Dupuytren's Interventions Surgery vs Collagenase

University of York

NHS University Hospitals of Leicester NHS Trust

DISC Adverse Event Initial Report Form

Participant study number: ☐☐☐☐

1. Details of study

Name of Principal Investigator:		Site ID Number: ☐☐

2. Details of AE

Please refer to the Participant's DISC Adverse Event Tracking Log to determine the next Event Number.

Event Number: ☐☐

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

Details of any complications associated with the procedure must also be recorded in the DISC Adverse Event Follow-Up Form and follow-up CRFs until resolved.

Full description of event, including body site, reported signs and symptoms and diagnosis where possible (ensuring patient identifiable information is not included)

Action taken:	***If 'Other', please specify below:**
☐ Treatment not given	
☐ Further procedure required	
☐ Other*	
☐ Not applicable	

Onset Date: ☐☐ / ☐☐ / ☐☐☐☐ (*day / month / year*) **End Date:** ☐☐ / ☐☐ / ☐☐☐☐ (*day / month / year*)

3. Outcome

☐ Resolved* ☐ Resolved with Sequelae*

☐ Ongoing* ☐ Ongoing with Sequelae* ☐ Died* (give cause and PM details if available)

*Give details (including confirmation if care has been passed on to another relevant team)	

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4. Relationship to study treatment and Expectedness (to be completed)

Treatment allocated:	Please confirm the relationship to study treatment	*If possibly, probably or definitely related, was the AE unexpected? (Unexpected means not described in the protocol)
☐ Collagenase	☐ Definitely related*	☐ Yes
☐ Surgery	☐ Probably related*	☐ No
	☐ Possibly related*	
	☐ Unlikely to be related	
	☐ Not related	

5. Seriousness

The event is/was:

☐ Not serious	☐ Results in disability or incapacity*
☐ Results in death*	☐ Congenital anomaly or birth defect*
☐ Life threatening*	☐ Other* (please specify below):
☐ Results in hospitalisation or prolongation of existing hospitalisation*	

*If considered SERIOUS please complete a DISC Serious Adverse Event (SAE) form **AND** this form (if completed), and send to the **York Trials Unit** either by fax: **01904 321387** or email: **Disc-Trial-Group@york.ac.uk** within 24 hours of becoming aware of the event.

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.

I confirm that the contents of this form are accurate and complete

Name of person completing form (if different to PI):

Name _____ Signature: _____

Assessor ID: ☐☐ Date: ☐☐ / ☐☐ / ☐☐☐☐ *(dd/mm/yyyy)*

Confirmed by PI/ Delegated medic:

Name _____ Signature: _____

Assessor ID: ☐☐ Date: ☐☐ / ☐☐ / ☐☐☐☐ *(dd/mm/yyyy)*

Please send a copy of the form to York Trials Unit either by fax: 01904 321387 or email: Disc-Trial-Group@york.ac.uk within 5 days of becoming aware of the event, and file the original form in your site files.