

European-Taiwan Cancer Screening Conference 2026

Quality assurance and research initiatives in Europe

*The European commission initiative on colorectal cancer
and ongoing projects of risk stratification within population-
based programs*

Carlo Senore

Epidemiology and screening unit – CPO

University hospital Città della Salute e della Scienza



Co-funded by
the European Union



No conflict of interest to declare

Three main pillars



Guidelines and QA schemes



Innovation – Risk-stratified screening



Monitoring

European Guidelines

- 2008 – European Parliament and Council ask the Commission to **develop new guidelines based on scientific evidence and quality assurance scheme** for screening and care
- Major discrepancies in the quality of care and access to care across EU

Europe's Beating Cancer Plan (Feb 2021)

The EU council recommends EU member states

.....

(2) to implement accessible screening programs in **accordance with European guidelines and quality assurance schemes**, where they exist, through a **stepwise approach** taking account of available human and financial **resources** as well as healthcare resources for implementation of the screening programs, within **national priorities**



Brussels, 29 November 2022
(OR. en)

14770/22

Interinstitutional File:
2022/0290(NLE)

SAN 608

NOTE

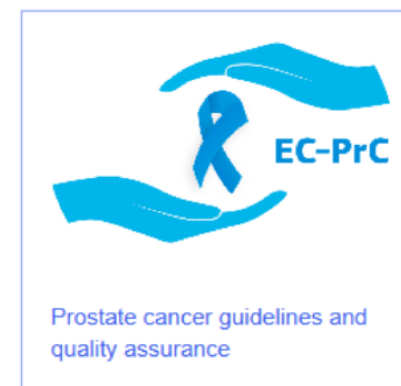
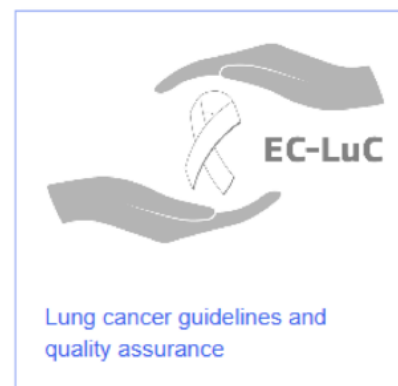
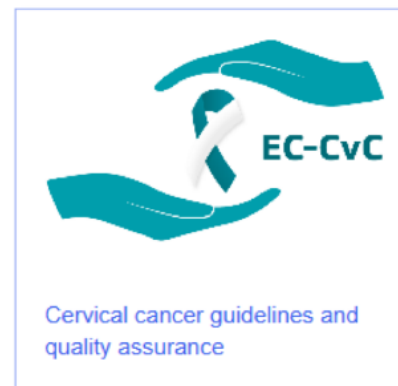
From:	General Secretariat of the Council
To:	Council
Subject:	Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC

European Guidelines

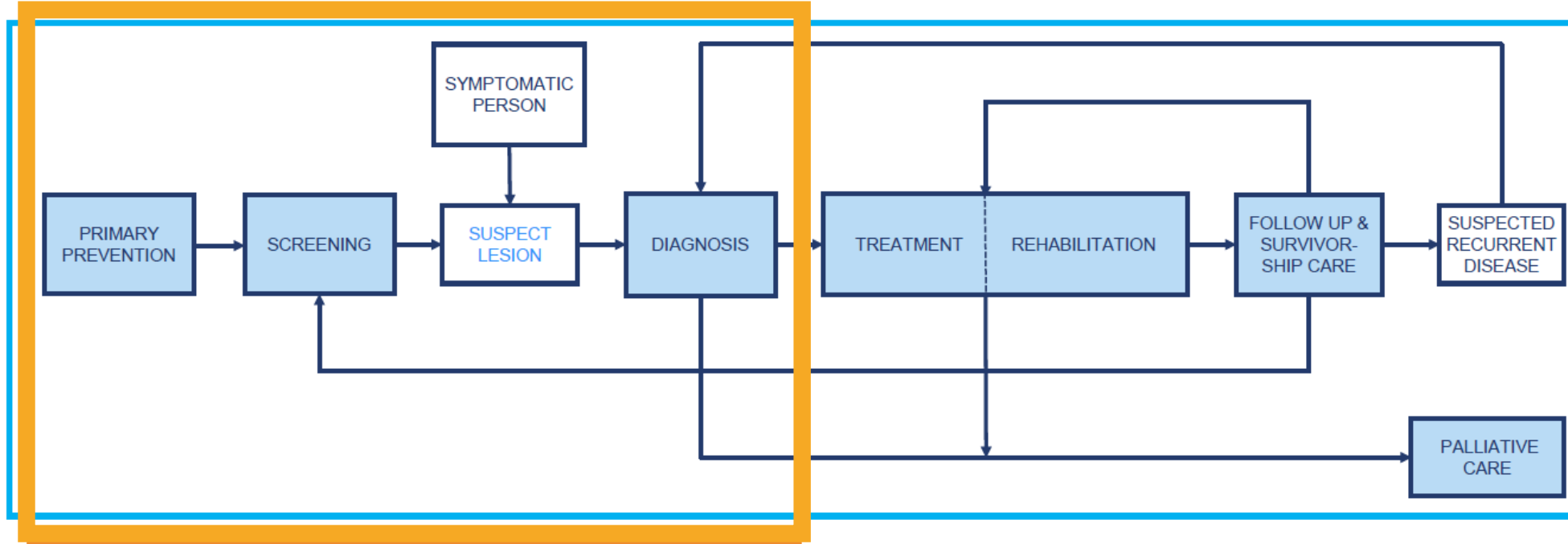
EC web-hub



[//cancer-screening-and-care.jrc.ec.europa.eu](https://cancer-screening-and-care.jrc.ec.europa.eu)



ECICC Scope

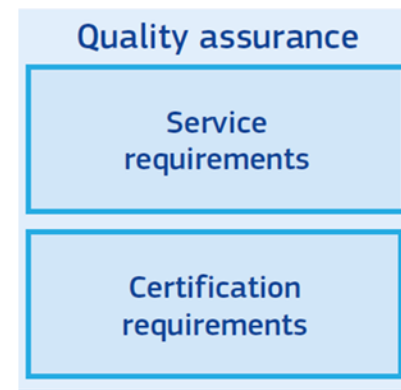


Guidelines

Quality assurance scheme

**Evidence based guidelines on primary prevention, screening and diagnosis
(including management and surveillance of SD lesions at endoscopy)**

QA schemes for healthcare services along the entire care process



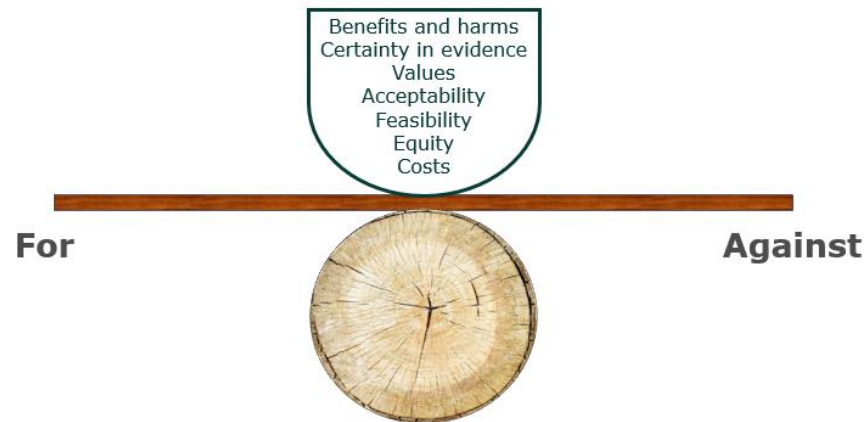
Main features



- **Organised population-based screening programmes**
- **Covers the entire care pathway**
- Scientific evidence-based, transparent process, reproducible methodology
- Regularly updated
- **Multidisciplinary panel of experts and patients**
- **Patient-centred products**
- Public consultations
- Voluntary application and step-wise approach
- Supportive instruments for practical implementation
- Standardised auditing mechanism included



