Summary Patient Information Sheet

A Study of 2 different treatments for Patients with Chronic Obstructive Pulmonary Disease

"Study Evaluating the Efficacy of Breztri/Trixeo on Cardiopulmonary Outcomes in Chronic Obstructive Pulmonary Disease (COPD)"

Thank you for showing an interest in this study. This summary sheet gives a brief overview of the study. The Main Patient Information Sheet provides more detail. You can ask us for more information at any point.

Condition Studied		Study Length	Number of visits	
Chronic Obstructive Pulmonary Disease		Up to 3 years	7 visits in the first year (3 in- person), then 1 virtual visit every 6 months for year 2 and 3, then 1 visit 4-weeks after the last dose	
What will the study involve?				
	Visit 1 (Screening Visit) Onsite Visit		Post-Bronchodilator Spirometry Blood collection and Vital Signs observations Commence Bevespi which is taken twice daily	
	Visit 2 (Randomisation Visit) Onsite Visit		Return previous Bevespi and commence either Bevespi or Trixeo that is taken twice daily Four-Meter-Gait Speed Test Health and Medication Review	
	Visit 3, 5, 6, 7, 8 ,9, 10, 11 Virtual Visits using phone ap	p	Health and Medication Review Bevespi/Trixeo re-supplied and old supply returned (all medication returned at Visit 11)	
	Visit 4 Onsite Visit		Health and Medication Review Bevespi/Trixeo re-supplied and old supply returned	
CD	Follow-Up Virtual Visit		Health and Medication Review	

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Could I be eligible to take part?			
 You must Be aged between 40-80 years. Have good inhaler-use technique. Be diagnosed with COPD. Be a current or former smoker. Have a cardiovascular risk. 	 You must not Have any other respiratory condition aside from COPD. Have had a heart or lung transplant or actively be listed for a transplant. Have a history of lung cancer and/or treatment for this in the last 5 years. Have used maintenance Inhaled Corticosteroids in the last 12months. Be unable to comply with study procedures, restrictions, or requirements. Be a currently pregnant female. 		

Why participate?

Information gained from this study may help in developing a more effective treatment for people with COPD.

You will be reimbursed for your travel and any meals or refreshments whilst attending your study visits. You can decide to stop taking part at any time.

Are there risks?

There are always risks with taking part in any study. There are risks associated with the study medication and risks associated with the study procedures.

These are described fully in the Main Patient Information Sheet.