# Improving clinical trial performance using adult-learning methods.

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**Background:** Timely and efficient accrual to oncology treatment trials is among the most vital components of clinical research. However, more than 80% of trials fail to reach enrollment targets, compromising outcome interpretation and cost. We hypothesized that a noveland customized application of adult-learning methods would enhance clinical trial screening and randomization. **Methods:** In collaboration with a multinational sponsor, Vaniam Group (VG) introduced a structured set of interventions to sites in 3 global randomized trials. Sites choosing to "opt in" formed the experimental group (EG). EG received tailored interventions: interactive Trial Educational Discussions (iTEDs: 30-min virtual meetings), and/or interactive Trial Acceleration Meetings (iTAMs: 4-hr liveworkshops of 10-30 investigators), and standard study support. Adult-learning techniques including the Socratic Method, case studies, and teach-back were used. Control group (CG) comprised sites receiving only standard study support. Primary endpoints were screening rate (SR) and randomization rate (RdR) compared atbaseline (6 mos prior to intervention) and 6 mos post-intervention (M6). Nonparametric statistical analyses compared between-group (Mann–Whitney U test) and within-group (Wilcoxon Signed-Rank test) differences. **Results:** Trial 1, a phase 3 placebo-controlled adjuvant trial had been open for 45 mos (54% enrolled) prior to intervention. At baseline, SR and RdR were similar between groups ($P>0.05$). At M6, SR increased 100% and RdR increased 37% in the EG; in the CG, SR did not change and RdR decreased 7%. For both endpoints, EG performed better than CG ($P=0.018$, $P=0.014$). Trial 2, a phase 3 neoadjuvant trial had been open for 49 mos (86% enrolled) with a projected 18 mos to completion. At M6, SR increased 3% in the EG, but decreased 39% in the CG. RdR increased 15% in the EG but decreased 33% in the CG. While changes in performance were not significant between groups ($P>0.05$), study met its target enrollment goal with no further delays. Trial 3, a phase 2 recurrence trial was 30% behind enrollment with a projected 51 mos to completion. At M6, increases in SR were recorded in both EG and CG at 116% and 18%, respectively. RdR increased in both EG and CG (90% and 50%, respectively), augmented by protocol amendment. Despite increases in both groups, SR and RdR were significantly enhanced by VG intervention ($P=0.009$ and $P=0.015$). **Conclusions:** Our novel, site-focused intervention strategy structured upon adult-learning methods significantly enhanced clinical trial performance, as measured by SR and RdR. Future work will expand these findings to different trial designs and outcome measures such as endpoint fidelity and cost. Research Sponsor: Department of Clinical Strategy and Solutions, Vaniam Group, LLC.

| Trial 1 | Mean SR Baseline | Mean SR Month 6 | *P* Value | Mean RdR Baseline | Mean RdR Month 6 | *P* Value |
|---|---|---|---|---|---|---|
| **Control** | 0.08 | 0.08 | >0.05 | 0.06862745 | 0.06372549 | > 0.05 |
| **Experimental** | 0.07511737 | 0.15023474 | 0.004 | 0.06338028 | 0.08685446 | > 0.05 |
| ***P* Value** | > 0.05 | 0.018 | | > 0.05 | 0.014 | |