

**VenUS IV: COMPRESSION HOSIERY TRIAL
SERIOUS ADVERSE EVENT FORM**

Patient ID Number: Nurse Code: - -
First three letters of SURNAME / day of birth / month of birth

Date of Birth: / /
day month year

Date of onset of event: / / 2 0 Sex: Male Female
day month year

Description of event:

Classification of SAE: *(Please cross all that apply)*

Death Life or limb threatening event Hospitalisation required/prolonged
 Persistent or significant disability/incapacity Other medically important condition

PLEASE OBTAIN COPIES OF ANY AVAILABLE SUPPORTING DOCUMENTS RELATING TO THE EVENT FOR FORWARDING TO THE VENUS IV TRIAL CO-ORDINATOR.

Please state outcome of event at time of this report *(Please cross one box only)*

		Date recovered/died				
Recovered fully	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Recovered partially	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Died	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Ongoing	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		<small>day</small>		<small>month</small>		<small>year</small>

Relationship of event to treatment *(Please cross one box only)*

Unrelated Unlikely to be related Possibly related Probably related Definitely related Not able to assess if related

York Trials Unit must be notified of any serious adverse event by telephone (01904 321904) within 24 hours of onset of the event.

Post or fax a copy of this form and any available supporting documents to
 within 48 hours of onset

Please note that we may need to inform the Research Ethics Committee of this event.

Final date of resolution if known: / /
day month year

Outcome if known: Recovered fully Recovered partially

Possible SAEs in the VenUS IV trial:

Patient has died; Limb compromise (limb requires revascularisation or amputation); Patient admitted to hospital, Patient hospitalised for longer than 24 hours for any reason, Participant cannot provide on-going consent, Systemic infection / sepsis**

**Please note this is not an exhaustive list, if you suspect an event is serious or are unsure, please contact the Trial Co-ordinator at the York Trials Unit. We would rather you erred on the side of caution and reported an event to us. **

Nurse name (Block capitals) Nurse signature