Report Supplementary Material 15 Change in Status Form

UK FROST TRIAL: CHANGE IN STATUS FORM

Guidance Instructions

- This form is very important for the UK FROST Trial Team to understand what changes have occurred to a patient after they have been enrolled into the study. This will help us monitor any changes to the treatment that patients are receiving and/or how we are collecting data on patients.

- Therefore the Research Nurse/Associate should complete this form when the following occurs:

  - **A patient died**
  - **A patient did not start or complete their randomised treatment i.e. one of the trial treatments available to the patients in the study**:
    - Early Structured Physiotherapy
    - Manipulation Under Anaesthesia (MUA) with injection and discharged from post-procedural physiotherapy
    - Arthroscopic Capsular Release (ACR) with MUA and discharged from post-procedural physiotherapy
  - **A patient had any further trial treatment after completion of their randomised treatment**
  - **A patient had any 'non-trial' treatment** e.g. ACR without MUA, Arthrographic (or ultrasound guided) capsular distension etc.
  - **A patient withdraws from questionnaire follow-up.**

- Please follow the instructions in the form as to which sections should be completed. You may also find that the flowchart overleaf helps you to identify which sections of the form to complete.

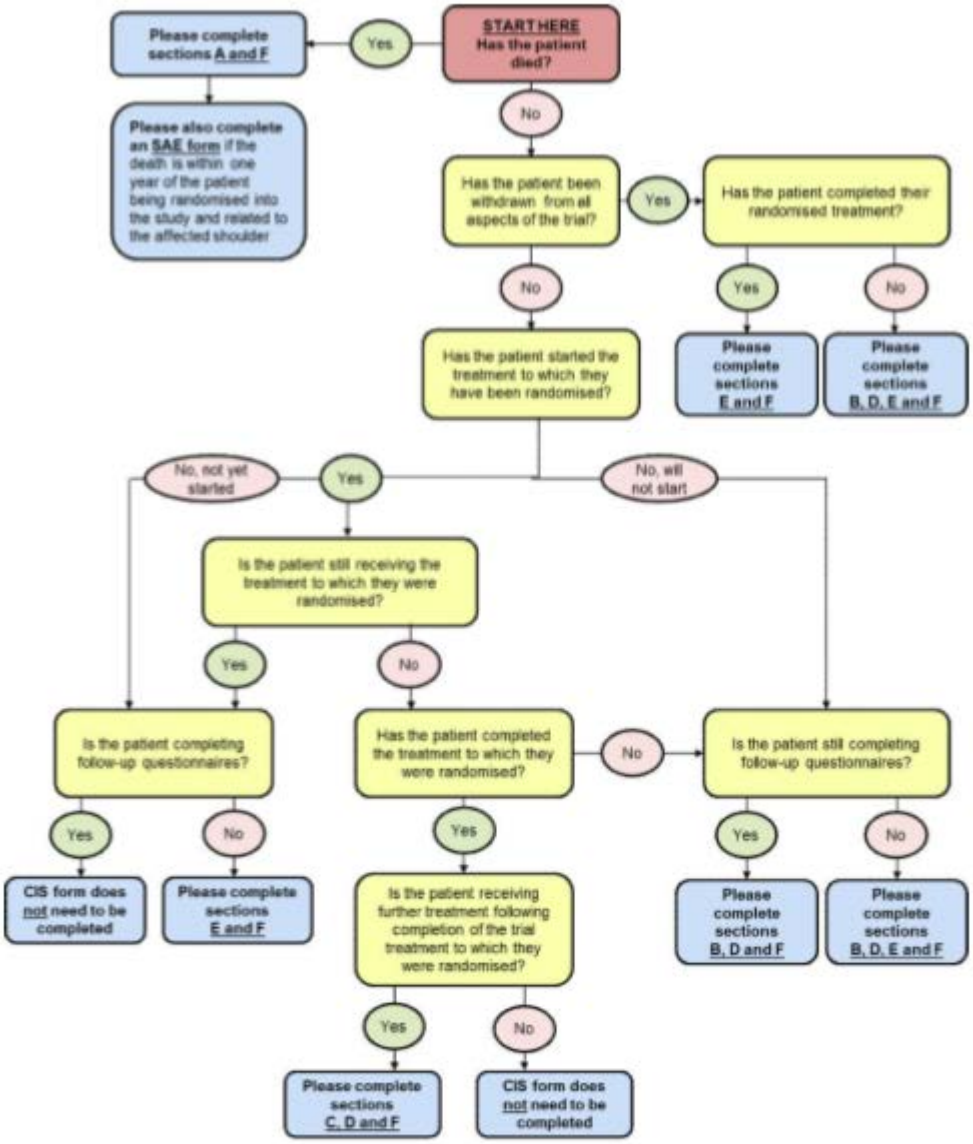
- Please complete the form at the earliest opportunity when you are aware that any of the above has occurred. We also need you to check every 3 months (throughout the 12 months that the patient is enrolled into the study) using hospital e-system or patient notes as to whether this form needs to be completed.

- You should only provide details about changes to treatment in a hospital setting. We will collect details on a 'non-trial' treatment delivered outside of the hospital directly from the patient.

- The 'further treatment' that we refer to in Section C concerns the treatment that patients receive having completed their randomised treatment. This could be one of the other two trial treatments or a 'non-trial' treatment. This 'further treatment' is for the purpose of treating ongoing symptoms of the patient's frozen shoulder and not for a complication of their treatment.

