SERIOUS ADVERSE EVENT/REACTION FORM EVerT Trial

STUDY DETAILS:

EVerT Cryotherapy versus salicylic acid for the treatment of verrucae.

EudraCT: 2004-000905-24 CTA: 22803/0001/001-0001 REC ref: 04/MRE04/59

SUBJECT DETAILS:

Patient's ID number ☐☐ ☐☐☐☐ Patient's initials ☐☐☐

Patient's date of birth _____/_____/_____ Male ☐ Female ☐
day month year

Patient's weight if known _____ Patient's height if known _____

EVENT DETAILS:

Date of onset of event _____/_____/_____
day month year

Description of event/reaction and action taken :

Classification of SAE: (Please tick all that apply)

Death ☐ Life or limb threatening event ☐ Hospitalisation required/prolonged ☐

Persistent or significant disability/incapacity ☐ Other medically important condition ☐ Congenital anomaly or birth defect ☐

Maximum intensity**:**

Mild ☐ Moderate ☐ Severe ☐

PLEASE OBTAIN COPIES OF ANY AVAILABLE SUPPORTING DOCUMENTS RELATING TO THE EVENT FOR FORWARDING TO THE TRIAL COORDINATOR.

OUTCOME of event at the time of this report:
(Tick one box only)

		Date Recovered/died Day month year
Recovered fully	☐	☐☐ ☐☐ ☐☐☐☐
Recovered with sequelae	☐	☐☐ ☐☐ ☐☐☐☐
Died	☐	☐☐ ☐☐ ☐☐☐☐
Ongoing	☐	

Relationship of event to treatment (tick one box only)

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

If possibly, probably or definitely related, was the SAE unexpected?
(Unexpected means not described in the protocol or SMPC).`

☐ Yes [1]

☐ No [2]

1 – The SAE is a SUSAR 2 – The SAE is not a SUSAR.

York Trials Unit must be notified of any serious adverse event by telephone (01904 321736) within 24 hours of onset of the event.

Post or fax top copy of this form and any available supporting documents to Sarah Cockayne, Trial Coordinator, Department of Health Sciences Area 4, Seebohm Rowntree Building, University of York, Heslington, York, YO10 5DD, within 48 hours of onset (Fax 01904 321387).

Please note that you may need to inform your Local Research Ethics Committee of this event.

MEDICINAL PRODUCT DETAILS:

Name of medicinal product (MP)_____

Batch number _____

Indication for which suspect investigational MP was prescribed _____

Dosage form and strength_____

Daily dose and regiment (specify units)_____

Route of administration_____

Starting date and time of day of reaction _____

Date and time last dose given, or duration of treatment_____

Date of treatments _____

CONCOMITANT MEDICATION:
(Details of administration of other medication concurrent with the IMP

_____

_____

_____

DETAILS OF REPORTER OF EVENT:

Name position and address of reporter of event:

_____

_____

_____

Telephone number:_____ Email address: _____

Profession (Speciality) _____

Signature _____

Date _____/_____/_____
day month year