Implementation of the Avantect Pancreatic Cancer Test in Newly Diagnosed Type 2 Diabetes Patients in a Clinical Setting

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INTRODUCTION

Pancreatic Cancer is the 3rd leading cause of cancer mortality and predicted to be the 2nd-leading cause by 2030. Pancreatic cancer is often diagnosed in late stages and has a poor survival. Studies have identified patients with new-onset type II diabetes (diagnosis made ≤36 months; NOD) as a high-risk patient population that may benefit from early detection of pancreatic cancer (1,2). **Patients with NOD have up to 6-8x greater risk of developing pancreatic cancer.**

ClearNote Health has validated a non-invasive, blood-based, epigenomic early detection pancreatic test called Avantect. The test has been validated in a large case-control study, including patients with NOD (3). The testing is performed in the ClearNote CLIA-certified, CAP-accredited laboratory.
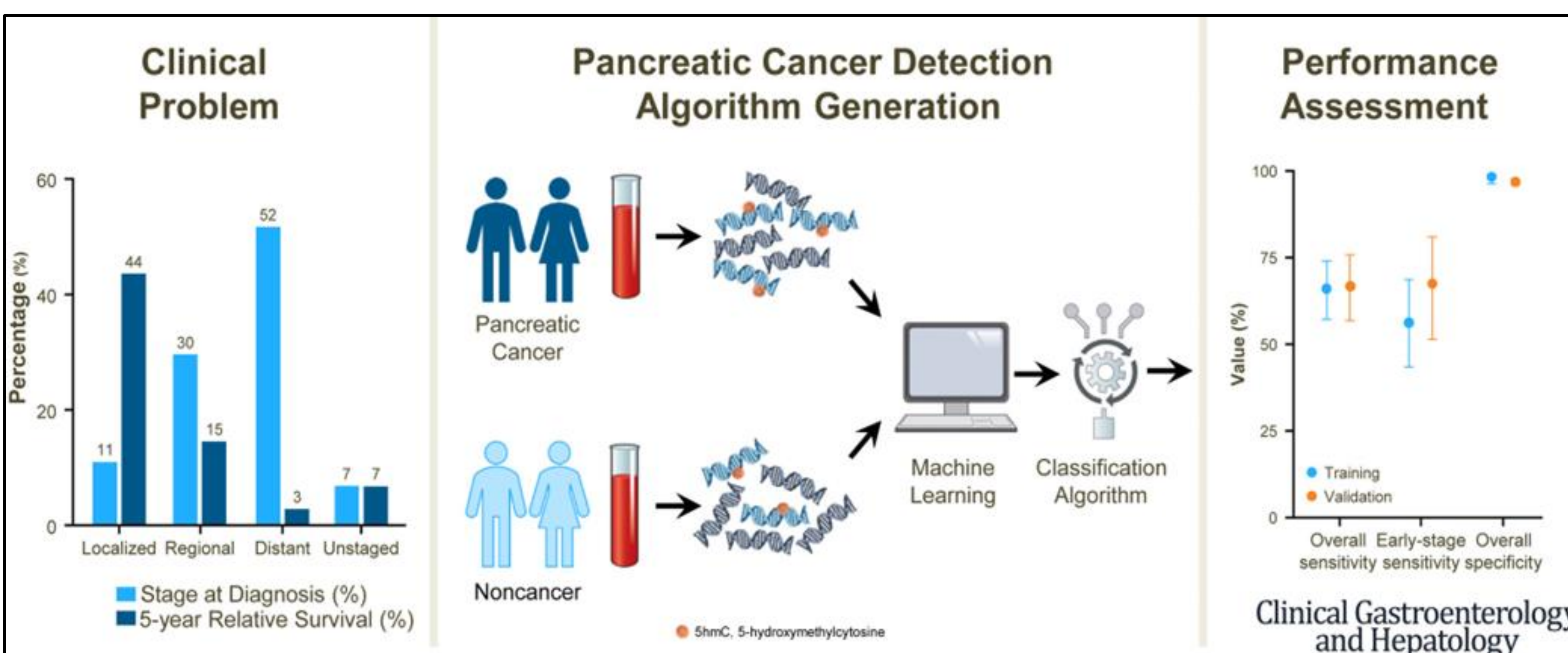
A pilot program has been initiated to deploy Avantect in a clinical setting of NOD, and other high-risk pancreatic cancer conditions, to assess the feasibility and integration of the test into current clinical practice.

