Dupuytren's Interventions Surgery vs Collagenase

One Year Visit - Case Report Form

FOR STUDY INVESTIGATOR COMPLETION

Site ID: ☐☐

Participant Study Number: ☐☐☐☐

Participant Initials: ☐☐☐

Visit date: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

University of York

NHS University Hospitals of Leicester NHS Trust

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Instructions for this Case Report Form

This Case Report Form (CRF) may be completed by the principal investigator or a delegated member of staff listed on the DISC Delegation Log.

The Screening Number pre-printed on the patient's Screening for Eligibility Summary Form should be entered as the Participant Study Number on the cover page of this CRF.

Please complete all sections of this CRF using the spaces provided, and sign off when complete.

When complete, please remove the staple and take a photocopy of the completed CRF for site records.

Please do not re-staple original. Place the unstapled original in a "DISC business reply envelope" and send via post to York Trials Unit.

Is the participant still willing to participate? ☐ Yes ☐ No

If 'Yes', please complete all sections, date and sign at the end of this CRF.

If 'No', please state reason below, date and sign at the end of this CRF and complete a DISC Participant Change of Status Form.

Signature of person completing page:

Date *(dd/mm/yyyy)*: / /

Assessor ID:

Section A: Treatment confirmation

1. Please confirm the participant's hand, digit and joint that are designated as reference for this study (as defined in the Baseline Investigator CRF) *(Please cross one box only)*

Left Hand			**Right Hand**		
Thumb	☐ MCP	☐ PIP	Thumb	☐ MCP	☐ PIP
Index	☐ MCP	☐ PIP	Index	☐ MCP	☐ PIP
Middle	☐ MCP	☐ PIP	Middle	☐ MCP	☐ PIP
Ring	☐ MCP	☐ PIP	Ring	☐ MCP	☐ PIP
Little	☐ MCP	☐ PIP	Little	☐ MCP	☐ PIP

2. Please confirm the treatment the participant was randomised to receive:

☐ Collagenase injection ☐ Limited fasciectomy surgery

3. Did the participant receive their randomised treatment?

☐ Yes ☐ No

Proceed to Section B

Signature of person completing page: Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Section B: Joint measurements

Part 1 – Total Active Movement

Please take 3 measurements of extension and flexion for the **reference digit**.

Please enter measurements below (key: MCP = metacarpophalangeal, PIP = proximal interphalangeal, DIP = distal interphalangeal)

MEASUREMENT 1	**MCP**	**PIP**	**DIP**
Extension	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees
Flexion	☐☐☐ degrees	☐☐☐ degrees	☐☐☐ degrees
			Not applicable ☐ (only to be ticked if the reference digit is the thumb)

MEASUREMENT 2	**MCP**	**PIP**	**DIP**
Extension	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees
Flexion	☐☐☐ degrees	☐☐☐ degrees	☐☐☐ degrees
			Not applicable ☐ (only to be ticked if the reference digit is the thumb)

MEASUREMENT 3	**MCP**	**PIP**	**DIP**
Extension	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees
Flexion	☐☐☐ degrees	☐☐☐ degrees	☐☐☐ degrees
			Not applicable ☐ (only to be ticked if the reference digit is the thumb)

If unable to obtain any measurements for a particular joint, please tick to confirm for which joint

☐ **MCP** ☐ **PIP** ☐ **DIP**

Signature of person completing page:

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Part 2 - Extension Deficit (<u>Passive Extension</u>)

Please take 3 measurements of extension for the **reference digit.**

Please enter measurements below (key: MCP = metacarpophalangeal, PIP = proximal interphalangeal, DIP = distal interphalangeal).

MEASUREMENT 1	**MCP**	**PIP**	**DIP**
Extension	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees
			Not applicable ☐ (only to be ticked if the reference digit is the thumb)
MEASUREMENT 2	**MCP**	**PIP**	**DIP**
Extension	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees
			Not applicable ☐ (only to be ticked if the reference digit is the thumb)
MEASUREMENT 3	**MCP**	**PIP**	**DIP**
Extension	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees
			Not applicable ☐ (only to be ticked if the reference digit is the thumb)

If unable to obtain any measurements for a particular joint, please tick to confirm for which joint

☐ **MCP** ☐ **PIP** ☐ **DIP**

Signature of person completing page: Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Part 3 - Photographs

