Inhaled Insulin Pulmonary Safety: Evidence Across Clinical Trials and Real-World Data

All pulmonary safety evidence summarized below is from adult populations with T1D or T2D

1 Key Pulmonary Safety Questions

Are there any lung cancer safety signals with inhaled insulin?

What does long-term evidence show about pulmonary adverse events?

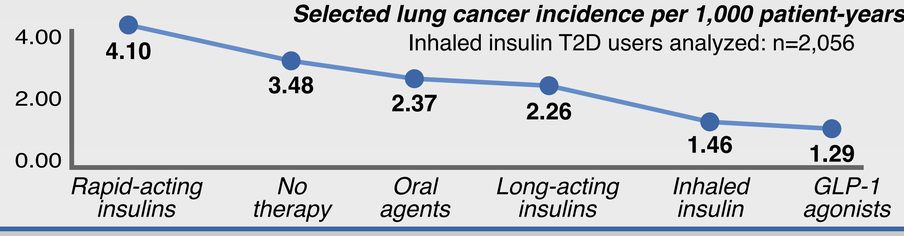
What does the evidence show about pulmonary safety related to FEV_1?

2 What the Evidence Shows

Kaiserman et al., 2026, EMR real-world evidence

Selected lung cancer incidence per 1,000 patient-years

Inhaled insulin T2D users analyzed: n=2,056



No increased lung cancer risk was observed among inhaled insulin users.

Burstain et al., 2026, Epic Cosmos real-world database

- Epic Cosmos database: >300M patients
- 647 inhaled insulin users matched to 1,830 RAA controls 1 year post index
- Median inhaled insulin exposure: 2.21 years
- Median follow-up: 3.47 years

Lung cancer: 0 cases in inhaled insulin users vs 2 cases (0.11%) in RAA controls

COPD/ emphysema/ chronic bronchitis: 1/627 (0.16%) in inhaled insulin users vs 27/1,830 (1.48%) in RAA controls

OR 0.107 (95% CI 0.014-0.787); P=0.007

McGill & Mayer, 2026, postmarketing reports

- >30,000 exposed individuals from 2015 to 2021
- 1 pulmonary malignancy report to FDA during that period, plus 1 additional case after 2021
- Of those pulmonary malignancy reports, both individuals had a history of smoking
- 1 reported case of asymptomatic pulmonary infiltrates resolved after discontinuation

Long-term animal studies showed no carcinogenic potential

Raskin et al., 2012, randomized, open-label study

- Prospectively followed over 2 years in adult patients with T1D or T2D.
- Inhaled insulin was non-inferior to usual care for mean change in FEV_1 from baseline to month 24 [mean (s.e.m.) 0.037 (0.0119) L: 95% CI 0.014 to 0.060]
- The most common respiratory event associated with inhaled insulin was mild, transient cough.

n= 730 Inhaled insulin

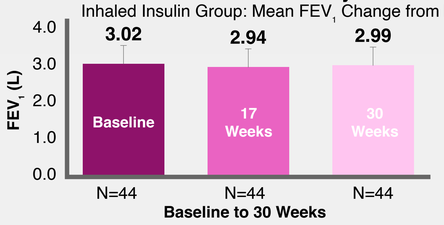
n= 824 Usual care

n= 145 Non-diabetes cohort

Beck et al., 2025, INHALE-3 clinical trial data

Pulmonary Function

Inhaled Insulin Group: Mean FEV_1 Change from Baseline to 30 Weeks[a]



Mean Change (95% CI) [P-Value][b]	
Baseline to 30 Weeks	-0.03 (-0.13, 0.07) [0.58]*
17 Weeks to 30 Weeks	0.05 (-0.03, 0.13) [0.24]*

[b] Mean change, 95% CI, and p-value estimated using a paired t-test

* 0% FEV_1 reduction ≥ 20%

[a] A repeat FEV_1 measurement was taken at 30 weeks for 1 participant but the original measure was used to calculate means

McGill & Mayer, 2026, pooled clinical trial safety

- Small declines in FEV_1 and FVC were observed during treatment and were generally reversible after cessation.
- High-resolution imaging in one study showed no significant long-term pulmonary parenchymal abnormalities.
- Overall, mild, reversible pulmonary changes; rare malignancies consistent with rates in the general diabetes population.

n= 5,505 Total adults analyzed

n= 3,017 Received inhaled insulin

3 Important Safety Information

Contraindicated in chronic lung disease (asthma, COPD) — boxed warning

Not recommended in current smokers or people who have recently stopped smoking

Pulmonary assessment: spirometry (FEV_1) before initiation, at 6 months, and annually thereafter

See Inhaled Insulin Prescribing Information

Across clinical trials, real-world evidence, and postmarketing surveillance, no increased pulmonary safety signals have been identified. Reference the label for long-term follow-up.

Beck et al. Diabetes Technol Ther. vol. 27,3 (2025): 170-178.2. Data on File (INHALE-3 Clinical Study Report, 2024).; Burstain et al. Diabetes Technol Ther. 2026 Jun;28(6):527-531; Kaiserman et al. Inhaled Insulin Assessment of Incident Lung Cancer Risk Among Adults with Type 2 Diabetes (T2D). Poster presented at: American Diabetes Association Scientific Sessions; June 5-8, 2026; New Orleans, LA.; McGill & Mayer. Diabetes Technol Ther. 2026 Feb;28(Suppl 15):19S-25S. Raskin et al. Diabetes Obes Metab. 2012 Feb;14(2):163-73.