	PRESENT:	ABSENT:
EORTC:	A Negrouk (AN)	C Coens
NCIC CTG:	M Bacon (MB)	E Eisenhauer
AGO:	G Elser (GE), A Reuss	
SGCTG:	K Carty KC), J Paul (JP)	
GOG:	M Brady, B Stonebraker	
NSGO:	G Andersen	
MRC:	J Bakobaki, W Qian	
ANZGOG:	J Martyn	V Gebski
RTOG:		K Winter
GINECO:	N LeFur, B Votan	
GEICO:	F Nepote	
GOG-J:	E Aotani	
NCI US:		
MaNGO:		R Fossati
MITO:	J Bryce (JaB), G Canzanella	S Pignata
AGO Austria:	B Volgger	
SWOG:		G Anderson
Website/Emmes:	M Schoenfeldt	
Observers:	K Morinaga (Taiho Pharmaceutical), K Look (EliLilly)	

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 copy of the documentation they use to MB prior to the next meeting

GE brought up that AGO and their sites had recently been asked to sign a secrecy agreement with a pharma company who they intend to work with. GCIG groups don't generally have these in relation to trial protocols as there is nothing secret in the protocols. NCIC have occasionally agreed to confidentiality agreements for very early stage trials but do not use a standard secrecy agreement. EORTC have a commitment statement that they use with sites and that deals with a number of issues including indemnity and confidentiality but this is not related to protocols or specific documents.

This led to a discussion of protocols in general. The lead group in intergroup trials is the owner of the protocol. Only pdf versions should be circulated. The preference is for group specific appendices so that the main protocol can be the same for all groups included in the trial. There is a possibility of having a confidentiality agreement that is circulated to sites with the protocol but each group will have different requirements. And different requirements are often imposed when we're doing industry trials compared with academic trials.

2 **Site and Investigator selection**: This was discussed at the last meeting. In the GCIG group contacts and summaries document it suggests that this is group specific but we don't currently have specific selection criteria identified for each group. Some groups have feasibility questionnaires that are used when identifying sites for trials. It was thought to be useful to collate this information together and Anastasia Negrouk agreed to lead on this.

Action Groups to send template and summary documents on how we select investigators and sites and how we assess their performance to AN for summary prior to next meeting.

3 Major protocol violation – experience from ICON7: JB summarised the ICON7 experience. There is a difference between protocol deviation and violation. In ICON7 we started calling deviations violations at the beginning but would differentiate in future. It is useful to collect this information in order to monitor site performance but care needs to be taken when defining what would be classified as a deviation or violation in the protocol. It might be useful to share monitoring plans and quality management documents more widely and particularly at the start of a trial. Central data monitoring is likely to be used more widely in trials that do not have the same funding and industry involvement and this needs to be discussed with participating groups upfront in terms of the roles and responsibilities of performing this sort of monitoring in the trials.

Action Groups to feedback group/trial specific experiences and country specific requirements to JB and JaB for summary prior to the next meeting.

4 New type of collaboration in GCIG studies: GE requested input from groups in leading trials that are legally sponsored by industry. Some groups expressed a willingness to be a part of those trials, whilst others did not at present. This was to be discussed further in the ovarian session the next day.

Action Groups to feedback advice/comments to GE.

Julie Bakobaki