



Thames Valley
Cancer Alliance



NHS-Galleri Interim Implementation Pilot

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[@Thames Valley Cancer Alliance](https://www.linkedin.com/company/thames-valley-cancer-alliance)



[@Thames Valley Cancer Alliance](https://www.youtube.com/channel/UC...)

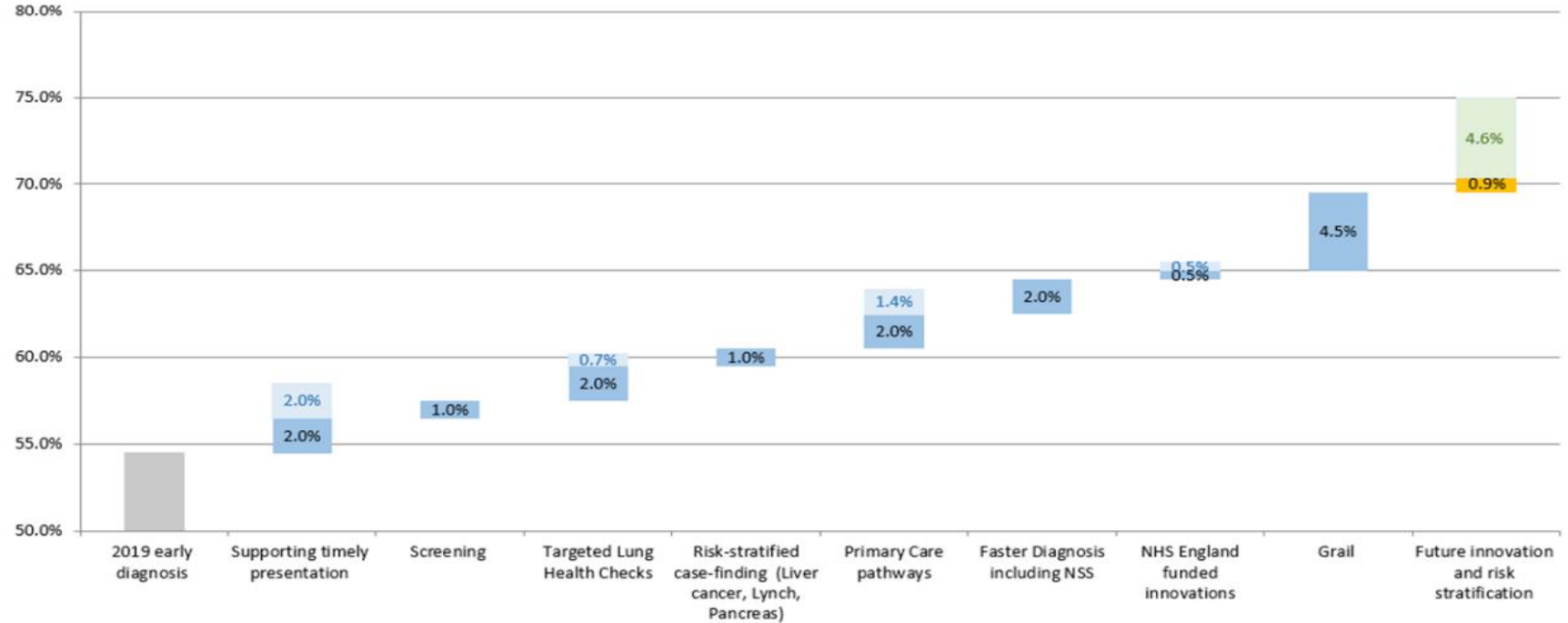


[@ThamesV_Cancer](https://twitter.com/ThamesV_Cancer)

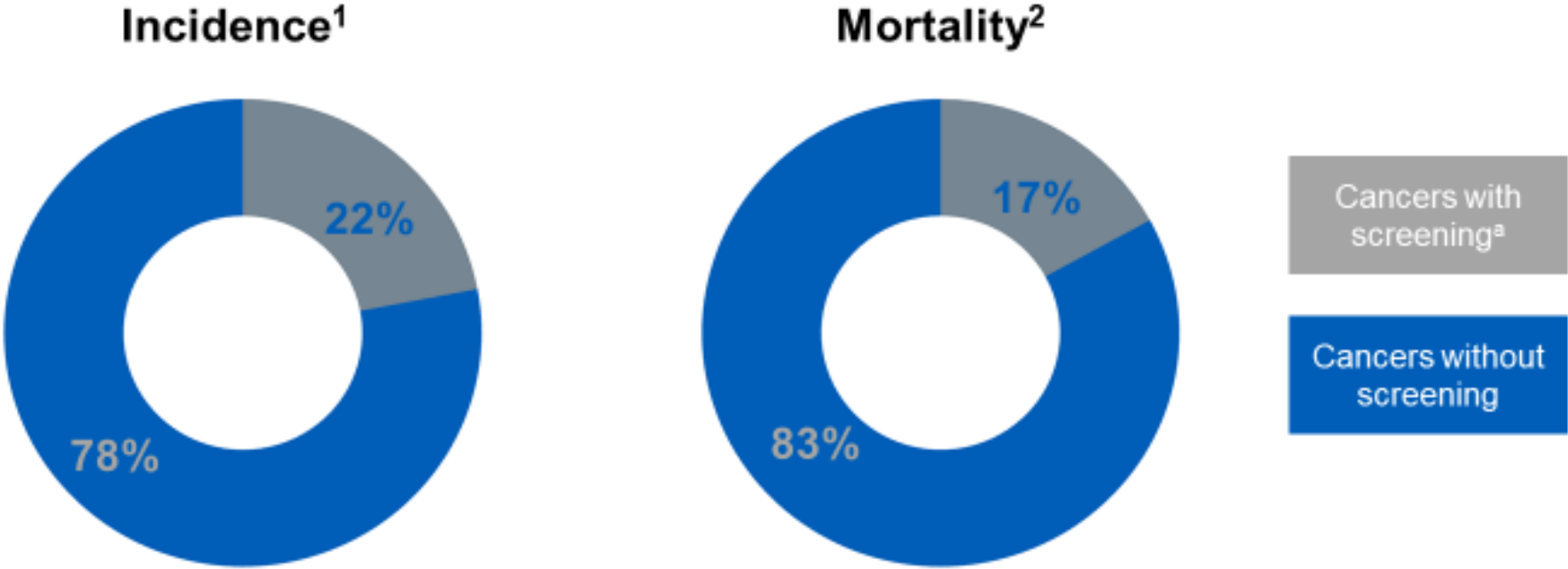
Early Diagnosis National Ambition

- Currently 58% of cancers are diagnosed at Stage I & II
- National ambition is to increase this to 75% by 2028

