NHS-Galleri Trial: Approaches to Retain a Diverse Participant Cohort Across Multiple Trial Appointments

Early Detection of Cancer Conference (EDCC)
October 21–23, 2025
Portland, OR

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INTRODUCTION

- Recruiting and retaining a diverse participant population helps support the validity, reliability and generalisability of clinical trial results[1-3]
  - High overall retention maintains statistical power and reduces attrition bias
- Despite growing evidence on approaches to improve recruitment of individuals from different sociodemographic groups to clinical trials,[4–6] little is known about the effectiveness of retention strategies
  - Research shows that cover letters informed by behavioural science, collecting detailed contact information, and text message prompts and reminders can support trial retention[7–9]
  - Multiple targeted outreach approaches may also support retention,[10,11] as well as developing community engagement strategies and offering community-based trial appointment locations[12]
- The NHS-Galleri trial (NCT05611632) is a large, prospective, randomised controlled trial assessing the clinical utility of a blood-based multi-cancer early detection (MCED) test (Galleri®; GRAIL, Inc., Menlo Park, CA, USA)[13]
  - The trial used a range of enrolment approaches to successfully recruit a sociodemographically diverse participant population, enriched for individuals from older age groups and more socioeconomically deprived neighbourhoods[14]
  - Participation in the trial entailed three appointments over a two-year period. Planned, iterative approaches were used to support continued participation of the enrolled cohort throughout the trial

OBJECTIVES

- To report on participant retention in the NHS-Galleri trial, including by age, sex, socioeconomic deprivation, and ethnicity
- To provide insights into retention approaches, to guide other trialists seeking to support retention of a diverse participant population

METHODS

- All participants were invited to provide a blood sample at three appointments over two years, approximately 12 months apart (enrolment [Y0], Year 1 [Y1], and Year 2 [Y2] appointments)
- **Direct communications** were developed to provide participants with the critical information and support required to successfully book and attend an appointment in Y1 and Y2
  - Depending on available contact details, participants received a 'get ready' email/text, an invitation letter, and subsequent reminders by email, letter, and/or phone
  - Direct communications were issued using bespoke software that timed communications according to the anniversary of each participant's Y0 appointment
  - Messages in these direct communications were developed using guidance from patient and public involvement focus groups
- **Supporting communications** provided additional information to participants, e.g., in community engagement activities and additional participant materials (such as leaflets and posters) to maintain awareness and understanding of the trial
- **Operational activities** focused on offering convenient appointment locations, dates, and times
  - All trial appointments were conducted in mobile clinics generally stationed in community-centred locations with good public transport (e.g. retail parks, supermarkets, leisure centres and sports stadiums)
    - Participants could attend appointments at whichever location was most convenient, with no requirement to visit the same location each year
    - Smaller mobile clinics could revisit locations, to give people who were unable to book an appointment (e.g., illness, vacations etc.) another opportunity to attend
  - Appointments were made available outside of working hours (i.e., in the evening and at weekends)

SUPPORTING DIVERSE RETENTION

- Additional measures were implemented specifically to support retention of a diverse participant cohort, particularly with respect to socioeconomic group and ethnicity. These included:
  - Prioritising individuals from sociodemographic groups expected to have lower retention rates for reminder phone calls;
  - Voluntary and community sector engagement, e.g., collaborating with mosques;
  - Accessibility and accommodations, e.g., offering wheelchair or step-free access, sighted or visual assistance, and language interpretation

ITERATIVE APPROACH TO RETENTION

- Appointment data from Y0 were used to support planning for Y1 and Y2, i.e., how many days and appointments were needed in the subsequent years
- We monitored cumulative total trial retention, retention at each appointment location, and participant feedback, and used this data to refine communications and operational planning

RETENTION TARGETS

- Participant retention targets were set to ensure statistical power for the trial primary outcome (reduction in late-stage [III and IV] cancers)
- Retention was defined in the trial as acquisition of a blood sample at Y1 and/or Y2 appointments
- Total cohort retention was defined as the proportion of participants returning in Y1 and Y2 relative to Y0 (enrolment). E.g., Y1 Total Cohort Retention = (Y1/Y0) x 100
  - Total cohort retention targets were set at 90.5% for Y1 and 82.4% for Y2, incorporating an estimated attrition from cancer death or diagnosis (1.5% in Y1, 1.0% in Y2) and allowing for up to 8% annual dropout
- Total cohort retention was calculated overall and by age, sex, ethnicity, and index of multiple deprivation (IMD; an area-based measure of relative deprivation)