A photograph has been taken of the reference hand in extension (from the side of the hand with little finger closest to the camera) ☐ Yes ☐ No

A photograph has been taken of the reference hand in flexion making a tight fist (from the side of the hand with the little finger closest to the camera) ☐ Yes ☐ No

A photograph has been taken of the reference hand in extension (camera directly above the hand) ☐ Yes ☐ No

If 'No', please indicate why photographs have not been completed

Proceed to Section C

Signature of person completing page: | Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ | Assessor ID: ☐☐

Section C – Procedure complications if RANDOMISED AND RECEIVED intervention (Collagenase injection)

Tick here if the participant was not randomised to collagenase and proceed to section D ☐

Please complete this section if RANDOMISED AND RECEIVED intervention (collagenase injection). PLEASE DO NOT INCLUDE COMPLICATIONS ARISING FROM OTHER TREATMENTS.

Has the participant had any injection complications since the 6 month visit?

☐ Yes ☐ No

If 'No', please proceed to Section D.

If 'Yes', please provide a Yes/No response to each of the following complications to confirm if the participant has been affected by that complication. If you have ticked 'Yes', please provide the start/stop date of the event, or tick to confirm if it is ongoing.

Please complete a DISC Trial Adverse Event Form if the participant has had a complication.

Injection Complications *(please tick)*	**Start date of complication** *(dd/mm/yyyy)*	**Stop date of complication** *(dd/mm/yyyy)*	**Adverse Event Number**
Lymphadenopathy, lymph node pain, axillary mass, axillary pain Yes ☐ No ☐	☐☐/☐☐/☐☐☐☐	☐☐/☐☐/☐☐☐☐ Event is ongoing ☐	☐☐
Paraesthesia Yes ☐ No ☐	☐☐/☐☐/☐☐☐☐	☐☐/☐☐/☐☐☐☐ Event is ongoing ☐	☐☐
Hypoaesthesia Yes ☐ No ☐	☐☐/☐☐/☐☐☐☐	☐☐/☐☐/☐☐☐☐ Event is ongoing ☐	☐☐
Burning sensation Yes ☐ No ☐	☐☐/☐☐/☐☐☐☐	☐☐/☐☐/☐☐☐☐ Event is ongoing ☐	☐☐
Dizziness Yes ☐ No ☐	☐☐/☐☐/☐☐☐☐	☐☐/☐☐/☐☐☐☐ Event is ongoing ☐	☐☐
Headache Yes ☐ No ☐	☐☐/☐☐/☐☐☐☐	☐☐/☐☐/☐☐☐☐ Event is ongoing ☐	☐☐

Signature of person completing page: _____ Date *(dd/mm/yyyy)*: ☐☐/☐☐/☐☐☐☐ Assessor ID: ☐☐

Injection Complications *(please tick)*	**Start date of complication** *(dd/mm/yyyy)*	**Stop date of complication** *(dd/mm/yyyy)*	**Adverse Event Number**
Nausea Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Pruritus Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Ecchymosis, contusion Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Blister Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Rash Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Erythema Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Hyperhidrosis Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Pain in extremity Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Arthralgia Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Joint swelling Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐

Signature of person completing page: _____

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Participant Study Number: ☐☐☐☐

Injection Complications *(please tick)*	**Start date of complication** *(dd/mm/yyyy)*	**Stop date of complication** *(dd/mm/yyyy)*	**Adverse Event Number**
Myalgia Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Peripheral oedema, swelling Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Injection site haemorrhage, pain or swelling Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Tenderness Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Inflammation Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Small skin laceration (less than 1cm) Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Medium skin laceration (1-2cm) Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Large skin laceration (Larger than 2cm) Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Other (Please specify): Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐

Proceed to Section D

Signature of person completing page: Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Section D - Procedure Complications if RANDOMISED AND RECEIVED control (Limited fasciectomy surgery)

Tick here if the participant was not randomised to limited fasciectomy surgery and proceed to section E ☐

Please complete this section if RANDOMISED AND RECEIVED control (limited fasciectomy surgery). PLEASE DO NOT INCLUDE COMPLICATIONS ARISING FROM OTHER TREATMENTS.

Has the participant had any surgical complications since the 6 month visit? ☐ Yes ☐ No

If 'No', please proceed to Section E.

If 'Yes', please provide a Yes/No response to each of the following complications to confirm if the participant has been affected by that complication. If you have ticked yes, please provide the start/stop date of the event, or tick to confirm if it is continuing or ongoing.

