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 : ***GERMANY***

B TRIAL IDENTIFICATION

B.1 EudraCT number :	***2021-000706-21***
B.2 Sponsor's protocol code number:	***AT-GTX-501-02, Amendment 3 dated 10 November 2021*** *(approved by CA, submitted to the EC for authorization on 25 Nov 2021)*
B.3 Full title of the trial :	***LONG-TERM FOLLOW-UP OF AT-GTX-501 SCAAV9 GENE TRANSFER IN SUBJECTS WITH CLN6 BATTEN DISEASE***

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	☐
A.1.1	Person or organisation authorised by the sponsor to make the application.	☒
C.1.3		
C.1.4	**Complete below**:	
A.1.1.1	Organisation :	*CTI Clinical Trial and Consulting Services Europe GmbH*
C.1.4.1	Name of person to contact :	*Dr. Günter Stetter*
C.1.4.2	Address :	*Schillerstrasse 1/15, Ulm, 89077, Germany*
C.1.4.3	Telephone number :	*0049 731 400084 12*
C.1.4.4	Fax number :	*0049 731 400084 29*
C.1.4.5	E-mail:	*gstetter@ctifacts.com*

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	☐
A.1.2	Person or organisation authorised by the sponsor to make the application.	☒
C.2.3		
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:	*CTI Clinical Trial and Consulting Services Europe GmbH*
C.2.5.2	Name :	*Dr. Günter Stetter*
C.2.1.1	Address :	*Schillerstrasse 1/15, Ulm, 89077, Germany*
C.2.5.3	Telephone number :	*0049 731 400084 12*
C.2.5.4	Fax number :	*0049 731 400084 29*
C.2.5.5	E-mail :	*gstetter@ctifacts.com*

[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. ***09 Dec 2021***	

D.2	**Date of the end of the complete trial in all countries concerned by the trial**?[3]	yes ☐ no ☒
D.2.1	(YYYY/MM/DD):	

D.3	**Is it an early termination?[4]**	yes ☒ no ☐
D.3.1	If yes, give date ***09 Dec 2021***	
D.3.2	Briefly describe in an annex (free text):	

The justification for early termination of the trial; ***The decision was made to require only remote visits moving forward in the study. Therefore, opening a site in Germany was no longer deemed necessary. All enrolled patients will be followed up with virtual visits at currently open sites.***

D.3.2.1 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;

In Germany, there were no patients enrolled for the AT-GTX-501-02 study.

D.3.2.2 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.
The sponsor anticipates minimal risk to the evaluation of the study results as patients will continue to be followed remotely for safety and the primary efficacy endpoint of Hamburg scoring. The sponsor feels that this minimal risk is far outweighed by the benefit of not subjecting patients to further travel for study visits.

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.[5]

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[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.

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	☒
E.2.1	Date :	20-Dec-2021 | 12:56:59 PM EST
E.2.2	Signature :	DocuSigned by: Günter Stetter Signer Name: Günter Stetter Signing Reason: I approve this document Signing Time: 20-Dec-2021 | 12:56:54 PM EST A1F9004FFAEB485696C054526CCF3584
E.2.3	Print name: ***Dr. Günter Stetter***	

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:	

DocuSign

Certificate Of Completion

Envelope Id: 5E07E8738F124B329900335BCB96B2EC
Status: Completed
Subject: Please DocuSign: 02.1_AT-GTX-501-02_DE_CA_EOT Declaration Form_20Dec2021.pdf
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Document Pages: 3
Signatures: 1
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Günter Stetter gstetter@ctifacts.com VP Global Regulatory Affairs Study Start-up CTI Clinical Trial and Consulting Services Europe GmbH Security Level: Email, Account Authentication (Required)	Günter Stetter Signature Adoption: Pre-selected Style Signature ID: A1F9004F-FAEB-4856-96C0-54526CCF3584 Using IP Address: 78.43.56.158 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 12/20/2021 12:51:21 PM Viewed: 12/20/2021 12:56:22 PM Signed: 12/20/2021 12:56:59 PM
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In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	12/20/2021 12:51:21 PM
Certified Delivered	Security Checked	12/20/2021 12:56:22 PM
Signing Complete	Security Checked	12/20/2021 12:56:59 PM
Completed	Security Checked	12/20/2021 12:56:59 PM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

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