

7. Serious adverse events

B. Patient information

1. Initials (first character first name, first and second character last name)

2. Date of birth

	/		/				
dd		mm		yyyy			

3. Sex

Male
 Female

4. Weight

5. Height (cm)

C. Report information

1. Site name

Leids Universitair Medisch Centrum
 Amsterdam Medisch Centrum
 VU Medisch Centrum
 Spaarne Gasthuis
 Deventer Ziekenhuis
 Medisch Centrum Haaglanden
 Universitair Ziekenhuis Leuven
 Universitair Ziekenhuis Antwerpen

2. Investigator

3. Type of report

Initial report
 Follow up report
 final report

4. Date report

	/		/				
dd		mm		yyyy			

D1. SAE information

1. (Preliminary) diagnosis AE

2. Date onset AE

	/		/				
dd		mm		yyyy			

3. Date AE became serious

	/		/				
dd		mm		yyyy			

Center-Patiëntnummer: _ _ _ - _ _ _ (Center=CIC ID)

(ga naar volgende pagina)

D1. SAE information	
4. Reason AE is serious	<input type="checkbox"/> Death <input type="checkbox"/> Life-threatening <input type="checkbox"/> (Prolongation of) hospitalization
5. Relationship to any trial medication	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Very likely <input type="checkbox"/> Unknown
6. Relationship to any trial procedure	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Very likely <input type="checkbox"/> Unknown
7. Unexpected SAE (investigator assessment)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

D2. SAE description									
1. SAE description	<table border="1"> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> </table>								
2. Comments	<table border="1"> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> </table>								

E. If patient was hospitalized																					
1. If patient was hospitalized, date of hospitalization	<table border="1"> <tr> <td> </td><td> </td><td>/</td><td> </td><td> </td><td>/</td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td colspan="2">dd</td><td colspan="2">/ mm</td><td colspan="2">/</td><td colspan="4">yyyy</td> </tr> </table>			/			/					dd		/ mm		/		yyyy			
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dd		/ mm		/		yyyy															
2. If patient was hospitalized, date of discharge	<table border="1"> <tr> <td> </td><td> </td><td>/</td><td> </td><td> </td><td>/</td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td colspan="2">dd</td><td colspan="2">/ mm</td><td colspan="2">/</td><td colspan="4">yyyy</td> </tr> </table>			/			/					dd		/ mm		/		yyyy			
		/			/																
dd		/ mm		/		yyyy															
3. If patient was hospitalized, outcome of SAE	<input type="checkbox"/> Resolved completely <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Ongoing <input type="checkbox"/> Death																				

Center-Patiëntnummer: _ _ _ - _ _ _ (Center=CIC ID)

= het antwoord op deze vraag is door u gewijzigd