

Your Breath: Your Health™

Non-Invasive Deep Lung Sampling

Dr. Sterghios A. Moschos FIBMS FRSC
CSO and founder



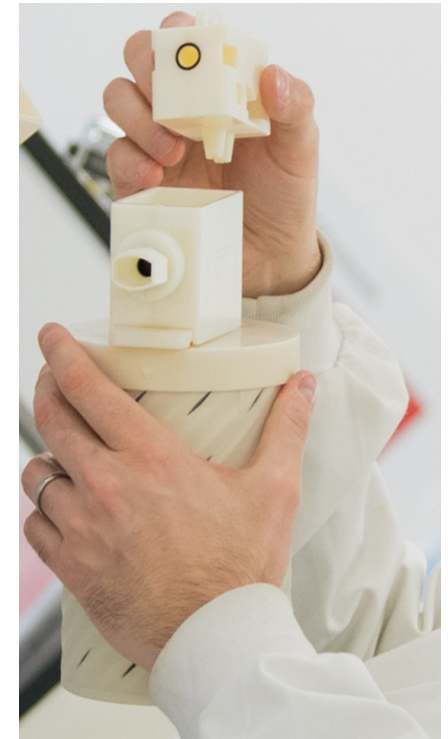
A spin-out from Northumbria University



Innovate UK

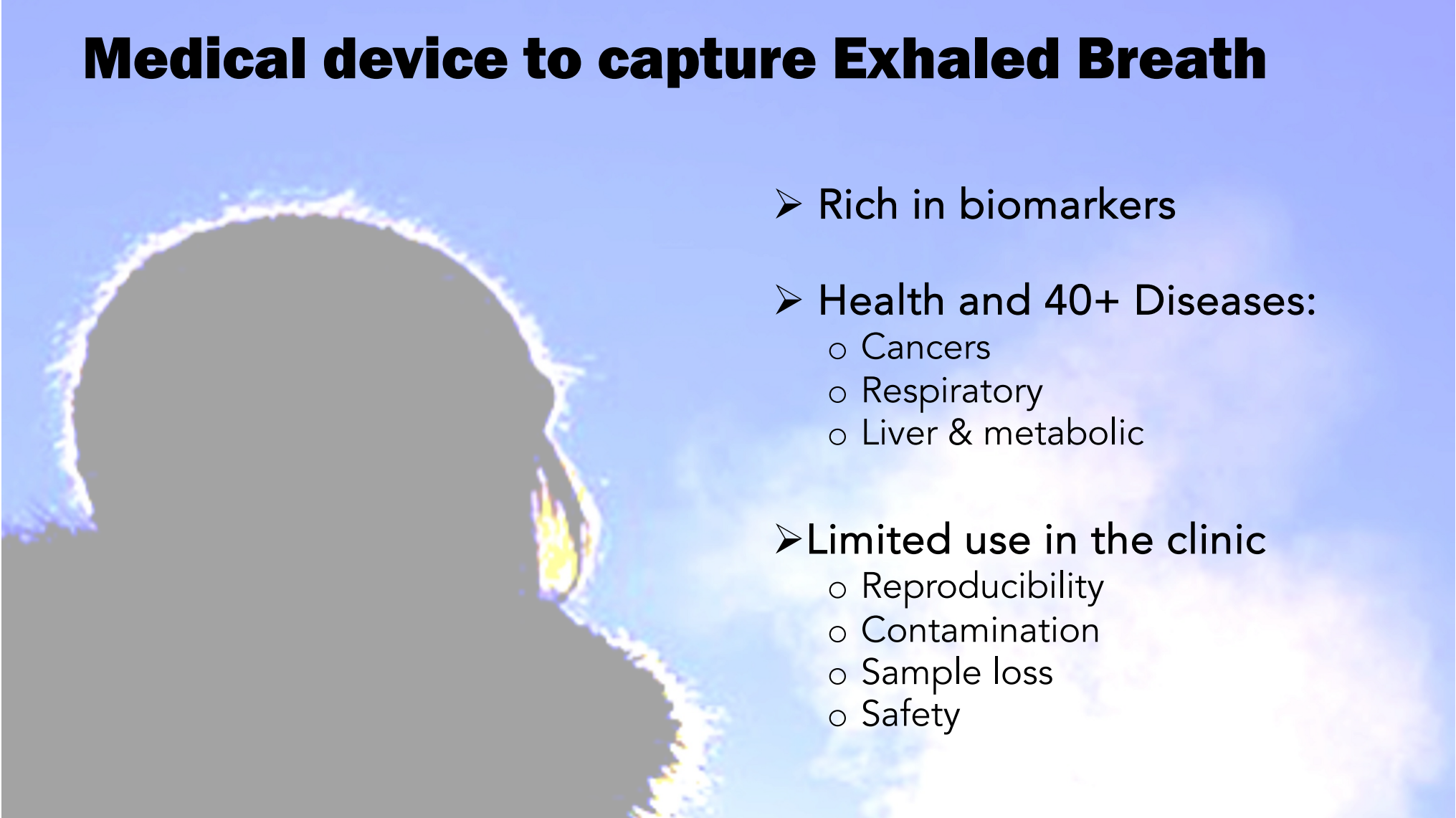
Overview

- Background
- Technical capability
- Clinical data update
- Future focus
- Collaboration and partnerships

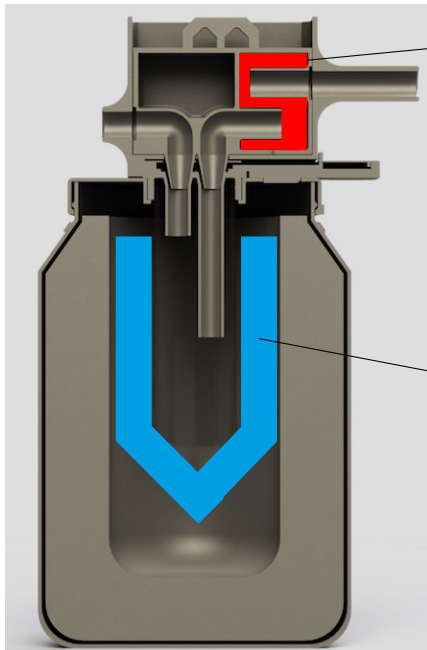


PBM-HALE™

Medical device to capture Exhaled Breath

- 
- Rich in biomarkers
