**A Cystic Fibrosis (CF) Antimicrobial Resistance Syndicate Project**

**Development of Patient-focused Target Product Profiles (TPP) for Lung Microbiological Diagnostic Tests in Cystic Fibrosis**

### Background
The CF AMR Syndicate was formed by the CF Trust and Medicines Discovery Catapult (MDC), and aims to accelerate the translation of CF antimicrobials to the clinic. This will ultimately bring better treatment options to people affected by CF, faster. In addition to new antimicrobials, diagnostics are needed to both predict when infections will cause pulmonary exacerbations and to avoid unnecessary use of antibiotics. This project brings together the complementary expertise of LifeArc, the NIHR Newcastle *In Vitro* Diagnostics Co-operative, the CF Trust and MDC to deliver a TPP for a CF lung microbiological diagnostic.

### Overview of the CF AMR Syndicate Diagnostic TPP project
A TPP outlines the necessary characteristics of a diagnostic to address an unmet clinical need and acts as a guiding document for test developers to develop and manufacture tests efficiently and that can aid clinical research and ultimately be readily adopted into practice for clinical decision-making. Current diagnostic practice in CF is centred on the detection of pathogens from sputum/cough swab through standard culture techniques and *in vitro* antibiotic susceptibility testing, as required either during routine outpatient checkups or during and following acute pulmonary exacerbation. Limitations include; that diagnostic microbiology can be slow, fails to detect emerging pathogens and presence of a specific pathogen doesn't necessarily inform treatment/clinical practice. It is also the case that in the era of highly effective modulator therapy, sputum is less readily available for diagnostic testing. There are therefore opportunities to bring about improvements in diagnosis for lung infections in CF. These TPPs will be informed by people with CF, clinical teams, regulatory bodies and industry, and will be directly representative of their needs and priorities.

We plan to initiate the project in May 2022 and to be in a position to share draft TPPs with the community in December 2022 with a schedule of activities in the first half of 2023 to drive consensus in needs and engage widely with key opinion leaders in the field. Once developed, the TPPs will be made available widely to guide diagnostic development efforts. Ultimately, we hope this activity will act as the basis for a future call for projects to which we would seek to align funding/resource through the capability and focus that LifeArc have in diagnostics.

### Next Steps and Opportunity to Engage

We are currently seeking to engage with a wider number of stakeholders to ensure we develop the project in the right way and identify organisations and/or individuals with common interests.

For further information or discussion please contact Rebecca Holmes (Diagnostic TPP Project Lead; Rebecca.Holmes@lifearc.org) or a member of the CF AMR Syndicate management team (cfamr@md.catapult.org.uk).