- **If you have recorded a change in the patient's treatment this should NOT change how the patient is followed up with data collection unless the patient informs you otherwise.**

- **Please do not withdraw any patient from the trial without consulting the UK FROST Trial team.**


START HERE
Has the patient died?
Yes
Please complete sections A and F
Please also complete an SAE form if the death is within one year of the patient being randomised into the study and related to the affected shoulder
No
Has the patient been withdrawn from all aspects of the trial?
Yes
Has the patient completed their randomised treatment?
Yes
No
Please complete sections E and F
Please complete sections B, D, E and F
No
Has the patient started the treatment to which they have been randomised?
No, not yet started
Yes
No, will not start
Is the patient still receiving the treatment to which they were randomised?
Yes
No
Is the patient completing follow-up questionnaires?
Yes
No
CIS form does not need to be completed
Please complete sections E and F
Has the patient completed the treatment to which they were randomised?
No
Is the patient still completing follow-up questionnaires?
Yes
Is the patient receiving further treatment following completion of the trial treatment to which they were randomised?
Yes
No
Please complete sections C, D and F
CIS form does not need to be completed
Yes
No
Please complete sections B, D and F
Please complete sections B, D, E and F

UK FROST TRIAL: CHANGE IN STATUS FORM

Participant ID: ☐☐☐☐

Section 1

Please place a cross in a box next to the single most appropriate statement below and proceed as requested.

☐ The patient has died	**Complete Sections A, F**
☐ The patient has not died	**Complete Section 2**

Section 2

Please place a cross in a box next to the single most appropriate statement below and proceed as requested.

☐ The patient is not starting or not completing their randomised treatment but will still complete follow-up questionnaires.	**Complete Sections B, D, F**
☐ The patient will no longer complete follow-up questionnaires but is still receiving their randomised treatment.	**Complete Sections E, F**
☐ The patient will be withdrawn from all aspects of the trial (before completion of their randomised treatment).	**Complete Sections B, D, E, F**
☐ The patient will be withdrawn from all aspects of the trial (after completion of their randomised treatment).	**Complete Sections E, F**
☐ The patient is receiving further treatment following completion of their randomised treatment.	**Complete Sections C, D, F**

Section A: Patient died

1. Date of death: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)
2. Cause of death (if known): _____
3. Was the death within one year of the patient being randomised into the study and related to the affected shoulder? ☐ Yes ☐ No

   If 'Yes' complete a Serious Adverse Event Form.

Section B: Patient did not start or not complete their randomised treatment

1. Date of treatment withdrawal: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)
2. Reason for treatment withdrawal *(Please cross one box only)*

☐ Patient decided not to start/complete Early Structured Physiotherapy programme

☐ Patient decided not to have Manipulation Under Anaesthesia (MUA) with injection

☐ Patient decided not to have Arthroscopic Capsular Release with MUA

☐ Clinician decided to change the patient's treatment allocation. Please specify the reason: _____

☐ Other reason. Please specify the reason: _____

3. Did the patient receive any other treatment? *(Please cross one box only)*

☐ Early Structured Physiotherapy Programme	Date started: ☐☐ / ☐☐ / ☐☐☐☐
☐ Manipulation Under Anaesthesia (MUA) with injection	Date of operation: ☐☐ / ☐☐ / ☐☐☐☐
☐ Arthroscopic Capsular Release with MUA	Date of operation: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)
☐ Other (Please give details in Section D)	
☐ None	

Section C: Any further trial treatment after completion of randomised treatment

Completed randomised treatment *(Please cross one box only)*	Further trial treatment *(Please cross one box only)*	Record further trial treatment details if known (including start date)
☐ Early Structured Physiotherapy Programme (completed when discharged)	☐ Early Structured Physiotherapy (following the trial surgery interventions)	day / month / year
☐ Manipulation Under Anaesthesia (MUA) with injection and discharged from post-procedural physiotherapy	☐ Manipulation Under Anaesthesia (MUA) with injection	day / month / year
☐ Arthroscopic Capsular Release with MUA and discharged from post-procedural physiotherapy	☐ Arthroscopic Capsular Release with MUA	day / month / year

Section D: Any 'non-trial' treatment (please skip this section if there was no 'non-trial' treatment intervention)

(Please cross all boxes that apply)

1. What alternative 'non-trial' treatment did the patient receive and record the date?

☐ Arthroscopic capsular release without MUA — Date delivered: day / month / year

☐ Arthrographic (or ultrasound guided) capsular distension — Date delivered: day / month / year

☐ Other physiotherapy — Date started: day / month / year

☐ Other. Please specify: _____ — Date started/delivered: day / month / year

Please record the reason for and details of the 'non'-trial treatment in the box below:

Section E: Withdrawal from questionnaire follow-up

1. Date of follow-up withdrawal: day / month / year

2. Please place a cross in the box next to all statements that apply:

☐ The patient does not want further follow-up data to be collected

☐ The patient agrees to hospital data to continue to be collected by the trial team

☐ The patient wants their contact details to be removed

3. Please specify the reason why the patient's follow-up status has changed:

4. Who decided to change the patient's follow-up status? *(Please cross all boxes that apply)*

Participant ☐ Clinician ☐ Relative ☐

Section F: Sign-off

Name of person completing the form: _____ Signature: _____ Date: day / month / year