 - Health and 40+ Diseases:
 - Cancers
 - Respiratory
 - Liver & metabolic
 - Limited use in the clinic
 - Reproducibility
 - Contamination
 - Sample loss
 - Safety

PBM-HALE™: Solves Key Problems:



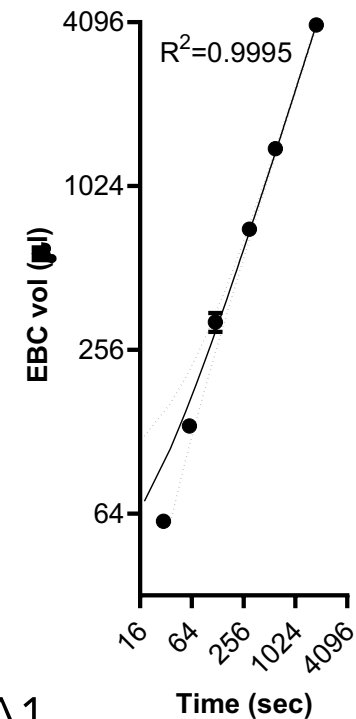
Large droplets

- Saliva, upper airways
- By inertial impaction

Fine aerosols

- Deep lungs
- By cold condensation

Fine aerosol capture



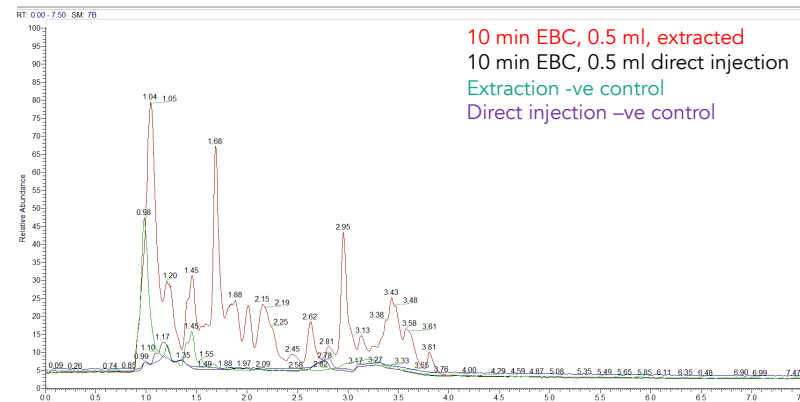
➤ Deep Lung samples: No intubation or sedation

