Dupuytren's Interventions Surgery vs Collagenase

Baseline Visit - Case Report Form

FOR STUDY INVESTIGATOR COMPLETION

Site ID: ☐☐

Participant Study Number: ☐☐☐☐

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

Note: Informed consent must be obtained prior to any procedures being undertaken, including completion of this form.

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

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

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

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

Participant Study Number: ☐☐☐☐ Visit date: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Section A: Demographic Data

Personal Details

1. Date of Birth ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

2. Gender ☐ Male ☐ Female

3. Ethnicity

White	Mixed Race	Asian or Asian British	Black or Black British	Chinese or other ethnicity
☐	☐	☐	☐	☐

4. Tobacco Smoking Status: ☐ Never ☐ Current ☐ Previous

5. Alcohol intake: ☐ Yes ☐ No If 'Yes' Units per week: ☐☐☐

6. Which hand is the patient's dominant hand? ☐ Left ☐ Right

Section B - Medical History

7. Has the patient previously experienced Dupuytren's contracture? ☐ Yes ☐ No
If 'Yes', please proceed to question 8.
If 'No', please proceed to question 12.

8. At what age did the patient first experience Dupuytren's contracture? ☐☐ years old

9. In which joints has the patient previously experienced Dupuytren's contracture?
(Please cross all that apply)

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

10. Has the patient previously received surgery for Dupuytren's contracture? ☐ Yes ☐ No
If 'Yes', in which joints has the patient previously received surgery for Dupuytren's contracture?
(Please cross all that apply)

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

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

11. Has the patient previously received collagenase injection for Dupuytren's contracture? ☐ Yes ☐ No

If 'Yes' in which joints has the patient previously received collagenase injection for Dupuytren's contracture? *(Please cross all that apply):*

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

12. Is there a family history of Dupuytren's contracture? ☐ Yes ☐ No
If 'Yes', please specify family member(s):

☐ Brother ☐ Sister ☐ Father ☐ Uncle ☐ Mother ☐ Aunt

☐ Other (please specify): _____

13. Does the patient have a history of Garrod's pads? ☐ Yes ☐ No

Does the patient currently have Garrod's pad's? ☐ Yes ☐ No

If 'Yes', which fingers show a clear Garrod's pad's? *(Please cross all that apply):*

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

14. Does the patient have a history of Peyronie's disease? ☐ Yes ☐ No ☐ Not applicable

15. Does the patient have a history of Ledderhose disease? ☐ Yes ☐ No

Does the patient currently have Ledderhose disease? ☐ Yes ☐ No

If 'Yes', which foot is affected? ☐ Left ☐ Right ☐ Both

Please provide the approximate size(s):

Left ☐☐.☐ cm Right ☐☐.☐ cm

Please proceed to Section B-1

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

Participant Study Number: ☐☐☐☐ Visit date: ☐☐ / ☐☐ / ☐☐☐☐
day month year

Section B-1: Comorbidity Record

Does the patient have any known comorbidities? ☐ Yes ☐ No

If 'No', please proceed to Section C

If 'Yes', please provide a response for all the conditions listed in the table below

Condition			Year first identified	Condition being treated at present		Is control satisfactory	
CHEST							
Heart Attack	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Chest Pains (or Angina)	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Rheumatic Fever	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Heart Murmurs	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Pacemaker fitted	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
High Blood Pressure	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
RESPIRATORY							
Shortness of Breath (when resting)	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Chronic Bronchitis	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Asthma	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Tuberculosis	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Pneumonia	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Pleurisy	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Coughing up blood	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Clot in Lung (PE)	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
BRAIN							
Nervous Problems	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Depression	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Epilepsy	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Migraine	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Mini Strokes (TIA)	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Stroke	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No

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

Condition			Year first identified	Condition being treated at present		Is control satisfactory	
DIGESTIVE							
Frequent Indigestion	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Hiatus Hernia	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Stomach Ulcer	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Jaundice	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
BLOOD							
Hepatitis (A, B or C)	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
HIV or AIDS	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Anaemia	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Blood problems e.g. sickle cell, leukemia	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Serious bruising or bleeding	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Leg clots (DVT)	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
URINARY							
Kidney problems	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Urinary problems	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
ENDOCRINE							
Thyroid problems	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Diabetes	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
CANCERS							
Cancer	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
MUSCULOSKELETAL							
Back problem	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Neck or jaw problem	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
Arthritis	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
INFECTIONS							
MRSA	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No
CDiff diarrhoea	☐ Yes	☐ No	☐☐☐☐	☐ Yes	☐ No	☐ Yes	☐ No

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

Does the patient have any other chronic illness not listed in the table? ☐ Yes ☐ No

If 'Yes', please specify and provide further detail as per table above (i.e. Year first identified, Is the condition being treated at present?, Is control satisfactory?)

