GLOBAL PHASE II STUDY: EARLY ENROLLMENT

Numerous site and data/quality monitoring solutions led to sooner-than-anticipated project completion within outlined budgets

STUDY OVERVIEW

IQVIA™ Biotech was selected to conduct a global Phase II study for an atopic dermatitis (AD) treatment. IQVIA Biotech was responsible for recruitment/enrollment management, vendor management, a risk-based monitoring approach, system integration (e.g., IWRS, EDC) and more.

CHALLENGES

Language, cultural and time differences as well as associated regulatory policies enforced in each country challenged the study. Moreover, the target AD study population is difficult to recruit, and because of seasonal changes – for example, AD worsens in colder weather – recruitment strategies needed to be tailored for each location. IQVIA Biotech was also responsible for managing a diverse network of vendors located worldwide and for maintaining communications and coordinating routine meetings among all parties (including a pilot virtual investigator meeting).

SOLUTIONS AND OUTCOMES

RECRUITMENT

Given the difficulty to recruit because of the study population and geographic challenges, IQVIA Biotech was asked to create a comprehensive recruitment management program. Initially, IQVIA Biotech established enrollment projections based on historical site recruitment and advertising performance metrics. Using these metrics, IQVIA Biotech developed a multimedia direct response advertising campaign to support enrollment efforts at the site level. This campaign included television, radio, print (newspaper) and online advertising. IQVIA Biotech customized the advertising and media placement plan based on the enrollment period and the most productive time of year for the therapeutic condition. Throughout the recruitment period, IQVIA Biotech continually analyzed the metrics to maximize the ability to make real-time decisions and rapid adjustments to the recruitment strategy, which included redirecting media resources to maintain the most cost-effective plan possible.

MANAGEMENT AND MONITORING

IQVIA Biotech synthesized enrollment, site performance and monitoring needs to create a foundation for the study. By analyzing historical site performance metrics, IQVIA Biotech identified and selected high-enrolling sites for AD. To meet time and budget limits, IQVIA Biotech developed a risk-based monitoring approach; a clinical monitoring plan outlined requirements. IQVIA Biotech also implemented a three-tiered (100 percent, random and critical variable) source data verification (SDV) strategy.

Close monitoring and cross-functional communication of site activity were key to ensure scheduling of the first monitoring visit at each site. On-site monitoring visits alternated with remote monitoring every five weeks and additional visits were scheduled as needed.

To identify data gaps, trends, safety issues and other items for follow-up, IQVIA Biotech participated in monthly reviews of the data for continuous data cleaning

SCOPE

- Three countries: U.S., Poland and Australia
- 30 sites: 20 in the U.S., five in Poland and five in Australia
- Four-week screening period, eight-week treatment period, follow-up only for ongoing prescription-related adverse events

TYPE

Double-blind; vehicle-controlled; three-arm; parallel group

POPULATION

- Mild to moderate AD affecting > 5 to ≤ 40% body surface area
- Investigator's global assessment score of two (mild) or three (moderate), one measurable target lesion
- 195 patients screened, 121 randomized, including adults, age 18 to 70, and pediatric patients, age ten to 17

and analysis. Reports on data trends were composed and deployed to the monitoring and management teams. These reports included items such as query responses/resolutions to ensure appropriate corrections; time between subject visit and data entry; number of outstanding queries; common pages and modules being queried and common issues being reported to a help desk.

