CAN-FIT: use of AI and blood testing to reduce colonoscopy demand on cancer pathways

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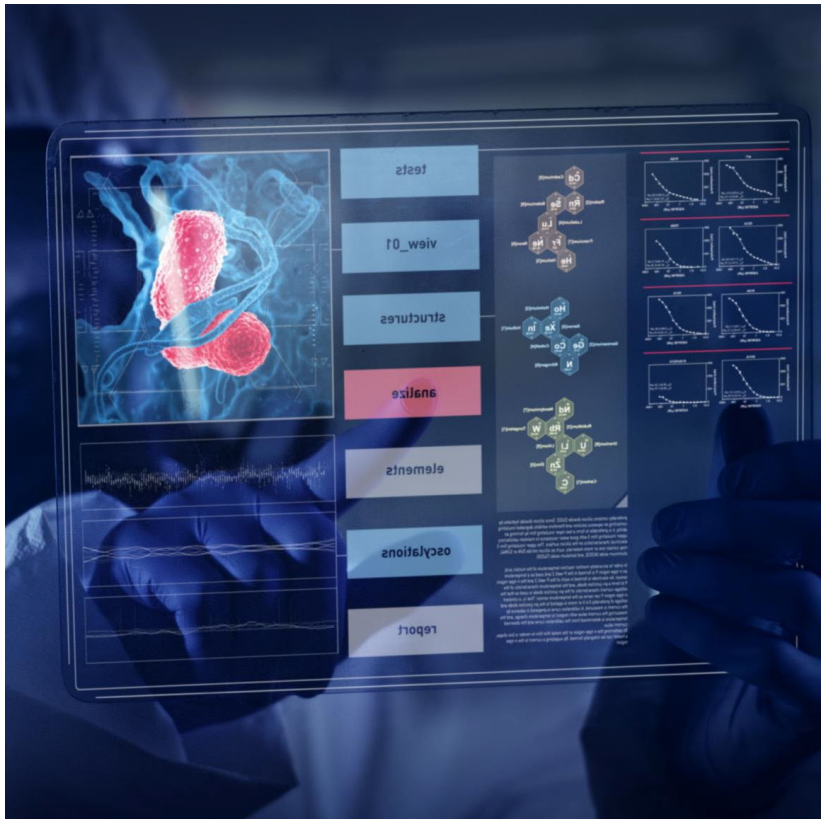
Global and UK Burden of Colorectal Cancer



Global Prevalence

Colorectal cancer ranks third in common cancers worldwide and is the fourth leading cause of cancer deaths globally.

Financial Impact on NHS

The UK's NHS spends approximately £293.9 million annually on colorectal cancer treatment and care.

Rising Incidence in Youth

Incidence of colorectal cancer is increasing rapidly in individuals under 50, signaling a demographic shift.

Future Projections

By 2030, new CRC cases are projected to exceed 2.2 million, with 1.1 million deaths worldwide.

Importance of Early Diagnosis

Impact of Early Diagnosis

Early-stage colorectal cancer diagnosis significantly increases survival rates up to 95%.

Challenges of Late Diagnosis

Late-stage diagnosis of colorectal cancer reduces five-year survival rate to just 8%, highlighting urgent screening needs.

Preventability through Screening

Detecting premalignant polyps allows intervention before cancer develops, preventing colorectal cancer.

Limitations of FIT Testing

Low Positive Predictive Value

FIT testing threshold of ≥10µg Hb/g faeces has only a 3% positive predictive value for colorectal cancer.

Resource Strain from Referrals

High false positives lead to many normal colonoscopies, overwhelming diagnostic resources and causing unnecessary procedures. (97%)

Impact of Anticoagulant Medications

Patients on anticoagulants often have false positive FIT results, complicating diagnostic accuracy and decision-making.

Need for Alternative Methods

NICE recommends researching new diagnostic tools to reduce unnecessary colonoscopies and improve accuracy.

Impact on NHS Diagnostic Capacity

Increased Diagnostic Demand

FIT testing has raised colorectal cancer referrals by 46%, increasing pressure on NHS diagnostic services.

Diagnostic Pathway Challenges

Only 33% of lower GI cancer cases meet the 62-day Single Cancer Pathway target, showing compliance issues.

Limitations of FIT Testing

A single cut-off value in FIT testing has not optimized colorectal cancer diagnosis, causing referral surges.

Need for Scalable Tools

Effective, scalable diagnostic tools are required to reduce pressure on colonoscopy services and improve patient care.

Technology and Diagnostic Advantages

Innovative Diagnostic Technology

CanSense-CRC uses Raman spectroscopy combined with machine learning for accurate colorectal cancer risk estimation.

Rapid and Scalable Testing

The blood-based test is rapid, scalable, and cost-effective, providing an alternative to traditional FIT testing methods.

