A Gamified Behavioral Science Intervention to Enhance Trial Enrollment: An Embedded Study within the FINEARTS-HF Trial

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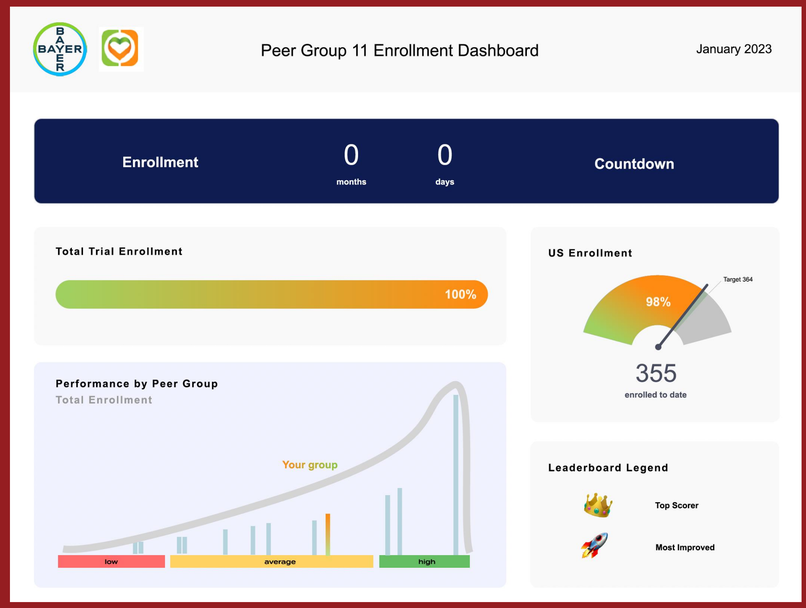
BACKGROUND

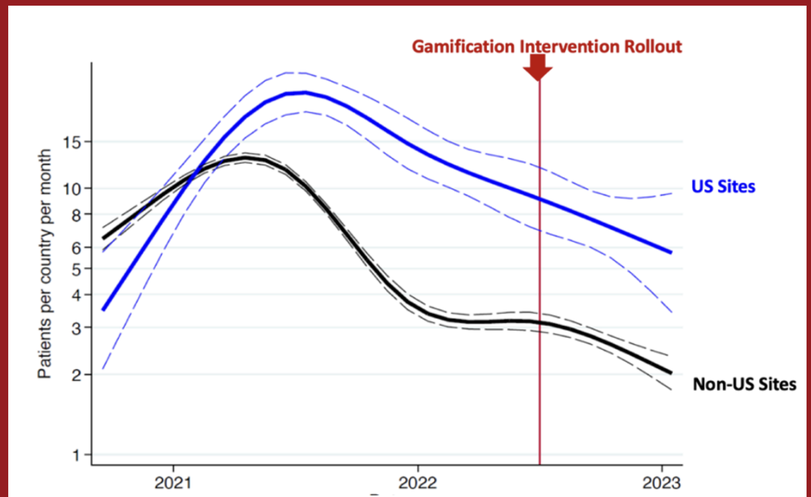
- Randomized clinical trials represent the gold standard for evidence generation.
- Despite large investments across cardiovascular clinical trials, major challenges and barriers remain in the recruitment of US participants; this has led to relative underrepresentation of US participants in global cardiovascular trials.
- Accelerating US site-based enrollment may improve the diversity and generalizability of trial findings and potentially reduce trial duration and associated costs.
- Behavioral science approaches, including gamification, have been shown to drive individual behavioral change; whether such strategies can be used to enhance trial enrollment is unknown.