Estimated impact of interventions on the early diagnosis rate



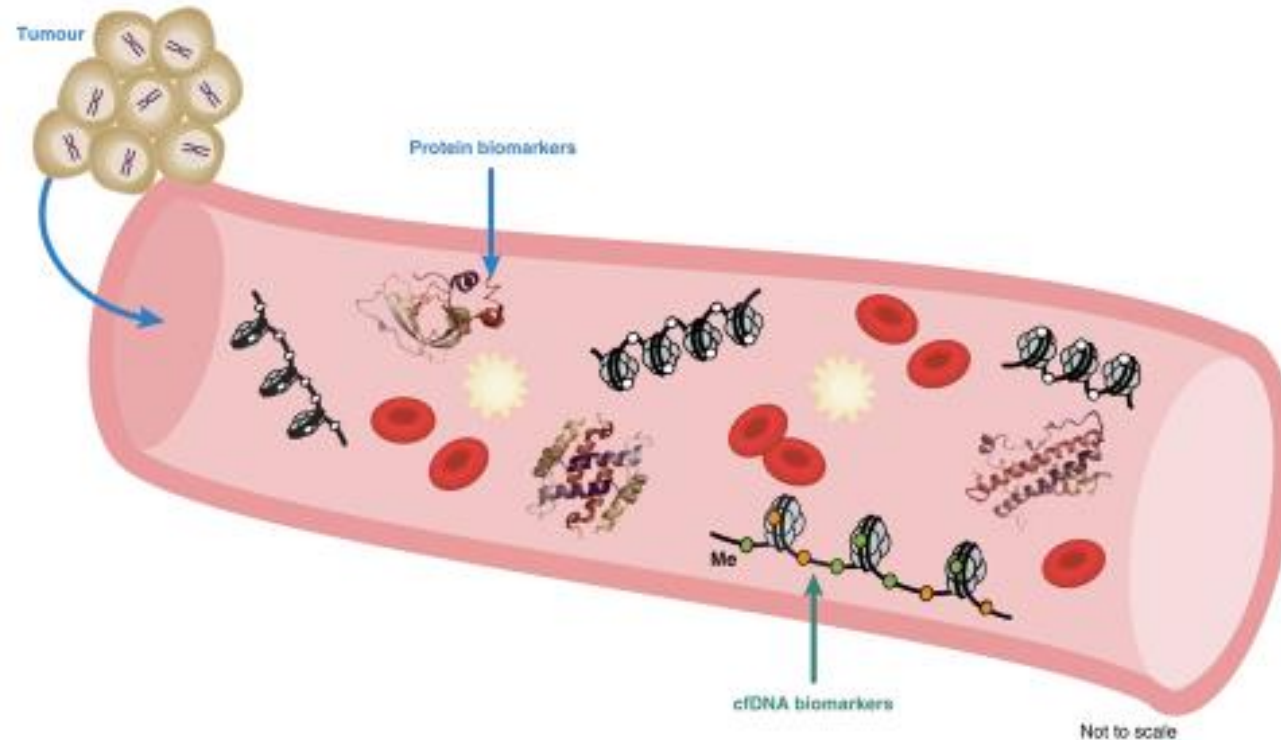
Cancers without a screening programme account for majority of cancer cases and deaths



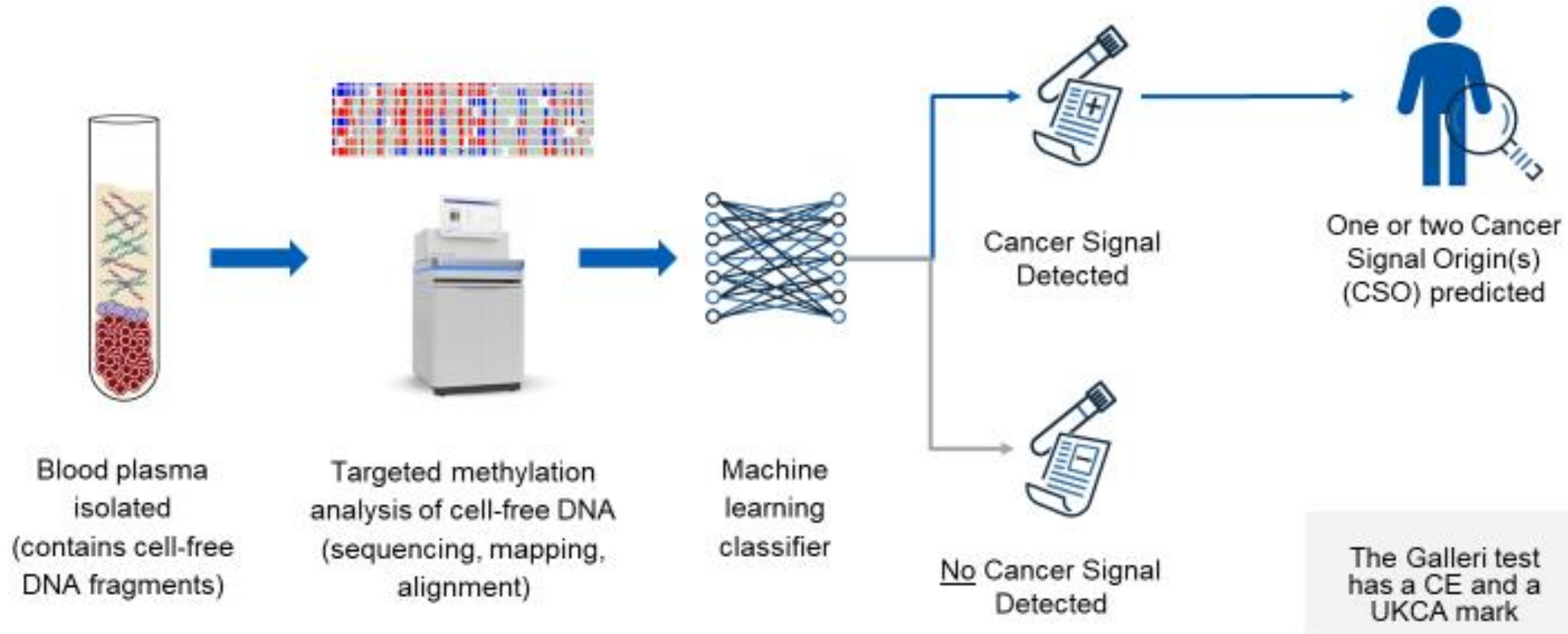
^aBreast, bowel and cervical cancer.
¹National Cancer Registration and Analysis Service (NCRAS). Cancer incidence and mortality for England, 2016-2020. https://www.cancerdata.nhs.uk/incidence_and_mortality. Accessed February 2023.
²Office for National Statistics. Mortality statistics - underlying cause, sex and age, 2016-2020. <https://www.nomisweb.co.uk/query/construct/summary.asp>. Accessed February 2023.