➤ Granted patents: WO2017153755A1 & WO2019053423A1

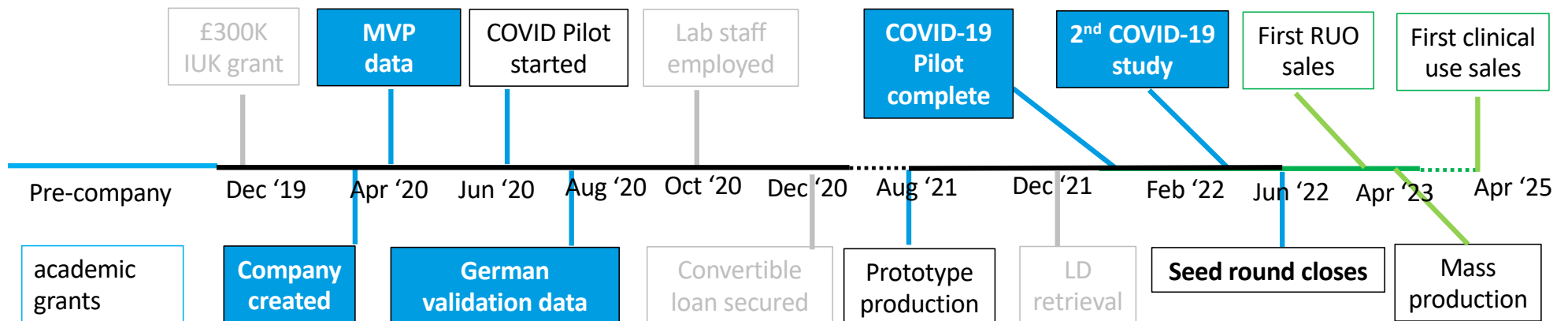
PBM-HALE™ offers access to all pathogen & biomarker classes

- Nanoparticles, viruses, bacteria, fungi
- DNA (0.50 µg/ml)
- RNA (6.03 µg/ml)
- Protein (0.83 µg/ml)
- Short-to-long chain fatty acids (C₆-C₂₄)
- Glycans, medications, drugs of abuse

Content is vesicular



Key event timeline



- Market research enabled
- Business plan COVID19 pivot
- First external study
- Product design development
- Product utility development
- Initial business plan

SARS-CoV-2 clinical data

Pilot study:

- Tidal breath
- Days 0-5 of symptoms (n=30)
- N>12 at days 6+
- Nasopharyngeal swab Ct > 13

- No virus detected in FA

Follow up study:

- Tidal breath vs singing loudly
- Days 0-5 of symptoms (n=30)

- 100% LD & FA singing samples positive
- FA load >>> LD load

Target markets:

➤ 0-5 year old wheeze

- 1/3 of all children <3yo¹
- >1.6 million USA cases per year
- "No way to test right now"