Please complete a DISC Trial Adverse Event Form if the participant has had a complication.

Surgical Complications *(please tick)*		**Start date of complication** *(dd/mm/yyyy)*	**Stop date of complication** *(dd/mm/yyyy)*	**Adverse Event Number**
Amputation	Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Arterial injury	Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Bleeding	Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Pain	Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Scar pain	Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Complex Regional Pain Syndrome (CRPS)	Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐

Signature of person completing page: ☐

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Injection Complications *(please tick)*	**Start date of complication** *(dd/mm/yyyy)*	**Stop date of complication** *(dd/mm/yyyy)*	**Adverse Event Number**
Infection Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Instability Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Nerve Injury Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Paraesthesia (including dysaesthesia, burning and hyperaesthesia) Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Scar related complications (including hypertrophy) Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Delayed healing Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Edge necrosis Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Stiffness Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Swelling Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Tendon injury Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐

Signature of person completing page: _____ Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Injection Complications *(please tick)*	**Start date of complication** *(dd/mm/yyyy)*	**Stop date of complication** *(dd/mm/yyyy)*	**Adverse Event Number**
Carpal tunnel syndrome starting within six weeks of limited fasciectomy surgery Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Tenosynovitis starting within six weeks of limited fasciectomy surgery Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Trigger finger starting within six weeks of limited fasciectomy surgery Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐
Other (Please specify): Yes ☐ No ☐	☐☐ / ☐☐ / ☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐ Event is ongoing ☐	☐☐

Proceed to Section E

Signature of person completing page: Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Section E – Complications related to other treatments

Has the participant had any complications related to other treatments for Dupuytren's since the 6 month visit?

☐ **Yes** ☐ **No**

If '**Yes**', please complete the table below and complete a DISC Trial Adverse Event Form.

If '**No**', please proceed to Section F.

Brief Description of Other Treatment	Brief Description of Complication	Adverse Event Number
		☐☐
		☐☐
		☐☐

Proceed to Section F

Section F – Concomitant Medication

Has the participant been taking any concomitant medication since the 6 month visit?

Please cross-check Section F of the 6 month Investigator CRF when completing

☐ **Yes** ☐ **No**

If '**Yes**', please complete the table below.

If '**No**', please proceed to Section G.

	Medication	Reason for use	Is this a new medication since the 6 month visit?
1.			☐ Yes (new) ☐ No (existing)
2.			☐ Yes (new) ☐ No (existing)
3.			☐ Yes (new) ☐ No (existing)
4.			☐ Yes (new) ☐ No (existing)
5.			☐ Yes (new) ☐ No (existing)
6.			☐ Yes (new) ☐ No (existing)
7.			☐ Yes (new) ☐ No (existing)
8.			☐ Yes (new) ☐ No (existing)
9.			☐ Yes (new) ☐ No (existing)
10.			☐ Yes (new) ☐ No (existing)

Proceed to Section G

Signature of person completing page: Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Section G – Outpatient visits

THIS SECTION MUST NOT BE COMPLETED FOR OUTPATIENT VISITS PREVIOUSLY REPORTED IN THE TREATMENT DELIVERY, 3 MONTH AND 6 MONTH INVESTIGATOR CRFS.

Please record the details of any outpatient visits since the 6 month visit

1. **Have there been any outpatient visits?** ☐ Yes ☐ No

   If '**Yes**', please complete the information below for each outpatient visit

   If '**No**', please proceed to Section H.

---

2. **Date of outpatient visit** ☐☐ / ☐☐ / ☐☐☐☐ (*dd* / *mm* / *yyyy*)

3. **Clinic Type**

   ☐ Hand Surgery ☐ Pain Clinic ☐ Trauma & Orthopaedics

   ☐ Occupational therapy ☐ Plastic Surgery ☐ Rheumatology

   ☐ Physiotherapy ☐ Unknown

   ☐ Other (please specify): _____

4. **Was the visit related to the reference hand?** ☐ Yes ☐ No

5. **Was the visit related to the reference digit?** ☐ Yes ☐ No

6. **Was the visit related to a post-treatment complication or adverse event?** ☐ Yes ☐ No

   If '**Yes**', please complete a DISC Trial Adverse Event Form and complete details of the complication in Section C/D/E of the Investigator Case Report Form.

