



New NSGO Trial Organisation NSGO Kliniske Forskningsfond (NSGO CTU Foundation)

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Background

One of the main objectives and activities of NSGO is to conduct clinical trials, and indeed our Society is engaged in several international multicenter trials. However, the regulations and obligations for conducting such trials have been increasingly more complex and demanding during the last years. The participation of NSGO in trials today infer both medical, juridical and economical commitments and risks. The former structure of NSGO was not well suited to meet the requirements of a modern efficient clinical trial organization. In order to secure the status of NSGO as a well recognized and reliable international trial partner the Board made the following proposal, which was accepted by the Extra General Assembly in Copenhagen on 2005-10-09. Due to Danish legal regulations the original documents have undergone some revisions to form the legal basis for the new “**Nordisk Selskab for Gynækologisk Onkologi’s Kliniske Forskningsfond**”, established on October 1st, 2006. Thus, NSGO now has founded a non-profit Foundation with the purpose to support Research in Gynecologic Cancer. The name of the new foundation is in Danish, which is demanded by the Danish authorities. In English and in daily use, the name will be NSGO-CTU.

The new Trial Organisation – The NSGO CTU

- A new permanent Trial Unit “**The NSGO Clinical Trial Unit**” has been formed.
 - NSGO-CTU has responsibility for managing clinical trials and is led by a **Director** responding to the Board of the Foundation “Nordisk Selskab for Gynækologisk Onkologi’s Kliniske Forskningsfond”.
 - **The Director should be contracted by the Foundation Board for a period of 3 years.** The Director can be appointed for several periods without limitations, as long as it is in the interest of the Foundation and NSGO. There should be a written formal contract, which also specifies the amounts of reimbursement. The Foundation Board can suspend the contract. The Director of the CTU should be present at NSGO Board meetings.
- NSGO-CTU consists of the Director, the staff of the Data Center and an Advisory Board (corresponding to a “Protocol Committee”).
- The Advisory Board is appointed by The Board of NSGO and consists of:
 - The Director
 - Two members from the NSGO Executive Board
 - At least one or two other NSGO members appointed by the NSGO Board
 - Members of the staff of the NSGO Data Centre:
 - Chief Data Manager
 - Chief Statistician
 - Members (except the Director and the staff from NSGO data centre) are elected for a two year period.
 - The task of the Advisory Board is to:
 - Evaluate study proposals on behalf of NSGO and approve or reject study proposals.
 - Help the development of accepted study proposals.
- The two members from the NSGO Board should be changed with the changing of the members of the NSGO Board. These two members should be the Chairman of NSGO and one other NSGO Board member.
- The members of the staff of the Data Center should be members as long as they have their position in the Data Center.
- The other NSGO members of the “CTU Advisory Board” should be appointed by the NSGO Board on basis of their personal skill and interest in clinical trials.



Approval of new Trials in NSGO:

Trial proposals

New trial proposals are sent to the CTU for approval and development.

The NSGO CTU will take care of practical issues:

- *Approval from the legal authorities*
- *Finalising of protocol and CRF*
- *Negotiations with medical companies for the economy and creating a contract with the companies and investigators*

Principle Investigator and Authorship

It is the responsibility of the CTU advisory board to appoint a principal investigator for a new study, with qualifications and competence for the task. The CTU should keep record of members with such competence and interest. A member who proposes a new study, which is then accepted, will normally be appointed as principal investigator. In case another person is appointed as principal investigator, the proposer will always be appropriately recognized.

Representation in the GCIG

NSGO has six representatives in the GCIG. At least three of these representatives should come from the CTU.

Rules for the Development and Processing of new Study Proposals

The CTU should create a guide with advice and a check list for the development of new clinical trials. A member, who wishes to propose a new study shall make a summary of the proposal in the form of a "Protocol Synopsis".

- 1 The synopsis is sent to the datacenter.
- 2 The datacenter sends the synopsis to all members in the CTU advisory board for comments
- 3 **A response is given to the proposer within one month.**
- 4 When a majority of the CTU advisory board members are in favor of the principles in the proposal, the CTU takes part in the further development of a protocol.
- 5 The next step will be to revise the synopsis according to the comments from the advisory board.
- 6 Economic support is sought
- 7 The revised synopsis is sent to all institutions to ask for preliminary commitment.
- 8 With sufficient economic support and patient recruitment, a full protocol is developed in cooperation between the CTU and the principal investigator.
- 9 CRF's are developed in cooperation between the CTU and the principal investigator.

Economy

The Clinical Trial Unit will have separate economy based on the income from the trials. Income will mostly come from medical companies. The CTU will negotiate the financial agreements with the companies and present contracts and the financial agreements for the investigators. The Director of the Clinical Trial Unit is responsible for the trial economy. The economy of the Clinical Trial Unit shall be externally reviewed by authorized accountants and the economy will be presented to the board of the Foundation and the NSGO Board. A report should be given to the NSGO General Assembly.

Turku, March 22, 2007

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Chairman of the board for NSGO Kliniske Forskningsfond