Title:	**Audits and inspections**	
Version:	02	
Effective date:	01-MAR-2015	
Author name	*Signature*	*Date*
P. Westveer		27-Jan-2015
Approver name	*Signature*	*Date*
J. Cornelissen		30-01-15

Scope of this policy

This policy applies to all and any types of audits or inspections of any facility, company, institution or other organization that is involved in a HOVON trial, i.e. a trial for which HOVON is the sponsor or a trial for which HOVON acts as co-sponsor.

This includes:

- Inspections by a regulatory agency
- Audits that are initiated by an external party, including internal audits
- Audits that are initiated by HOVON

Regulatory inspections

HOVON and any organization involved in a HOVON trial should give their full cooperation in case of an inspection by a regulatory authority that is requested in compliance with applicable laws and regulations. This includes inspections of central facilities and inspections of investigational sites.

An inspection will require access to all study records for inspection, including source documents for comparison with the CRFs. Patient privacy must, however, be respected.

The investigator or organization representative should immediately notify HOVON if they have been contacted by a regulatory agency concerning an upcoming inspection.

HOVON will provide any assistance necessary to help prepare for the inspection.

If the inspection is focused exclusively on the conduct of a HOVON trial, HOVON reserves the right to request that HOVON is consulted regarding communication with the regulatory agency.

Any findings related to the conduct of HOVON trials should be regarded as confidential.

Internal audits

Organizations involved in HOVON trials may have internal audits at their own discretion. Any findings related to the conduct of HOVON trials should be regarded as confidential.

HOVON welcomes any feedback that is provided based on the outcome of an internal audit, should the organization that requested the audit be inclined to do so.

HOVON will follow this guideline with respect to other organizations if they should have an internal audit performed at HOVON.

Audits initiated by an external party

Any audit, with the exception of internal audits, that includes the review of data, documents or procedures pertaining to a HOVON trial may only be performed after approval of the HOVON executive board.

The possibility to request an audit of central facilities and/or investigational sites should be agreed to in advance and documented in a trial related contract between HOVON and a company, institution or organization. HOVON may include in this agreement that HOVON and/or audited organizations will be compensated for their time and costs.

Regulations require that a sponsor is able to perform an audit of central facilities or investigational sites in order to review the quality of trial conduct. Therefore HOVON will ensure that access to study records and source documents by (a representative of) HOVON is granted by sites and other organizations involved in the trial. If HOVON has agreed in advance to give another organization the right to perform an audit, their access to study records should be ensured also.

The HOVON executive board should receive an advance notice at least 4 weeks prior to any actual audit, including a description of the scope of the audit. HOVON will immediately inform the representative of the organization that will be the subject of the audit, if applicable.

The organization to be audited should receive a detailed audit plan at least 2 weeks prior to the audit, including a list of documents to be provided or prepared, a list of persons who need to be involved and the expected time they need to invest in the audit. They should also receive an agenda of the audit at least 5 business days prior to the audit. The audited organization may be entitled to compensation for their time by HOVON, if this has been agreed to before the start of the trial.

Any audit findings related to the conduct of HOVON trials should be regarded as confidential.

HOVON recognizes that the audit findings and audit report are the sole property of the organization that requested the audit. However, HOVON welcomes any feedback that is provided based on the outcome of an audit, should the organization that requested the audit be inclined to do so.

Audits initiated by HOVON

HOVON may audit any company, institution, facility or other organization that provides services or products that are used in a clinical trial sponsored by HOVON.

This includes organizations acting as co-sponsor in an international trial.

The aim of such a supplier audit is to verify that the service or product meets the expectations and requirements determined by applicable regulations and the agreement made with HOVON.

HOVON will initiate a supplier audit when entering into an agreement with a new supplier, unless sufficient evidence is provided by the supplier that the required quality is assured. Such evidence would for example be quality certifications, audit reports and certificates, records from systematic internal quality assurance activities.

HOVON will also initiate a supplier audit if there is reason to suspect insufficient quality of the service or product, for example recurrent issues in trials.

HOVON may audit any investigational site that is participating in a clinical trial sponsored by HOVON.

The aim of a site audit is to verify that the HOVON trial(s) at the site are conducted in compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

HOVON will initiate a site audit if there is reason to suspect serious inadequacies that may harm patient safety or the validity of trial results, and other quality management activities such as a for cause monitor visit have failed to clarify or resolve the situation.

HOVON audit procedure

The HOVON executive board decides to initiate an audit after consulting the full HOVON board.

HOVON will enlist the services of a qualified and independent auditor to perform a supplier audit or site audit.

The audit scope and audit plan will be determined by HOVON and the auditor.

HOVON will provide auditee contact details to the auditor. The auditor will contact the auditee to arrange the audit.

The auditee will receive an advance notice at least 4 weeks prior to the audit, including a description of the scope of the audit.

The auditee will receive a detailed audit plan at least 2 weeks prior to the audit, including a list of documents to be provided or prepared, a list of persons who need to be involved and the

expected time they need to invest in the audit. They should also receive an agenda of the audit at least 5 business days prior to the audit.

The auditor will conduct the audit in accordance with the audit plan. At the end of the audit, the auditor will summarize any findings and discuss them with the auditees.

The auditor will provide a detailed report of the audit activities, findings and discussions to HOVON, including recommendations for corrective and preventive actions.

HOVON will share the audit report with the auditee.

Depending on the outcome of the audit, HOVON will take appropriate actions to ensure the quality of the trials affected by the audited subject.