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

*Lay Summary*

People with cystic fibrosis (CF) are highly susceptible to developing frequent lung infections which can be difficult to treat, and over time lead to a loss in lung function. The development of new antimicrobial treatments has been highlighted as a key priority area of research by people with CF, and so the CF Trust joined forces with Medicines Discovery Catapult to form the CF Antimicrobial Resistance Syndicate with a mission to speed up the development of new drugs to treat infections associated with CF.

The Syndicate brings together clinicians and people with CF, alongside those in industry i.e., large and small pharmaceutical and biotech companies. Together, the combined expertise of the Syndicate members and the wider research community is driving new research efforts to bring new antimicrobial treatments for CF to the clinic. Going hand in hand with finding new antimicrobials, new diagnostic tools (i.e. to detect and predict infection) are needed which better predict the onset of lung infections requiring treatment, while on the other hand avoid unnecessary treatment where it is not required.

Currently, sputum samples are used for detecting and identifying bacteria or other infectious agent (like viruses or fungi) to help with treatment selection. This process is slow, and nowadays many people with CF on modulator treatment like kaftrio cough up less sputum and find it difficult to ‘produce’ sputum on demand when they come to clinic. Without knowing whether new or previously persistent infectious agents still reside in the lungs, the decision to stop, start or review treatment becomes increasingly difficult due to the lack of sputum samples available to test. In addition, with more clinics being conducted virtually, the need for new and effective diagnostic tools which are easy to use at home, school or work is becoming more evident.

A TPP is an ‘ideal checklist’ that developers of diagnostic tests can use to ensure their new product adequately meets specific patient and clinical needs and requirements. The CF Diagnostic TPP project aims to develop TPPs for diagnosing CF lung infections. It will help set the key characteristics for detection and any ongoing follow up (or monitoring), as well as the criteria that it needs to meet in order to be useful for people with CF. These TPPs will be directly informed by people with CF and be reflective of their needs. To do this, we would like to engage with people from the CF community to get their perspectives and understand more deeply what their needs and priorities are. Once developed, the TPPs will be made widely available for use as a guide by companies and Universities globally so they can ensure their innovative diagnostic test aligns with the needs of people with CF.