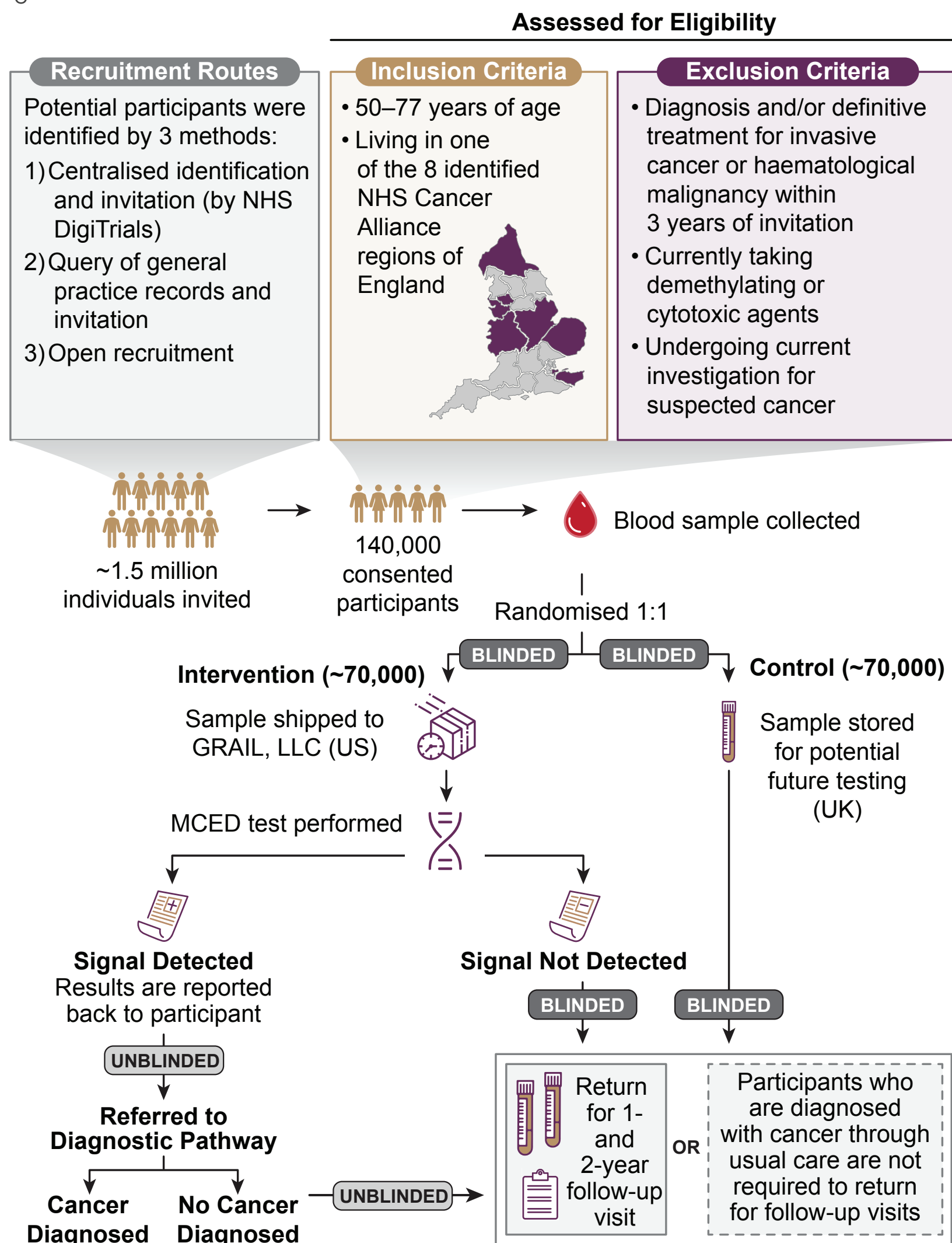


THE NHS-GALLERI TRIAL USED MULTIPLE ENRICHED ENROLMENT APPROACHES TO ENSURE REPRESENTATIVENESS IN STUDY RECRUITMENT, WITH THE GOAL OF ENROLLING A PARTICIPANT POPULATION REFLECTIVE OF THE GENERAL POPULATION AGED 50–77 YEARS IN ENGLAND.

Introduction: The NHS-Galleri trial (NCT05611632) is a randomised controlled trial (RCT) assessing the clinical utility of a multi-cancer early detection (MCED) test in an asymptomatic population alongside current screening programmes. The primary objective is to demonstrate a significant reduction in the incidence rate of stage III and IV cancers diagnosed in the intervention arm compared with the control arm 3–4 years after randomisation.¹

Trial Design

Over 140,000 asymptomatic participants were enrolled in ~10.5 months by inviting ~1.5 million people aged 50–77 in select regions of England via the NHS DigiTrials service.