METHODS

ClearNote Health has initiated a pilot program which allows early access of the Avantect test for clinicians who manage patients at a high-risk of developing pancreatic cancer. The program currently includes multiple clinical practices of varying clinical specialties and patient populations.

Patient test result data and clinical characteristics were summarized for one clinical site that completed testing on 50 patients with new-onset diabetes. Test results were delivered to the clinical site for post-test follow-up. Feedback on the clinical impact of the testing and logistical details of test implementation were reviewed at the conclusion of patient testing.

AVANTECT TEST OVERVIEW AND VALIDATION PERFORMANCE



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AVANTECT WORKFLOW

| Request Specimen Collection Kit | Collect and ship sample | Receive test result within 14 days |

COHORT CHARACTERISTICS

Characteristics	N; 50 Participants
Gender at Birth	
Male, n (%)	30 (60%)
Female, n (%)	20 (40%)
Ethnicity	
Hispanic	46 (92%)
African American	1 (2%)
Unknown	3 (6%)
Mean age (Range)	68 (38-87)
Diabetes Status	
NOD - Diagnosis Made ≤ 36 months from Testing (%)	50 (100%)
Average Time from Diagnosis to Blood Draw - Months (SD)	22.9 (11.4)
Additional Risk Factors	
Family History of Pancreatic Cancer (%)	29 (58%)
History of Smoking	17 (34%)

TEST RESULTS

- Detected (n=2)
- Not Detected (n=42)
- Cancelled Test/Inadequate Blood Volume Drawn (n=6)
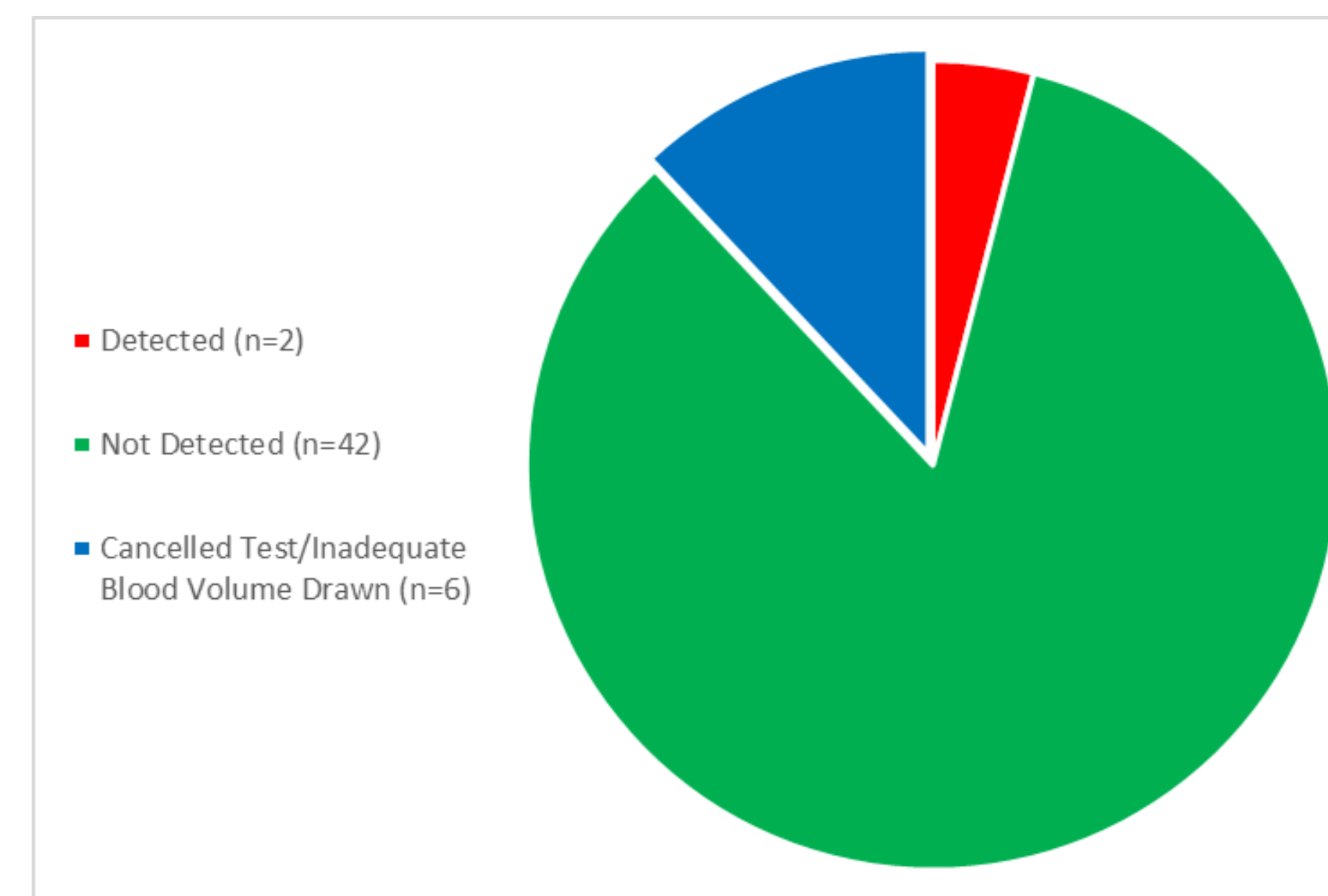
- Patient testing was successfully completed for ALL samples with adequate blood volume collected (N=44).
- An abnormal signal was **DETECTED** in 2 patients. Clinical follow-up is in progress.
- An abnormal signal was **NOT DETECTED** in 42 patients.
- The detection rate aligns with the published pancreatic cancer detection rate in this population in conjunction with validation test performance.
- The clinical team found Avantect testing to integrate well into existing workflows.