If there are any co-morbid conditions that are not currently controlled satisfactorily, please cross here to indicate that the participant is still suitable to undergo treatment as part of the DISC trial. ☐

If the participant is not suitable to undergo treatment as part of the DISC Trial please proceed to Section F.

Patient is using anticoagulants (for reasons other than a diagnosed coagulation disorder)? ☐ Yes ☐ No

Patient using anti-platelet agents (eg aspirin, clopidogrel)? ☐ Yes ☐ No

Please proceed to Section C

Section C: Concomitant Medication

Please record all concomitant medication used by the participant in the 6 months prior to this visit.

Is the subject taking any concomitant medications? ☐ Yes (complete below) ☐ No

1.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

2.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

3.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

4.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

5.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

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

6.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

7.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

8.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

9.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

10.

Medication:	Reason for use:	Dose:	Units:	Frequency:	Route:

Start Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ Stop Date (dd/mm/yyyy) ☐☐ / ☐☐ / ☐☐☐☐ unknown ☐ **OR** cross if ongoing at time of Baseline visit ☐

Has the patient used Tetracycline antibiotics in the last 14 days? ☐ Yes ☐ No

If 'Yes', patient must not receive study intervention until 14 days have elapsed

Please proceed to Section D

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

Section D: Clinical Assessment

1. Which hand is currently affected by Dupuytren's contracture?
(Please cross all that apply e.g. if both hands are affected then cross both boxes)

☐ Left Hand ☐ Right Hand

2. How many digits are currently affected by Dupuytren's contracture? ☐☐

3. Which digits and joints are affected?

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

4. How many joints are affected in total on the hand that will be treated? ☐☐

5. How many joints are you planning to treat? ☐☐

6. Which hand, digit and joint will be designated as reference for this study?
(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

Please proceed to Section E

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

Section E: 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)

Please also complete measurements for any other affected digits using the DISC Supplementary Page for Joint Measurements.

Please tick to confirm which digit this assessment relates to:

☐ Thumb ☐ Index ☐ Middle ☐ Ring ☐ Little

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 (Passive Extension)

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

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

Please also complete measurements for any other affected digits using the DISC Supplementary Page for Joint Measurements.

Please tick to confirm which digit this assessment relates to:

☐ Thumb ☐ Index ☐ Middle ☐ Ring ☐ Little

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 (camera directly above the hand) ☐ Yes ☐ No

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

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

Please proceed to Section F

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

Section F: Checklist

1. Does the participant meet all inclusion criteria? ☐ Yes ☐ No
2. Does the participant meet any of the exclusion criteria? ☐ Yes ☐ No
3. Is the participant still willing to proceed in the trial? ☐ Yes ☐ No

If 'No', please provide details: _____

4. All sections of the Investigator CRF have been completed as required? ☐ Yes ☐ No
5. All sections of the Participant CRF have been completed? ☐ Yes ☐ No
4. A copy of all photographs taken have been sent to York Trials Unit? ☐ Yes ☐ No

Please proceed to Section G

Section G: Randomisation

Date of Randomisation* ☐☐ / ☐☐ / ☐☐☐☐
day / month / year

Randomised to receive: ☐ Intervention (collagenase) ☐ Control (surgery)

If allocated to intervention (collagenase), has a prescription been requested? ☐ Yes ☐ No

Date surgery or injection scheduled for: (if known) ☐☐ / ☐☐ / ☐☐☐☐
day / month / year

*It is expected that randomisation will be completed on the same day as Baseline, or immediately following the visit.

Please proceed to Section H

Section H: Case Report Form Sign Off

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

Name: _____ Signature: _____

Assessor ID: ☐☐ Date: ☐☐ / ☐☐ / ☐☐☐☐
day / month / year

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