NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE UK COMPETENT AUTHORITY

To be filled in by the applicant

A TRIAL IDENTIFICATION

A.1 EudraCT number: **(2019-003172-40)**
A.2 Sponsor's protocol code number: **(19/GAS/276)**
A.3 Full title of the trial: **High dose Loperamide in patients with intestinal failure (IF): plasma concentration and electrocardiogram (ECG) changes.**

B APPLICANT IDENTIFICATION (please tick the appropriate box)

B.1	**DECLARATION FOR THE MHRA**	
B.1.1	Sponsor	☒
B.1.2	Legal representative of the sponsor	☐
B.1.3	Person or organisation authorised by the sponsor to make the application.	☐
B.1.4	**Complete below**:	
B.1.4.1	Organisation: **University Hospitals Plymouth NHS Trust**	
B.1.4.2	Name of person to contact: **Dr Chris Rollinson**	
B.1.4.3	Address: **University Hospitals Plymouth NHS Trust | The Research Office | Level 2 MSCP | Bircham Park Offices | 1 Roscoff Rise | Derriford | Plymouth | PL6 5FP**	
B.1.4.4	Telephone number: **01752 431045**	
B.1.4.5	Fax number: **N/A**	
B.1.4.6	E-mail: **crollinson@nhs.net**	

C END OF TRIAL

C.1	**Is this the end of the trial in the UK only**? [1]	**Yes** ☒	No ☐
C.1.1	If yes, give date (YYYY/MM/DD): **2022/11/01**		

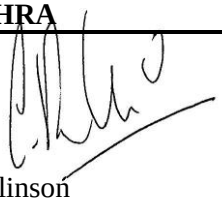
C.2	**Is this the end of the complete trial in all countries concerned by the trial**? [1]	**Yes** ☒	No ☐
C.2.1	If yes, give date (YYYY/MM/DD): **2022/11/01**		

C.3	**Is it an early termination?**	**Yes** ☒	No ☐
C.3.1	If yes, give date (YYYY/MM/DD): **2022/11/01**		
C.3.2	Briefly describe in an annex (free text): **COVID-19 pandemic required the study be placed on hold as resources were diverted to urgent public health studies. A subsequent issue regarding the validation of the UoP HPLC equipment has meant the study is currently no longer viable.**		
C.3.2.1	The justification for early termination of the trial; **Failure to validate HPLC equipment and methodology**.		
C.3.2.2	Number of patients still receiving treatment at time of early termination in the UK and their proposed management; **Nil**		
C.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: **No results to evaluate and therefore, no overall risk benefit assessment of the investigational medicinal product**		

D SIGNATURE OF THE APPLICANT IN THE UK

D.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

D.2	**APPLICANT TO THE MHRA**
D.2.1	Date: 01st Dec 2022
D.2.2	Signature: 
D.2.3	Print name: Christopher Rollinson

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

1) At the end of the trial in the UK, section C1.1. shall be completed and submitted to the MHRA.

2) At the global end of the trial, the sponsor shall complete section C.2.1. with the global trial end date and the completed form shall be submitted to the MHRA 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, the form shall be submitted only once to the MHRA with both sections C1.1. and C2.1 complete.