

Backup phone calls improved data quality and representation without meaningfully changing study conclusions in the PROSPECT trial

Sensitivity of Study Results to Patient-Reported Data Collected Through Backup Phone Calls (NCCTG N1048 [Alliance])

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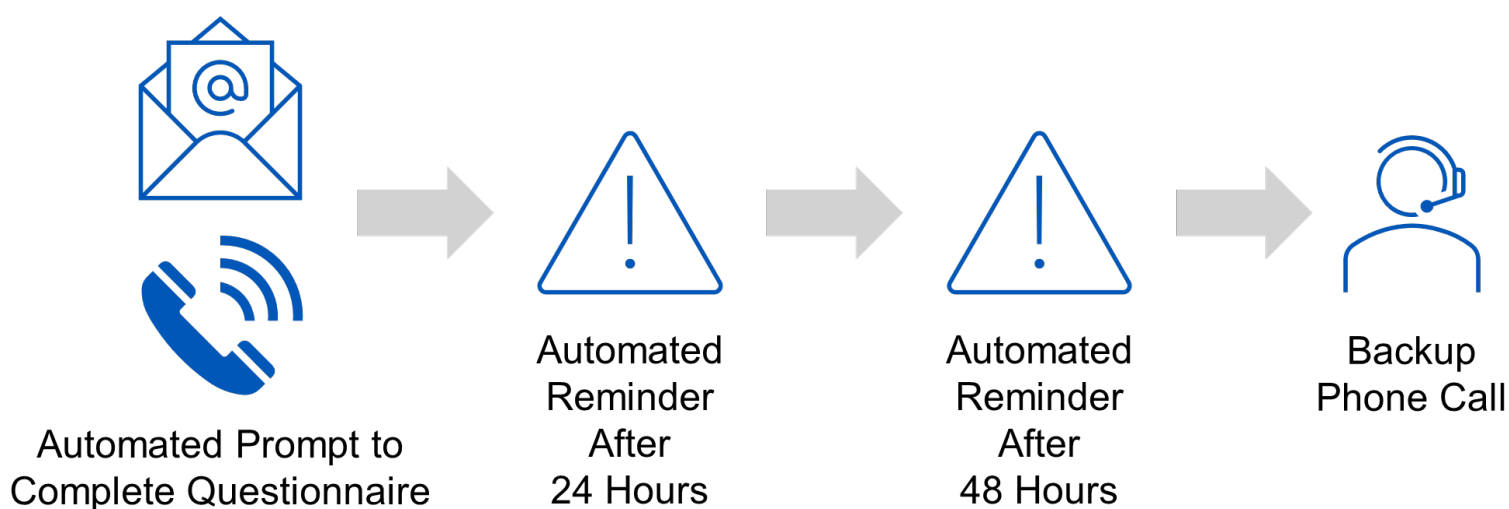
BACKGROUND

- Calling participants to complete overdue questionnaires can minimize missing data but requires substantial effort and raises concerns about mode equivalence

OBJECTIVES

- Examine the importance of collecting missing questionnaires via backup phone calls
- Assess the sensitivity of PROSPECT trial results to the PRO-CTCAE data made available through backup phone calls

