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


**Document Version:**
Peer reviewed version

**Queen's University Belfast - Research Portal:**
Link to publication record in Queen's University Belfast Research Portal

**Publisher rights**
Copyright ©ERS 2018. This work is made available online in accordance with the publisher’s policies. Please refer to any applicable terms of use of the publisher.

**General rights**
Copyright for the publications made accessible via the Queen's University Belfast Research Portal is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

**Take down policy**
The Research Portal is Queen's institutional repository that provides access to Queen's research output. Every effort has been made to ensure that content in the Research Portal does not infringe any person's rights, or applicable UK laws. If you discover content in the Research Portal that you believe breaches copyright or violates any law, please contact openaccess@qub.ac.uk.

Download date: 15. May. 2020
Multiple Breath Washout (MBW) training, certification and quality control during the iBEST-1 trial in bronchiectasis (BE).


1Wellcome-Wolfson Institute for Experimental Medicine, Queen’s University - Belfast (United Kingdom), 2School of Pharmacy, Queen’s University - Belfast (United Kingdom), 3Novartis Pharma AG - Basel (Switzerland), 4Cambridge Centre for Lung Infection, Papworth Hospital - Cambridge (United Kingdom), 5Host Defence Unit, Royal Brompton Hospital, Imperial College London, - London (United Kingdom), 6Wellcome-Wolfson Institute for Experimental Medicine, Clinical Research Facility - Belfast (United Kingdom), 7Wellcome-Wolfson Institute for Experimental Medicine, Queen’s University Belfast; Host Defence Unit, Royal Brompton Hospital, Imperial College London - London (United Kingdom)

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.

Support received from EU/EFPIA IMI-JU iABC grant n° 115721.