KEYS TO SUCCESS

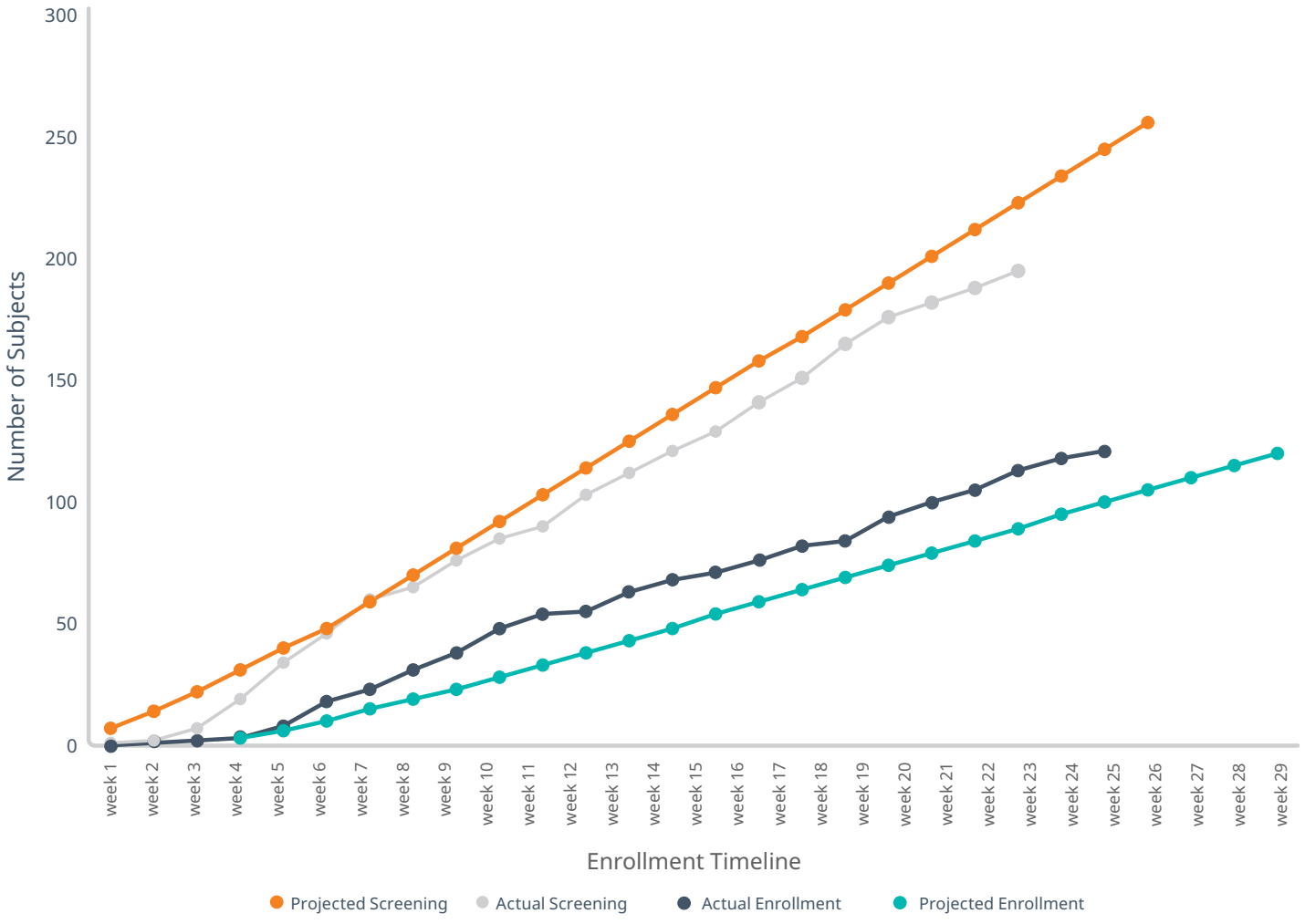
Cross-functional communication was critical to the study's success. IQVIA Biotech coordinated weekly sponsor, CRO, CRA and ad hoc vendor meetings to maintain timely operations by keeping teams informed. For all partners, IQVIA Biotech also regularly emailed expectations, timelines and milestones, all while encouraging and replying to feedback and inquiries.

IQVIA Biotech helped ensure monitoring queries were actively addressed and conducted continuous data and performance analyses to stay ahead of trends and share findings with the greater study team. IQVIA Biotech also pinpointed critical study metrics to monitor, report, and train/retrain teams as necessary to maintain efficient and compliant research conduct. As part of this training, IQVIA Biotech offered access to specialists and resources specifically for AD and established on-demand training modules (e.g., protocol, electrocardiogram and rater training). IQVIA Biotech also implemented a team development program, driven by Tuckman's "Forming Storming Norming Performing" model. This program built a shared sense of ownership and opened communication channels among the various teams, which was essential to reaching milestones efficiently and completing the overall project on time and on budget.

RESULTS

- Well-established working relationships with selected sites led to the planning of first subject randomized four weeks ahead of schedule.
- Early completion of enrollment and monitoring plans as well as custom approaches for targeted (30 percent) and continuous tracking of SDV metrics and query resolution helped meet faster project deadlines.
- Database lock occurred three weeks ahead of schedule.
- Enrollment achieved four weeks early and under budget.
- Within the six-month enrollment period, IQVIA Biotech achieved:
  - » First patient enrollment 3.5 weeks ahead of schedule
  - » Last subject, first visit four weeks ahead of schedule
  - » Last subject, last visit 3.5 weeks ahead of schedule

Atopic Dermatitis Study Projected vs. Actual



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