Multi-cancer early detection tests can detect signs of many types of cancer

- Tumours shed substances into the blood, such as tumour cells, proteins and tumour DNA (known as cell-free DNA).
- Multi-cancer early detection (MCED) tests can detect many different cancers from a sample of blood - screening individuals for any cancer, instead of screening for individual cancers.
- MCED tests complement existing screening approaches.



The Galleri multi-cancer early detection test



Predicting Cancer Signal Origin(s)

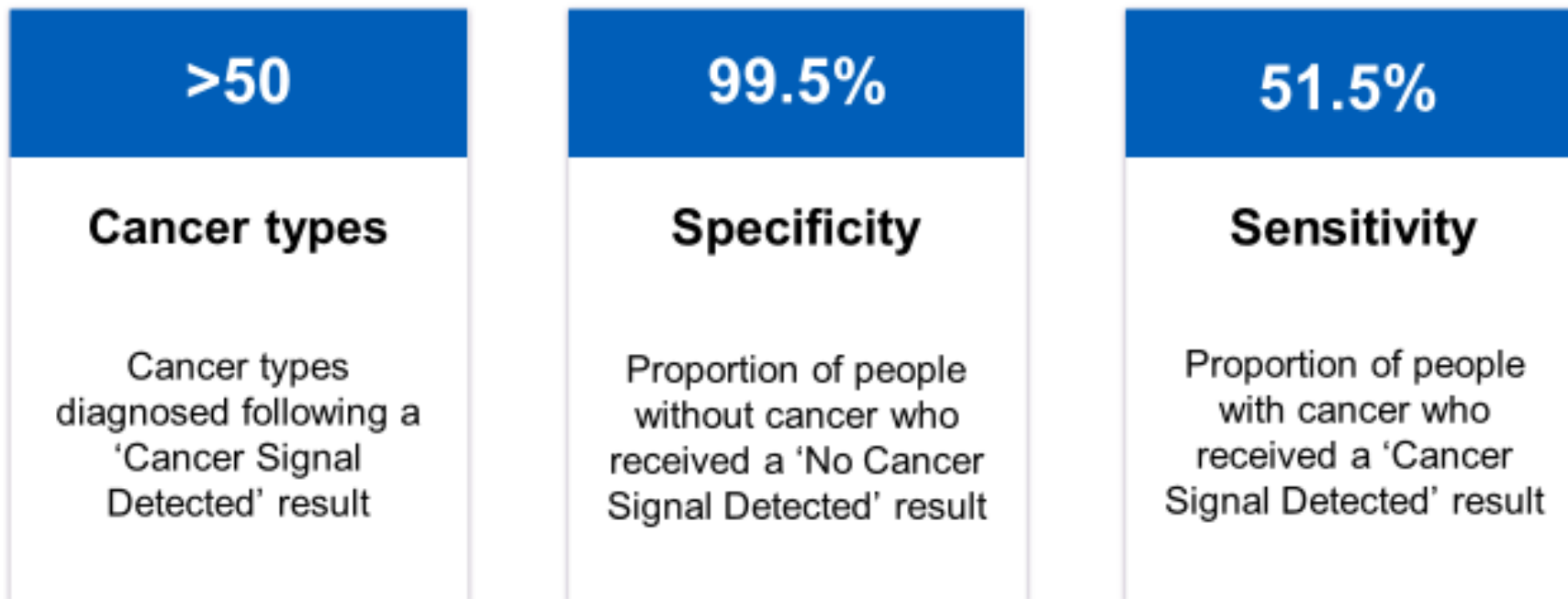
The Galleri test has 21 possible Cancer Signal Origins (CSOs)

CSO reported	What is included
Anus	Anus
Bladder, Urothelial Tract	Bladder, Renal Pelvis, Ureter, Urethra
Bone and Soft Tissue	Skeletal muscle and other connective tissue, Vascular tissue, Bone and cartilage
Breast	Breast
Cervix	Cervix
Colon, Rectum	Colon, Rectum, Appendix
Head and Neck	Oropharynx, Hypopharynx, Nasopharynx, Larynx, Lip and oral cavity (including oral tongue), Nasal cavity, Paranasal sinuses, Major salivary glands
Kidney	Kidney
Liver, Bile Duct	Liver, Intrahepatic bile duct
Lung	Lung, Bronchus

CSO reported	What is included
Lymphoid Lineage	Lymphoid Lineage
Melanocytic Lineage	Melanocytic Lineage
Myeloid Lineage	Myeloid Lineage
Neuroendocrine Cells of Lung or other Organs	Neuroendocrine Cells of Lung or other Organs
Ovary	Ovary, Fallopian tube, Primary peritoneum
Pancreas, Gallbladder	Pancreas, Extrahepatic bile duct, Gallbladder
Plasma Cell Lineage	Plasma Cell Lineage
Prostate	Prostate
Stomach, Esophagus	Stomach, Esophagus
Thyroid Gland	Thyroid Gland
Uterus	Uterus

Galleri key performance features

Based on a prospective, observational study of people with and without cancer (NCT02889978)¹