GRADE Evidence to Decision framework



Criteria	
Problem	Is the problem a priority?
Desirable & undesirable effects	How substantial are the desirable anticipated effects?
	How substantial are the undesirable anticipated effects?
Certainty	What is the overall certainty of the evidence of effects?
Values	Is there important uncertainty about or variability in how much people value the main outcomes?
Balance	Does the balance between desirable and undesirable effects favour the option or the comparison?
Resource use	How large are the resource requirements (costs)?
	What is the certainty of the evidence of resource requirements?
	Does the cost effectiveness of the option favour the option or the comparison?
Equity	What would be the impact on health equities?
Acceptability	Is the option acceptable to key stakeholders?
Feasibility	Is the option feasible to implement?

Adults aged 50 to 69: screening versus non screening



Healthcare question

Should screening vs. no screening be used for colorectal cancer in asymptomatic adults aged 50-69 with an average risk of colorectal cancer?

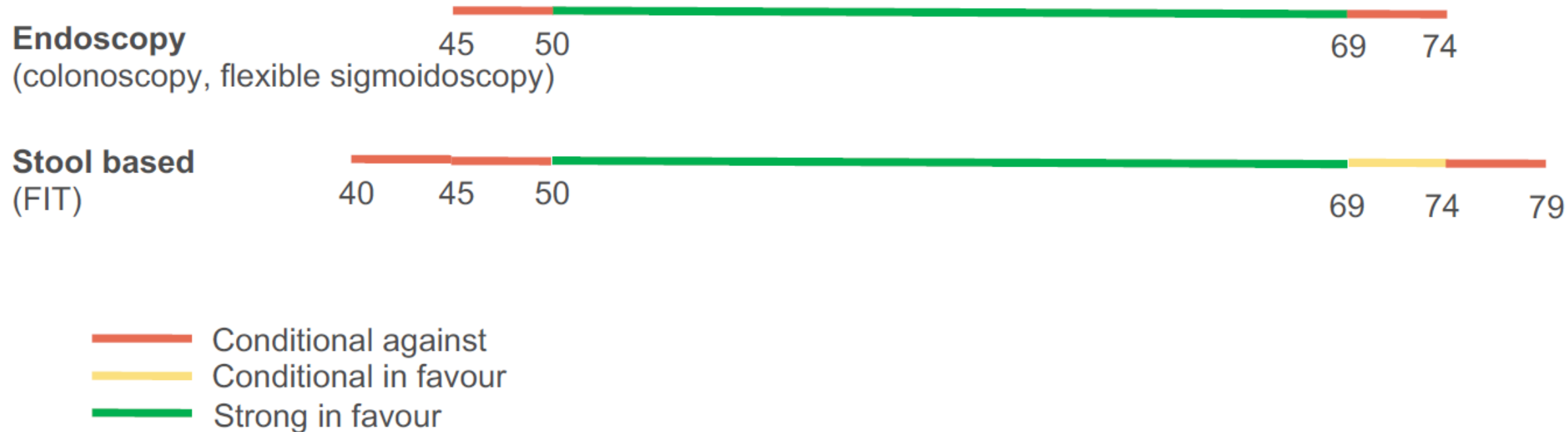
Recommendation

For asymptomatic adults aged 50-69 with an average risk of colorectal cancer, the ECICC working group (WG) recommends screening for colorectal cancer in the context of an organised population-based screening programme.

Recommendation strength

- ✓ Strong recommendation
- ✓ Moderate certainty of the evidence

Target age range



Screening intervals



Intervention	Frequency compared	Recommendation
FIT	1 year vs 2 years	Suggest every 2 years over every 1
FIT	2 vs 3 years	Suggest every 2 years over every 3 years
Flexible Sigmoidoscopy	5 vs 10 years	Suggest every 10 years over ever 5 years
Flexible Sigmoidoscopy	10 years vs once in a lifetime	Suggest every 10 years over once in a lifetime
Colonoscopy	10 years vs once in a lifetime	Suggest every 10 years over once in a lifetime
Colonoscopy	15 vs 10 years	Suggest every 15 years over ever 10 years

Healthcare question

Should faecal immunochemical test, flexible sigmoidoscopy, or colonoscopy be used for colorectal cancer screening in asymptomatic average risk adults?

Recommendation

The ECICC Working Group (WG) recommends organised, population-based colorectal cancer screening programmes for all average-risk adults aged 50 to 69 (strong recommendation, moderate certainty of the evidence). As the preferred approach, the WG suggests screening with Fecal Immunochemical Test (FIT) every two years, and continuing until the age of 74 (conditional recommendations, low certainty of the evidence).

If FIT is not implemented, the WG suggests endoscopy-based screening until the age of 69 and using colonoscopy every 15 years over flexible sigmoidoscopy every 10 years (conditional recommendation, low certainty of evidence), which are both conditionally recommended.

The WG also suggests no screening for adults under the age of 50 (conditional recommendations, very low certainty of the evidence).



Recommendation

The ECICC Working Group suggests using a letter including the self-sampling FIT kit over using a letter alone to invite eligible asymptomatic adults to an organised, population-based, colorectal cancer screening programme.

Recommendation strength

- ✓ Conditional recommendation
- ✓ Low certainty of the evidence



Recommendation

The ECICC Working Group suggests using a letter including a general practitioners (GP)'s signature over a letter without a GP's signature to invite eligible asymptomatic adults to an organised population-based colorectal cancer screening programme.

Remarks: The technical and legal capability to correctly assign the appropriate GP's signature to the corresponding individual patient invitation letter is crucial for implementing this recommendation.

Recommendation strength

- ✓ Conditional recommendation
- ✓ Low certainty of the evidence

Current status



16 recommendations on screening
4 recommendations on primary prevention



4 Good Practice Statements on healthy lifestyles



First set of requirements for colorectal cancer care services

Forthcoming activities



Additional recommendations on screening and diagnosis



Risk stratified approach for colorectal cancer screening



Requirements for screening, diagnosis and treatment of colorectal cancer

Risk-stratified screening

to facilitate the development of piloting ‘risk-stratified cancer screenings’ protocols, guidelines, and indicators for high quality and accessible cancer screening programmes on a national and, where appropriate, regional level with adequate territorial coverage including rural and remote areas;

Colorectal cancer:

Quantitative faecal immunochemical testing (FIT) is considered the preferred screening test for referring individuals for follow-up colonoscopy between 50 and 74 years old. Quantitative information from FIT results might be used on the basis of further research with a view to implement risk-tailored strategies, introducing thresholds defined per sex, age and earlier test results. Endoscopy may be adopted as a primary tool to implement combined strategies.

