

**Please note that this form has to be completed and submitted in ALEA.**

More information about the submission of the Breaches eCRF in ALEA can be found in the instruction manual.

In case of (other) questions, contact the Breach coordinators at [hovonbreaches@erasmusmc.nl](mailto:hovonbreaches@erasmusmc.nl)

**New or updated Breaches that cannot be entered digitally can also be sent to the Breach coordinators via [hovonbreaches@erasmusmc.nl](mailto:hovonbreaches@erasmusmc.nl).**

In the last case, please use this form to report all breaches as described in the trial protocol and manual.

An **initial report** must be submitted / sent to HOVON as soon as becoming aware of the breach.

## 0. SPONSOR INTERNAL IDENTIFICATION AND INFORMATION ON BREACH REPORT

0.4	Who identified the breach?	<input type="checkbox"/> Local datamanagement <input type="checkbox"/> Site Staff <input type="checkbox"/> Monitor <input type="checkbox"/> Other
0.5	Breach type	<input type="checkbox"/> Protocol <input type="checkbox"/> Regulation (EXTR, GxP, GDPR or other) <input type="checkbox"/> Quality Management System <input type="checkbox"/> Other breach/incident/issue
0.6	Immediate action taken?	<input type="checkbox"/> No, please specify at 0.6.0 <input type="checkbox"/> Yes, please specify at 0.6.1 <input type="checkbox"/> Not applicable, please specify at 0.6.2
0.6.0	<i>Explain why no immediate action was taken</i>	
0.6.1	<i>Describe which immediate action was taken (what, by who, date, time, etc.)</i>	
0.6.2	<i>Explain why immediate action was not applicable</i>	

## BREACH REPORT

A. GENERAL INFORMATION		
A.0.0	Date of becoming aware of the breach	
A.0.1	Was the date of becoming aware of the breach the same as the date of the breach?	<input type="checkbox"/> Yes <input type="checkbox"/> No
A.0.2	Date of breach	
A.2	Involved HOVON trial	
A.5	Are other clinical trials impacted by the same breach?	<input type="checkbox"/> No <input type="checkbox"/> Not Known <input type="checkbox"/> Yes
A.5.1	Involved other (HOVON) trial name	
A.5.3	Specify EU CTR number <i>(if it does not concern a HOVON trial)</i>	
A.6	Details of the site where the breach occurred	
A.6.0.1	Country	
A.6.0.2	City	
A.6.0.3	Site name	
A.6.1	Tel. no. site	
A.6.2	E-mail site	
A.6.3	Involved patient(s) <i>(Please fill out Patient Study ID if applicable)</i>	

## BREACH REPORT

B. DETAILS OF THE BREACH		
B.1	Brief description of the breach	
B.2	(Potential) impact of the breach	
B.2.1	Safety of the trial Participant?	
B.2.1.1	Category of impact	<div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"><input type="checkbox"/> IMP</div> <div style="width: 50%;"><input type="checkbox"/> Temperature monitoring</div> <div style="width: 50%;"><input type="checkbox"/> IRT issues</div> <div style="width: 50%;"><input type="checkbox"/> Potential fraude</div> <div style="width: 50%;"><input type="checkbox"/> Source data</div> <div style="width: 50%;"><input type="checkbox"/> Emergency unblinding</div> <div style="width: 50%;"><input type="checkbox"/> Sample processing</div> <div style="width: 50%;"><input type="checkbox"/> Protocol compliance</div> <div style="width: 50%;"><input type="checkbox"/> SAE reporting</div> <div style="width: 50%;"><input type="checkbox"/> Consent</div> <div style="width: 50%;"><input type="checkbox"/> Access to data</div> <div style="width: 50%;"><input type="checkbox"/> Randomization/stratification errors</div> <div style="width: 50%;"><input type="checkbox"/> DSMB/DMC</div> <div style="width: 50%;"><input type="checkbox"/> Privacy</div> <div style="width: 50%;"><input type="checkbox"/> Other</div> </div>
B.2.1.2	Description of the impact	

### BREACH REPORT

B.2.2		Rights of the trial Participant?	
B.2.2.1	Category of impact	<input type="checkbox"/> IMP <input type="checkbox"/> IRT issues <input type="checkbox"/> Source data <input type="checkbox"/> Sample processing <input type="checkbox"/> SAE reporting <input type="checkbox"/> Access to data <input type="checkbox"/> DSMB/DMC <input type="checkbox"/> Other	<input type="checkbox"/> Temperature monitoring <input type="checkbox"/> Potential fraude <input type="checkbox"/> Emergency unblinding <input type="checkbox"/> Protocol compliance <input type="checkbox"/> Consent <input type="checkbox"/> Randomization/stratification errors <input type="checkbox"/> Privacy
B.2.2.2	Description of the impact		

B.2.3		Data reliability & robustness?	
B.2.3.1	Category of impact	<input type="checkbox"/> IMP <input type="checkbox"/> IRT issues <input type="checkbox"/> Source data <input type="checkbox"/> Sample processing <input type="checkbox"/> SAE reporting <input type="checkbox"/> Access to data <input type="checkbox"/> DSMB/DMC <input type="checkbox"/> Other	<input type="checkbox"/> Temperature monitoring <input type="checkbox"/> Potential fraude <input type="checkbox"/> Emergency unblinding <input type="checkbox"/> Protocol compliance <input type="checkbox"/> Consent <input type="checkbox"/> Randomization/stratification errors <input type="checkbox"/> Privacy
B.2.3.2	Description of the impact		

**BREACH REPORT**

B.2.4	Regulatory?	
B.2.4.1	Category of impact	<input type="checkbox"/> IMP <input type="checkbox"/> Temperature monitoring <input type="checkbox"/> IRT issues <input type="checkbox"/> Potential fraude <input type="checkbox"/> Source data <input type="checkbox"/> Emergency unblinding <input type="checkbox"/> Sample processing <input type="checkbox"/> Protocol compliance <input type="checkbox"/> SAE reporting <input type="checkbox"/> Consent <input type="checkbox"/> Access to data <input type="checkbox"/> Randomization/stratification errors <input type="checkbox"/> DSMB/DMC <input type="checkbox"/> Privacy <input type="checkbox"/> Other
B.2.4.2	Description of the impact	
B.2.5	Other (HOVON trials)?	
B.2.5.1	Category of impact	<input type="checkbox"/> IMP <input type="checkbox"/> Temperature monitoring <input type="checkbox"/> IRT issues <input type="checkbox"/> Potential fraude <input type="checkbox"/> Source data <input type="checkbox"/> Emergency unblinding <input type="checkbox"/> Sample processing <input type="checkbox"/> Protocol compliance <input type="checkbox"/> SAE reporting <input type="checkbox"/> Consent <input type="checkbox"/> Access to data <input type="checkbox"/> Randomization/stratification errors <input type="checkbox"/> DSMB/DMC <input type="checkbox"/> Privacy <input type="checkbox"/> Other
B.2.5.2	Description of the impact	

## BREACH REPORT

B.3

Other relevant details /  
information