Molecular stool testing as an alternative for colonoscopy surveillance (MOCCAS)

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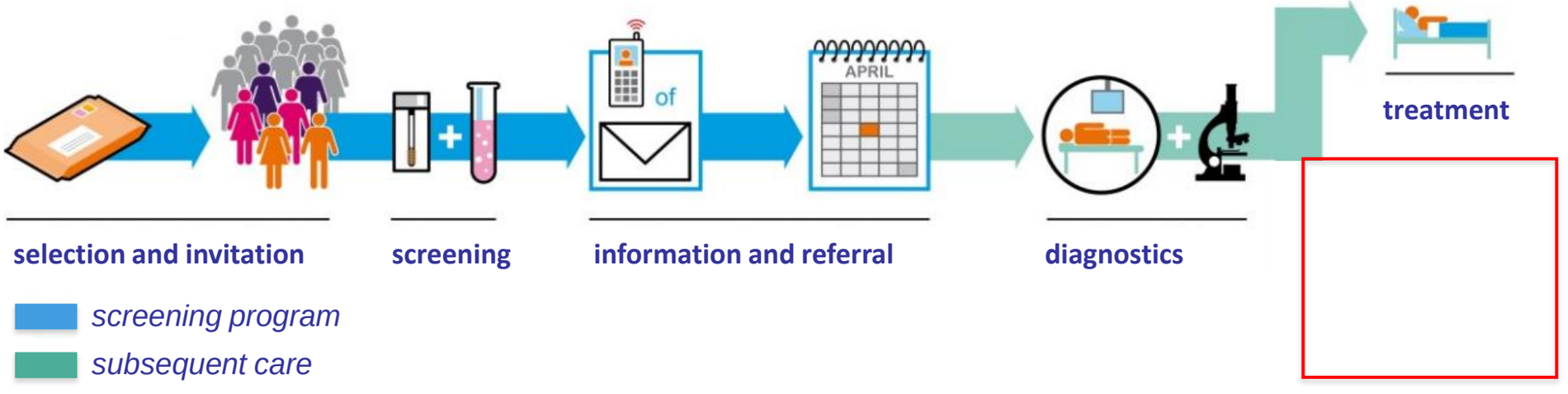
Screening for colorectal cancer

Goal: to reduce mortality and suffering from colorectal cancer



Current surveillance strategy

Colonoscopy

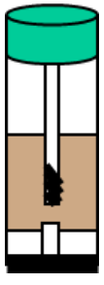
3 or 5 years

- overdiagnosis and overtreatment
- overuse of colonoscopy capacity
- high costs
- high patient burden

Is there an alternative strategy?

MOLECULAR SURVEILLANCE

Multitarget stool DNA test



- human hemoglobin

- mutant KRAS
- hypermethylated BMP3 and NDRG4
- β-actin

cologuard®

exact sciences

Madison, WI, USA

MOlecular stool testing for Colorectal Cancer Surveillance (MOCCAS)

Current surveillance strategy

3 or 5 years

Possible future surveillance strategy

?

+ test

MOlecular stool testing for Colorectal Cancer Surveillance (MOCCAS)

Can molecular stool tests provide an alternative strategy for

colonoscopy surveillance?

Possible future surveillance strategy

?

+ test

MOCCAS

Primary endpoints

- Accuracy of molecular tests
  - Cologuard®
  - FIT OC Sensor (Eiken, Chemical, Tokyo, Japan)
  - FOB Gold (Sentinel, Milan, Italy)
- Decision model for a molecular surveillance strategy

Secondary endpoints

- Presence of progression markers on resected polyps
- Presence of diagnostics Cologuard® markers on resected polyps

MOCCAS

Study population

Inclusion

- Age 50-75
- Indication for surveillance colonoscopy (history of polypectomy, CRC or familial colon cancer)

