

**Communication Plan**

(Trial Name/number) CLINICAL TRIAL

 Full Title

( Enter Name of Legal Entity represented by or acting through- Lead group/Sponsor name here )

*Version Date:*

*Version Number:*

CONFIDENTIAL

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**Introduction/Purpose**

The purpose of the communication plan is to ensure relevant, accurate, and consistent information about the project is provided to all involved parties ensuring their timely and efficient involvement, support and cooperation where required.

The communication plan provides a framework to manage and coordinate the wide variety of communications that take place during the project. The communication plan covers who will receive the communications, how the communications will be delivered, what information will be communicated, who communicates, and the frequency of the communications. It will also include status reporting and issue escalation process.

**Figure 1:** GCIG Participating Groups collaborating on **name of trial** study

# Scope

The processes defined in this communication plan shall apply to all parties (and their respective personnel) involved in the collaboration.

#  Study Communication levels and Governance

The following paragraph is to provide an overview of the parties contributing to the global management of the trial. Contact details are provided in the Appendix A - Contact Information.

|  |  |  |  |
| --- | --- | --- | --- |
| Communication level | Entity | Purpose | Composition / List |
| 1 | Trial Steering Committee(TSC) | The role of the TSC is to provide the overall supervision of the trial. The TSC should monitor trial progress and conduct and advice on scientific credibility. | TSC should include members who are independent of the investigators, their employing organisations, funders and sponsors. *(To be replaced by trial specific wording*) |
| 1 | Trial Management Team | The role of the group is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself | includes those individuals responsible for the day-to-day management of the trial, such as the Chief Investigator, statistician, trial manager, research nurse, data manager(*To be replaced by trial specific wording)* |
| 1 | Independent Data Monitoring Committee (IDMC) | The IDMC is responsible for safeguarding the interests of study participants. The IDMC will provide the Study Sponsor with recommendations for action with respect to study conduct and the management of patients treated under the auspices of the study protocols | The IDMC usually consists of 3 members - two independent physicians and an independent biostatistician. |
| 2 | Participating groups |  | Group1, group2… |
| 2 | Industrial partners | Providing drug for free, funding | IND1, IND2… |
| 2 | Vendors | Drug supply, sample shipment, central bio bank | CRO1, CRO2, BB1 |
| 3 | Sites & investigators | NA | NA |
|  |  |  |  |

# Communication level 1

## Trial Steering Committee

**Lead Group/SPONSOR** may form a Trial Steering Committee (TSC) which will include the scientific coordinator of the trial, trial statisticians, data management staff and chief investigators from several participating GCIG Groups.

The TSC is an oversight committee which provides supervision of the overall conduct of the trial on behalf of the funder(s) and sponsor. The TSC reviews recommendations of the IDMC and, on consideration of this information, recommends appropriate amendments/actions for the trial as necessary.

The TSC will meet regularly in person or by phone to review the progress of the Study within all clinical centres including recruitment, problems with protocol compliance, unexpected toxicities and need for protocol amendments.

TSC Meeting Organisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Meeting**  | **Chair** | **Frequency** | **Attendees** | **Agenda & Minutes Responsibility** |
| Trial Steering Committee Meeting | Scientific coordinator of the trial | Face to face meeting once a yearAdhoc Teleconferences  | Trial statisticians,Data management staff,Chief investigators from participating GCIG GroupsOperational representatives as observersInvited Pharmaceutical Company | Chair |

## Trial Management Team

Trial Management Team (TMT) is the study team involved in the operational conduct of the trial and may comprise the Lead Group project manager, others members of the lead group (medical expert, pharmacovigilance, biostatistician) and central CRO involved in data management, monitoring as well as pharmaceutical company project manager if any.

