Using Infra-red Spectroscopy to Detect and Monitor Chronic Obstructive Pulmonary Disease

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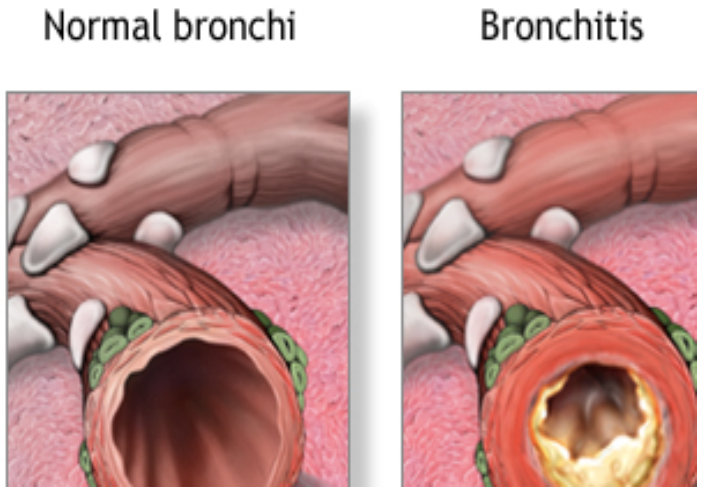
Company History

- PulmonIR was founded in February 2016 to commercialise the work of Professor Paul Lewis at Swansea University
- It is a spin-out of Swansea University Medical School and is currently focused on the detection and monitoring of Chronic Obstructive Pulmonary Disease
- PulmonIR has received investment from IP Group, Finance Wales and the Swansea University Innovation Fund to conduct preliminary clinical trials in collaboration with Cwm Taf University Health Board
- PulmonIR has also received funding from the Welsh Government's Health Technology and Telehealth Fund to purchase specialist equipment for conducting the clinical trials

Chronic Obstructive Pulmonary Disease (COPD)

- Obstructive lung disease characterized by chronically poor airflow
- Tobacco smoking is the most common cause
- Long-term exposure causes an inflammatory response in lungs = narrowing of the small airways and breakdown of lung tissue
- Most patients have chronic bronchitis & cough up sputum



- Worsening of condition = exacerbation = hospitalization
- Average of 3.5 exacerbations /year
- Patients with stable disease are at baseline

- 330 million people affected worldwide (5%)
- 3rd leading cause of death (2.9 million/annum)
- Economic cost of $2.1 trillion in 2010

- Exacerbation hospital costs/annum to NHS
  - UK £4 billion

No current biomarkers for exacerbation

Huge cost-saving to healthcare providers

COPD Diagnosis

The Global Initiative for Chronic Obstructive Lung Disease (GOLD)

Diagnosing COPD

- Chronic cough
- Breathlessness
- Increased sputum production
- Measure lung function = degree of airflow obstruction (FEV) - Spirometry

Exacerbation Symptoms

- Shortness of breath
- Increased coughing
- Increased sputum volume and/or purulence
- Reduced FEV

Spirometry

- Inaccurate
- Insensitive – 60% accuracy at best

SPEDIC Trial

Spectroscopic Technology to Predict Exacerbations and Diagnose COPD

PulmonIR

Longitudinal Study

- COPD Exacerbation detection
- Raw sputum
- 50 patients
- 5 sputum samples per week
- 12 months

Prince Charles Hospital, Merthyr
Cwm Taf University Health Board

Swansea University
Prifysgol Abertawe

PulmonIR

Case-Control Study

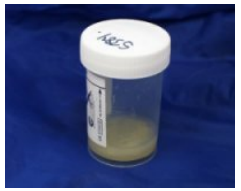
- COPD diagnostic study
- Raw sputum & urine
- Collection @ time of diagnosis
- 100 newly diagnosed cases
- v
- 100 non-COPD smokers

FTIR @ Point-of-Care

Clinical Trial Overview

50 Patients

Sputum (& Urine)



SPEDIC Trial

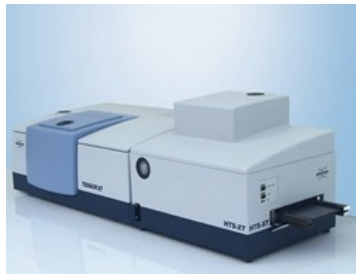
Daily paper diaries:

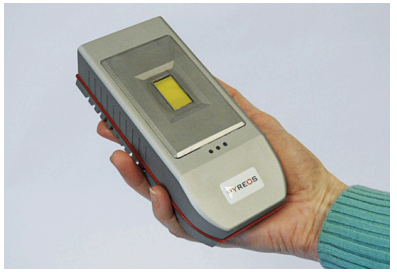
- Clinical COPD Questionnaire
- Level of breathlessness
- Sputum production
- Signs of infection
- Medication
- Interaction with health professionals

COPD clinics / in-patients

Baseline → Exacerbation → Baseline → Exacerbation → Baseline → **12 Months**

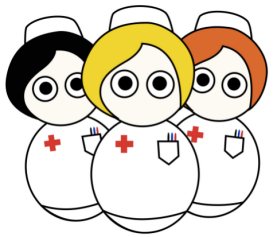
An exacerbation reported by a patient will be confirmed using the Anthonisen criteria.





Clinical Trial Logistics

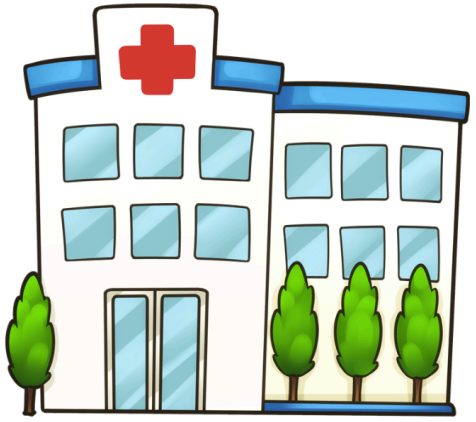
Patients recruited in wards/clinics