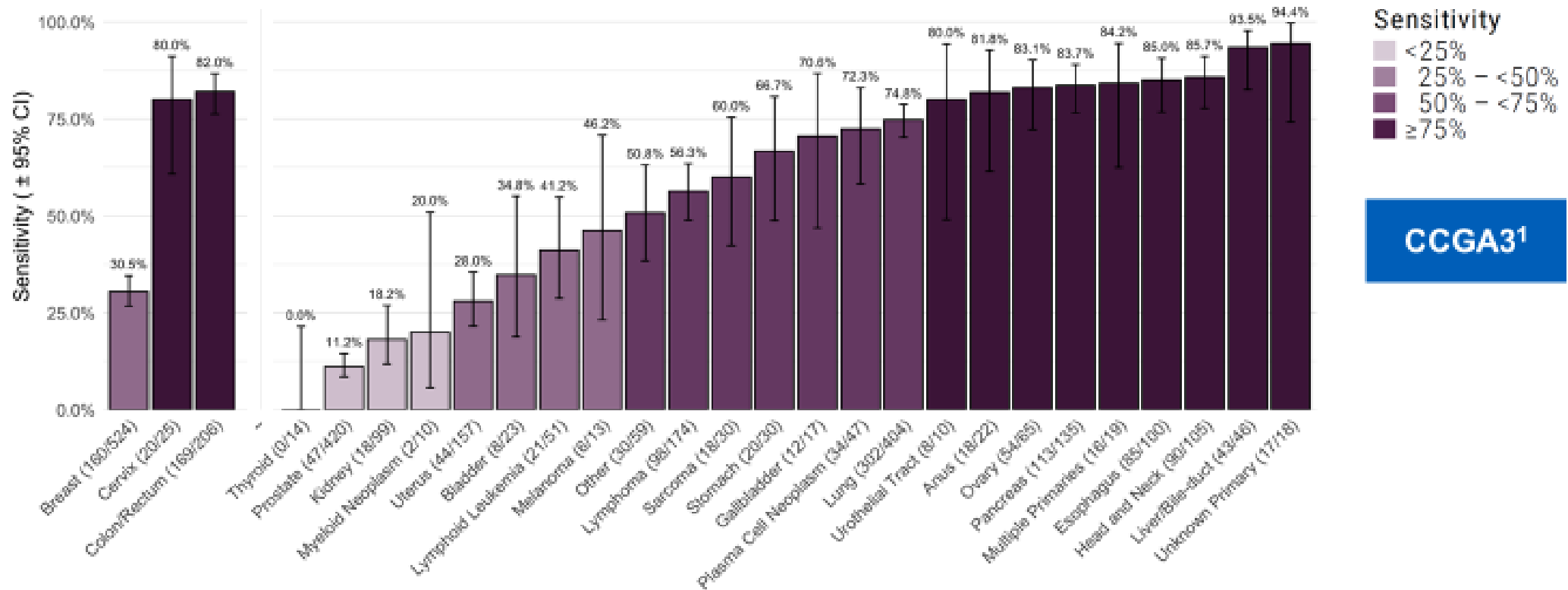


The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur.

Sensitivity of Galleri cancer signal detection by cancer type¹

Cancers with common screening options: 46.2%

Cancers without common screening options: 53.0%



Galleri key performance features

Based on a prospective, interventional, return-of-results study in people with and without cancer symptoms (NCT04241796)¹

43.1%

Positive predictive value

Proportion of people with a 'Cancer Signal Detected' result diagnosed with cancer

88.0%

Cancer Signal Origin (CSO) prediction accuracy

Proportion of correct first (or second) CSO prediction(s) among participants with cancer and a 'Cancer Signal Detected' result

The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur.

Galleri demonstration projects in the NHS

In 2020, the NHS and healthcare company GRAIL, LLC announced a partnership to transform cancer outcomes in a large testing implementation programme



NHS-Galleri trial (ISRCTN91431511)¹

- Randomised controlled trial
- Approx 140,000 asymptomatic participants
- Designed to establish whether screening with the Galleri test reduces the incidence of late-stage cancer when used in combination with existing NHS cancer screening programmes

SYMPLIFY trial (ISRCTN10226380)²

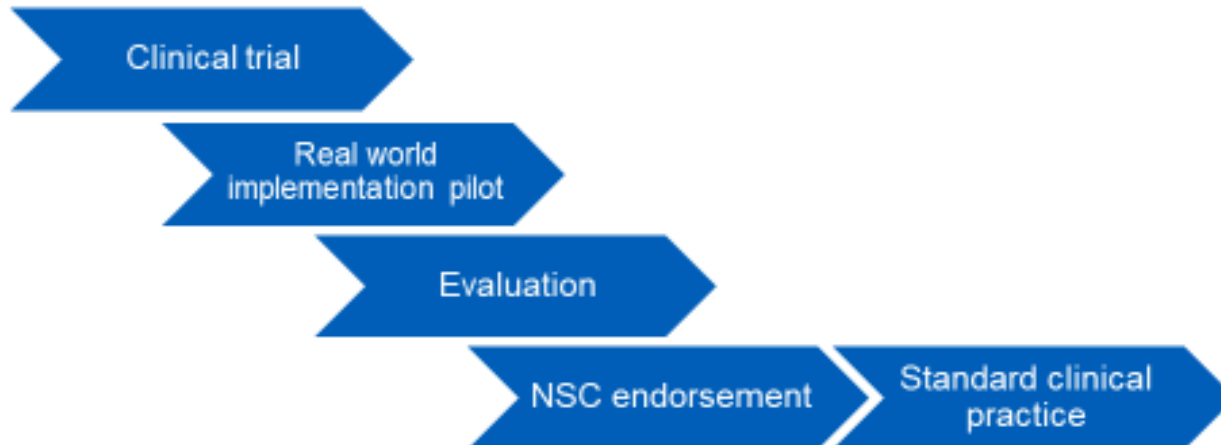
- Observational prospective cohort study
- Approx 6,000 symptomatic participants presenting to primary care and referred for diagnostic tests for suspicion of cancer
- Designed to evaluate the performance of the Galleri test for the detection of cancer in symptomatic patients in primary care

Speeding up the pathway to business-as-usual

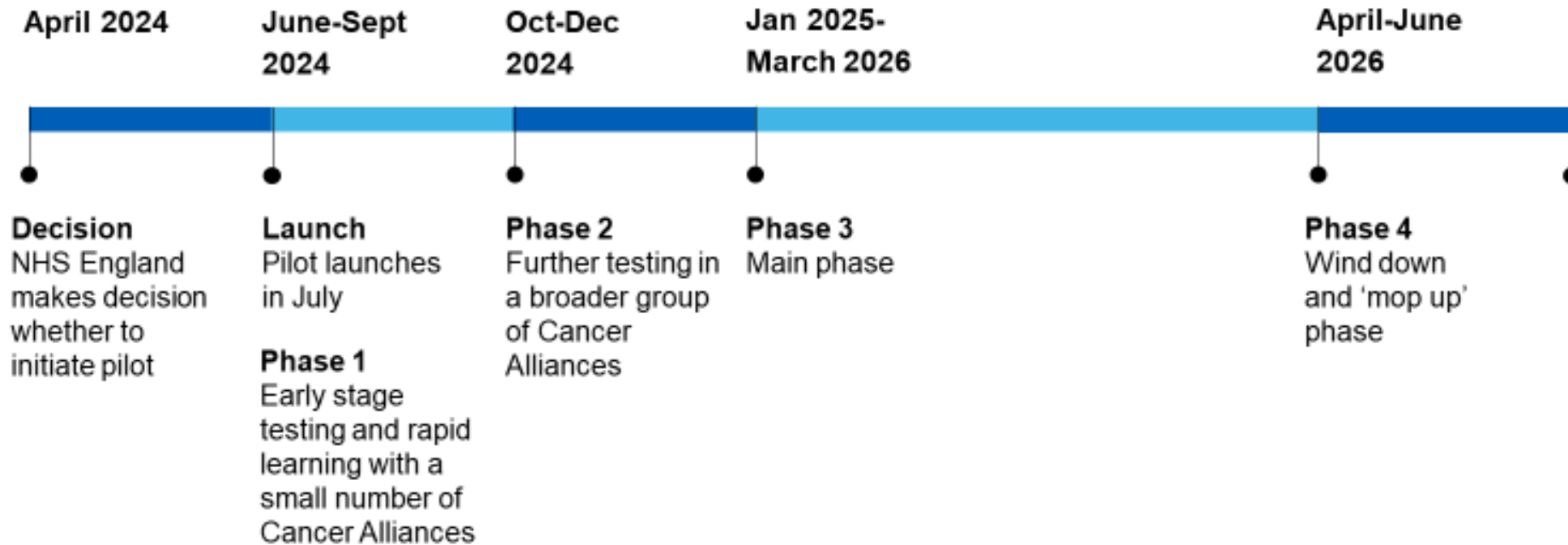
Standard adoption pathway for new screening tests



