

**CLINICAL EVENTS CLASSIFICATION**

**PART I: IDENTIFYING INFORMATION**

1. Patient's ID Number:  ID 2. Current Clinic:  SITE
3. Patient's Letter Code:  INITS 4. Week #:  -  sequence VISIT SEQNO
5. Event Start Date:  -  -  VIS\_DT  
Month Day Year

**PART II: CLASSIFICATION**

1. Reviewer: TK MS CON MED REVIEWER  
(1) (2) (3) (4)
2. Date of review  -  -  REVIEWDT  
Month Day Year
3. Classification decision CLASSDEC  
Final (1)  
Pending (2)
- If FINAL, Skip to PART III
4. Additional information requested? Yes No ADINFO  
(1)\* (2)

\*a. Specify \_\_\_\_\_ ADINFOSP

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**PART III: BODY SYSTEM(S) AFFECTED CLASSIFICATION**

		Yes	No
1. Blood and lymphatic system disorders	SOC_01	(1)	(2)
2. Cardiac disorders	SOC_02	(1)	(2)
3. Congenital, familial and genetic disorders	SOC_03	(1)	(2)
4. Ear and labyrinth disorders	SOC_04	(1)	(2)
5. Endocrine disorders	SOC_05	(1)	(2)
6. Eye disorders	SOC_06	(1)	(2)
7. Gastrointestinal disorders	SOC_07	(1)	(2)
8. General disorders and administration site conditions	SOC_08	(1)	(2)
9. Hepatobiliary disorders	SOC_09	(1)	(2)
10. Immune system disorders	SOC_10	(1)	(2)
11. Infections and infestations	SOC_11	(1)	(2)
12. Injury, poisoning and procedural complications	SOC_12	(1)	(2)
13. Investigations	SOC_13	(1)	(2)
14. Metabolism and nutrition disorders	SOC_14	(1)	(2)
15. Musculoskeletal and connective tissue disorders	SOC_15	(1)	(2)
16. Neoplasms benign, malignant and unspecified (incl cysts and polyps)	SOC_16	(1)	(2)
17. Nervous system disorders	SOC_17	(1)	(2)
18. Pregnancy, puerperium and perinatal conditions	SOC_18	(1)	(2)
19. Psychiatric disorders	SOC_19	(1)	(2)
20. Renal and urinary disorders	SOC_20	(1)	(2)
21. Reproductive system and breast disorders	SOC_21	(1)	(2)
22. Respiratory, thoracic and mediastinal disorders	SOC_22	(1)	(2)
23. Skin and subcutaneous tissue disorders	SOC_23	(1)	(2)
24. Social circumstances	SOC_24	(1)	(2)
25. Surgical and medical procedures	SOC_25	(1)	(2)
26. Vascular disorders	SOC_26	(1)	(2)

**PART IV: FINAL CLASSIFICATION OF OUTCOME EVENT**

1. Event Type		Yes	No
A. Severe splenic sequestration	SEVSPLSQ	(1)	(2)
B. Stroke	STROKE	(1)	(2)
C. Transient ischemic attack	TIAFCL	(1)	(2)
D. Acute chest syndrome	ACUTE	(1)	(2)
E. Death	DEATH	(1)*	(2)

\*1. Immediate cause

DEATHIMM

\*2. Primary underlying cause

DEATHPRM

F. Other

FCLOTHR

(1)\*

(2)

\*1. Specify event/diagnosis

FCLOTHSP

ID Number

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Visit

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Seq

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		Yes	No
2. Event Severity			
A. Serious adverse event <sup>†</sup>	<b>SERIOUS</b>	(1)	(2)
B. Severity	<b>SEVER</b>		
Mild		(1)	
Moderate		(2)	
Severe		(3)	
Life threatening		(4)	
Disabling		(5)	
Fatal		(6)	
Unknown		(7)	
C. Attribution to study treatment	<b>ATTRIB</b>		
Definite		(1)	
Probable		(2)	
Possible (may be related)		(3)	
Unlikely (doubtfully related)		(4)	
Unrelated (definitely not related)		(5)	

**PART V: COORDINATION**

1. Checked for completeness and accuracy:
- A. Certification number:   -   **CERT\_NO**
- B. Signature: \_\_\_\_\_ **CERT\_SIG**
- C. General Comments: \_\_\_\_\_ **GEN\_CMNT**

<sup>†</sup>Defined to be death, life-threatening event, hospitalization (initial or prolonged), severe splenic sequestration, stroke, TIA, acute chest syndrome or disability.

ID Number	Visit	Seq
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