Exploiting Host Response for the Early Diagnosis of Infection and Sepsis

Presymptom Health

Presymptom Health has been selected to participate in the UK's pioneering Innovative Devices Access Pathway (IDAP) pilot – a new pathway designed to ensure that technology is helping UK patients as quickly as possible.

Founded in 2019, **Presymptom Health** is developing a diagnostic portfolio based on the results from a major £16M, 8-hospital study.

Presymptom Health technology is being developed to address significant Antimicrobial Stewardship & Sepsis diagnostic opportunities, leveraging datasets from 7 ongoing or completed clinical discovery and validation trials encompassing nearly 5,500 patients.

Our first antibiotic stewardship product will launch in the UK in 2025. This product (InfectiClear) will offer 95% accuracy up to 3 days before current clinical diagnosis.

Presymptom has raised a total of £3m, including closing of a £1.5m round announced on March 21, 2024.

Highly Differentiated Host Response Technology

Presymptom Health's technology platform focuses on RNA-based host response analytics. Providing a highly sensitive pathogen-agnostic early signal of active infection and severity/sepsis.

This overcomes the significant limitations associated with traditional pathogen-centric approaches:

- Long time-to-result of microbiological culture exceeds acute care window and low accuracy;
- Molecular panels yield uncertain diagnostic etiology in majority of patients (75% of patients uncertain in recent 4,600 patient PERFORM cohort; 2023);
- Clinicians don't know whether to treat and what to treat.

> **"Ruling out the presence of infection (Presymptom Health's initial product) is as important as antibiotic development to address the Antimicrobial Resistance crisis"**
>
> **Chris Witty, Chief Medical Officer, England, October 2023**

Clinical Focus Areas (Antimicrobial Resistance & Sepsis):

11m infection-related deaths per annum. Standard of diagnostic care is slow (1-3 days) and lacks accuracy; (50-80%)

Late and imprecise diagnosis leads to:

Inappropriate care pathway and **inefficient resource allocation**.

Antimicrobial Misuse & Resistance (AMR) associated with 1-5M deaths; $20B cost in US alone.

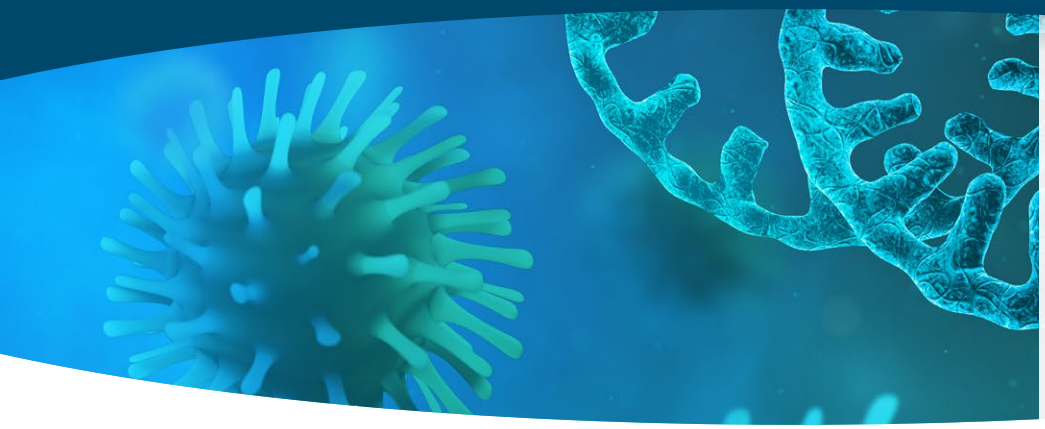
Poor outcomes.
7.6% mortality per hour from delayed sepsis diagnosis.

Presymptom USPs:

Early diagnosis of:
- **Infection**
- **Sepsis**

> **"The work of Presymptom Health has potential for high impact to patients and high return to the UK economy"**
>
> **Ron Daniels, CEO, the Sepsis Trust**

Presymptom Health



Foundational Discovery Study:

10-year presymptomatic **clinical study**. [dstl]

4,385 elective **surgery patients**.

Daily blood samples (PAX, serum, plasma).

c100,000 sample/aliquot proprietary biobank, full clinical annotation.

100 collaborating **clinicians/researchers**.

Results published 2022.

Core Strategy

Leverage host response genomics to transform early diagnosis of Illness (infection) and severity (sepsis) by:

- Generating and exploiting unique clinical cohorts & evidence base
- Applying machine learning pipeline to develop actionable insights
- Deploying lean core team overseeing outsourced providers to develop portfolio of novel tests under ISO13485 framework to 1st regulatory milestones
- Partnering for commercial distribution & exploitation

Our Technology & Clinical Studies:

Over 5,500 Patients

7 Clinical Studies: PRECISION, SEPTIMET, NIH National Institutes of Health, UMC Utrecht, ISARIC 4C, -EBI, GenOMICC

12 UK/EU Hospitals

mRNA-based infection & sepsis blood tests

Deployment on **diverse lab** & **near-patient cartridge-based systems**

Product Development: UKCA mark by mid-2025

Our first antibiotic stewardship product will launch in the UK in 2025.

- Host response PCR test for Antibiotic Stewardship.
- Will be run on existing 3rd party PCR systems.
- Target time to result: 1-6 hours (platform dependent).
- Result will be delivered as infection risk score; can be used to either rule out or rule in infection.

infectiClear

RULING OUT INFECTION

For further information contact:

Iain D. Miller, Ph.D.
CEO, Presymptom Health Ltd
iain.miller@presymptom.com