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Title: Spirometric data quality as assessed by repeatability in COPD exacerbations

Mr. Aleck 9793 Harrison aleck.harrison@btopenworld.com [1], Dr. Hardip 9794 Kaur Nagra hardip.kaurnagra@vitalograph.co.uk [2], Mr. Grant 9795 Sowman grant.sowman@vitalograph.co.uk [2], Ms. Deidre 9796 Price deidre.price@novartis.com [3], Mr. Matthew 9797 Brown matt.brown@novartis.com [3] and Dr. Paul 9798 Ford paul.ford@novartis.com MD [3]. [1] Clinical Research, AJH Partners, Wallingford, Oxon, United Kingdom, OX10 0LT ; [2] Clinical Trials, Vitalograph Ltd, Maids Moreton, Buckingham, United Kingdom, MK18 1SW and [3] Translational Sciences, Novartis International AG, Horsham, West Sussex, United Kingdom, RH12 5AB .

Body: Pharmaceutical trials are reliant on accurate data to meet endpoints and eventual registration. Using standardised equipment, well trained technicians[1] and over-readers[2] can improve data quality; however the patient factor is significant when low values are expected for COPD patients struggling with an exacerbation. In an international multicentre trial, 91 COPD patients (Gold II – IV) with an exacerbation were enrolled into the trial. Spirometry was performed at both the initial emergency admission and subsequent sessions using the Vitalograph Spirotrac Spirometry System with trial specific software and over-reading. The repeatability for both FEV1 and FVC was calculated as the difference between the two highest acceptable readings from a total of 672 sessions. The mean figures for each country's repeatability (Fig 1) are within the ATS/ERS recommendation of both 100ml and 150ml.

Overall the majority of the manoeuvres met the ATS/ERS 150 ml criteria FVC 96% and FEV_1 99% with just 4% FVC and 1% FEV_1 of the manoeuvres outside the limit. With standardised equipment, well trained technicians and independent over-readers, patients with COPD exacerbations and low volume manoeuvres were able to produce accurate and reliable data in this clinical trial. 1. MR Miller et al. ATS/ERS Task Force: Standardisation of Spirometry, ERJ 2005;26:319-338 2. AJ Harrison et al. Quality control of respiratory measurements in global trials. ERJ 2006;28:S50,984.