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

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 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.

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 group:
October 2022: Two separate groups
Questions around current diagnostic path, challenges, unmet need and discussion of TPP characteristics

Work packages

WP 1: Systematic Review
- Develop search strategy
- Run search and organize data
- Screen articles
- Analysis and report writing
Output: Report on Dx in use and in development

WP 2: Scoping/drafting
- Map KOLs
- Hold focus groups with pwCF, clinical team, industry 1:1s
- Conduct working group
- Draft TPPs
- Analyze, develop TPPs
Output: Unmet need, key characteristics/priorities, 1st draft TPPs

WP 3: 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: Finalized TPPs, peer-reviewed publication

Timeline and deliverables

WP 1: Systematic Review
- 1st draft TPPs (unmet need, characteristics, priorities)
- Final draft TPPs Q3 2023

WP 2: Scoping/drafting
- 1st draft TPPs Q1 2023
- Final draft TPPs Q3 2023
- Publication Q1 2024

WP 3: Formal TPP elicitation exercise
- Report on current diagnostics and those in development December 2022
- First draft TPPs Q1 2023
- Final draft TPPs Q3 2023

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.