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 :	2019-001061-32
B.2 Sponsor's protocol code number:	mRNA-3704-P101
B.3 Full title of the trial :	A Global, Phase 1/2, Open Label, Dose Escalation Study to Evaluate the Safety, Pharmacodynamics, and Pharmacokinetics of mRNA-3704 in Patients with Isolated Methylmalonic Acidemia Due to Methylmalonyl-CoA Mutase Deficiency

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: NDA Regulatory Science Ltd.	
C.1.4.2	Name of person to contact: [redacted]	
C.1.4.3	Address : Grove House, Guildford Road, Leatherhead, KT22 9DF, UK	
C.1.4.4	Telephone number : [redacted]	
C.1.4.5	Fax number : [redacted]	
C.1.4.6	E-mail: [redacted]	

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 :	

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

2 According to national legislation.

D END OF TRIAL

D.1 Date of the end of the trial in this Member State ? [3]	yes ☒ no ☐
D.1.1. (2020/08/18):	

D.2 Date of the end of the complete trial in all countries concerned by the trial? [3]	yes ☒ no ☐
D.2.1 (2020/08/18):	

D.3 Is it an early termination? [4]	yes ☒ no ☐
D.3.1 If yes, give date (2020/08/18):	
D.3.2 Briefly describe in an annex (free text):	
D.3.2.1 The justification for early termination of the trial; **Provided as an annex at the end of this document.**	
D.3.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; **Provided as an annex at the end of this document.**	
D.3.2.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. **Provided as an annex at the end of this document.**	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm on behalf of the sponsor that:

- 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.[5]

E.2 APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1)	☒
E.2.1 Date : 1st September 2020	
E.2.2 Signature : [redacted]	
E.2.3 Print name: [redacted]	

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:	

[3] In case of a multi-country trial, if the national and global end of trial dates are different in a given Member State, the sponsor shall submit this form two times :

1) At the end of the trial in the individual Member State, section D1.1. shall be completed and submitted to the respective National Competent Authority.

2) At the global end of the trial, the sponsor shall complete section D.2.1. with the global trial end date and the completed form shall be submitted to all participating Member States in order to allow the sponsor to prepare the trial result summary within the 12-months (or 6-months in case of paediatric trials) timeframe.

If the national and global end dates coincide in a concerned Member State, the form shall be submitted only once to the National Competent Authority of this Member State with both sections D1.1. and D2.1 complete.

[4] Cf. Section 4.2. of the detailed guidance CT-1.

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

Justification for Early Termination

Justification for Early Termination

Sequence and process improvements have been made to the mRNA-3704 Drug Substance. The MHRA has indicated that the changed product is considered a new IMP and recommended that a new CTA be filed for the clinical trial. In light of this feedback, Moderna is terminating the mRNA-3704-P101 study.

Number of Patients Receiving Treatment at the Time of Early Termination

At the time of termination, one patient was enrolled, underwent clinical assessments during the observations period. However, no treatment was administered to this patient.

Consequences of the Early Termination

As no patients were treated with mRNA-3704, there are no consequences to this early termination.