



Complete for all SAEs as part of the SWiFT trial

Trial ID: R ____ Participant Initials: ____

Type of report:

- ☐ Initial
- ☐ Follow-up 1
- ☐ Follow-up 2
- ☐ Follow-up 3
- ☐ Follow-up 4

SAE Name: _____

Date of SAE onset: 20 ____ / ____ / ____ (yyyy/mm/dd)

Time of SAE onset: ____ : ____ (24 hr time)

Describe the SAE:

Treatment / Test given:

Seriousness of the event:

- ☐ Death
- ☐ Life threatening
- ☐ Requires hospitalisation or prolongs existing hospitalisation
- ☐ Likelihood of persistent or significant disability or incapacity
- ☐ Congenital abnormality of birth defect
- ☐ Other important medical event

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Please select causal relationship for each PRODUCT given after randomisation. (Please refer to pre-Hospital Form (1) for the randomisation date. Please mark applicable field with an 'X')

	Not applicable	Unrelated	Unlikely related	Possibly related	Probably related	Definitely related
Whole Blood						
RBC						
Fresh Frozen						
Lypholised						
Other						

Status of SAE:

- ☐ Resolved
☐ Resolved with sequelae
☐ Ongoing
☐ Worsening
☐ Fatal

Was trial treatment discontinued as a result of this event (i.e. transfusion stopped prematurely)?

- ☐ No
☐ Yes

Form completed by (PRINT NAME): _____ Signature: _____

Date of Completion (yyyy/mm/dd) : 20 ____ / ____ / ____

IMPORTANT: PI Signature is required for each SAE

PI Name (PRINT NAME): _____ PI Signature: _____

Date (yyyy/mm/dd) : 20 ____ / ____ / ____

Please email this form to: serious_adverse_events@nhsbt.nhs.uk within 24hrs of becoming aware of the event!