mannkind

# Inflo-2
## nintedanib DPI for IPF

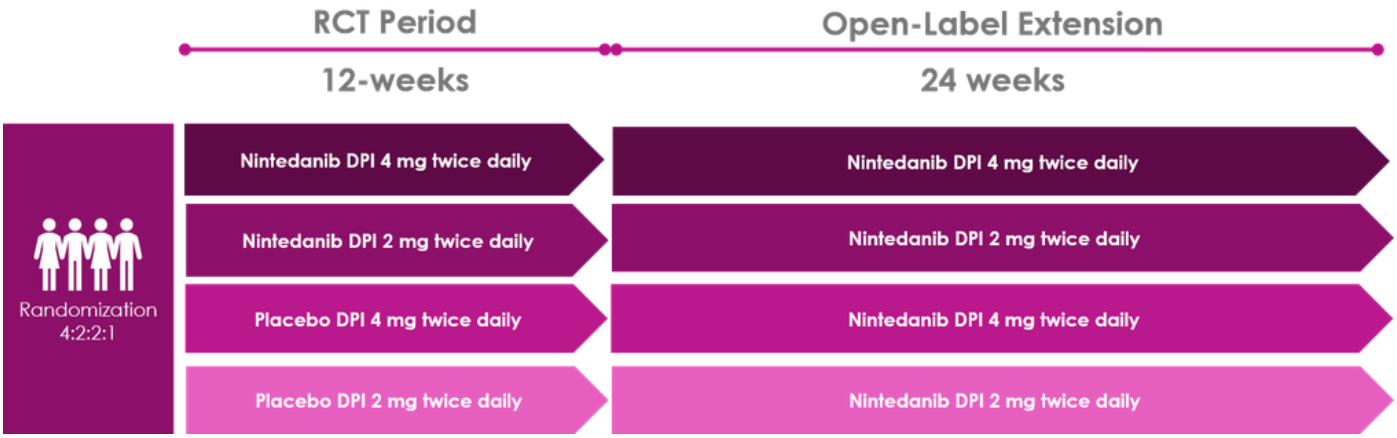
## INFLO-2: Phase 2 Study of Inhaled Nintedanib (MNKD-201) for Idiopathic Pulmonary Fibrosis (IPF)[1,2]

NCT07679893

- **Study Design:** Randomized, double-blind, placebo-controlled 12 week-study with 24-week open label extension
- **Primary Objective:** Assess the safety and tolerability of different doses of Nintedanib DPI over 12 weeks in patients with IPF
- **Treatment Arms & Approximate Enrollment:**
  - Nintedanib DPI 4mg twice daily (n=68)
  - Nintedanib DPI 2mg twice daily (n= 34)
  - Placebo DPI 4mg twice daily (n=34)
  - Placebo DPI 2mg twice daily(n=17)
- **Safety Endpoints:** Events of clinical bronchospasm, change in $FEV_1$ and $FEV_1$/FVC ratio from Baseline to Week 12, Rate of study drug discontinuations, drug dose reduction TEAEs, treatment-related adverse events, SAEs and device deficiencies
- **Primary Efficacy Endpoint:** Annualized rate of decline in FVC over 12 weeks
- **Total Study Target Enrollment:** 153 participants globally

$FEV_1$, forced expiratory volume in 1 second; FVC, forced vital capacity; DPI, dry powder inhalation; IPF, idiopathic pulmonary fibrosis; TEAE, treatment emergent adverse event; SAE, serious adverse event

## STUDY DESIGN




Background treatment: Either without current background IPF treatment or on stable pirfenidone / nerandomilast background therapy up to 70% of trial patient population
DPI, dry powder inhalation; IPF, idiopathic pulmonary fibrosis; RCT, randomized controlled trial

Nintedanib DPI (MNKD-201) is an investigational product. The safety and efficacy of Nintedanib DPI have not been established. This information is provided for scientific exchange purposes only and is not intended to promote the use of any investigational product.

**References: 1.** ClinicalTrials.gov. *Phase 2 Clinical Trial of MNKD-201 (Nintedanib Dry Powder Inhalation) in Patients With Idiopathic Pulmonary Fibrosis (INFLO-2).* ClinicalTrials.gov identifier: NCT07679893. Updated September 14, 2026. Accessed September 21, 2026. https://clinicaltrials.gov/study/NCT07679893. **2.** Data on File. (MKC-NI-003 Protocol V2.0, 2026). MannKind Corporation.

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