eCOA Solutions
CASE STUDY

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

STREAMLINING GLOBAL RESPIRATORY TRIAL COMPLEXITIES WITH ROBUST DATA CAPTURE STRATEGY

OVERVIEW

A leading global pharmaceutical company partnered with Signant Health to elevate the quality and efficiency of a Phase III multinational clinical trial in idiopathic pulmonary fibrosis (IPF). By implementing Signant Health's electronic Clinical Outcome Assessment (eCOA) solutions, the sponsor ensured capture of high-quality endpoint data.

TRIAL SUMMARY

Study Phase: III

Therapeutic Area: Respiratory

Patient Population: Adult & Elderly

Number of Countries: 34

Number of Sites: 350

Number of Patients: 1,125

Instruments: 10

Languages: 55

CHALLENGES

1. Ensuring that adult and older adult participants could confidently complete their home-based e-diaries using provisioned smartphones

2. Maintaining high level of patient engagement and e-diary completion throughout the long study duration

3. Providing sites with visibility into participant compliance during e-diary entry windows to proactively manage adherence

4. Seamlessly migrating and deploying numerous patient-reported outcome measures (PROMs) electronically, supporting direct patient data entry in multiple languages

SOLUTIONS

1. Signant's user-friendly eCOA design allows participants to confidently engage with study tasks, regardless of age or technological literacy. Allowing patients with lower technology confidence to run through training more than once before starting ensured optimal onboarding.

2. Built-in notifications and alarms prompt participants to complete e-diary entries within designated entry windows, with time- and date-stamped records to ensure full regulatory traceability.

3. Reporting dashboards give sites direct access to patient-reported data and completion rates, enabling effective patient oversight and proactive intervention to minimize missing data.

4. Electronic study PROMs, migrated and implemented with support from Signant's technical and clinical expertise, ensure adherence to industry best practices and regulatory standards.

RESULTS

Signant successfully deployed provisioned smartphones to 1,125 elderly IPF patients across 350 sites in 34 countries. Despite substantial logistical challenges in this complex multinational trial, including device provisioning, import regulations, and 55-language support, the study launched on schedule and continues generating audit-ready data with full regulatory traceability through 2025. The implementation enabled reliable daily breathing assessments in a challenging patient population while overcoming traditional paper-based assessment limitations.