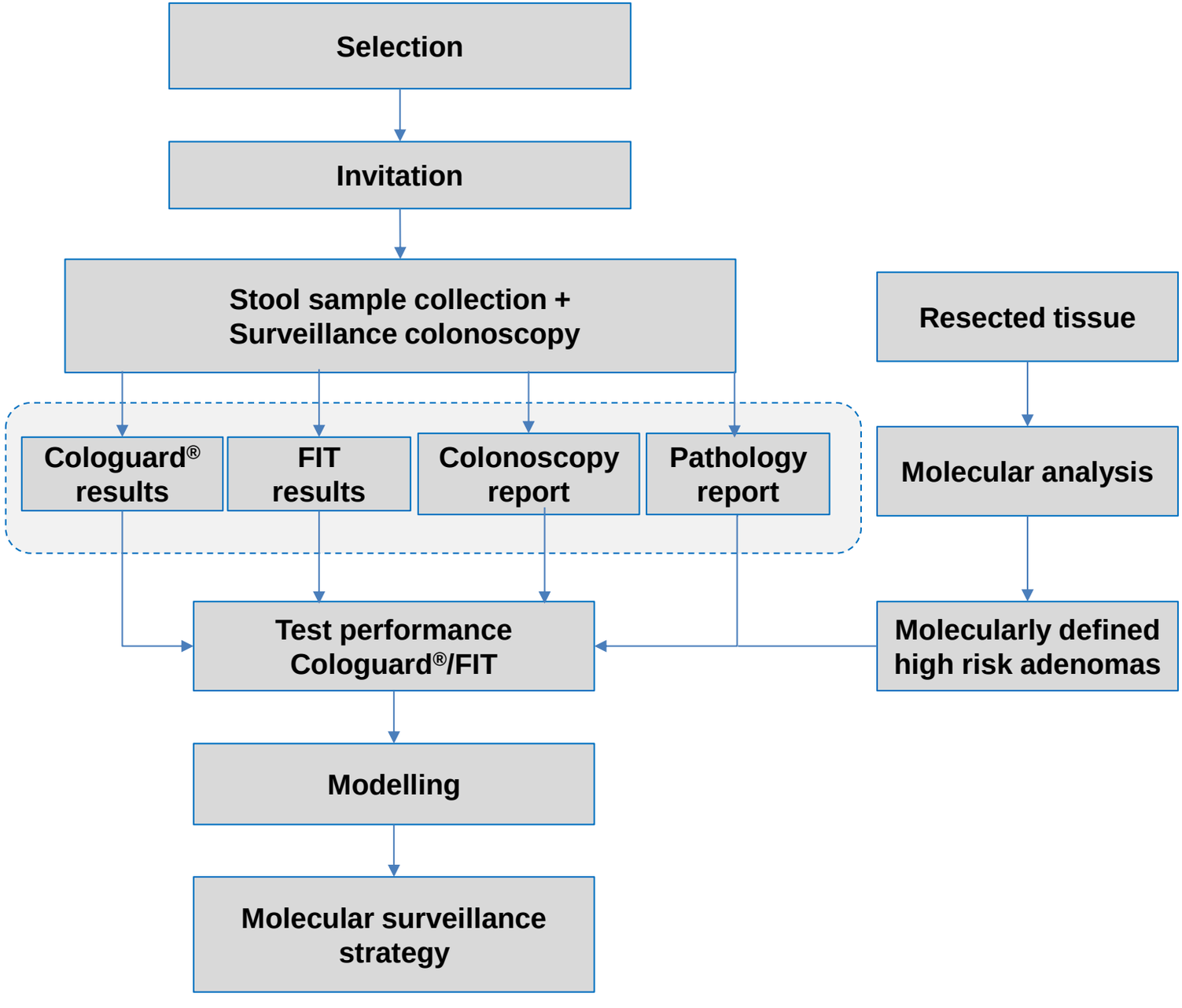
Exclusion

- Inflammatory bowel disease (IBD)
- Hereditary colon cancer
- Total proctocolectomy
- Colonoscopy in previous 6 months

