

Achieving Recruitment Objectives in Dermatology Trial: Reducing Timeline and Cost

For a large dermatology trial in the U.S., an innovative, metric-driven recruitment strategy helped the sponsor surpass goals in enrollment timing

Situation •

IQVIA Biotech was selected to help a U.S. biopharmaceutical company examine the safety and efficacy of its investigational therapy for the treatment of moderate-to-severe hidradenitis suppurativa (HS), a chronic skin condition that causes small, but painful lumps under the skin. The sponsor selected IQVIA Biotech for our dermatology experience and expertise in insight-driven site identification and centralized patient recruitment. Beyond the recruitment strategy for the general population, the goal was to develop media tactics to successfully reach specific ethnic populations, meet target enrollment milestones and ultimately, accelerate the trial timeline for the Phase II study.

IQVIA Biotech's dermatology team leveraged IQVIA CORE™ data capabilities along with extensive expertise in dermatology to lead the patient recruitment and enrollment strategy in the U.S. This case study will highlight IQVIA Biotech's unique strategies for site selection and centralized recruitment approach to drive enrollment.

Challenge -

Though no longer considered a rare disease, HS is a rarely diagnosed disease, which can generally make it more challenging to identify patients of interest given significant screen failure rates. As HS is more prevalent in African-American and Hispanic individuals, darker skin tones may increase the difficulty in screening for HS.

IQVIA Biotech considered the potential higher incidence among African American/Hispanic populations and the understanding that HS is more likely to flare in warm humid climates. With the need to maximize site selection and advertising effectiveness, the challenge was to

select sites with diverse and dense populations as well as maintain a list of sites predominantly in warmer southern regions.

Solution

Along with decades of history with dermatology trials and site relationships, the foundation of the strategy leveraged IQVIA CORE data and input from IQVIA's Applied Data Science Center to help drive enrollment. IQVIA Biotech's centralized recruitment efforts were maximized as the site selection strategy provided the groundwork for reaching general recruitment objectives, including:

- Determining medium-to-large U.S. cities that were the most densely populated with the target patient populations or patient hot spots based on HS prescribing data and focusing more efforts in these areas
- To take further advantage of the dense populations in these medium/large U.S. cities, our team purposefully "clustered" multiple sites in these cities. With an average of 2.5 sites per medium/large city, this allowed for maximizing advertising effectiveness, ease of site access for patients, potential to reduce patient travel, and provided surrounding area physicians a greater number of options to refer patients

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- Selecting sites positioned in the southern U.S. to achieve strong media coverage in this warmer region
- Evaluating the breadth of nearby referring physicians who may have patients of interest

Our centrally managed patient recruitment strategy included implementation of a geo-targeted, medium/ large city focused recruitment plan utilizing the following media tactics:

- Traditional media (television, radio, print)
- · Digital media
- · Outreach to patient advocacy organizations
- · Physician referral programs

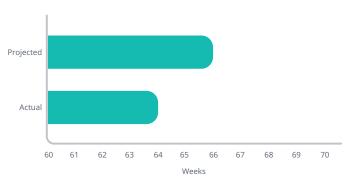
Ongoing monitoring of performance allowed the team to adjust and streamline recruitment efforts throughout the enrollment period, thereby allowing for maximum advertising effectiveness, continued patient referrals, consistent conversion of referrals and highest possible return on investment against media spending.

Results -

Aiming to reach enrollment targets within 66 weeks, leveraging IQVIA CORE data and therapeutic expertise, the team met initial enrollment targets two weeks earlier—in mid-March 2020, as COVID-19 began to affect global clinical development.

HS Enrollment Projection

Reached enrollment goal two weeks early



Centralized recruitment strategy achievements:

- Reached projected initial enrollment goal two weeks early
- Directly generated 40 percent of total randomized subjects
- 73 percent of recruitment management randomized subjects were in southern regions
- 49 percent of African American/Hispanic randomized patients were located in medium-to-large markets

Upon completion of the recruitment phase, IQVIA Biotech not only met initial patient enrollment targets but surpassed projections.

