GCIG Harmonization Committee

Criteria for joining [Trial name] as a GCIG group - Prospective Collaborating Country (PCC)

GCIG Group: _____

Please confirm that you meet the following criteria by deleting as appropriate:

**These documents are not required if the GCIG group is a previous collaborator (within the previous 5 years)*

1.	The PCC must have a trials office with fully dedicated personnel and adequate resourcing, who abide by their own SOPs (for safety, monitoring, site initiation and closure).	List of SOPs provided to GCIG LEAD GROUP CTU?* Yes / No	Organisational Structure provided to GCIG LEAD GROUP CTU?* Yes / No
2.	Named Chief Investigator for the PCC (must be Gynaecological or Medical oncologist) who will undertake responsibilities of the sponsor.	CV provided for review? Yes / No	
3.	The PCC must work from the same protocol version as the current UK version. Group Specific Appendix (GSA) may be individualised for each PCC.	GSA required? Yes / No	
4.	PCC procedures must be consistent with the EU / FDA safety reporting regulations .(OR insert relevant national regulations)	SAEs reported within 24hours. Yes / No	SUSARs 7 and 15 day rule Yes / No
5.	Portfolio of trials to be supplied to determine extent of prior experience (must have experience of Phase II/III trials and use of IMPs). List of GCIG trials which PCC have participated with must be supplied.	Portfolio of trials Yes / No	GCIG Trials List Yes / No
6.	Compliance with principles of ICH GCP	Yes / No	
7.	Regulatory/National ethics information must be supplied to GCIG LEAD GROUP prior to collaboration, with details of reports required.	Regulators and any reports* Yes / No	National Ethics and any reports* Yes / No
8.	Guarantee that participants in STUDY NAMEwill be followed up at randomising hospital (unless an emergency).	Yes / No	
9.	Each participating site in the PCC will have to sign the STUDY NAMEchecklist and an Investigator's agreement.	Agree Yes / No	
10.	Archiving facilities available (records to be kept at end of trial for 10 years).	Yes / No	
11.	Laboratory GCP (accreditation in PCC)	Yes / No	
12.	Translation of the protocol, clinical guidelines and GSA may be performed. GCIG LEAD GROUP will perform back translations.	Necessary? Yes / No	
13.	GCIG LEAD GROUP CTU to be provided with estimated total number of potential participants as well as number of sites that will be opened in PCC.	No. of participants (total for PCC)	No. of sites

Name of Chief Investigator in PCC: _____

(Print name in capitals letters)

Signature: _____ Date: _____

The ultimate decision regarding collaboration is decided by the GCIG LEAD GROUP and legal sponsor name