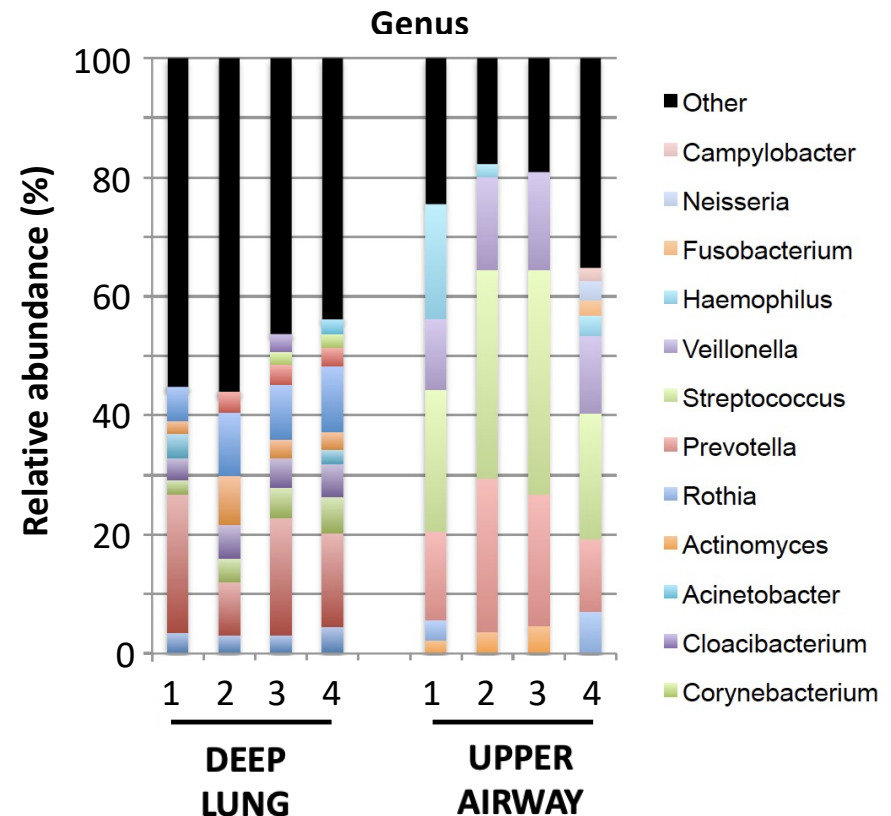
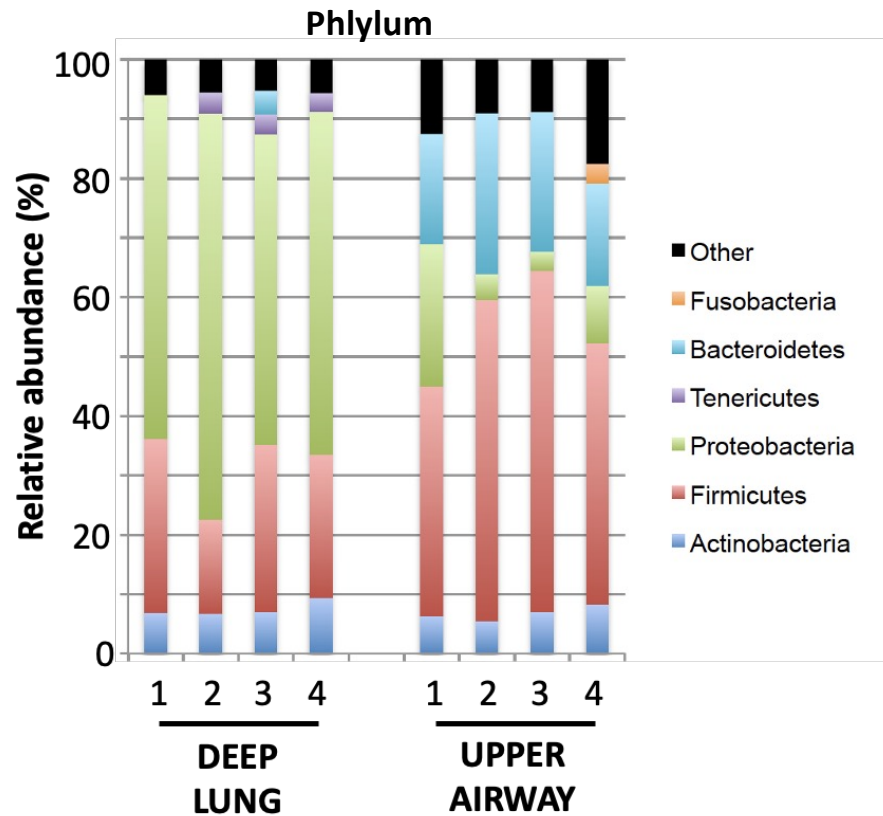
➤ Elderly lung infections

- >960,000 USA hospital admissions p.a.⁴
- >120,500 cases among 65yo+ in UK p.a.^{5,6}
- "Antibiotics and hope for the best"



