DISCLOSE

SOP 3

Version 1

Date: 02/09/2025

Collection and Registration of AEs - DISCLOSE TRIAL

This standard operating procedure (SOP) provides instructions for the collection and registration of serious adverse events (SAEs) from informed consent until 12 months 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)

Collection:

- SAEs are recorded from the time informed consent is given until 12 months after the intervention.
- SAEs are collected via:
    1. Observations by the treating clinicians
    2. The patient's electronic medical record
    3. Follow-up visits or calls at 3 months and 12 months

Registration:

The treating staff will report events to the local research team and the primary investigator (PI), who then collect and record adverse events directly into the patient's electronic Case Report Form via the "Events" module in REDCap.

The start and end dates of the event are documented during patient follow-up to record the event outcome. The Trial Steering Committee automatically receives an email notification whenever an event is registered. The local PI then evaluates the event's relationship to the study treatment and determines its severity (SAEs). For SAEs, the PI must notify the Steering Committee within 24 hours of becoming aware of them.