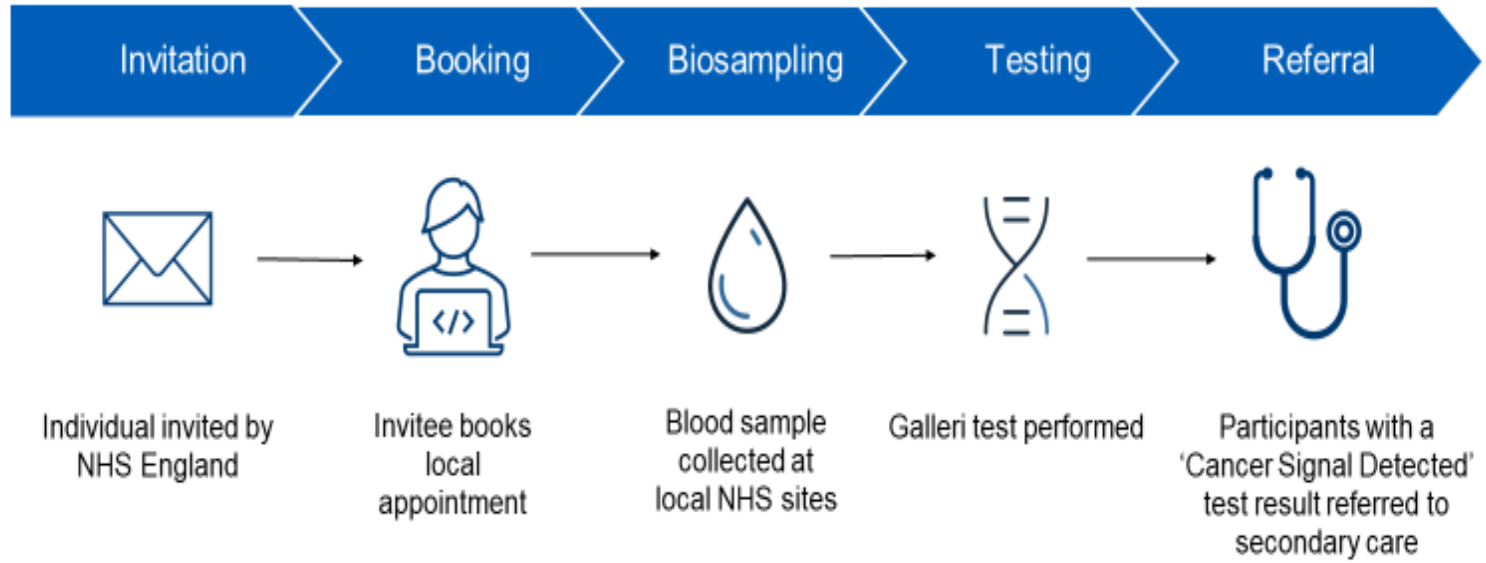
NHS-Galleri pathway



Pilot timeline*: phased approach

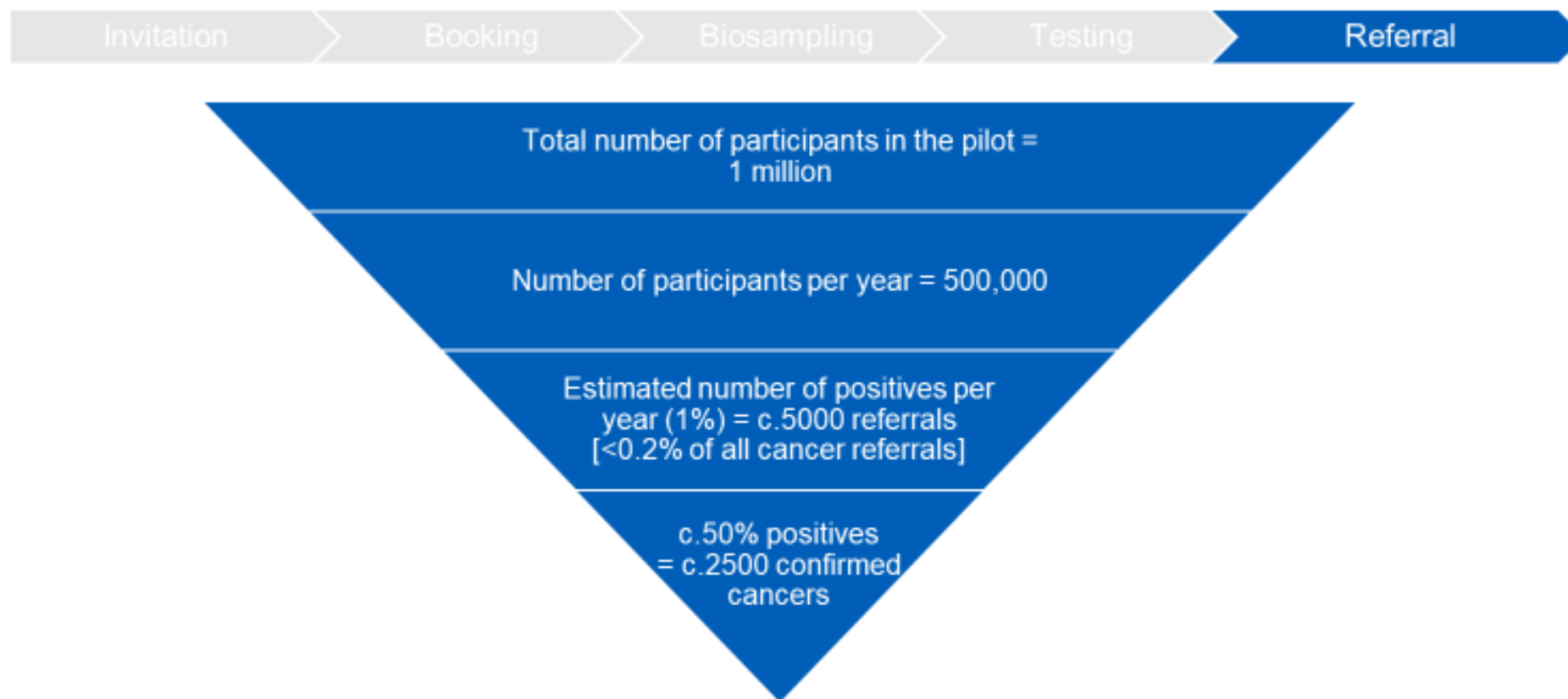


Process overview

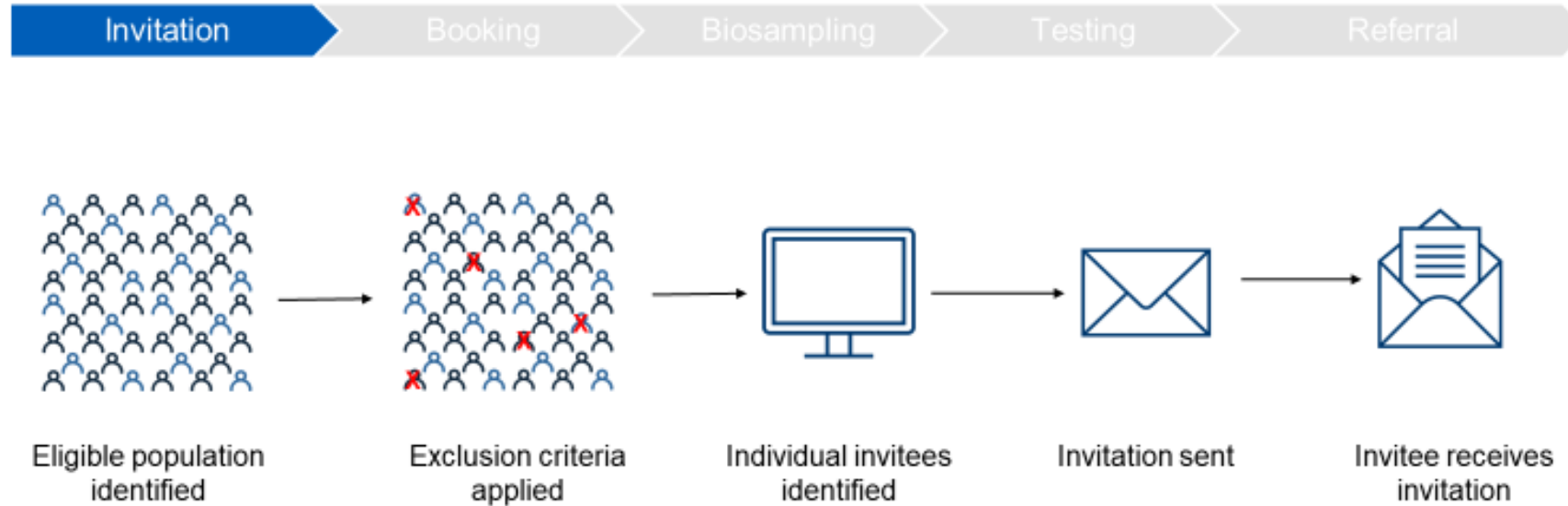


- The proposed delivery model for the pilot is to use local NHS phlebotomy services for blood sample collection.
- Participants with a 'Cancer Signal Detected' test result would be referred to local Trusts for diagnostic investigation(s) on a non-specific symptoms two-week wait pathway.

