Title:	**Local Investigator responsibilities**	
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As outlined in HOVON Policy Investigator terminology, each site participating in a trial has one local investigator. At each site there may be one or more sub-investigators appointed by the local investigator.

It is the responsibility of the local investigator to personally supervise that at his/her site the trial is conducted in accordance with ICH-GCP, the protocol, applicable SOPs and policies and applicable laws and regulations.

The local investigator may delegate trial related tasks to other site staff, which should be recorded on a site delegation log. It is the responsibility of the local investigator to ensure that each person with a delegated task is qualified and adequately trained for that task, and to supervise the correct execution of that task.

GCP training is a requirement to be qualified for any trial related task. Site staff should be trained on relevant aspects of the protocol and trial procedures relating to their delegated task. Please note that patients should not be informed about the trial before kick-off time point of the trial.

The sub-investigator executes trial related tasks that require medical judgment, such as making decisions about the eligibility or treatment of study patients. The sub-investigator may have to function as a temporary replacement for the local investigator if he/she is absent. The local investigator should therefore only appoint sub-investigators with sufficient medical qualifications. Preferably a hematologist or oncologist, and a hematologist in training only if this person is sufficiently trained and supervised in trial related procedures and GCP.

The following tasks should always be performed by the investigators (local investigator or sub-investigator) personally and cannot be delegated to other site staff:

- Review of all trial data for accuracy and completeness. This includes CRF pages, e-CRF entries, query or data clarification forms, final SAE reports. The review needs to be confirmed by a signature (an electronic signature for e-CRF)
- Ensuring trial data are reported in the CRF in a timely manner. Data-entry should be done in a timely manner after each patient visit, queries should be answered within 2 weeks, unless otherwise specified in trial specific correspondence from the HOVON study team.
- Review of eligibility criteria and deciding if the patient is eligible for inclusion in the trial or, if applicable, eligible to proceed with the next phase of the trial e.g. a second randomization.
- Obtaining informed consent and signing the informed consent form.
  Please note that other site staff, such as a research nurse, may contribute to the informed consent process and co-sign the informed consent form with the investigator.
- Any decision relating to the trial that requires medical judgment. For example: dose modifications of study drug, response assessment, assessment of the relationship between adverse events and study drug.

Please note that the personal involvement of the investigators in the tasks listed above should be substantiated by source documents, preferably the patient's medical records or otherwise correspondence filed with the medical records or with the trial documents (investigator trial file)

Please note that prolonged failure to report CRF data in a timely manner, will be followed up by HOVON with escalating consequences. Insufficient response will lead to a review of the site and a request to present a corrective action plan. Ultimately, a site may be (temporarily) closed for new inclusions or participation in new trials.