Improved Patient Triage

Advanced algorithms enable efficient triage by prioritizing patients with higher colorectal cancer risk for faster diagnosis.

Healthcare System Benefits

This technology reduces diagnostic burden on healthcare services and supports earlier intervention for better outcomes.

Improving Equity and Patient Acceptability

Enhanced Diagnostic Acceptance

Blood tests are strongly preferred over faecal testing, increasing patient willingness for cancer screening.

Addressing Healthcare Barriers

Blood testing is especially favored by ethnic minorities and socio-economically deprived groups facing screening challenges.

Supporting Equity and Inclusion

CanSense-CRC promotes health equity by improving access and reducing disparities in cancer diagnosis.

Benefits to NHS and Diagnostic Pathways

Improved Triage Accuracy

CanSense's blood test enhances triage accuracy, reducing unnecessary colonoscopies and prioritizing high-risk patients.

Enhanced Diagnostic Efficiency

Faster, accurate diagnosis supports compliance with cancer pathways and improves patient outcomes in the NHS.

Alignment with NICE Guidelines

The blood test aligns with NICE recommendations, offering a reliable alternative to traditional FIT testing.

Scalability and Cost-Effectiveness

CanSense-CRC is scalable and cost-effective, supporting NHS resource optimization and growing referral volumes.

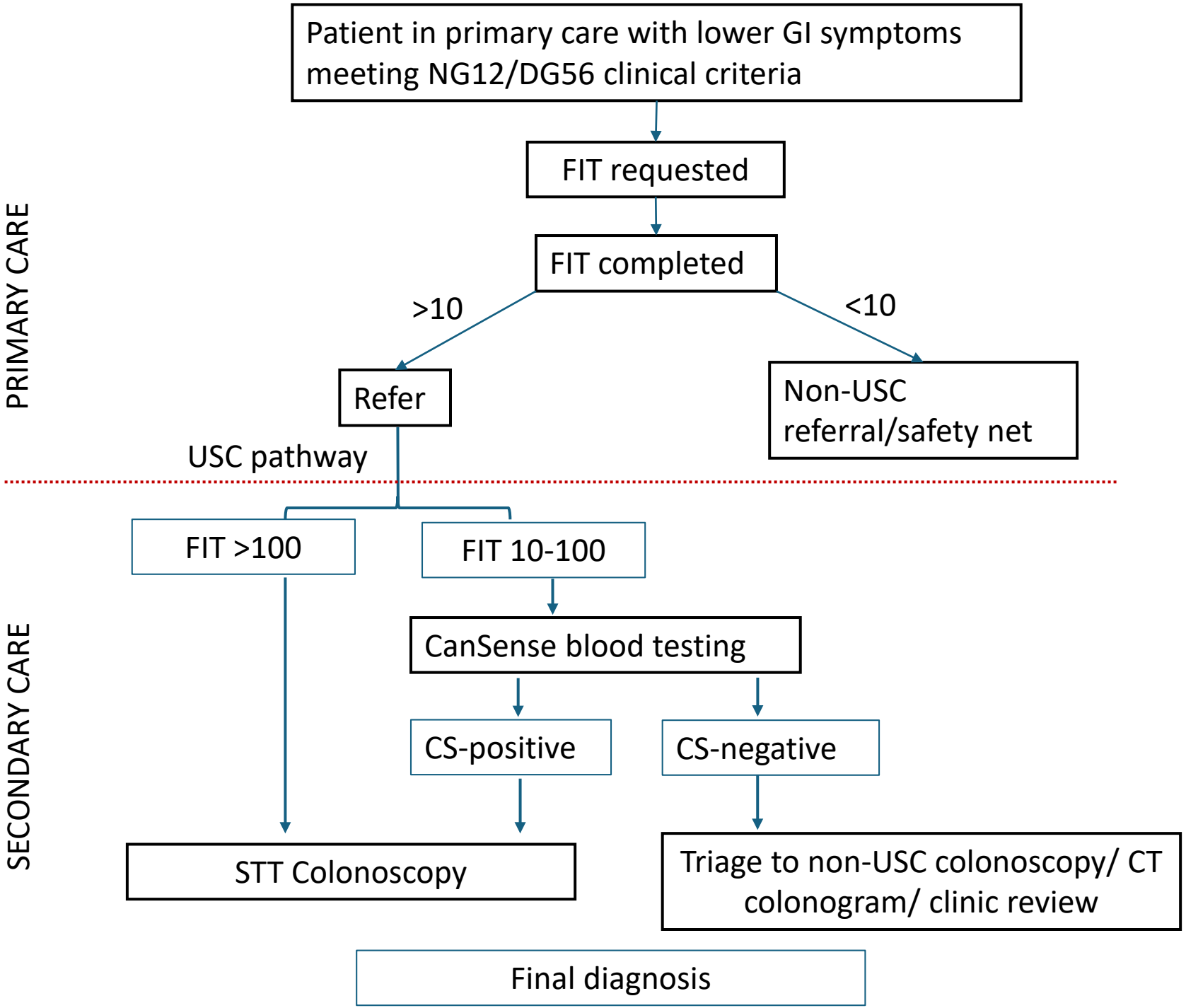
AIM

PRIMARY

- The aim is to confirm the efficacy and safety and the pathway benefits of deployment of the CanSense blood test for the detection of colorectal neoplasia in its intended population as an adjunct to FIT Cwm Taf Morgannwg UHB.

