Hospital ID Code		**Hospital Name**	
Patient Identifiers	Initials, randomisation code		

TRIAL TITLE

ADVERSE EVENT REPORT FORM

Please report on this form any adverse event occurring (timeline)
Please refer to the Protocol / Study file for events which need to be reported.

1. REPORT TYPE *(circle)*	**Initial**	**Follow-up**	**2. COUNTRY**	

I. ADVERSE EVENT INFORMATION

3. DO YOU KNOW THE DATE OF BIRTH	a) YES	*day*	*month*	*year*	b) NO – approximate age	*years*	**4. Sex**	**F / M**

5. ADVERSE EVENT IN MEDICAL TERMS ***(diagnosis if possible)***

6. Is the event due to progression of underlying illness? *(circle)*	**NO**	**YES**	**7. ONSET OF FIRST SIGNS/SYMPTOMS OF AE**	*day*	*month*	*year*

8. SERIOUSNESS CRITERIA

(tick all appropriate to event)

☐ **NONE OF THE FOLLOWING**:
Does not fulfil serious criteria

Please send this page only (page 1)to the coordinating centre as soon as possible

☐ Patient died — *Day* | *month* | *year*

☐ Involved or prolonged in-patient hospitalisation
☐ Results in persistent or significant disability / incapacity
☐ Life-threatening
☐ Congenital abnormality / birth defect
☐ Other, medically important

If any of the serious criteria is ticked, send all 3 pages to the trial coordinating centre within 24 hours.

9. ASSESSMENT OF CAUSALITY [NOT SUSPECTED OR SUSPECTED] ***(Relationship to study drug)***

☐ **NOT SUSPECTED TO BE RELATED TO TRANEXAMIC ACID BECAUSE OF**
- ☐ Basic disease / pre-existing condition
- ☐ Intercurrent disease
- ☐ Concomitant medication
- ☐ Non-drug therapy / intervention
- ☐ Prior to randomisation
- ☐ Other non-drug cause, specify:

_____

☐ **SUSPECTED TO BE RELATED TO TRANEXAMIC ACID / PLACEBO:** Please state reason for causality assessment:

10. OUTCOME OF THE PATIENT / AE / SAE

☐ Completely recovered, date of recovery	*day*	*month*	*year*

☐ Recovered with sequelae
☐ Condition improving
☐ Condition still present and unchanged
☐ Condition deteriorated
☐ Death

11. INFORMATION SOURCE FOR NON-SERIOUS ADVERSE EVENT

a) Investigator name:

c) Signature:

d) Date reported	*day*	*month*	*year*

if the event is not serious please fax only this page to the coordinating centre

Hospital ID Code		**Hospital Name**	
Patient Identifiers	Initials, randomisation code		

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ADVERSE EVENT REPORT FORM

II. TRIAL DRUG INFORMATION

12A. START OF TRIAL TREATMENT	*day*	*month*	*year*	**12B. END OF TRIAL TREATMENT**	*day*	*month*	*year*

13. TIME ELAPSED BETWEEN LAST DRUG ADMINISTRATION AND ONSET OF FIRST SIGNS / SYMPTOMS OF SAE	*minutes*	*hours*	*days*	*months*

14. ROUTE OF ADMINISTRATION		**15. Random code broken** *(circle)*	NO	YES

III. HISTORY

16. HEIGHT	*cm*	**17. WEIGHT**	*kg*	Estimated if actual values not available

18. PATIENT'S PAST MEDICAL HISTORY ***(e.g. co-existing medical conditions such as disease, allergies, similar experiences)***

19. CONCOMITANT DRUGS ***(list all below)***

20. COMMENTS ***(if adverse event is considered to be caused by a concomitant medication, please note it here)***

Hospital ID Code		**Hospital Name**	
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TRIAL TITLE

ADVERSE EVENT REPORT FORM

21. ACTION TAKEN ***(tick all that apply)***

- ☐ No action taken
- ☐ Trial drug dosage adjusted / temporarily interrupted*
- ☐ Trial drug permanently discontinued due to this adverse event
- ☐ Non-drug therapy given**
- ☐ Drug therapy taken**
- ☐ Hospitalisation / prolonged hospitalisation

** if ticked, enter new dosage information in field 23* *** if ticked, provide therapeutic measure in field 23*

22. TEST / LABORATORY FINDINGS ***(relevant for SAE diagnosis or description)***

23. ADDITIONAL INFORMATION:
Case description of the above SAE (include related signs/symptoms/lab results, treatment, outcome and suspected cause of the SAE)

IV. INFORMATION SOURCE

24. INVESTIGATOR DETAILS	a) Full Name	b) Telephone number	c) Signature

25. DATE REPORTED	*day*	*month*	*year*

NOW PLEASE FAX ALL THREE PAGES OF THIS FORM TO THE COORDINATING CENTRE