SAFE-D Trial design: Targeted pancreatic cancer screening to evaluate stage and resectability rate shift in patients with new onset diabetes

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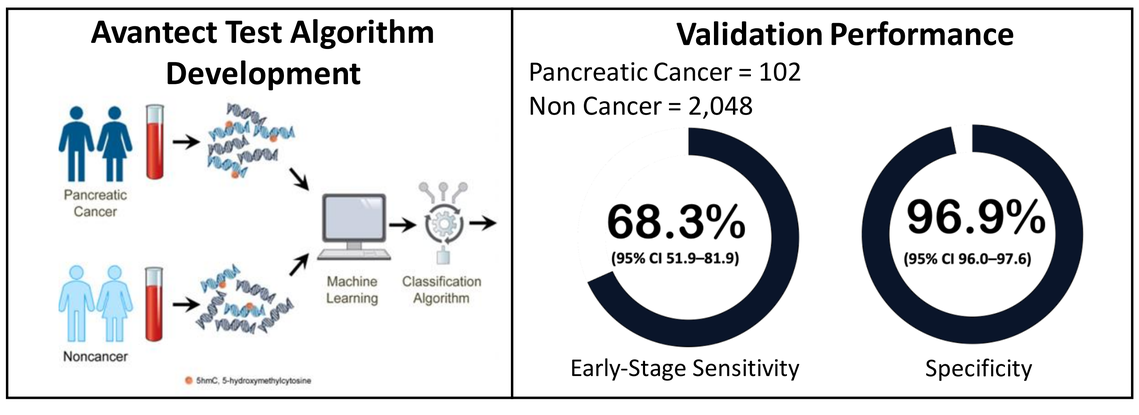
INTRODUCTION

Pancreatic cancer (PC) is among the deadliest cancer worldwide and often detected too late when potentially curative interventions, such as surgery, are no longer an option. Whilst early detection of PC can drastically improve survival rates, there is a lack of acceptable molecular tests for individuals at either average risk or higher risk for disease.

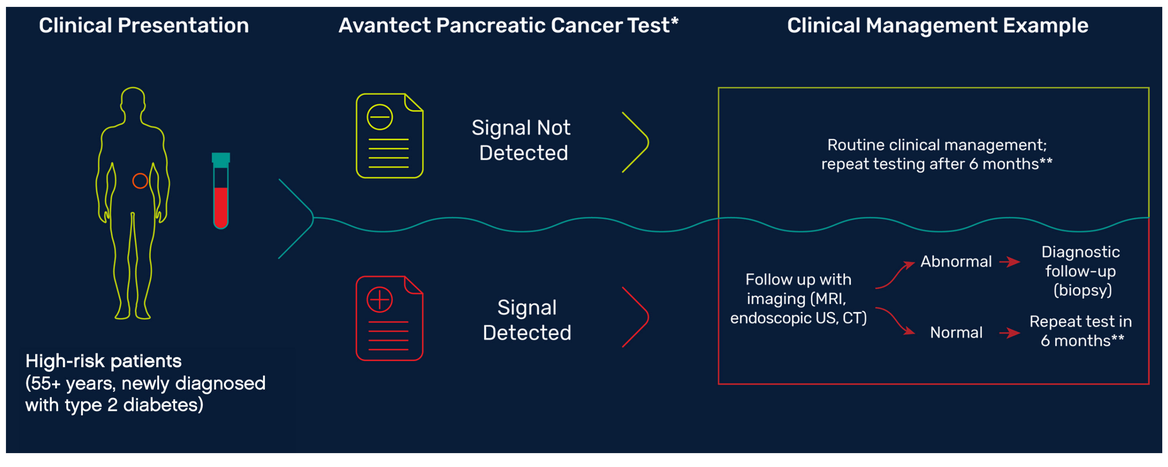
Studies have identified individuals with new-onset type II diabetes (diagnosis made <36 months; NOD) as a high-risk population that could benefit from early detection of PC. The Southampton Clinical Trial Unit (SCTU) has designed SAFE-D (**S**creening for p**A**ncreatic health a**F**ter diab**e**tes **D**iagnosis), a study that aims to detect PC early to improve the frequency of curative surgical intervention, leveraging the epigenomic, non-invasive blood based Avantect Pancreatic Cancer Test.

