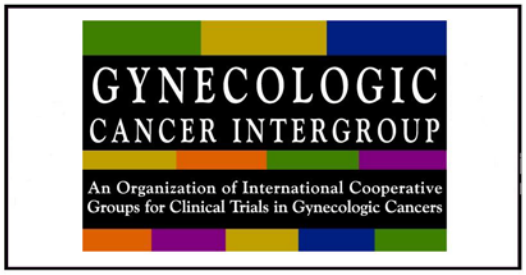

HARMONIZATION WORKING GROUP

GROUP CONTACTS & SUMMARIES

Oct 2013

Contents

AGO-AUST (Arbeitsgemeinschaft Gynaekologische Onkologie Austria)

Background

Group Structure: The AGO-Austria was founded in 1991 as a subgroup of the Austrian Society of Obstetrics and Gynaecology. It was the devoted aim of this group of Austrian gynecologic oncology specialists to discuss urgent questions of research and treatment of gynaecologic cancers.
The AGO- study group was founded in 2002 with the coordinating office located at the Department of Obstetrics & Gynaecology, Medical University Innsbruck. The executive board consists of 10 Austrian gynaecological oncology specialists who meet on a regular basis.
Advisory board meets every second month to discuss progress of ongoing trials, to present ideas for new trials and to consider participation in international trials.
Legal entity: Legal body is the Medical University of Innsbruck. Whereas the AGO Studienzentrale is a project of the Medical University of Innsbruck.
Membership criteria: Centers who wish to participate are being discussed in the regular meetings. However, participation is open to all interested physicians.
Funding: Depending on protocol, but mostly no payment to the institution. Partial payments (hourly wages) for a study nurse to support investigators depending on center and trial. Mostly the center has to manage all clerical and administrative procedures.
Some travel costs for group meetings are funded.
Coordinating/data centre: AGO-Studienzentrale is the coordinating trial center

Study approval process

Concept development and approval: New concepts developed by group members and new protocols from external sponsors are reviewed by individuals who have been designated for a specific indication. These designees give a summary and feed-back on the proposed trial to be discussed by the Advisory Board. Then a recommendation is made regarding the scientific validity of the study and the potential for the group to participate.
Protocol development: Executive board, advisory board, central office team; procedures according to SOPs
For local studies: the individual who puts forward the concept is involved in protocol design. Trial statistician and central office team is appointed to assist in development and control trial design and analysis plan.
A protocol template is provided with (mandatory) sections.
Eligibility Criteria -- gynecological malignancies
Informed Consent -- The informed consent needs to be approved by the Coordinating Ethical Committee and will be revised according to the comments from each local EC.
Toxicity Criteria -- Common Terminology Criteria for Adverse Events (CTCAE) of the National Cancer Institute, version 4.03 (older protocols 3.0)
Amendments/Revisions: Amendments need to be approved by the Coordinating EC and each local EC.
Companions -- depending on protocol
Quality of Life – PRO, QoL, QLQ depending on protocol
Economics -- depending on protocol
Translational Research – is encouraged, depending on protocol
Pharmacokinetics -- is encouraged, depending on protocol
Protocol approval: The advisory board finalizes concepts and presents these to the executive board for approval. After approval participating centers are selected and submission to ethics committee by the coordinating group follows.
Protocol numbers are assigned as AGO-XX with consecutive numbers.
The executive board makes final decisions on trial design and makes final protocol revisions.

Data management systems

General: Standards adapted to trial specific needs

CRF and database development: General – statistician is being involved.
QA Review: finalization after discussion with team and CRA
Computerization: All sites are computerized and have the ability to use electronic CRFs. Electronic databases are being used. Electronic procedures for patient registration and/or randomization are in use.
eCRF usage: eCRFs used for newer trials, older trials still paper CRF
Randomisation and enrolment: Randomization techniques – trial specific randomization/registration at the group coordinating center or at site (depending on trial) via fax/phone/electronic.

Ethics and regulatory considerations

Ethics approval: Depending on type of trial, lead ethical committees can give approval for all of Austria (trials according to AMG) with single ECs only to be notified. For other trials approvals have to be gained by the ECs of all the centers involved. Approval process last in general 4-8 weeks after submission.
Regulatory approval:
National: BASG/AGES Ministry of Health, Leading Ethics Committee
Local: institutional ethics committee, local hospital approval, local university approval
Adverse event reporting: When acting as sponsor in a trial the lead administration office will inform principal investigator, co- investigators, medical company, ethic committees and other legal authorities after SAE was reported to the lead office by any participating centre.

Study activity

Start up: Local Activation: essential documents check: protocol approvals, investigator agreements/commitments, CVs, ethics approval, local health authorities, delegation of duties, list of signatures, participating departments, pharmacy, etc.
Centers interested in participating in the study will sign a commitment form and a contract of duties and responsibilities.
CRFs: design in cooperation with statistician and CRO.
Center ID's: Each participating Centre is assigned a specific Centre Code, which remains the same across all AGO protocols.
Patient ID's**:** Design depending on the protocol. – Usually only numeric, in order to allow for data safety.
SC: involved in all trial related activities according to agreement before start: ISF, Trial Master Files, etc.
The lead administration office manages IRB approvals, regulatory requirements, insurance, funding, and other administrative duties.
For some trials a CRO is contracted who is responsible for CRF supervision, management of queries, SAE management, regulatory requirements, and other administrative duties outlined per individual trial contract.
Monitoring: External monitoring – trial specific contracts with CRA. In some low-budget trials only in-house monitoring done by project manager
Audit: Sponsor audits

Promotion and recruitment:

Regular central and local scientific meetings; regular newsletter
Recruitment: Via Austrian centers of gynecological oncology
All participating centers are required to present center and trial specific results/activities at regular national scientific meeting. Regular attendance of national meetings are mandatory.

Group Contacts

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OA Dr. Gerhard Bogner, MSc. (g.bogner@salk.at)

Dr. Birgit Volgger (b.volgger@onet.at)
Prof. Dr. Karl Tamussino (karl.tamussino@medunigraz.at)
Harmonization (Operations): Regina Berger, AGO-Studienzentrale, Medical University Innsbruck, Dept. of Gynecology & Obstetrics, Anichstr. 35, A-6020 Innsbruck, Tel.: +43(0)50504-24132; fax: +43(0)50504-22458: e-mail: Regina.Berger@i-med.ac.at; global e-mail: ago.studienzentrale@i-med.ac.at
Harmonization (Statistics):

ACRIN (American College of Radiology Imaging Network) - pending

Background

Group structure:
Legal entity:
Membership criteria:
Funding:
Coordinating Centre:

Study approval process

Concept development and approval:
Protocol development:
Protocol approval:

Data management systems

General:
CRF and database development:
eCRF usage:
Randomisation and enrolment:

Ethics and regulatory considerations

Ethics approval:
Regulatory approval:
Adverse event reporting:

Study activity

Site selection and feasibility:
Start up:
Monitoring:
Audit:

Promotion and recruitment

Group Contacts

Address:
Phone:
Group Chair:
Harmonization (Operations):
Harmonization (Statistician):
Website:

AGO (Study Group of the Arbeitsgemeinschaft Gynaekologische Onkologie)

Background

Group structure: The AGO Study Group is a non-profit scientific association with the aim to enhance the treatment of gynecologic tumors in women. It developed from the AGO Ovarian Cancer Study Group (AGO-OVAR), which was founded in 1993.
There is the Executive Board, the Study Coordinating Group and the Central study office.
Cooperation with the Coordinating Centre for Clinical Trials of the University of Marburg-Giessen (KKS) regarding all statistic issues and quality assurance.
Legal entity: AGO Research GmbH is the legal entity that takes on the role of sponsor for trials conducted by the AGO Study Group.
Membership criteria: New sites interested in participating in AGO trials have to complete a questionnaire to give an overview on equipment, site staff, experience in conducting clinical trials, etc.
If they fulfill all requirements they are invited to participate in an AGO trial. They receive an AGO Site ID as soon as they enroll the first patient into an AGO trial.
There is no fee for joining the AGO Study Group.
Recruitment of at least one patient per calendar year is expected.
Funding: There is no central funding to the AGO Study Group. Funding for individual trials is based on kind of the trial, e.g. pure academic trials, industry sponsored trials. A minority of trials is supported upon request of applications to German Cancer Aid or to the Federal Ministry of Education and Research, and donations.
Coordinating/data centre: The Coordinating Centre for all clinical trials is the central study office which is located in Wiesbaden, together with the satellite offices located in Marburg and Essen.

Study approval process

Concept development and approval: Any member of the Study Coordinating Group is entitled to present ideas for new protocols and to present a proposal to the Executive Board, who considers scientific merit and feasibility. If the proposal is accepted by this Board, it will be distributed to the Study Coordinating Group. In case of favorable opinion the Study Coordinating Group nominates the Coordinating Investigator and an AGO Study ID will be assigned.
Ovary: AGO-OVAR #
Gynecologic tumors: AGO-GYN #
Surgical trials: AGO-OVAR OP.#
Protocol development: The protocol will be created by the respective Coordinating Investigator, the central study office team and the statistician (+/- third partners) according to SOPs. Usage of checklist grants that all essential topics are included in the protocol.
Protocol approval: After protocol finalization submission to the Ethics Committee and Competent Regulatory Authority will be done.

Data management systems

General: The AGO cooperates with the data management team of the KKS consisting of database developers, programmers and biostatisticians.
CRF and database development: CRFs are generated by using generic modules / common elements. CRFs are reviewed by clinicians, statistics and data management.
Database testing is carried out by the respective project manager including verification of available data plausibility programs. If eCRF is used site staff being involved in the trial usually receives access to a test database firstly.
eCRF usage: Since 2010 all IITs coordinated by the AGO use the Electronic Data Capture system by KKS.
Randomisation and enrolment: Quality checks of the main inclusion/exclusion criteria before enrolment by the respective project manager and his/her substitute. Randomizations/Enrolment via central study office after

release of the patient; depending on trial randomization via IVRS / IWRS possible (randomization technique: block randomization). Randomization result will be send to the site via fax.

Ethics and regulatory considerations

Ethics approval: In Germany we divide in Central Ethics Committee and Local Ethics Committee.
The Central Ethics Committee is the EC of the German Coordinating Investigator and verifies the whole trial; exclusively taking of a decision.
Local Ethics Committees verify the qualification of the Investigators and the suitability of the local sites regarding the trial.
The Central Ethics Committee reviews and approves the Protocol, the Patient Information and Informed Consent Form, Modul 1 (Annex 1 of the ENTR/CT1 guideline), Modul 2 (Annex 2 of the ENTR/CT1 guideline), Insurance and Investigators Brochure or Summary of Product Characteristics (SmPC). Favourable opinion is given for the whole trial duration, but can be withdrawn at any time.
Any Investigators being involved in a clinical trial have to be approved by their local and central Ethics Committee before being authorized to work on study related procedures, especially obtaining informed consent, study related procedures regarding patients' safety.
Regulatory approval: German Competent Regulatory Authorities are the Paul-Ehrlich-Institute (PEI) or Federal Institute for Drugs and Medical Devices (BfArM). PEI/BfArm reviews and approves the Protocol, Modul 1 (Annex 1 of the ENTR/CT1 guideline), Insurance and Investigators Brochure or Summary of Product Characteristics (SmPC).
Sites have to be notified to their respective regional administrative authority before the beginning of the trial.
Notification must be in place from Ethics-Committee AND from Competent Authority before a clinical trial site can be activated.
Adverse event reporting:

- SUSARs. Expedited reporting of SUSARs occurring in the trial to the Central Ethics Committee, the Competent Regulatory Authority, all Investigators and to the authorities of involved EU member states (if applicable).
- - Fatal or life-threatening events: reporting within 7 days
- - Non-fatal and non-life-threatening events: reporting within 15 days
- Shipment to Ethics and Authority by post; to sites by e-mail
- Once per year the Development Safety Update Report (DSUR), formerly known as Annual Safety Report (ASR) has to be sent to Central Ethics Committee and the Competent Regulatory Authority including benefit-risk evaluation of the sponsor.

Study activity

Start up:
Essential Documents:

- Suitability form of sites; feasibility check depending on trial
- Investigator agreement including consent of the administration department
- If applicable consent of radiology and/or pharmacy
- Financial Disclosure Statement
- Scientific CV including evidence of experience in conduction clinical trials and ICH-GCP knowledge
- Ethics approval
- Notification to the respective regional administrative authority
- Monitoring Training for all monitors being involved in the trial
- Site initiation visit (SIV) with the site personnel being involved in the trial; all participants have to sign the Start up Meeting log. After the SIV new trial staff has to be trained before carrying out trial related procedures; training has to be documented.
- Site initiation can also be done via telephone in individual trials.

Monitoring: Usually there is an onsite monitoring conducted by a preferred monitoring company (CRO). Intervals for monitoring visits are defined in the monitoring plan and depend on the accrual rate at the local site.

Tasks monitoring:

- Source data verification depending on monitoring plan
- Verify site's compliance with regulations/requirements
- Study drug accountability

A monitoring report will be send to the responsible project manager who reviews the report and initiates actions if necessary. In some low-budget trials there is only an in-house monitoring done by the responsible project manager.

Audit: Audits by sponsor. Inspections by regional authorities. Planned: Audits of AGO sites by QA department

Promotion and recruitment

- Websites www.ago-ovar.de & www.ago-online.org
- Promotion at regional meetings
- Annual Investigator meeting
- Regular study updates to the Executive Board and the Study Coordinating Group (Study Leading Group meets 3 times a year; Executive Board 4 times a year)
- Weekly recruitment updates to Coordinating Investigator and data managers
- Trial specific newsletters

Group Contacts

Address: AGO Study Group, Kaiser-Friedrich-Ring 71, 65185 Wiesbaden, Germany
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Dr. med. Philipp Harter, email: p.harter@gmx.de
PD Dr. med. Felix Hilpert, email: fhilpert@email.uni-kiel.de
PD Dr. med. Sven Mahner, email: sven.mahner@gmx.de
Prof. Dr. med. Jacobus Pfisterer , email: jacobus.pfisterer@googlemail.com
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Harmonization (Statistics): Alexander Reuss, Coordination Center for Clinical Trials. Department of the Philipps-University Marburg, Karl-von-Frisch-Str. 4, 35043 Marburg, Germany; Phone: +49-(0)6421-2866580, Fax: +49-(0)6421-2866517, E-Mail: alexander.reuss@kks.uni-marburg.de

ANZGOG (Australia New Zealand Gynaecological Oncology Group)

Background

Group structure: ANZGOG was established in 2000 as a not-for-profit organization. In 2009 it became an incorporated company with an elected Board of Directors and a Board appointed Executive Director and admin staff. There are a Research Advisory Committee (RAC), Consumer and Community committee, Audit committee and Study Coordinators committee within ANZGOG. There is also an Operations Executive which comprises both ANZGOG and NHMRC CTC members.

