## 1239P

# NHS-Galleri Trial Enrolment Approaches and Participant Sociodemographic Characteristics

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### INTRODUCTION

- o Inclusive recruitment in cancer clinical trials is required for a diverse participant population and an outcomes analysis that is generalisable to the intended use population<sup>1</sup>
- However, those from more socioeconomically deprived neighbourhoods, minority ethnic groups, and older individuals are often underrepresented in clinical trials<sup>2-5</sup>
- The clinical utility of a previously validated<sup>6</sup> blood-based multi-cancer early detection (MCED) test is currently being assessed among adults aged 50-79 in England, in the large, pragmatic, randomised controlled trial, the NHS-Galleri trial (NCT05611632)<sup>7</sup>

### OBJECTIVES

- o Enable the recruitment of a sociodemographically diverse population with respect to England and the participating Cancer Alliance regions from which participants were recruited, using innovative, dynamic, enriched enrolment approaches
- o Determine how many invitations were sent to obtain one enrolment (the number needed to invite, NNI) by age, sex, ethnicity, and index of multiple deprivation (IMD, an area-based measure of relative deprivation)

## METHODS

#### Recruitment

- o Participants were recruited from eight Cancer Alliances in England between 31 August 2021 and 16 July 2022 (46 weeks; Figure 1)
- o Cancer Alliances were selected based on their relatively high levels of socioeconomic deprivation and cancer mortality, and poor early-stage diagnosis<sup>7</sup>
- o A planned national-level communications campaign (press, radio, and television coverage of the trial) coincided with recruitment opening

#### Recruitment Routes

Centralised Targeted Invitation	General practitioner (GP) Participant Identification Centre (PIC) Invitation	Open Enrolment
NHS DigiTrials Recruitment Service used NHS data to identify eligible individuals and send invitations to them on behalf of the trial <sup>8,a</sup>	By GP surgeries in selected regions; two rounds of recruitment (weeks 1–2 and 38–40)	Self-referral, often following engagement by local organisations in more deprived/diverse areas

<sup>a</sup>Of eligible individuals, only those who had not opted out of having their data used for research purposes were invited. Only de-identified data was passed to GRAIL for the purposes of analysis.

#### Enriched Enrolment Approaches

- o All appointments took place in mobile clinics located in some of the most socioeconomically deprived locations in the Cancer Alliances throughout the trial
- They were also stationed in more ethnically diverse areas in weeks 37-45
- o Centralised targeted invitation lists were reviewed and generated weekly using a dynamic invitation algorithm designed to address inequity and protect against low rates of cancer due to healthy volunteers9
- Adjustments by ethnicity (from week 35) and IMD were made using proxy values based on individuals' registered GP surgeries
- o Black and Asian individuals were specifically invited during the second round of GP PIC recruitment (weeks 38-40) to increase representation of these groups in the trial
- o Partnering with local voluntary and community organisations, we arranged local media coverage, distribution of leaflets and information by local champions (e.g., faith leaders), and e-poster displays in community hubs and at events in more deprived and ethnically diverse communities (weeks 36–45)
- We developed a bespoke social media toolkit to guide communications for use by partner organisations

#### Reducing Barriers to Participation

- o On-demand language translation and translated materials, wheelchair and step-free access, and hearing assistance including sign language interpretation were offered to all individuals
- o All invitations, information sheets, and consent forms were developed before the start of the trial with input from behavioural researchers at King's College London, patients, and a diverse group of the general public, via a specialist communications agency

