Prove
Physiotherapy Rehabilitation of Osteoporotic Vertebral Fracture

Adverse Events:

Has the patient experienced any Adverse Events since signing the Informed Consent?

Yes ☐ No ☐

If an adverse event has occurred please use DATIX (incident reporting system) to log and describe event and note below

Adverse Event 1	Details
Date of event: __ __ / __ __ / __ __ __ __	Diagnosis if known or signs and symptoms:
Logged on DATIX Yes ☐ No ☐	Severity 1 = Mild 2= Moderate 3 = Severe
Action Taken	
Outcome 1= Resolved 2 = Recovered with sequelae 3= Continuing	
Withdrawn from study due to SAE? 1= No 2= Yes, happy for existing data to be used 3= Yes, data destroyed	

Adverse Event 2	Details
Date of event: __ __ / __ __ / __ __ __ __	Diagnosis if known or signs and symptoms:
Logged on DATIX Yes ☐ No ☐	Severity 1 = Mild 2= Moderate 3 = Severe
Action Taken	
Outcome 1= Resolved 2 = Recovered with sequelae 3= Continuing	
Withdrawn from study due to SAE? 1= No 2= Yes, happy for existing data to be used 3= Yes, data destroyed	

Add more pages if there are more than 2 adverse events.

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OFF STUDY FORM

Date Off Study: __ __ / __ __ / __ __ __ __
(DD/MM/YYYY)

Date Of Last Assessment: __ __ / __ __ / __ __ __ __
(DD/MM/YYYY)

Reason Off Study (Please mark only the primary reason. **Reasons other than Completed Study require explanation next to the response**)

- ☐ AE/SAE **(complete AE CRF & SAE form, if applicable**_____
- ☐ Lost to follow-up_____
- ☐ Non-compliant participant _____
- ☐ Medical contraindication ___ _____
- ☐ Withdraw consent _____ _____
- ☐ Death **(complete SAE form)** _____
- ☐ Other _____