A randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of nintedanib for at least 52 weeks in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) (NCT02597933)\(^1\)

**Design**

- **Nintedanib 150 mg bid (n=260)**
- **Placebo (n=260)**

Visit 1: 1:1 randomization; bid, twice daily.

**Endpoints**

**Primary endpoint**
- Annual rate of decline in FVC (mL/year) assessed over 52 weeks

**Key secondary endpoints**
- Change from baseline in modified Rodnan Skin Score at week 52
- Change from baseline in St. George’s Respiratory Questionnaire total score at week 52

**A global clinical trial**