1 x Research Nurse
3 x Healthcare Assistants

SPEDIC Trial

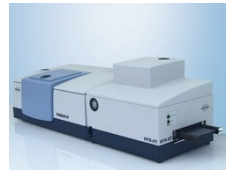
5 sputum samples / patient / week



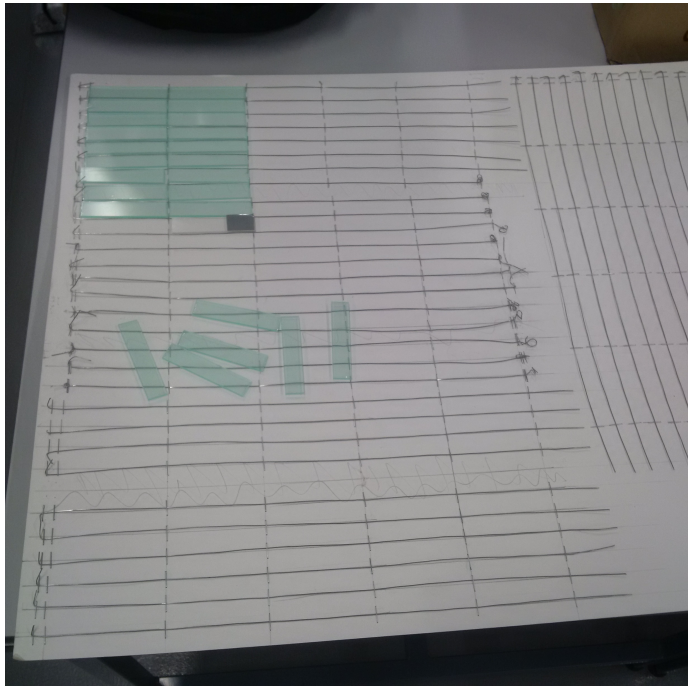
Prince Charles Hospital

FTIR analysis Swansea University

FTIR analysis



Swansea Laboratory Setup

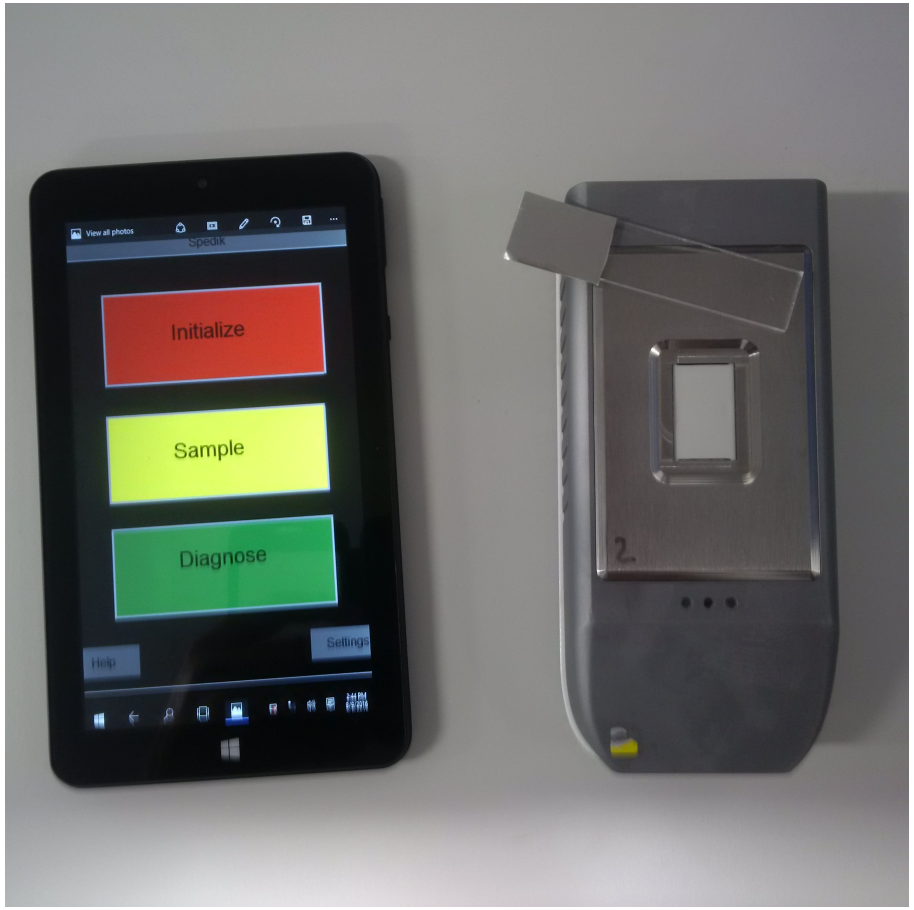


SPEDIC Trial

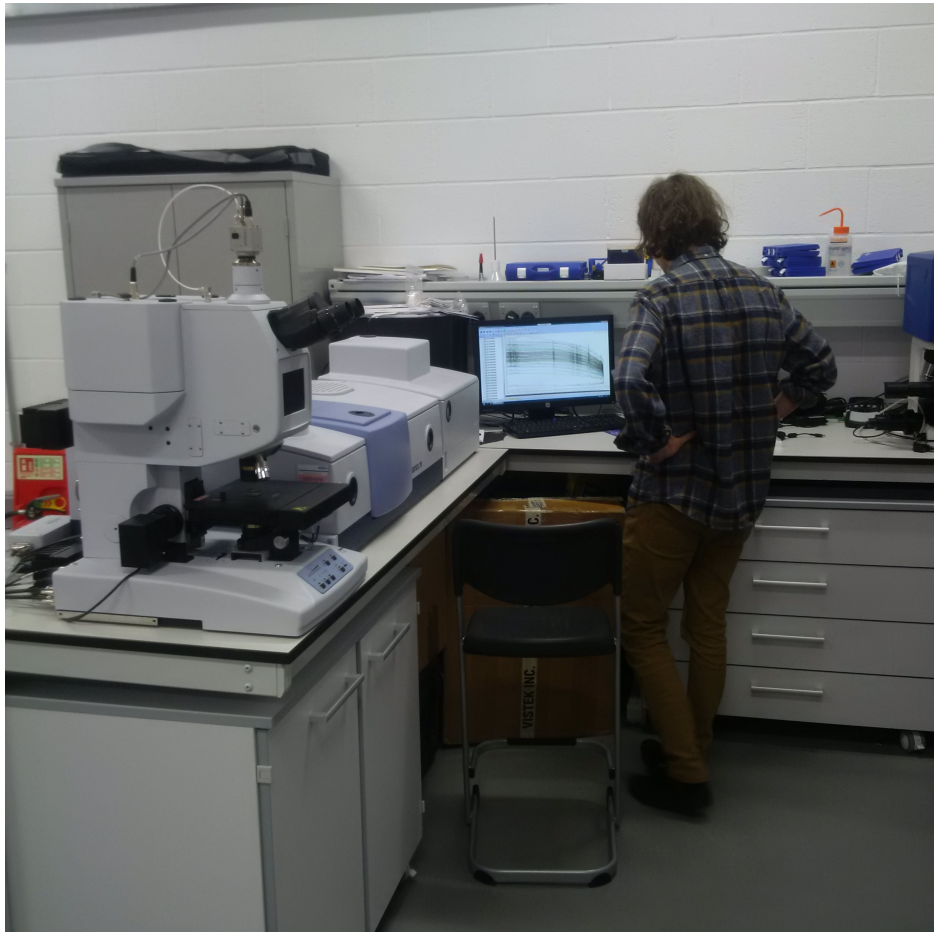
- 1 Technician
- 50 samples a day x 3 replicates = 2 HTS plates
- 5 Handheld devices in parallel
- Reproducibility will be assessed

