FLUIDDA

Respiratory solutions
for better patient care

Delivery Optimization

Take control of your drug delivery processes by efficiently evaluating every aerosol deposition scenario and simulating reality.

TIME-SAVING

FLEXIBLE

VALIDATED

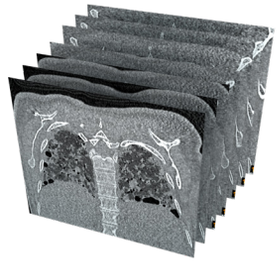
www.FLUIDDA.com

FRI

Functional Respiratory Imaging

Functional Respiratory Imaging (FRI) is a clinically meaningful and non-invasive measurement of the patient-specific respiratory system. A set of distinct biomarkers analyzes *exposure, structure and function* of the lungs and airways in any respiratory disease.

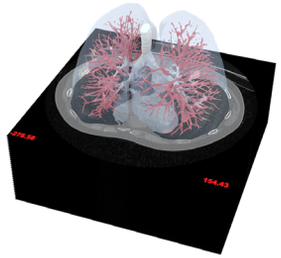
The usage of FRI biomarkers as endpoints in therapy development is scalable and easy to implement:



1

Image acquisition

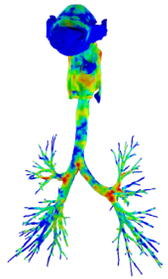
The process starts with the acquisition of low dose, high-resolution computed tomography (HRCT) scans of the patient's thorax



2

Structure segmentation

Measurements are performed on the segmented 3-dimensional geometries from these scans



3

Flow simulation

Computational fluid dynamics (CFD) is used to quantify airflow and exposure to inhaled particles

OVERCOME

the difficulty of radio-labelling a compound and running expensive, time-consuming scintigraphy studies

the inability to assess different scenarios within the same patient population simultaneously

THROUGH THE USE OF FRI IN

Deposition

Observational studies to assess real life lung exposure
Phase I to support dose finding
Phase II as part of safety or efficacy
Phase IV to improve value proposition

Particle delivery optimization

Preclinical to optimize powder characteristics

Device delivery optimization

Preclinical to guide device selection

- **Avoid actively recruiting** patients
- Investigate how your **device or particle (alternatives)** affect(s) deposition in a controlled environment
- Assess the **influence of disease** on your device performance or aerosol deposition at a very early stage
- Easily assess how the device's or particle's performance is influenced by **the way the patient inhales**
- Assess **many different scenarios** (devices, APSD, populations, breathing profiles) and change each parameter independently
- Fully **validated against scintigraphy and SPECT/CT** for a multitude of different devices, compounds and diseases [De Backer, J. et al., 2010]

1.75%
difference from in vivo

When comparing aerosol deposition with scintigraphy and SPECT/CT

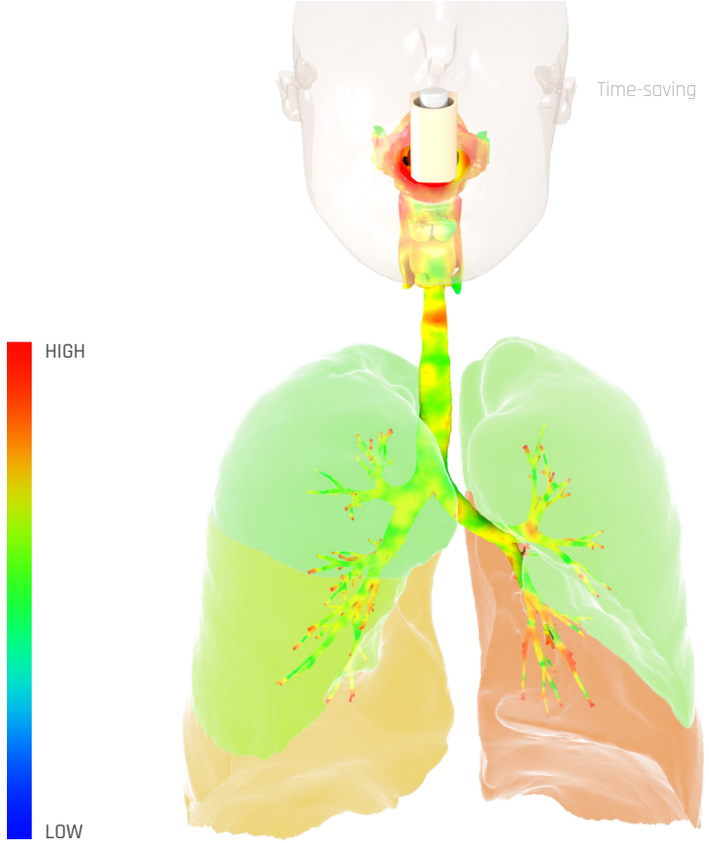
De Backer, J. et al., 2010
http://www.fluidda.com/index.php?p=1828