Legal entity: ANZGOG is a legal entity but to date the University of Sydney is the legal entity that takes on the role of sponsor for clinical trials conducted by ANZGOG and coordinated by the NHMRC Clinical Trials Centre.

Membership criteria: Membership is open to anyone with an interest in gynaecological cancer. Applications for membership are ratified by the Board, prior to acceptance. Applicants may apply to be Full, Community, Industry, Associate or Sustaining members.

Funding: Cancer cooperative groups in Australia receive limited infrastructure support from Federal and State based initiatives. Funding for individual trials may be from competitive grant applications, from per patient payments for Intergroup studies, or from industry.

Coordinating centre: The NHMRC Clinical Trials Centre (CTC) at the University of Sydney is the Coordinating Centre for all Phase III clinical trials. Some Phase II studies are coordinated at other hospital based data centres. The CTC provides expertise in protocol development, biostatistics, database development, and all aspects of study conduct, according to Standard Operating Procedures.

Study approval process

Concept development and approval: Concepts may be presented at the Annual Scientific Meeting, or to any RAC meeting, held quarterly by teleconference or face-to-face. A concept development checklist is provided. Concepts may be approved, recommended for further development, or rejected.

Protocol development: The CTC has a protocol template to assist with ensuring coverage of all essential elements including eligibility criteria, study endpoints, statistical considerations, schedule of assessments, toxicity criteria and publication planning.

Protocol approval: A final copy of a study protocol should be submitted for review by the Research Advisory Committee. Intergroup protocols (either GCIG, or with other ANZ cancer cooperative groups) can be submitted for consideration at any RAC meeting. Approval to proceed may be given based upon scientific quality and importance, demonstrated feasibility, adequate funding. Locally developed protocols are given an ANZGOG Study ID, Intergroup protocols are not. The Consumer and Community committee and the CTC Research and Operations Committees also review all protocols.

Data management systems

General: The CTC has a data management team consisting of database developers and programmers. They work closely with the trials teams and biostatisticians.

CRF and database development: CRFs are developed from a library of generic template forms, and are reviewed by clinicians, statistics and data management. User Acceptance Testing is carried out by trials staff.

eCRF usage: All Phase III ANZGOG studies coordinated through the CTC use electronic Data Capture (EDC). Most studies with electronic data capture currently use “InForm” by Phase Forward.

Randomisation and enrolment: Randomisations/registrations are carried out by site staff, using web-based systems. A fax based back-up system is in place in the event that there are problems with the web-based system.

Ethics and regulatory considerations

Ethics approval: Individual states in Australia have implemented central ethical review to varying degrees, and there is a central system covering the 3 largest states but there is currently no completely national system in place. New Zealand has had Multi-centre Ethical review in place for a number of years.

Human Research Ethics Committees (HRECs) review and approve the protocol, Patient Information Sheet and consent form, investigator brochure or prescribing information and any material given to patients. Approval is usually given for 3-5 years with progress reports to be provided annually.
HRECs review safety data in accordance with the guidance of the NHMRC, Australian Research Council and Australian Vice-Chancellors committee and the ICH GCP guidelines, as adopted by the Therapeutic Goods Administration (TGA)
Regulatory approval: The TGA in Australia operates a Clinical Trial Notification (CTN) scheme for new drugs or devices or new indications for already registered drugs/devices. The CTN notification must be in place before a clinical trial site can be activated.
The regulatory body in New Zealand is Medsafe. Medsafe approval is required for a new medicine being used for the first time in New Zealand or for a new dose form or strength of an approved medicine.
Adverse event reporting: SUSARs occurring in Australia or New Zealand are reported to the relevant regulatory authority with 7 or 15 days for fatal or life threatening events and to local Ethics Committees according to institutional requirements. Reporting of all other adverse events is according to local institutional requirements and/or as specified in the protocol.

Study activity

Site selection and feasibility: Site selection is based on response to feasibility assessment forms, recruitment to previous studies, previous site performance.
Start up: Essential documents as per Appendix. Once all pre-study requirements have been met, site training is either face to face, via webcast or teleconference.
Monitoring: Minimum of 2 visits/site/trial where funding allows, with additional for-cause visits. Central monitoring for compliance and data quality issues.
Audit: According to Audit plans of both ANZGOG and CTC audit committees

Promotion and recruitment

(i) Annual Scientific Meeting, (ii) Group newsletters (quarterly), (iii) Monthly study updates to PI's and data managers and (iv) Trial Management Committee for each study oversees recruitment and other issues

Group Contacts

Address: ANZGOG, NHMRC Clinical Trials Centre, Locked Bag 77, Camperdown NSW 1450, Australia
Phone: +61 2 9562 5000
Group Chair: Dr Alison Brand, email: Alison.Brand@swahs.health.nsw.gov.au
Harmonization (Operations): Dr Julie Martyn, email: julie.martyn@ctc.usyd.edu.au
Harmonization (Statistics): Prof Val Gebski, email: Val@ctc.usyd.edu.au
Website: www.anzgog.org.au

COGi (Cooperative Ovarian Cancer Group)

Background

The Cooperative Ovarian Cancer Group (COGi) is a consortium of ovarian cancer researchers from 10 leading academic medical centers throughout the United States, including Stanford University, Harvard University, Memorial Sloan Kettering Cancer Center, University of Pennsylvania, and the University of Washington. In addition, COGi has about 34 affiliate sites participating in COGi clinical trials. The group was formed in 2004 to expressly focus on the development of vaccines and innovative therapies for ovarian cancer. Laboratory programs in these areas have initiated and developed specific approaches that are being translated into clinical applications and trials.

To date, COGi research activities have discovered unique antigens in ovarian cancer that serve as targets for vaccine development and for new immunotherapeutic strategies. Phase I vaccine clinical trials started in 2010.

Partnering with industry, COGi researchers have conducted phase II and III protocols using monoclonal antibodies for the treatment of women with ovarian cancer.

Group structure: COGi is led by group principal investigator and prominent gynecologic oncologist, Dr. Jonathan Berek, Laurie Kraus Lacob Professor and Director, Stanford Women's Cancer Center, Stanford Cancer Institute, Chair, Department of Obstetrics and Gynecology, Stanford University School of Medicine.

Legal entity:

Membership criteria:

Funding: COGi came into existence in 2004 through the support of the OCRF. Currently, cooperative clinical research programs have been undertaken with the support of several industry partners.

Coordinating/data centre: The central management of the consortium is performed by Stanford University personnel.

Study approval process

Concept development and approval: New concepts developed by COGi investigators' and new protocols from industry partners are reviewed and discussed at the COGi annual meeting. Recommendations are made concerning the scientific validity of the study as well as the potential for group participation.

Protocol development:

Protocol approval:

Data management systems

General: N/A

CRF and database development: N/A

eCRF usage: N/A

Randomisation and enrolment: N/A

Ethics and regulatory considerations

Ethics approval: N/A

Regulatory approval: N/A

Adverse event reporting: N/A

Start up: N/A

Monitoring: N/A

Audit: N/A

Promotion and recruitment

Studies are promoted at the annual COGi meeting, via the COGi website, and through email.

Patients are recruited through affiliate sites participating in COGi clinical trials.

Studies are activated through grants, industry partners and COGi investigators.

Group Contacts

Address: Stanford University, 300 Pasteur Drive, Room HH-333, Stanford, CA 94305
Group Chair: Jonathan S. Berek, MD, MMS
Harmonization (Operations): Ashley Powell
Harmonization (Statistics):
Website: http://cogi.stanford.edu

DGOG (Dutch Gynecologic Oncology Group) - pending

Background

Group structure:
Legal entity:
Membership criteria:
Funding:
Coordinating Centre:

Study approval process

Concept development and approval:
Protocol development:
Protocol approval:

Data management systems

General:
CRF and database development:
eCRF usage:
Randomisation and enrolment:

Ethics and regulatory considerations

Ethics approval:
Regulatory approval:
Adverse event reporting:

Study activity

Site selection and feasibility:
Start up:
Monitoring:
Audit:

Promotion and recruitment

Group Contacts

Address:
Phone:
Group Chair:
Harmonization (Operations):
Harmonization (Statistics):
Website:

EORTC (European Organisation for Research and Treatment of Cancer)

Background

Group structure:

EORTC represents a network of more than 300 institutions from 29 different countries and about 2,000 collaborators (clinicians, pathologists, researchers ...).The **General Assembly** is the legislative body of the EORTC. Policies, proposals, and strategies are discussed and approved by the General Assembly. The General Assembly delegates specific functions to the Board, Committees, or appointed persons.

The EORTC Network is organized into groups of scientists and/or clinicians, each with a specific area of interest in cancer research. These groups conduct translational research and/or clinical trials on all types of cancers using a multidisciplinary approach. The effective voting members of the General assembly are the President, the past three Presidents, each Group Chair, the Task Force Chairs, each of the Committee Chairs, and a representative from each of the top 15 accruing institutions. The General Assembly meets at least once a year and elects a new EORTC Board once every three years.

The **Board** is the steering and executive body which advises the General Assembly on new activities and formulates proposals to be ratified by the General Assembly. The Board meets at least twice a year. The Board consists of 21 elected (voting) members and several *ex officio* members. The Board members select among themselves the President, Vice-President, Treasurer, and Secretary General.

The **Executive Committee** provides support to the President in the decision making and strategy planning process. The Executive Committee consists of several voting members of the Board plus the Director General and the Director who are *ex officio* (non-voting) members of the Executive Committee. The Executive Committee meets as often as needed (once every six weeks on average), and communicates via phone and e-mail on a weekly basis. The Executive Committee reports to the Board.

The **Director General** coordinates all administrative, legal and financial management activities of the organization; and implements the strategies and policies as defined by the Board. Additional responsibilities include EU projects coordination, information dissemination and logistic support for EORTC courses and conferences.

The **Director** is appointed by the Board and is in charge of daily management and scientific activities of EORTC Headquarters.

Legal entity: Yes, the EORTC is an international non-for-profit organisation under Belgian law. The registered office of the EORTC is 83 Av. E. Mounier, B-1200 Brussels, Belgium

Membership criteria:

Effective Membership

All members of the General Assembly are effective members of the EORTC. In addition, members of the EORTC Groups / Task Forces and EORTC Committees are associate members of the organization.

Associate Membership

Investigators who recruit patients into EORTC clinical trials and contribute to laboratory research conducted for these clinical studies or to other EORTC activities approved by the Board are admitted as associate members. They must be natural persons.

Applications of candidate associate members are submitted for assessment by the Membership Committee. They may be submitted by the candidate directly or by a Group Chair. The Membership Committee delivers its recommendation to the Board. A Group Chair may appeal to the General Assembly against the refusal of an application he or she had submitted.

Associate membership is granted for an initial probationary period ending immediately prior to the date of the third ordinary General Assembly held after the admission of the associate member. Associate membership can then be renewed for successive periods of three years. The Board decides on the renewals at its last meeting before each ordinary General Assembly. A Group Chair may appeal to the General Assembly against the refusal to renew the associate membership of a member of his or her group.

The Board may withdraw the associate membership from members who no longer meet the admissibility criteria applied by the Board (a minimum of 15 patients recruited over the last three years across all EORTC Groups / Task Forces).
In some circumstances, other types of membership may be considered for scientists who bring a substantial contribution to the activities of a group without recruiting patients into clinical trials (basic scientists, pathologists, and radiologists, etc.). Foreign membership may be considered for 'temporary' affiliation of an institution with an EORTC Group in the context of a specific clinical trial provided that EORTC rules allowing foreign membership have been followed.

Funding:

The EORTC is funded through several sources including the EORTC Charitable Trust providing a core grant which is mainly supported by numerous national cancer leagues.
Since 1972, the US National Cancer Institute (NCI) has provided core support to EORTC Headquarters, and with this support a close scientific collaboration has been maintained to promote transatlantic research projects.
A core grant from the Fonds Cancer, FOCA (BE), provides support for the EORTC Headquarters staff.
EORTC Headquarters receives annual grants allocated by BELSPO (the Belgian Federal Science Policy Office) and by the Belgian National Lottery.
Funding for the Fellowship Program is obtained from several sources including the Vlaamse Liga tegen Kanker, the Dutch Konigin Wilhehmina Fonds Kankerbestrijding, the Schroeder Foundation, the Melvin Seiden Foundation, and the Pfizer Foundation (within the framework of the PROBE Project). This funding program is coordinated by the EORTC Charitable Trust.
In addition to support from the EORTC, fellowships for medical doctors are also provided on ongoing basis by the Fonds Cancer / FOCA (Belgium), since 1991.
On the occasion of the 50th Anniversary of the EORTC (March 2012), a fellowship has been allocated by Bristol Myers Squibb (BMS) to evaluate new models of partnership between academia and industry.
In addition, grants for EORTC research projects are received from the European Commission under the 6th and the 7th Framework Programme and the Innovative Medicines Initiative (IMI).
Clinical studies evaluating new drugs for potential registration or testing innovative therapeutic agents, including some educational projects, are conducted in cooperation with pharmaceutical industry partners. Pharmaceutical industry sponsorship is also provided in the form of 'unrestricted grants' for EORTC conferences.
The finances of the EORTC include all accounts from the EORTC Headquarters as well as all EORTC Groups and Task Forces. These accounts are consolidated as required under Belgian Law. The EORTC accounts are audited by Ernst & Young.

Coordinating/data center:

The EORTC is the only European organization that unites European cancer experts from all disciplines to establish international collaborations that facilitate, accelerate, conduct, and coordinate independent clinical and translational research on all types of cancer. Therefore the structure and functioning of EORTC Headquarters reflect the need to support its mission by providing expertise over a broad range of activities and research areas from strategic development to publication of research results.
Not only does EORTC Headquarters support the operational aspects of clinical research through protocol development, data and project management, regulatory affairs, and pharmacovigilance, but over the years EORTC Headquarters has become the essential partner of the EORTC Groups in implementing sound scientific strategy. This is achieved through expertise provided by the:

- Statistics Department;
- Medical Department;
- Translational Research, Radiotherapy, and Imaging Department.

