GLOBAL HYPERHIDROSIS STUDY ACHIEVES 105% OF ENROLLMENT GOAL

IQVIA™ Biotech's strategic training approach dramatically reduced screen failure rates

STUDY OVERVIEW

IQVIA Biotech was asked to conduct a Phase III safety and efficacy study of a treatment for hyperhidrosis (excessive sweating) at sites in the U.S. and Germany. The protocol called for two phases of screen fails, which had resulted in screen failure (SF) rates of 33 percent in previous trials. IQVIA Biotech's past experience with hyperhidrosis studies led it to improve collection techniques and adjust the timing of the gravimetric measurement, resulting in SF rates that showed up to a 20 percent improvement over initial projections.

CHALLENGES

The study required a large patient population in order to meet all the inclusion criteria, which included frequent visits and sweat production of >50 mg. To shorten the study startup timeline, sites with experience in hyperhidrosis and gravimetric measurement were needed.

SOLUTIONS AND OUTCOMES

Because IQVIA Biotech realized it needed to address the very real potential for a high screen failure rate, the company chose investigative sites that had worked on hyperhidrosis studies in the past and therefore had known patient populations who met the inclusion and exclusion criteria. IQVIA Biotech also adopted a media strategy to maximize the number of potential patients.

To support the sites' enrollment efforts, the recruitment management strategy relied on television, radio and, to a limited extent, print. TV and radio were preferred because they draw a large and varied audience, enabling the message to reach new potential participants each week and thus generating a consistent response.

Because of its previous experience with hyperhidrosis studies, IQVIA Biotech concentrated on radio as the primary recruitment medium.

INDICATION
Axillary Hyperhidrosis

SCOPE
- 41 U.S. sites
- Ten German sites
- Four-week screening period; four-week treatment period
- Planned: 948 patients screened, 660 randomized
- Actual: 997 patients screened, 697 randomized

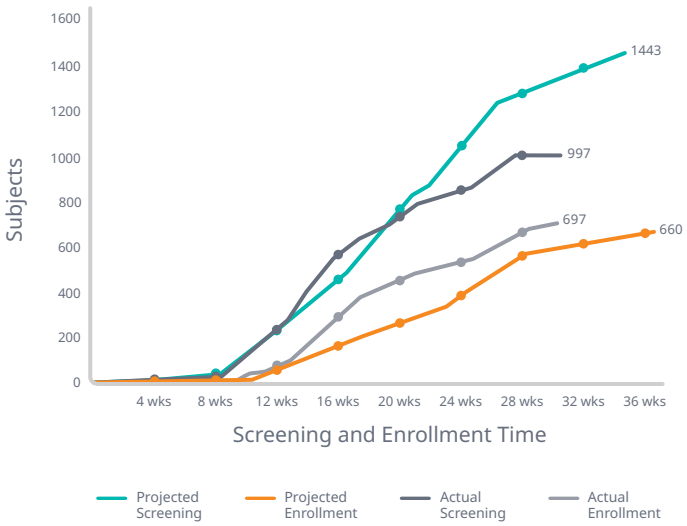
TYPE
- Randomized, double blind; vehicle controlled; efficacy and safety study

POPULATION
- Gravimetric measurement of sweat production of at least 50 mg over five minutes in each axilla
- Hyperhidrosis disease severity score of three or four at baseline
- Average axillary sweating daily diary item #2 score of ≥4 at baseline
- Adults, 18 years of age or older
- Pediatric volunteers, nine to 17 years

In addition to its media strategy, IQVIA Biotech improved screen failure rates by adjusting collection techniques at the sites (arms up vs arms down), using a different pad for collection, and adjusting the timing of the gravimetric measurement.

The initial enrollment objective was to randomize half the study's enrollment targets (330) within the first 22 weeks of a planned 38-week enrollment period – a goal that IQVIA Biotech easily exceeded. At that milestone, 504 subjects had been randomized, 53 percent more subjects than targeted. After 31 weeks, IQVIA Biotech had met 105 percent of the goal – a goal of 660 randomized subjects – using only 82 percent of the enrollment timeline. The last-subject, first-visit took place four weeks ahead of schedule.

105% of Enrollment Goal Met Ahead of Schedule



KEY ELEMENTS TO SUCCESS

TRAINING

IQVIA Biotech provided gravimetric measurement training at the investigator meetings and for the Clinical Research Associates. In addition, after enrollment started, the sponsor provided another whiteboard training video.

Less Time, More Patients

MILESTONE	PLANNED	ACTUAL	% CHANGE
50% OF TIMELINE	330	504	53% Increase
# OF PATIENTS RANDOMIZED	660	697	6% Decrease
ENROLLMENT TIMELINE	38 Weeks	31 Weeks	18% Decrease

CROSS-FUNCTIONAL COMMUNICATION AND RECRUITMENT MANAGEMENT

Because of its experience, IQVIA Biotech recognized the importance of building trust and respect among all the teams involved. Regular meetings with internal and external teams were supplemented with site teleconference calls to discuss enrollment challenges. By sharing recruitment strategies with each other, sites were encouraged to enroll subjects on their own. Without IQVIA Biotech's comprehensive recruitment management strategy, recruitment timelines for this study could have increased by almost 70 percent.

MANAGEMENT FOCUS AND DATA ANALYSIS

Key data trends were analyzed and reported on regularly, and retraining was conducted as needed. IQVIA Biotech kept communication lines open with the core management team to discuss enrollment metrics and planned site activity.

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