

## DISCLOSURES

This study was funded by BI through a contract with RTI Health Solutions (RTI-HS). The contract provides the research team independent publication rights. CR, JAg, and AWG are salaried employees of RTI-HS, an independent nonprofit research organization that does work for government agencies and pharmaceutical companies. EH and JO are employees of the PHARMO Institute for Drug Outcomes Research. This independent research institute performs financially supported studies for government and related health care authorities and several pharmaceutical companies. JAs is an employee of IQVIA, an independent research institute that performs financially supported studies for health care authorities and several pharmaceutical companies. KL and VE are salaried employees of Aarhus University/Aarhus University Hospital. JM and LW are employees of Boehringer Ingelheim.

## BACKGROUND

- Olodaterol and indacaterol are inhaled long-acting beta2-agonists (LABAs) authorized only for the treatment of adults with chronic obstructive pulmonary disease (COPD).
- Use of these drugs in patients with asthma without COPD has been associated with increased morbidity and mortality and is considered off-label.

## OBJECTIVE

- To describe the baseline characteristics of patients initiating olodaterol and indacaterol.
- To quantify off-label use of olodaterol and indacaterol to treat asthma in three European countries: the Netherlands, Denmark, and France.

## METHODS

- This descriptive drug utilization study used routinely collected health data in the PHARMO Database Network in the Netherlands (PHARMO overall, and PHARMO-GP for the subset of patients with general practitioner [GP] data), the Danish population registers, and the IMS Real-World Evidence Longitudinal Patient Database (RWE LPD) (GP panel and pulmonologist panel) in France.
- All new (treatment naïve) users of olodaterol or indacaterol between March 2014 and December 2016 in PHARMO and Denmark and from October 2015 to November 2017 in the IMS RWE LPD panels were included in the study.
- Evaluation of off-label use and characterization of new users was descriptive and conducted based on all available information in each data source prior to the index date (i.e., since 1994 in Denmark, 1998 in the Netherlands, and 1994 for the RWE LPD GP panel and 2007 for the RWE LPD pulmonologist panel in France). Medication use was assessed for the 1-year period prior to the index date.

### Outcome Definitions

- **On-label use** = use among adults with a recorded diagnosis of COPD
- **Off-label use** = use among adults with a recorded diagnosis of asthma without a recorded diagnosis of COPD or as use among patients ≤ 18 years
- **Potential off-label use** = no recorded diagnosis of either COPD or asthma
- **Probable COPD** = patients in the potential off-label group who had a record of COPD medication use after age 40 years but no recorded diagnosis of COPD or asthma

## CONCLUSIONS

- New users of olodaterol and indacaterol are elderly patients with a high prevalence of comorbidity and use of medications.
- The prevalence of off-label use of both drugs was low, lower than reported in other studies evaluating off-label use of medications across Europe, and practically no pediatric use was observed.
- Lack of direct evidence on indication (potential off-label) for a high proportion of patients is a limitation for some data sources, although indirect evidence supports the conclusion that off-label use is likely low.
- Off-label is higher in RWE LPD panels probably due to a higher degree of underestimation of COPD.

## CONTACT INFORMATION

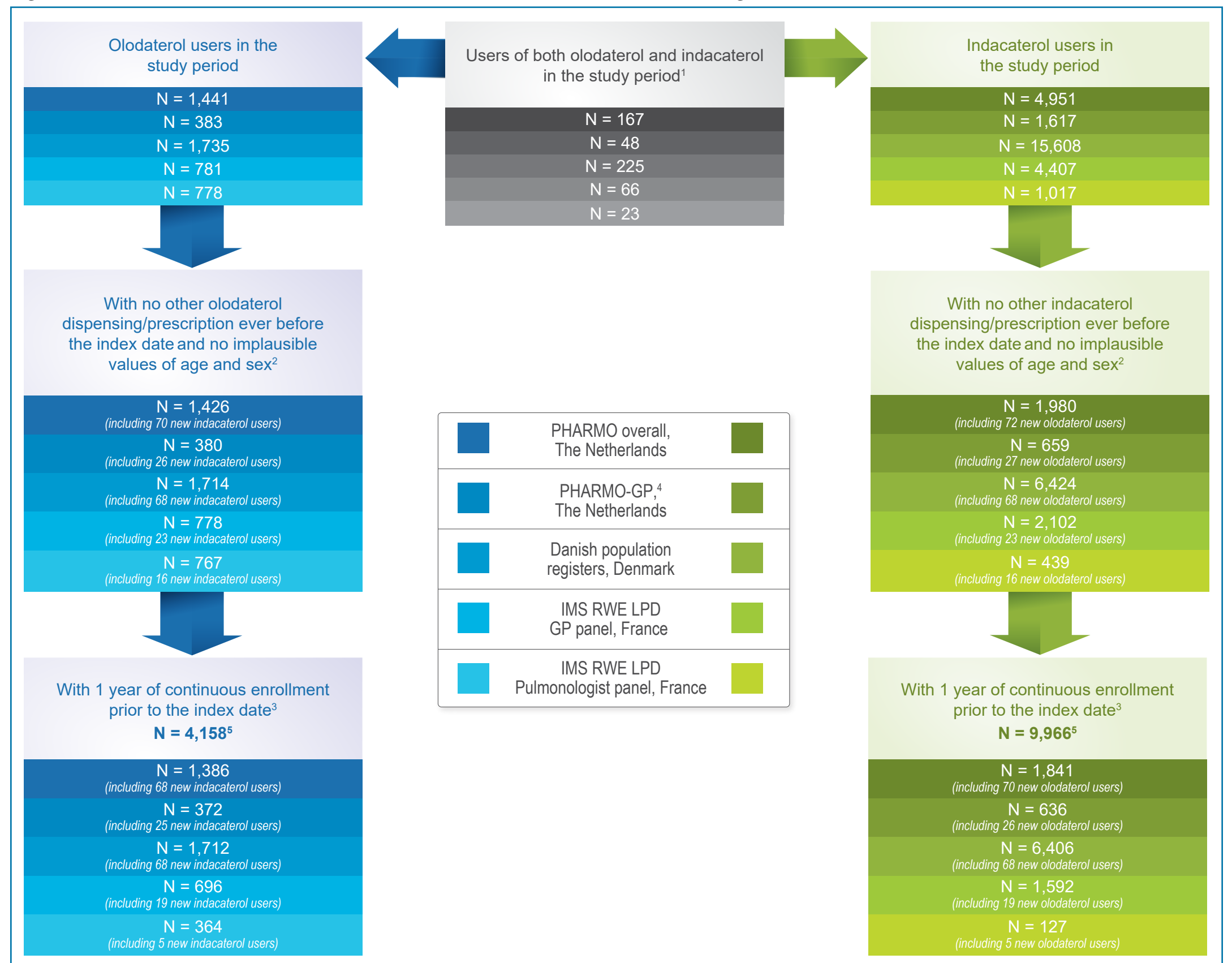
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## RESULTS

