MATREX TRIAL - ADVERSE EVENT REPORT FORM

PATIENT DETAILS

Recruiter initials:	Patient initials:	Hospital Number:	Trial ID:	Trial arm:

DETAILS OF ADVERSE EVENT (see overleaf for checklist)

Description / diagnosis	Date of onset	Resolution date	Did AE occur during treatment?	In the opinion of the physiotherapist, was the event related to the therapy Name of Physio:_____

Brief description of the course of the AE and the outcome, including details of any investigations and treatments:

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Details of follow-up action (see reporting procedure overleaf): ……

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ADVERSE EVENT	OBSERVATION
Increased intracranial pressure	• Disorientation • Loss of consciousness • Enlarged pupils • Headache • Vomiting
Acute hypotension	• Pallor • Sweating • Reduced consciousness
Pulmonary haemorrhage	• Visible loss of blood
Dysrhythmia	• Pallor • Sweating • Chest pain • Reduced consciousness
Vomiting & aspiratation	• Visible vomit • Harsh breathing • Oropharyngeal sounds • Prolonged coughing
Hypoxia	• Falling O_2 sats • Tachpnoea • Blue lips • Tachycardia • Confusion
Bronchospasm	• Tight chest • Audible wheeze • Abdominal paradox
Pain or injury to muscles, ribs, or spine	• Patient response
Other event you, the physiotherapist or other clinician consider adverse to the patient	• Record detail

ACTION	BY WHOM
Report AE in line with individual Trust's Incident Reporting Procedures	Trial Recruiter
Provide Trust R&D Manager with copy of Adverse Event Report form	Trial Recruiter
Report AE to Trial Manager	Trial Recruiter
Report AE to Site Lead Investigator	Trial Recruiter
Consider individual AEs and report any concerns to Trial Manager	Site Lead Investigator
Collate and report monthly AEs to Trial Management Group (TMG)	Trial Manager
Consider monthly AEs and report any concerns to DMEC & TSC	TMG
Collate and report bi-annual AEs to Data Monitoring & Ethics Committee (DMEC)	Trial Manager
Consider bi-annual AEs and report to Trial Steering Committee (TSC)	DMEC
Consider DMEC report on AEs and report to funder	TSC

ADVERSE EVENT REPORTING PROCEDURE: