Final document based on meeting Frankfurt February 19th 2015

Guidelines for ENGOT minimal requirements for site selection

1. List of the 7 minimal requirements for site selection

1.1. Agreement to collaborate with group – ENGOT Roadmap[(1)]

1.2. Staff with CT experience/resources (PI, SC; SN, DM)[(1)]

1.3. Adherence to GCP[(1)]

1.4. Adequate infrastructure for study requirements (facilities) [(1)]

1.5. Information about participation in other trials within the last 3 years

1.6. Minimum enrollment documentation

2. Feasibility checks performed to ensure that these 7 requirements are met

The 7 minimal requirements are checked prior to participation through means of a feasibility check including the following topics :

1.1. Agreement to collaborate with group

- Minimum ENGOT requirement

1.2. Adequate experience and staff (resources)

- Experience in different trial phase(s) / Commercial or non-commercial trials
- Organization on site and no. of site staff members available for trial

1.3. Adherence to GCP

- Certificate/prove of GCP training (based on the country specific requirements). Training is available on ENGOT website for untrained site staff.

1.4. Adequate infrastructure for study requirements (facilities)

- Questions related to required infrastructure are customized depending on type/phase of trial (IMP/pharmacy, pathology, radiology, labs., etc.)

1.5. Information about participation in other trials within the last 3 years

- Phase and indication/disease
- no. of trials (ENGOT or other)?
- PI details, any conflicting/competing trials

1.6. Minimum enrollment

- Number of cases in protocol indication seen within the last year
- Anticipated recruitment taking into account the protocol specific eligibility criteria.

[1] Roadmap for ENGOT trials; Int J of Gynecological Cancer: 2013, 23: pp 1339-1343