Additionally, the Quality of Life Department develops and analyzes the quality of Life component of EORTC trials, the Early Project Optimization Department (EPOD) supports the development of the strategies for upcoming projects, and the fellowship program serves a unique role in supporting data optimization and utilization while also providing invaluable training to young oncologists.

There are also specific EORTC Headquarters units which support educational activities, contracts, legal and intergroups collaborations, as well as surveillance of quality assurance and control.

Study approval process

Concept development and approval: Any idea is first endorsed by EORTC executive committee (for strategy)
Thereafter the outline needs to be approved by protocol review committee- PRC - (scientific review, includes review by independent external experts). In parallel, feasibility needs to be confirmed (recruitment capacity, budget, resources etc…). This review is continuous (projects can be submitted any time) and lasts about 4 weeks – 8 weeks (depending of the nature of eventual comments).
EORTC has put in place a mutual recognition system with partners having similar systems in place to avoid duplication of independent external review. Protocols having already been reviewed by independent experts are simply checked by internal team which accelerates the process.
Protocol development: Based on the standard template, version controlled.
Protocol approval: After PRC review (internal quality check only if no major changes is done to the outline); for non-EORTC Intergroup protocols take it or leave it principle is applied.

Data management systems

General: Full data management capacity supported by Vista Clinical Trials, state of the art Clinical Data Management System for multicenter clinical trials. Vista Clinical Trials is EORTC proprietary software fully validated and CDISC compliant software.
Within the framework of ECRIN Integrated Activities (European Clinical Research Infrastructures network and biotherapy facilities), EORTC will make this software available to ECRIN members at affordable conditions. The deployment of Vista Clinical Trials to ECRIN members will take place shortly, after the upgrades aiming to adapt the system to the needs of new users within the frame of ECRIN as a European Research Infrastructure Consortium supported by Member states. The user support will be organized by EORTC in cooperation with ECRIN.

CRF and database development: e-CRFs are used & study specific database development is very easy and can be rapidly done by data managers; CRFs are reviewed by the form review committee for quality control.
eCRF usage: Web based system available 24h 7/7d – homemade software called VISTA
Randomisation and enrolment: Web based system available 24h 7/7d – EORTC proprietary fully validated software called ORTA

Ethics and regulatory considerations

Ethics approval: As per legislation – expertise for > 30 countries, mainly EU
Submission to Ethical committees is frequently delegated to national coordinators and supported by EORTC HQ. EORTC has established liaison offices in a number of countries (currently United Kingdom, France, Poland and Germany) which enable EORTC to provide more support to national coordinators and investigators in these countries, where submissions to
Regulatory approval: As per legislation – expertise for > 30 countries, mainly EU
Adverse event reporting: Yes, full capacity for reporting to EC/CA and EVCTM as per legislation

Study activity

Start up: Case by case depending on the trial arrangements
Monitoring: Limited capacity in house, need for a CRO for extensive monitoring
Audit: Systematic audits every 3 years for biggest recruiters, case by case on-purpose audits for other sites

Promotion and recruitment

All EORTC trials are posted on the web site.
All trials are discussed 2 times a year during group meetings

Recruitment is closely monitored by project managers, policy is available to manage poorly recruiting trials

Group Contacts

Address: EORTC, *European Organisation for Research and Treatment of Cancer,* AISBL-IVZW, Avenue E. Mounierlaan, 83/11, Bruxelles 1200 Brussel, Belgique – Belgïe. Tel: +32 (0)2 774 16 35. Fax:+32 (0)2 779 50 97
E-mail: denis.lacombe@eortc.be. Group Chair: Antonio Casado Herraez, Hospital Universitario San Carlos, C/ Profesor Martin Lagos, s/n 28040 Madrid , E-mail: antoniocasado@telefonica.net
Harmonization (Operations): Anastassia Negrouk
Harmonization (Statistics):
Website: www.eortc.be; http://www.eortc.be/Groups/agroup.asp?gr=8&SH=EORTC GCG

GEICO (The Grupo Español de Investigación en Cáncer de Ovario)

Background

Group structure: Executive Board (Steering Committee), Directive Board (formed by SC plus each working group coordinator), 8 working groups (Cervical, Endometrium, Ovarian, Gynaecologic (Surgical), Translational, Scientific Office, Communication and Image Office, Continuing education Office), Technical Secretariat.
Legal entity: Yes.
Membership criteria: *Representative member*: Clinical Oncologist. Once the application is submitted to GEICO Secretariat, the Executive Board evaluate and within 30 days, the applicant receive the official communication, regarding its application. One per Site. They can vote during assemblies.
Active Member: Clinical Oncologist, Graduates in Health Science whose professional activities is oriented to the diagnosis, treatment study and research of the gynecological tumors, working in association with / in sites members of GEICO. Once the application is submitted to GEICO Secretariat, the Executive Board evaluate and within 30 days, the applicant receive the official communication, regarding its application, they can attend the assembly. It is possible to be more than one member per Site. They don't vote unless the "representative member" delegate this activities in special situations.
Observer members: They can attend assemblies. They don't vote. They are as observer until they are accepted as active member.
Funding: No government funding.
Coordinating/data centre: GEICO Technical Secretariat – MFAR, S.L., Secretari Coloma, 64-68, esc. B, entlo. 5ª, 08024 Barcelona, email: secretaria@grupogeico.org, Tel 93 434 44 12, Fax 93 253 11 68

Study approval process

Concept development and approval: The scientific committee of the group (formed by the corresponding Working Group (depending de Pathology), and the Steering committee) review the proposals which can be initiated by an individual member, a cooperative group (mainly the GCIG) or by the industry through a member of the GEICO. All the proposals are presented at the general meeting (twice a year), where must be approved. Then the protocol is submitted to all the members interested in order to suggest modifications. Finally the scientific committee review the suggestions and write the definitive protocol which will be submitted to the Spanish Drug Agency (AEM) and ethics committees (Central and Local).
Protocol ID, GEICO XXYY XX=number of protocol YY=year
Protocol development: A study-coordinator is nominated for Intergroup trials. For local studies, the GEICO member proposing the study concept is nominated the study-coordinator.
The Chief Investigator (Coordinator) or its designee is in charge of the protocol development.
Protocol approval: The scientific committee of the group (formed by the corresponding Working Group (depending the Pathology), and the Steering committee) review the proposals which can be initiated by an individual member, a cooperative group (mainly the GCIG) or by the industry through a member of the GEICO. All the proposals are presented at the general meeting (twice a year), where must be approved. Then the protocol is submitted to all the members interested in order to suggest modifications. Finally the scientific committee review the suggestions and write the definitive protocol which will be submitted to the Spanish Drug Agency (AEM) and ethics committees (Central and Local).
Protocol ID, GEICO XXYY XX=number of protocol YY=year

Data management systems

General: The CRO contracted is the responsible of collecting CRF, management of queries, SAE management, IRB approvals, regulatory requirements, and other administrative duties.
CRF and database development: The CRO contracted is the responsible of collecting CRF, management of queries, SAE management, IRB approvals, regulatory requirements, and other administrative duties.
eCRF usage: Protocol Specific. All GEICO sites can use eCRF.

Randomisation and enrolment: Protocol Specific. Registration via Fax for local protocols with confirmation after randomization sent to the investigator via FAX. For GCIG protocols GEICO use to contract a CRO. All GEICO Sites can perform on-line randomisations.
For phase II trials recruitment is limited to a number of centers depending on the sample size required. The selection of centers is bases on previous activity or participation.

Ethics and regulatory considerations

Ethics approval: The protocol must be approved by the Spanish Drug Agency (AEMPS) and by a reference ethical committee. The reference ethical committee use to be the ethical committee of the study-coordinator institution. Investigator commitment and CV required when presenting the protocol at the ethical committee. Medical Director and Financial Director approval required.
Regulatory approval: Spanish Agency of Medicines and Medical Devices, by means of EudraCT V 8.0 application.
Adverse event reporting: Only SUSARs as per European Directive. 7 days if dead, 15 days if no exitus. Reporting to: Central Ethic Committee, Local Ethic Committee, Competent Authorities and Autonomous Community in which SUSAR has occurred. Biannual safety reports in case of International Clinical Trials, Annual safety reports for the rest of Clinical trials.

Study activity

Start up: The CRO contracted is the responsible of collecting CRF, management of queries, SAE management, IRB approvals, regulatory requirements, and other administrative duties.
Monitoring: GEICO use to contract a CRO for protocol monitoring. Monitoring may be on site or by phone depending on funding.
Audits: Depending on protocol and funding.

Promotion and recruitment

The studies are promoted at semi-annual meetings. All protocol proposals are circulated by e-mail to GEICO members. Active protocols can be consulted in the web site www.grupogeico.org . In some cases, mailshots to all members are used for particular clinical trials.
Activity of protocols are updated twice a year during the GEICO meeting.

Group Contacts

Address: C/ Conde de Aranda 20, 5º Dcha 28001 - Madrid – Spain.
Technical Secretariat Address: GEICO Technical Secretariat - MFAR, S.L., Secretari Coloma, 64-68, esc. B, entlo. 5ª, 08024 Barcelona
Email: secretaria@grupogeico.org, Tel 93 434 44 12, Fax 93 253 11 68
Group Chair: Dr. Andres Poveda
Harmonization (Operations): Federico Nepote (GEICO Secretariat)
Harmonization (Statistics): Protocol specific – Subcontracted if needed.
Website: www.grupogeico.org

GICOM (Grupo de Investigación en Cáncer de Ovario y Tumores Ginecológicos de México, A.C.)

Background

Group structure: Created in 2007, GICOM is a non-profit association that has contributed to establish standard therapies against gynaecological cancer and its main objective is the development of clinical, basic and translational Research within the gynaecological cancer area, working with the different Cancer Centers in the country. In addition to this, GICOM contributes to academic activities, prevention and early detection strategies, by developing alliances with national universities. At this moment GICOM has 140 Oncology Professionals all over the country in a network for Oncology Research and educational work in the Gynaecologic Cancer area.
Legal entity: GICOM is a legal entity that takes the role of Co-Sponsor for the Intergroup clinical trials
Membership criteria: Professionals in the field of Oncology area.
Funding: Private and Public funding. For Intergroup clinical trials funds are limited.
Coordinating/data centre: The Coordinating Centre is located at GICOM central office located in México City

Study approval process

Concept development and approval: Any GICOM member is entitled to present a proposal of a new protocol to the Executive Board, who considers scientific merit and feasibility. In case the proposal is accepted by this Board and the Study Coordinating Group, it will be distributed to the Study
Protocol development: The protocol will be created by the respective Member/ Investigator who proposed the protocol, and the team assigned for such purpose.
Protocol approval: Once the protocol has the green light of GICOM Team, this is submitted to the local REC of the selected site.

Data management systems

CRF and database development: Protocol Specific.
eCRF usage: Protocol Specific. All GICOM sites can use eCRF if the web system is provided by the Sponsor. For intergroup studies paper CRF has been used
Randomisation and enrolment: Protocol Specific. All GICOM sites randomisations/registrations are carried out by site staff, using web-based systems. There is fax based back-up system in place in case this be required for any unexpected event.

Ethics and regulatory considerations

Ethics approval: In México, no Central REC exists, each site must have its local REC. When the local REC is work overloaded a request for transferring the submission to an Independent Research and Ethics Committee is presented.
Each participating site/PI should submit the protocol to its local Research and Bioethics Committees. In all cases the trial protocols, ICDs, Patient information Sheet, Patient Questionnaires, Investigator Brochure and any information provided to the patient must be reviewed and approved by both committees. Timeline between submission and approval varies depending on the REC meeting frequency as well as their workload. GICOM PM, oversees this activity
Regulatory approval: For Intergroup Trials, GICOM is the Regulatory Responsible before the Health authorities. Once the study trial has been approved by the local REC, GICOM PM collect from the participating sites, the required documents for its incorporation to the regulatory dossier application. When completed the dossier is reviewed by the PM and GICOM´s Regulatory Representative and it is submitted to the Comisión Federal para la Protección de Riesgos Sanitarios (COFEPRIS), an MOH entity.
Adverse event reporting: SUSARs occurring in México are reported to local RECs with 7 or 15 days for any suspected events and/or fatal or life threatening events to local RECs and the National Commission of Pharmacovigilance . Principal Investigator reports to his/her local EC the event and GICOM as regulatory

responsible in the country, must coordinates/supervise/submit such reports to the regulatory authority until the event is closed.
SUSARs for non Mexican sites are reported to the Local RECs every six months and to the COFEPRIS every year .

Study activity

Site selection and feasibility: Previous to the evaluation visit, GICOM asks to its members feedback on the prospect sites. They assess previous site/staff performance, recruitment rates (other trials), local REC´s timelines, etc. An evaluation visit is performed and the feasibility, site assessment forms are completed, based on the result of the evaluation the site is selected or not.
Start up: Once:

- Ethics and regulatory approvals are obtained
- Essential Documents are in place
- Site Initiation Training completed
- Site Activation approval

Monitoring: Depending on the protocol specific schedule, recruitment and funding. An external local CRA is hired by GICOM for performing this task
Audit: According to the Protocol development at the site, usually every two years or before if required. GICOM PM performs QC visits minimun 2 visits/site/trial/year

Promotion and recruitment

GICOM members

Group Contacts

Address: Business & Therapy Place, Gran Sur Oficina 12. Ave. del Imán 151. Col Pedregal de Carrasco. 04700 México,D.F. México.
E-Mail: gicomgrupomexicano@yahoo.com.mx
Website: www.gicom.org.mx
Group Chair: Dolores Gallardo Rincón,MD, email: dolores.gallardo@prodigy.net.mx
Harmonization (Operations): Adriana Chávez-Blanco,DVM, adrianachavezblanco@gmail.com
Harmonization (Statistics): Luis Oñate MD

GINECO (Group d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens)

Background

Group structure: GINECO is a cooperative clinical trials group of clinicians dedicated to gynaecological cancer (and metastatic breast cancer) research in France- ARCAGY is the legal entity and the operational team of the GINECO group and is a non profit organisation
Legal entity: No legal entity for GINECO and non profit organization for ARCAGY
Membership criteria: No specific criteria to be a membership of the GINECO group which represents more than 100 oncology sites (public and private) and more than 600 investigators
Funding: Most funding from Pharma Industries – minor public funding
Coordinating/data centre: ARCAGY is the GINECO study office = 18 people team

Study approval process

Concept development and approval: Each project is discussed first within a working group (7 working groups = ovarian first line, ovarian relapse, elderly, endometrium and cervix, translational, rare tumours and breast) and then validated within the scientific committee of GINECO (around 30 people)
Protocol development: The Pi is the one who puts forward the concept and is involved in protocol design; a project manager is specifically dedicated. Data management could be internally if this is a national study. For international studies, it depends
Protocol approval: Should be approved by Ethics Committee (central) and by CA (French Health Agency)

Data management systems

General: There is a data management team within ARCAGY consisting of data developers and programmers. The interaction with the clinical trial teams and the biostatistical team is very important.
CRF and database development: CRF are developed from CRF template by the clinical project leader and reviewed by clinician, data management, safety and monitors. Database is developed when CRF is validated.
eCRF usage: Calypso was performed under eCRF and studies conducted in partnership with pharmaceutical companies. Arcagy is currently seeking an eCRF solution for Arcagy-sponsored studies
Randomisation and enrolment: Randomisations/registrations are carried out by Arcagy staff, using home-based systems : the sites fax randomization request at ARCAGY first. When randomization is done a notification is sent to the sites.

