Comparison Study of Unsupervised Remote and Supervised Clinic Spirometry Measurements in a Clinical Trial Setting

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Purpose

To assess the role of app-based spirometry for remote monitoring in clinical trials by **comparing unsupervised remote spirometry with supervised in-clinic spirometry with** in a phase 2a clinical trial.

Methods

- Spirometry data were analyzed from a **phase 2a study of SNSP113 for safety and efficacy**
- **Adults living with cystic fibrosis from 7 sites in Europe** were **evaluated using in-clinic and remote spirometry with the NuvoAir Air Next spirometer and connected app**
- In-clinic spirometry was measured at screening visit, baseline, weeks 1,2,4, and 6; NuvoAir spirometry was measured at screening visit, baseline, and 3 times/week throughout the 16-month trial.
- **Bioequivalence testing on FEV_1 and FVC** was performed using the Statistical Approaches to Establishing Bioequivalence (FDA.gov) by comparing in-clinic data to NuvoAir data recorded within ±1 day of the clinic measurement
- The ratio of the values and 90% CI was calculated and **deemed bioequivalent if the confidence intervals were within 80 -120%**

Figure 1. Pearson correlations in absolute FEV_1, FVC, and FEV_1 % predicted measurements between in-clinic and remote spirometry

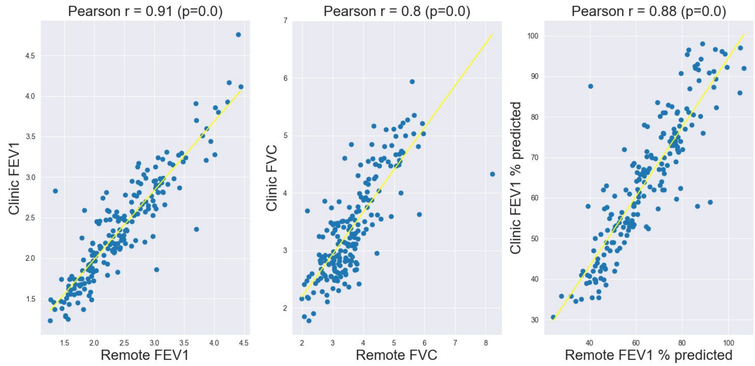
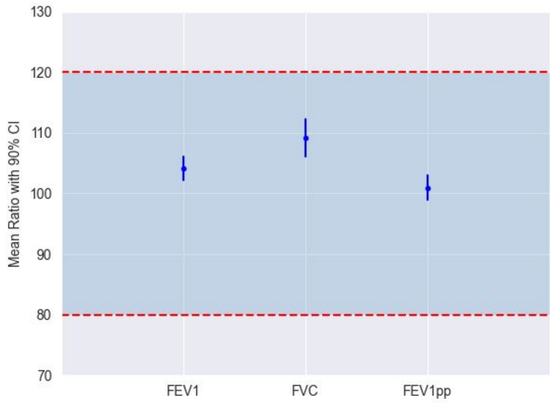


Figure 2. Bioequivalence testing results for absolute FEV_1 and FVC measurements between in-clinic and remote spirometry



Results

- 48 out of 65 screened patients were randomized for treatment
- Patients aged 18-44 years old, 44% female, and median BMI was 21 (IQR:19-23)
- Median FEV_1 % predicted at baseline was 64.8% (IQR:52.3% – 76.3%)
- Data from 276 in-clinic and 1009 remote spirometry sessions were obtained. 196 matched sessions were analyzed
- The test-to-reference ratio for FEV_1 was 104.1% (90% CI:102.1% – 106.1%), for FVC was 108.3% (90% CI:105.1% - 111.5%)
- **Data from clinic and NuvoAir measurements showed a close correlation (Pearson r for FEV_1 is 0.92 and FVC is 0.83)** (Figure 1)
- **Both FEV_1 and FVC were well within bioequivalence limits of 80 - 120%** (Figure 2)

Conclusion & Clinical Implications

This analysis shows **bioequivalence and concordance** between supervised in-clinic and unsupervised remote spirometry using Air Next with in-app coaching. These results show that **remote spirometry can be used to accurately collect lung health data as well as to obtain a higher frequency of data**, **enabling a reduction in-person clinic visits**, and providing ample benefits to patients, healthcare providers, and clinical trials.