SECONDARY

- To measure the impact of the CanSense-CRC test on 28-day and 62-day Single Cancer Pathway metrics.



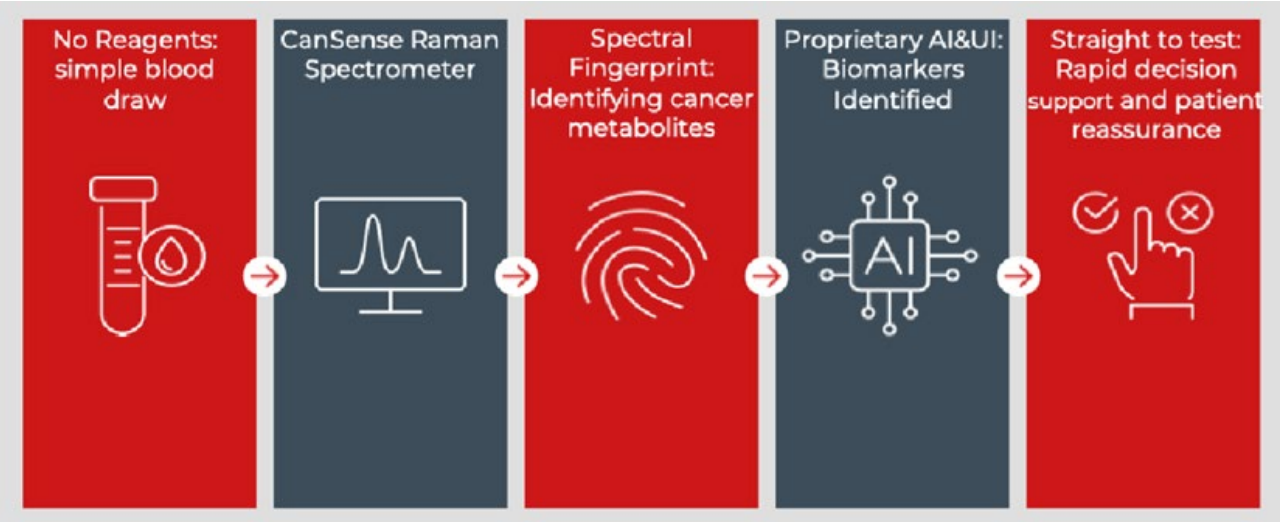
- Patients with FIT between 10 and 100 and having confirmatory colonoscopy were invited to participate in phase 1 of the study. Clinicians blinded to patient outcome were provided with the GP referral letter, FIT result and CanSense-CRC test result (namely high/low likelihood of CRC) and asked to regrade the referrals in light of the CanSense-CRC result to model its impact on the pathway.

Phase 1 plan

- Observational recruitment of n=100
- patients with FIT 10-100 with at least 5 CRCs
- All had confirmatory colonoscopy invited to participate in phase 1 of the study
- Batched CanSense test analysis
- Confirm model performance
- Clinicians blinded to patient outcome were provided with the GP referral letter, FIT result and CanSense-CRC test result (namely high/low likelihood of CRC) and asked to regrade the referrals in light of the CanSense-CRC result to model its impact on the pathway.

Outputs

- Modelled impact on lower GI pathway based on phase 1 results (by blinded clinicians given GP letter/FIT result/CanSense-CRC test report) (n=58 referrals)



- CanSense model output*
  - FIT 10-100 alone- 66/69 were false positives (FIT>10) based on 3 cancers=95.7%
  - FIT and CanSense-CRC together- 27/66 false positive rate=**40.9%**
  - **55% reduction in FPR** exceeding the target <**80%** false positive rate for the study
- *as fewer than 5 cancers included in phase 1 to date sensitivity calculation not possible.
- [FPR=(FP/FP+TN)]

Highlights of modelled impact of CanSense test

37.9% patients were downgraded from USC pathway (22/58)

