Protocol for a Diagnostic Study: The CORMORANT (COPD tRansforMation of diagnOstic pathways in pRimary cAre using N-Tidal) study

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Current Problem

Spirometry is the gold standard for COPD diagnosis, but is difficult for patients, time-consuming, and requires specialist training leading to variability in access and quality. This contributes to ~1.5 million undiagnosed, untreated patients in the UK, where COPD disproportionately affects underserved communities. Delayed diagnosis worsens outcomes and increases pressure on the NHS, especially during winter when respiratory illnesses peak.

The Solution

TidalSense has developed and regulated N-Tidal Diagnose that can be used in combination with the N-Tidal Handset as a point-of-care diagnostic solution for COPD. The shape of the exhaled CO_2 waveform, captured using the N-Tidal Handset during 75 seconds of normal breathing, is automatically interpreted using N-Tidal Diagnose diagnostic AI-algorithms. A diagnostic result is outputted to a web-based dashboard within 10 minutes of starting the test.

Aim

The CORMORANT study will evaluate the diagnostic performance and acceptability of N-Tidal Diagnose in primary care, compared to spirometry. Findings will also support future health economic evaluations and inform potential implementation into primary care.

Figure 1: N-Tidal Handset in use
The N-Tidal Handset is used to record levels of CO_2 in the patient's breath for a period of 75 seconds.

Methods

CORMORANT is a post-market diagnostic accuracy study, recruiting 500 adults aged ≥35 years, referred for diagnostic spirometry, across 24 primary care sites purposively selected to include areas of higher deprivation. Following consent and questionnaires online, participants will use N-Tidal Diagnose prior to spirometry. A subset of participants and professionals will be interviewed on feasibility and acceptability.

Results

The study opened in July 2025 and 6 sites are open to recruitment. The primary outcome is the diagnostic accuracy of N-Tidal Diagnose (index test) compared to consensus expert panel diagnosis based on spirometry (reference test).

If shown to be accurate and acceptable, N-Tidal Diagnose could offer a faster, simpler alternative to spirometry, reducing delays in diagnosis of COPD. This will help reduce health inequalities and NHS winter pressures by improving access to COPD diagnosis in primary care.

Figure 2: N-Tidal Diagnose web-based Dashboard
N-Tidal Diagnose on-cloud software processes the CO_2 breath record and applies machine learning algorithms to provide a diagnostic output on the web-based N-Tidal Diagnose Dashboard. The result can then be interpreted by a healthcare professional who can make a respiratory diagnosis.
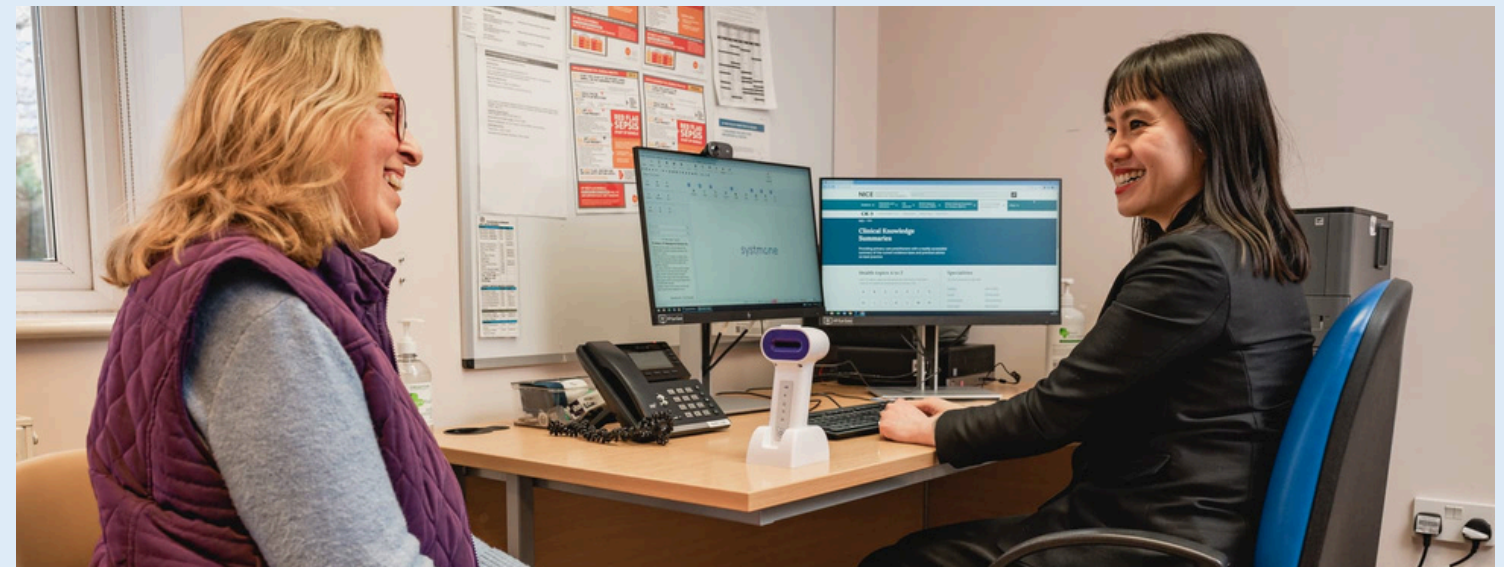
Get Involved!

We are looking for:

ARTP-registered professionals to perform spirometry interpretation (flexible/remote and would be paid)
COPD experts to perform clinical diagnosis adjudication (flexible/remote)
All professionals involved in diagnosis of COPD to complete our survey about COPD diagnosis where you work: Please scan the QR code below (it takes about 20 minutes and is SmartPhone-friendly)

If you are interested in helping us transform COPD diagnosis in primary care, please contact us with the details below.

Contact us
cormorant@phc.ox.ac.uk
www.phctrials.ox.ac.uk/recruiting-trials/cormorant

Clinician Survey