REQUIRED ITEMS ON SAE REPORT

INITIAL SAE REPORT (to be sent within 24 hours)

	Description	Mandatory*
	Patient information	
	Patient study number**	■
	Sex	■
	Report information	
	Site name	■
	Investigator name	■
	Type of report	■
	Date of report	■
	Serious Adverse Event information	
	Adverse Event term (single term !) **	■
	Date onset AE	
	Date AE became serious	■
	Reason AE is serious	■
	Date site became aware of SAE	■
	Severity of AE	
	SAE description and comments	
	SAE description and comments	
	Trial medication	
	Treatment arm	■
	Protocol phase	■
	IMP's	
	Trial medication**	■
	Total daily dose	
	Date first dose	
	Date last dose	
	Relationship to SAE**	■
	Action taken as a result of this SAE	
	Other trial medication	
	Trial medication	
	Total daily dose	
	Date first dose	
	Date last dose	
	Relationship to SAE**	
	Action taken as a result of this SAE	
	Possible causes other than IMP's	
	Possible causes other than IMP's ***	
	Outcome of SAE	
	Outcome of SAE	
	Date SAE resolved	
	Date of death	
	Cause of death	
	Signatures	
	Name reporter function date signature	■
	Name (sub)investigator date signature	

■ Mandatory

***) missing items will be queried**

****) - missing items required for evaluation whether SAE is a SUSAR, will be queried immediately as urgent query**
- relationship must always be assessed by local investigator (treating physician)

*****) all items**

FOLLOW UP SAE REPORT

	Description	Mandatory*
	Patient information	
	Patient study number**	■
	Sex	■
	Report information	
	Site name	■
	Investigator name	■
	Type of report	■
	Date of report	■
	Serious Adverse Event information	
	Adverse Event term (single term !)	■
	Date onset AE	■
	Date AE became serious	■
	Reason AE is serious	■
	Date site became of aware of SAE	■
	Severity of AE	■
	SAE description and comments	
	SAE description and comments	■
	Trial medication	■
	Treatment arm	■
	Protocol phase	■
	IMP's	
	Trial medication**	■
	Total daily dose	■
	Date first dose	■
	Date last dose	■
	Relationship to SAE	■
	Action taken as a result of this SAE	■
	Other trial medication	
	Trial medication	■
	Total daily dose	■
	Date first dose	■
	Date last dose	■
	Relationship to SAE**	■
	Action taken as a result of this SAE	■
	Possible causes other than IMP's	
	Possible causes other than IMP's ***	■
	Outcome of SAE	
	Outcome of SAE	■
	Date SAE resolved	
	Date of death	
	Cause of death	
	Signatures	
	Name reporter function date signature	■
	Name (sub)investigator date signature	

■ Mandatory

***) missing items will be queried**

****) - missing items required for evaluation whether SAE is a SUSAR, will be queried immediately as urgent query**
- relationship must always be assessed by local investigator (treating physician)

*****) all items**

FINAL SAE REPORT (as soon as outcome is known)

	Description	Mandatory*
	Patient information	
	Patient study number**	■
	Sex	■
	Report information	
	Site name	■
	Investigator name	■
	Type of report	■
	Date of report	■
	Serious Adverse Event information	
	Adverse Event term (single term !)	■
	Date onset AE	■
	Date AE became serious	■
	Reason AE is serious	■
	Date site became of aware of SAE	■
	Severity of AE	■
	SAE description and comments	
	SAE description and comments	■
	Trial medication	■
	Treatment arm	■
	Protocol phase	■
	IMP's	
	Trial medication**	■
	Total daily dose	■
	Date first dose	■
	Date last dose	■
	Relationship to SAE	■
	Action taken as a result of this SAE	■
	Other trial medication	
	Trial medication	■
	Total daily dose	■
	Date first dose	■
	Date last dose	■
	Relationship to SAE**	■
	Action taken as a result of this SAE	■
	Possible causes other than IMP's	
	Possible causes other than IMP's ***	■
	Outcome of SAE	
	Outcome of SAE	■
	Date SAE resolved	■
	Date of death	■
	Cause of death	■
	Signatures	■
	Name reporter function date signature	■
	Name (sub)investigator date signature	■

■ Mandatory
■ Mandatory if applicable

***) missing items will be queried**

****) - missing items required for evaluation whether SAE is a SUSAR, will be queried immediately as urgent query**
- relationship must always be assessed by local investigator (treating physician)

*****) all items**

REQUIRED ITEMS ON SAE REPORT

OVERVIEW SAE REPORT				
	description	**IN***	**FU***	**FI***
	Patient information			
	Patient study number **	■	■	■
	Sex	■	■	■
	Report information			
	Site name	■	■	■
	Investigator name	■	■	■
	Type of report	■	■	■
	Date of report	■	■	■
	Serious Adverse Event information			
	Adverse Event term (single term !)**	■	■	■
	Date onset AE		■	■
	Date AE became serious	■	■	■
	Date site became aware of SAE	■	■	■
	Reason AE is serious	■	■	■
	Severity of AE		■	■
	SAE description and comments			
	SAE description and comments		■	■
	Trial medication			
	Treatment arm	■	■	■
	Protocol phase	■	■	■
	IMP's			
	Trial medication**	■	■	■
	Total daily dose		■	■
	Date first dose		■	■
	Date last dose		■	■
	Relationship to SAE**	■	■	■
	Action taken as a result of this SAE		■	■
	Other trial medication			
	Trial medication		■	■
	Total daily dose		■	■
	Date first dose		■	■
	Date last dose		■	■
	Relationship to SAE**		■	■
	Action taken as a result of this SAE		■	■
	Possible causes other than IMP's			
	Possible causes other than IMP's ***		■	■
	Outcome of SAE			
	Outcome of SAE		■	■
	Date SAE resolved			■
	Date of death			■
	Cause of death			■
	Signatures			
	Name reporter function date signature	■	■	■
	Name (sub)investigator date signature			■

■ Mandatory
■ Mandatory if applicable

***) missing items will be queried**

****) - missing items required for evaluation whether SAE is a SUSAR, will be queried immediately as urgent query**
- relationship must always be assessed by local investigator (treating physician)

*****) all items**

Query handling:
Answers to queries are preferably provided by sending a revised report via email.

Please answer e-mails within the time lines set at the bottom of the e-mail (2 days for urgent queries and 2 weeks for non urgent queries).
This will reduce the number of reminders.

When you send a reply to an e-mail sent by us, please do not change the title/subject.

When you address us a question by e-mail, please specify in the title: HOVON study number/patient number, AE term and specify "Urgent_" if applicable.

Please contact us when you have any questions when filling out the SAE report.
tel.: +31(0)107041560
e-mail: hdcsafetydesk@erasmusmc.nl

SAE REPORTING

Please send in initial report within 24 hours after occurrence.

When sending an initial SAE report, please fill out:

- basic patient data: patient studynumber, sex.
- basic hospital data: site name, investigator name.
- single AE term.
- date AE became serious.
- reason AE is serious.
- treatment arm.
- protocol phase.
- all applicable IMP's.
- relationship of IMP's to SAE.
- name reporter, function, date and signature.

Please see our website www.hovon.nl → over de HOVON→HOVON Data Center →Safety Desk for:
- frequently asked questions. (FAQ's)
- SAE instructions.
- additional information.