Ongoing trials

Perfect FIT trial



Analysis

Comparison between arms

f-Hb level at previous round

20,000
individuals
with ≥ 1
screening round

10,000 usual care: interval of
2 years;

10,000 intervention: interval of
- 3 years: $<2.6\mu\text{g}$
- 2 years: $2.6\text{-}15\mu\text{g}$
- 1 year: $15\text{-}47\mu\text{g}$

Endpoints

AN Yield : increase of AN detection from 1.7% to 2.2%

Participation



Ongoing trials

BIOFIT trial

Analysis

Within risk-groups comparisons

Cumulative f-Hb level
measured over 2 consecutive negative tests

High risk $\geq 20 \mu\text{g/g}$	Intermediate risk 4-19.9 $\mu\text{g/g}$	Low risk < 4 $\mu\text{g/g}$
Immediate TC	FIT 2 years	FIT 3 years
FIT 1 year		FIT 2 years
FIT 2 years		

Ratio
1:1:1

Ratio
2:1

Endpoints



Positivity
rate

DR
Advanced
adenoma and
CRC

PPV
Advanced
adenoma
CRC

Interval
cancer rate

Ongoing trials

MyFIT trial

Analysis

Comparison
between arms

Invited individuals
FIT - in previous round
Consent to enrolment

POSITIVE

Colonoscopy

NEGATIVE

CONTROL ARM

Standard screening
2-year interval

Cumulative f-Hb level
measured over 2 consecutive
negative tests

**RISK-STRATIFIED
PROTOCOL**

High
($\geq 20 \mu\text{g/g}$)

TC

Intermediate
($10\text{-}19.9 \mu\text{g/g}$)

One year

Average
($4\text{-}9.9 \mu\text{g/g}$)

Two years

Low
($< 4 \mu\text{g/g}$)

Three years

Endpoints



Participation

DR
Advanced
adenoma
and CRC

Interval
cancer rate

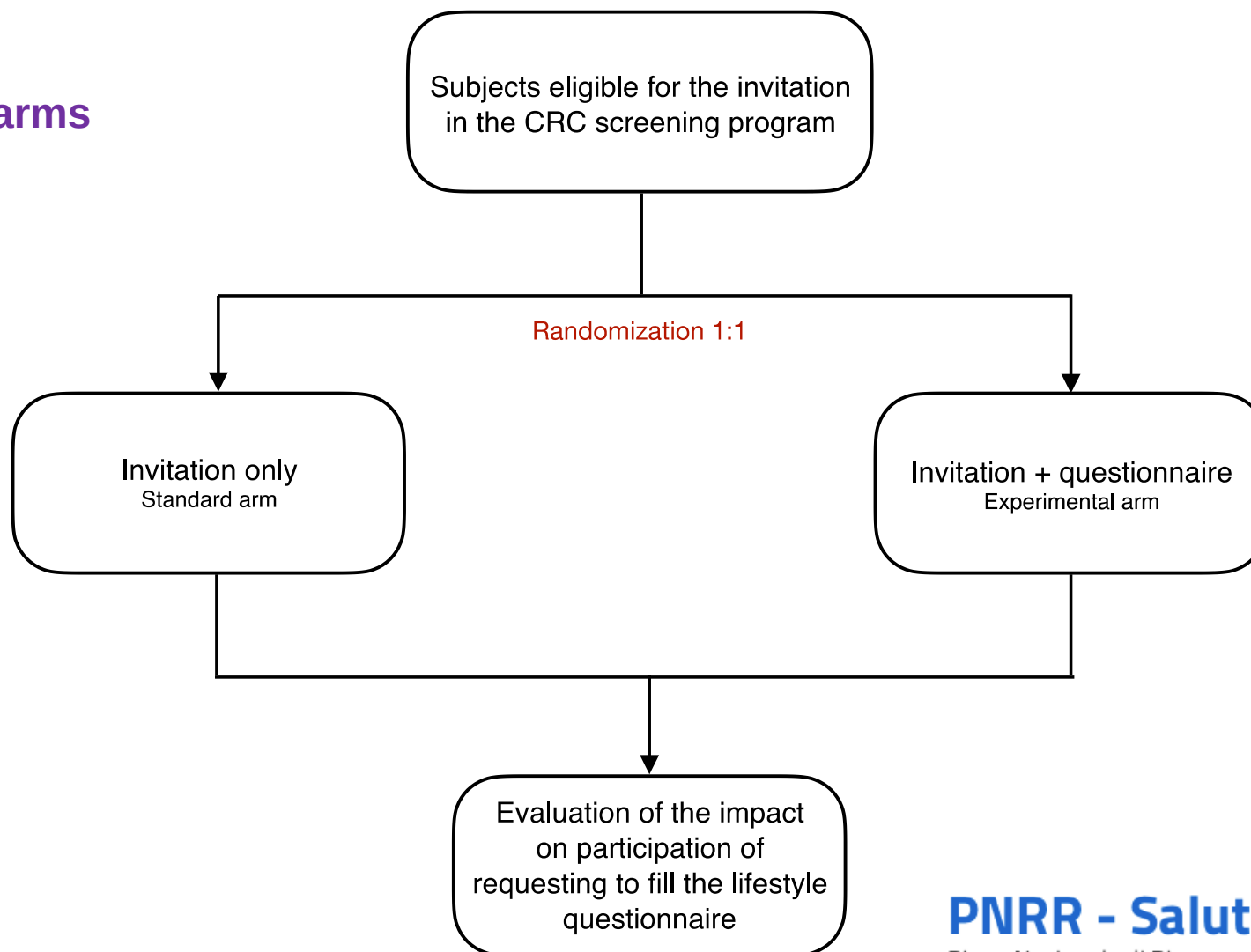
Analysis

Comparison between arms

Endpoints

Participation

Association
between
lifestyle and
prevalence of
neoplasia



Analysis

Comparison between arms

Risk stratification using the Qcancer calculator and previous faecal haemoglobin concentrations