*it can be worthwhile to specify here the frequency of meetings and teleconferences and primary participants* i*n case of a complex organization implying multiple stakeholders (ie central CRO involved in the conduct of the trial, pharma company)*

TMT Meeting Organisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Meeting**  | **Chair** | **Frequency** | **Attendees** | **Agenda & Minutes Responsibility** |
| Trial Management Update Meeting | Lead Group/Sponsor Project manager | TeleconferenceWeekly/biweeklyFace to face meeting twice a year | Sponsor Project managerLead Group Project managerPrimary participant from central CROFurther participants from Pharma Company | Lead Group/Sponsor Project manager |

##  Independent data Monitoring Committee (IDMC)

The members of the IDMC identified are responsible for safeguarding the interests of study participants, assessing the safety and efficacy of all study procedures, and monitoring the overall conduct of the study*.* This Committee will serve as an independent advisory group to the steering committee and the sponsor and is required to provide recommendations about continuing and stopping the study.

The IDMC is an independent multidisciplinary group usually consisting of two clinicians, a biostatistician that, collectively, has experience in the management of patients with ovarian cancer and in the conduct and monitoring of clinical trials.

IDMC Meeting Organisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Meeting**  | **Chair** | **Frequency** | **Attendees** | **Agenda & Minutes Responsibility** |
| IDMC meetingAfter safety analyses defined by the protocol | IDMC member | *According to protocol* | IDMC membersSponsor Medical Director (during open meeting)TSC Chair (during open meeting)Trial Statistician (during open meeting) | IDMC chair |

# Communication level 2

## Communication with GCIG Participating Groups

**Lead Group/SPONSOR** shall ensure regular communication to **Participating Groups** and provide information on the progress of the Study.

The following forms of communications can be used

* Regular teleconferences with minutes provided by the Lead Group
* Newsletters from the Lead group to the participating groups which will then be distributed (and adapted) to their sites
* Emails to inform Participating Groups on important timelines and study status
* Face to face meeting: operational meetings linked to GCIG (satellite meetings)
* TSC meetings

GCIG Meeting Organisation

See examples below (to be updated on case by case)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Meeting**  | **Chair** | **Frequency** | **Attendees** | **Agenda & Minutes Responsibility** |
| CountrySpecific - Kick Off MeetingOr/and All Groups Kick-off meeting | Lead Group Project manager | Once | Lead Group Project managerParticipating GCIG group lead/national study coordinators  | Lead Group Project manager |
| Lead Group - Participating GCIG group Update Meetings | Lead Group Project manager | TeleconferenceMonthlyFace to face meeting once a year (satellite GCIG meetings for example) | Lead Group Project managerParticipating GCIG group lead/national study coordinator | Lead Group Project manager |

## Communication with industrial partners

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Meeting**  | **Chair** | **Frequency** | **Attendees** | **Agenda & Minutes Responsibility** |
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## Communication with vendors

### Communication with Global CRO

This is under the project manager’s responsibility to ensure that communication occurs on a frequent and appropriate basis and that a consistent message is distributed throughout the whole CRO.

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| **Type of Meeting**  | **Chair** | **Frequency** | **Attendees** | **Agenda & Minutes Responsibility** |
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### Communication with CRO2

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Meeting**  | **Chair** | **Frequency** | **Attendees** | **Agenda & Minutes Responsibility** |
|  |  |  |  |  |

# Communication level 3: sites

## Investigator Communication and Questions

1. Investigators are instructed that the CRA/Project Manager is their primary contact for all practical issues or questions regarding the conduct of the study. All medical queries and protocol questions (including eligibility questions) should be sent to the Lead Group/Sponsor CTU. Responses will be prepared by the Lead Group/Sponsor CTU. If the same question has already been answered, the CRA can provide the answer to the site.
2. Responses to Investigators’ queries will be provided as a matter of urgency. If the answer is not immediately known, the CRA/Project Manager will acknowledge the Investigator’s query with confirmation that a response will be provided following discussion within Participating group or Lead group.
3. An official ‘Question & Answer’ (FAQ) document is maintained and routinely updated.
4. A phone report will be issued with phone calls which are relevant and essential for the study conduct.

# Other Communication tools

## Frequently Asked Questions (FAQ)

All questions, from either monitors or other team members are forwarded to the Lead Group Project Manager. This person will either provide the answer or will forward the question to the TMT. The answers will be added to the “Questions and Answers” document on a regular basis.