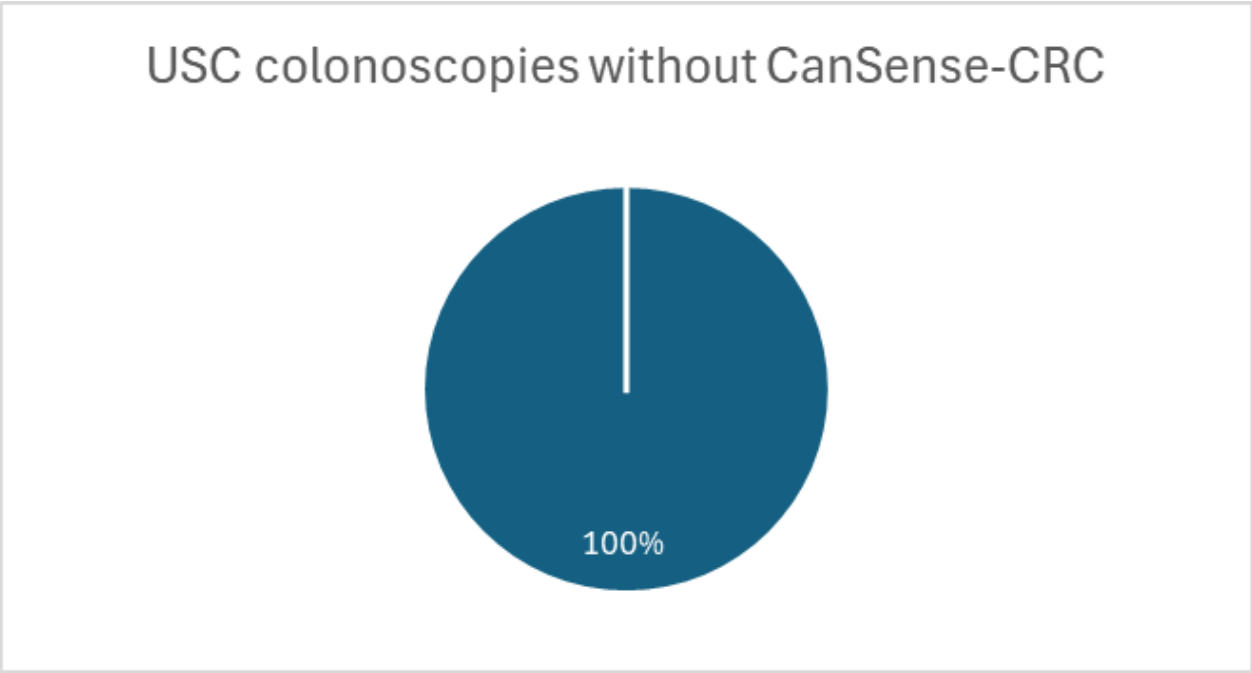
Just 36.2% of referrals continued to require a USC colonoscopy **(63.8% reduction) (21/58)**

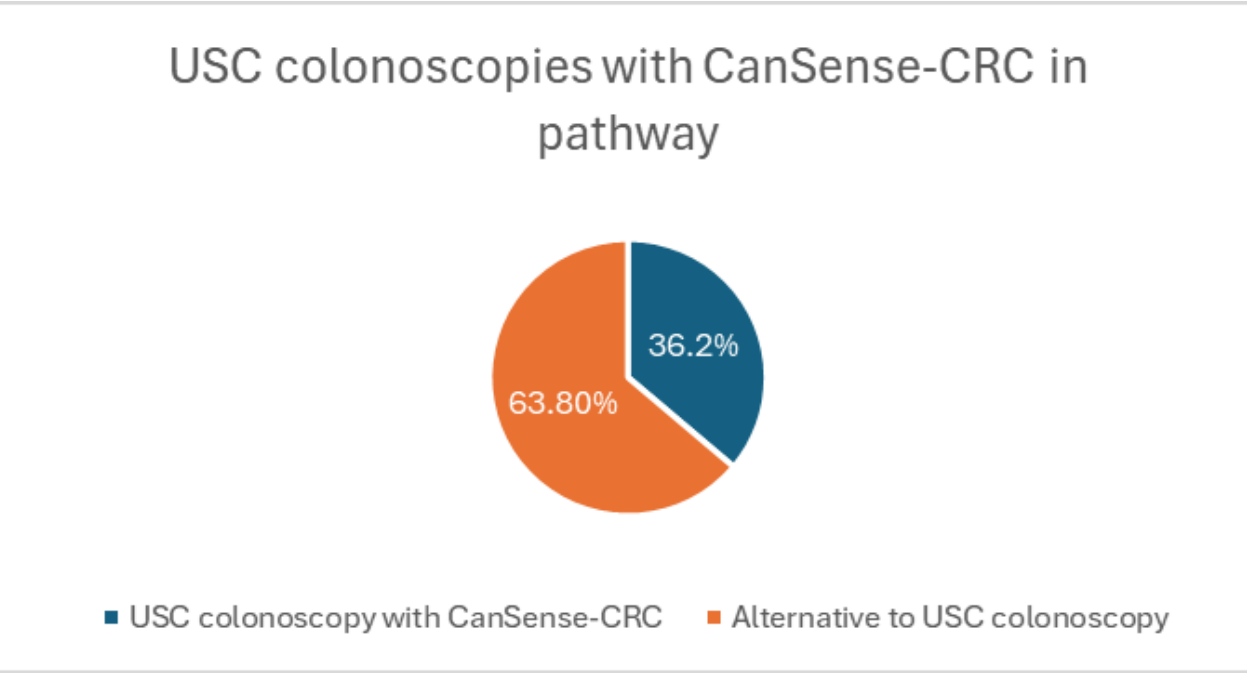
19% converted from colonoscopy to flexible sigmoidoscopy (11/58)