Expected number of referrals is small*

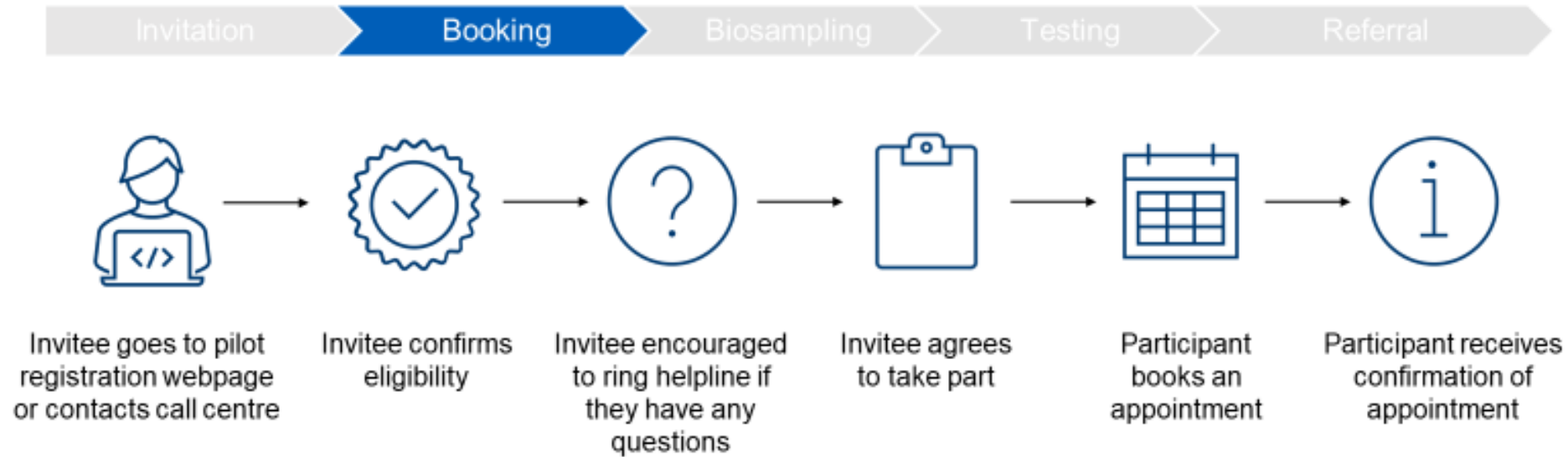


Participant identification and invitation process



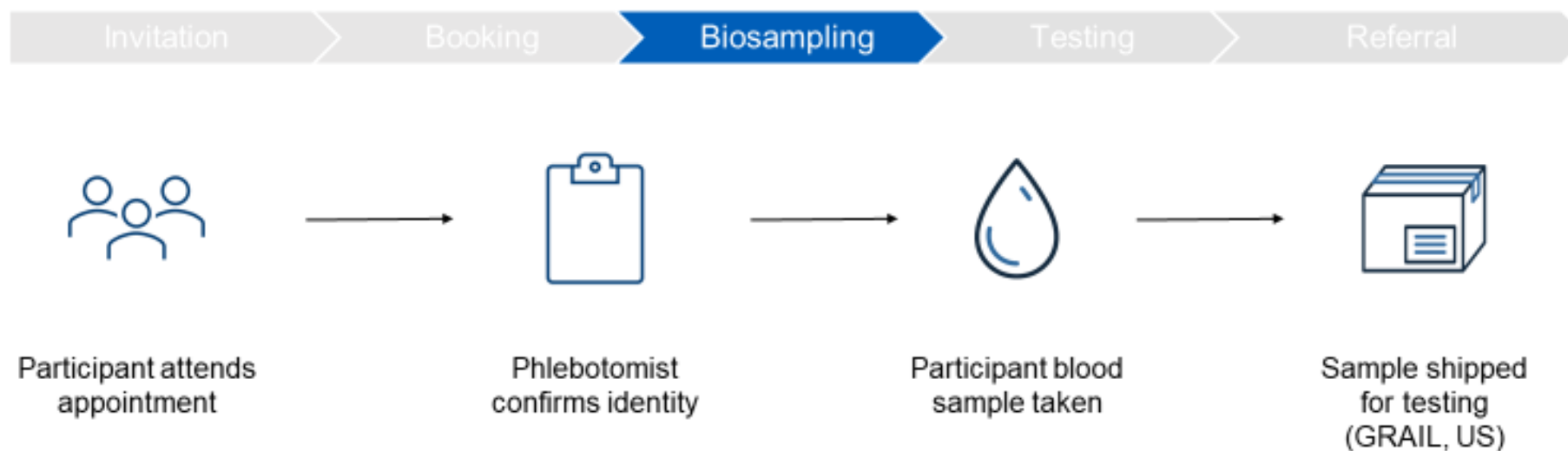
People aged between 50 and 77 inclusive and registered with a General Practitioner (GP) practice within a participating Cancer Alliance region in England will be eligible to take part in the NHS-Galleri Interim Implementation Pilot.

