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 : Finland

B TRIAL IDENTIFICATION

B.1 EudraCT number : (2016-002251-13)
B.2 Sponsor's protocol code number: (24052016)
B.3 Full title of the trial :The effect of intravenous single-dose dexamethasone on pain after total knee replacement surgery. Laskimonsisäisen deksametasonin kerta-annoksen vaikutus polven tekonivelleikkauksen jälkeiseen kipuun.

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	**X**
C.1.1	Sponsor	**X**
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 :Oulu university hospital	
C.1.4.2	Name of person to contact :Matti Kyllönen	
C.1.4.3	Address :OpTA anestesia PL 21 90029 OYS Finland	
C.1.4.4	Telephone number :050 5794380	
C.1.4.5	Fax number :	
C.1.4.6	E-mail matti.kyllonen@ppshp.fi	

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:	
C.2.5.2	Name :	
C.2.5.3	Address :	
C.2.5.4	Telephone number :	
C.2.5.5	Fax number :	
C.2.5.6	E-mail :	

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):

D.2	**Is it an early termination?**[3]	yes **X** 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): 2018/04/10
D.2.2	Briefly describe in an annex (free text): Recruitment was much more difficult than expected: mostly due to co-morbidities of the patients screened for the study. The main investigator quit working in the department, in which the study was conducted.
D.2.2.1	The justification for early termination of the trial; Through 2017/02/15 – 2018/01/09 only 27 patients of the planned 96 were recruited and completed the study protocol, thus anticipated duration of the study exceeded 3 years. We weren't able to find a new main investigator.
D.2.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; 0 patients.
D.2.2.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. It's not possible to evaluate the effect of dexamethasone on pain or make risk-benefit assessment, due to the small amount of recruited patients. No adverse effects caused by dexamethasone were observed.

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that (delete which is not applicable):

- The above information given on this declaration is correct.

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	**X**
E.2.1	Date :12.2.2019	
E.2.2	Signature :	
E.2.3	Print name: Matti Kyllönen	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☐
E.3.1	Date :	
E.3.2	Signature :	
E.3.3	Print name:	