METHODS

Avantect is a cell-free DNA (cfDNA)-based blood test. It combines epigenomics and genomic features to detect the presence or absence of an abnormal signal in the blood associated with pancreatic cancer.



Haan D, et al. Epigenomic Blood-Based Early Detection of Pancreatic Cancer Employing Cell-Free DNA. *Clin Gastroenterol Hepatol*. 2023



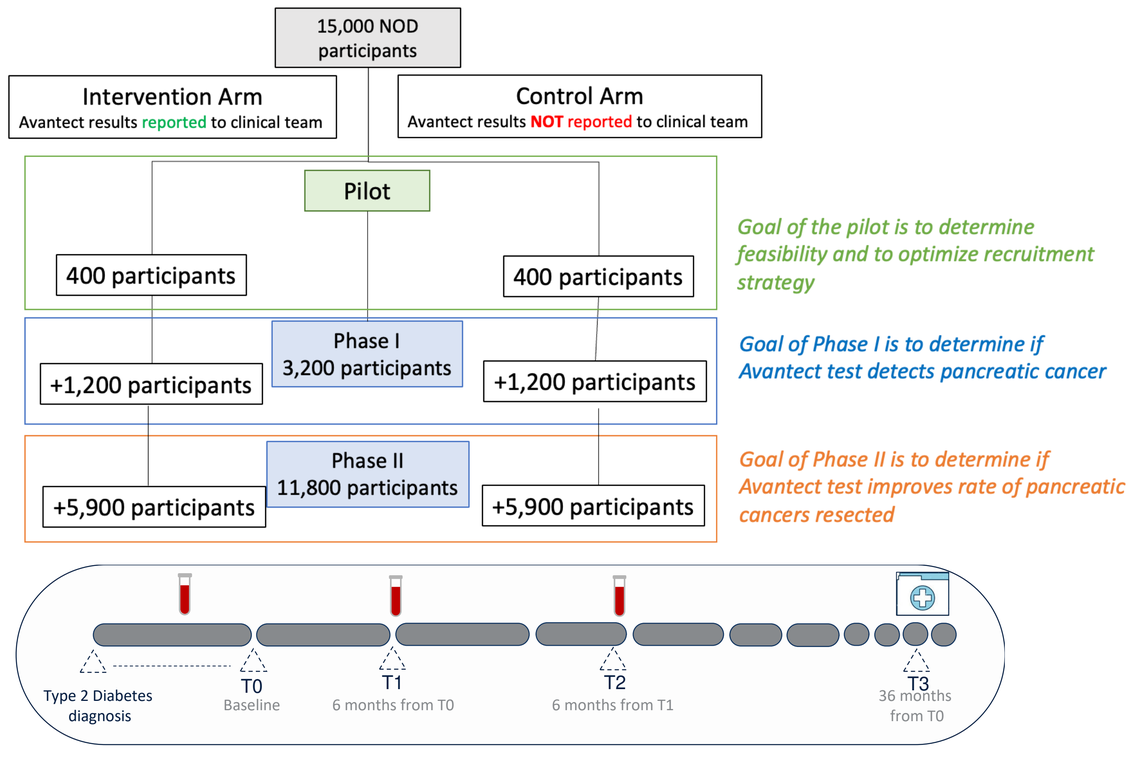
STUDY OVERVIEW

Study Design: Prospective, single blinded interventional randomized controlled multicentre study.