   Please confirm the Adverse Event Number ☐☐

   If '**No**', please provide a description of the event below:

Signature of person completing page: _____ Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

7. Did the patient receive actual treatment (as opposed to reassurance/observation)?

☐ Yes ☐ No

If '**Yes**', please specify the treatment/s received

☐ Physiotherapy ☐ Splinting of finger ☐ Wound Care

☐ Collagenase injection ☐ Limited Fasciectomy Surgery

☐ Dermofasciectomy ☐ Percutaneous Needle Fasciotomy

☐ Other (please specify)

Signature of person completing page:

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Section G – Outpatient visits (continued)

THIS SECTION MUST NOT BE COMPLETED FOR OUTPATIENT VISITS PREVIOUSLY REPORTED IN THE TREATMENT DELIVERY, 3 MONTH AND 6 MONTH INVESTIGATOR CRFS.

Please record the details of any outpatient visits since the 6 month visit

1. **Date of outpatient visit** ☐☐ / ☐☐ / ☐☐☐☐ (*dd* / *mm* / *yyyy*)

2. **Clinic Type**

☐ Hand Surgery ☐ Pain Clinic ☐ Trauma & Orthopaedics

☐ Occupational therapy ☐ Plastic Surgery ☐ Rheumatology

☐ Physiotherapy ☐ Unknown

☐ Other (please specify): _____

3. **Was the visit related to the reference hand?** ☐ Yes ☐ No

4. **Was the visit related to the reference digit?** ☐ Yes ☐ No

5. **Was the visit related to a post-treatment complication or adverse event?** ☐ Yes ☐ No

If '**Yes**', please complete a DISC Trial Adverse Event Form and complete details of the complication in Section C/D/E of the Investigator Case Report Form.

Please confirm the Adverse Event Number ☐☐

If '**No**', please provide a description of the event below:

_____

6. **Did the patient receive actual treatment (as opposed to reassurance/observation)?** ☐ Yes ☐ No

If '**Yes**', please specify the treatment/s received

☐ Physiotherapy ☐ Splinting of finger ☐ Wound Care

☐ Collagenase injection ☐ Limited Fasciectomy Surgery

☐ Dermofasciectomy ☐ Percutaneous Needle Fasciotomy

☐ Other (please specify) _____

Proceed to Section H

Signature of person completing page: _____ Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Section H – Accident & Emergency Visits

Please record the details of any Accident & Emergency visits since the 6 month visit

1. Have there been any Accident & Emergency visits? ☐ Yes ☐ No

If '**Yes**', please complete the information below for each Accident & Emergency visit

If '**No**', please proceed to Section I.

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2. Date of visit ☐☐ / ☐☐ / ☐☐☐☐
dd *mm* *yyyy*

3. HRG codes related to the visit Tick if not known ☐

☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐

4. Was the visit related to the reference hand? ☐ Yes ☐ No

5. Was the visit related to the reference digit? ☐ Yes ☐ No

6. Was the visit related to a post-treatment complication or adverse event? ☐ Yes ☐ No

If '**Yes**', please complete a DISC Trial Adverse Event Form and complete details of the complication in Section C/D/E of the Investigator Case Report Form.

Please confirm the Adverse Event Number ☐☐

If '**No**', please provide a description of the event below:

7. Did the patient receive actual treatment (as opposed to reassurance/observation)? ☐ Yes ☐ No

If '**Yes**', please specify the treatment/s received

☐ Wound Care

☐ Other (please specify)

8. Was the patient admitted as an inpatient following the visit? ☐ Yes ☐ No

If Yes, please complete Section I

Signature of person completing page:

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Section H – Accident & Emergency Visits (continued)

Please record the details of any Accident & Emergency visits since the 6 month visit

1. Date of visit | | | / | | | / | | | | |
dd *mm* *yyyy*

2. HRG codes related to the visit Tick if not known ☐

3. Was the visit related to the reference hand? ☐ Yes ☐ No

4. Was the visit related to the reference digit? ☐ Yes ☐ No

5. Was the visit related to a post-treatment complication or adverse event? ☐ Yes ☐ No

If '**Yes**', please complete a DISC Trial Adverse Event Form and complete details of the complication in Section C/D/E of the Investigator Case Report Form.

