

Mentoring (welcome package/on-line tutorial)  
Chicago GCIIG meeting – 2013  
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MARKETING FARMACÉUTICO & INVESTIGACIÓN CLÍNICA

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# LEIDEN 2012 – GCIG MEETING

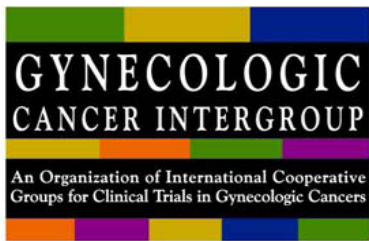


## Harmonisation Information available at GCIG website:

1. Harmonisation Guidebook. [What is GCIG, Practical issues, SAE, Insurance, IDMC, DM, others.](#)
2. Appendix 1: Intergroup Agreement Template (Company Intellectual Property Acknowledgement and GCIG/ Roles and Responsibilities). [Agreement for intergroup collaboration \(general frame\).](#)
3. Appendix 2 : Data Monitoring Committees for GCIG Trials. [Monitoring Board, mandatory for GCIG Phase III trials.](#)
4. Appendix 3: Checklist for Tissue Banking Consent Form. [Prevent essential information missing CF.](#)
5. Appendix 4: Essential Documents Check-list. [Minimal requirements for CA approvals per Group.](#)
6. Harmonization Working Group, Group Contacts & Summaries. [How are Groups organized.](#)
7. Group Participation Summary. [What are groups doing within GCIG.](#)
8. Group Specific Appendix, GSA Guidelines. [Special agreements for project specific issues.](#)
9. Summary of EDC and archiving by GCIG Groups. [EDC and archiving electronic data capability.](#)

## Other Information available at GCIG website:

10. Principles of independence.
11. Membership policy.
12. Governance and statutes. [GCIG publication statement](#)
13. GCIG meetings. [Last meeting presentations.](#) Provide information of what GCIG has done recently (web)
14. Roster. [Identify contact data for each group \(web\)](#)
15. Clinical Trials and Contacts (web)
16. Groups web links. [Provide groups information \(including activities outside GCIG\) \(web\)](#)
17. Events. [Provide information of what is coming \(web\)](#)



# LEIDEN – GCIG MEETING POTENTIAL SOLUTIONS

## What could we do?

To take 5-10 minutes in each meeting to identify new participants and mentoring necessities.

To create a mentoring register or add this information in the Roster.

To classify the available information in categories (ie. Membership Package, Welcome package, Collaborative Group Package, Leading Group Package), to optimize reading and perform friendly incorporation of new members to working groups.

To create an on-line tutorial with this information.

# WELCOME PACKAGE PROPOSAL (I)



## A) Membership package

- 1.1. Information about GCIG Membership – [Criteria to join to GCIG.](#)
- 1.2. GCIG Governance Document and Statutes - [How is organized GCIG and its members.](#)
- 1.3. GCIG Membership Committee Policy Document – [How the application will be evaluated.](#)
- 1.4. GCIG Membership Application form

## B) New member package

2. Harmonisation Guidebook. [What is GCIG, Practical issues, SAE, Insurance, IDMC, DM, others.](#)
3. GCIG Harmonization Working Group, Group Contacts & Summaries: [How are Groups organized](#)
4. GCIG Group Participation Summary: [What are groups doing within GCIG.](#)

Relevant information available in GCIG website:

5. GCIG meetings. Last meeting presentations. [Provide information of what GCIG has done recently](#)
6. Principles of independence
7. Roster. [Identify contact data for each group.](#)
8. Clinical Trials and Contacts. [To know what clinical trials are ongoing.](#)
9. Groups web links. [Provide groups information \(including activities outside GCIG\).](#)
10. Events. [Provide information of what is coming.](#)

# WELCOME PACKAGE PROPOSAL (II)



## C) Collaborative Group Package:

1. Intergroup Agreement Template (Company Intellectual Property Acknowledgement and GCIG/ Roles and Responsibilities). [Agreement for intergroup collaboration \(general frame\)](#).
2. Group Specific Appendix, GSA Guidelines. [Special agreements for project specific issues and the instructions for using it.](#)

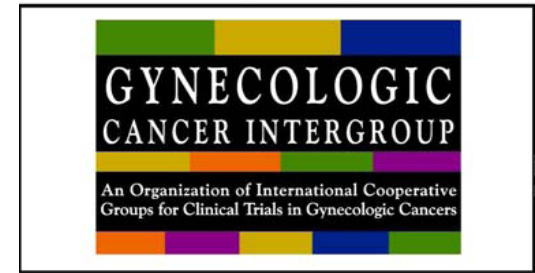
## D) Leading Group Package:

1. Data Monitoring Committees for GCIG Trials. [Monitoring Board, mandatory for GCIG Phase III trials.](#)
2. Checklist for Tissue Banking Consent Form. [Prevent essential information missing CF.](#)
3. Essential Documents Check-list. [Minimal requirements for CA approvals per Group.](#)

## E) Educational Package and Tools:

1. CTCAE Submission Package
  - 1.1 CTCAE v4.0 Public Draft
  - 1.2. General Grades Guidelines
  - 1.3. Review Comments Template
2. CCRN Overview for Harmonization - June 2012
3. Neurotoxicity Binder

# CHICAGO 2013 MEETING CURRENT STATUS



## What have we done? What could we do in addition?

To take 5-10 minutes in each meeting to identify new participants and mentoring necessities. **Already implemented.**

To create a mentoring register or add this information in the Roster. **In procedure. Volunteers for mentoring. Need for mentoring in this meeting.**

To classify the available information in categories (ie. Membership Package, Welcome package, Collaborative Group Package, Leading Group Package), to optimize reading and perform friendly incorporation of new members to working groups. **Proposal presented.**

To create an on-line tutorial with this information. **Could it be this set of slides? Any other information missing? Volunteers to work on this?**

**Volunteers:** Please, email Monica [ops.gcig@gmail.com](mailto:ops.gcig@gmail.com), or Jane: [jane.bryce@usc-intnapoli.net](mailto:jane.bryce@usc-intnapoli.net), detailing the activity preferred



***MANY THANKS...***