

SEVERE ADVERSE EVENT FORM

IDENTIFICATION	IDENTIFICATION	IDENTIFICATION
Identification (UIC) <input style="width: 100%;" type="text"/> Result of Randomisation <input type="checkbox"/> No Transplant <input type="checkbox"/> Autotransplant Patient's initials <input style="width: 100%;" type="text"/>	Identification code of the patient within the hospital administration <input style="width: 100%;" type="text"/> Date of birth <input style="width: 100%;" type="text"/> (as yyyy/mm/dd) Sex of patient <input type="checkbox"/> male <input type="checkbox"/> female	DATE OF REPORT <input style="width: 100%;" type="text"/> (as yyyy/mm/dd) S.A.E. FORM Weight (in kg) <input style="width: 100%;" type="text"/> Height (in cm) <input style="width: 100%;" type="text"/>

S.A.E. REPORTING	S.A.E. REPORTING	S.A.E. REPORTING
Relevant medic.history <input style="width: 100%;" type="text"/> Adverse event <input style="width: 100%;" type="text"/>	Reason for reporting <input type="checkbox"/> requires or prolonges hospitalization <input type="checkbox"/> permanently disabling or incapacitating <input type="checkbox"/> cancer <input type="checkbox"/> congenital anomaly <input type="checkbox"/> life-threatening <input type="checkbox"/> overdose <input type="checkbox"/> death	Clinical description <input style="width: 100%;" type="text"/> Date of occurrence <input style="width: 100%;" type="text"/> (as yyyy/mm/dd)

CONCOMITANT MEDICATIONS	CONCOMITANT MEDICATIONS	CONCOMITANT MEDICATIONS
1. Drug name <input style="width: 100%;" type="text"/> 1. Indication <input style="width: 100%;" type="text"/> 1. Daily dose <input style="width: 100%;" type="text"/> 1. Route administration <input style="width: 100%;" type="text"/> 1. Date begin <input style="width: 100%;" type="text"/> (as yyyy/mm/dd) 1. Date end <input style="width: 100%;" type="text"/> (as yyyy/mm/dd)	2. Drug name <input style="width: 100%;" type="text"/> 2. Indication <input style="width: 100%;" type="text"/> 2. Daily dose <input style="width: 100%;" type="text"/> 2. Route administration <input style="width: 100%;" type="text"/> 2. Date begin <input style="width: 100%;" type="text"/> (as yyyy/mm/dd) 2. Date end <input style="width: 100%;" type="text"/> (as yyyy/mm/dd)	3. Drug name <input style="width: 100%;" type="text"/> 3. Indication <input style="width: 100%;" type="text"/> 3. Daily dose <input style="width: 100%;" type="text"/> 3. Route administration <input style="width: 100%;" type="text"/> 3. Date begin <input style="width: 100%;" type="text"/> (as yyyy/mm/dd) 3. Date end <input style="width: 100%;" type="text"/> (as yyyy/mm/dd)

CONCOMITANT MEDICATIONS	CONCOMITANT MEDICATIONS	S.A.E. REPORT
4. Drug name <input style="width: 100%;" type="text"/> 4. Indication <input style="width: 100%;" type="text"/> 4. Daily dose <input style="width: 100%;" type="text"/> 4. Route administration <input style="width: 100%;" type="text"/> 4. Date begin <input style="width: 100%;" type="text"/> (as yyyy/mm/dd) 4. Date end <input style="width: 100%;" type="text"/> (as yyyy/mm/dd)	5. Drug name <input style="width: 100%;" type="text"/> 5. Indication <input style="width: 100%;" type="text"/> 5. Daily dose <input style="width: 100%;" type="text"/> 5. Route administration <input style="width: 100%;" type="text"/> 5. Date begin <input style="width: 100%;" type="text"/> (as yyyy/mm/dd) 5. Date end <input style="width: 100%;" type="text"/> (as yyyy/mm/dd)	Relationship medication <input type="checkbox"/> not related <input type="checkbox"/> unlikely <input type="checkbox"/> possibly <input type="checkbox"/> probably <input type="checkbox"/> definitely Outcome of event <input type="checkbox"/> resolved <input type="checkbox"/> ongoing <input type="checkbox"/> death Date of outcome event <input style="width: 100%;" type="text"/> (as yyyy/mm/dd) Investigator's name <input style="width: 100%;" type="text"/>