

**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	<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> IMP</td> <td><input type="checkbox"/> Temperature monitoring</td> </tr> <tr> <td><input type="checkbox"/> IRT issues</td> <td><input type="checkbox"/> Potential fraude</td> </tr> <tr> <td><input type="checkbox"/> Source data</td> <td><input type="checkbox"/> Emergency unblinding</td> </tr> <tr> <td><input type="checkbox"/> Sample processing</td> <td><input type="checkbox"/> Protocol compliance</td> </tr> <tr> <td><input type="checkbox"/> SAE reporting</td> <td><input type="checkbox"/> Consent</td> </tr> <tr> <td><input type="checkbox"/> Access to data</td> <td><input type="checkbox"/> Randomization/stratification errors</td> </tr> <tr> <td><input type="checkbox"/> DSMB/DMC</td> <td><input type="checkbox"/> Privacy</td> </tr> <tr> <td><input type="checkbox"/> Other</td> <td></td> </tr> </table>	<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	
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<input type="checkbox"/> Other																		
B.2.1.2	Description of the impact																	
B.2.2	Rights of the trial Participant?																	
B.2.2.1	Category of impact	<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> IMP</td> <td><input type="checkbox"/> Temperature monitoring</td> </tr> <tr> <td><input type="checkbox"/> IRT issues</td> <td><input type="checkbox"/> Potential fraude</td> </tr> <tr> <td><input type="checkbox"/> Source data</td> <td><input type="checkbox"/> Emergency unblinding</td> </tr> <tr> <td><input type="checkbox"/> Sample processing</td> <td><input type="checkbox"/> Protocol compliance</td> </tr> <tr> <td><input type="checkbox"/> SAE reporting</td> <td><input type="checkbox"/> Consent</td> </tr> <tr> <td><input type="checkbox"/> Access to data</td> <td><input type="checkbox"/> Randomization/stratification errors</td> </tr> <tr> <td><input type="checkbox"/> DSMB/DMC</td> <td><input type="checkbox"/> Privacy</td> </tr> <tr> <td><input type="checkbox"/> Other</td> <td></td> </tr> </table>	<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	
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B.2.2.2	Description of the impact																	

**BREACH REPORT**

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		
B.2.4		Regulatory?	
B.2.4.1	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.2.4.2	Description of the impact		
B.2.5		Other (HOVON trials)?	
B.2.5.1	Category of impact	<input type="checkbox"/> IMP <input type="checkbox"/> 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.2.5.2	Description of the impact		
B.3	Other relevant details / information		