Ethics and regulatory considerations

Ethics approval: 1 central Ethics committee – approval given within 3 weeks after submission
Regulatory approval: CA = French Health Agency (European directive) – same XML file for all European countries – approval given within 60 days
Adverse event reporting: Investigators send the SAE by fax to the GINECO study office which are entered in the PV data base

Study activity

Start up: Site initiation visit either by phone + quiz done by the site or on site- no specific study investigators meeting, usually done at the GINECO annual meeting
Monitoring: Internal CRAs for national studies – For international studies or big studies, use of a CRO
Audit: Internal Quality assurance department – internal audits (SOPs, TMF…) and sometimes on site audits – Audits from sponsor when Pharma Industry – Inspection from French CA

Promotion and recruitment

The studies are promoted at regular meetings. When the protocol is ready, all potential investigators are called for commitment (sending of an information letter). Investigators interested to participate in the study fill a

commitment form and fax this form to the GINECO study office. For small studies where a small number of sites is required, or for registration studies, only a few sites are called for commitment

Group Contacts

Address: Hôpital Hôtel-Dieu – Place du Parvis Notre Dame – 75004 Paris
Group Chair: Pr Pujade-Lauraine – GINECO founder - The formal leadership of the GINECO includes 3 people in the role of Chair, co-chair and past-chair. The chair is elected as 1 year as co-chair, 1 year as chair and 1 year as past-chair
Harmonization (Operations): Bénédicte VOTAN = General Manager of GINECO study office
Harmonization (Statistics): No specific internal statistician – collaboration with external stat depending on the studies
Website: www.arcagy.org

GOG (Gynecologic Oncology Group)

Background

Group structure: The Gynecologic Oncology Group (GOG) is one of the National Cancer Institute's (NCI) cooperative cancer research groups. GOG is the only U.S. cooperative group which focuses its research on women with pelvic malignancies, such as cancer of the ovary, uterus, and cervix. The GOG was organized in 1970 by a group of farsighted gynecologic surgeons with special interest in quality clinical research. They recognized the need for a collaborative research effort, not only among institutions, but also among the various disciplines involved in the treatment of women with gynecologic cancers. The GOG was among the first organizations to adopt a multidisciplinary, multi-institutional, prospective approach to the management of pelvic malignancies in women. Currently over 3,300 patients are registered each year to approximately 60 GOG research trials. To date, GOG has completed over 300 clinical trials and contributed over 440 manuscripts to the peer reviewed medical literature. GOG continues to pave the way in gynecologic oncology trials, setting the standard for cancer research and treatment. The Administrative Office of the Group Chair is located in Philadelphia, Pennsylvania. The Statistical and Data Center resides in Buffalo, New York

Legal entity:

Membership criteria:

Funding: Funding is based on per capita reimbursement specific to the protocol. Funding sources include the NCI main grant, NCI individual trial grants, and industry sponsored trials.

Coordinating/data centre

Study approval process

Concept development and approval: A study concept may be initiated by an individual member investigator within the GOG, by a GOG committee (usually a site committee or a special studies committee), by CTEP, by other cooperative groups, or by industry through a member of the GOG. A study concept is typically a brief outline summarizing the study's objectives, proposed methods, background and rationale. Depending on the study's objectives, these concepts are placed on the agendas for one or more of the Group's scientific committees which consider new concepts at each semi-annual GOG meeting. These committees make recommendations for approval, modification, or disapproval to the Protocol Committee through the chair and co-chair of the committee who sit as members of the Protocol Committee. The Protocol Committee's decision, by majority vote, determines which concepts will be fully developed into GOG studies. Studies are identified with the prefix GOG followed by a protocol number assigned by GOG (e.g. GOG-0182).

Protocol development: An approved study concept is assigned to a Principal Study Chair (usually the investigator proposing the study concept) plus a study co-chair representing each scientific discipline (Quality of Life, surgical, translational research, etc.) involved in the study. These individuals, with the statistician and data manager, develop a full protocol document for review by the GOG Protocol Committee at its quarterly meetings. Once the study has final Protocol Committee approval, it is submitted to CTEP and other appropriate agencies or sponsors for review and approval. Finally, each study must have local IRB approval prior to activation. Standard operating procedures are outlined in the Protocol Procedures Manual.

Protocol approval:

Data management systems

General: Generic forms are developed utilizing Cardiff Teleform. Protocol specific forms are designed when needed

CRF and database development: Forms are reviewed and developed in the GOG SDC with input from study chairperson, data management, IT, and statistical staff. All developed forms are required to comply with NCI approved Common Data Elements (CDE's) prior to activation.

eCRF usage: Teleform forms can be submitted electronically utilizing SEDES (Statistical and Data Center Electronic Data Entry System).

Randomisation and enrolment: Patient registration and randomization are conducted via the Web through the Statistical and Data Center. Fast Fact Sheet (FFS) eligibility questions are answered online during registration and study number confirmation is generated via the web. Telephone entry is available for selected phase II and phase I study patient entry. Randomization techniques – both, minimization and block randomization

Ethics and regulatory considerations

Ethics approval
Local IRB
Regulatory approval
National: CTEP, FDA, CIRB, DCPC, GOG IRB
Adverse event reporting
CTC V3.0 as of January 2005

Study activity

Start up: All phase III studies are activated through the GOG Administrative Office following CIRB approval. Documentation of local IRB approval is required before patients can be registered. An activation memo is distributed to all participating institutions on the date of official study activation. In addition, all protocols are subjected to GOG IRB approval prior to activation. The GOG IRB meets semi-annually at each GOG Business Meeting. Interim meetings are held via teleconference as needed.
Local Activation: All CTEP approved trials are subject to either the National CIRB (central IRB) or local IRB approval at each institution. All institutional IRB's are required to obtain an FWA (Federalwide Assurance Number). Investigators are required to obtain an Investigator Number and submit an FDA Form 1572.
Center ID's – Three digit assigned number (e.g. 001…119).
CCOP's (Cancer Clinical Oncology Program) 800's (e.g. 801….819).
Patient ID's –Ten digit number (Institution ID code – Protocol number – 3 digit sequencing) (e.g. 038-0182-004).
Center/Investigator approval:
Monitoring
Audit

Promotion and recruitment

The GOG is promoted through its own web site www.gog.org .
All GOG trials are registered on the NCI's PDQ data base for clinical trials.
Patients are recruited through participating institutions and through CTSU for selected phase III studies.

Group Contacts

Address:
Group Chair: Philip DiSaia
Harmonization (Operations): Bette Stonebraker
Harmonizations (Statistics): Mark Brady
Website: www.gog.org

GOTIC (Gynecologic Oncology Trial and Investigation Consortium)

Background

Group structure:
Legal entity:
Membership criteria:
Funding:
Coordinating Centre:

Study approval process

Concept development and approval:
Protocol development:
Protocol approval:

Data management systems

General:
CRF and database development:
eCRF usage:
Randomisation and enrolment:

Ethics and regulatory considerations

Ethics approval:
Regulatory approval:
Adverse event reporting:

Study activity

Site selection and feasibility:
Start up:
Monitoring:
Audit:

Promotion and recruitment

Group Contacts

Address:
Phone:
Group Chair:
Harmonization (Operations):
Harmonization (Statistics):
Website:

ICORG (All Ireland Cooperative Oncology Research Group)

Background

Group structure: All Ireland Cooperative Oncology Research Group was set up in 1996 by a group of cancer consultants. The aim was to create more research opportunities for patients by putting a formal structure in place to make Ireland more attractive as a location to international cancer research groups and the pharmaceutical industry. Today it counts more than 95% of the Islands cancer treating consultants among its membership ensuring that research into cancer develops at a national level across all localities. Since its inception ICORG has opened 260 research protocols and this has allowed access to research treatments for more than 7500 Irish cancer patients across 20 Irish centres. ICORG currently has numerous studies open in the following Disease Areas: Breast, Lung, CNS, Gastrointestinal, Genitourinary, Gynaecology, Haematology/Lymphology, Head & Neck, Melanoma, Paediatric and Translational.

Legal entity: ICORG is a not-for-profit registered charity.

Membership criteria:

Funding: ICORG is partly funded by the Irish Cancer Society and through a Health Research Board (HRB) grant.

Coordinating/data centre: The ICORG GCO has responsibility for all the operational aspects of ICORG activities, facilitating the 20 hospital sites throughout the country of Ireland in all aspects of the ICORG clinical research programme. A dedicated team of Clinical Trials Assistants, Clinical Research Associates and Project Managers work on a variety of trials. The project teams are supported by the Chief Executive Office, Group Statistician, Quality/Training Manager, Data Management Department, Pharmacovigilance Department and Finance Department.

Study approval process

Concept development and approval: New concepts developed by group members and new protocols from external sponsors are reviewed and discussed by the Disease Specific Sub Group (DSSG) and then a recommendation is made regarding the scientific validity of the study and the potential for the group to participate. An external peer review is required for in-house ICORG protocols. The scientific management group (SMG) and ICORG Executive must review and approve studies approved by the DSSG(s) from a resource feasibility perspective and group priority before studies can be submitted to the ethics committees and competent authority.

Protocol ID: ICORG YY-XX YY=year XX=number of protocol

Protocol development: General: A study concept can be submitted to the relevant DSSG by an ICORG member. If approved by the DSSG the concept is assigned to a Chief Investigator (usually the investigator proposing the study concept). The Chief Investigator with the central office team, Statistician and Data manager, develop a full protocol document in accordance with ICORG's Protocol development SOP for re-review by the DSSG at its quarterly meetings. An external peer review is required for in-house ICORG protocols. The scientific management group (SMG) and ICORG Executive must review and approve the protocol from a resource feasibility perspective and group priority before studies can be submitted to the ethics committees and competent authority.

A protocol concept should include the following mandatory sections:

- Protocol Title:
- Principal Investigator/Interested Colleagues:
- Rationale:
- Patient Population/Key Inclusion Criteria:
- Treatment of Interest (and comparator if relevant):
- End Points:
- Anticipated resources required from ICORG group and investigator sites
- Translational Aspect
- Collaborative Nature of the project
- External Peer Review

- Eligibility Criteria --
- Informed Consent --
- ICORG template consent
- Toxicity Criteria --
- NCI CTCAE Version 4
- Amendments/Revisions --
- Companions --
- Quality of Life --
- Translational Research --
- QA --
- ERI --
- Other --

Data management systems

General: Standard modules are used and adapted according to the needs of a certain protocol
CRF and database development: Reviewed by all the team (Chief Investigator, Project Manager, CRA, Data Manager). Also reviewed by company if pharmaceutical sponsor study
eCRF usage: Medidata Rave® eCRF is in development
Randomisation and enrolment:

Ethics and regulatory considerations

Ethics approval:
Regulatory approval:
International: Country specific.
National: IMB approval
Central: REC approval
Regional:
Local: Local hospital approval
Adverse event reporting:

Study activity

Start up: Following site initiation visit and receipt of required essential documents (Ethics approval, IMB approval, local hospital approval, signed site specific assessment form, clinical indemnity scheme cover, protocol signature page, investigator's CV, signed contract, completed delegation log, proof of Investigator training and financial disclosures if applicable) sites are activated.

- Organisation of drug supply
- Every investigation centre has an ID number
- Patients will have a sequential number

Monitoring: Central monitoring is performed by the ICORG Group Central Office according to the rules specified in protocol.
Study accrual is monitored quarterly at the DSSG meeting.
Review by a Data and Safety Monitoring Board (DSMB) if applicable
Audit: Conducted by the ICORG Quality & Training Manager internally and also by external sponsors.

Promotion and recruitment

All ICORG trials are listed on the www.icorg.ie website
All ICORG trials are registered on the NCI's data base for clinical trials.
All new and active studies discussed monthly with all ICORG members at the Disease Specific Sub Group (DSSG) meetings

Disease Specific Sub Group meetings take place four times a year
Central Activation: The protocol must be approved by a central ethics committee and the IMB before centres are initiated
Recruitment: Total ICORG accrual is ~1000 patients/year across

Group Contacts

Address: ICORG, 60 Fitzwilliam Square, Dublin 2, Ireland.
Group Chair: Dr Dearbhaile O' Donnell, Consultant Medical Oncologist and Chair of the ICORG Gynaecological DSSG. Address: St James Hospital, James Street, Dublin 8, Ireland. Email: dodonnell@stjames.ie
Harmonization(Operations): Anna Shevlin, ICORG Gynaecological DSSG Coordinator. Tel: +353 1 6677211
Fax: +353 1 6697869, Email: anna.shevlin@icorg.ie
Harmonization (Statistics): Imelda Parker, Tel: +353 1 6677211, Fax: +353 1 6697869, Email: Imelda.Parker@icorg.ie
Website: www.icorg.ie

JGOG (Japanese Gynecologic Oncology Group)

Background

Group structure: Japanese Gynecologic Oncology Group is a non profit organization exclusively for the clinical trials in gynecological malignancies. JGOG was founded in 1981. The reformation of the group started in 2002 to improve its performance and to build more solid financial structure. The Group Chairman of the JGOG is Kazunori Ochiai, MD, PhD.

The main purpose of JGOG is to establish new evidences for the treatment of gynecologic malignancies by performing high quality clinical trials. To accomplish this goal, JGOG holds up three missions to be attained.

The first mission is to execute high quality clinical trials among the member institutions nation wide. To accomplish this mission, there are site oriented committees, such as cervix, corpus, and ovary, as well as committees for data center, pathology, and radiation oncology for quality control and assurance. The second mission is to execute international collaboration trials for gynecologic malignancies. The third mission is education, public relation and publications. The members of JGOG believe the importance of educating physicians, trial coordinators, health care providers, and patients and families, as well as the importance of high quality clinical trials to establish new standard treatments, that will improve the treatment outcomes and will provide better quality of life in gynecologic cancer patients.