Participant booking process



Invitees receive a reminder if they have not completed a booking within two weeks of receiving their invitation.

Participant biosampling process



The proposed delivery model for the pilot is to use local phlebotomy services for blood sample collection.

- Phlebotomy commissioning would take place through Integrated Care Boards (ICBs).
- The National Biosampling Service Specification sets out standards of how biosampling would be developed.

Participant biosampling logistics



Front-end

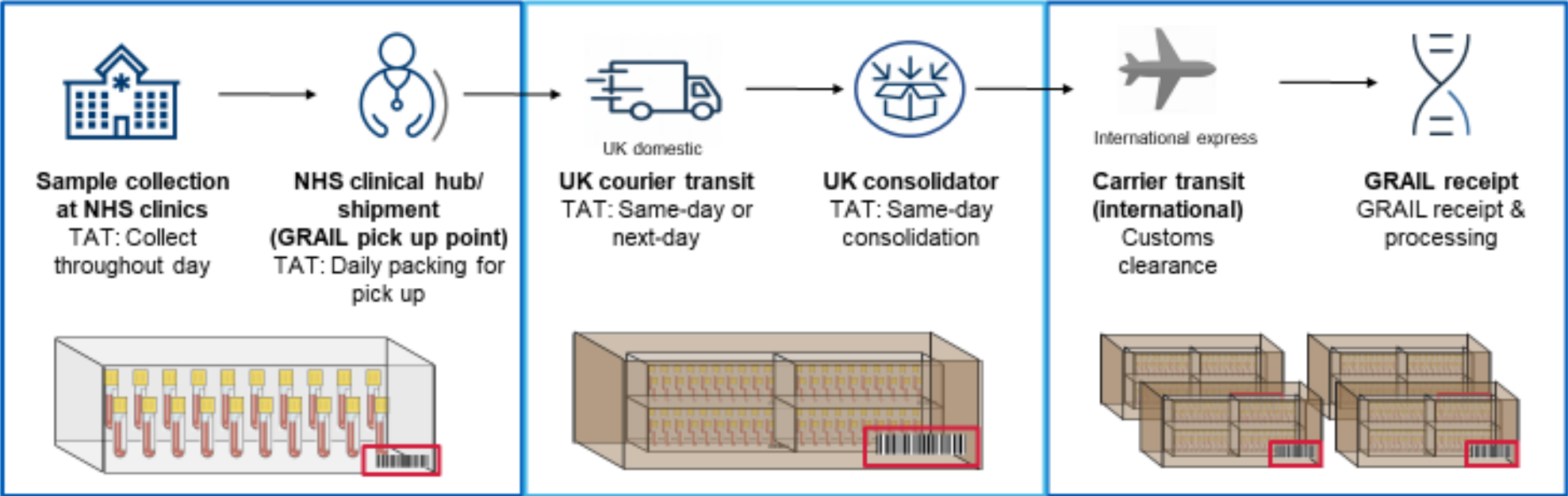
Location: NHS clinic
Custody: NHS

Middle

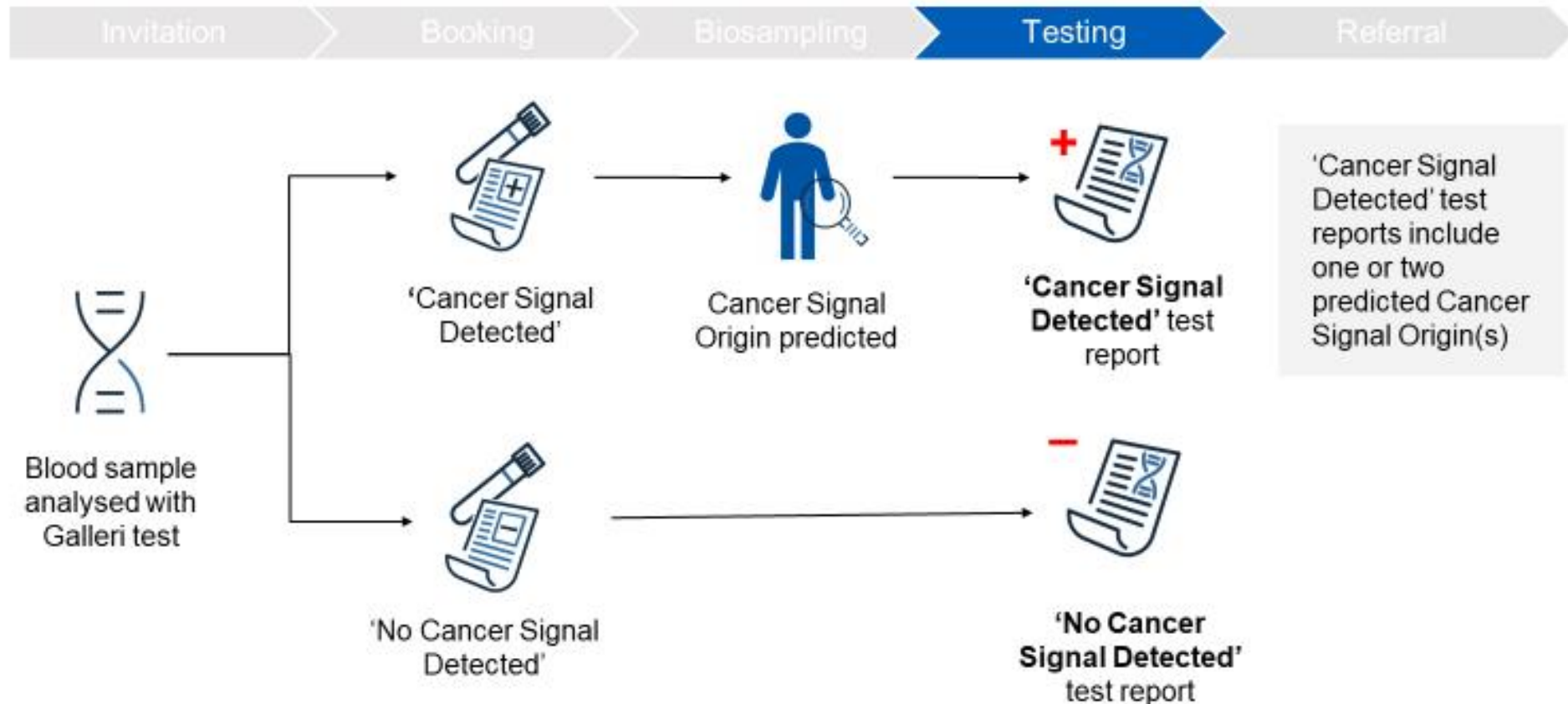
Location: Pick-up hub
Custody: UK courier