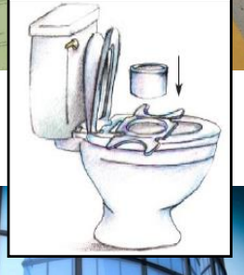
Sample size

- 4000 individuals

Study flow


Selection
Invitation
Stool sample collection + Surveillance colonoscopy
Cologuard® results
FIT results
Colonoscopy report
Pathology report
Resected tissue
Molecular analysis
Test performance Cologuard®/FIT
Molecularly defined high risk adenomas
Modelling
Molecular surveillance strategy

Sample collection



< 72 hours

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BMC Cancer

STUDY PROTOCOL Open Access

Molecular stool testing as an alternative for surveillance colonoscopy: a cross-sectional cohort study

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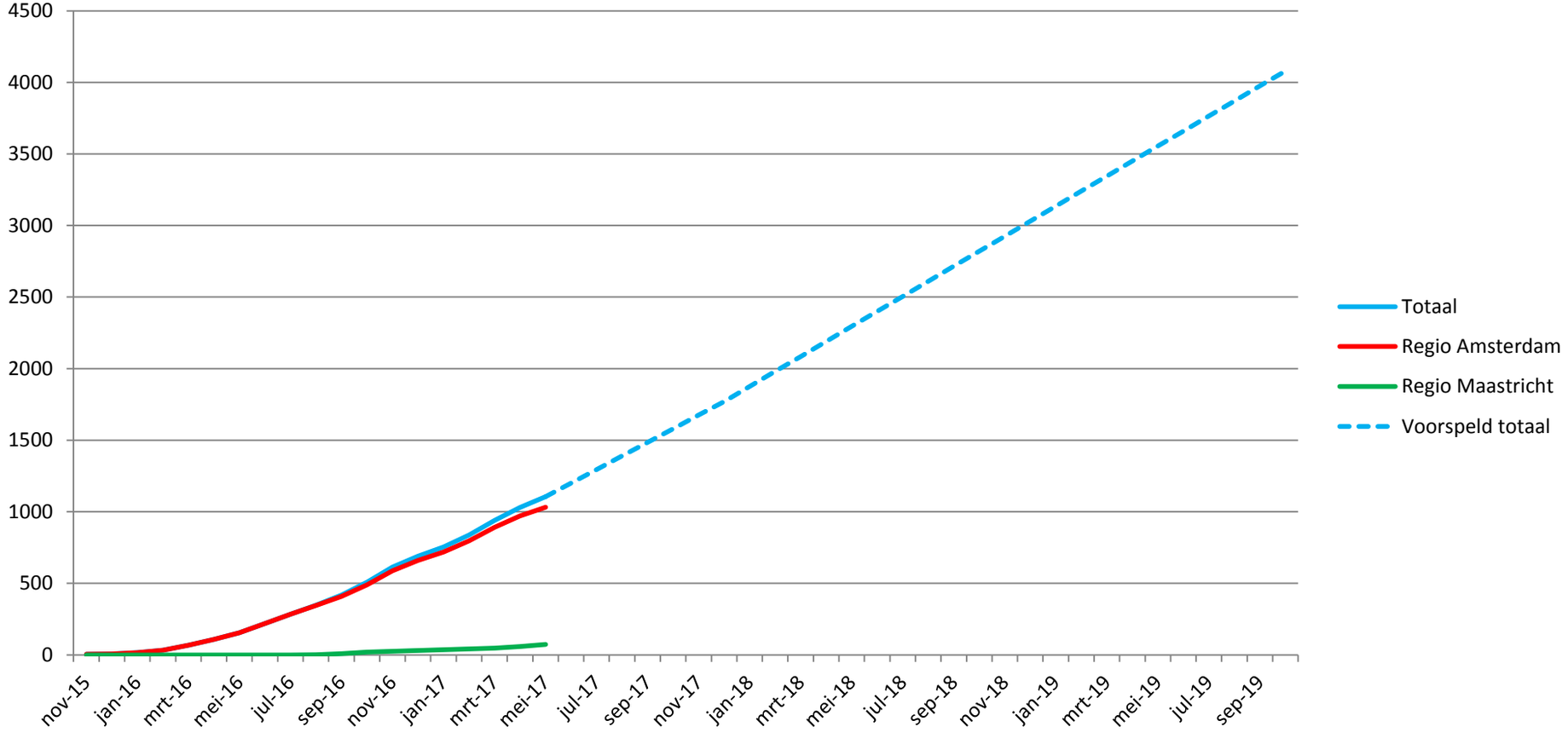
Status update – Total inclusions

