MULTI-BREATH WASHOUT BETTER DETECTS EARLY-STAGE LUNG DISEASE PROGRESSION

IDENTIFY DIAGNOSTIC DETAILS NOT VISIBLE BY SPIROMETRY ALONE

Lung clearance index (LCI) measured by multiple breath washout has become an increasingly popular technique for detecting early pulmonary changes. Whereas relevant forced expiratory flow-volume (FEV1) parameters in healthy patients and early disease-state patients mostly reflects proximal airways, LCI reflects abnormalities of smaller airways which are considered the site of early lung injury in cystic fibrosis (CF), early COPD and mild asthma.

In early stages of disease, spirometry values often do not show abnormalities as the larger airways are not yet affected. While the multiple breath washout method is able to detect progression of early-stage lung disease on the small airways more accurately than spirometry measurements, there are still limited data regarding device-specific reference ranges, repeatability and reproducibility.

CENTRALIZED LCI SOLUTIONS FOR CLINICAL TRIALS

We offer centralized LCI services through integration of the ndd® EasyOne Pro® LAB device into the ERT EXPERT® platform. Our extensive training programs further optimize LCI, diffusing capacity of the lungs for carbon monoxide (DLCO) and spirometry collection. Combined with our experience collecting cardiac safety, eCOA and imaging data, you will benefit from increased data quality, reduced site burden, improved study oversight and shortened timelines. Our cloud-enabled services deliver near real-time evaluation, notifications, expert overread, data reconciliation and reporting — along with optional EDC integration and business intelligence reporting solutions.

CENTRALIZED LCI SERVICES

Advanced LCI collection and analysis for your clinical trial
Custom configuration
Customize your LCI measurement configuration based on your protocol needs, testing, review and interpretation of data.

Increase site and patient performance
Leverage comprehensive site training on device and coaching patient test performance.

Convenient set-up and ease of use
Minimal space requirements, high-resolution touch screen, automatic calibration and user guidance supports ATS/ERS standards.

Real-time notifications and central overread
Real-time inclusion and exclusion criteria evaluation is delivered via email notifications. Central overread by ERT Respiratory experts provides quality control, best-test review and criteria re-evaluation within flexible turnaround times.

Integrate for enhanced data insights
Integrate ECG, eCOA and Imaging endpoints through additional ERT solutions, as required. Secure Internet data transmission is delivered via integration with the ERT EXPERT platform. Additionally, leverage optional data integration into your EDC and ERT Enhanced Business Intelligence for Respiratory Trials for site performance oversight and outlier data analysis.

SITE
- LCI, DLCO and spirometry data assessment with ndd® EasyOne Pro® LAB
- Review of data/feedback
- Review of data/feedback

ERT
- Inclusion/exclusion criteria evaluation after data received
- Pre-overread PFT analysis report
- Data available in ERT portal
- Overread assessment (QC/BTR) re-evaluation of criteria
- Final PFT analysis report
- Final data available in ERT portal

SPONSOR
- Review of data/feedback
- Review of data/feedback
- Review of data/feedback
- Review of data/feedback
- Final PFT data available for sponsor

Advanced LCI collection and analysis for your clinical trial. For more information, go to ert.com or email info@ert.com.

QUALITY AND SAFETY
ERT operates a Quality Management System according to EN ISO 13485 and 21 CFR Part 820.