PI responsibilities and qualifications for the Dutch Colorectal Cancer Group (DCCG)

The DCCG board bears the final and overall sponsor responsibility for all DCCG trials. DCCG delegates to the Principal Investigator (PI) the responsibility to safeguard the progress, safety and validity of the trial. The PI is coordinating the trial on behalf of DCCG and bears executive responsibility for the overall conduct of the trial.

The **tasks of the PI** in **all DCCG trials** include the following:

- Inform DCCG and Central Datamanagement Office (data center) of a new trial
- Collaborate with data center to compose and approve a project plan for the trial
- Ensure that all logistic requirements of the trial are arranged before start of the trial (supply of trial medication, courier services for sample collection, services and procedure central labs, services and procedure central review, etc.)
- Ensure that a Data Safety and Monitoring Board is installed
- Ensure that a protocol writing committee is appointed
- Provide data on the feasibility of the trial, and perform site selection
- Provide draft version of protocol and informed consent form to data center
- Provide trial related manuals for data center (lab manuals, nursing guideline)
- Collaborate with data center in editing protocol, ICF, CRF and other trial documents into a final version
- Review and sign for approval final version of protocol, ICF, CRF and other trial documents
- Sign application letters to Ethics Committees, Competent Authorities and other institutions that need to approve the trial
- Answer questions/respond to comments by Ethics Committees, Competent Authorities and other institutions that need to approve the trial
- Speak at investigator meetings, inform participating investigators about the medical and scientific aspects of the trial
- Speak at other training meetings for the trial: training of local data managers, training of data center staff (safety, monitoring, central data management)
- Collaborate with data center to compose a data management plan for the trial
- Collaborate with statistician to compose a statistical analysis plan for the trial
- Collaborate with data center to compose a safety plan for the trial
- Collaborate with data center to compose a monitoring plan for the trial
- Assist data center in performing tasks in safety management (medical review of SAE's)
- Review safety information regarding medicinal products used in trial (e.g. safety letters, SUSAR reports) for relevance to the safety of subjects in the trial

- Safeguard overall safety in the trial
- Assist data center in performing tasks in data management (medical data review)
- Answer questions of participants regarding medical and scientific aspects of the trial
- Collaborate and solve any issues with the trial
- Keep track of the progress of the trial, including review and approval of project progress reports and changes in the project plan
- Report to DCCG Board, working groups and other stakeholders on the progress, safety and validity of the trial
- Write annual progress and safety reports for Ethics Committees and Competent Authorities
- Write formal trial correspondence and reports
- Collaborate with data center to implement amendments
- Inform sites and authorities of the end of the trial
- Acknowledge the DCCG in all presentations/publications that are related to the trial

Additional tasks and responsibilities of PI's in DCCG sponsored trials:

- Collaborate with DCCG Board and DCCG Management to compose a trial budget and ensure sufficient funding
- Negotiate and make logistic arrangements with third parties involved in the trial, such as pharmaceutical companies, co-sponsors, central laboratories, central pharmacies and reviewers. Please note that all contracts and financial agreements with third parties are the responsibility of DCCG
- Collaborate with DCCG management to monitor the Study financially by checking invoices and financial Study information reports

Qualifications of a PI:

- Expert knowledge of and experience with the disease under study
- Experience in performing clinical trials, at least as a local investigator and preferable as co-investigator to a PI
- Knowledge of the laws and regulations concerning sponsorship of clinical trials, including GCP certificate: BROK course or equivalent
- Willing to comply with GCP and other regulatory requirements
- Knowledge of DCCG policy and mission
- Willing to always speak and act in accordance with the requirements set by the protocol
- Willing and able to commit sufficient time to the trial
- Readily available for questions and consultation by investigators and the data center; during absences the PI ensures the availability of the co-investigator or another suitable deputy PI
- Good communicative and organizational skills
- Always speak and act with integrity and respect
- Proactive and committed
- Willing and able to cooperate closely with several parties