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Functional Respiratory Imaging (FRI) to assess bio-equivalence of inhaled medication

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Demonstrating bio-equivalence of inhaled drugs is challenging. The conventional pharmacodynamics (PD) endpoints often lack the sensitivity to differentiate between different products while the pharmacokinetic (PK) endpoints are usually too sensitive and subject to batch to batch variability. Functional Respiratory Imaging (FRI) is a novel imaging biomarker used in respiratory drug development, which has the potential to bridge between PD and PK measures. FRI consists of a combination of high resolution computed tomography (HRCT) imaging and computational fluid dynamics (CFD). While the HRCT provides structural information of the respiratory system, CFD yields functional characteristics such as resistances and aerosol deposition characteristics. This study demonstrates that by providing regional characteristics of the airway volumes, airway resistances and aerosol deposition, FRI has an increased sensitivity to differentiate between products. Two examples will be shown, one cross over study between salbutamol and ipratropium bromide in COPD patients and a cross over study using Fluticasone Salmeterol (branded versus generic) in asthma patients. These cases demonstrate that when products are different, unlike the conventional PD measures, FRI can differentiate the two. When products are equivalent, FRI yields additional evidence supporting the claims. In addition when test and reference products are not equivalent, FRI allows identifying the cause (inhalation profile, aerosol deposition, etc) that can lead to product optimization. While still being a novel method, FRI has proven to be very useful in drug development for innovator products and the first results demonstrate a large potential in the field of bio-equivalence.

Biography

Jan De Backer graduated from Delft University of Technology, The Netherlands as aerospace engineer. He attained an MSc degree in Aerodynamics and specialized in applied biomedical computational fluid dynamics leading to a PhD from the University of Antwerp, Belgium. He is an alumnus of the MBA programs at London Business School, London and Columbia Business School, New York. He has received several awards for his innovative research and his work has been published in international journals. He founded FLUIDDA in 2005 and holds the position as Chief Executive Officer since 2007.

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