Dupuytren's Interventions Surgery vs Collagenase

University of York

NHS University Hospitals of Leicester NHS Trust

DISC Serious Adverse Event Report Form

FOR UHL SPONSORED CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

Participant study number: ☐☐☐☐

Sponsor Reference Number:	**87230**
Study Title:	**DISC**
Site ID Number:	☐☐
Principal Investigator Name:	
Participant Initials:	☐☐☐
SAE Event Number* *** Please refer to the participant's DISC Serious Adverse Event Tracking Log to determine the Event Number**	☐☐

This form is to be completed within 24 hours of becoming aware of the Serious Adverse Event

1. Type of report (Tick relevant box) ☐ **Initial** ☐ **Follow Up** ☐ **Final** ☐ **Initial & Final**

Brief description of Serious Adverse Event: ☐

Date of onset: ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

Date study team aware: ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

Stop date of event ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*) OR Tick if event is ongoing ☐

2. Serious criteria:

- ☐ Resulted in death
- ☐ Life threatening
- ☐ In-patient hospitalisation or prolongation of existing hospitalisation
- ☐ Persistent or significant disability/incapacity
- ☐ Congenital anomaly/birth defect
- ☐ Surgical or medical intervention to prevent above
- ☐ Other (please specify): ☐

Participant study number: | | | | |

3. Narrative

Is the Serious Adverse Event a complication of the procedure (surgery/collagenase)? ☐ Yes ☐ No

Details of any complications associated with the procedure must also be recorded in follow-up CRFs until resolved.

Briefly describe the event ensuring patient identifiable information is not included (attach supporting documentation if applicable). Include confirmation if care has been passed on to another relevant team.

If applicable, please complete the admission date and discharge date.

Admission date: ☐☐ / ☐☐ / ☐☐☐☐ (*day / month / year*) Discharge date: ☐☐ / ☐☐ / ☐☐☐☐ (*day / month / year*)

Participant study number: ☐☐☐☐

Both the Causality & Expectedness MUST be completed by the Chief/Principal Investigator or other medically qualified Investigator as agreed by the Sponsor for all IMP studies

4. Causality and Expectedness

Please tick to confirm the treatment the participant was randomised to receive

☐ **Collagenase injection** ☐ **Limited fasciectomy surgery**

Evaluation of causal relationship with treatment

Definitely related*	Probably related*	Possibly related*	Unlikely to be related	Unrelated
☐	☐	☐	☐	☐

Assessment of expectedness

The assessment of expectedness must be based on the information contained in the approved Reference Safety Information.

☐ Expected ☐ Unexpected*

***If the event is possibly, probably or definitely related and unexpected it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and requires expedited reporting. Inform York Trials Unit immediately by fax: 01904 321387 or email: Disc-Trial-Group@york.ac.uk**

5. Study Medication Information:

To be completed only if randomised to receive collagenase

Participant has been administered study drug?

☐ Yes *(Provide details in box below)* ☐ No: ____ *(Give reason i.e. randomised but not yet been treated with collagenase)*

Name of medication	Indication(s) for use	Volume administered	Route of administration	Date of administration *(dd/mm/yyyy)*
				☐☐ / ☐☐ / ☐☐☐☐
				☐☐ / ☐☐ / ☐☐☐☐
				☐☐ / ☐☐ / ☐☐☐☐
				☐☐ / ☐☐ / ☐☐☐☐

Participant study number: | | | | |

6. Action taken with investigational product due to event:

- ☐ Treatment not given
- ☐ Further procedure required
- ☐ Other – provide details: _____
- ☐ Not applicable

7. Outcome of the event

- ☐ Resolved — Date of resolution: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)
- ☐ Resolved with Sequelae
- ☐ Ongoing
- ☐ Unknown at present
- ☐ Fatal — Date of death: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Cause of death: _____

Cause of death obtained from (cross one box):

☐ Working Diagnosis ☐ Coroners Inquest ☐ Death Certificate

Supporting documentation to be supplied with SAE

If the participant's status has changed as part of the event, please complete a DISC Participant Change of Status Form and send a copy to York Trials Unit.

Reporting person:	Principal Investigator/Delegated medically qualified individual as agreed by the sponsor:
Name:	Name:
Role:	Role:
Assessor ID: ☐☐	Assessor ID: ☐☐
Signature:	Signature:
Date: ☐☐ / ☐☐ / ☐☐☐☐	Date: ☐☐ / ☐☐ / ☐☐☐☐
Contact No:	Contact No:

Please send a copy of the form and any additional documents to York Trials Unit either by fax: 01904 321387 or email: Disc-Trial-Group@york.ac.uk and file the original form in your site files.