Innovative Breath-Based Diagnostics for Infectious Diseases

🫁 ***BreathForDx | Newsletter #1***
https://www.breathfordx.org

🔬 About the Project

BreathForDx is a multidisciplinary EU-funded research initiative (2024–2026) aimed at improving diagnosis of respiratory infections through exhaled breath aerosol (XBA) sampling. It combines non-invasive diagnostic innovation with clinical research to detect tuberculosis and viral infections rapidly and accurately. The project aims to develop and evaluate a mask-based and blow-tube based novel breath collection devices (AveloMask and AveloCollect).

📰 Latest News:

📣 BreathForDx Joins Bluesky

We've expanded to Bluesky! Follow us at @breathfordx.bsky.social for news updates and research stories.

🤝 First Annual Consortium Meeting – Milan

The meeting, held on 17 September 2024, brought together all partners to discuss progress in study implementation, clinical workflows, and regulatory aspects.

🧪 Study Sites & Devices

BreathForDx is conducting work across 5 countries:

→ Heidelberg, **Germany** (coordinating center): migrant health screening at a migrant arrival centre (Patrick Henry Village).

→ Milan, **Italy**: migrant health screening at a migrant arrival centres.

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→ **South Africa**: Diagnosis of tuberculosis in symptomatic adults using breath, and comparison with the Respiratory Aerosol Sampling Chamber studies (RASC) for benchmarking and optimization.

→ **Romania**: Diagnosis of tuberculosis in symptomatic adults using breath in primary care clinics.

→ **Switzerland**: Manufacturing and technical refinement of breath collection devices.

Devices Under Study:

AveloMask (facemask-based device): Worn for 45 minutes, collects bioaerosols via controlled coughing and passive respiration.

AveloCollect (blowtube-based device): Collects aerosols after structured coughing and breathing cycles.

Both are being evaluated for detecting: Mtb, Influenza A/B, RSV, and SARS-CoV-2.

📜 Regulatory Insight

The project navigated key EU regulatory challenges in classifying XBA devices. Initial designation as Research Use Only (RUO) conflicted with their intended medical use. Regulatory guidance confirmed classification under IVDR 2017/746, allowing studies to proceed under professional law conditions. Devices are now designated as Class A IVDs (low-risk specimen receptacles), with results excluded from clinical decision-making.

👥 Meet the Team

Led by **UKHD** (**Germany - https://www.klinikum.uni-heidelberg.de/zentrum-fuer-infektiologie/abteilung-infektions-und-tropenmedizin)**, the consortium includes:

OSR (**Italy - https://research.hsr.it/en/divisions/immunology-transplantation-and-infectious-diseases/emerging-bacterial-pathogens.html)**

Avelo AG (**Switzerland - https://www.avelolife.com/about)**

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IPMN (**Romania - https://marius-nasta.ro/sectie/bacteriologie/**)

Desmond Tutu Health Foundation (South Africa https://desmondtutuhealthfoundation.org.za/what-we-do/aerobiology-and-tb-research-unit/)

Scientific leads include Claudia Denkinger, Ankur Gupta-Wright, Daniela Cirillo, Tobias Broger, and Robin Wood. Team members span clinical researchers, engineers, molecular biologists, and implementation scientists.

📅 Upcoming Events

May 31, 2025 – Webinar: “Breath Analysis in Infectious Disease Diagnostics: Challenges & Perspectives”

June 2-3, 2025 Spring school PREPARE-EU - Connecting European Expertise for Pandemic Preparedness", Leuven, Belgium

June 2025 – Pilot site launches in Italy and Germany

✅ Study Within A Trial (SWAT) Recruitment Completion

We are pleased to announce that the teams at Ospedale San Raffaele (OSR) and the University of Heidelberg have completed participant recruitment for the Study Within A Trial (SWAT) phase of a clinical study assessing the feasibility of breath-based screening for respiratory infections in migrants. This is part of the EU-funded BreathForDx project.

This marks a key milestone in the study’s journey toward improving diagnostic strategies for respiratory infectious diseases. With recruitment for the Study Within A Trial now finalised, the focus will shift to data analysis and applying our learning to the design and implementation of the study intervention for the main study, using the SWAT framework.