Participant follow-up data are accrued in routine NHS datasets.

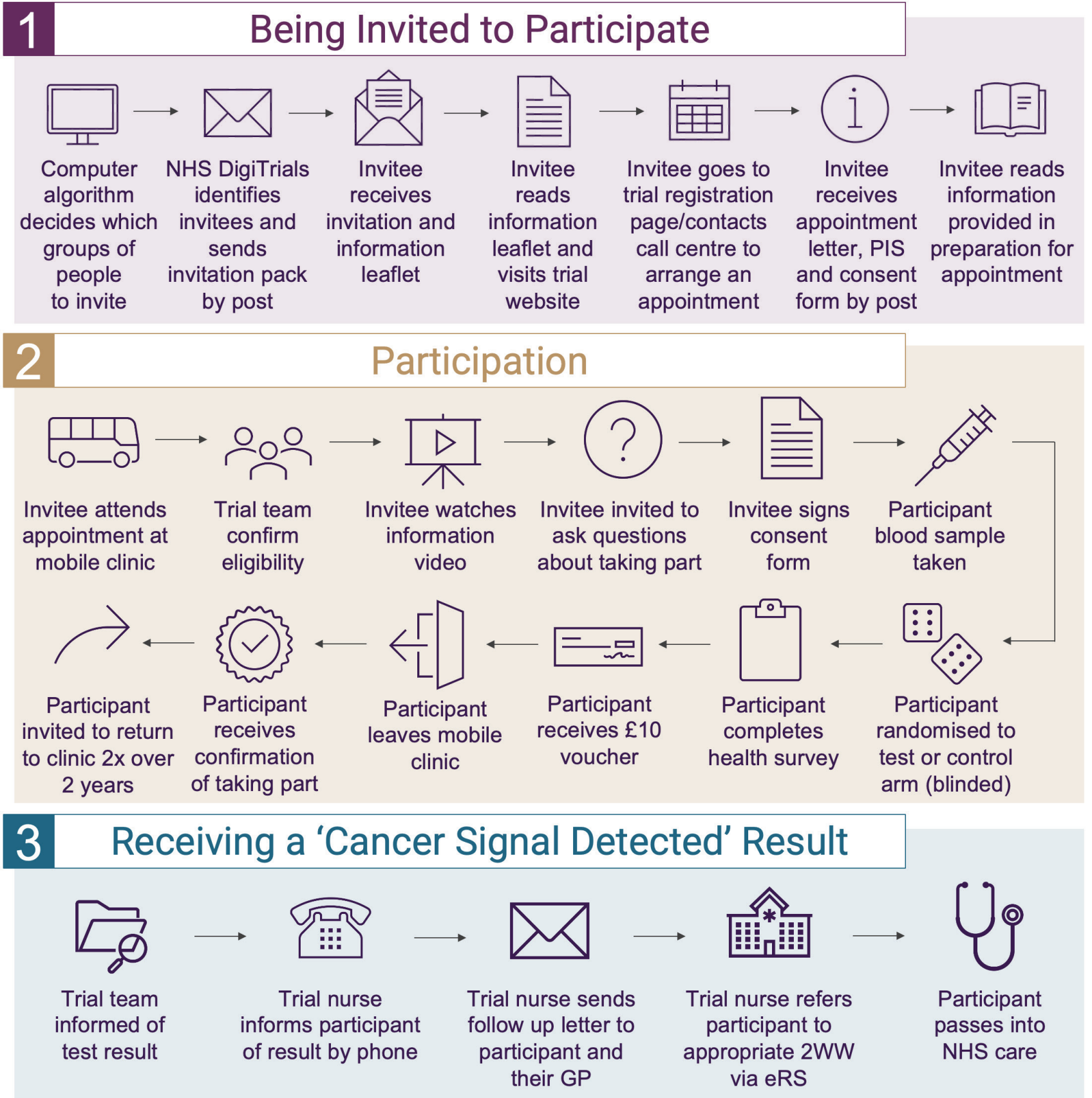
Enriched Enrolment Approaches

A variety of enriched enrolment approaches were used to recruit a representative* study population, including:

- Monitoring participant clinical and demographic factors, and dynamically adjusting invitation lists²
- Stationing mobile clinics in socioeconomically deprived and ethnically diverse areas
- Engaging with voluntary and community sector organisations in socioeconomically deprived and ethnically diverse communities to encourage enrolment
- Implementing measures to remove access barriers (eg, interpreters, wheelchair/step-free access)

*Defined as including a reasonable absolute number of participants across sexes, neighbourhood-based socioeconomic groups, and major ethnic minority groups.