Number of points of endoscopy demand reduced by over a third (116 points down to 73 points, **37% reduction**)

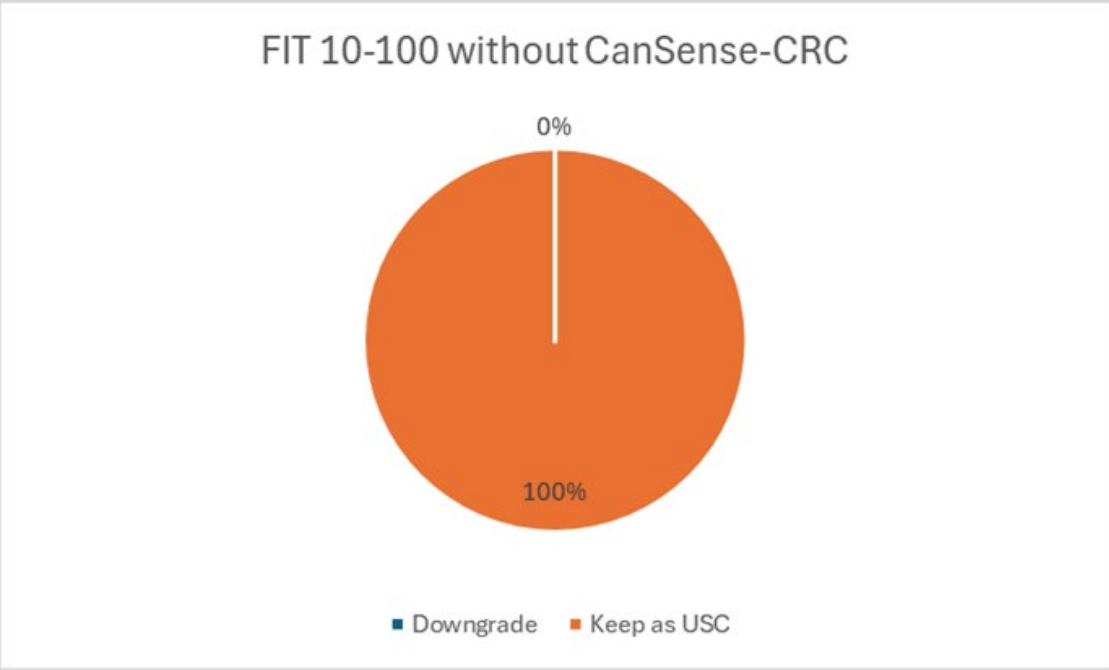
First real-world integration of CanSense-CRC blood test hardware analysis and seamless AI software interpretation to produce lab test reports.