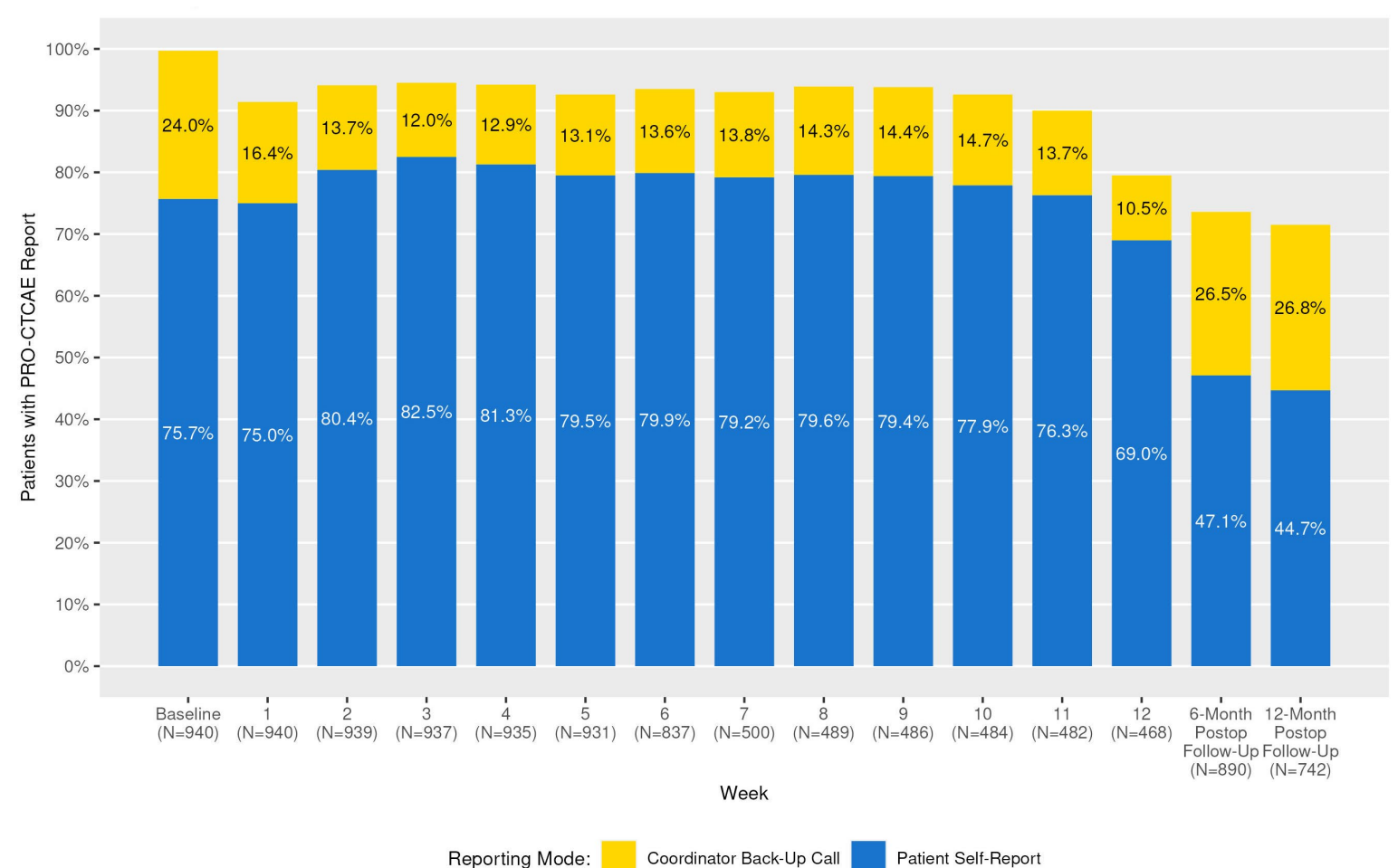
PRO-CTCAE DATA COLLECTION



METHODS

- Compared treatment assignment, demographic characteristics, and baseline PRO-CTCAE composite scores between PROSPECT trial participants who did versus did not require backup phone calls
- Conducted between-arm comparisons of the incidence of 14 treatment-emergent symptoms during neoadjuvant treatment and at 12 months post-surgery while using:
 1. All available data,
 2. Only data collected without backup phone calls, and
 3. All available baseline data plus post-baseline data collected without backup phone calls

DATA FROM BACKUP PHONE CALLS



RESULTS

- 21% (201/940) of participants never required backup phone calls, 37% (351/940) required 1-2, and 41% (388/940) required 3+
- Participants requiring backup phone calls were more likely to be in the FOLFOX+selective 5FU CRT arm, be non-white, have a high school degree or less, and have chosen the interactive voice response system for questionnaire completion (all $p < 0.05$)
- Participants requiring backup phone calls reported greater mean neuropathy, dyspnea, mucositis, and pain at baseline (all $p < 0.05$)
- For 27/28 between-arm comparisons of the incidence of 14 treatment-emergent symptoms during neoadjuvant treatment and at 12 months post-surgery, statistical significance and study conclusions were consistent across the 3 scenarios evaluated where backup phone calls occurred for:
 1. Both baseline and post-baseline questionnaires,
 2. Neither baseline nor post-baseline questionnaires, or
 3. Baseline questionnaires only

CONCLUSION

- Backup phone calls can improve data quality and representation, though including data collected from backup phone calls did not meaningfully change study conclusions in the PROSPECT trial

SUPPORT

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