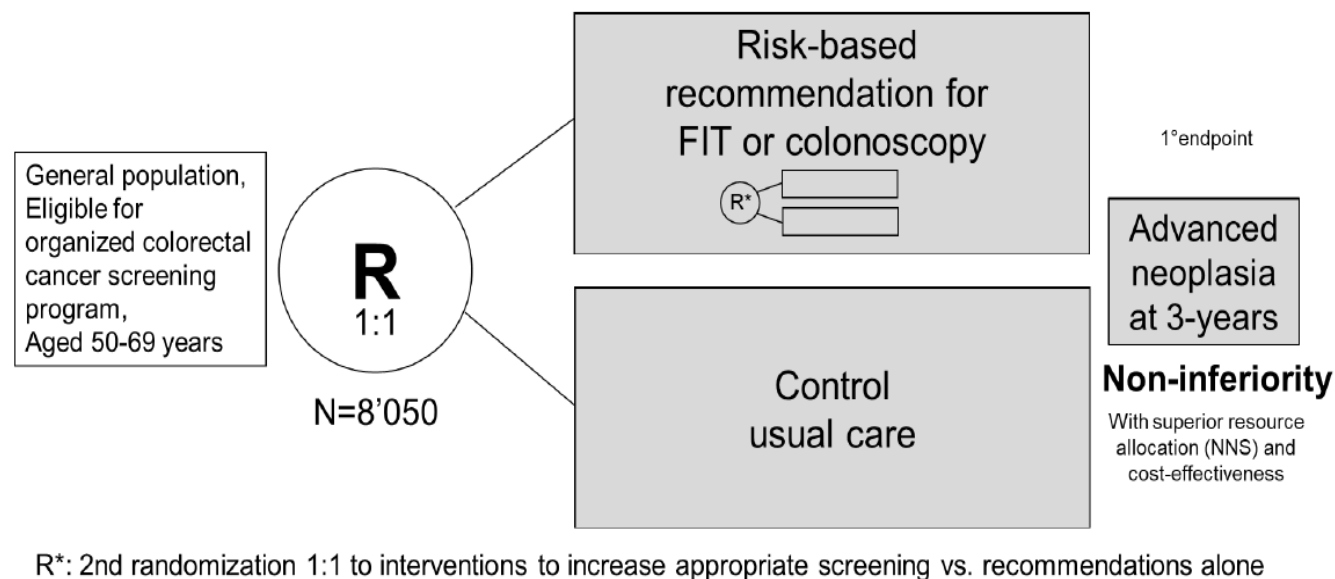
Endpoints



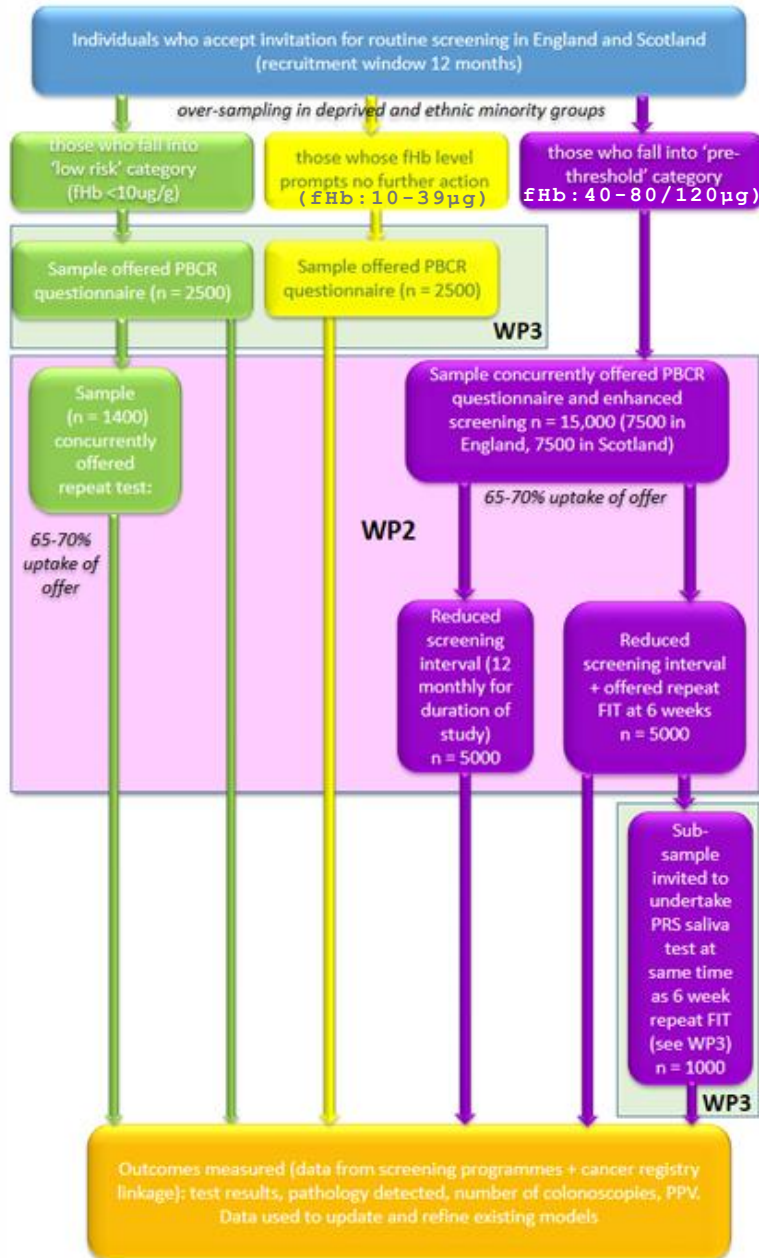
Cost-effectiveness

DR
Advanced adenoma and CRC

NNS



Ongoing trials



Bowel Star UK

BOWEL cancer screening STrAtified by Risk

Weller, D and Sasieni, P et al

Added value of risk information

1. IN THE PRESENCE OF FHB LEVEL INFORMATION, IS PBCR INFORMATION HELPFUL IN GENERATING STRATIFIED SCREENING PROTOCOLS? HOW DOES THE UTILITY OF THE INFORMATION VARY ACROSS FHB RANGES (E.G. PRE-THRESHOLD AND LOW RISK (<10UG/G)?

2. ARE PBCR DATA, GENERATED THROUGH OUR COHORT, HELPFUL IN VALIDATING/UPDATING EXISTING MODELS OF CRC RISK (WHICH INCLUDE PERSONAL RISK)?

1. USING MICROSIMULATION MODELLING, WHAT ARE THE PREDICTED LONG TERM IMPACTS OF RISK STRATIFIED SCREENING? (SUCH AS IMPACT ON LATE STAGE INCIDENCE, CRC MORTALITY, QALYS, ENDOSCOPY CAPACITY, ETC.)

2. WHAT IS THE PREDICTED IMPACT OF RISK STRATIFIED SCREENING ON HEALTH INEQUALITIES?

1. HOW ACCEPTABLE WILL STRATIFIED APPROACHES TO CRC (EITHER FHB-DRIVEN OR INCORPORATING PBCR INFORMATION) BE TO THE UK POPULATION?

2. HOW CAN WE BEST ENSURE THAT STRATIFIED APPROACHES DON'T EXACERBATE EXISTING HEALTH INEQUALITIES?

3. WHAT MIGHT BE THE PSYCHOLOGICAL IMPACT OF STRATIFIED CRC SCREENING APPROACHES IN THE UK POPULATION?

1. HOW WILL MOVING TO STRATIFIED APPROACHES IMPACT ON UK BOWEL CANCER SCREENING PROGRAMMES?

2. WHAT ARE THE KEY ORGANISATIONAL AND IT CHANGES REQUIRED TO ACCOMMODATE STRATIFIED APPROACHES TO BOWEL SCREENING?

3. WHAT ARE THE ESSENTIAL ELEMENTS OF RECOMMENDATIONS FOR NHS BOWEL SCREENING STAKEHOLDERS TO ASSIST IN TRANSITIONING TO STRATIFIED SCREENING?

