date: ________________
APPENDIX 4 Guidelines for Authorship for Trials run within ENGOT Update June 2017

1. **General.**
   a. Authorships and Co-authorships are not granted by individual institutions but by groups or consortia of study centres. A waiver (e.g. for surgical trials) must be defined prospectively before and accepted by ENGOT before an ENGOT number is given to the trial.
   b. All calculations regarding the number and position of co-authorships will be based on numbers of recruited patients by group, unless a protocol defines a specific exception (i.e. numbers according to individual recruitment per centre).
   c. Each group is 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). However, general guidelines as the NIH guideline should be respected during this selection process by the study groups.
   d. 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.
   e. If possible, all centres who have actively recruited in the trial should be mentioned at least as co-authors in the appendix.
   f. The following “rules” should guarantee participation and benefits with respect to scientific publications for all groups involved and share as much attractive positions among the groups as possible.

2. **Fixed authorship positions for publication of the primary analysis (including the primary endpoint).**
   a. All co-authorship positions depend on recruitment of groups except one authorship position of the International Principal Coordinator (appointed by leading group) and, in phase II/III studies additionally one for the statistician of the study (usually 4th position). Both positions do not count for calculation of positions per group
   b. No further fixed positions of prominent authorship positions (e.g. 2nd, 3rd, or senior) should be granted to Co-PI etc., to avoid de-motivation for the groups. ENGOT policy is not to allow co-PI-ship in any trial.
   c. International Principal Coordinator is first author or senior author depending on the occasion unless he grants this to anyone else. Usually, PI is first author of the main manuscript and can be co-author in subproject papers. In the latter cases first authorship is given to a leader of a respective subproject and PI is senior author (or co-author at another position if subproject demands both most prominent positions being provided to the subproject working group).
   d. The best recruiting group can choose between 2nd author or senior author; in the latter case 2nd author would be granted to the 2nd best recruiting group, 3rd author by the 3rd best recruiting group etc. (example see below). If the leading group is the best recruiting group, they are treated as 2nd best recruiters and the senior (or 2nd position) is given to the next best recruiting group to avoid both, 1st and senior authorship be given to one study group and motivating all groups to recruit well.
   e. 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 should be rather the exception than the rule.
   f. If NON-ENGOT groups participate as cooperating group within an ENGOT trial they have the same rights as ENGOT groups (e.g. getting the senior authorship if they recruit best).

3. **Number of authors per group for publication of the primary analysis (including the primary endpoint).**
a. Each group receives their first guaranteed authorship position when the group has recruited 1-2% of the total number of patients. The exact cut-off (1 or 2%) must be specified in the protocol (commonly the larger the study is the lower the threshold should be).

b. Further positions are granted according to recruitment numbers and depend on the total number of authorships possible. The latter defines the number of recruited pts per co-authorship position (e.g. if overall 30 positions are available per definition of the journal/congress or other and 10 groups participated, 18 positions would be available for further distribution after PI, statistician and the first co-author of each study group had been settled).

c. The first authorship per group is defined by the lowest recruitment number of the last group classifying for authorship (i.e. have recruited more than 1 or 2%) and is the same for all groups. E.g. 10 groups participate in a trial with 1,000 pts. and 9 of the groups have recruited more than 10 pts. and, therefore, qualify for authorship. Among the 9 groups the lowest recruitment was 15 pts. in group X and considerable higher numbers in the remaining 8 groups. In this case, the pts. equivalence for the first authorship position per group is 15 pts. Summing up all recruitment numbers for the first authorships (in our example 9 x 15 pts = 135 pts) and subtracting them from all 1,000 recruited pts. will give the number for calculation of the further recruitment rate necessary per authorship position; in this example 1,000 – 135 = 865 which is the number for calculation of further additional authorship positions. If, in this example, 18 more co-authorship positions are available, each authorship position is qualified by 865: 18 = 48 pts/position.