The administrative office of JGOG is located in Tokyo, Japan.

Legal entity:

Membership criteria

Funding: Depending on protocol, but mostly no payment to the institution. JGOG points that can be used for traveling costs to attend JGOG meetings are given for each patient registration.

Coordinating/data centre: The data center is located in the Clinical Trial Coordinating Center of the Kitasato University Research Center for Clinical Pharmacology (CTCC) in Tokyo, Japan. The CTCC collects all CRF's and SAE reports. CTCC is responsible for all data management aspects of study, such as eligibility checks, data reviews, and data analysis. Otherwise the JGOG administration office manages IRB approvals, regulatory requirements, funding, and other administrative duties.

Study approval process

Concept development and approval: Any member of J-GOG is entitled to propose a protocol concept for consideration to the site oriented committees, such as cervix, corpus, and ovary. After consideration of feasibility and scientific importance, one or two protocol concepts are selected in each site oriented committee. Then, the selected protocol concepts are developed as protocol drafts and submitted to the protocol committee. The protocol committee's decision determines which concepts will be fully developed as J-GOG studies. The final approval as J-GOG studies are done by the J-GOG executive board.

Protocol numbers are assigned with one thousand # (for cervix); two thousands # (for endometrial); three thousands # (for ovary).

Protocol development

Protocol approval: Major amendments need to be reviewed by the JGOG Data Monitoring Committee.

Data management systems

General: Standard JGOG forms modified for specific protocol.

CRF and database development: Forms are developed and reviewed within the JGOG DC with input from study chairperson, data managers, IT people, and statistical staff.

eCRF usage: Oracle-base database (HITCANDIS made by HITACHI)

Data logical checking programs

Web-based Patient Entry System has been utilized.

Since 2009, Medidata "Rave" has been introduced as Electric Data Capturing System. Web-based Randomization system by HITACHI has been utilized since 2006, and since 2010 it will be switched to Medidata "Balance".

Randomisation and enrolment: Randomization techniques – Study registration forms are faxed to the data center, and eligibility and stratification data are checked. Computer based randomization is performed using the minimization method. Following randomization, a printed result of the randomization is sent to the institution. Since 2006, web-based randomization has been utilized.
Randomization techniques – minimization, block randomization
Centre ID: Four digit assigned number (e.g. 0001…1119).
Patient ID: JGOG+4+3 digit number (4 protocol number - 3 digit sequencing number) (e.g. JGOG3016—007

Ethics and regulatory considerations

Ethics approval: All approved trials are subject to the local IRB approval at each institution.
All institutional IRB's are required to submit the approval certification form to the JGOG administration office before enrolling patients.
Regulatory approval: International: CTEP, OHRP, FDA,
National: Ministry of Health, Labour and Welfare, Japanese Ethical Guideline for Clinical Research, JGOG Ethics Committee
Local/regional: Local IRB
Adverse event reporting: Toxicity: Japanese Translation of NCI CTC version 3.0, and CTCAE version 4.0

Study activity

Start up:
Monitoring: Protocol dependent.
For the group-wide protocol, the central monitoring will be performed by the Kitasato Data Center according to the rules specified in protocol. For all indication-directed clinical trials, as well as some trials under the newly developed regulatory system called Evaluation System for Advanced Medical Care, site monitoring including SDV is performed.
For the developmental therapeutic protocol sponsored by pharmaceutical companies, the on-site monitoring may be performed by CRO that has a contract with the pharmaceutical company
Audit: Protocol dependent.
For the group-wide protocol the audit will be performed by the members of protocol-specific audit committee.
For the developmental therapeutic studies sponsored by pharmaceutical companies, the participating institutions are subject of audit by Japanese Government as well as audit teamd from the sponsor.

Promotion and recruitment

As of August 2010, JGOG has 238 approved member institutions, including academic medical centers, cancer centers, city hospitals, and private practice clinics. The number of individual member is 815. The studies will be promoted at the regular meetings and announced at the JGOG web site (www.jgog.org). Quarterly issues of newsletters inform the GOG members about progress of all JGOG studies.
Recruitment of the group-wide protocol is limited within JGOG member institutions. International collaboration protocol is planned to enroll the patients from overseas trial groups with agreement of collaborations.
Protocol is activated after approval from JGOG Clinical Trial Review Committee and JGOG Ethics Committee.
Annual meeting for business and scientific session for all participants is held in November. Site-specific group meetings are held 3 - 4 times a year.
International committee meetings for GOG-Japan are held 7-8 times a year.

Group Contacts

Address:
Group Chair: DR K Ochiai

Harmonization (Operations): Eriko Aotani, Clinical Trial Coordinating Center, Kitasato University Research Center for Clinical Pharmacology, 5-9-1, Shirokane, Minato-ku, Tokyo 108-8642, Japan, phone#81 3 5791 6398, fax# 81 3 5791 6399, email: aotani-e@insti.kitasato-u.ac.jp
Harmonization (Statistics): Masahiro Takeuchi, Division of Biostatistics, Kitasato University Graduate School, 5-9-1 Shirokane, Minato-ku, Tokyo 108-8641, Japan, phone#81 3 5791 6322, fax# 81 3 3444 2546, email: takeuchim@pharm.kitasato-u.ac.jp
Website:

KGOG (Korean Gynecological Oncology Group)

Background

Group structure: Korean Gynecologic Oncology Group is a non-profit organization exclusively for the clinical trials in gynecological malignancies. KGOG was organized in 2002, and the Group Chairman is Soon-Beom Kang, MD, PhD. Members of the group are specialists in gynecologic oncology, pathology, radiotherapy, and statistics. KGOG is composed of 3 tumor site committees, 2 treatment modality committees, pathology, translational research, and statistics and data management committees.

The main purpose of KGOG is to establish up-to-date guidelines for the treatment of gynecologic malignancies by performing multi-center clinical trials, and to execute international collaboration trials for gynecologic malignancies. KGOG has developed 39 clinical trials so far, and is participating in GOG, JGOG/GCIG clinical trials. The administrative office of KGOG is located in Seoul, South Korea.

Legal entity:

Membership criteria:

Funding: KGOG does not cover the costs related to trial conduction. The costs are mostly covered by the sponsor (either profit or non-profit) of the protocol.

Coordinating/data centre:

Study approval process

Concept development and approval: A study concept may be initiated by any individual member of KGOG. After consideration of feasibility and scientific importance in each tumor site committee, the protocol concepts submitted to KGOG executive board for approval. Protocol numbers are assigned with one thousand # (for cervix, vulva and vagina); two thousands # (for endometrium and GTD); three thousands # (for ovary, tune and PPC).

Protocol development:

Protocol approval:

Data management systems

General: Standard forms modified for specific protocol.

CRF and database development: Forms reviewed internally by Tumor Site Committee members, statistician.

eCRF usage: Web-based CRF is under development.

Randomisation and enrolment

Randomization techniques – Study registration forms are faxed to the data center, and eligibility and stratification data are checked. Registration for KGOG protocols with confirmation after randomization sent to the investigator via fax.

Randomization – Block randomization

Centre ID: Two digit assigned number (01...99)

Patient ID: Nine digit number (Protocol number – Institution ID code - 3 digit sequencing) (e.g. 1012-01-001).

Ethics and regulatory considerations

Ethics approval:

Regulatory approval:

International: CTEP, OHRP, FDA,

National: Ministry of Health and Welfare

Local/regional: Local IRB

Adverse event reporting:

Study activity

Start up: Following receipt of required essential documents (e.g. ethics approval, regulatory approval (where required), investigator's CV, investigator agreement).

Monitoring: Conducted on trials which require on site monitoring by the RA. Extensive study validation programs written for each study used to verify data and helps generate queries. Some data goes through a visual review by an RA. Study is monitored for timing of interim efficacy and/or other possible early stopping rule analyses and final analyses.
Audit: Once the trial is underway the KGOG may wish to carry out random audits of individual studies.

Promotion and recruitment

Promotion: The studies will be promoted at the regular meetings and announced at the KGOG web site (www.kgog.org). When the protocol Is ready the data secretariat will call for commitment to all possible departments.
Patients are recruited through participating KGOG member institutions. There are 5 centers approved by GOG including 4 affiliate centers.
Protocol is activated after approval by the KGOG Steering Committee for Clinical Trials and after approval by the IRB of the Coordinating Centre. Patients' accrual at each participating Centre can be made only after approval by the local IRB.
Group Meetings: Twice a year (Spring and Autumn), updates on current activity of disease sites and strategy meetings for future projects. Newsletters generated annually.

Group Contacts

Address:
Group Chair:
Harmonization (Operations): Jae Weon Kim, MD, Department of Obstetrics and Gynecology, Seoul National University College of Medicine, 28 Yongon-dong, Chongno-gu, Seoul 110-744, South Korea.
Phone #82 2 2072 3511, fax #82 2 762 3599, Email : kjwksh@snu.ac.kr
Harmonization (Statistics): Byung-Ho Nam, Ph.D. Cancer Registration and Biostatistics Branch, Division of Cancer Control & Epidemiology, Research Institute, National Cancer Center, 111 Jungbalsan-ro, Ilsandong,-gu, Goyang-si, Gyeonggi-do, 410-769, Korea. Tel. #82 31 920 2033, Fax: #82 31 920 2034:
e-mail: byunghonam@ncc.re.kr
Website:

MaNGO – pending

Background

Group structure:
Legal entity:
Membership criteria:
Funding:
Coordinating Centre:

Study approval process

Concept development and approval:
Protocol development:
Protocol approval:

Data management systems

General:
CRF and database development:
eCRF usage:
Randomisation and enrolment:

Ethics and regulatory considerations

Ethics approval:
Regulatory approval:
Adverse event reporting:

Study activity

Site selection and feasibility:
Start up:
Monitoring:
Audit:

Promotion and recruitment

Group Contacts

Address:
Phone:
Group Chair:
Harmonization (Operations):
Harmonization (Statistician):
Website:

MITO (Multicenter Italian Trials in Ovarian cancer and gynecologic malignancies group)

Background

Group structure: Head office of the MITO Group is at the National Cancer Institute in Naples, Italy. MITO group is a non-profit association that aims to improve cooperation in the field of Gynecologic Oncology. Members of the group are specialists in gynecology, medical oncology, radiotherapy, and general practitioner. The MITO group promotes relationship with other Italian and international associations involved in Gynecologic Oncology. Furthermore, the group acts as a promoter of experimental and clinical research in this field in Italy.
Legal entity: The legal entity that takes on the role of Sponsor for MITO clinical trials is the Institute that is the legal sponsor of the specific trial.
Membership criteria: Membership is open to anyone with an interest in gynecological cancer. Applications for membership are received by the Membership Committee, and ratified by the Board.
Funding: There is no central funding to the MITO group. Funding for individual trials is negotiated through the legal sponsor of the trial, and is dependent upon the type of trial.
Coordinating/data centre: The coordinating data centre is at the National Cancer Institute, Naples Italy, and the role may be shared with other Institutes who are legal sponsor of individual MITO trials. The coordinating center is responsible for, and provides expertise in - Statistical design and sample size collection
- Protocol development
- Funding applications
- Design of CRF
- Randomisation procedures
- Data collection and data management
- Data monitoring
- Quality Assurance and Pharmacovigilance
- Trial Management
- Analysis and reporting

Study approval process

Concept development and approval: Proposals for new trials can be submitted by each of the Members of the MITO Group to the President, who forwards these new proposals to the members of the MITO Scientific Committee for Clinical Trials. All new protocols, in order to obtain the support of the MITO group, must be designed according to the current law ruling conduction of clinical trials. If the proposal is approved by the MITO Scientific Committee for Clinical Trials, MITO Group will support the study, and the protocol will be assigned a MITO Code (MITO-XX). MITO Group does not cover the costs related to trial conduction. These costs are covered by the sponsor (either profit or non-profit) of the protocol. All clerical and administrative procedures are managed by the proponent investigator, that has the role as a Study Coordinator.
Protocol development: MITO has a protocol template to assist with development of the protocol.
Protocol approval: The Institute that takes legal sponsorship of the trial is responsible for obtaining regulatory approvals.

Data management systems

General: Trial-specific, based on a standard MITO format, with web-based platform
CRF and database development
Forms are prepared and discussed by clinicians, data managers and statistician involved in each protocol.
eCRF usage: Remote data capture is used for nearly all MITO studies. Electronic CRFs are trial specific, though basic structure is similar across all MITO studies. Paper CRFs are available on the website and on request to centres.

Randomisation and enrolment: Each participating Centre is assigned a specific Centre Code, which remains the same across all MITO protocols. Randomization / enrollment is web-based, performed by the local site Investigator or Study Coordinator.
For each protocol, a progressive code is assigned to each patient (e.g. 1, 2.. xx). On the case report forms, each patient is identified by Centre ID and Patient ID.

Ethics and regulatory considerations

Ethics approval: Independent Ethics Committee of the Coordinating Centre of each protocol and independent Ethics Committee of each participating Institution.
Regulatory approval:
National: Ministry of Health
Adverse event reporting: According to current EU Clinical Trial Directives. SAEs are to be reported by Investigators immediately by fax or eCRF. All SAEs are clinically reviewed and SUSARs are reported in Eudravigilance/AIFA within the 7 or 15 days, according to expedited reporting guidelines

Study activity

Start up
Central activation: Protocol is activated after approval by the MITO Scientific Committee for Clinical Trials and after approval by the Ethics Committee of the Coordinating Centre. Patients' accrual at each participating Centre can be made only after approval by the local EC.
Monitoring: Each clinical trial has a monitoring plan in the protocol, and the level of monitoring is based on risk. All trials have centralized monitoring. On-site monitoring may be planned, and may be carried out by the coordinating center or by a CRO.
Audit: Systematic audit plan for MITO centers is under development. Internal audit may be conducted at coordinating center (Institution), and regular or for cause auditing may occur at recruiting centers.

Promotion and recruitment

Promotion: MITO activity is promoted on the MITO website (www.mito-group.it), available in Italian and English version). The Group holds regular meetings every 6 months, with progress reports of ongoing protocols, promotion of approved protocols and discussion of new study proposals
Recruitment: Italian centers treating patients with ovarian cancer and gynecological malignancies. According to each specific protocol, participation is open to international participation.

