

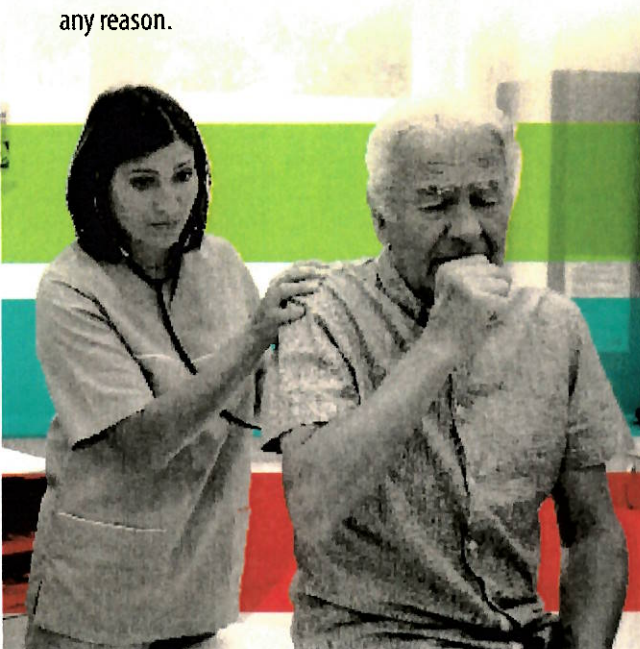
effects; therefore, it is possible that participants may experience some discomforts.

■ **What are the potential benefits of participating?**

Participants may or may not receive any personal benefit from participating in the TRITON Study. This study, however, may help to find new options to treat COPD. New information received from this study may help to answer questions that doctors and medical researchers have about maintenance therapies for COPD.

■ **What are the next steps?**

If you think participating in the TRITON Study may be right for you, please talk with your family and your doctor. If you wish to take the next step toward possible participation, or if you have more questions, please contact us as directed on the back of this brochure. Contacting us does not obligate you to participate in this research study, and if you decide to participate, you may withdraw at any time for any reason.



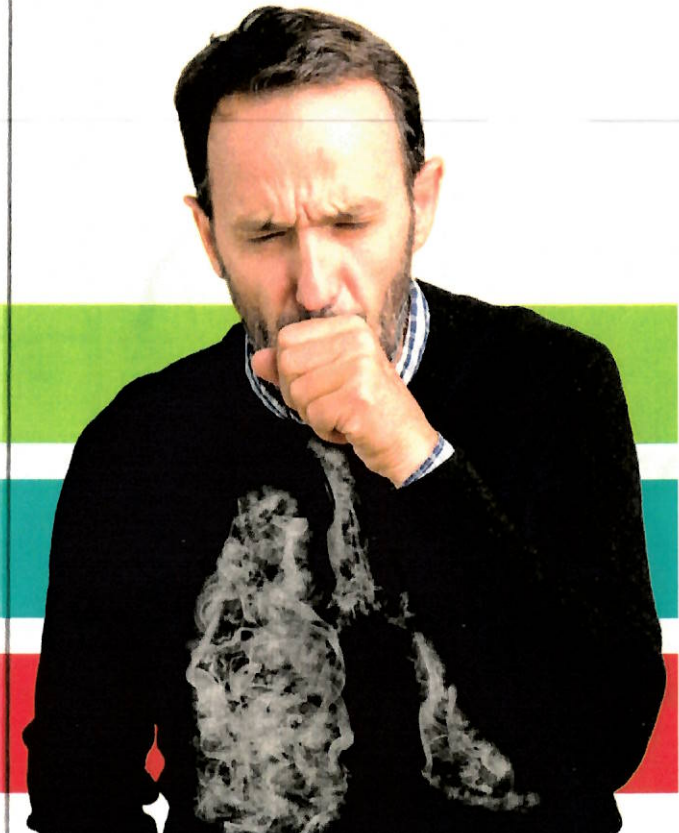
TRITON

For more information about the TRITON Study,
please contact:

DO YOU HAVE COPD?

