SOP 2

Version 1

Date: 02/09/2025

Guidance for collection of baseline and follow-up data – DISCLOSE TRIAL

This standard operating procedure (SOP) provides instructions for the collection of baseline and follow-up data in the trial titled:

A Randomised Controlled Trial Comparing No Reduction to Closed Reduction for Distal Radius Fractures in Patients 65 Years and Older (DISCLOSE trial)

DISCLOSE

Role Overview

Study nurses or other designated research personnel are responsible for coordinating patient follow-up, collecting baseline and outcome data, maintaining blinding, supporting patient communication, and ensuring data integrity in compliance with GCP and trial protocol.

Trial Steering Committee sincerely appreciates the vital role study nurses and other research personnels play in ensuring the success of the DISCLOSE trial.

Remember to remain blinded - **do not open the patient's ER visit text under any circumstances.**

Baseline Data Collection

- Contact patient **within 2 working days** of randomisation.
- Enter patient's unique Trial Identification Number (TIN) and Personal identification number (PIN) to key code register, stored in the hospital database (varies between study sites).
- Collect all baseline variables **via telephone interview** (blinded to group allocation) to REDCap modules:
    - **Baseline (**including **Clinical Frailty Scale [CFS])**
        - CFS is built into REDCap as consecutive questions that reveal the classification at the end
    - **Baseline PRWE+NRS+EQ-5D-5L**
        - Baseline questionnaires represent the symptoms **BEFORE the injury.**

Follow-Up Visits

- Schedule follow-up assessments at **3 months** and **12 months**.
- Offer both **in-person and remote follow-up** options:
    - **In-person**: assist with questionnaires, ensure radiographs taken at 3 months
    - **Remote**: send questionnaires and wrist accelerometers by mail, conduct interviews by phone if needed
- Ensure **blinding** to treatment allocation is maintained at all times.

Patient Communication

- Provide **clear instructions** for completing PROMs and using the accelerometer wristbands.
- Be available for **questions or concerns**, especially regarding pain, discomfort, or complications.

- Direct patients to **contact emergency services or treating physician** for urgent clinical issues.

Adverse Events

- Document and report any **adverse events** per protocol to electronic Case Report Form instrument under REDCap module *Events*.
- Report all events to the local primary investigator.
- Ensure any crossovers are clearly documented.

Observational Arm

- Coordinate remote follow-up for patients in the **observational cohort** using the same schedule and tools.
- Maintain equal attention to data collection and blinding for these participants.