**Confidential Once Completed** Please answer all the questions

PD COMM Trial No.: P☐☐☐☐ | Participant DOB: MMM / YYYY | Participant Initials: ☐☐☐

For information on how to complete this form, refer to page 2

## Adverse Events Log

**Page No:**

Has the participant experienced any Adverse Events (AEs) **associated with vocal strain or abuse believed to be related to trial treatment** since beginning protocol defined SLT treatment?

No ☐ ---> Completed by: Name _____ Signature: _____ Date: DD / MMM / YYYY

Yes ☐ ---> Specify below

| AE no. | Adverse Event (diagnosis (if known) or signs/symptoms) | Start Date & Stop Date | Status of AE<br>1= Resolved no sequelae<br>2= Resolved sequelae<br>3= Continuing | Severity/grade<br>1=Mild<br>2=Moderate<br>3=Severe<br>4=Life threatening<br>5=Death | Action taken with PD COMM SLT intervention<br>1 = None<br>2 =Treatment interrupted<br>3 = Dose reduced<br>4 = Discontinued<br>5 = Other (state) | Does this adverse event fulfil the definition of serious?<br>If yes, please ensure this has been reported to the Trials Office on an SAE form | Completed by |
|---|---|---|---|---|---|---|---|
| | | START DD/MMM/YYYY<br>STOP DD/MMM/YYYY | | | | No ☐<br>Yes ☐ | Name:_____<br>Signature:_____<br>Date: DD / MMM / YYYY |
| | | START DD/MMM/YYYY<br>STOP DD/MMM/YYYY | | | | No ☐<br>Yes ☐ | Name:_____<br>Signature:_____<br>Date: DD / MMM / YYYY |
| | | START DD/MMM/YYYY<br>STOP DD/MMM/YYYY | | | | No ☐<br>Yes ☐ | Name:_____<br>Signature:_____<br>Date: DD / MMM / YYYY |

**Only Adverse Events associated with vocal strain or abuse should be reported on this form. Adverse Events should only be reported up until 30 days after the last trial intervention has been given. Please remember to ask the participant at the last treatment session for any Adverse Events and let them know they can report this to you within the next 30 days.**

**Complete one form per participant in the LSVT or standard NHS therapy arm**. Fill in all participant identifiers.

**AE number**: Adverse Event numbers should allocated chronologically as they are recorded.

**Start & Stop Date**: If the AE has not resolved, record the 'Status of AE' as continuing.

**Severity/grade**: The severity of an AE should be classified accordingly:

1. Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
2. Grade 2 Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL*.
3. Grade 3 Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL**.
4. Grade 4 Life-threatening consequences; urgent intervention indicated.
5. Grade 5 Death related to AE.

*Activities of Daily Living (ADL)*
**Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.*
***Self care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.*

AEs highlighted in red (grade 4, 5 and potentially 3) meet the definition of Serious (see below) and so should be reported to the Trials Office within 24 hours awareness (see protocol).

**Does this adverse event match the definition of serious?** The definition of a Serious Adverse Event is an untoward event that involves any of the following:

1. results in death;
2. is life-threatening*;
3. requires hospitalisation** or prolongation of existing hospitalisation;
4. results in persistent or significant disability or incapacity;
5. or, is otherwise considered medically significant by the Investigator

**The term "life-threatening" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.*