Group Contacts

Address: Istituto Nazionale Tumori Fondazione G. Pascale, Dipartimento di Uro-ginecologia, Via Mariano Semmola, 80131 Naples, ITALY
Group Chair: Sandro Pignata,MD, Ph.D, email: s.pignata@istitutotumori.na.it
Harmonizarion (Operations): Jane Bryce, Clinical Trials Unit, National Cancer Institute, Via Mariano Semmola, 80131 Naples ITALY. Email: Jane.bryce@usc-intnapoli.net
Harmonization (Statistics): Protocol specific, depending on trial Sponsor and Coordinating Center.
Website: www.mito-group.it

National Cancer Research Institute UK (NCRI) and MRC CTU/ UCL CTC

Background

Group structure: The National Cancer Research Institute (NCRI) is a UK-wide partnership between the government, charity and industry which promotes co-operation in cancer research among its member organisations.

Interest in gynaecological cancer trials is led by clinical members and the NCRI gynaecological cancer Clinical Studies Group and sub-groups.

Two main organisations undertake the management and organisation of GCIG trials sponsored in the UK, these clinical trials units (CTUs) are: the MRC Clinical Trials Unit (MRC CTU) and the CR UK & UCL Cancer Trials Centre (UCL CTC). Both are NCRI accredited CTUs.

Where UK sites are recruited to GCIG trials sponsored outside UK, these CTUs act as co-ordinating centres within the UK.

Legal entity: The NCRI is not a legal entity; therefore sponsorship has to be obtained from relevant institutions. For non-commercial trials the institution within which the CTU resides, for example: the Medical Research Council or University College London, will undertake sponsor requirements.

Membership criteria: N/A

Funding: Each CTU receives 'core' funding to support its trial activities, and then applies for project specific funds from relevant funding bodies (predominantly charitable and academic funding bodies) to manage a particular trial.

Coordinating/data centre: Trial coordination and data management of GCIG trials in the UK is currently predominantly undertaken by the MRC CTU and/or the UCL CTC.

Study approval process

Concept development and approval: The NCRI gynecological clinical study group (CSG), and sub-groups may initiate and/or develop ideas for new trials. Concepts may be presented at the Annual Joint Meeting NCRI Ovarian Sub Group and SGCTG (Scottish Gynaecological Cancer Trials Group) meeting. Endometrial trial concepts are discussed at the Annual NCRI endometrial sub-group workshop.

The NCRI also hold an annual Cancer conference where new and existing trials may be presented.

Before developing a protocol, the concept must also be agreed/approved for support by the relevant review group at the CTU involved. Sponsor institutions may also undertake a review and/or risk assessment. External peer-review is required and organized by funding bodies.

Protocol development: Protocol development is undertaken by the Chief Investigator and multi-disciplinary Trial Management Group, which will include CTU members who would coordinate the development and ensure version control. CTUs have template protocols and SOPs related to protocol development.

Protocol approval: CTUs will arrange appropriate external (e.g. CPAS) and internal protocol reviews and sign off by the CI and sponsor representative.

Data management systems

General: CTU data management systems are followed

CRF and database development: Template CRFs and database forms are available at the CTUs, and relevant SOPs are followed.

Trial data received on CRFs from sites are entered into and held in an appropriately validated database. User acceptance testing and scenario testing is carried out on a trial database before entry of live data commences.

eCRF usage: N/A

Randomisation and enrolment: Methods may vary per trial, but will usually be by phone or fax to the relevant CTU. On line/telephone systems (IWRS/IVRS) are used for some trials.

Ethics and regulatory considerations

Ethics approval: A single ethical approval for research in the UK is obtained through submission to a Research Ethics Committee (REC). RECs are managed by the National Research Ethics Service. http://www.nres.nhs.uk/
All research that involves NHS patients or resources must also gain NHS permission and be approved by relevant NHS Research & Development offices.
A centralised submission portal is in place for necessary regulatory and ethical approvals – IRAS https://www.myresearchproject.org.uk/Signin.aspx
Regulatory approval: The Medicines and Healthcare Regulatory Agency (MHRA) is the UK competent authority which reviews and provides approval for the conduct of research falling under the EU Clinical Trials Directive. The MHRA provides the Clinical Trials Authorisation (CTA) for an approved trial.
Adverse event reporting: Sites are required to record all AEs on case report forms. In addition SAE reports (as per trial protocol) must be sent to the relevant CTU for processing and any necessary expedited reporting, to relevant ethics committee(s) and competent authority(ies)

Study activity

Start up: Trial start-up is undertaken according to the CTU/sponsor's SOPs.
Initiation of sites is undertaken either by on-site visit or teleconference, dependant on risk and training needs, related to the trial and to the site. Site activation is confirmed in writing by the relevant CTU acting for the sponsor.
Monitoring: Decisions on the type and frequency of monitoring for a trial are risk-based.
The CTU involved will develop a trial monitoring plan for each trial. Monitoring usually involves a mixture of on-site and central monitoring methods. Monitoring activities are undertaken by CTU staff, third party contractors or for a GCIG trial may be delegated to another GCIG group to undertake within their country.
Audit: CTUs are subject to regulatory inspection, sponsor audit, and have internal audit/review systems in place. Audits of trial sites and third party suppliers etc may be undertaken by the CTUs if indicated, based on risk.

Promotion and recruitment

Promotion of UK led GCIG endorsed trials occurs:

- On the CTU websites (see below) – and with links from cancer charity & NCRI websites
- At annual NCRN/I meetings
- At annual trial specific meetings
- In trial & CTU specific newsletters
- By gynae roadshows (to promote trial in areas where recruitment is slow.)
- Through regular Trial Management Group meetings, including international collaborators

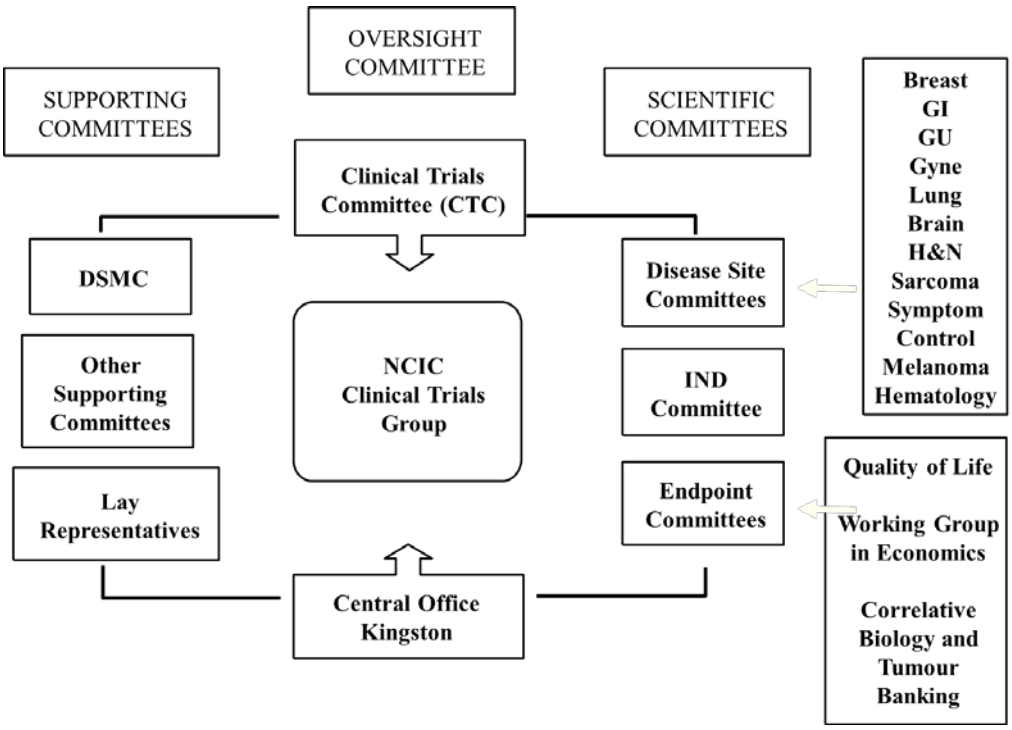
Group Contacts

Address: MRC CTU, Aviation House, 125 Kingsway, London, WC2B 6NH, UK and CR UK & UCL CTC, 90 Tottenham Court Road, London, W1T 4TJ
Harmonization (Operations): Laura Farrelly (lf@ctu.mrc.ac.uk); Nicky Gower NCRI?)
Harmonization (Statistics): Andrew Embleton (aem@ctu.mrc.ac.uk)
Websites: http://www.ncri.org.uk/ http://www.ctu.mrc.ac.uk/ http://www.ctc.ucl.ac.uk/

NCIC CTG (NCIC Clinical Trials Group)

Background

Group structure:



Legal entity: Queen's University, Kingston, Ontario, Canada

Membership criteria: General Requirements for NCIC CTG Member Centres:

All institutions in Canada providing care to cancer patients are potentially eligible to be ongoing member centres of the NCIC CTG.

The basic requirements for centre membership in the Clinical Trials Group are as follows:

- an investigator with appropriate credentials willing to take responsibility for NCIC CTG trials management and liaison (i.e. serve as Centre Representative)
- a demonstrated commitment to providing data management dedicated to NCIC CTG trials;
- an indication that the level of patient accrual will be sufficient to ensure continuity of data management staff
- an established system for ethical review of protocols (or written policy that confirms local acceptance of second party institution review, e.g. from an affiliated university)
- access to laboratory and radiological/nuclear medicine facilities for trial investigations to be carried out.

Additional requirements are in place for the conduct of phase I and II trials

Funding: Canadian Cancer Society Research Institute, National Cancer Institute US (NCI US), Industry, Other Granting Agencies

Coordinating/data centre: NCIC Clinical Trials Group, Queen's University, 10 Stuart Street, Kingston, ON, Canada K7L 3N6

Study approval process

Concept development and approval:

- Ideas for new clinical trials may be developed by central office faculty, investigators, other cooperative groups or pharmaceutical companies.

- The appropriate disease site committee and disease site executive assesses whether a proposed concept is high priority and is feasible in terms of centre interest.
- If the concept is sanctioned, a trial development team is formed.
- The trial development team, with input from other investigators, and Central Office staff if required, will draft the protocol synopsis.
- The Clinical Trials Committee (for phase III studies only) will review and rank the trial using the draft protocol synopsis.
- Central Office then reviews the synopsis and considers aspects of budget, drug supply, central office resources and timelines.

Protocol development: NCIC CTG protocols have a standard format and table of contents compatible with ICH-GCP requirements and are developed using the Central Office Data Executive (CODE) approved NCIC CTG generic protocol. A sample trial consent form is also created. This document addresses all consent form elements required by ICH-GCP and applicable regulations and can be used as a template for participating cooperative groups.

Scientific sections will include: the objectives and rationale for the study; methodologic chapters such as design, evaluation criteria, statistical design and analysis and role of the data safety monitoring committee; medical chapters, including inclusion and exclusion criteria, response criteria, detailed description of the protocol therapy, and all clinical, radiological and laboratory investigations to be performed; and the rationale and evaluation methods for special outcome measures requiring particular expertise (e.g. correlative studies, quality of life, economic evaluation, nursing research).

The administrative/operational sections of the protocol will detail all practical, ethical and regulatory procedures to be followed (e.g. authorization to participate, obtaining informed consent, registration/ randomization process, data collection, drug distribution procedures, adverse event criteria and procedure for reporting serious adverse events, modality quality control, ethical considerations and administrative responsibilities, flow of data, publication policy, study contacts).

Study participants will be managed and data collected in compliance with the protocol that has received prior approval/favourable opinion of the relevant regulatory authorities and institutional review boards. Changes in practice may only occur after appropriate approval.

If participating cooperative groups are identified at the very early stages of protocol development, then certain aspects of their group's participation logistics may be incorporated directly into the main protocol. Those groups that join after the protocol has been finalized may opt to include their administrative logistics in an appendix.

A participating institution may not make any institution-specific changes to an NCIC CTG protocol.

Protocol approval: Internal and external reviews of the protocol will be conducted in parallel.

Internal Review:

Protocols, trial sample consent form(s), and Canadian appendices are reviewed by the NCIC CTG's Audit and Monitoring Group (AMG), Ethics and Regulatory Group (ERG) as well as for special outcome measures and Investigational Medicinal Product (IMP), when applicable.

External Review

Phase III protocols will be reviewed by industry if applicable. These protocols plus IND protocols will also be reviewed by the clinical research associate (CRA) and pharmacist representatives on the disease site (if appropriate).

For NCI US affiliated studies, appropriate NCI US (CTEP) procedures will be followed.

For trials that require a Clinical Trials Application to be filed require review by Health Canada.

Final sign-off on the protocol is done by the Physician Coordinator.

Data management systems

General: The pivotal principles of the NCIC CTG data management process are:

- Standard operating procedures
- Work instructions and reference documents

- Standard templates for protocol development and data collection
- Use of standard dictionaries and validated instruments (e.g. Common Terminology Criteria for Adverse Events, EORTC QLQ-C30)
- Continuing education and training
- Ongoing consistency and compliance review

CRF and database development: Case report forms (CRFs) may be paper based or electronic. NCIC CTG CRFs are cycle based, although some CRFs are 'rolling' and capture data from more than one cycle.

Case report forms will be developed according to the Forms Development SOP, using approved templates, and must capture all data specified in the protocol. Significant variance from approved templates must be approved by CODE. The responsible senior biostatistician and physician coordinator and team leader must review and approve the CRFs prior to finalization.

Final case report forms and guidelines for completion (generic ± trial specific) must be available to sites prior to enrolment of the first study participant. Paper CRFs are downloaded by sites.

eCRF usage: In general, all new trials use the Electronic Data Capture (EDC) system by Medidata Rave. This is a web-based system that does not require any software or systems to be installed at the participating site. SAE reporting for EDC trials is also done via the Medidata Rave system which automatically integrates the SAE information with the rest of the trial information.

Randomisation and enrolment: Enrollments (randomization/registration) for NCIC CTG led trials are done by the NCIC CTG using a web-based, password protected electronic patient allocation system. The enrollment process includes standardized checks to ensure only credentialed sites and investigators are able to enter study subjects.

Enrollment of subjects includes a series of programmed checks to confirm eligibility/ ineligibility criteria and to permit only allowable values/dates for specified tests.

Ethics and regulatory considerations

Ethics approval: The NCIC CTG central office contains an Ethics and Regulatory Group and a Safety Desk. This group reviews all protocols and sample consent forms at the time of trial activation/trial modification and also collects and reviews the ethics documentation for our member centres according to GCP and the *Regulations* (as applicable). They process all safety updates and notices and provide periodic line listings of these events to our member centres.

