

ongoing trials - trial from other registries

## **A Phase 3 Double-blind, Randomized, Placebo-controlled Study Evaluating the Efficacy and Safety of ELX/TEZ/IVA in Cystic Fibrosis Subjects 6 Years of Age and Older With a Non-F508del ELX/TEZ/IVA-responsive CFTR Mutation**

**Code:** EudraCT Number: 2021-005320-38 **Year:** 2021 **Date:**

**Author:**

### **Study design (if review, criteria of inclusion for studies)**

Controlled: Yes.1 Randomised: Yes.2 Open: No.3 Single blind: No.4 Double blind: Yes.5 Parallel group: No.6 Cross over: No

### **Participants**

Subjects (male or female) 6 years of age and older with stable CF disease, FEV1 value >40% and

### **Interventions**

The efficacy and pharmacodynamics (PD) of ELX/TEZ/IVA

### **Outcome measures**

Primary end point(s): Absolute change from baseline in percent predicted forced expiratory volume in 1 second (ppFEV1) through Week 24

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-005320-38/ES/>

### **Keywords**

Adult; Aged; CFTR Modulators; Genetic Predisposition to Disease; pharmacological\_intervention; placebo; VX-770; VX-661; ivacaftor; Aminophenols; tezacaftor; VX-445; elexacaftor; Trikafta;