Please confirm the Adverse Event Number | |

If '**No**', please provide a description of the event below:

6. Did the patient receive actual treatment (as opposed to reassurance/observation)? ☐ Yes ☐ No

If '**Yes**', please specify the treatment/s received

☐ Wound Care

☐ Other (please specify)

7. Was the patient admitted as an inpatient following the visit? ☐ Yes ☐ No

If Yes, please complete Section I

Proceed to Section I

Signature of person completing page: Date *(dd/mm/yyyy)*: | | / | | / | | | | | Assessor ID: | |

Section I – Inpatient Admissions

THIS SECTION MUST NOT BE COMPLETED FOR INPATIENT ADMISSIONS PREVIOUSLY REPORTED IN THE TREATMENT DELIVERY, 3 MONTH AND 6 MONTH INVESTIGATOR CRFS.

Please record the details of any inpatient admissions since the 6 month visit

1. **Have there been any inpatient admissions?** ☐ Yes ☐ No

   If '**Yes**', please complete the information below for each inpatient admission

   If '**No**', please proceed to Section J.

---

2. **Date of admission** ☐☐ / ☐☐ / ☐☐☐☐ *dd / mm / yyyy*

3. **Date of discharge** ☐☐ / ☐☐ / ☐☐☐☐ *dd / mm / yyyy*

4. **HRG codes recorded at discharge** Tick if not known ☐

   ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐

5. **Was the admission related to the reference hand?** ☐ Yes ☐ No

6. **Was the admission related to the reference digit?** ☐ Yes ☐ No

7. **Was the admission related to a post-treatment complication or adverse event?** ☐ Yes ☐ No

   If '**Yes**', please complete a DISC Trial Adverse Event Form and complete details of the complication in Section C/D/E of the Investigator Case Report Form.

   Please confirm the Adverse Event Number ☐☐

   If '**No**', please provide a description of the event below:

8. **Did the patient receive actual treatment (as opposed to reassurance/observation)?** ☐ Yes ☐ No

   If '**Yes**', please specify the treatment/s received

   ☐ Physiotherapy ☐ Splinting of finger ☐ Wound Care

   ☐ Collagenase injection ☐ Limited Fasciectomy Surgery

   ☐ Dermofasciectomy ☐ Percutaneous Needle Fasciotomy

   ☐ Other (please specify)

Signature of person completing page: Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Section I – Inpatient Admissions (continued)

THIS SECTION MUST NOT BE COMPLETED FOR INPATIENT ADMISSIONS PREVIOUSLY REPORTED IN THE TREATMENT DELIVERY, 3 MONTH AND 6 MONTH INVESTIGATOR CRFS.

Please record the details of any inpatient admissions since the 6 month visit

1. **Date of admission** ☐☐ / ☐☐ / ☐☐☐☐ (*dd* / *mm* / *yyyy*)

2. **Date of discharge** ☐☐ / ☐☐ / ☐☐☐☐ (*dd* / *mm* / *yyyy*)

3. **HRG codes recorded at discharge** Tick if not known ☐

   ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐ ☐☐☐☐☐

4. **Was the admission related to the reference hand?** ☐ Yes ☐ No

5. **Was the admission related to the reference digit?** ☐ Yes ☐ No

6. **Was the admission related to a post-treatment complication or adverse event?** ☐ Yes ☐ No

   If '**Yes**', please complete a DISC Trial Adverse Event Form and complete details of the complication in Section C/D/E of the Investigator Case Report Form.

   Please confirm the Adverse Event Number ☐☐

   If '**No**', please provide a description of the event below:

7. **Did the patient receive actual treatment (as opposed to reassurance/observation)?** ☐ Yes ☐ No

   If '**Yes**', please specify the treatment/s received

   ☐ Physiotherapy ☐ Splinting of finger ☐ Wound Care

   ☐ Collagenase injection ☐ Limited Fasciectomy Surgery

   ☐ Dermofasciectomy ☐ Percutaneous Needle Fasciotomy

   ☐ Other (please specify)

Proceed to Section J

Signature of person completing page: Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Section J – Case Report Form Sign Off

		YES	NO
1.	All sections of the Investigator CRF have been completed	☐	☐
2.	All sections of the Participant Questionnaire Booklet have been completed	☐	☐
3.	Any adverse events have been reported appropriately (if applicable) or participant has confirmed that no adverse events have occurred	☐	☐
4.	A copy of all photographs taken have been sent to YTU	☐	☐

CRF Sign Off (To be completed by assessor (clinician or research nurse) taking responsibility for visit and CRF content)

Name: _____

Signature: _____

Assessor ID Number: ☐☐

Date: ☐☐ / ☐☐ / ☐☐☐☐
dd *mm* *yyyy*

Signature of person completing page: _____

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