Acceptability Equity

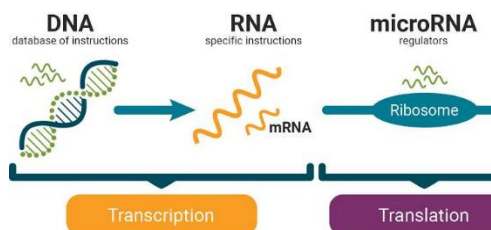
Feasibility Organizational impact

New biomarkers for risk stratification

Microbiome



MicroRNA



Fecal MicroRNA-Based Algorithm Increases Effectiveness of Fecal Immunochemical Test–Based Screening for Colorectal Cancer

Duran-Sanchon S et al. CGH 2021

A Fecal MicroRNA Signature by Small RNA Sequencing Accurately Distinguishes Colorectal Cancers: Results From a Multicenter Study

Pardini B et al. Gastroenterology 2023

Microbiome signatures for detection of colorectal lesions in population-based FIT screening

Birkeland EE et al. Nat commun 2026

Framework for risk stratified screening

European Journal of Cancer 240 (2026) 116746

Contents lists available at ScienceDirect

European Journal of Cancer

journal homepage: www.ejccancer.com



Review

Risk-stratified cancer screening: A consensus-based conceptual framework from EUCanScreen

OBJECTIVES

ELSI

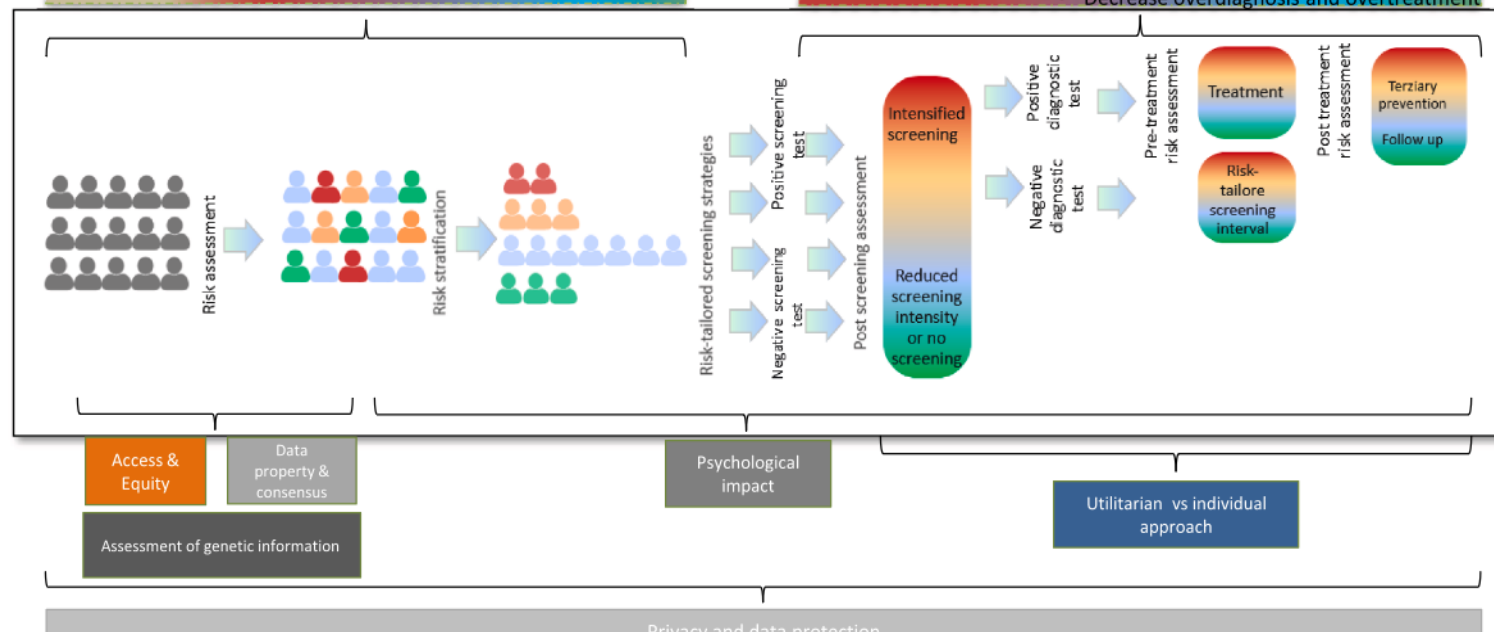
Paolo Giorgi Rossi^{a,*}, Carlo Senore^{b,1}, Livia Giordano^b, Lucie Veron^c, Tala Haddad^d, Andrea Guida^e, Massimo Vicentini^a, Francesca Leoni^{a,f}, Laura Bonvicini^g, Cinzia Colombo^g, Paola Armaroli^b, Francesco Venturelli^h, Gianluigi Ferrante^b, Cristiano Piccinelli^b, Elisa Betti^h, Gabrielle Schittecatteⁱ, Béatrice Fervers^j, Yelena Tarasenko^k, Cinzia Campari^a, Silvia Deandrea^{l,m}, Andrea Buron^{n,o}, Cristina Barrufet^{n,o}, Nataša Antoljak^p, Anneza Yiallourou^q, Erika Korobeinikova^r, Itziar Gardezabal^g, Carlos López López^g, Uwe Siebert^{u,v,w}, Marcello Di Pumpo^x, Maria Isabel Portillo Villares^y, Gaby Sroczynski^t, Beate Jahn^z, Trude Andreassen^z, Suzette Delaloge^{e,2}, Paola Mantellini^{b,2}

- Reduce cancer-specific mortality and, where possible, overall incidence
- Reduce the incidence of advanced cancers, increase the detection of precancerous lesions, and decrease interval cancers and late-stage diagnoses
- Ensure or enhance sustainability through feasible and scalable solutions

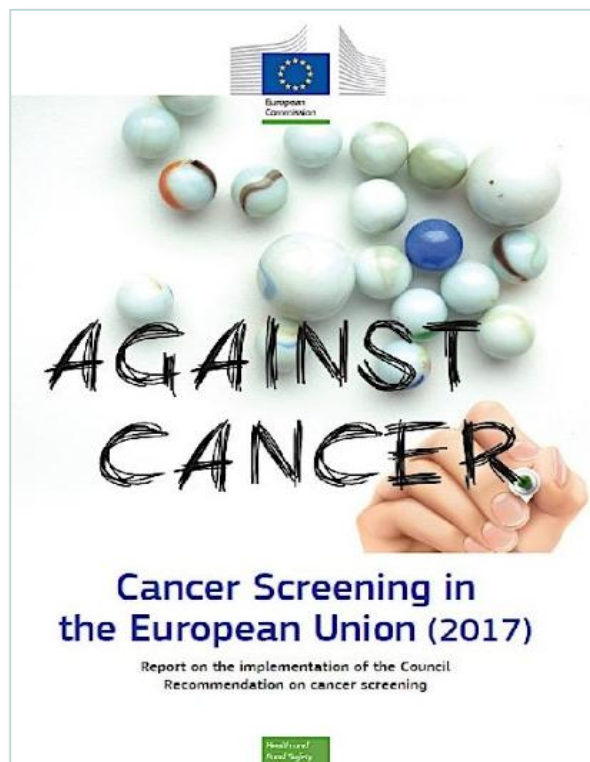
- Improve equity while avoiding discrimination