Roll-out

- start date: 1st November 2015
- participating centers: 12
- participants included: 1141



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.....

DUTCH CANCER SOCIETY

…and of course

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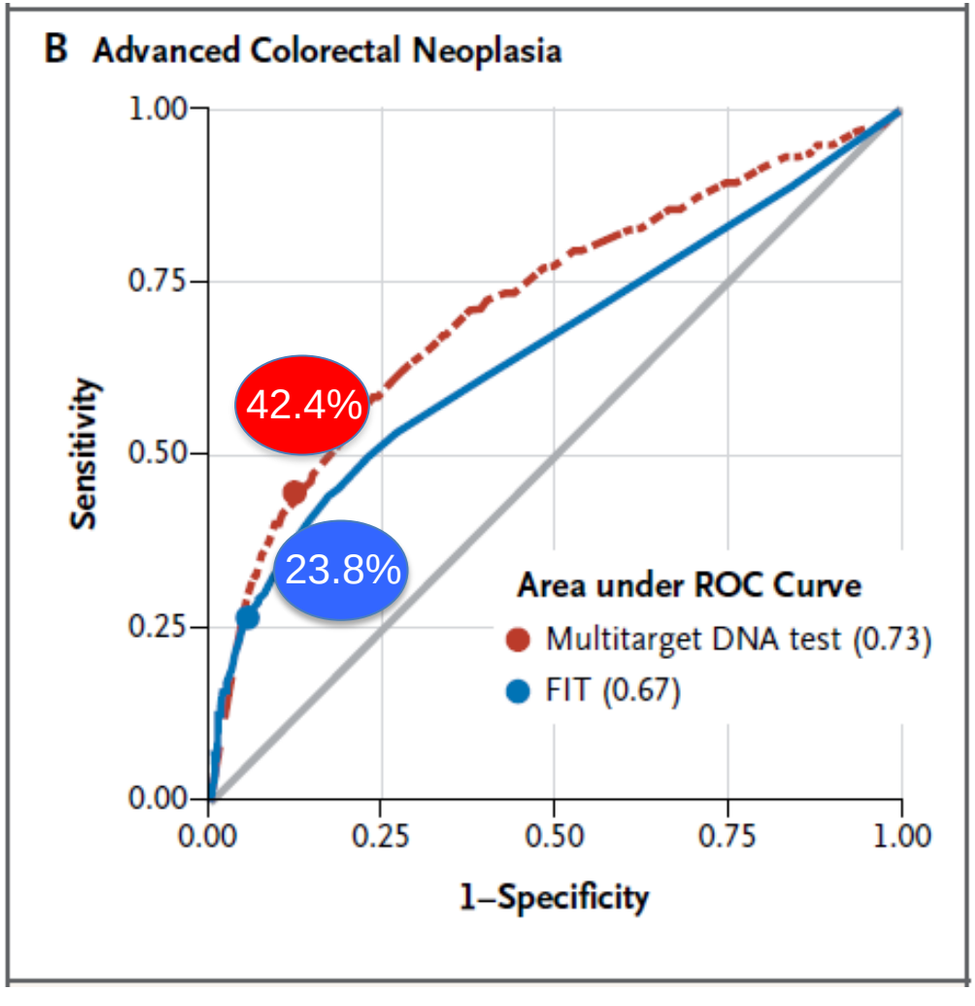
DUTCH CANCER SOCIETY