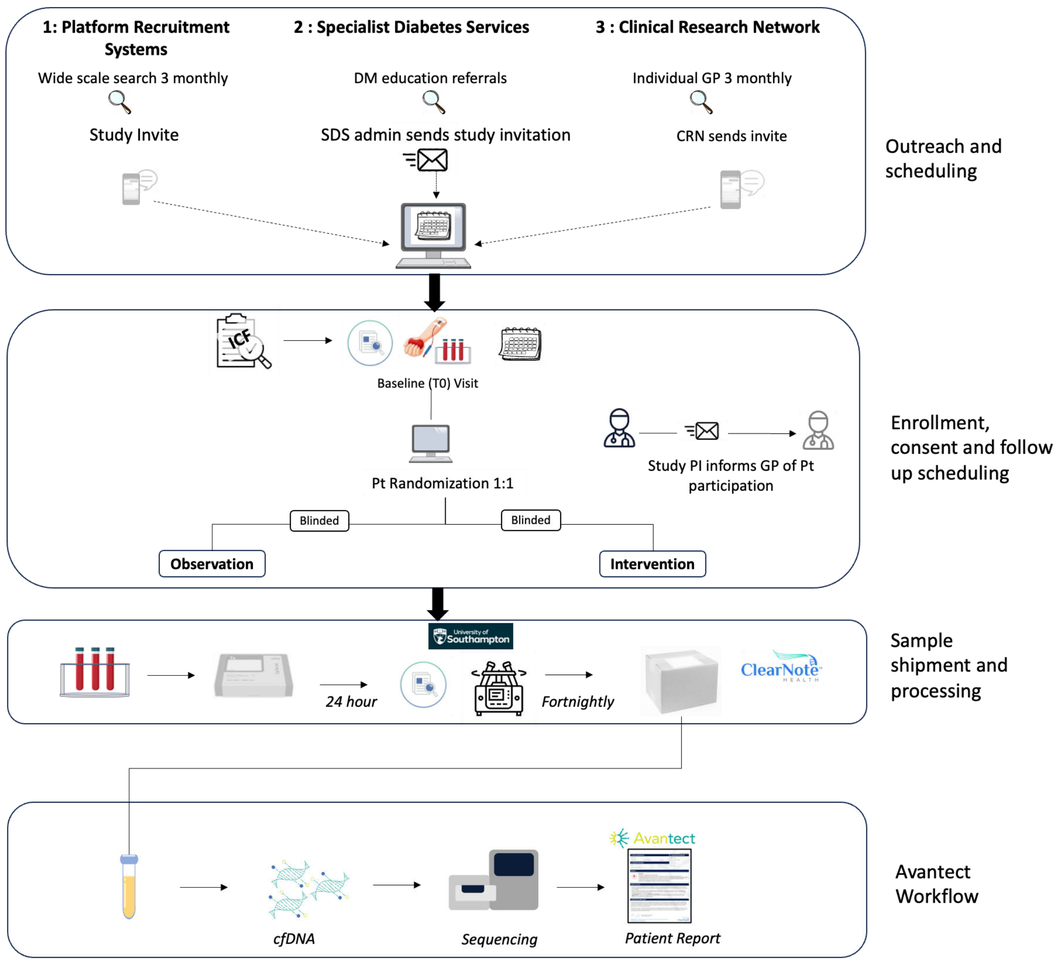
- Intervention arm: Only Avantect "detected' results will be shared with the participants and their General Practitioners (GPs) and follow up MRI or CT will be conducted.
- Observation arm (standard of care): Participants will undergo routine clinical care. Avantect test will analyzed on an annual basis and results will not be shared with the participants and their General Practitioners (GPs).

Eligible Participants: ≥ 55 years old Male and Female, <32 BMI and within 6 months Type 2 Diabetes diagnosis

Number of Study Visits: 3 blood draws. At T3 (36 months from T0) medical record review and cancer registry information will be reviewed.



RECRUITMENT STRATEGY and SAMPLE PROCESSING



The study will initiate with a pilot involving three modes of recruitment:

1. From GP practices using web-based recruitment platform systems
2. From Specialist Diabetes Service
3. From GP practices through NIHR Clinical Research Network Primary Care Networks

At the end of the pilot, feasibility and adjustments to improve enrolment will be assessed.

STUDY OBJECTIVES

1. Evaluate the positive predictive value (PPV) of the Avantect test in detecting pancreatic cancer in NOD subjects.
2. Evaluate the fraction of pancreatic cancers that are deemed resectable across intervention arm and observation arm.