REPORT ON OCCURRENCE OF SERIOUS ADVERSE EVENTS IN COURSE OF CLINICAL TRIAL

EudraCT number (in absence of EudraCT number, sponsor's trial protocol number) and reference number of the State Agency of Medicines:		**Contact details of person reporting**	

Information on adverse reaction						
1. Initials of patient	1a. Country	2. Date of birth ---------- dd/mm/yy	2a. Age	3. Sex	4-5. Time of commencement of adverse event ---------- dd/mm/yy	8-12. Check all appropriate to adverse event patient died involved or prolonged inpatient hospitalisation involved persistence or significant disability or incapasity for work life-threatening
7-13. Description of adverse event (incl. relevant results of laboratory analyses, end, etc.)						

Information on suspected medicinal products(s)	
14. Name(s) of suspected medicinal products(s) and other information (batch, etc)	20. Did the adverse event cease after the termination of the

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<tr><td>15. Daily dose(s)</td><td colspan="2">16. Route(s) of administration</td><td>administration of the medicinal product?
Yes
No
Not known</td></tr>
<tr><td colspan="3">17. Indication(s) for use</td><td rowspan="2">21. Did the adverse event reoccur after the termination of the administration of the medicinal product?
Yes
No
Not relevant</td></tr>
<tr><td colspan="2">18. Beginning and end of the administration of the medicinal product (from/to)
/</td><td>19. Duration of the use of the medicinal product</td></tr>
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<table>
<tr><th>Concurrent treatment and anamnesis</th></tr>
<tr><td>22. Concomitant medicinal product(s), period of use (dates) (except medicinal products used for the treatment of the adverse event)</td></tr>
<tr><td>23. Other relevant history (allergy, pregnancy, etc.)</td></tr>
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<tr><th colspan="4">Manufacturer information</th></tr>
<tr><td>24a. Name and address of the manufacturer</td><td>24b. Manufacturer's control number</td><td rowspan="2"></td><td rowspan="3"></td></tr>
<tr><td>24c. Date received by manufacturer</td><td>24d. Report source
Clinical trial
Literature
Health professional</td></tr>
<tr><td>25. Date of this report</td><td>25a. Report type
Initial
Follow-up
(Report no…)</td><td></td></tr>
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