GCIG Harmonization Committee

Site Selection Checklist

Site Name:_____

Site City and Country:_____

Please confirm that your site meets the following criteria by initialling your response in the appropriate column:

	Yes	No
1. The site will regularly undertake the treatment of gynecologic cancers.		
2. The investigator will have appropriate experience of conducting trials according to good clinical practice (GCP).		
3. The site will have an adequate number of qualified clinical staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.		
4. The site will have gyne-oncologists trained in the delivery of Chemo/bio and/or Radiation therapies who specialise in the treatment of gynecologic cancer, and who are integrated into the gyne-oncology multidisciplinary team		
5. Clinical trial site staff will be familiar with the use of the experimental regimens, as described in the protocol and in the relevant Summary of Product Characteristics (SmPC).		
6. The site will have adequate cover from other senior colleagues at time of PI absences' to maintain best practice whilst managing trial patients. Delegation of responsibilities to junior staff should only be done after assurance of familiarity with trial protocol, GCP and clinical management guidelines.		
7. The site (or an associated hospital where the surgery will take place) will have experienced surgeons accredited in gynae-oncology who specialise in the management of patients with gynaecological malignancies.		
8. The site will have appropriate pathologists who specialise in the reporting of gyne-oncology specimens.		
9. Chemo/bio/radiation therapy prescribing will conform to best local practice, including computerised prescribing, where available.		
10. All staff assisting with the trial will be adequately informed about the protocol, the investigational product and their trial related duties.		
11. The trial will be conducted in accordance with the current protocol and changes		

will only be made when necessary to protect the safety, rights and welfare of patients.		
12. Standard local practice guidelines will be in place at the site to deal with acute medical or surgical complications of treatment.		
13. The site will run a 24 hour specialised oncology on call service to which patients experiencing treatment-related toxicities will be referred.		
14. The trial will be conducted in accordance with the STUDY NAME, to GCP standards and applicable regulatory requirements.		
15. The site agrees to participate in the monitoring and audit plans for STUDY NAME giving access to representatives of their GCIG group and the LEAD GROUP, to all relevant trial documents including site files, patient records, reports and data. In addition sites may also be required to allow access to trial documents to regulatory authorities should the trial be audited.		
16. The site will maintain an Investigator Site File which will contain essential documents for the conduct of the trial.		
17. All trial data will be submitted in a timely manner, and as described in the Investigator's statement and protocol. If participation fails to meet required standards in terms of data returns and protocol compliance or recommended trial conduct then a site's continued participation will be addressed by the Lead Group.		
18. All Serious Adverse Events (SAE) will be reported within one working day to the LEAD GROUP, except for those that the protocol identifies as not requiring immediate reporting.		
19. Initial SAE reports will be promptly followed by detailed written reports as appropriate.		
20. No trial data will be disclosed without the approval of the Trial Steering Committee (TSC).		
21. All trial related documents will be retained for 10 years after the trial is closed.		
How many patients do you typically see with newly diagnosed gynaecologic (INSERT specific site or histology) cancer per year?		
How many of those patients are likely to be eligible for Study Name?		
Which gynaecologic (INSERT specific site or histology) cancer trials have been opened at your site in the last year?		
Will there be a dedicated research nurse / data manager and/or clinical research associate working on study name at your site? (please specify which)		

Name of Principal Investigator: _____
(Print name in capitals letters)

Signature: _____ **Date**: _____