#### Participant Sociodemographic Distribution and Number Needed to Invite (NNI)

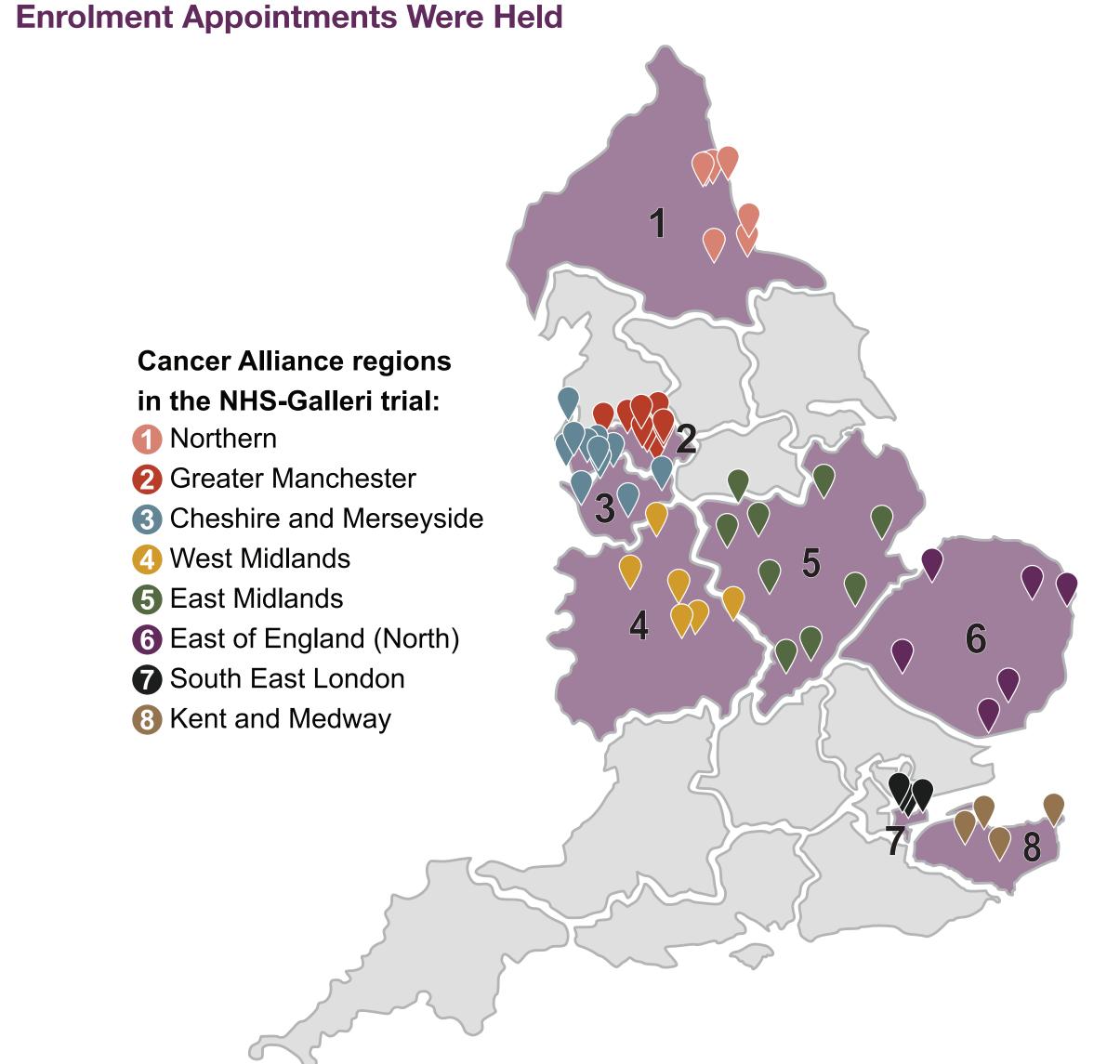
- We examined the sociodemographic distribution of trial participants versus the total England and Cancer Alliance populations based on the 2021 census
- o We calculated the NNI (invited/enrolled individuals via centralised targeted invitation) by age and sex, IMD and ethnicity (using proxy data for invitees based on their GP surgery)
- We compared the ethnic distribution of invitations and enrolments via centralised targeted invitation to determine whether enrolment of Asian and Black individuals were enriched in East Midlands and South East London (selected for their large Asian and Black populations, respectively) compared with other Cancer Alliances

## KEY RESULTS: ENROLMENT APPROACHES ENABLED RECRUITMENT OF A DIVERSE PARTICIPANT POPULATION WITH RESPECT TO AGE AND SOCIOECONOMIC DEPRIVATION

