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

**Diagnostic TPP Clinical Focus Group – Agenda and Briefing Document**

**1. Introduction**

***Background***

*The* [*CF AMR Syndicate*](https://md.catapult.org.uk/what-we-do/syndicates/cf-amr-syndicate/) which is managed by the CF Trust, Medicines Discovery Catapult (MDC), and LifeArc, aims to accelerate the translation of CF antimicrobials to the clinic, ultimately bringing 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.

The project was initiated in May 2022 and we aim 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.

To enable input from people with CF on their priorities and needs for novel diagnostics to detect and monitor lung infections associated with CF, a focus group was held in July 2022. The focus group was attended by 6 people affected by CF, 3 male and 3 female.

**2. Aim of the Clinical Focus Group**

The aim of the clinical focus group is to gain input from across the CF clinical care team on: The clinical need across the TPPs in development by exploring:

* Existing practices for diagnosing infection in CF
* The unmet needs in CF infection/diagnostics and how this affects delivery of care
* Reflections on the key findings from the patient focus group

**3. How will we use information about you?**

We will need to use information from you for this research project.

This information will include your:

* Name
* Job title
* Place of work
* Contact details (email)

No personal information will be shared outside of the direct research team at any point of this project, and any information used in formal reports and publications will be anonymised. We will keep all information about you safe and secure on a password protected server at Newcastle University.

Newcastle University will keep identifiable information about you for five years after the project has finished. After this time it will be securely destroyed. Any content you provide for this study will be anonymised.

**4. Agenda for the Clinical Focus Group**

The focus group will be joined by:

|  |  |
| --- | --- |
| **Member Photo** | **Title and Role** |
|  | [redacted]   NIHR Newcastle MIC team   * [redacted] will open and lead the session |
|  | [redacted]  NIHR Newcastle MIC team |
|  | [redacted], Cystic Fibrosis Trust  PPI Coordinator |
|  | [redacted]  CF AMR Syndicate Partnership Manager Medicines Discovery Catapult |

|  |  |  |  |
| --- | --- | --- | --- |
| **Time** | **Topic** | **Lead** | **Further info** |
|  | Welcome, introduction to project team and session overview | [redacted] |  |
|  | Overview of the CF AMR Syndicate including diagnostic TPP project, | [redacted] |  |
|  | Q&A | All | After Q&A we will ask for permissions to record the session, see below\* |
|  | Focus group roundtable introductions. Followed by discussion on required & desired diagnostic test characteristics to develop patient focused TPPs for diagnosing infections and exacerbations in CF | [redacted] |  |
|  | Wrap up   * Final comments, next steps and close | [redacted] |  |

\* We would like to seek your permission at the start of the focus group to make a recording to support note taking and analysis.  If everyone is in agreement, we will only start the recording after we have introduced the project. All outputs will be completely anonymised.  Please let us know if you would prefer the focus group was not recorded.

**Teams teleconferencing “etiquette”:**

* If you feel comfortable, please do put your webcam on
* Please mute your microphone when you’re not speaking to reduce background noise
* Please use the ‘raise hand’ function if you would like to ask or respond to a question, or feel free to jump into the conversation as appropriate
* If you have any technical issues, send an email to [redacted] and I will do my best to help
* Feel free to use that chat function on Teams to send a message to the group e.g. links to online documents

**5. Next steps of the TPP project**

Following the clinical focus group and further clinical review as relevant, we will engage a group of industry representatives from companies working in diagnostic development and CF, to ensure that the TPPs are useful for industry and to finalise the documents.

Once developed, the TPPs will be disseminated by:

* Development of an engaging and interactive online tool with video case studies from people with CF
* Submission of a peer review publication

The TPPs will then be shared widely with companies and Universities globally to guide diagnostic development efforts and to ensure that new diagnostic technologies meet the needs of people with CF. We will also explore additional approaches to support the dissemination of the TPPs, for example, via a virtual online symposium that will bring together diagnostic/CF companies with people with CF to discuss the TPPs and the needs and priorities of people with CF.

**More information on Diagnostic TPPs**

The following are examples of the kind of characteristics that are considered in diagnostic TPPs for infections:

* **‘Time to result’** i.e. The length of time it takes for a result to appear
* **‘Result Output**’ i.e. how the test result is reported e.g. in the form of a number or positive/negative result
* **‘Organisms covered’** i.e. the type of bacteria/fungi/virus most easily detected by the test.
* **‘Sample type’** i.e. the nature of the sample and/or the way it is taken e.g. finger prick, cough swab, throat swab.
* **‘Sample preparation’**, i.e. any preparation that the sample has to undergo first before it can be tested.
* **‘Size’**, e.g. the proportions/dimensions of the device/technology.
* ‘**Storage and use’** i.e. of the device/technology including shelf-life and storage conditions e.g. room temperature, fridge
* **‘Performance’**, i.e. the specificity and sensitivity of the test in accurately detecting an infectious agent
* **Test Format**, ie the way the test kit is presented, including any materials and accessories
* **Patient population**, ie those groups people for who the tests are most suitable for.