EXCEEDED ENROLLMENT GOAL TIMELINES AND REDUCED STUDY SPENDING

Patient recruitment services fulfilled actinic keratosis (AK) enrollment goals up to 75% faster than sponsor-projected timelines and significantly reduced overall study spending

CUSTOMERS

Leading pharmaceutical companies focused on dermatology selected IQVIA™ Biotech to conduct large Phase III actinic keratosis (AK) studies each involving from approximately 60 to 960 patients at U.S. sites. IQVIA Biotech's dermatology team was selected because of its reputation as a provider of quality clinical trial management services and its proven patient recruitment process. If IQVIA Biotech could deliver enrollment numbers on par with its record, the sponsors would save significant time and money.

CHALLENGE

Failure of sites to fulfill enrollment expectations on time often leads to major delays in clinical development programs. Based on the sponsors' historical data and prior experiences, each sponsor indicated that reducing enrollment timelines was critical to their overall clinical development plans. IQVIA Biotech noted that with robust recruitment management plans (RMPs), enrollment of the required subjects could be met without sacrificing subsequent data quality.

	STUDY 1	STUDY 2	STUDY 3	STUDY 4
Subjects required	800	960	440	60
Number of sites	45	52	20	3
Projected weeks without RM support	16	20	12	22
Required enrollment (rate/site/week – without RM support)	1.11	.92	1.83	.91
Planned RM support	50%	64%	60%	20%

SOLUTION

IQVIA Biotech's patient recruitment process includes predictive enrollment, which offers valuable insights into managing, tracking and reviewing enrollment metrics and forecasts. To help ensure that enrollment goals were met on each of the studies, IQVIA Biotech designed patient recruitment campaigns targeted toward a specific segment of the protocol population, tailored to leverage the population's media viewing habits. Through ongoing media and screening/randomization performance analysis, IQVIA Biotech executed efficient recruitment campaigns and provided accurate enrollment forecasting.

STUDY DESIGN

Four Phase III, multicenter studies:

- Study 1: 4 – 8 AKs in a contiguous 25 cm^2 area of the face, balding scalp or body
- Study 2: 4 – 8 AKs in a contiguous 25 cm^2 area of the face or balding scalp
- Study 3: 4 – 8 AKs on the face or scalp
- Study 4: 15+ AKs on a 250 cm^2 area of either the face, balding scalp or arm (not including back of hand); 20 subjects required in each group

STUDY DRUG

Topical formulations, various treatment regimens

STUDY POPULATION

Adults with clinically diagnosed actinic keratosis

STUDY PARAMETERS

The number of subjects required varied from 60 to 960; the number of sites varied from three to 45. In all cases, robust recruitment management support was required to reduce enrollment timelines.

RESULTS

For each AK study, IQVIA Biotech:

- Completed enrollment in fewer weeks
- Provided higher levels of recruitment management (RM) contributions than originally projected
- Recognized significantly higher RM enrollment rates per site per week than sites' rates

Because site-by-site enrollment goals were reached 15 to 75 percent faster than original timelines projected, advertising campaigns were stopped earlier than planned, reducing media spending and overall study costs in areas such as project management, clinical monitoring, etc.

	STUDY 1	STUDY 2	STUDY 3	STUDY 4
Subjects required	800	960	440	60
Projected weeks without RM support	16	20	12	22
Actual subject	851	969	440	61
Actual weeks	6	10	3	19/6RM
Enrollment timeline reduced	63%	50%	75%	15%
RM contribution	57%	64%	69%	33%
Rate per site per week – SITES	3.41	.67	2.26	.72
Rate per site per week – RM	4.56	1.19	5.06	1.11
RM rate	33% higher	77% higher	123% higher	54% higher

Moreover, in the increasingly competitive landscape, as speed of enrollment and reduction of overall study timelines was critical in each of these cases, IQVIA Biotech was instrumental in assisting these sponsors with moving forward efficiently with their overall clinical development plans.

IQVIA™ BIOTECH

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