The IMPACT study:
InforMing the PAthway of COPD Treatment[1]

Trelegy Ellipta is not approved for use anywhere outside the US.

IMPACT in numbers[1,2]

- Around **10,000 COPD** patients randomized
- Approx **1,070 study centers** worldwide
- **37** countries
- **52** weeks

GSK's latest COPD study

- One of the largest phase III pre-registration COPD studies ever conducted
- The first study to compare three different classes of COPD medications with the same molecules in the same inhaler type and with the same dosing frequency
- Will expand the evidence base for GSK's broad portfolio of once-daily treatments delivered via the Ellipta inhaler

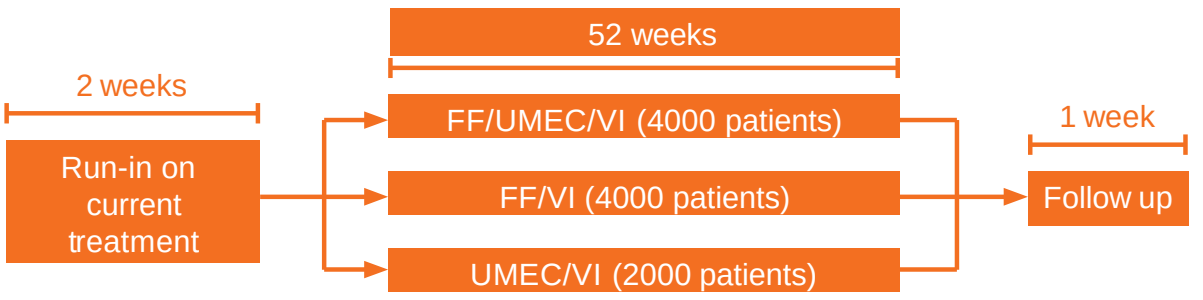
Single inhaler triple therapy

All treatments administered **once daily** via the **Ellipta inhaler**

Trelegy Ellipta, a single inhaler triple therapy combination fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI), is an approved treatment for COPD that provides an ICS, a LAMA and a LABA as a single once-daily inhalation.

Study design[1]

IMPACT was a phase III, randomised, double-blind, three-arm, parallel-group, global multicenter study comparing the rate of moderate and severe exacerbations between FF/UMEC/VI (Trelegy) and FF/VI (Breo) or UMEC/VI (Anoro) over 52 weeks:



COPD: chronic obstructive pulmonary disease
LAMA: long-acting muscarinic receptor antagonist
LABA: long-acting ß2-adrenergic receptor agonist
ICS: inhaled corticosteroid

Key inclusion criteria:[1]

At study entry

- Patients ≥40 years
- Established clinical history of COPD
- Spirometry confirmed COPD diagnosis
- 2-week run-in on current treatment

AND either:

Post-BD FEV_1:	<50% predicted normal	or	≥50% but <80% of predicted normal
Exacerbations in prior year:	+ ≥1 moderate or severe		+ ≥2 moderate or ≥1 severe (hospitalised)

ALB/SAL = albuterol/salbutamol; BD = bronchodilator; FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity

Key exclusion criteria:[1]

- Pregnancy
- Current diagnosis of asthma or other respiratory disorders/risk factors
- Alpha1-antitrypsin deficiency as cause of COPD
- Other diseases or abnormalities as specified

Primary endpoints[1]

Annual rate of on-treatment moderate and severe exacerbations for:
- **Trelegy vs Anoro**
- **Trelegy vs Relvar/Breo**

Other endpoints[1]

Change in FEV_1 for Trelegy vs Breo

Change in quality of life as measured by SGRQ for Trelegy vs Breo

Safety assessments including:
- Incidence of adverse events
- Incidence of pneumonia
- Incidence of cardiovascular events

Annual rate of on-treatment moderate and severe exacerbations for Trelegy vs Anoro in patients with blood eosinophil count ≥150 cells/µL

Annual rate of on-treatment severe exacerbations for Trelegy vs Anoro and vs Breo

Time to first on-treatment moderate or severe exacerbation for Trelegy vs Anoro and vs Breo

SGRQ = St George's Respiratory Questionnaire

References
1. Pascoe SJ, et al. A phase III randomised controlled trial of single-dose triple therapy in COPD: the IMPACT protocol. *Eur Resp J* 2016;48:320–330.
2. ClinicalTrials.gov. A Study Comparing the Efficacy, Safety and Tolerability of Fixed Dose Combination (FDC) of FF/UMEC/VI With the FDC of FF/VI and UMEC/VI; Administered Once-daily Via a Dry Powder Inhaler (DPI) in Subjects With Chronic Obstructive Pulmonary Disease (COPD). Available at: https://clinicaltrials.gov/ct2/show/record/NCT02164513. Last accessed: August 2017.

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