

Title:	Site selection	
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Site selection criteria

The Principal Investigator in coordination with the HOVON working group and the HOVON Data Center will establish specific site selection criteria for each trial in an early stage of trial development. The following general criteria will be applied:

- ◆ Availability of required medical facilities and staff to conduct the trial according to the protocol
- ◆ Availability of sufficient facilities and staff to conduct the trial according to regulatory requirements (GCP)
- ◆ Willingness to comply with all protocol procedures and regulatory requirements
- ◆ Expected availability of eligible patients

HOVON echelon classification in relation to site selection

For hospitals in the Netherlands HOVON has established a classification by echelon (see HOVON policy "Echelon Classification"). The echelon level reflects the general status of the site with regard to the first three site selection criteria listed in the previous paragraph. The Principal Investigator will establish for each trial in an early stage of trial development which echelon level is required for the trial. Separate phases in the protocol schedule may be assigned a different echelon level requirement.

A site from the Netherlands may only participate in a HOVON trial after it has been classified. The site should have a sufficient level to perform all protocol phases or should have an agreement for cooperation with another site to perform the procedures that require a higher echelon level. Trial specific site selection criteria apply in addition to the echelon level.

For sites from other countries, all site selection criteria should be reviewed for each individual trial, both trial specific criteria and general criteria equivalent to the echelon classification.

Site selection procedure

Only sites that fulfill the selection criteria for a trial will participate.

The HOVON Data Center, under supervision of the Principal Investigator, will review if a site fulfills the established selection criteria. In case of doubt or differences in opinion, the working group will review the case and make the decision.

All hospitals in the Netherlands that have the required echelon level for the trial will be invited to apply for participation in the trial.

Suitable HOVON affiliated hospitals in Belgium will always be invited to apply for participation in the trial, unless it has been established by the working group in consultation with the HOVON manager for Belgium that it is not feasible to perform the trial in Belgium.

In the event that there is a limitation on the number of sites that can participate in the trial and the number of sites that fulfill the selection criteria exceeds that number, the working group will discuss and decide which sites are selected to participate. This discussion will be based on factors relevant to the successful completion of the trial.