Regulatory approval: A Clinical Trials Application (CTA) must be filed with Health Canada for any trial involving a new drug or when an existing drug is being used outside of the approved indication, dose or schedule. The regulatory office performs all of the CTA submissions to Health Canada for trials for which NCIC CTG is sponsor.

Adverse event reporting: As trial sponsors in Canada, NCIC CTG is responsible for notifying Health Canada any time a Canadian patient on a clinical trial suffers an adverse event that is deemed serious, unexpected and related. These designations are assigned initially by the responsible investigator and are confirmed by the NCIC CTG Physician Coordinator who oversees the trial.

Study activity

Start up: NCIC CTG education and training includes web based training for applicable regulations and guidelines (NIH, ICH-GCP, Health Canada) as well as trial and process specific training provided via trial specific web pages, NCIC CTG Spring/Fall Meetings, and Investigator Meetings (where applicable). All member centres are subject to routine on-site audit and monitoring visits which include facility reviews. In addition, a central Centre Performance Index (CPI) is run biannually and assesses compliance of member centres routinely. Unless specifically required, site initiation or start up visits are not typically done.

Centre Performance Index: The Centre Performance Index (or CPI) is a means by which NCIC CTG as sponsor of clinical trials can assess member centre performance via a centralized mechanism. The index is run biannually for all centres and more frequently (quarterly) for centres of concern. Quality assurance reports are also provided monthly to facilitate centre compliance. Currently the index includes: Eligibility Rate, Data Quality

(Form submission timeliness), and Ethics Compliance (annual re-approvals, amendment approvals, and safety report submissions).

Monitoring: The NCIC CTG Central Office contains a large Audit and Monitoring Group (AMG) that performs on site monitoring (OSM) for Canadian institutions. The OSM program has 3 main programs: On-site Monitoring Canada: Standard Monitoring Program (OSM-C), On-Site Monitoring International (OSM-I), and On-Site Monitoring Residual (OSM-R).

On-Site Monitoring Canada: Standard Monitoring Program

The OSM-C or standard program applies to the majority of NCIC CTG trials. As part of this program, the Audit and Monitoring Group (AMG) will select centres for monitoring as part OSM-C standard monitoring program. The selection of centres and timing of the monitoring visits will be based on but is not limited to the following:

- New centres within 18 months of initial accrual
- Other centres a minimum once every 36 months
- Phase I/II IND centres and high accruing centres will be visited annually

Centres of concern as flagged by previous monitoring/auditing findings trial team following central monitoring, may be visited more frequently. In addition to centre and frequency requirements, trial complexity or risk are factored into review requirements at each centre. Aspects considered include but are not limited to enrolment, agents under CTA or US IND, safety issues, and trial complexity.

Further, if an unacceptable rating has been assigned in one or more categories of review, the next monitoring visit will be conducted within 12 months of the non-compliant visit. The follow up visit will be conducted either on site or by fax depending on nature of the issues noted.

During on site review patient, pharmacy, ethics, essential documents, and standard operating procedures are reviewed. A minimum of 10% of patient cases per trial per centre is selected for review depending on the criteria and/or issues noted. With respect to patient review, source data verification and protocol compliance assessment is conducted on informed consent, eligibility, baseline, treatment, follow up, SAE, and endpoint information for cases selected.

On-site Monitoring International (OSM-I)

The OSM-I or International program utilized similar principles as described for OSM-C but it applies to single study centres in the United States. These centres participate directly through NCIC CTG. Where no other audit and monitoring oversight is in place, NCIC CTG will conduct audit and monitoring.

On-site Monitoring Residual (OSM-R)

The OSM-R residual or intensive monitoring program is similar to an industry model where centres are visited every 6-8 weeks and up to 100% source data verification is completed. Separate contracts and budgets are in place for this type of monitoring. Generally this is performed for NDA trials.

Audit: The NCIC CTG audit program includes on site audits of trials, vendors, and internal audits of NCIC CTG trials and associated processes.

With respect to on site audits of trials, audits are conducted at participating centres for Phase III trials for which NCIC CTG is the sponsor which includes trials which are monitored by a pharmaceutical company or contract research organization (CRO). Other trials (phase I or II trials, or trials for which NCIC CTG is not the sponsor) may be selected for audit as part of a routine program or based on prior monitoring/auditing findings of concern. In general, audits are conducted at Canadian centres, but audits of international centres may also be conducted for selected trials.

Centre Selection: Once the trials to be audited are identified, AMG will select centres for audit. The selection of centres will be based on but not limited to the following:

- Centre enrolment, with emphasis toward high enrolling centres.
- Centre workload.
- Centres using a new investigator, new staff, or new systems.
- Co-coordinating investigator centres.
- Centres considered of concern based on central or prior monitoring/auditing.

Promotion and recruitment

NCIC CTG led trials are registered with clinicaltrials.gov.
The Group works to facilitate trial promotion and recruitment directly with member sites, by sharing information via newsletters, conference calls and at an annual Meeting of Participants.

Group Contacts

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Group Chair: Dr Elizabeth Eisenhauer (interim)
Harmonization (Operations): Ms. Andrea Hiltz (GCIG Harmonization-Ops representative)
Harmonization (Statistics): Dr. Dongsheng Tu
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NOGGO (North-Eastern-German Society of Gynaecological Oncology)

Background

Group structure: The North-Eastern-German Society of Gynaecological Oncology (NOGGO) was founded in March 1998 as an interdisciplinary and interprofessional society with the aim of improving the life expectancy and recurrence-free survival among different tumour entities, decisively under special consideration of the quality of life. Today it has just 700 members who use the continuing education offer of the NOGGO or take part actively in working groups or in trials of the NOGGO.
The executive board consists of 4 gynaecological oncology specialists who meet on a regular basis.
Advisory board consisting of 14 gynaecological oncologists meets at least 2 times a year to discuss new ideas for trials and to progress ongoing trials, to present ideas for new trials and to consider participation in international trials.
Legal entity: NOGGO is a non-profit society that can take on the role of sponsor for trials.
Membership criteria: Any physician, nurse or other medical staff can become a member to support the aims of NOGGO. New sites interested in participating in NOGGO trials have to complete a questionnaire to give an overview of interests, experience, site staff etc. in order to be certificated as a NOGGO-center.
Funding:
Coordinating/data centre: The coordinating centre for all trials is the office located in Berlin.

Study approval process

Concept development and approval: New concepts developed by group members and new protocols from industrial partners are reviewed and discussed by the Advisory Board. Subsequently the trial will be recommended concerning the scientific validation of the study as well as the potential for the group to participate.
Protocol development: The protocol will be created by the Coordinating Investigator or its designee, the central study office team and the statistician (+/- third partners) according to SOPs. Usage of checklist grants that all essential topics are included in the protocol.
Protocol approval: After protocol finalization submission to the Ethics Committee and Competent Regulatory Authority will be done.

Data management systems

General: The cooperating CRO is responsible of collecting CRF, management of queries, SAE management, regulatory requirements, and other administrative duties.
CRF and database development: CRFs are reviewed by clinicians, statistics and data management.
Database testing is carried out by the respective project manager including verification of available data plausibility programs.
If eCRF is used site staff being involved in the trial usually receives access to a test database firstly.
eCRF usage: Protocol Specific. All NOGGO sites can use eCRF.
Randomisation and enrolment: Checks of the main inclusion/exclusion criteria before enrolment by the respective project manager and his/her substitute → trial specific randomization at the group coordination center or at site via IVRS/IWRS. Randomization result will be send to the site via fax.

Ethics and regulatory considerations

Ethics approval: In Germany we divide in Leading Ethics Committee and Local Ethics Committee.
The leading Ethics Committee is the EC of the German Coordinating Investigator and verifies the whole trial; exclusively taking of a decision.
Local Ethics Committees verify the qualification of the Investigators and the suitability of the local sites regarding the trial.

The leading Ethics Committee reviews and approves the Protocol, the Patient Information and Informed Consent Form, Insurance and Investigators Brochure or Summary of Product Characteristics (SmPC). Favourable opinion is given for the whole trial duration, but can be withdrawn at any time.
Any Investigators being involved in a clinical trial have to be approved by their local Ethic committees before being authorized to work on study related procedures, especially obtaining informed consent, study related procedures regarding patients' safety.
Regulatory approval: German Competent Regulatory Authorities are the Paul-Ehrlich-Institute (PEI) or Federal Institute for Drugs and Medical Devices (BfArM). PEI/BfArM reviews and approves the Protocol, Insurance and Investigators Brochure or Summary of Product Characteristics (SmPC).
Sites have to be notified to their respective regional administrative authority before the beginning of the trial.
Notification must be in place from Ethics-Committee AND from Competent Authority before a clinical trial site can be activated.
Adverse event reporting: SUSARs will be reported to the leading ethics committee, regulatory Authority, all investigators in case of fetal or life-threatening events within 7 days and in case of non-fetal and non-life-threatening events within 15 days.
Once per year the Development Safety Update Report (DSUR) has to be sent to leading Ethics Committee and the Competent Regulatory Authority including benefit-risk evaluation of the sponsor.

Study activity

Start up: Following site initiation visit and receipt of required essential documents (e.g. Ethics approval, notification of regional administrative authority, signed contracts, investigator's CV, completed delegation log, proof of Investigator training and financial disclosures if applicable) sites are activated.
Site initiation can also be done via telephone in individual trials.
Monitoring: Protocol dependent. Usually the cooperating CRO conducts the monitoring defined by the monitoring plan.
Tasks monitoring:

- Source data verification depending on monitoring plan
- Verify site's compliance with regulations/requirements
- Study drug accountability

A monitoring report will be send to the responsible project manager who reviews the report and initiates actions if necessary.
Audit: Audits by sponsor. Inspections by regional authorities

Promotion and recruitment

- Websites www.noggo.de
- Promotion at regional meetings and education offers
- Annual Investigator meeting
- Regular meetings of the Executive Board (5 times a year) and the Advisory board (3 times a year)
- Weekly recruitment updates to Coordinating Investigator and data managers
- Trial specific newsletters (in planning)
-

Group Contacts

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NSGO (Nordic Society of Gynaecological Oncology)

Background

Group structure: NSGO is a non-political, non-profit society founded in 1986. The society has members from all the Nordic countries: Sweden, Norway, Denmark, Finland and Iceland. Members represents all specialities involved in the treatment of cancer, surgical oncology, radiotherapy, medical oncology, pathology, physicists and research people involved in research for gynaecological cancer. One of the main objectives and activities of NSGO is to conduct clinical trials. The participation of NSGO in trials today infers both medical, juridical and economical commitments and risks. In order to secure the status of NSGO as a well recognized and reliable international trial partner NSGO in October 2006 founded a non-profit foundation with the purpose to support Research in Gynecologic Cancer. The name of this foundation is in Danish (Nordisk Selskab for Gynækologisk Onkologi's Kliniske Forskningsfond) which is demanded by the Danish authorities. In English and in daily use, the name is NSGO Clinical Trial Unit (NSGO – CTU).
The NSGO structure consists of the NSGO Board, NSGO Clinical Trial Unit Foundation Committee, NSGO CTU Executive Board and NSGO Clinical Trial Unit with the NSGO office located at Rigshospitalet, Copenhagen, Denmark
Legal entity: Nordisk Selskab for Gynækologisk Onkologi's Kliniske Forskningsfond
Membership criteria: Full membership is open to any individual in a Nordic country, who is professionally or scientifically active in the field of gynaecological cancer. Associate membership is open for individuals from outside Nordic countries. Representatives from the pharmaceutical industry cannot be members.
Funding: NSGO does not receive any governmental support. NSGO-CTU if funded by clinical trials while NSGO is funded by membership fee and NSGO sponsors from pharmaceutical industry.
Coordinating/data centre: The coordinating centre for all clinical trials is the NSGO office.

Study approval process

Concept development and approval: Every member of the society can purpose new trials. The proposals are discussed within the NSGO CTU Executive Board. If NSGO CTU Executive Board approves the trial synopsis the trial is conducted as an NSGO trial. The NSGO-CTU takes over the responsibility to develop the trial and assist PI in all relative aspects. The proposing member is lead PI of the trial. The NSGO CTU Medical Director negotiates for the financing of the trial.
Protocol development: The trial is developed by the respective Investigator with support from the NSGO CTU and reviewed by NSGO CTU Executive Board in order to suggest modifications.
Protocol approval: After protocol finalization submission to the Ethics Committees and Competent Regulatory Authorities are done.

Data management systems

General:
CRF and database development: Forms are prepared and discussed by clinicians, the NSGO office and statisticians.
eCRF usage: Trial specific. All NSGO sites can use eCRF.
Randomisation and enrolment: Trial specific.

Ethics and regulatory considerations

Ethics approval: Each Nordic country needs separate ethical approval. Regulatory bodies: The Nordic countries except Finland have regional ethical committees. Finland has institutional committees.
Regulatory approval: Each Nordic country needs separate approval from Regulatory Competent Authority.
Adverse event reporting: NSGO office is responsible for regulatory reporting of Serious Adverse Events and SUSAR's.

Study activity

Start up: The NSGO Office ensures that relevant approvals from Ethic Committees and Regulatory Competent Authorities are in place before starting a trial. Usually every Nordic Country has a National Investigator contacting the relevant Ethic Committee and Regulatory Competent Authority.
Monitoring: Trial specific
Audit: Trial specific

Promotion and recruitment

The trials are promoted at the regular face to face meetings (two meetings per year) and announced at the NSGO web site (www.nsgo.org). When the trial synopsis is accepted by NSGO CTU Executive Board the NSGO office calls for commitment to all possible departments in the Nordic countries. Departments interested in participating in the trial afterwards receive a commitment form and a contract of duties and responsibilities of the Investigator and the NSGO Office.