- Ensure correct information, promote shared decision

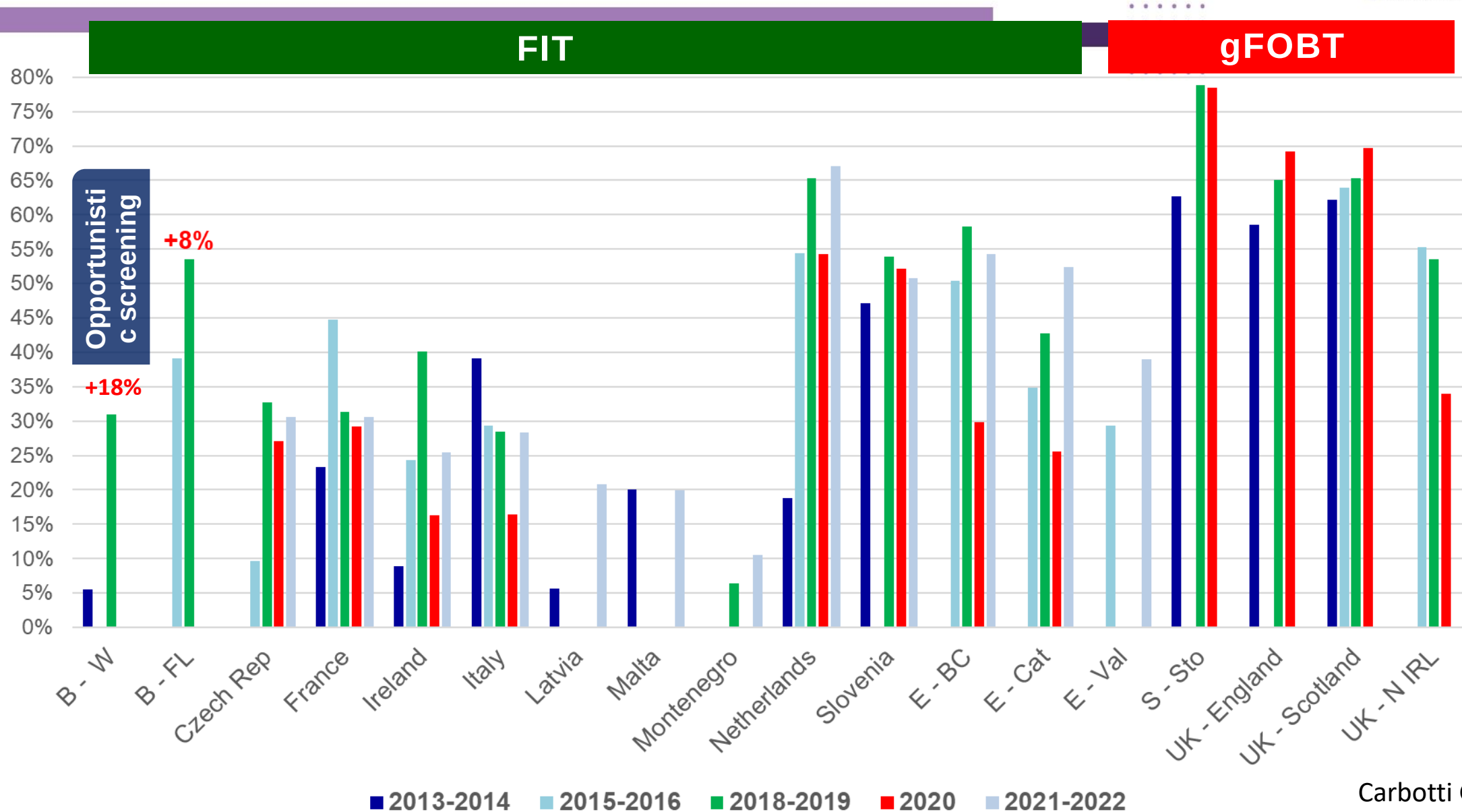
- Increased benefits
 - Decrease false-positive and unnecessary invasive procedures
 - Decrease overdiagnosis and overtreatment