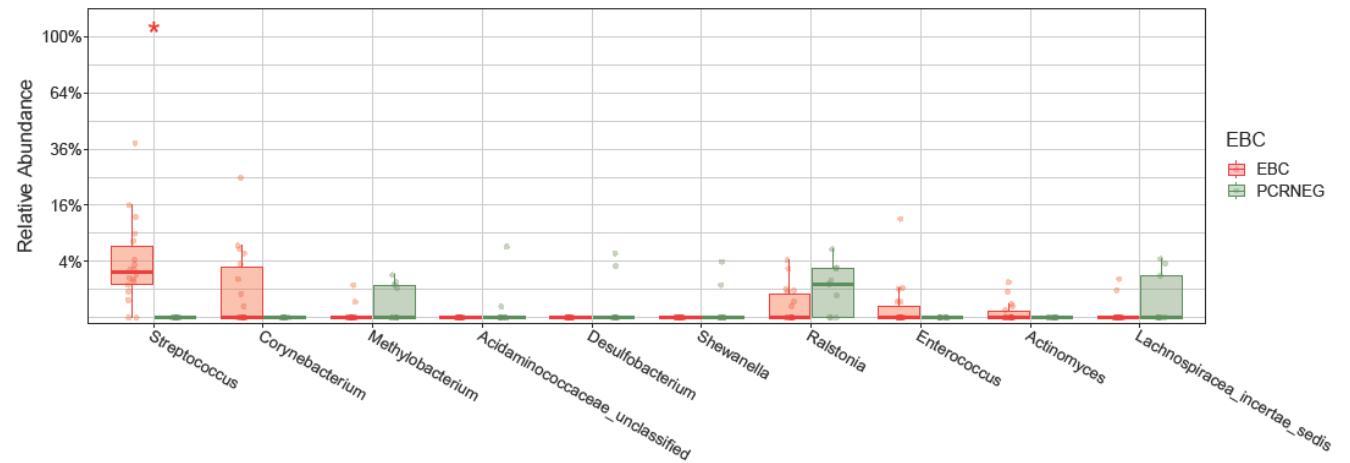
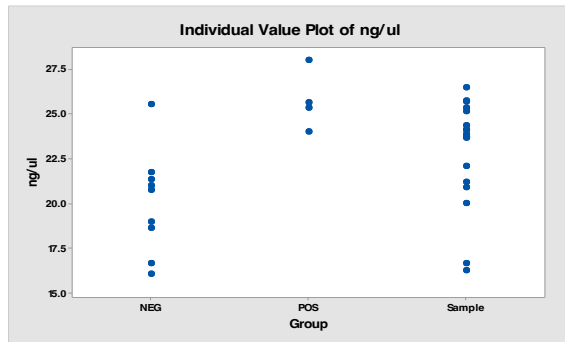
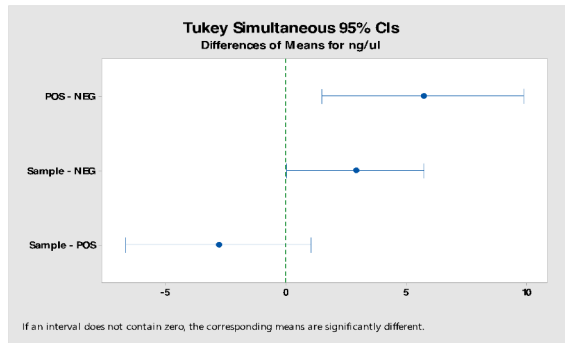
1. Martinez FD NEJM 1995; 2. Brand PL ERJ 2014; 3. USA, EU, Canada, Japan; China: anticipated higher due to pollution; 4. [ATS 2019](#). 5. ONS 2019; 6. [LGA 2017](#).

PBM-HALE™: Stable microbiota in breath



Closest samples: lung surgery (Sze. MA et al. Am. J. Resp. Crit. Care Med. 2012)

Case study: *Streptococcus* in mild cough



Higher DNA content vs background controls.

Detection of *Streptococcus* (FDR $q = 0.019$) by amplicon generation w/out extraction in mild cough.

Detailed work under way to optimize processes, polymerases, pipelines.

Customers: Paediatric asthma clinicians



"PBM-HALE™ could solve asthma diagnosis in pre-schoolers."

"A quarter of all children need this test."

Dr Louise Fleming
Clinical Senior Lecturer
National Heart & Lung Institute

Imperial College
London



NHS
Royal Brompton
& Harefield
NHS Foundation Trust

Customers: Respiratory Clinicians



*"PBM-HALE™ is
FIT FOR PURPOSE,
AS IS"*

Wonnie Ryu MD
Pulmonary Critical Care Clinician
Assistant Professor at Yale



Current activities

Research

- Microbiota SOP
- Adult asthma study
- Pediatric wheeze study
- KOL partnerships

Development

- Complete DFM
- Initiate mass production
- RUO sales
- Class I FDA registration (KGX)

Collaborations & partnerships

Clinical research groups

- Asthma and COPD
- Respiratory infections
- Lung cancer
- Organ rejection

Analytical platforms companies

- Nucleic acid tests
- MS and GC/MS
- Lab / POC / PON

Pharmaceuticals & biotech

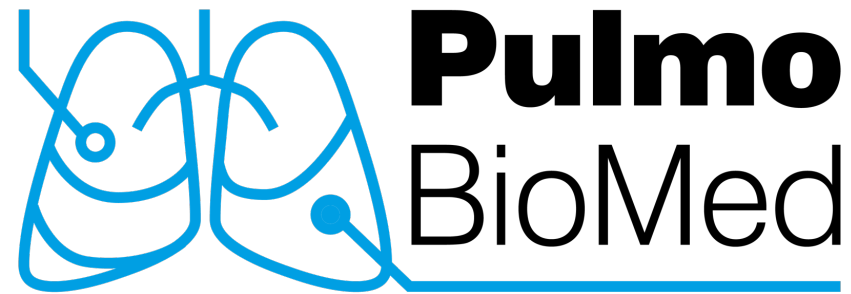
- Biomarker discovery
- Companion diagnostics



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