METHODS

- We designed a prospective, non-randomized, pre-post gamification intervention delivered to all active US enrolling sites in the ongoing global FINEARTS-HF (FINerenone trial to investigate Efficacy and sAfety superior to placebo in paTientS with Heart Failure) trial.
- Sites were assembled into ‘peer groups’ based on US region and prior enrollment rate.
- The intervention consisted of a gamified enrollment dashboard delivered electronically to all US sites every 2-4 weeks starting in June 2022.
    - The dashboard included the following components, each motivated by behavioral science principles: (1) overall and US specific enrollment targets, (2) an enrollment countdown, (3) a leaderboard ranking site recruitment performance over the prior two weeks against peer sites, and (4) and an audit-and-feedback visual aid comparing individual peer group performance to all other peer groups.
- A difference-in-difference design was used to examine the effectiveness of the gamification intervention by comparing six-months prior to (Dec 2021 - May 2022) and after (Jun - Nov 2022) rollout, with all active sites outside the US serving as intercurrent controls.

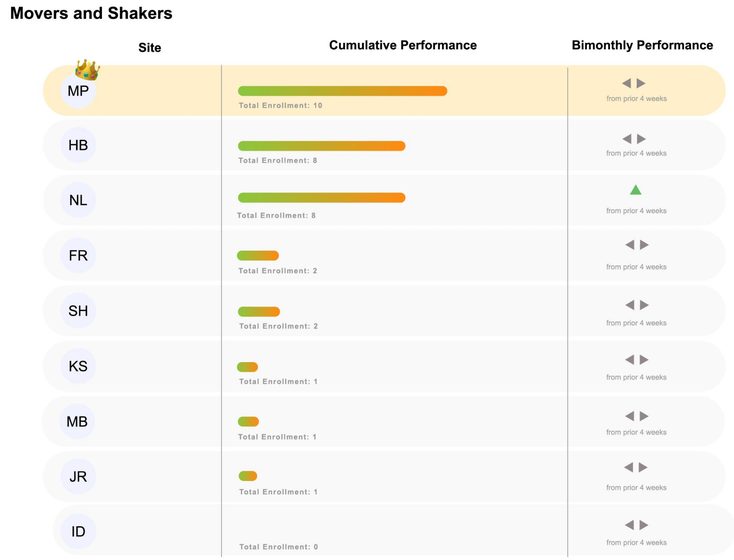
FINEARTS-HF





A gamification intervention introduced to active US sites late in the enrollment period was not associated with a change in rates of new randomization or screening when compared to expected patterns seen in sites outside the US.

GAMIFIED ENROLLMENT DASHBOARD



RESULTS

- 92 U.S. sites were included in this pilot study. At the time of intervention rollout, US sites had achieved 72% of target enrollment. Rates of randomization were generally declining at intervention rollout.
- Among US sites, mean randomization rates prior to dashboard rollout were 12.3 (9.8, 15.5) patients/month/country vs. 7.30 (9.8, 15.5) patients/month/country after rollout (ratio pre vs. post intervention: 0.57 [0.42, 0.77]). Among non-US sites, randomization rates were 3.7 (3.1, 4.4) patients/month/country and 2.7 (2.2, 3.2) patients/month/country, respectively (ratio pre vs. post intervention: 0.72 [0.62, 0.82]).
- The intervention introduced in US sites was not associated with a change in enrollment rate compared with non-US sites (ratio of ratios: 0.79, 95% CI: 0.57 to 1.10; P=0.17).
- The intervention was not associated with a change in mean screening rate in US sites compared with non-US sites (ratio of ratios: 0.96; 95% CI: 0.70 to 1.31; P=0.79).

CONCLUSIONS/ DISCUSSION

- Several reasons may account for these findings:
    - The intervention in this pilot was implemented late during recruitment, when >70% of target US enrollment had been achieved; an earlier rollout, when sites may have had greater motivation and resources to enroll, may have altered our findings.
    - Much of the intervention relied on audit-and-feedback of both site and peer group performance in relation to other study sites; the inclusion of further gamified elements including points, badges, and rewards as adjuncts to the congratulatory email by study leadership may have further enhanced the effectiveness of the intervention.
- This study was limited by comparison between US and non-US trial sites; enrollment patterns and timing may differ by global region.
- Future adaptations, including earlier implementation and pairing with other behavioral science approaches to boost clinical trial enrollment among underrepresented groups require further study.

ASB has no disclosures relevant to this work.