Monitoring - Sources of data



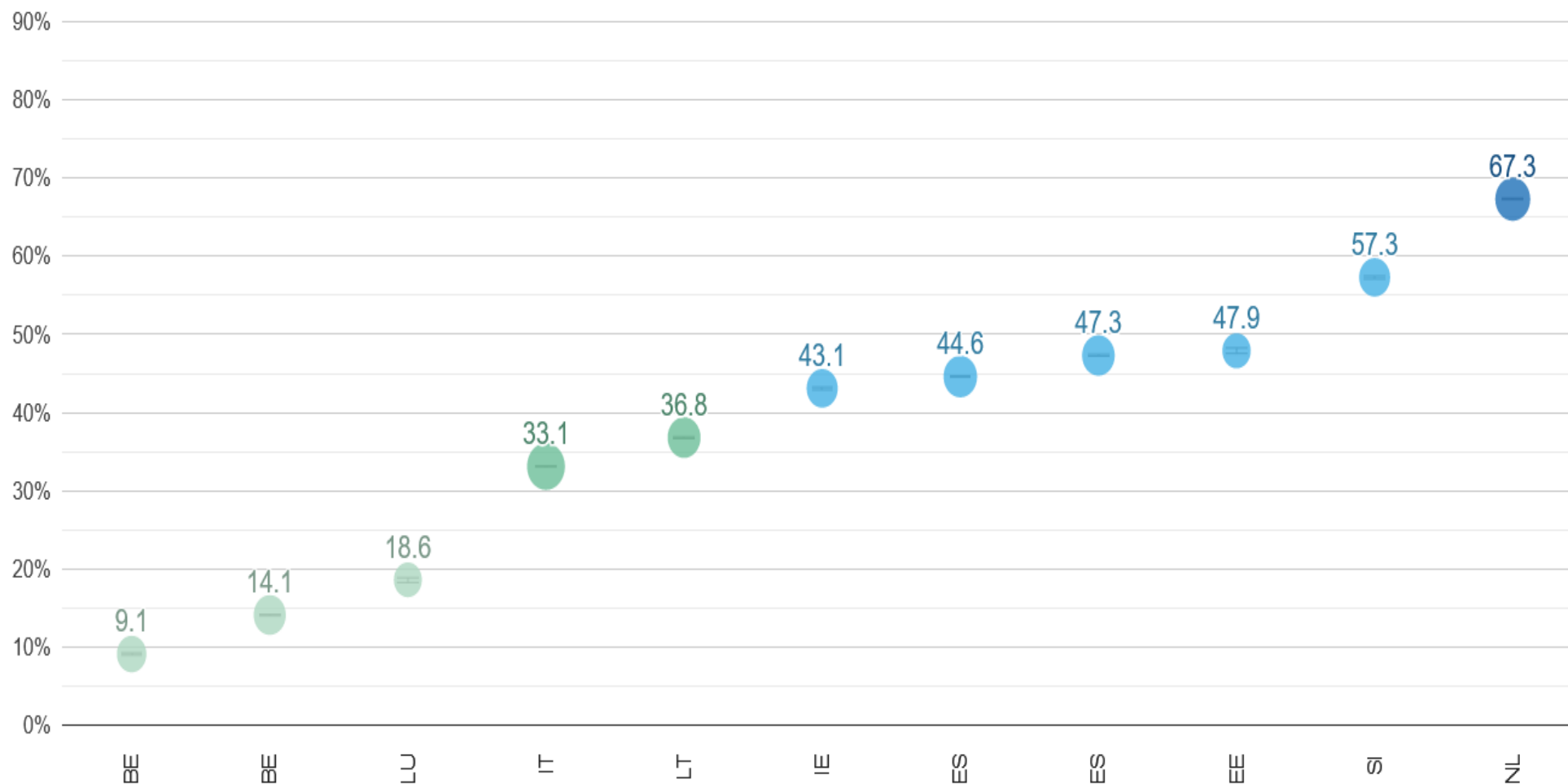
Examination coverage





Participation rate

Participation rate %, FIT

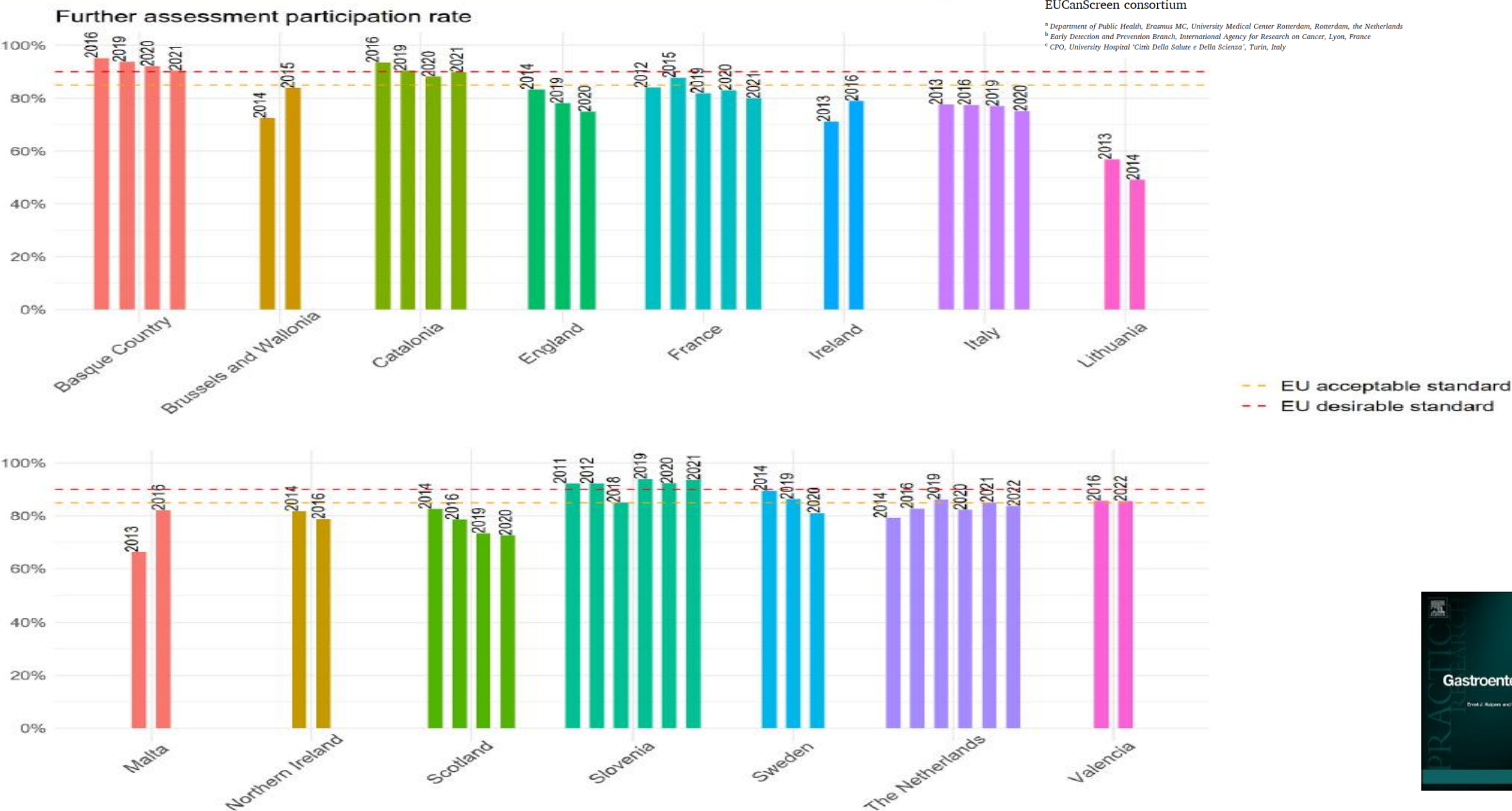


Compliance with TC referral

Developments in the roll-out and performance of CRC screening in Europe

Giulia Carbotti ^{a,*}, Danica MN. van den Berg ^a, Andre L. Carvalho ^b, Carlo Senore ^c,
Eveline AM. Heijnsdijk ^a, Harry J. de Koning ^a, Iris Lansdorp-Vogelaar ^a, On behalf of CanScreen-
ECIS data providers, of ICSN CRC interest group COVID-19 survey data providers and of the
EUCanScreen consortium

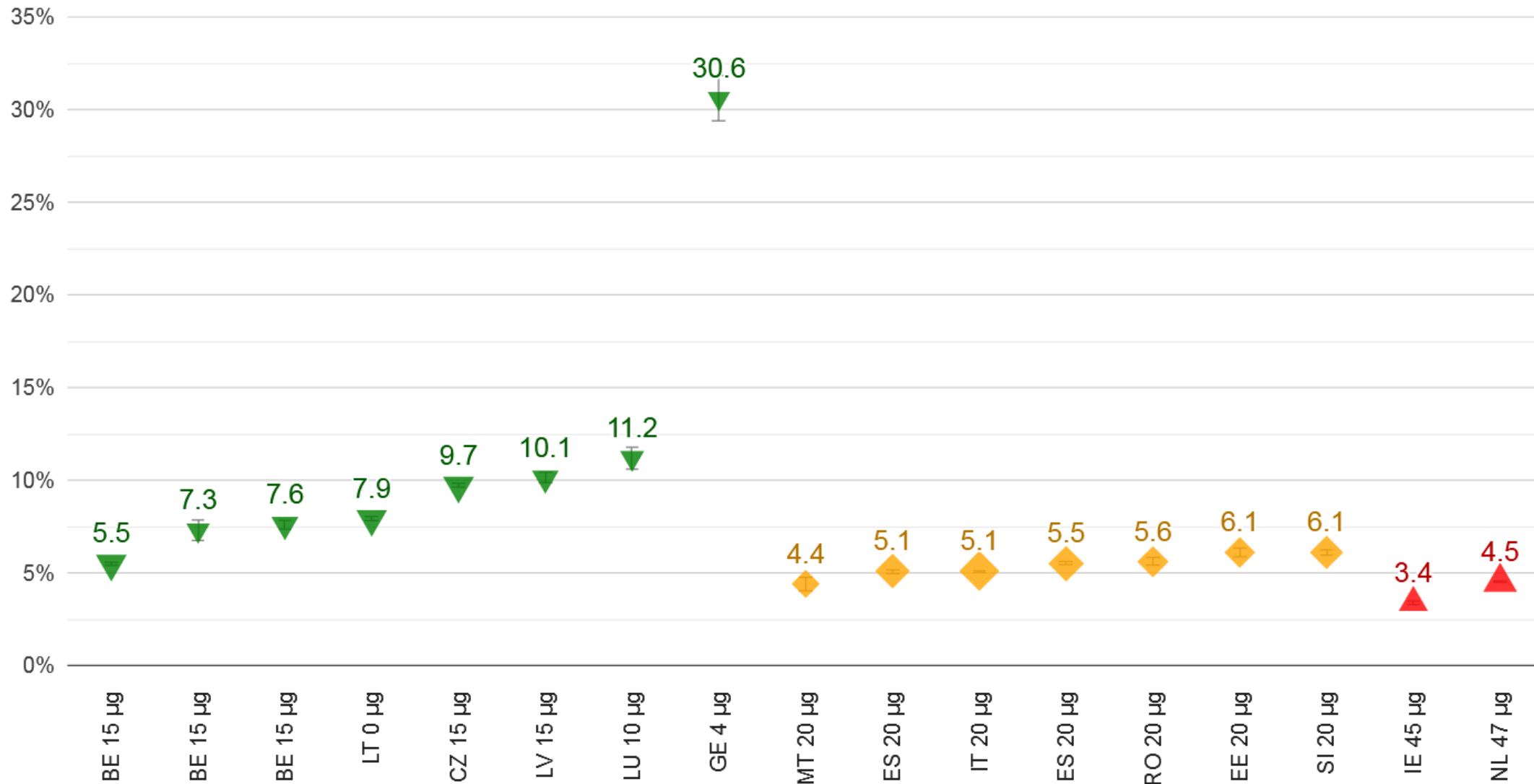
^a Department of Public Health, Erasmus MC, University Medical Center Rotterdam, Rotterdam, the Netherlands
^b Early Detection and Prevention Branch, International Agency for Research on Cancer, Lyon, France
^c CPO, University Hospital 'Città Della Salute e Della Scienza', Turin, Italy