4. Position of the authors for publication of the primary analysis (including the primary endpoint).

a. 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, etc. group A would deserve the senior authorship position, group B the 2nd authorship position and group C the 3rd authorship position etc.

b. If the leading group is also the highest recruiting group a waiver gets active and the 2nd highest recruiting group gets the senior authorship position and the leading group is regarded as 2nd highest recruiter – to avoid that the leading group has 1st and last authorship position in an ENGOT intergroup trial.

Example: the whole trial recruited 1,000 pts. Groups A-H participated and group A was leading group. The 1% limit was 10 pts. The target Journal allows 25 authors

- Group H had the lowest recruitment and had 2 pts.
- Group G had the 2nd lowest with 9 pts.
- Group F recruited 19 pts.
- Group E recruited 39 pts.
- Group D recruited 48 pts.
- Group C recruited 183 pts.
- Group B recruited 325 pts
- Group A recruited 375 pts.

The calculation resulted in the following authorship distribution:

- Group H: no authorship per first round (leftover = 2 pts.)
- Group G: no authorship per first round (leftover = 9 pts.)
- Group F received 1 authorship for 19 pts. (> 1% threshold passed; thus defining 19 as prerequisite per authorship position)
- Group A-E receive their first authorship with 19 pts. each. Which makes A-F x 19 = 6 x 19 = 114 pts. That leaves 1,000 – 114 = 886 for further distribution.
- The leading group has the 1st position (as PI), the statistician has position 4, groups A-F have 6 further positions including senior, so 17 further positions can be distributed. => 886: 17 = 52 pts/position.
• As group A was leading and best recruiting group, therefore senior authorship goes to group B and group A gets 2nd position. Group C gets 3rd position, group D gets 5th position, group E gets 6th position, and group F gets 7th position – leaving position 8-24 for the remaining positions:

• Overall, group A would receive 7 authorships (plus PI): 1 on position 2nd for pts 1-19 and 6 for patients 20-331 – 52 per position – leftover 44 pts

• Group B would receive 6 authors (1 = senior author for pts 1-19 and 5 for pts 20-279) – leftover 46 pts

• Group C would receive 4 authors (1 for pts 1-19 and 3 for pts 20-175) – leftover 8 pts

• Group D would receive 1 author (1 for pts 1-19) - leftover 29 pts.

• Group E would receive 1 author for pts 1-19 - leftover 20 pts

• Group F would receive 1 author for all their 19 pts.

This first round would result in 22 authorship positions including PI and statistician. The left three authorship positions stand in front of 153 pts. who are so far not compensated (sum of the pts. “leftover”). The ranking of leftovers is: groups B > A > D > E > G > C > H. Here the protocol should foresee which way should be chosen: either groups B, A, and D (those with the highest leftover) receive each one additional position, or the leftovers are used for groups G and H (smaller groups which did not meet the threshold for the first position) and the left for group B with the highest leftover (the latter being a model “solidarity over power by size”, the first model can be called “size does matter”).

5. Additional sequential publications of planned analyses of secondary endpoints

a. For additional publications on planned secondary endpoints analyses, not included in the primary endpoint publication, the first authorship should alternate amongst the groups.

b. The steering committee of the study should define the sequence of importance of the secondary endpoints if there are more than one subsequent separate analysis.

c. The most important secondary endpoint should be presented by the group with the highest recruitment if this is not the leading group. If so, the second best recruiting group and the leading group may change position regarding the distribution of subsequent presentations/publications. The second most important endpoint will be presented by the group with the second highest recruitment (or the leading group if best recruiter), and so on.

d. When the Leading group is not first author of a separate publication on secondary endpoints, the International Principal Investigator of the study gets the senior (last) position.

e. Furthermore, the number of authors per group and positions per groups follow the rules as outlined for the publication of the primary endpoint at the time of the primary analysis.