KEY RESULTS: TOTAL COHORT RETENTION EXCEEDED TARGETS

TOTAL COHORT RETENTION

- Total cohort retention targets were exceeded for both Y1 and Y2 (**Figure 1**)
  - Overall, 2.4% of the enrolled population attended in Y2 but not in Y1
- Retention was consistently high across age, sex and IMD groups (**Table 1**)
  - Retention was particularly high among those from a White ethnic background
  - Retention among those from other ethnic backgrounds was lower, but still matched or exceeded 80%

Figure 1. Total cohort retention at Y1 and Y2 in the NHS-Galleri trial.

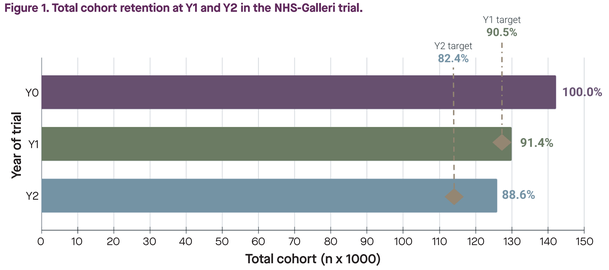


Table 1. Total cohort retention at Y1 and Y2 in the NHS-Galleri trial by sociodemographic group.

Sociodemographic characteristic		Y0 (n)	Y1 (n [%])	Y2 (n [%])	Attended Y2 but not Y1 (n [%])
Sex	Female	71,462	65,465 (91.6)	63,590 (89.0)	1,727 (2.4)
	Male	70,788	64,489 (91.1)	62,378 (88.1)	1,738 (2.5)
Age at enrolment (years)[a]	50–54	15,352	13,506 (88.0)	13,022 (84.8)	564 (3.7)
	55–59	22,328	20,057 (89.8)	19,597 (87.8)	722 (3.2)
	60–64	26,720	24,466 (91.6)	23,911 (89.5)	691 (2.6)
	65–69	30,668	28,460 (92.8)	27,690 (90.3)	564 (1.8)
	70–74	30,290	28,046 (92.8)	27,061 (89.3)	571 (1.9)
	75–79	16,891	15,419 (91.3)	14,687 (87.0)	353 (2.1)
Ethnicity[b]	Asian	4,725	3,931 (83.2)	3,876 (82.0)	255 (5.4)
	Black	2,054	1,647 (80.2)	1,641 (79.9)	159 (7.7)
	White	133,118	122,410 (92.0)	118,519 (89.0)	2911 (2.2)
	Mixed	1,544	1,299 (84.1)	1,283 (83.1)	93 (6.0)
	Other	627	510 (81.3)	502 (80.1)	44 (7.0)
Socioeconomic group (IMD quintile)[b]	1 (most deprived)	32,133	28,304 (88.1)	27,404 (85.3)	1,052 (3.3)
	2	27,922	25,289 (90.6)	24,410 (87.4)	745 (2.7)
	3	29,990	27,639 (92.2)	26,829 (89.5)	684 (2.3)
	4	28,848	26,871 (93.1)	26,065 (90.4)	575 (2.0)
	5 (least deprived)	22,883	21,427 (93.6)	20,840 (91.1)	391 (1.7)

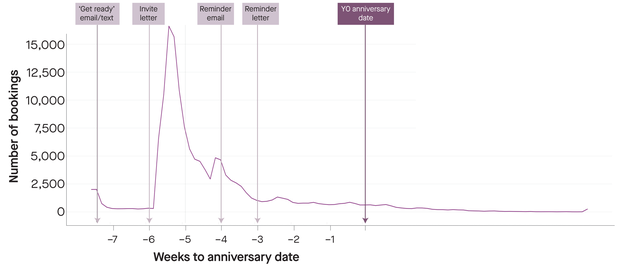
[a]Data for a small number of participants who fell outside of the eligible age range has not been presented in this table.
[b]Participants with missing data have not been presented in this table. IMD: index of multiple deprivation.