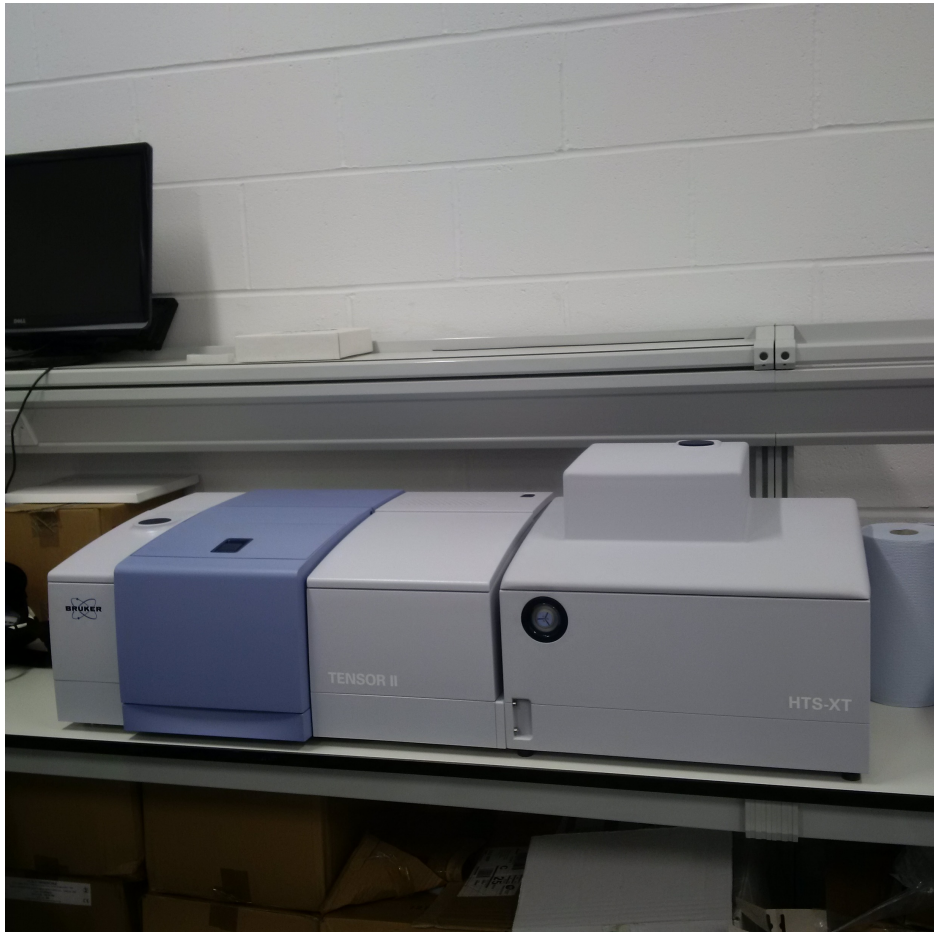
Sample strips manufactured weekly on batch

Handheld Spectrometers used in the Clinical Trial



High-throughput Benchtop FT-IR system





Future Plans

- Following completion of the current trials, PulmonIR will need to:
  - Carry out additional clinical trials;
  - Pursue further product development; and
  - Secure CE marking for the system prior to launch
- Funding is in place to begin the necessary work in 2017
- PulmonIR is well-positioned to launch this exciting technology into the NHS and other international health systems in due course