

Change of Status Form



PD COMM Trial Participant Number <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Participant initials: _ _ _	Date of Birth: : _____ MMM / YYYY
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For instructions on how to complete this form, see page 2

Has the participant died? No Yes

If Yes: date of death DD / MMM / YYYY cause of death:

Is the participant ineligible? No Yes

If yes, what is the reason for ineligibility:.....

If yes, will participant exit the trial?* No Yes *please ensure this has been discussed with the Trials Office

If Yes, date of trial exit DD / MMM / YYYY

Participant would like:

1. To discontinue completing questionnaires? No Yes

If Yes, date of decision DD / MMM / YYYY and reason

2. To discontinue completing HBT diaries (if applicable)? No Yes N/A

If Yes, date of decision DD / MMM / YYYY

3. To discontinue clinical data being supplied to the Trials Office? No Yes

If Yes, date of decision DD / MMM / YYYY

4. To discontinue trial treatment (if applicable)? No Yes N/A

If Yes, date of decision DD / MMM / YYYY

5. Other: No Yes

If Yes, date of decision DD / MMM / YYYY

Please give further details

Reason for discontinuing.....

If a participant answers 'yes' to 1, 2 (if applicable), 3 and 4 (if applicable) then they are to be considered as completely withdrawn from the PD COMM trial. Anything less than this, indicates trial involvement in some capacity – i.e. partial withdrawal.

If the participant has completely withdrawn (see above guidance), are they willing for data provided **prior** to their withdrawal to still be used in the trial analysis? No Yes N/A

Your patient was randomised to the (please circle):
Lee Silverman Voice Treatment / Standard NHS SLT / Control group.

Please answer the appropriate question for the participant:

If randomised to the control group, was Speech and Language therapy prescribed in the last 12 months?
No Yes if yes, please give details

If randomised to SLT, did they receive additional SLT after completing their trial treatment?
No Yes if yes, please give details (including the type of SLT)
.....

Form completed by (print name):

Signed: Date: DD / MMM / YYYY

Confidential upon completion

Once complete, store original in Site File and send a copy to BCTU

Form completion guidelines:

This form should be completed in order to notify the Trials Office that the patient has either died, has been found to be ineligible, or has withdrawn (either partially or completely).

“Has the participant died?” - This section should be used to notify the Trials Office of a participant’s death. Please notify the Trials Office as soon as possible upon awareness so that no questionnaires are sent to the deceased’s home.

“Is the participant ineligible?” – This section should be used to notify the Trials Office if a participant is found to be ineligible after randomisation. It is possible that a participant may be required to exit the trial or allowed to continue in it, dependant on advice from the Trials Office, so ensure this is discussed with them.

“Participant would like” – This section is used to record either partial or complete withdrawal from the PD COMM trial. Non-compliance, such as not turning up to treatment appointments, or failing to complete a questionnaire, does not constitute a partial or complete withdrawal unless the participant states they no longer intend to continue with one or more aspects of the trial.

Partial withdrawal is therefore when the participant overtly states they wish to discontinue with certain aspects of the trial but are happy to continue with others (ie will continue to receive trial treatment but no longer want to complete questionnaires). A participant is only considered as fully withdrawn if they answer ‘yes’ to all questions applicable to them in this section.

NB: Whenever a participant mentions withdrawing from the PD COMM trial, it is important to discuss with them exactly what it is they want to withdraw from, and that partial withdrawal as an option is made clear to them. If at all unsure on how to complete this section of the form, contact the Trials Office.