Attending: Gabriele Elser (GE), Monica Bacon (MB), Mason Schoenfeldt (MS), Julie Martyn (JM), Gerda Andresen (GA), Benedicte Votan (BV), Jane Bryce (JaB), Natalie le Fur (NF), Sandra Polleis (SP), Betty Stonebraker (BS), Karen Carty (KC), Denis Lacombe (DL) ……

1 **Definition of Protocol Signature/Site Acceptance Form** (owner NCIC – MB): There is no common form used by multiple groups, therefore we should follow that used by the lead group in intergroup trials.

Action: Each group to send a template of their protocol signature page to MB prior to the next meeting

2 **Survey of policies / processes - Queries / Deficiencies / Monitoring**

MB did a survey to the groups and available results were presented. Data of following GCIG groups were available: AGO, GEICO, GINECO, GOG, MaNGO, MITO, NCIC CTG, NSGO and SGCTG.

Queries:

There were no differences seen regarding minimum criteria. Almost all groups are using query date, Study ID, Patient ID; CR Form ID, Question Area, Reply area and Reply date. Queries can be signed by Investigator or designee. Deadlines vary from 2 up to 6 weeks.

Different templates of queries were shown. MB prefers the query format of the EORTC which includes also information like institution, patient initials, date of birth, chart no.

Problem in some countries: Patient initials and date of birth must not be listed on one form due to data protection law.

SAE queries:

All groups are using the same format for SAE queries as for other queries.
Timelines for answer SAE queries vary from 24 hours up to 2 weeks.
NCIC Clinical Trial Group lists for every trial all unanswered queries older than 14 days → Reminder to site via phone or email.

Repeat queries:

Timing for repeating unanswered queries varies between 14 tod 45 days. There were no differences to initial queries. Exception GOG: new query number will be assigned.

Reminders for late CRFs and Deficiency Reports

In principle it is an automated process. Timelines for reminders differ from 2 weeks up to 6 months.
NCIC CTG integrates in protocol one page with timelines, when singular CRF pages should be sending. When CRFs were not sent in time a reminder will be generated.
Problem: This page is not integrated in the protocol of GCIG trials.

Regarding issues in deficiency reports, monitoring and auditing, it turns out that the survey questions were misleading. Therefore the analysis is not meaningful.

GINECO, NSGO and AGO stated that CRAs collect CRFs at the sites. Thereby time delays were caused, the advantage is that less queries are necessary.

EORTC stated that monitoring is a risk driven approach. In trials with unlicensed drug a 100% monitoring is done.

NCIC CTG state that audit means local monitoring at site every 3 years, where 10% of the patients of all studies were monitored.

Action: Survey will be circulated again due to misleading questions

Deviation list:

Definition of deviation and violation – this wording needs to described more detailed.

Action: Jane (JB) will collect protocol deviation forms to give an update at the next meeting.

## 3 Site and Investigator selection

This issue was not discussed.

## 4 TMF compilation in Intergroup trials: Discussion based on CALYPSO trial

The following items were discussed:

1) What documents need to be collected? → Practical and realistic view for collection

2) Who should take care of documents archiving? → Archiving by leading group

3) Which documents are considered as original? → faxed and scanned documents are considered as original

4) Signature of protocol by PI only? → Every investigator for protocol acceptance Protocol acceptance form was only signed by PI not by each sub-investigator.

5) Investigators and sub-investigators CVs. → CVs of principal and sub-investigators need to be collected only. The delegation of duties list should be updated accordingly

6) What shall we do with documents foreign language? → Agreements with hospital /site in local language should be collected by the leading group

It was agreed to provide a template of e.g. agreement (in English), and a tabulation of sites and all effective dates, for all sites the cover + signature page of the agreement.

7) Documents in sites initiated but had no recruitment? → Same procedure and documents collection

8) Shall eCRFs be kept in electronic version or printed out? → Print-outs of all eCRFs for archiving is necessary. GINECO has the printouts of all eCRFs for archiving. eCRFs have to be filled at sites as well.

9) Assertion of thorough consent procedure → Checklist of signed consents, with respective dates

10) Tracking of shipment / drug accountability? → Shipments, drug accountability and destruction certificates should be sent to leading group

**Conclusion of discussion**: It has to be clarified at the beginning of new studies which documents have to be sent to the leading group for archiving. This should be added into the group agreement together with shipment details/timeframes.

Action: GCIG guidebook has to be updated (Trial Master File definitions)

Minutes taken: Sandra Polleis