Back-end

Location: International carrier to GRAIL
Custody: GRAIL



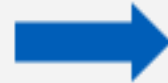
Sample testing



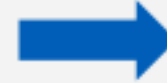
Communicating test outcome



'Cancer Signal Detected'
test result



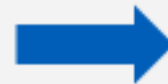
Participant
phoned



Letter sent

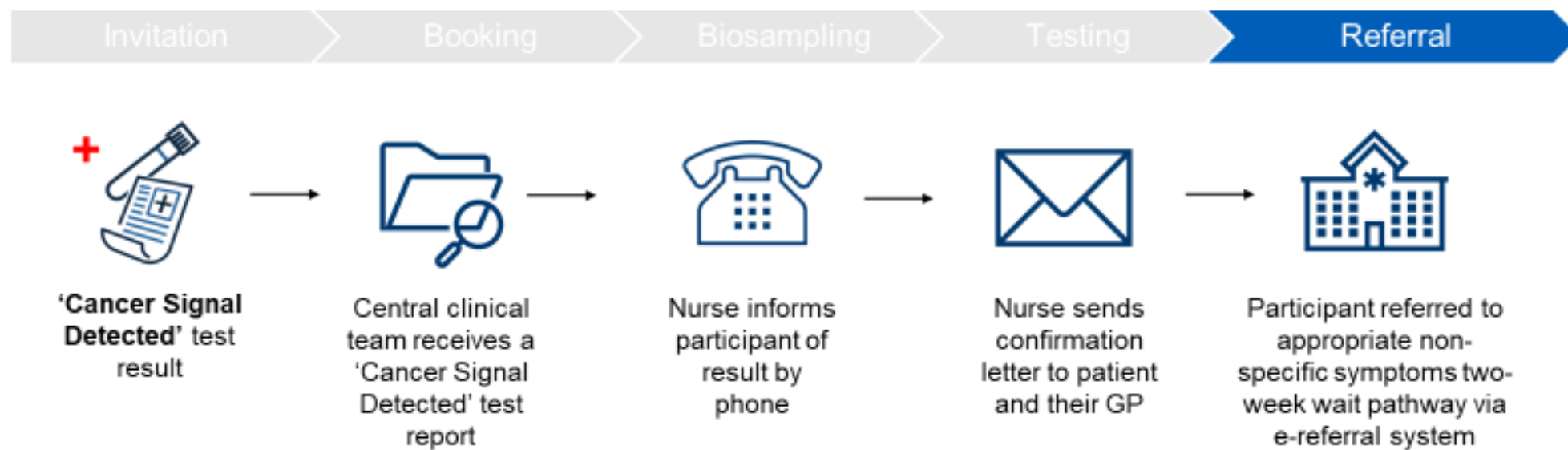


'No Cancer Signal Detected'
test result



Letter sent

Participant referral to secondary care



Participants who have a cancer signal detected by the test are referred to a non-specific symptoms two-week wait pathway via the e-referral system

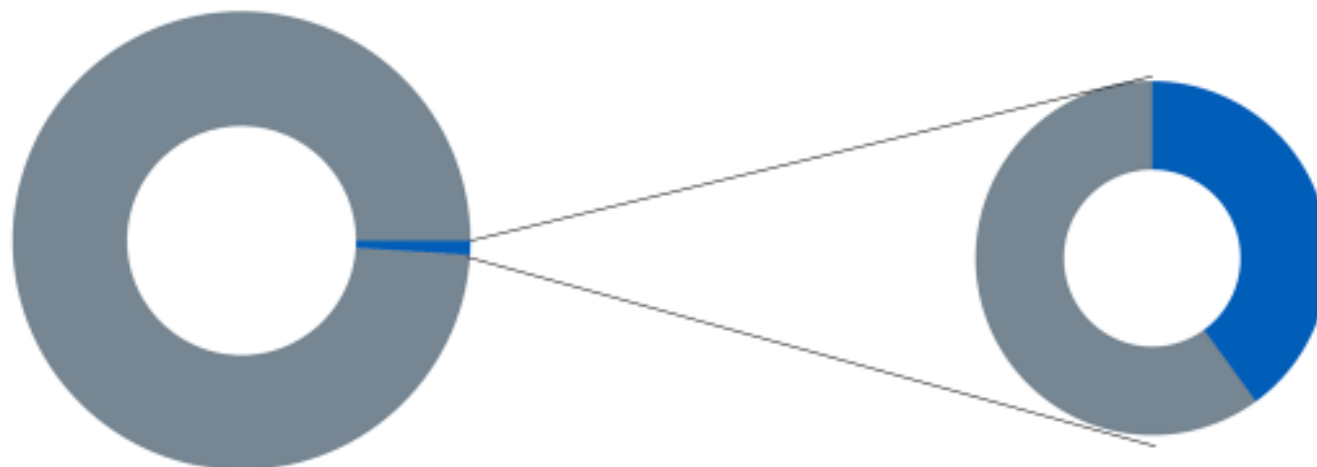
- A 'Cancer Signal Detected' result is not a diagnosis of cancer.
- Diagnostic investigations must take place to confirm if the participant has cancer.

Within secondary care:

- Obvious single signal should be referred directly to that tumour site
- 2 or more signals to be referred on appropriately
- No clear tumour site of origin to remain with NSS
- Guidance as to which tests required next per tumour site



Expected number of 'Cancer Signal Detected' results*



An estimated 1-2% of participants are expected to have a 'Cancer Signal Detected' test result*¹

Around 40% of these people would be expected to have cancer following diagnostic testing (Galleri test positive predictive value is 43.1%²)

If the predicted Cancer Signal Origin does not result in a cancer diagnosis, it could mean the cancer could not be detected, is in another location, or is not present.

Projected BOB numbers

		Bucks	Oxon	Berks W
Total Eligible	595,367	188,676	239,241	167,450
10% expected uptake over 2 yrs	59,367	18,868	23,924	16,745
Tests req per yr	29,768	9,343	11,962	8,373
Tests req per wk	572	181	230	161
Conversion to NSS per month	25	8	10	7
Likely diagnosis	238	75	96	67

Any Questions?

<https://www.nhs-galleri.org>

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