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 :	2016-003941-27
B.2 Sponsor's protocol code number:	UMCN-AKF16.06/Hep-NED004
B.3 Full title of the trial : Bioequivalence study of CRUshed Sofosbuvir/velpAtasvir compareD to the wholE tablet (CRUSADE-1)/Hep-NED004	

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 : Radboud university medical center	
C.1.4.2	Name of person to contact : David M. Burger	
C.1.4.3	Address : Geert Grooteplein-Zuid 10	
C.1.4.4	Telephone number : +31 24 3617744	
C.1.4.5	Fax number : +31 24 3668755	
C.1.4.6	E-mail : david.burger@radboudumc.nl	

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: Radboud university medical center	
C.2.5.2	Name : David M. Burger	
C.2.5.3	Address : Geert Grooteplein-Zuid 10	
C.2.5.4	Telephone number : +31 24 3617744	
C.2.5.5	Fax number : +31 24 3668755	
C.2.5.6	E-mail : david.burger@radboudumc.nl	

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): 2019/03/22

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): 2019/03/22
D.2.2 Briefly describe in an annex (free text):
D.2.2.1 The justification for early termination of the trial;
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;
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 reason for early termination of the trial is the lack of patients who are eligible for inclusion. Since the approval date we have not been able to include any patient. There are two main reasons;

1. The number of patients treated for HCV has decreased significantly. Therefore, there are less patients starting HCV treatment in the participating facilities.
2. In most cases treatment with the new combination Maviret® is shorter than treatment with Epclusa®. This is an important reason for patients to choose for treatment with Maviret®.

We expect that we are not able to include the desired amount of patients in the participating facilities and it is not feasible for us to expand the trial to other facilities. Therefore, we decided to end the study without risking an incomplete amount of included patients.

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 :
E.2.2	Signature :
E.2.3	Print name:

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:

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