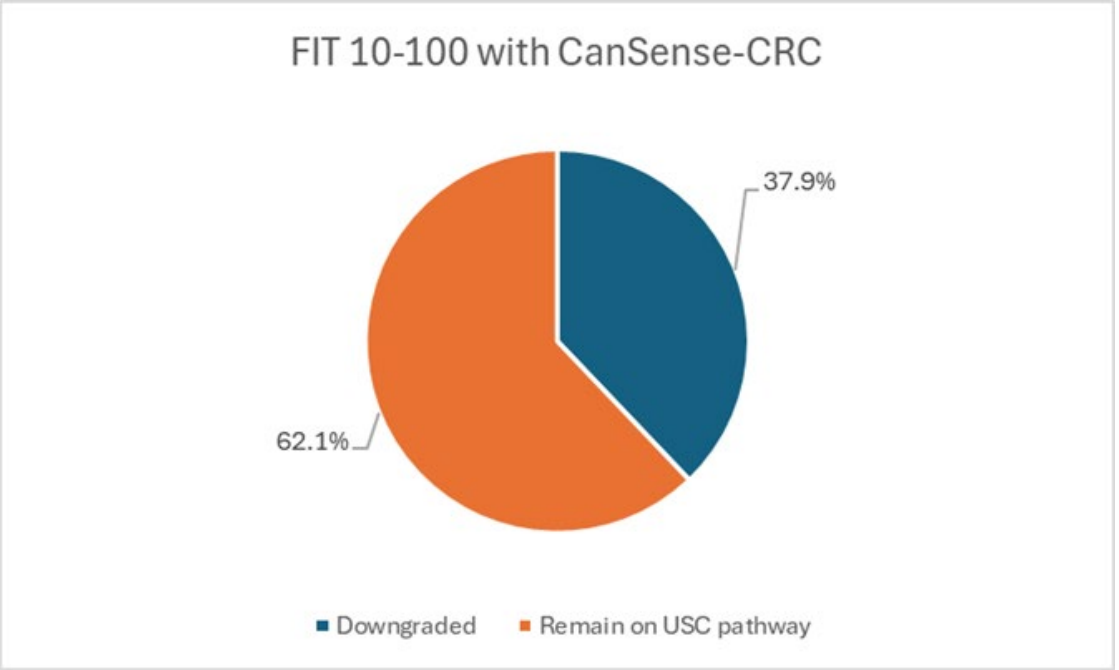
Impact on USC colonoscopy demand

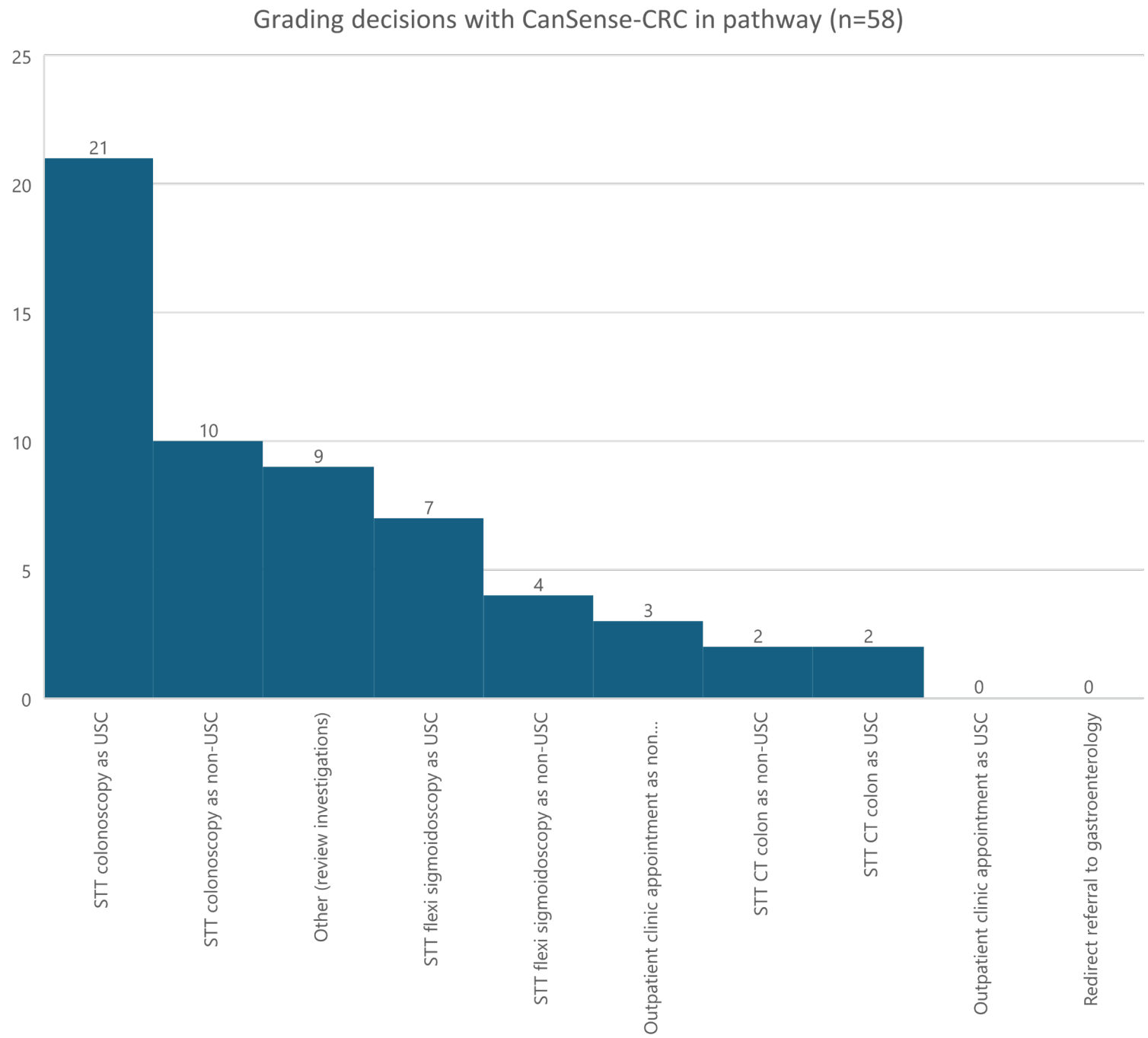




Impact on clinician grading decision



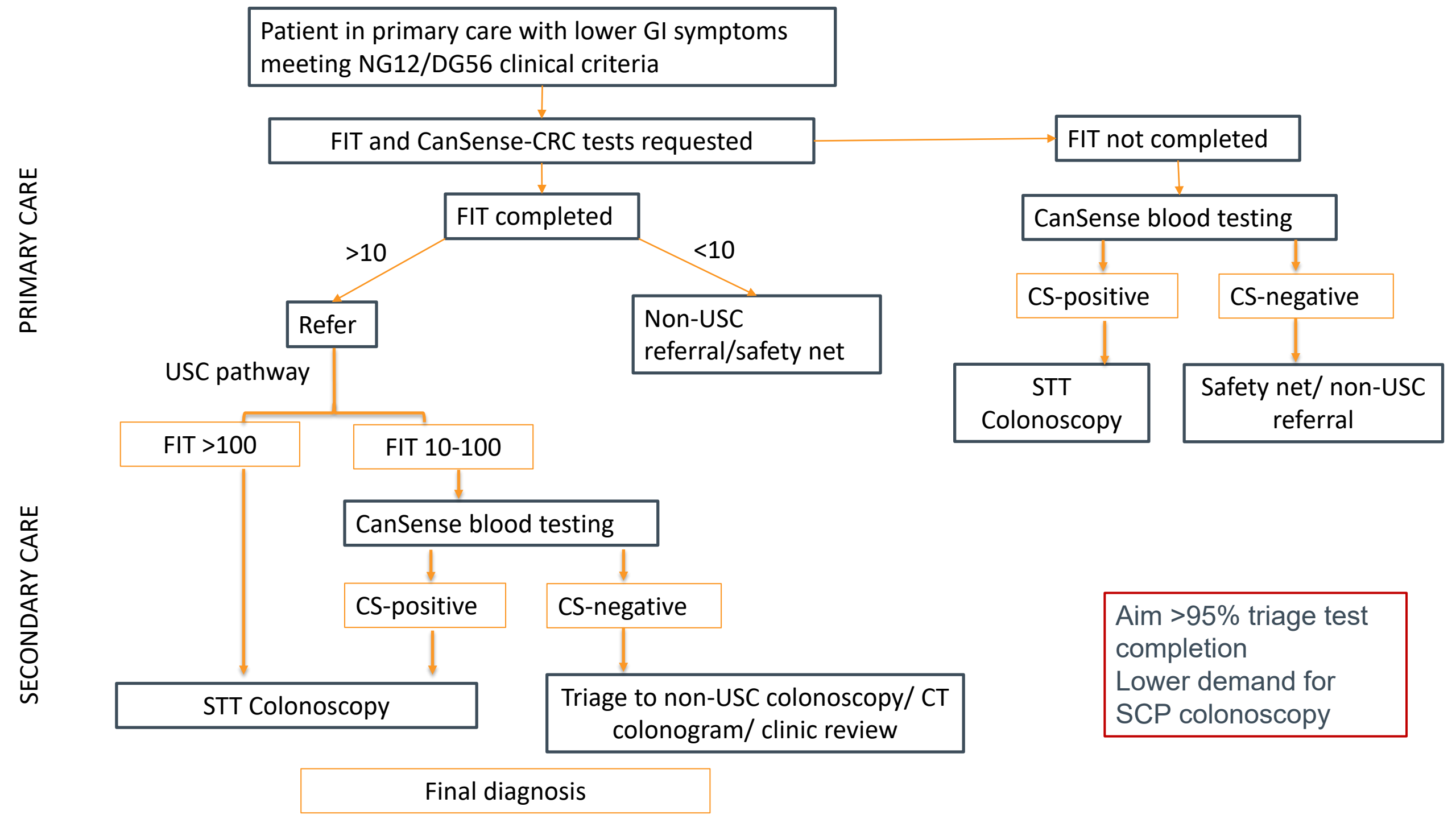




47% fewer colonoscopies overall (27/58)

Willingness to use flexible sigmoidoscopy and CT scans with low risk CanSense result

Endoscopy points required reduced from 116 to 73: releasing capacity


PRIMARY CARE
SECONDARY CARE
Patient in primary care with lower GI symptoms meeting NG12/DG56 clinical criteria
FIT and CanSense-CRC tests requested
FIT not completed
CanSense blood testing
CS-positive
CS-negative
STT Colonoscopy
Safety net/ non-USC referral
FIT completed
>10
<10
Refer
Non-USC referral/safety net
USC pathway
FIT >100
FIT 10-100
CanSense blood testing
CS-positive
CS-negative
STT Colonoscopy
Triage to non-USC colonoscopy/ CT colonogram/ clinic review
Final diagnosis
Aim >95% triage test completion
Lower demand for SCP colonoscopy

CONCLUSION

- A testing strategy of using CanSense-CRC® and FIT could release the much-needed colonoscopy diagnostics capacity needed to detect symptomatic cancers more prudently and efficiently

- This will lead to projected improvements in 28 d and 62d cancer pathway targets.