6. Additional publication of subgroup data or sub-projects:

f. If possible, each participating group should receive a dataset of patients recruited by the respective study group after final analysis.

g. 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 (Trial Steering Committee [TSC] or data committee after dissolution of TSC) should be informed on each project.

h. Further subgroup analysis of the whole population should be prospectively discussed among the groups and agreed. For acceptance and distribution of subprojects the TSC should be in charge – later on a reduced subproject committee can take over this task

i. First author should be of the group performing the sub-analysis.
j. Other groups should be mentioned and have co-authorship positions similar to the rules for primary and main publication but with reduced numbers according to the positions already covered by project members.

k. International Principal Investigator is usually senior author for main subprojects (eg. OS analysis after first publication of PFS primary endpoint) but can be replaced by others in secondary subprojects (e.g. prognostic factors, subgroup analysis) either in a rotating system or as reward for study groups very active in the respective subproject.

l. The statistician responsible for the subproject analyses gets an usually the 4th authorship position, however, this may change to an even more prominent position in case of, e.g. for methodological/statistical subprojects.

m. All sub-publications or meta-analyses can only be published after the full manuscript of the study has been published.

n. Full paper on general analyses of secondary endpoints (e.g. quality of life, prognostic factors etc.) should be shared among the groups with rotating first authorship position by recruitment.

o. Smaller groups (who did not recruit the necessary 1% of the total number of patients) might either have an authorship granted by calculation model “group solidarity over size” or must have co-authorships in 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 authors and without all groups mentioned; anyhow the International Principal Investigator should be mentioned as senior author.
   c. International presentations may be scheduled according to available data and rotate among the groups (a plan should be made by the TSC).

7. **Specific scenarios**:

7.1 **Surgical trials**

Exceptions from the above mentioned rules may be defined in specific trials and protocols, as eg. surgical trials in which the role of strong single centres is more dominant and important than in large chemotherapy trials. Furthermore, recruitment is often much more difficult and honorarium sparse indicating a higher need to reward the individual centres (selected / confirmed by the groups). Furthermore, centres of countries without ENGOT groups could participate and could be rewarded. For such studies, co-authorship positions and numbers could be modified by recruitment strength of the individual centres within the study group. Anyhow, respective rules must be agreed on by ENGOT in advance and accepted when the trial receives an ENGOT number (the model must be presented at the time the study applied for receiving an ENGOT number).

7.2 **Phase 1 and 2 Trials, including translational activity**

When a phase 1 or 2 trial has a substantial translational research component, and as clinical and translational research coordinators may differ in a group, separate rules compared with the general rules as pointed out above will apply when a manuscript is primarily aimed to publish results of a combined clinical end-point (e.g. PFS) and a translational research end-point. This could also make it necessary to include authors not primarily affiliated with a study group but contributing with lab work. In these specific protocols rules must be agreed on in advanced and presented to ENGOT when the group applies for an ENGOT number. The recommendation for defining authorship rules prospectively applies in particular for projects in which the PI of the clinical study may neither get the first nor the senior position.
Overall, the model should consider both groups’ contribution and TR lab activities. At minimum 51% of authorship positions should be distributed by the study groups and reflect the general rules as pointed out above (with the exception of authorship positions which may also reward lab work for prominent position next to PI).

7.3. ENGOT trials with study lead of a non-ENGOT group (e.g. ANZGOG, GOG-F et al.)
If ENGOT decides to participate in an intergroup trial not lead by an ENGOT leading group, it will negotiate authorship numbers and positions that reflect the ENGOT contribution to the trial (e.g. senior authorship if ENGOT as a whole is the best recruiter or second best after the leading group of the trial lead by another group that offers the PI and first author). For organisation and representation ENGOT will elect one member group as coordinating group (CG). This CG should represent ENGOT during all negotiations with the extra-European leading group and sponsors and guarantee adherence to the ENGOT minimal requirements for study performance. The ENGOT authorships will be distributed among the participating ENGOT groups while the CG deserves the most prominent position (i.e. the senior authorship if ENGOT recruits the most patients or is the 2nd best recruiter after the leading group). All other authorship positions assigned to ENGOT will be distributed within ENGOT according the above mentioned general rules adapted to the ENGOT patient subset. Independent from both publication rules and CG function the trial TSC should allow participation of as many as possible actively recruiting ENGOT groups.