



Respiratory Measures That Matter

The High-Quality Data You Need — From Anywhere

Koneksa leads with science and delivers with software. We conduct research to validate the digital health technologies (DHTs) and the DHT-derived measures that support our remote data collection solutions. Rigor is the key to providing remote optimized respiratory measures that paint a more complete picture of patient health. Our remote respiratory measures enable you to confidently evaluate the impact of your treatment and make cost-effective go/no-go decisions earlier using convenient and frequent data collection and real-time transmission in our configurable platform.

We know the common challenges of respiratory clinical trials:

- Limited data points
- Inability to capture diurnal variability in lung function
- Large sample size and related study duration
- The need for patients to travel to the sites, limiting study participation
- Burden-induced dropout

We solve these problems by empowering you to collect comprehensive respiratory data from patients from any location. Our solution simultaneously lowers patient burden and facilitates the holistic picture of patient health needed to accurately detect treatment effect.

Research-Backed Solutions Matter — We Have Them

Koneksa's scientists are dedicated to continuously improving lung function data quality in respiratory clinical trials. Our experience in respiratory clinical research has included studies in numerous indications, and every element of the solutions we provide to our partners has been subjected to the most rigorous scientific scrutiny.

We have conducted studies in the following indications:



Allergy



Asthma



COPD



COVID-19



Idiopathic
pulmonary fibrosis

We conduct scientific and technical evaluations when selecting devices for clinical trials and we validate corresponding measures to assess their utility and validity. Koneksa also partners with the study sponsor during the design phase of a clinical trial to ensure that selected devices and measures are fit for purpose and deliver the data your trial needs.

We Deliver the Data That Matters — for Your Trial

As an experienced team focused on accelerating drug development, we deliver on our commitment to being a science-driven one-stop shop for your trial. Our complete respiratory solution follows American Thoracic Society (ATS) guidelines and includes a highly sensitive ultrasonic spirometer that enables remote patient data collection. Peer-reviewed research found that our mobile spirometer provided remote data that was highly correlated with in-clinic spirometry (Figure 1).¹

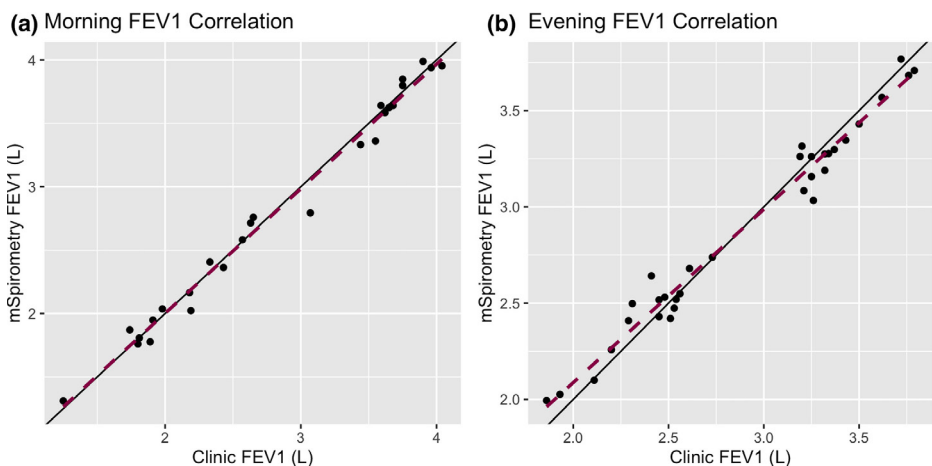


Figure 1: The comparison of mobile spirometry (mSpirometry above) and in-clinic forced expiratory volume in one second (FEV1) measurements, in terms of correlation (a, b). Panel a describes morning FEV1 values and panel b describes afternoon/evening FEV1 values. The solid black diagonal lines denote perfect agreement; the dashed purple lines indicate the observed linear relationships between mobile spirometry and in-clinic FEV1 measurements.

The spirometer deployed in our studies is far superior to traditional turbine-based devices as it has automatic calibration, a larger flow range, and higher accuracy; in addition, it is easy to disinfect, and it has no disposable hardware beyond filters. It comes with everything patients need to complete successful data collection in a remote setting.

Configurable scheduling, assessment reminders, in-app audio, and on-screen coaching based on ATS and European Respiratory Society guidelines ensure the pulmonary function test measures are accurate and reliable. With our multi-language capabilities, we can support your clinical studies globally.

More Than a Spirometry Solution — Much More

Koneksa works with you to ensure you have and understand everything needed to collect your respiratory trial's pertinent remote measures. For example, we provide additional measures that can be of utility in respiratory clinical research: physical activity data that can elucidate how physically fit patients are and pulse oximetry measures that can provide another dimension on lung function. These can be supplemented with ePRO instruments and electronic patient diaries. Additionally, with our 24/7 help desk support that covers the globe, we can work with you to make mobile spirometry data collection happen.

Better Data — in Real Time

Participants' generated data are transmitted in real time to Koneksa's device-agnostic platform where they can be viewed along with the additional features, like full flow volume loops. The emerging data is also monitored for quality and compliance. With all your data available in our platform in real time, you are empowered to confidently collect data for measures that matter for your study — around the clock and around the world.

Configurable scheduling capabilities provide another valuable set of benefits. By collecting more data from each participant, you can control for factors that drive variability in lung function, so your study *gains power*, may require *fewer patients*, and can be *completed faster*.

Our turnkey spirometry toolkit includes:

- A provisioned iPhone with the Koneksa mobile app which guides patients through the data collection procedure
- A Bluetooth-enabled ultrasonic spirometer
- Detachable hygienic filters
- Nose clips
- An easy-to-follow patient guide



Mobile spirometry measures include:

- FEV1
- FEV1/FVC
- FVC
- BEV
- PEF
- FIVC

¹ Huang, C., et al. [Remote FEV1 Monitoring in Asthma Patients: A Pilot Study. Clinical and Translational Science](#). Published 2020 October 13.



Koneksa is the global leader in digital biomarkers. We offer support from design to approval, ensuring our tailored solution delivers the critical insights you need to detect treatment effect and make timely, confident decisions.

Talk to us today to optimize your next respiratory trial.

Contact Koneksa

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