EXAMPLE RETENTION APPROACHES

Personalised communications schedule

- Appointment bookings increased around the estimated dates that participants received their invitation letter and subsequent reminder email
- The majority of participants booked their Y2 appointment following the estimated date that they received their Y2 invitation letter (**Figure 2**)

Figure 2. Estimated date that participants received direct communications and number of appointment bookings made in Y2.



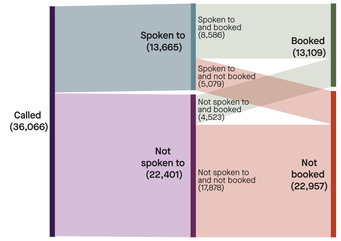
Reminder telephone calls

- Overall, 36,066 participants received a reminder telephone call for their Y2 appointment and 13,109 made an appointment booking (**Figure 3**)
  - 13,665 of the participants who were called were spoken to, and 8,586 (63%) of these conversations converted into appointment bookings
  - A further 4,523 appointments were booked after missed calls, and may have been made in response to receiving a voicemail

Participant attendance at different appointment locations

- In total, 30% of participants attended a different location in Y1 compared with Y0, indicating that flexibility in the appointment locations and capacity supported retention

Figure 3. Booking outcomes following Y2 reminder telephone calls.



CONCLUSIONS

- Total cohort retention in the NHS-Galleri trial exceeded targets, and was higher than typical values for cancer screening trials[15,16]
- The wide range of approaches used in the NHS-Galleri trial, particularly personalised communications schedules, reminder telephone calls, permitting appointment attendance at different locations in different years and permitting attendance in Y2 after non-attendance in Y1, supported retention of a diverse participant population
- Retention of a diverse cohort required continuous focused effort, monitoring, and iteration in response to appointment data and participant feedback
- Future trials should collect and report data on retention by sociodemographic characteristics to support benchmarking and improvement in trial cohort diversity

RECOMMENDATIONS FOR TRIALISTS

DO...

- Make the trial as accessible as possible, ideally in the community and with a focus on flexible opening and appointment times, to make it as easy as possible for participants to return to trial appointments
- Use reminder communications in addition to invitations and employ retention callers to contact participants who have not booked an appointment, focusing on groups with low retention rates in the first instance
- Engage early with community groups to build relationships with leaders; be mindful that these groups are often run by volunteers, so requests need to be clear and achievable
- Consider what data you might need to collect to monitor retention and build collection of these data in from the start; this may differ from data collection for trial outcome analyses
- Ensure there is a planned means to change trial processes and materials promptly, to support rapid response to data and participant feedback and to unforeseen issues

DON'T...

- Limit participants to attending appointments at the same location each year
- Set out retention approaches at the start of the trial and leave them unchanged; instead, respond to feedback and data iteratively
- Underestimate the importance of seemingly minor operational aspects on participant retention; in particular, the ease of finding the trial clinic
- Assume all participants will want to receive communications in the same way; instead consider how to accommodate individual communications preferences

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Disclosures: This work was supported by GRAIL Bio UK, Ltd. LK, SH, WL and SW are employed by GRAIL Bio UK, Ltd. and hold stock in GRAIL, Inc. CP, IL, GE, ZK, EL and PS are funded for their work on the NHS-Galleri trial by GRAIL Bio UK, Ltd. CS and RDN provide their services as NHS-Galleri trial Co-Chief Investigators through university consultancies funded by GRAIL Bio UK, Ltd. PS and CS are paid members of GRAIL's Scientific Advisory Board (SAB). CS is an AstraZeneca advisory board member and Chief Investigator for two AZ clinical trials. CS receives consultant fees from Achilles Therapeutics (SAB member), Genentech, Medaxi, Roche Innovation Centre Shanghai, Bicycle Therapeutics (SAB member), and the Sarah Canon Research Institute. CS currently has stock options in Epic Bioscience, Bicycle Therapeutics, and Achilles Therapeutics; and is co-founder of Achilles Therapeutics.

Acknowledgements: Writing and editorial assistance provided by Emma B Saxon (Royston, UK). Graphic assistance provided by PosterDocs (Oakland, CA, USA).