- A larger study is ongoing to evaluate the real-world impact of this dual-triage testing strategy.

Acknowledgments

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  - Catrin Vaughan, Lisa Roche, Keri Turner, Hannah Davies, Eleanor James, Lauren Nunnerley, Lauren Geen, Alysha Hancock, Lisa Mellish and Meryl Rees

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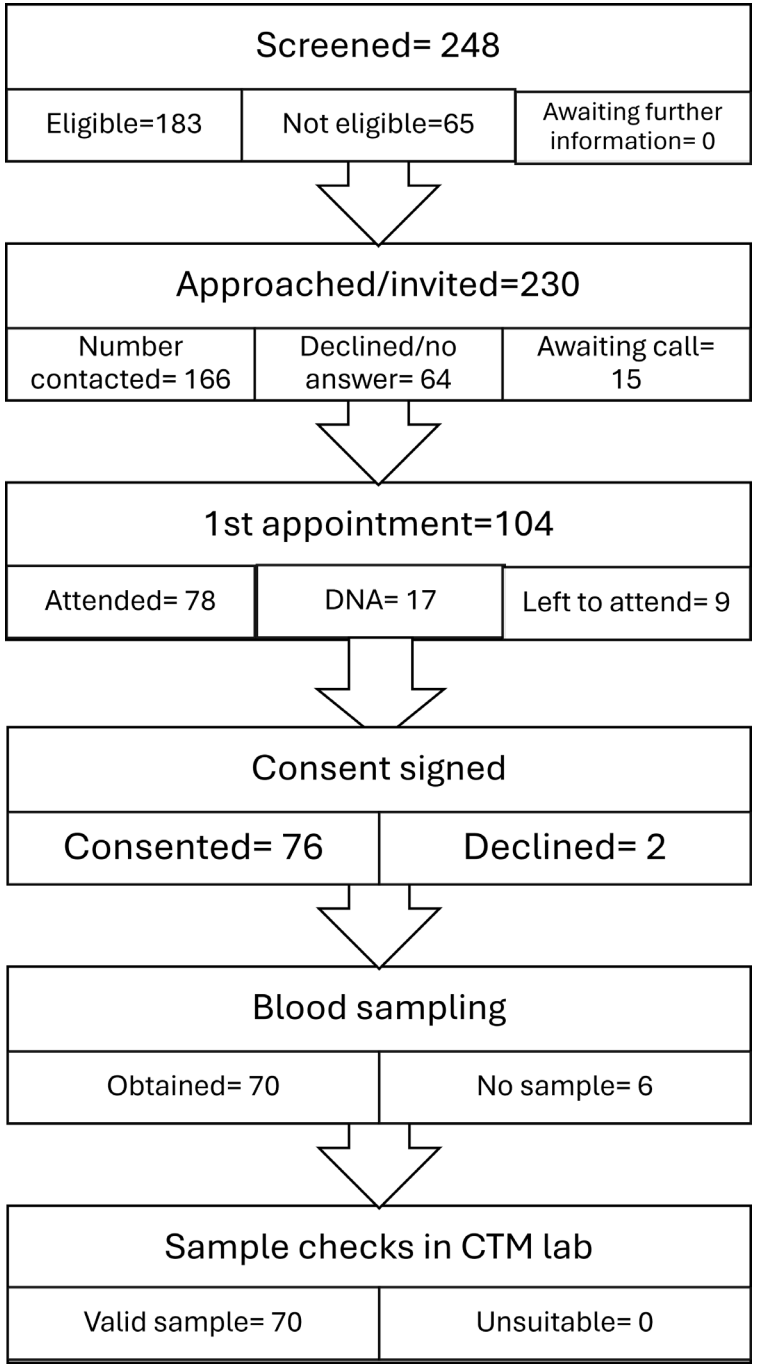
  - members of the CTMUHB Colo-rectal Surgical team Rose Thomas and Gemma Chapman.

- The study team are also grateful for the support of the Endoscopy units at Royal Glamorgan and Prince Charles Hospitals.



Project challenges

- Protocol completion and ethics approval
- DPIA/cyber sign-off
- Lower than expected recruitment rate:
  - ineligibility (patients who have already had colonoscopies done who had adenomas removed already; history of other cancers; lack of capacity);
  - declining participation (don’t want to take part; have too much going on already);
  - declining on the day as they no longer wanted to take part;
  - unable to obtain the blood test after consent;
  - do not wish to come back for further appointment after they had already had their colonoscopy.