#### Overall Enrolment

- o Overall, 1,480,548 individuals were invited, and 142,940 participants were enrolled in the NHS-Galleri trial over 10.5 months
- Of these, 139,617 (97.7%) participants were enrolled via centralised targeted invitation, 2358 (1.7%) via open enrolment, and 965 (0.7%) via the GP PIC route
- Of those enrolled via the GP PIC route, 167 (17.3%) were enrolled in a targeted ethnicity drive in 2022
- o Enrolment appointments were conducted in 11 mobile clinics (seven large and four small) at 151 locations (**Figure 1**)
- O Step-free access was used at 7727 (5.4%) appointments, language interpretation at 626 (0.4%) appointments with 45 languages spoken, and visual and hearing assistance at 144 (0.1%) appointments.

Figure 1. Map of Geographical Locations of the Mobile Clinics at Which



#### Demographic Characteristics of the NHS-Galleri Trial **Enrolled Population**

- o Compared with the Cancer Alliance and England populations aged ≥50 years, the trial participant population had (**Table 1**):
- A smaller percentage of participants aged 50-54 and 55-59 years and a greater percentage aged 60-64, 65-69, and ≥70 years, by design
- A greater percentage of individuals in each of the three most deprived IMD quintiles and a smaller percentage in the two least deprived quintiles, by design
- A greater percentage of individuals in the White and Mixed ethnic groups and a smaller percentage in the Asian, Black and Other ethnic groups
- o The median age of the NHS-Galleri trial cohort was 66 years (interquartile range, 59-71)

### Enrolment by Route

- o There were proportionally more Asian and Black individuals among those recruited via GP PIC sites (Asian, 5.6%; Black, 13.0%) and open enrolment (6.9% and 3.2%) than those recruited via centralised targeted invitation (3.2%) and 1.3%; **Table 1**)
- For GP PIC sites, this ethnic diversity was primarily due to the targeted recruitment drive in 2022 (n = 167 enrolled; 58.1% Black, 22.2% Asian, and 14.4% Mixed ethnicity)
- Overall numbers enrolled via GP PIC sites and open enrolment comprised a small proportion of the total enrolled population, so this had a limited impact on ethnic diversity in the trial (**Table 1**)

Table 1. Demographic Characteristics of the Participant Population Enrolled in the NHS-Galleri Trial, by Invitation Route and Overall (n [%])

