Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number : 2017-003875-77
B.2 Sponsor's protocol code number: 1870
B.3 Full title of the trial : : Morphine or Intravenous Paracetamol in Acutely Injured Neck of Femur Fractures

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	☐
C.1.1	Sponsor	☑
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below**:	
C.1.4.1	Organisation : University Hospitals of North Midlands NHS Trust	
C.1.4.2	Name of person to contact : Professor Tony Fryer	
C.1.4.3	Address : Royal Stoke University Hospital, University Hospitals of North Midlands NHS Trust, Newcastle Road, Stoke-on-Trent, Staffordshire, ST4 6QG	
C.1.4.4	Telephone number : 01782 675378	
C.1.4.5	Fax number : 01782 675399	
C.1.4.6	E-mail: Anthony.Fryer@uhnm.nhs.uk	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	☑
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
•	Co-ordinating investigator (for multicentre trial):	☐
•	Principal investigator (for single centre trial):	☐
C.2.5	**Complete below** :	
C.2.5.1	Organisation: University Hospitals of North Midlands NHS Trust	
C.2.5.2	Name : Professor Tony Fryer	
C.2.5.3	Address : Royal Stoke University Hospital, University Hospitals of North Midlands NHS Trust, Newcastle Road, Stoke-on-Trent, Staffordshire, ST4 6QG	
C.2.5.4	Telephone number : 01782 675378	
C.2.5.5	Fax number : 01782 675399	
C.2.5.6	E-mail : Anthony.Fryer@uhnm.nhs.uk	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial?**
D.1.1	(YYYY/MM/DD): 2019/03/26

D.2	**Is it an early termination?**[3]	yes ☑ no ☐

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.
2 According to national legislation.
3 Cf. Section 4.2. of the detailed guidance CT-1.

D.2.1 If yes, give date (YYYY/MM/DD): 2019/03/26

Briefly describe in an annex (free text): As Sponsor we were unable to continue with the planned methodology of the trial due to the legislative issue around the administering of IMP and placebo by the paramedics. We had been told by the MHRA legal team that the paramedics are unable to administer the trial IMP as per the current protocol (i.e. As saline is a prescription medicine it can only be delivered in the same line as active drug under the written direction of a doctor for a named patient). After discussion with the TSC we have taken the unfortunate decision to now longer continue with the proposed trial as it would require a complete rewrite of the protocol as well as resubmission to the REC and MHRA for approval to be run as an open label study.

D.2.1.1 The justification for early termination of the trial; legislative issue around the administering of IMP and placebo by the paramedics

D.2.1.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; 0

D.2.1.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product; No participants have been screened or recruited to the trial.

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[4]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	☑
E.2.1	Date :	26/3/19
E.2.2	Signature :	A. A. Fryer
E.2.3	Print name:	A. A. FRYER

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) :	☑
E.3.1	Date :	26/3/19
E.3.2	Signature :	A. A. Fryer
E.3.3	Print name:	A. A. FRYER

[4] Section 4.3. of the detailed guidance CT-1.