Participant ID Number:	☐☐☐☐☐☐	Participant Gender:	Male ☐ Female ☐
Participant Initials:	☐☐☐	Participant Date of Birth:	☐☐ / ☐☐☐ / ☐☐☐☐

PD COMM

Serious Adverse Event Form

TO BE COMPLETED FOR SERIOUS ADVERSE EVENTS ASSOCIATED WITH VOCAL STRAIN OR ABUSE, OCCURRING WITHIN THE PROTOCOL-DEFINED REPORTING PERIOD

1. Site Details			
Site Name:		Name of PI:	
2. Report type (use BCTU allocated unique SAE number if this is a follow-up or final report)			
Initial Report	☐		
Follow-up Report	☐ Please insert Unique SAE number ☐☐☐☐☐☐ / ☐☐		
Final Report	☐ Please insert Unique SAE number ☐☐☐☐☐☐ / ☐☐		
3. Event Information			
Signs and Symptoms			
4. Event Diagnosis			
Diagnosis			

Event Severity	☐ Mild ☐ Moderate ☐ Severe

5. Seriousness of Event				
Seriousness of event (please provide a response to each question)	Yes	No	Details	
Death	☐	☐	Date of death:	☐☐ / ☐☐☐ / ☐☐ ☐☐
			Cause of death:	
Life threatening event	☐	☐		
In-patient hospitalisation or prolongation of existing hospitalisation	☐	☐	Initial	☐
			Prolonged	☐
			Date of discharge:	☐☐ / ☐☐☐ / ☐☐ ☐☐
Persistent or significant disability/incapacity	☐	☐		
Congenital anomaly or birth defect	☐	☐		

Participant ID Number:	☐☐☐☐☐☐	Participant Gender:	Male ☐ Female ☐
Participant Initials:	☐☐☐	Participant Date of Birth:	☐☐ / ☐☐☐ / ☐☐☐☐

Other medical reason for reporting?	☐	☐	Please specify

6. Details of Event

Date of Onset	☐☐ / ☐☐☐ / ☐☐☐☐	Date became serious	☐☐ / ☐☐☐ / ☐☐☐☐
Date became aware	☐☐ / ☐☐☐ / ☐☐☐☐	Tick if ongoing	☐
Date resolved (if applicable)	☐☐ / ☐☐☐ / ☐☐☐☐	☐ Resolved no sequelae ☐ Resolved with sequelae (give details below)	
Details of sequelae (if appropriate)			
Is the event listed in the protocol as an expected SAE?	Yes ☐	If Yes, please insert reason code from current protocol ☐	
	No ☐	If No, please send to BCTU within 24 hours with relevant reports	

7. Causality Asssessment

Relatedness to Trial Treatment **1**=Unrelated to trial treatment or procedure **2**=Unlikely to be related to trial treatment or procedure **3**=Possibly related to trial treatment or procedure **4**=Probably related to trial treatment or procedure **5**=Definitely related to trial treatment or procedure Codes 1 or 2 will ultimately be classified as unrelated, codes 3-5 will be classifed as related *If the event is classified as (1)unrelated or (2)unlikely to be related, please provide details of an alternative explanation for the event*	☐ Please select a code number from the left and give reason below:
What action was taken?	
List any underlying comorbidities, concomitant medications or investigations etc. that may be relevant.	*(Where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only).*

8. Details of person reporting

Participant ID Number:	☐☐☐☐☐☐	Participant Gender:	Male ☐ Female ☐
Participant Initials:	☐☐☐	Participant Date of Birth:	☐☐/☐☐☐/☐☐☐☐

Name of person reporting	Job title of person reporting		Date reported
			☐☐/☐☐☐/☐☐☐☐
Signature of person reporting (must appear on delegation log)		Date of signature	☐☐/☐☐☐/☐☐☐☐
Signature of Principal Investigator or medically qualified delegate		Date of PI/delegate signature	☐☐/☐☐☐/☐☐☐☐

Once complete, please fax form to 0121 415 9135 and ring PD COMM Trial Office (0121 415 9127) to confirm receipt

9. TO BE COMPLETED BY THE CHIEF INVESTIGATOR OR NAMED DELEGATE

Review of relatedness to the study by Chief Investigator or delegate	Related ☐	Unrelated ☐
1=Unrelated to trial treatment or procedure **2**=Unlikely to be related to trial treatment or procedure **3**=Possibly related to trial treatment or procedure **4**=Probably related to trial treatment or procedure **5**=Definitely related to trial treatment or procedure Codes 1 or 2 will ultimately be classified as unrelated, codes 3-5 will be classifed as related *If the event is classified as (1)unrelated or (2)unlikely to be related, please provide details of an alternative explanation for the event*	☐ Please select a code number from the left and give reason below:	
Assessment of expectedness with reference to the Protocol by Chief Investigator or delegate	Expected ☐	Unexpected ☐
Is the event related and unexpected? *Serious related and unexpected events require reporting to the REC and sponsor*	Yes ☐	No ☐

10. Signatures - In signing this form the Investigator or delegate confirms the **Causality** and **Expectedness** of the event

Name of Chief Investigator or delegate	Signature of CI or delegate	Date of CI or delegate signature
		☐☐/☐☐☐/☐☐☐☐

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SAE Reference Number	☐☐☐☐☐☐/☐☐
Date reported to REC	☐☐/☐☐☐/☐☐☐☐
Date reported to Sponsor	☐☐/☐☐☐/☐☐☐☐