| Title: | **Initiating a HOVON trial** | |
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Related document: Guideline for initiating a HOVON trial

## HOVON trials

There are two different scenarios in which a trial is considered to be a “HOVON trial”

1. HOVON initiated trial
   The trial is initiated by a HOVON affiliated investigator. HOVON acts as primary sponsor of the trial. This means HOVON bears full sponsor responsibility for the trial. There may be partner organizations involved in the trial such as a study group or company. HOVON may delegate trial tasks to these partners and offer them the opportunity to contribute to the trial design.

2. Study group initiated trial
   The trial is an investigator initiated trial initiated by another study group. The study group acts as primary sponsor of the trial. This means the study group bears full sponsor responsibility for the trial. HOVON is involved as a partner organization. The study group has delegated trial tasks to HOVON in a co-sponsor agreement.
   HOVON working group members should have the opportunity to contribute to the trial design.
   Sites from the Netherlands, Belgium and Luxembourg participate in the trial under HOVON affiliation.

## HOVON affiliated trials

HOVON may choose to be involved as a partner in a company sponsored trial. The trial is initiated by a pharmaceutical company. The company acts as primary sponsor of the trial. This means the company bears full sponsor responsibility for the trial. HOVON is involved as a partner organization. The company may delegate some trial tasks to HOVON.
HOVON working group members should have the opportunity to contribute to the trial design.
Sites from the Netherlands, Belgium and Luxembourg participate in the trial under HOVON affiliation. Such company sponsored trials are not assigned a HOVON trial number and are not considered to be a “HOVON trial”, but are a “HOVON affiliated company trial”.

HOVON may also choose to endorse a trial sponsored by another study group, institution or company. HOVON has no further involvement or tasks in such a trial, but considers the trial relevant in relation to their primary objective “to promote optimum treatment of adult patients with malignant haematological diseases”. HOVON will share information regarding the trial in the HOVON network. Such trials are not assigned a HOVON trial number. These are “HOVON affiliated trials”

## HOVON trial approval

Before a trial is accepted as a HOVON trial or HOVON affiliated (company) trial, it has to be approved by the HOVON executive board.

The criteria for a trial to be accepted as a HOVON trial are:

- The trial is in accordance with the working group's long term planning for the type and number of trials that are to be performed over the following 5 years.
- The trial design is discussed with and accepted by the relevant HOVON working group
- The trial design is discussed with and accepted by a representative number of HOVON affiliated investigators not part of the working group
- It is feasible to conduct the trial as proposed with the available HOVON facilities and resources
- For a non-HOVON initiated trial there is sufficient opportunity for HOVON to contribute to the trial design and publications
- For a non-HOVON initiated trial there should be a significant contribution of the trial to the HOVON objective "to promote optimum treatment of adult patients with malignant haematological diseases"

The criteria for a trial to be accepted as a HOVON affiliated (company) trial are:

- The trial design is discussed with and accepted by the relevant HOVON working group
- The trial constitutes a significant contribution to the HOVON objective "to promote optimum treatment of adult patients with malignant haematological diseases"
- For a HOVON affiliated company trial there is sufficient opportunity for HOVON to contribute to the trial design and publications, and there is sufficient financial compensation for any tasks delegated to HOVON

## HOVON trial number

Each HOVON trial is assigned a HOVON trial number by the HOVON executive board.

A HOVON affiliated trial or a HOVON affiliated company trial do not receive a HOVON trial number.

A HOVON trial number is formatted as "HOVON xxx YYY", with xxx being the sequence number and YYY the abbreviated name of the disease under study, such as AML or MM.

The HOVON trial number is to be used in all communication related to the trial by HOVON and HOVON affiliated organizations such as the HOVON Data Center and HOVON affiliated sites.

## HOVON protocol review committee (PUC)

The protocol, informed consent form, CRF and trial related manuals (lab manual, nursing guideline, etc) of a HOVON trial have to be reviewed by the HOVON protocol review committee (protocol uitvoerbaarheids commissie, PUC) before start of the trial.

The purpose of the PUC review is to ensure that the trial is practically feasible to perform in a clinical setting.