<6 weeks

is the average time in which clients receive their results after having delivered all input data

Internal BI analysis

TIME-SAVING
FLEXIBLE
VALIDATED

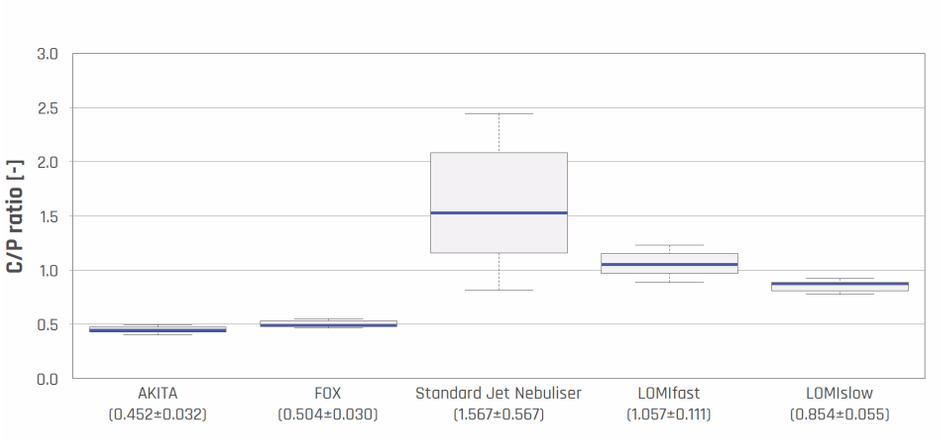


Zone	Delivery (% of DD)
Extrathoracic	68.67
Intrathoracic	1.43
Central	3.57
Peripheral	7.87
RUL	4.01
RML	1.66
RLL	8.48
LUL	5.23
LLL	7.37
Suspended	0.00

The regional concentration of an inhaled drug expressed as a percentage of delivered dose (yellow-red = high, blue-green = low). The colours of the lobes represent the peripheral deposition in that lobe.

RUL right upper lobe
RML right middle lobe
RLL right lower lobe
LUL left upper lobe
LLL left lower lobe

CASE STUDY >



Deposition patterns of different inhalation therapies in IPF patients

Describing delivery performance of a device in relation to a patient's condition and the use of lung deposition modeling to optimize delivery in idiopathic pulmonary fibrosis.

Smart nebulization using FAVORITE™ (long-slow-deep) inhalation offers several advantages:

- Higher overall whole lung deposition
- Greatly enhanced targeting of small airways with Akita compared with the other devices
  CP ratio of Akita compared with jet and other devices is higher
- Standard nebulizer is not as good at targeting the deep lung

Munro, S. et al., DDL 2017

CLIENT EXPERIENCE

We have found FRI to be a really useful mechanism via which to explore the potential differences in lung deposition for different inhalation delivery systems in specific patient populations

Sandy Munro

Vice President
Pharmaceutical Development
at Vectura

OUR EXPERIENCE SINCE 2005 >

40+	Partnering pharmaceutical companies/hospitals
100+	Clinical centers trained worldwide
140+	Clinical studies
50+	Delivery optimization studies
90+	Disease characterization & Therapy analysis

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