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 : (2019-003604-12)
B.2 Sponsor's protocol code number: (ITM201902)
B.3 Full title of the trial : Evaluation of a chlorhexidine mouthwash for the eradication of asymptomatic pharyngeal Neisseria gonorrhoeae infection

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 : Institute of Tropical Medicine	
C.1.4.2	Name of person to contact : Dr. Chris Kenyon	
C.1.4.3	Address : Nationalestraat 155, 2000 Antwerpen - België	
C.1.4.4	Telephone number : /	
C.1.4.5	Fax number : /	
C.1.4.6	E-mail: ckenyon@itg.be	

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: Institute of Tropical Medicine	
C.2.5.2	Name : Dr. Chris Kenyon	
C.2.5.3	Address : Nationalestraat 155, 2000 Antwerpen - België	
C.2.5.4	Telephone number : /	
C.2.5.5	Fax number : /	
C.2.5.6	E-mail : ckenyon@itg.be	

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): 2021/03/23

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 (2021/03/23):
D.2.2 Briefly describe in an annex (free text):
D.2.2.1 The justification for early termination of the trial;
As mentioned in the approved protocol, an interim analysis was planned after the first 5 participants reached the primary endpoint, to assess the success rate and continuation of the study. Of these 5 participants *Neisseria gonorrhoeae* (NG) eradication should have been confirmed by culture by day 7 in at least 4 out of this 5 participants. Only if this was confirmed, enrollment of the next participant would have started.

A total of 6 participants were enrolled in the study, 3 of who had a negative NG lab result at day 1 and were exited from the study. The remaining 3 subjects had a positive NG result at day 7. As these 3 remaining subjects all had a positive NG result at day 7, the required criteria of a negatived NG result at day 7 for at least 4 out of the first 5 participants could never be reached.

Therefore it was decided, after discussion and approval of the study's data safety monitor, to terminate the study early.
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;
All patients had excited the study at the time of early termination.
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.
The stopping rule, on which the early termination has been based upon, was incorporated into the protocol. Therefore this early termination will not affect the evaluation of the results and the overall risk benefit assessment of the investigational medicinal product.

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 :31 MAR 2021
E.2.2 Signature :

E.2.3 Print name: Dr. Chris Kenyon

E.3 APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) **:** ☒

E.3.1 Date : 31 MAR 2021

E.3.2 Signature :

E.3.3 Print name: Dr. Chris Kenyon

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