Case study:

Increasing patient randomisation rate by 200% for a global pharma

Moderate to Severe Hidradenitis Suppurativa

Phase: 2A **Countries: 3** **Sites: 63**

Introduction

Hidradenitis Suppurativa (HS) is a chronic, inflammatory, recurrent, debilitating skin disease that usually presents after puberty with painful, deep-seated, inflamed lesions in the apocrine gland-bearing areas of the body. The client was looking to randomise 192 patients (156 completers) with moderate to severe HS at 60 sites across the USA, Canada and Australia. Innovative Trials was asked to provide support with patient recruitment.

Challenges

At the time of this study, anticipated recruitment challenges included:

- The study had a placebo arm, which can be a deterrent for some potential participants
- It permitted only 20% of patients with a background of concomitant antibiotic therapy
- A high number of study visits and the long length of each visit
- Patients could find difficulty in adhering to study schedules, especially those with work commitments
- There were exclusionary medical conditions or concomitant medications
- An overall lack of knowledge in the medical community around HS.

Solutions

Innovative Trials adopted a multi-faceted approach to patient recruitment for this study, comprehensively covering the entire process from study awareness, through to randomisation and patient retention:

Site Optimisation Calls

Up to four recruitment calls per site were conducted by Innovative Trials' Clinical Enrolment Managers (CEMs), discussing existing strategies, new strategies and offering advice on overcoming potential barriers.

Recruitment Materials

Production of a suite of materials, both site-facing and patient-facing, to help raise awareness of the study and aid patient engagement, as well as support sites in their recruitment and retention.

Digital Outreach

An online outreach campaign with multimedia advertisements across search and social media platforms driving users towards a study website with a pre-screening questionnaire, allowing potential patients to refer themselves to their chosen participating site.

Community Outreach

An initiative to raise the profile of the study in targeted destinations around participating sites, paying particular attention to diverse populations. Any of the four approaches listed above can be effective in their own right, but experience tells us that applying multiple complementary methods to patient recruitment can produce more efficient results, as each tactic supports the others.

Innovative Trials' CEMs conducted optimisation calls with sites and supported them with online referrals, ensuring sites are equipped to log in to the portal, view the relevant details and make timely contact with potential study participants. The range of materials, both printed and digital, aimed to catch the attention of patients unknown to sites, as well as assisting sites in educating and recruiting from their own networks.

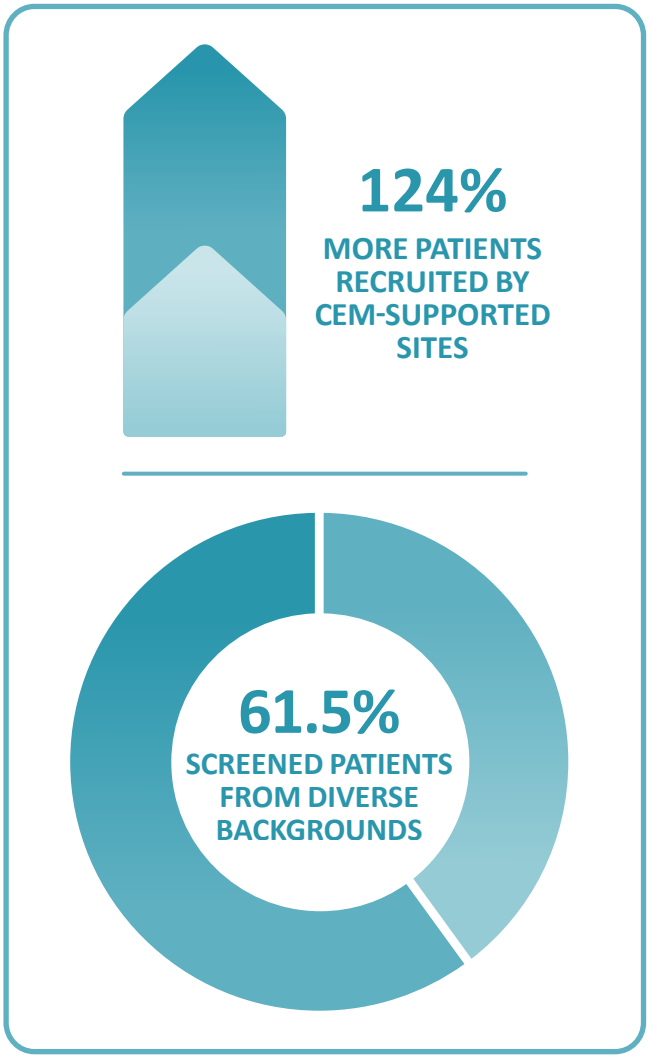
Performance

The following points stand out as a demonstration of the impact that Innovative Trials' support had on recruitment for this study:

- CEM-supported sites randomised 200% higher on average compared to non-supported sites
- CEM-supported sites recruited 124% more patients than sites without CEM support. There were four active sites that did not receive CEM support, screening an average of 2.5 patients per site. The 62 CEM-supported sites screened an average of 5.6 patients per site
- Sites that were engaged and responsive to CEM follow-up regarding digital referrals were more than six times faster at viewing a new referral and three times faster at updating the status of new referrals in the portal
- The number of referrals delivered by the digital campaign exceeded the projections by 56%
- CEM-supported sites participating in community outreach recruited 140% more patients than sites not participating in community outreach
- 90.3% of CEM-supported sites screened at least one patient
- Post outreach implementation, 61.5% of screened patients were from minority backgrounds

Outcomes

This study eventually screened 18.6% more patients than originally anticipated, with 357 actual screened patients against a planned 301. CEM-supported sites screened 224% higher than sites without CEM support, with 61.5% of patients screened after the implementation of community outreach coming from minority backgrounds.



Conclusions

Studies have demonstrated a need to improve treatment options for patients with HS, to provide a better outlook for the roughly 60% of patients who do not respond well to existing treatment. The client needed to recruit 192 patients at 60 sites in 3 countries and, despite several obvious recruitment challenges, Innovative Trials demonstrated that a multi-faceted patient-centric recruitment strategy with a focus on optimising site engagement can overcome potential obstacles and deliver faster, more efficient results.

CS_IVY_12.21(V1)

www.innovativetrials.com | info@innovativetrials.com |

Innovative Trials, Innovative House, Avenue One, Letchworth, Hertfordshire, SG6 2WW