MOCCAS – per lesion analysis

- Number of lesions detected in these 177 individuals = 401
  - 3 (0.7%) carcinomas
  - 190 (47%) adenomas
    - 22 (5.5%) advanced adenomas (≥ 10mm, TV/V histology, HGD)
  - 126 serrated lesions
    - 14 (3.5%) advanced serrated lesions (≥ 10mm, dysplasia)
  - 82 (20%) other (no PA, inflammatory polyp, not evaluable, other lesion)

Multitarget stool DNA test

cologuard®

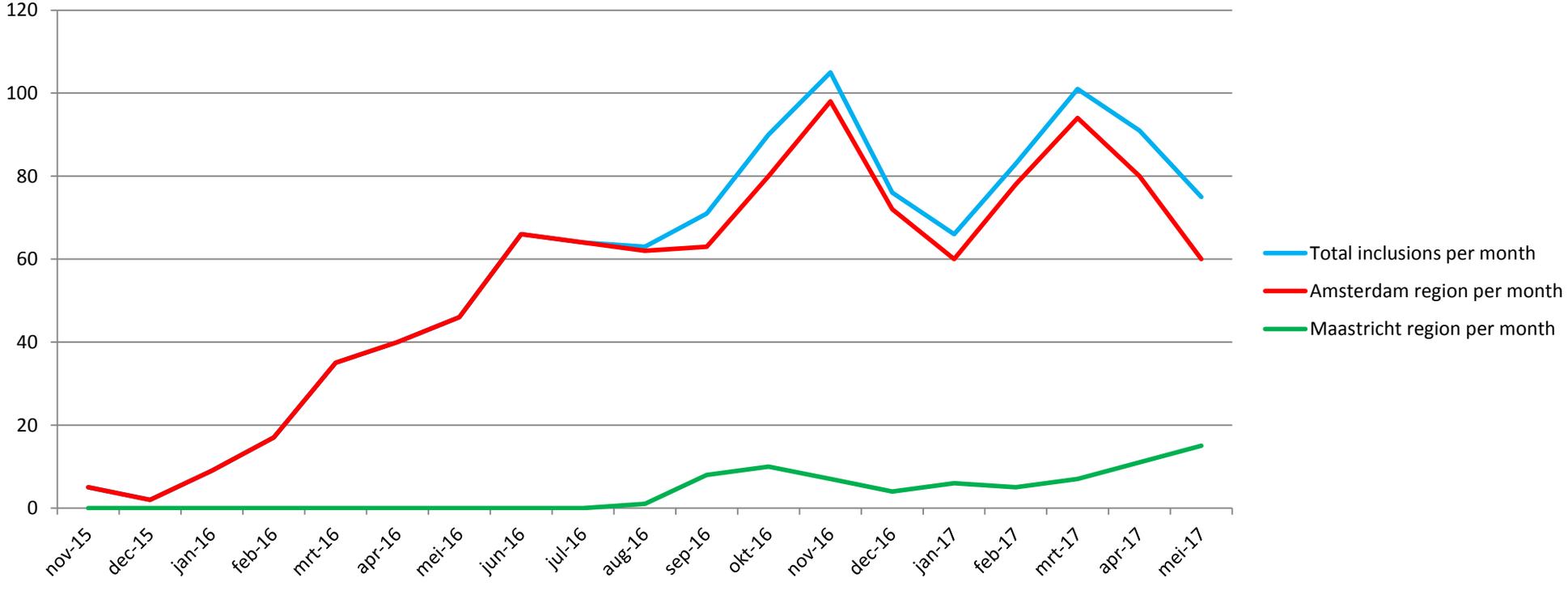


- Higher sensitivity
