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Multiple Breath Washout (MBW) training, certification and quality control during the iBEST-1 trial in bronchiectasis (BE).

Bronchiectasis, Lung function testing

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Background: Lung clearance index (LCI) measured by MBW, is an exploratory endpoint in iBEST-1. MBW set up requires staff training, certification and central “over-reading” for data quality control. Evaluation of these processes is essential to inform the inclusion of LCI in future BE studies.

Objectives: To summarise the time duration between MBW training & certification and the proportion of tests excluded after over-reading. **Methods:** Twenty-seven sites are participating in the LCI sub-study. MBW training was a 1 day face to face session, eLearning tool and mentoring support. Certification required the submission of 8/10 valid tests. Once certified, sites submitted trial MBW data for assessment by a trained “over-reader” using pre-defined criteria (Jensen et al. 2016, PLOS ONE).

Results: Training: 20/27 sites completed training. Six had previously completed training & certification. One site was unable to participate (language barrier). Of the 20 sites that completed training, 12/20 (60%) were MBW naive. 13/20 (65%) completed certification with a mean (range) time since training of 6 (4-14) months. Certification for 6/20 sites is on-going with a mean (range) time since training of 10 (3-17) months. One site dropped out (no equipment space). Over-reading: To date, 146 tests from 10 sites have been submitted. 52/146 (36%) tests were excluded, most commonly due to leak, irregular breathing pattern and technical issues.

Conclusions: Sites require a mean of 6 months to train and certify in MBW testing for BE trials. The study is on-going to determine the support necessary to minimise test exclusion.

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