		Centralised Targeted Invitation N=139,617	Open Enrolment N=2358	GP PIC Sites N=965	NHS-Galleri trial N=142,940	Cancer Alliance Regions <sup>a</sup>	England <sup>b</sup>
	50-54	14,851 <b>(10.6)</b>	429 <b>(18.2)</b>	157 <b>(16.3)</b>	15,437 <b>(10.8)</b>	1,700,000 <b>(21.4)</b>	3,908,000 <b>(21.0)</b>
Years of Age <sup>c</sup>	55–59	21,864 <b>(15.7)</b>	470 <b>(19.9)</b>	131 <b>(13.6)</b>	22,465 <b>(15.7)</b>	1,678,000 <b>(21.1)</b>	3,806,000 <b>(20.5)</b>
	60-64	26,087 <b>(18.7)</b>	506 <b>(21.5)</b>	228 <b>(23.6)</b>	26,821 <b>(18.8)</b>	1,450,000 <b>(18.3)</b>	3,256,000 <b>(17.5)</b>
	65-69	30,142 <b>(21.6)</b>	434 <b>(18.4)</b>	239 <b>(24.8)</b>	30,815 <b>(21.6)</b>	1,247,000 <b>(15.7)</b>	2,767,000 <b>(14.9)</b>
	70–74	29,911 <b>(21.4)</b>	358 <b>(15.2)</b>	161 <b>(16.7)</b>	30,430 <b>(21.3)</b>	1,266,000 <b>(16.0)</b>	2,797,000 <b>(15.1)</b>
	75–77	16,426 <b>(11.8)</b>	157 <b>(6.7)</b>	48 <b>(5.0)</b>	16,631 <b>(11.6)</b>	599,000 <b>(7.5)</b>	1,323,000 <b>(7.4)</b>
Sex <sup>c</sup>	Female	69,876 <b>(50.0)</b>	1444 <b>(61.2)</b>	536 <b>(55.5)</b>	71,856 <b>(50.3)</b>	4,072,000 <b>(51.3)</b>	9,169,000 <b>(51.4)</b>
	Male	69,741 <b>(50.0)</b>	914 <b>(38.8)</b>	429 <b>(44.5)</b>	71,084 <b>(49.7)</b>	3,869,000 <b>(48.7)</b>	8,687,000 <b>(48.7)</b>
Ethnicity <sup>d</sup> E	White	130,399 <b>(93.4)</b>	2055 <b>(87.2)</b>	730 <b>(75.6)</b>	133,184 <b>(93.2)</b>	8,737,000 <b>(91.9)</b>	19,206,000 <b>(89.9)</b>
	Asian	4509 <b>(3.2)</b>	163 <b>(6.9)</b>	54 <b>(5.6)</b>	4726 <b>(3.3)</b>	401,000 <b>(4.2)</b>	1,127,000 <b>(5.3)</b>
	Black	1856 <b>(1.3)</b>	76 <b>(3.2)</b>	125 <b>(13.0)</b>	2057 <b>(1.4)</b>	226,000 <b>(2.4)</b>	594,000 <b>(2.8)</b>
	Other	604 <b>(0.4)</b>	13 <b>(0.6)</b>	10 <b>(1.0)</b>	627 <b>(0.4)</b>	77,000 <b>(0.8)</b>	267,000 <b>(1.3)</b>
	Mixed	1467 <b>(1.1)</b>	43 <b>(1.8)</b>	35 <b>(3.6)</b>	1545 <b>(1.1)</b>	67,000 <b>(0.7)</b>	177,000 <b>(0.8)</b>
IMD Quintile <sup>c,e</sup>	1 - Most Deprived	31,766 <b>(22.8)</b>	365 <b>(15.5)</b>	222 <b>(23.0)</b>	32,353 <b>(22.7)</b>	1,694,000 <b>(21.3)</b>	2,870,000 <b>(16.7)</b>
	2	27,315 <b>(19.6)</b>	456 <b>(19.3)</b>	299 <b>(31.0)</b>	28,070 <b>(19.7)</b>	1,521,000 <b>(19.2)</b>	3,194,000 <b>(18.6)</b>
	3	29,340 <b>(21.0)</b>	529 <b>(22.4)</b>	257 <b>(26.6)</b>	30,126 <b>(21.1)</b>	1,620,000 <b>(20.4)</b>	3,560,000 <b>(20.8)</b>
	4	28,258 <b>(20.2)</b>	539 <b>(22.9)</b>	170 <b>(17.6)</b>	28,967 <b>(20.3)</b>	1,618,000 <b>(20.4)</b>	3,726,000 <b>(21.9)</b>
	5 - Least Deprived	22,479 <b>(16.1)</b>	461 <b>(19.6)</b>	14 <b>(1.5)</b>	22,954 <b>(16.1)</b>	1,488,000 <b>(18.7)</b>	3,805,000 <b>(22.2)</b>

N=21,371,000; IMD, N=15,166,000; °Cancer Alliance and England data age range 50-77 years; dCancer Alliance and England data age range ≥50 years; eIMD quintile was based on lower-layer super output areas GP, General practitioner; IMD, Index of multiple deprivation; PIC, Participant identification centre.

## Number Needed to Invite (NNI)

- o For the centralised targeted invitation route, the overall NNI was 10.6 (139,617 enrolled/1,477,051 invited)
- o The NNI was higher for:
- Younger than older age groups (50-54 years of age, 14.8; 75-77 years of age, 10.7)
- Men (11.1) than women (10.0)
- O Black (32.8) and Asian (28.2) ethnic groups than White (9.7) and Mixed (8.1) ethnic groups
- More deprived than less deprived groups (most deprived, 21.5; least deprived, 4.6)

#### Ethnic Distribution of Invited and Enrolled Individuals by Cancer Alliance

- o In East Midlands and South East London, selected for their ethnic diversity, proportionally more Asian and Black individuals were invited via centralised targeted invitation compared with the total population (Table 2)
  - This led to enriched enrolment in East Midlands and South East London relative to the total population
- o In the other Cancer Alliances combined, the proportion of Asian or Black ethnic groups was slightly lower relative to the total population