  - CRC
  - advanced lesions
- Lower specificity

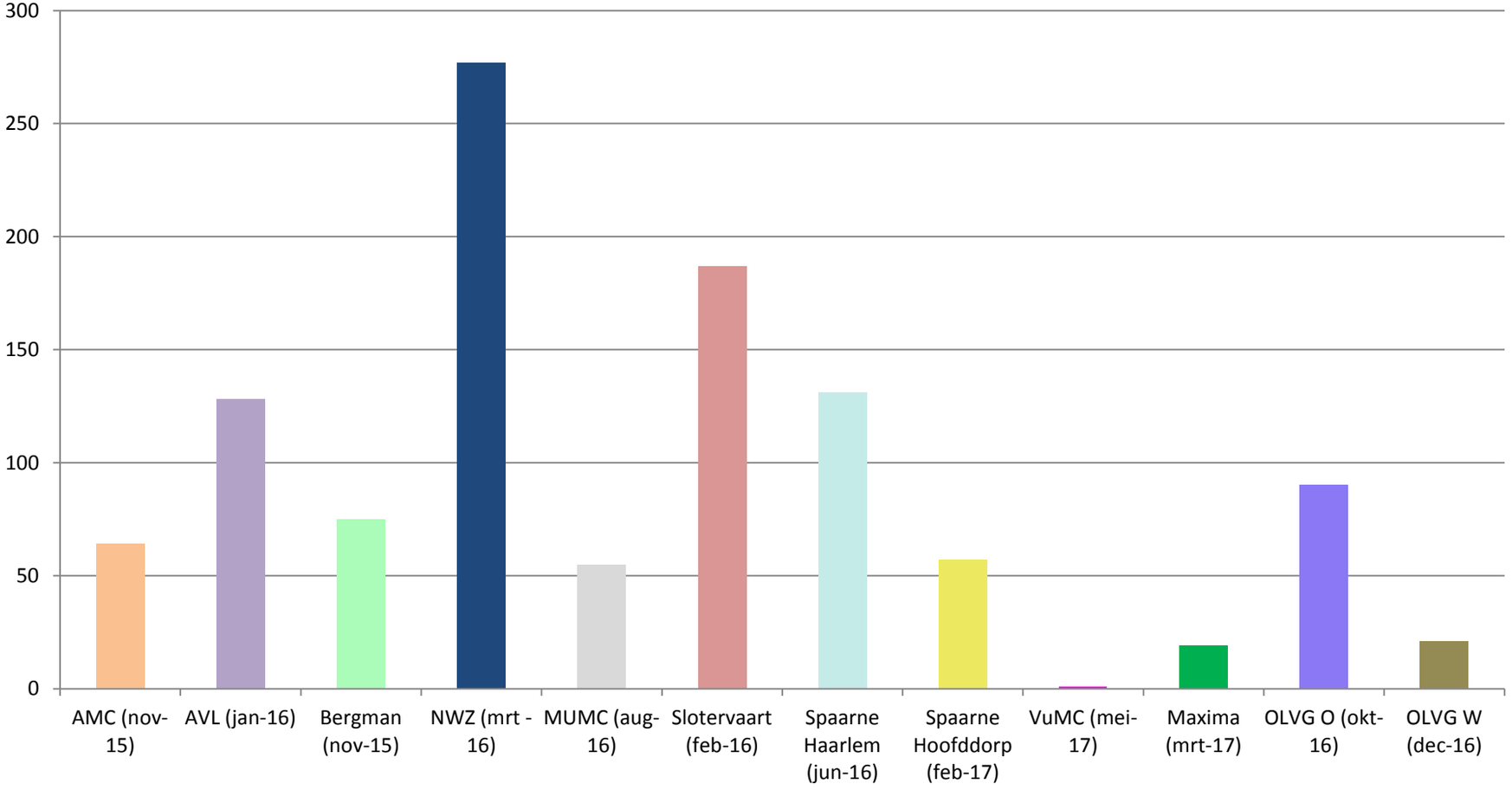
Test characteristics suitable for surveillance

Imperiale, *NEJM* 2014

Status update – Inclusions per month



Status update – Inclusions per center



Status update – FIT FOB Gold

Participants included n = 1141

- Not performed n=10
- FIT OC Sensor measured n = 1096

→ Amsterdam n=1022

→ Maastricht n=74

  - Prozone effect n = 0
  - Remeasurement needed n = 2