If so, perhaps you can join the TRITON Study
and possibly help find better treatment options
for future sufferers of COPD. Learn more.

TRITON



The World Health Organization estimates that 65 million people worldwide have moderate to severe COPD. COPD is a major cause of disability and is expected to become the leading cause of death globally within the next two decades.

The severity of COPD symptoms varies. However, COPD can have a dramatic impact on the quality of life of those living with it, and severe COPD can limit everyday activities. A sudden worsening of symptoms, called an “exacerbation”, can lead to serious complications. This is why it is so important that we learn more about new ways to treat COPD, which is the goal of the TRITON Study.

There is no cure for COPD, but there are some treatments available for doctors to prescribe. For people with advanced symptoms or a high risk of exacerbations, doctors often prescribe a daily maintenance treatment of an inhaled corticosteroid (ICS). The ICS is usually combined with a longer-acting drug that belongs to a group of drugs known as a LAMA (long-acting muscarinic antagonist) or LABA (long-acting beta-2 agonist).

The drug being researched in the TRITON Study (the “Study Drug”), combines an ICS with drugs from both the LAMA and LABA drug groups. The primary purpose of the TRITON Study is to see how safe the Study Drug is and how well it works to control the symptoms of COPD.

■ What is the TRITON Study researching?

All participants in the TRITON Study will receive an active treatment. One-half of the participants will receive the Study Drug, a combination of 3 drugs in a single inhaler. The Study Drug is approved for use in Europe and is sold under the name of Trimbow®. The other half of the study participants will receive a combination treatment that combines two drugs in a single inhaler (an ICS and a LABA). The second treatment is also approved in Europe and is sold under the name of

Foster®. Both of these combination treatments are being investigated in the US. All drugs that make up these combinations are well-known and approved for use in the US as stand-alone drugs.

■ Who can participate in the TRITON Study?

To join the TRITON Study, potential study participants must satisfy the following requirements:

- Be at least 40 years of age
- Have had COPD for at least 12 months with current symptoms
- Be a current or ex-smoker
- Have had a COPD exacerbation in the past 12 months that either:
 - Required hospitalization; OR
 - Required oral/injected corticosteroids and/or antibiotics
- Must be taking a daily inhaled maintenance therapy for their COPD

There are additional requirements to participate. The staff at the study center will explain the complete list of requirements.

■ What will happen during the TRITON Study?

The study doctor’s staff will first give a detailed explanation of the TRITON Study and its potential risks and benefits. This explanation will be made verbally and in writing. Only after obtaining written consent from the potential participant will study-specific procedures take place. Study staff will give instructions regarding medications that should not be taken before the next visit, as well as fasting requirements. Rescue medication (albuterol or salbutamol) will be dispensed in case it is needed.

Next, the study doctor and the doctor’s staff will conduct a series of study-related examinations to see if the study participant satisfies all the requirements to participate in the TRITON Study.

If requirements are met, participants will be given an electronic diary to record daily symptoms.

Study participants who qualify will be assigned to receive either the Study Drug or the double-combination treatment. The chances of being assigned to either treatment is 50%, like flipping a coin. Neither the study participants nor their study doctor will know which treatment has been assigned.

During the 52-week treatment period, study participants will take one dose of the Study Drug (two inhalations, or “puffs”) in the morning and one dose in the evening. Participants will record their doses in their electronic diary daily, along with assessments of their COPD symptoms once a day.

The TRITON Study will involve approximately 2,934 study participants.

■ How long will the study last?

Complete participation in the TRITON Study will last about 55 weeks and will involve 12 visits to the study center. There will be a telephone follow-up visit with study personnel about one week after the last study visit.

■ Does it cost anything to participate?

There is no cost to participate. Qualified participants receive their assigned drug as well as all required study-related medical assessments and examinations at no cost. Compensation for time and travel expenses incurred as a result of study participation may be available to those who satisfy applicable requirements.

■ Are there any risks to participating in this research study?

There may be potential risks to participating in the TRITON Study. All drugs and medical procedures carry a risk of side