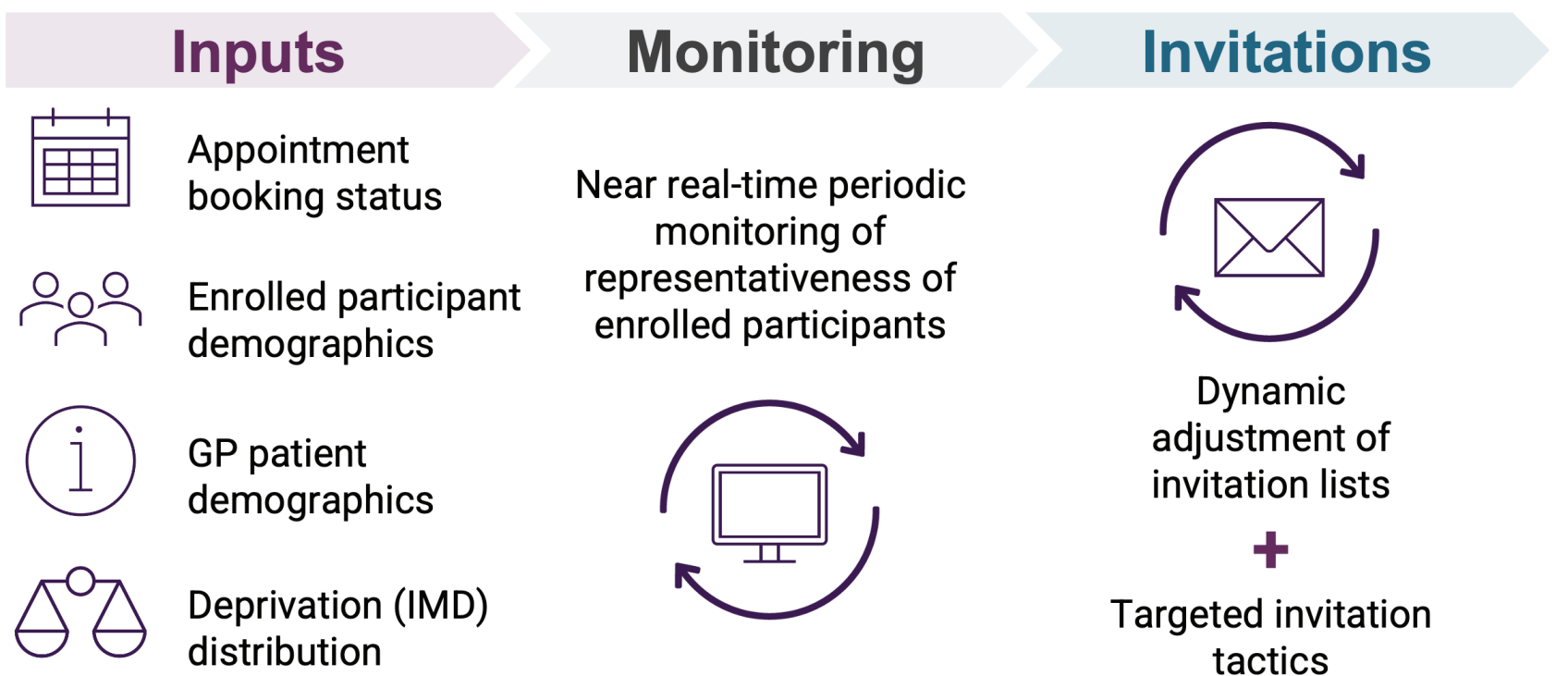
Participant Journey



2WW, two-week wait diagnostic pathway; eRS, e-referral system; GP, general practitioner; PIS, Participant Information Sheet.

Using specialised mobile clinics, peripheral blood is collected by routine venipuncture at up to three study visits one year ± six weeks apart, reflecting an annual screening approach.

Dynamic Targeting Of Invitations



The representativeness of enrolled participants compared with the general population aged 50–77 years was characterised and monitored during recruitment, and invitation lists were adjusted dynamically as needed.²

References: 1. Neal RD, et al. 2022. *Cancers*. 14(19): 4818. 2. Brentnall AR, et al. 2023. *Clinical Trials*. doi: 10.1177/17407745231167369

Conclusions: The NHS-Galleri trial is the first RCT that is statistically powered to assess the clinical utility, including harms and benefits, of an MCED test alongside the standard of care. The trial aimed to enrol a representative population sample to promote health equity and to

minimise 'healthy volunteer bias' observed in prior screening studies. The trial successfully used a number of enriched enrolment approaches to recruit a diverse participant group representative of the intended use population.