SERIOUS ADVERSE EVENT (SAE) REPORT FORM

Please submit the SAE Report Form within 24hours of becoming aware of the event to the Northern Ireland Clinical Trials Unit by Email: clinicaltrials@nictu.hscni.net

You are not required to enter the SAE form onto the MACRO EDC database.
This will be completed by staff at the Northern Ireland Clinical Trials Unit

REPORT DETAILS					
Type of Report:	☐ Initial ☐ Follow Up, Number _____				
TRIAL DETAILS					
Protocol Acronym:	**MARCH**	**Protocol No:**	**20131DMcA-AS**	**EudraCT No:**	**2021-003763-94**
SITE DETAILS					
Site Number:		**Site Name:**			
PATIENT DETAILS					
Participant Study Number:		**Patient Initials:**		**Date of Birth:** DD MM YYYY	**Sex:** ☐ Male ☐ Female

EVENT DETAILS	
Date of Onset of Serious Adverse Event:	DD MM YYYY
Date Site Became Aware of the Event:	DD MM YYYY
Seriousness (Why was the Event Serious?):	☐ Resulted in death ☐ Is life-threatening ☐ Requires hospitalisation or prolongation of existing hospitalisation ☐ Results in persistent or significant disability or incapacity ☐ Consists of a congenital anomaly or birth defect ☐ Other Important Medical Event
If Other, please specify:	
If Resulted in Death, Date of Death:	DD MM YYYY
Cause of Death:	

Main Diagnosis/Symptom (SAE Term)	**Severity/Grade[1]**	**SAE Status[2]**	**Date Resolved**
			DD MM YYYY

[1]Severity/Grade:	1 = Mild (Grade 1)	2 = Moderate (Grade 2)	3 = Severe (Grade 3)	4 = Life Threatening (Grade 4)	5 = Death (Grade 5)
[2]SAE Status:	1 = Resolved	2 = Resolved with Sequelae	3 = Unresolved	4 = Fatal	

Please indicate which treatment group the patient is in:							
Carbocisteine	☐	Hypertonic Saline	☐	Carbocisteine & Hypertonic Saline	☐	Usual Airway Clearance Management	☐

Trial Mucoactive	**Causality[1]**	**Expectedness[2]**	**Please provide date of approved Reference Safety Information used**
			Date (if applicable)
Carbocisteine			DD MM YYYY
Hypertonic Saline			DD MM YYYY

[1]Causality:	1 = Not related	2 = Unlikely	3 = Possibly	4 = Probably	5 = Definitely	6 = N/A
	Indicate the extent to which the event may be related to the study drug.					

[2]Expectedness:	1 = Expected	2 = Unexpected	3 = N/A
	If 'Causality' is graded as Possibly, Probably or Definitely related please indicate whether the event is 1 = Expected or 2 = Unexpected as per the Reference Safety Information. If 'Causality' is graded as Not Related or Unlikely to be related, please record 'Expectedness' as 3 = N/A.		

If the event is related and unexpected it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and requires expedited reporting in collaboration with the NICTU and within regulatory timelines.

ASSESSMENT OF EVENT COMPLETED BY (This section must be completed by a medically qualified investigator)					
Name:		**Signature:**		**Date Assessed:**	DD MM YYYY

DESCRIPTION OF EVENT:

Provide a medical description of the event including, any treatment given and any relevant tests (e.g. lab tests) carried out.
Continue on separate sheet if necessary.

Trial Mucoactive	Date of First Administration	Date of Most Recent Administration	Dose at Most Recent Administration	Units[1]	Route[2]	Action Taken with Trial Drug[3]	Date Trial Drug Stopped (if applicable)
Carbocisteine	DD MM YYYY	DD MM YYYY					DD MM YYYY
Hypertonic Saline	DD MM YYYY	DD MM YYYY					DD MM YYYY

[1]Units:	1 = Milligram (mg)	2 = Microgram (µg)	3 = Gram (g)	4 = Millilitre (ml)	5 = Tubs/tubes	6 = Puffs/inhalers
	7 = Drops	8 = Spray(s)	9 = Bottles	10 = Packs	11 = International Unit (IU)	12 = Other
[2]Route:	1 = Enteral	2 = Nebulised	3 = Oral	4 = Other		
[3]Action Taken:	1 = None	2 = Dose Reduced	3 = Treatment Delayed	4 = Treatment Reduced & Delayed	5 = Treatment Stopped	6 = Other

DETAILS OF TRIAL MUCOACTIVE REDUCTION AND/OR DELAY OR OTHER ACTION TAKEN:

If trial mucoactive was reduced and/or delayed, specify length of delay and how much dose was reduced by.
If 'Other' action was taken, please provide details below.

TREATMENT GIVEN FOR MANAGEMENT OF THE SERIOUS ADVERSE EVENT (SAE)

Was the patient given any medication to treat the event? ☐ Yes ☐ No

Drug Name	Total Daily Dose	Units[1]	Route[2]	Start Date	Ongoing	Stop Date
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY
				DD MM YYYY	☐ Yes ☐ No	DD MM YYYY

CONCOMITANT MEDICATIONS

Was the patient on any concomitant medications? ☐ Yes ☐ No

Drug Name	Total Daily Dose	Units[1]	Route[2]	Start Date	Ongoing	Stop Date
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY
					☐ Yes ☐ No	DD MM YYYY

[1]Units:	1 = Milligram (mg)	2 = Microgram (µg)	3 = Gram (g)	4 = Millilitre (ml)	5 = Tubs/tubes	6 = Puffs/inhalers
	7 = Drops	8 = Spray(s)	9 = Bottles	10 = Packs	11 = International Unit (IU)	12 = Other
[2]Route:	1 = IV	2 = Oral	3 = Subcutaneous	4 = Other		

MEDICAL HISTORY

Any relevant medical history/concurrent conditions? ☐ Yes ☐ No

OTHER RELEVANT INFORMATION?

Any other relevant information? ☐ Yes ☐ No

ADDITIONAL INFORMATION

Was trial mucoactive taken as per protocol?	☐ Yes	☐ No	☐ N/A		
Was the patient withdrawn from the study because of the event?	☐ Yes	☐ No			

REPORTERS DETAILS

Name:		**Signature:**		**Date:**	DD MM YYYY

FOR CTU USE ONLY		FOR CLINICAL REVIEWER USE ONLY	
Date Received:	DD MM YYYY	**Event:** ☐ SAE ☐ SAR ☐ SUSAR	
Form Received By:		**Comments:**	
SAE Event No.:			
If Event was a SUSAR		**Preferred Term**	
Date Reported to Sponsor:	DD MM YYYY	**Body System Organ Class**	
Date Reported to MHRA:	DD MM YYYY	**Date Reviewed:**	DD MM YYYY
Date Reported to Ethics:	DD MM YYYY	**Reviewer Signature:**	