Figure 1. Number of Users of Olodaterol and Indacaterol Before and After Fulfilling Inclusion/Exclusion Criteria in Each Data Source



<sup>1</sup> Number of patients with at least one prescription/dispensing for olodaterol or indacaterol during the study period.

<sup>2</sup> Number of users of olodaterol or indacaterol with no other prescriptions/dispensings of olodaterol or indacaterol ever before the index date and no implausible values of age and sex.

<sup>3</sup> Number of new users of olodaterol or indacaterol with at least 1 year of continuous enrollment prior to index date.

<sup>4</sup> PHARMO-GP is a subset of PHARMO overall.

<sup>5</sup> Total number of patients included is the sum of PHARMO overall, Denmark population registers, IMS RWE LPD GP, and pulmonologist panels.

Table 1. Description of Demographics, Comorbidities, and Comedications of New Users of Olodaterol and Indacaterol at the Time of Treatment Initiation

	PHARMO Overall, The Netherlands		PHARMO-GP, The Netherlands		Danish Population Registers, Denmark		IMS RWE LPD GP Panel, France		IMS RWE LPD Pulmonologist Panel, France	
	Olodaterol (N = 1,386)	Indacaterol (N = 1,841)	Olodaterol (N = 372)	Indacaterol (N = 636)	Olodaterol (N = 1,712)	Indacaterol (N = 6,406)	Olodaterol (N = 696)	Indacaterol (N = 1,592)	Olodaterol (N = 364)	Indacaterol (N = 127)
Males, %	49	52	47	53	43	48	54	56	65	67
Age, median (IQR)	68 (60-75)	67 (59-75)	68 (60-76)	68 (59-75)	71 (64-79)	69 (61-77)	63 (53-72)	63 (53-73)	67 (59-75)	68 (59-78)
<b>History of Respiratory diseases, %</b>										
Pneumonia	15	10	14	14	33	19	27	20	13	7
Other respiratory conditions	14	10	12	9	26	10	9	8	28	15.0
<b>History of Nonrespiratory diseases, %</b>										
Ischemic heart disease	15	14	13	11	24	19	13	11	8	6
Arrhythmias	12	10	13	12	16	12	12	12	6	4
Hypertension	19	16	26	25	33	27	44	43	23	13
<b>Respiratory medications 1 year prior to index date, %</b>										
LABA <sup>a</sup>	28	10	28	10	26	6	14	4	14	4
LABA/ICS	37	28	37	27	40	18	28	21	19	19
LAMA	79	59	74	58	72	24	43	18	65	31
SABA	45	35	38	33	58	39	25	22	33	15
ICS	27	18	21	15	18	10	17	13	15	14
Systemic glucocorticosteroids	49	34	40	35	39	19	41	32	15	10
<b>Nonrespiratory medications 1 year prior to index date, %</b>										
Cardiovascular medications	65	64	66	62	73	67	60	54	3	2
Systemic antibacterials	60	50	53	50	69	55	67	58	23	14

ICS = inhaled glucocorticosteroids; IMS RWE LPD = IMS Health Information Solutions Real-World Evidence Longitudinal Patient Database; IQR = interquartile range;

LAMA = long-acting muscarinic antagonist; SABA = short-acting beta2-agonists; SAMA = short-acting muscarinic antagonists.

<sup>a</sup> Prior use of LABA includes use of indacaterol for those in the olodaterol group but not the indacaterol group and vice versa.

Note: Percentages from column totals are displayed.

Figure 2. Proportion of Patients with On-Label, Off-Label, Potential Off-Label, and Probable COPD Use in New Users of Olodaterol and Indacaterol