Table 2. Proportion of Individuals Invited and Enrolled by Ethnicity in East Midlands and South East London Versus the Other Cancer Alliances Combined (n [%])

		Population	Invited	Enrolled
East Midlands	White	1,646,449 <b>(92.4)</b>	142,663 <b>(76.4)</b>	16,454 <b>(88.9</b> )
	Asian	88,100 <b>(4.9)</b>	35,713 <b>(19.1)</b>	1479 <b>(8.0</b> )
	Black	26,806 <b>(1.5)</b>	5535 <b>(3.0)</b>	241 <b>(1.3</b> )
	Other	10,186 <b>(0.6)</b>	1272 <b>(0.7)</b>	75 <b>(0.4</b> )
	Mixed	10,525 <b>(0.6)</b>	1503 <b>(0.8)</b>	181 <b>(1.0</b> )
	Missing	N/A	N/A	77 <b>(0.4</b> )
	Total	1,782,066 <b>(100.0)</b>	186,686 <b>(100.0)</b>	18,507 <b>(100.0</b> )
South East London	White	348,682 <b>(68.8)</b>	61,685 <b>(63.5)</b>	6563 <b>(79.9</b> )
	Asian	35,199 <b>(6.9)</b>	7813 <b>(6.9)</b>	345 <b>(4.2</b> )
	Black	92,715 <b>(18.3)</b>	28,339 <b>(25.1)</b>	731 <b>(8.9</b> )
	Other	11,879 <b>(2.3)</b>	2139 <b>(1.9)</b>	138 <b>(1.7</b> )
	Mixed	18,043 <b>(3.6)</b>	2907 <b>(2.6)</b>	345 <b>(4.2</b> )
	Missing	N/A	N/A	92 <b>(1.1</b> )
	Total	506,518 <b>(100.0)</b>	112,883 <b>(100.0)</b>	8214 <b>(100.0</b> )
Other Cancer Alliances Combined <sup>a</sup>	White	6,742,002 <b>(93.4)</b>	1,053,832 <b>(89.5)</b>	107,382 <b>(95.1</b> )
	Asian	277,474 <b>(3.8)</b>	83,562 <b>(7.1)</b>	2685 <b>(2.4</b> )
	Black	106,487 <b>(1.5)</b>	27,037 <b>(2.3)</b>	884 <b>(0.8</b> )
	Other	44,710 <b>(0.6)</b>	5530 <b>(0.5)</b>	391 <b>(0.3</b> )
	Mixed	48,615 <b>(0.7)</b>	7453 <b>(0.6)</b>	941 <b>(0.8</b>
	Missing	N/A	N/A	613 <b>(0.5</b> )
	Total	7,219,288 <b>(100.0)</b>	1,177,414 <b>(100.0)</b>	112,896 <b>(100.0</b> )

<sup>a</sup>Cheshire and Merseyside, East of England (North), Greater Manchester, Kent and Medway, Northern, West Midlands; N/A, Not available

## CONCLUSIONS

- o Enrolment approaches used in the NHS-Galleri trial enabled the recruitment of a diverse participant population with respect to age, socioeconomic deprivation and ethnicity
- Compared with the England and Cancer Alliance populations, the enrolled population was enriched for those in more deprived and older age groups, but not those in ethnic minority groups
- A pre-planned, concerted effort was made to boost ethnically diverse recruitment; while successful, most approaches were used in the last 10 weeks of recruitment, so the proportions of Black and Asian individuals were lower in the enrolled than the England and the Cancer Alliance populations
- Better ethnicity data availability in central health service records could enable better invitation targeting to further enhance ethnically diverse recruitment
- o High NNIs among younger, more deprived, and Black and Asian individuals may reflect life stressors acting as barriers to recruitment<sup>10</sup>, mistrust in clinical trials and the healthcare system<sup>10</sup>, and perceived low personal relevance<sup>11</sup>, but the reasons for non-participation in this trial are unknown

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