Group Contacts

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Harmonization (Statistics):

PMHC (Princess Margaret Consortium)

Background

Group structure: The Princess Margaret Cancer Centre is home to the Princess Margaret Consortium (PMHC), the only non-US site funded through the National Institutes of Health. Since its inception in 2001, PMHC has been responsible for 100 Phase I/II clinical trials with novel agents, and enrolment surpassing 2000 patients onto Consortium-led trials. Trials are designed and written by physicians across the consortium, providing them the opportunity to lead multi-centre trials. PMHC has been critical to the rapid enrolment of patients and to leveraging disease-specific expertise across sites which has significantly impacted on the productivity of clinical trials. The group has longstanding expertise in running and managing clinical trials across Canada.
Legal entity: Princess Margaret Cancer Centre
Membership criteria: The current PMHC affiliates span Canada with a major base and depth in Ontario. All the Canadian sites have previously worked together in other programs and projects. All centres are university-affiliated teaching centres that have extensive experience with clinical research and the conduct of multi-centre clinical trials.
Funding: National Cancer Institute US (NCI US), other Granting Agencies
Coordinating/data centre: PMHC Central Office is part of the Drug Development Program located at the Princess Margaret Cancer Centre

Study approval process

Concept development and approval: Protocol concepts are able to develop from an individual idea, the result of collaboration, or are the direct result of a previous clinical trial. A proposal needs to be drafted and peer-reviewed by the applicable PMHC disease group committee to determine if the scientific rationale is strong and if it could develop into a clinical trial that could be supported by the consortium.
Protocol development: Protocols are developed based on a standardized template that are version controlled
Protocol approval: A protocol is approved once the PMHC Central Office and the PMHC Executives approve the final draft.

Data management systems

General
CRF and database development: PMHC Central Office Study Coordinators design trial specific CRFs, that upon approval from the Program Manager, Biostats, and the Principle Investigator are submitted to the in house programmers for development of the eCRFs.
eCRF usage: The Princess Margaret Cancer Centre self-hosts Medidata Rave
Randomisation and enrolment: Randomization and patient enrollment is centralized at the PMHC Central Office. At the time of registration, the signed consent and eligibility checklist CRF are required to be submitted to Central Office. If eligibility is met, a confirmation of registration with the patient's trial specific number and treatment plan is communicated back to the registering centre.

Ethics and regulatory considerations

Ethics approval: An Institutional Ethics Board or a centralized Ethics Board can be utilized
Regulatory approval: Health Canada needs to issue a No Objection Letter
Adverse event reporting: Adverse Events that are serious, unexpected and related needs to be reported to Health Canada. A PMHC Executive Designee reviews potential Health Canada reportable events for reportability.

Study activity

Start up: Each centre is activated centrally once they provide PMHC Central Office with the requested trial documentation and a local start-up meeting has been completed.

Monitoring: A formal data management and monitoring plan is developed for each trial in which PMHC is the lead. All quality control monitoring utilizes a targeted approach based on risk.

Data is entered by sites directly into the database using guidelines developed by PMH. Training of staff will be required at all levels to ensure understanding of tasks. A formal data management plan will be in place for the PMHC studies. The study coordinators in DDP will receive the data and perform data management activities. Queries will be produced electronically and can be efficiently tracked and managed. Data will be cleaned prior to final analysis. Quality control procedures will be in place as outlined by the data management / monitoring plan developed for each trial, as stated above. Onsite monitoring will validate the e-CRF against the source data.

There is a Data and Safety Monitoring Board (DSMB) for all clinical trials run by the PMHC. The Board consists of three experts in the area of the study diseases and the members are completely unrelated to any clinical trials. The statistician provides the Board all safety data and the Board convenes regularly and reviews the progress of all trials.

Audit: A formal auditing plan will be developed for trials lead by PMHC through the GCIC. It will take into account specific quality control measures that will be reviewed: i) On-site monitoring to perform checks on source data to confirm congruency with the data collected in the electronic CRFs ; ii) Reviewing staff adherence to data management SOPs; and iii) Cross checking training records to online training, site delegation lists.

Promotion and recruitment

Group Contacts

Address: Princess Margaret Cancer Centre, 610 University Avenue, Toronto Ontario Canada M5G2M9
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Clinicians: Dr. Amit Oza
Harmonization (Operations): Chantale Blattler
Harmonization (Statistics): NA

RTOG (Radiation Therapy Oncology Group)

Background

Group structure: The Radiation Therapy Oncology Group (RTOG) is a national clinical cooperative group created for the purpose of conducting radiation therapy research and cooperative clinical investigations. The group originated under the direction of Dr Simon Kramer in 1968 and has grown considerably since the activation of its first study in 1968. The Radiation Therapy Oncology Group, under its multi- institutional umbrella, has activated 300 protocols and has accrued a total of about 60,000 patients to cooperative group studies.

Legal entity:

Membership criteria:

Funding:

Coordinating/data centre:

Study approval process

Concept development and approval: Concepts can be submitted by any member. Concepts are reviewed by the Gyn steering committee and discussed at the semi-annual meetings. Appropriate statistics hypotheses are generated. Concepts are then forwarded for RTOG group wide approval via the RTOG steering committee.

Protocol development: Principal Investigator, disease site concept, research Strategies team (RTOG) group chair, deputy chair**,** physicians, statisticians, protocol development associates, data managers (Research Associates) and dosimetrist to review initial concept which includes eligibility criteria

Protocol approval:

Data management systems

General

CRF and database development: Forms reviewed internally by Gynecologic disease site team members consisting of (2) research associates, a statistician, a dosimetrist and medical forms designer.

eCRF usage: RTOG designed clinical database and automated validation system. Form specific validations created by research associates and statistician. Forms available on RTOG web page.

Randomisation and enrolment:

Ethics and regulatory considerations

Ethics approval: Informed consent: Protocol sample, mandatory elements

Regulatory approval:

Adverse event reporting: CTC v.2- CTC CAE v.3.0, RTOG/EORTC Late Morbidity Scoring Scheme, mandatory ADEERS reporting, CCOP-Med watch required

Study activity

Start up: The protocol must be approved by the IRB, RTOG steering committee, and NCI

Monitoring:

Audit:

Promotion and recruitment

The studies are promoted at semi-annual meetings. Occasionally advertised in RTOG publications.

Recruitment: RTOG member institutions in USA and Canada.

Group Contacts

Address:

Phone:

Group Chair:

Harmonization (Operations):
Harmonization (Statistician): Kathryn Winter
Website:

SGOG (Shanghai Gynecologic Oncology Group)

Background

Group structure: Shanghai Gynecologic Oncology Group (Shanghai GOG, SGOG) came into existence in 2009. The missions are creating evidence of the new standard care for ovarian cancer as well as other gynecologic malignancies by performing high quality clinical trials, and executing international collaboration trials for gynecologic malignancies. Physician-initiating phase 2 trials are the main task during the first decade.
SGOG is now led by trial principal investigators and prominent gynecologic oncologists, with Steering Committee (Executive Board, Mentor Board), Ovarian Cancer Committee, and Endometrial Cancer Committee.
The administrative office of SGOG is located in Shanghai, China.
Legal entity:
Membership criteria: Steering committee does a complete evaluation of the new site which is interested in participating in SGOG trials. The evaluation includes the clinical practices, site staff, experience in conducting clinical trials, etc.
If the sites fulfill all requirements they are invited to participate in SGOG clinical trials. They would receive a SGOG Site ID as soon as they enroll the first patient into a SGOG trial.
Funding: There is no special funding on SGOG organization. Now for the two ongoing clinical trials in SGOG, funding depends on each protocol.
Coordinating Centre: The coordinating/data centre is located in Shanghai.

Study approval process

Concept development and approval: Members of the SGOG group are encouraged to present new concepts. The presented new protocols would be discussed by the Executive Board, Mentor Board. And then considering the scientific validity and feasibility the committee makes a recommendation. If the proposal is accepted, any site which is eligible for conducting the trial in the SGOG group could participate in the study.
Protocol development: According to the standard operating procedures, the protocol will be created by the main investigators who present the new concepts, as well as approved by the executive board. The statisticians participate in trial design on statistical analysis.
Protocol approval: Should be approved by local Academic Committee and Ethics Committee.

Data management systems

General: SGOG data management systems are under construction. We are collecting the information of CRF according to the clinical trial protocols.
CRF and database development:
eCRF usage:
Randomisation and enrolment: If the subjects in line with the inclusion/exclusion criteria, sign the inform consents, fill in the screening form, and then randomization.
Randomization result will be send to each site via fax.

Ethics and regulatory considerations

Ethics approval: Local Ethics committee
Regulatory approval:
Adverse event reporting: The toxicities are evaluated by CTCAE version 4.0. All the SAEs will be reported to the local EC within 24 hours. And investigators in each institution will be aware of by faxed.

Study activity

Site selection and feasibility:
Start up: Following receipt of required essential documents (e.g. ethics approval, regulatory approval (where required), investigator's CV, investigator agreement).

Monitoring: Each clinical trial is monitored by the data managers and site chair in local site. And they are overviewed by the executive committee once every two weeks.
Audit: Systematic audit plan for SGOG is under development. Two ongoing clinical trials of SGOG are audited by Local Ethics committee.

Promotion and recruitment

Group Contacts

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Website:

SGCTG (Scottish Gynaecological Cancer Trials Group)

Background

Group structure: The Scottish Gynaecological Cancer Trials Group is a group of individuals involved in the research and treatment of gynaecologic cancers.

Legal entity: The University of Glasgow and Greater Glasgow Health Board are the legal entities which take on the role of sponsor for clinical trials conducted by SGCTG and co-ordinated by the Cancer Research UK Clinical Trials Unit, Glasgow.

Membership criteria: The SGCTG consist of two types of members:

Full members

Honorary/Probationary members

To qualify for **Full Membership** status, individuals will be practicing physicians with a specialist interest in the field of gynaecologic oncology. Individuals should have actively participated in previous clinical trials run by the SGCTG, and have an ongoing interest in the current trial portfolio. Full membership status can also be afforded to an eligible, named clinician as representative of a specific Cancer Treatment Centre.

Clinicians, Scientists, Clinical Trial Co-ordinators, Research Nurses or other individuals who have contributed to the work of the SGCTG may be invited, or put themselves forward to become **Honorary Members**. These individuals may be unable to enter patients into SGCTG trials, but because of their specialist knowledge, have contributed to the work of the Group.

Individual clinicians that have not entered any patients into previous or ongoing SGCTG studies will be afforded the status of **Probationary Membership**. Once they have recruited to an active SGCTG study, their membership category will be upgraded to **Full**.

Funding: Funding for individual trials tends to be from competitive grant applications to funding bodies in UK (e.g Cancer Research UK, MRC etc) or from industry depending on trial.

Coordinating/Data Centre: The Cancer Research UK Clinical Trials Unit (CTU) Glasgow is the co-ordinating centre. The CTU provides expertise in the design, management and analysis of clinical trials, including the following areas:

- Statistical design and sample size collection
- Protocol development
- Funding applications
- Design of CRF
- Randomisation
- Data collection and data management
- Data monitoring
- Quality Assurance and Pharmacovigilance
- Trial Management
- Analysis and reporting

Study approval process

Concept development and approval: Concepts/proposals for new studies are submitted to the SGCTG protocol review committee (PRC) for review. The committee consists of Chair, Secretary, Treasurer, Tumour Site Coordinators (ovarian, cervix, endometrium, vulval/vaginal/rare tumour, biological), Statistician, Clinical Trial Coordinator, Non-clinical scientist and pathologist.

Once a concept/proposal approved in principal by the PRC (for scientific merit and feasibility) it will be presented to SGCTG members.

Protocol development: The CTU has a clinical trial protocol template, using this template ensures all the essential elements are included in the protocol to meet GCP requirements.

Protocol approval: Protocol reviewed and approved by Trial Management Group prior to submission for regulatory approval.

Data management systems

General: The CTU has an IT department which consists of 4 computer programmers and 1 computer manager. The IT Department work closely with the trial team (Project Manager, Statistician and Clinical Trial Coordinator).

CRF and database development: CRFs are designed by Project Manager from library of template forms and adapted according to needs of the trial. CRFs are reviewed by trial team (Chief Investigator, Statistician, Computer Manager and Clinical Trial Coordinator).

Forms are programmed by Computer Manager/ Computer Programmer on ORACLE database with validation checks. Checked by Statistician, Project Manager/Clinical Trial Coordinator.

eCRF usage: eCRFs are not currently used by CTU.

Randomisation and enrolment: Following completion of study registration form (eligibility and stratification data), randomizations/registration can be done via telephone, fax or web (dependent on study) to the CTU. Computer based randomization is performed using minimization method. Following registration/randomization email confirmation of randomization/registration is sent to site.

Ethics and regulatory considerations

Ethics approval: (UK) Ethics favourable opinion is required from a Main Research Ethics Committee (REC) prior to commencement of the trial. The REC review and approve the clinical trial protocol, patient information sheet/consent form, GP letter and other relevant study documentation.

Annual progress and development safety update reports (DSUR) require to be submitted annually to the REC.

In addition each participating site in the UK require to obtain local approval by submitting a site specific assessment to their appropriate Research & Development department for management approval.

Regulatory approval: The regulatory body/competent authority in the UK is the Medicines and Healthcare product Regulatory Agency (MHRA). For any study involving an investigational medicinal product (IMP) a clinical trial authorisation (CTA) is required from the MHRA to conduct the trial.

Development safety update reports (DSUR) require to be submitted annually to the MHRA.

Adverse event reporting: Pharmacovigilance for studies the SGCTG are the lead group will in general be managed by Pharmacovigilance Department of CTU.

Serious Adverse Events (SAE) require to be reported by sites to the CTU within 24 hours of becoming aware of the event.

Reporting of Serious Unexpected Serious Adverse Reaction (SUSAR):

Expedited reporting of all SUSARs is required to the MHRA and any other appropriate regulatory authorities, main research ethics committee, Principal Investigators at trial sites, the trial sponsor and pharmaceutical company (where applicable):

- Fatal or life threatening SUSARs require to be reported within 7 days of the CTU receiving the initial report. Any additional information requires to be reported within eight days of sending the first report.
- All other SUSARs require to be reported within 15 days of the CTU receiving the initial report.

Study activity

Start up: Investigator meeting (if trial budget allows). Site Activation/ Initiation - prior to activation of site to recruitment sites require to return essential documentation pertaining to site and are required to participate in site initiation to ensure compliance with protocol and allow training on study procedures and data collections method. This can be done via a teleconference between CTU and appropriate site staff or via accessing on line initiation slides from CTU's website.

Monitoring: On site monitoring performed by CTU monitoring team, level of on site monitoring performed determined by risk assessment of each trial and monitoring budget available for trial.

Central monitoring performed to check for compliance with protocol, data consistency, missing data and timing.

Audit: According to audit plans of CTU. In addition studies may be subject to inspection and audit by study sponsor and other regulatory bodies i.e. MHRA to ensure adherence to GCP.

Promotion and recruitment

SGCTG Meetings (Approx 2/3 per year)
National Cancer Research Institute (NCRI) meetings
Newsletters
Trial Management Group (TMG) for each trial oversees recruitment for trial.

Group Contacts

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