Title:	**Premature termination of a trial or investigational site**	
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Premature termination of a trial

The decision to prematurely terminate a HOVON sponsored trial can only be made by the HOVON executive board.

The Principal Investigator in coordination with the applicable HOVON working group and the Data Safety Monitoring Board (if applicable) will advise the HOVON executive board to prematurely end a trial if there is reason to do so.

HOVON may decide to terminate the trial prematurely for the following criteria only:

- One of the stopping rules as defined in the protocol has been reached
- There is evidence of an unacceptable risk for trial subjects (i.e. safety issue)
- There is reason to conclude that it will not be possible to collect the data necessary to reach the study objectives and it is therefore not ethical to continue enrolment of more patients; for example insufficient enrolment that cannot be improved
- The DSMB recommends to end the trial based on viable arguments other than described above

HOVON, in coordination with the Principal Investigator and the HOVON Data Center, will promptly notify all concerned investigators, the Ethics Committee(s) and the regulatory authorities of the decision to terminate the trial.

HOVON, in coordination with the Principal Investigator, will provide information regarding the time lines of study termination and instructions regarding treatment and data collection of enrolled patients.

All involved parties should observe confidentiality rules concerning premature termination of a trial. Also see the HOVON policy regarding crisis management.

Premature termination of a treatment arm

The decision to prematurely terminate a specific treatment arm in a randomized HOVON sponsored trial can only be made by the HOVON executive board.

The Principal Investigator in coordination with the applicable HOVON working group and the Data Safety Monitoring Board (if applicable) will advise the HOVON executive board to prematurely end a treatment arm if there is reason to do so.

HOVON may decide to terminate the treatment arm prematurely for the following criteria only:

- One of the stopping rules as defined in the protocol has been reached
- There is evidence of an unacceptable risk for trial subjects (i.e. safety issue)
- There is evidence to conclude that the effect of the treatment arm is inferior and it is therefore not ethical to continue treatment of more patients with this inferior arm
- The DSMB recommends to end the treatment arm based on viable arguments other than described above

HOVON, in coordination with the Principal Investigator and the HOVON Data Center, will promptly notify all concerned investigators, the Ethics Committee(s) and the regulatory authorities of the decision to terminate the treatment arm.

HOVON, in coordination with the Principal Investigator, will provide information regarding the time lines of treatment termination and instructions regarding treatment and data collection of enrolled patients in the terminated arm.

All involved parties should observe confidentiality rules concerning premature termination of a treatment arm. Also see the HOVON policy regarding crisis management.

Urgent safety measures

In the occurrence of an immediate hazard to the safety of trial subjects, while no member of the HOVON executive board is available for consultation, the Principal Investigator is authorized to take urgent safety measures including the suspension of further enrollment and/or treatment of trial subjects. The Principal Investigator will then promptly inform the HOVON executive board, the regulatory authorities and other parties involved.

Premature termination of participation of an investigational site

Participation of an investigational site may end prematurely for the following reasons:

- The investigator is unable or unwilling to continue participation and no mutually acceptable replacement is available
- HOVON decides to terminate participation due to severe and/or continuing noncompliance of the site
- HOVON decides to terminate participation due to insufficient enrollment by the site that cannot be improved, if this poses a risk for successful completion of the trial; this will only occur after discussion with the site and investigator(s) concerned

The decision to prematurely terminate participation of an investigational site in a HOVON sponsored trial due to noncompliance or insufficient enrollment can only be made by the HOVON executive board. Also see the HOVON policy on the handling of trial related issues.

HOVON, in coordination with the Principal Investigator and the HOVON Data Center, will promptly notify the Ethics Committee(s) and the regulatory authorities of the decision to terminate participation of the site.

HOVON, in coordination with the Principal Investigator, will discuss with the site the options for continuation of treatment and data collection of any enrolled subjects. Transfer of enrolled patients to another investigational site may be possible. The patient's interest will always be the first priority in any decision made.

All involved parties should observe confidentiality rules concerning premature termination of site participation. Also see the HOVON policy regarding crisis management.