## Status Reports/Newsletters

Lead Group will provide GCIG participating groups with the newsletters for distribution to the Sites. GCIG participating groups can adapt the newsletter and add local information.

Status reports will be provided by Lead Group study management to GCIG participating groups. This status reports will comprise recruitment status, queries status, SAE listings, and Protocol violations.

## WWW

As much as possible each participating groups are encouraged to display information regarding the study on their group website for the purpose of communication towards patients and sites.

# Issue Escalation and Resolution

## Purpose of Issue Escalation:

The purpose of Issue Escalation is to raise emerging and/or unresolved issues to Lead Group/Sponsor and TMT attention for timely resolution. Both Lead Group/Sponsor and participating group staff are encouraged to identify issues proactively.

Events that may require escalation include, but are not limited to:

1. Project status issues

* Timeline concerns
* Site recruitment issues
* Patient enrolment issues
* Quality or compliance issues
* Site resource issues
* Investigational product supply issues
* Notification of regulatory inspections at a site/Group office

2. Communication issues

## Issue Escalation & Resolution Process

1. If issues arise during study conduct, the appropriate primary contacts at Lead Group/Sponsor or participating GCIG group should be notified by phone and/or e-mail. Refer to Appendix A for Lead Group/Sponsor and participating GCIG group contact details and responsibilities.
2. Procedures/steps to be taken to resolve the issue will be discussed between the respective participating GCIG group and Lead Group/Sponsor contact and documented by email, including:
	* A timeframe in which to resolve the issue
	* Person(s) responsible for resolution of the issue
3. If the issue is not resolved within the agreed timeframe or to the satisfaction of participating GCIG group or Lead Group/Sponsor, the TSC should be notified, as appropriate.

#  Appendix

Glossary of Terms *(to be updated as needed*)

|  |  |
| --- | --- |
| **Acronym** | **Definition** |
| AGO | Arbeitsgemeinschaft für Gynäkologische Onkologie |
| A-AGO | Austrian Arbeitsgemeinschaft für Gynäkologische Onkologie |
| BGOG | Belgian Gynaecological Oncology Group |
| CRAs | Clinical Research Associates  |
| CTU | Clinical Trial Unit |
| DGCG | Danish Gynaecological Cancer Group |
| eCRF | Electronic Case Report Form |
| ENGOT | European Network of Gynaecological Oncology Trials Groups |
| GCIG | Gynaecologic Cancer InterGroup |
| GINECO | Groupe des Investigateurs Nationaux pour l’Etude des Cancers de l’Ovaire et du sein |
| ICF | Informed Consent Form  |
| IDMC | Independent Data Monitoring Committee |
| MANGO | Mario Negri Gynecologic Oncology group |
| MITO | Multicenter Italian Trials in Ovarian Cancer and Gynaecological Malignancies Group |
| NCRI | National Cancer Research Institute (UK) |
| NSGO | Nordic Society of Gynecologic Oncology |
| PI | Principal Investigator |
| PM | Project Manager |
| TSC | Trial Steering Committee |
| TMT | Trial Management Team |

## Appendix A – Contact Information

### Primary Contact at LEAD GROUP/SPONSOR

| **Name/Title** | **Phone/Email** | **Responsibility** |
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### Primary Contacts at GCIG Participating Groups

| **Groups** | **Country** | **Name** | **Phone/Email** | **Responsibility** |
| --- | --- | --- | --- | --- |
| **AGO-A** | **Austria**  |  |  |  |
| **BGOG** | **Belgium**  |  |  |  |
| **NSGO** | **Denmark, Norway, Finland**  |  |  |  |
| **AGO** | **Germany**  |  |  |  |
| **MITO** | **Italy** |  |  |  |
| **MANGO** | **Italy**  |  |  |  |
| **GEICO** | **Spain** |  |  |  |
| **GINECO** | **France** |  |  |  |
| **DGOG** | **Netherlands** |  |  |  |

### Primary Contact at Global CRO

| **Country** | **Name/Title** | **Phone/Email** | **Responsibility** |
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### Primary Contact at Pharma Company

| **Country** | **Name/Title** | **Phone/Email** | **Responsibility** |
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