Target product profiles (TPPs) for lung infection diagnostics in cystic fibrosis

Project team:
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Medicines Discovery Catapult: Connie Takawira, Beverley Isherwood
NIHR Newcastle In Vitro Diagnostics Co-operative (NIHR Newcastle-MIC): Raasti Naseem, Kile Green, Will Jones

Scan to find out more about the LifeArc Chronic Respiratory Infection Translational Challenge

Overview

LifeArc is partnering with The Cystic Fibrosis Trust, Medicines Discovery Catapult and Newcastle In Vitro Diagnostics Co-operative (Newcastle-MIC) to develop target product profiles (TPPs) to accelerate the development of new infection diagnostic tests for people living with cystic fibrosis (CF). A TPP outlines the necessary characteristics of a diagnostic to address an unmet clinical need. The TPP acts as a guiding document enabling new tests to be developed and manufactured efficiently, that can also aid clinical research and ultimately be readily adopted into practice for clinical decision-making. Developed in consultation with people with CF (pwCF), healthcare professionals and industry, the TPPs will identify what tests are required to deliver optimal treatment for patients. The final published TPPs will be a resource for the community, providing areas of focus for industry and highlighting key priorities for investment.

The challenge: PwCF suffer frequent, often chronic, lung infections requiring gruelling treatment regimens. The ability to detect infections earlier and monitor how well an infection is responding to therapy, could enable clinicians to target treatment more effectively, reducing side-effects and the likelihood of resistance emerging. In the era of highly effective modulator therapies, sputum is less readily available in many patients resulting in a need for new diagnostic tests using different sample types.

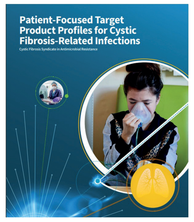
Partners

LifeArc
- Medical research charity with expertise in supporting translation
- Dedicated capability in diagnostic development
- Translational challenge on Chronic Respiratory Infections
- CF AMR Syndicate managing partner

NIHR | Newcastle In Vitro Diagnostics Co-operative
- Member of the NIHR MedTech and In Vitro Diagnostics Co-operative (MIC)
- Expertise in generating high quality evidence that demonstrates potential benefits of a new medical test

Cystic Fibrosis Trust
- Only UK-wide charity dedicated to uniting for a life unlimited for everyone affected by CF
- Funds cutting edge research, provides confidential advice, support, and information
- Strong network and active CF community involvement
- CF AMR Syndicate managing partner

CATAPULT Medicines Discovery
- Not-for-profit part of national innovation infrastructure
- Dedicated capability in biomarkers/ personalised medicine
- Key focus on Infectious Disease
- CF AMR Syndicate managing partner



This project will draw on experience of CF antimicrobial resistance (AMR) Syndicate in developing therapeutic TPPs for tackling CF infections

Left picture: Project team partner organisations
Right Picture: Brochure outlining CF AMR Syndicate CF infection therapeutic TPPs

TPP development process

1. Focus group of pwCF
2. Clinical focus group
3. Industry insights and expertise
4. Delphi Survey
5. Virtual Symposium

Scoping

Patient focus group:

July 2022:
6 people (3 male 3 female)

Questions around current diagnostic path, challenges, unmet need

Clinical focus groups:

October 2022:
Two separate groups

Questions around current diagnostic path, challenges, unmet need and discussion of TPP characteristics

Group 1

Role	Trust
Clinician (adult)	Royal Brompton
Clinician (adult)	Liverpool H&C
Pharmacist (paeds)	Royal Brompton
Physio (adult)	York&Scarborough
Biomed. Scientist	Newcastle
Nurse	Cardiff Vale

Group 2

Role	Trust
Clinician (adult)	Cardiff Vale
Clinician (paeds)	Leeds
Physio (adult)	Liverpool H&C
Pharmacist (adult)	Cardiff Vale
Biomed. Scientist	Newcastle
Nurse (paeds)	South Warwickshire

Analyse, develop TPPS

1:1s

Role	Affiliation
Clinician (adult)	Royal Brompton
Clinician (adult)	Southampton, UK
Industry	France
Clinician (adult)	Manchester, UK

Top picture: TPP development process
Bottom image: plan for clinical input including focus groups and 1:1s

Work packages

WP1: Systematic Review
- Develop search strategy
- Run search and organise data
- Screen articles
- Analysis and report writing

Output: Report on Dx in use and in development

Lead: Newcastle-MIC

WP2: Scoping/drafting
- Map KOLs
- Hold focus groups with pwCF, clinical team
- Industry 1:1s
- Convene working group
- Draft TPPs
- Analysis, develop TPPs

Output: Unmet need, key characteristics/priorities, 1st draft TPPs

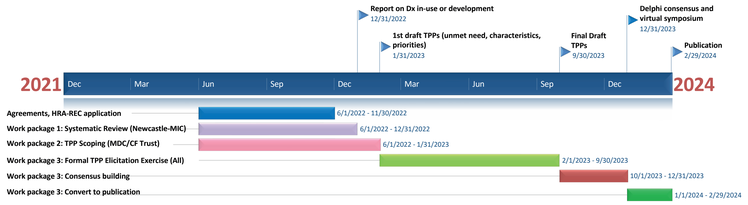
Lead: MDC and CF Trust

WP3: Formal TPP Elicitation Exercise
- Recruitment of patients and clinical experts
- PwCF and clinical 1:1s
- Industry, regulator 1:1s
- Engage working group
- Analysis and report writing
- Delphi consensus exercise/ virtual symposium

Output: Finalised TPPs, peer-reviewed publication

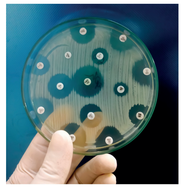
Lead: All

Timeline and deliverables



Key dates/deliverables

- Project initiated in June 2022
- Patient focus groups July 2022
- Clinical focus groups October 2022
- Report on current diagnostics and those in development December 2022
- First draft TPPs Q1 2023
- Final draft TPPs Q3 2023
- Publication Q1 2024



TPPs will aim to cover:
- Unmet clinical need
- Desirable analytical performance
- Clinical validity
- Human factors
- Infrastructural requirements
- Regulatory requirements
- Clinical utility

The final published TPPs will be a guiding document for test developers and will help stimulate interest and investment into new diagnostics for lung infections in people with pwCF

Top picture: Work-packages; middle picture: Project timelines
Bottom image: Antibiotic susceptibility testing