TEST RESULTS CLINICAL FOLLOW UP
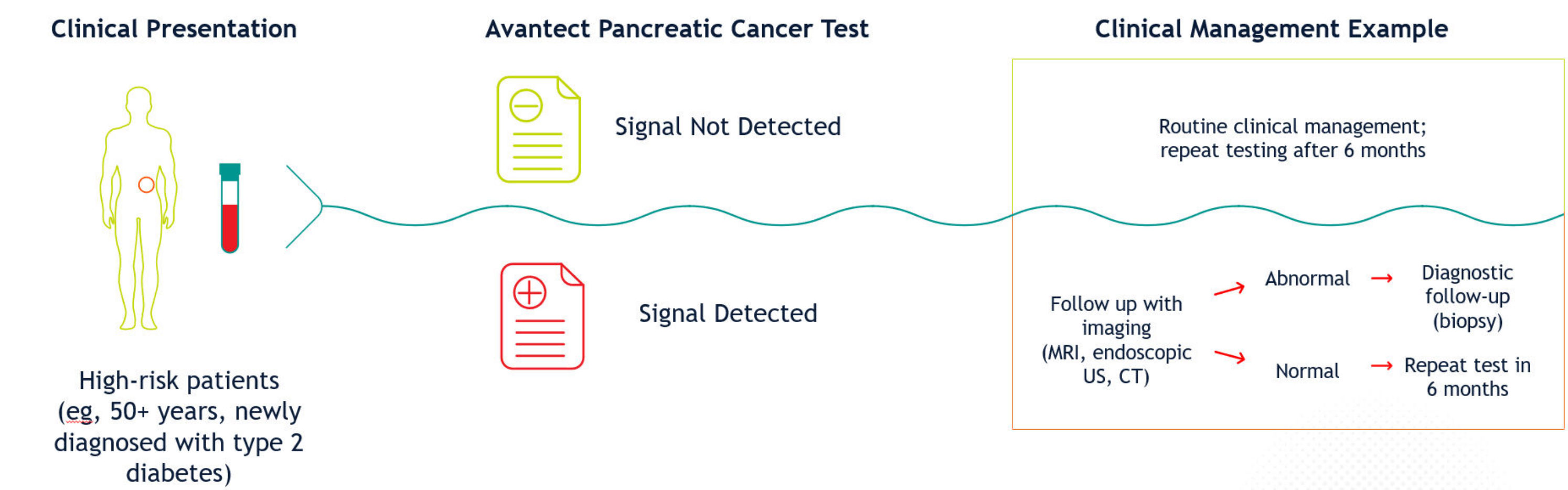
A patient report containing information whether a pancreatic cancer signal is detected is generated. If a pancreatic cancer signal is "detected", imaging is required to establish a cancer diagnosis. If the result is a "signal not detected" follow-up testing after six months can be considered (4).

CONCLUSIONS

- These results demonstrate early success in the delivery of the Avantect test to a clinical practice of diabetic patients.
- Newly diagnosed diabetic patients represent a high-risk patient cohort that may benefit from the Avantect test.
- The test is tailored to facilitate clinical implementation as it is a non-invasive blood test that can help expand patient access for the early detection of pancreatic cancer.
- Further clinical studies are on-going to further establish clinical utility of the test.

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