FIT positivity rate – by cut-off

age 55 to 69

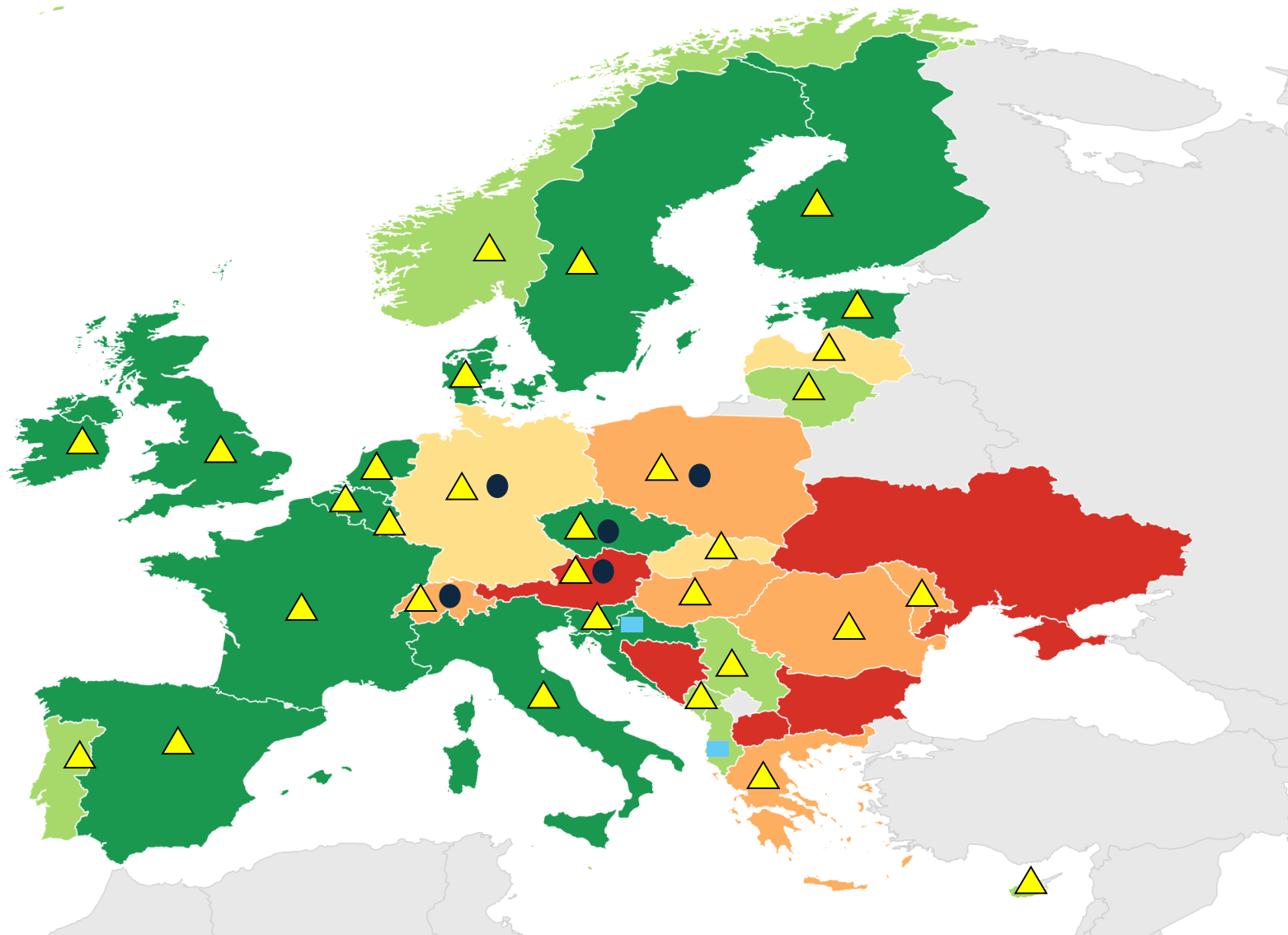


Colorectal Cancer Screening in Europe

- ▲ FIT
- Colonoscopy
- gFOBT

Screening status

- opportunistic
- pilot
- roll-out-opportunistic
- roll-out ongoing
- roll-out completed



CONCLUSIONS



- 📌 Organized population based programs have been implemented, or are in the roll-out phase, in most countries in Europe
- 📌 Guidelines and QA schemes will favour harmonization and standardization of the screening pathways across Europe
- 📌 Ongoing trials will provide insight about cost-effectiveness, health impact and feasibility of risk-stratified screening
- 📌 Efforts aimed to ensure and consolidate systematic monitoring are needed to inform decision making about innovative approaches



Thank you for your attention

carlo.senore@cpo.it



Actors

- **European Commission:** DG SANTE
- **Working group:** decision making body that provides direction for development of guidelines and quality assurance scheme
(17 members) **Kick off in June 2022**
- **Topic-specific groups:** prepare draft recommendations and requirements;
- **Systematic review group:** perform systematic reviews of the scientific evidence available and summarize the evidence
- **Partner and collaborators:** support in identifying priorities, ensure complementarity with other initiatives and provide feedback

BIOFIT – RCT of risk-stratified screening

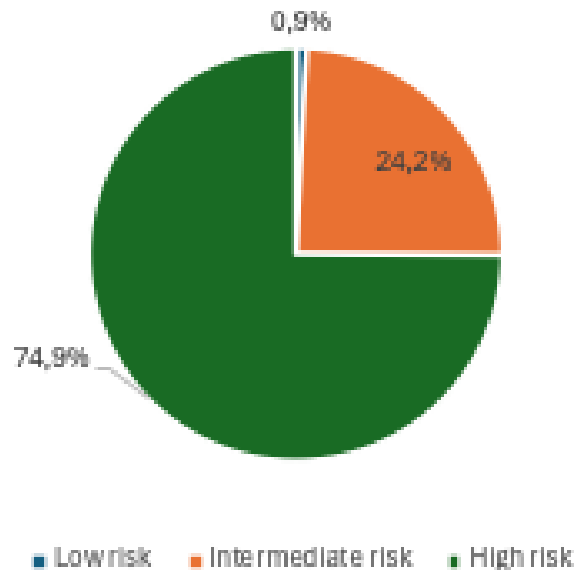
Preliminary Results



28,9
%

Consent to participation in the study and randomization (n. of people invited -> 118.308)

Risk distribution



TOT: 25.915

High risk

Immediate colonoscopy	FIT 1 year	FIT 2 years
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94	102	101
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Low risk

FIT 2 years	FIT 3 years
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8.573	17.045
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VPP for
Advanced
Neoplasia
22,9%
(16/70)

