CASE STUDY

Proven Success in Atopic Dermatitis

STUDY CONTEXT

Therapeutic Area:	Indication:	IP:	Phase:
Dermatology	Atopic Dermatitis	Topical cream	III + Long term safety

- Pair of registration/pivotal studies including LT safety treatment included within protocols
- 600 patients per study (1, 200)
- 120 adolescent patients per protocol
- Approx. 150 sites
- 10 countries across North America and Europe
- 35% expected SFR
- Initial six-month enrollment timeline
- 8-week vehicle-controlled treatment period
- 52-week treatment period

CHALLENGES

1. Revised submission strategy (VHP) in EMEA condensed regional recruitment period
2. Targeted and specific patient population required; 75% of patients needed to have an IGA score of 3 with 20% adolescents added late
3. Study complexity was high due to an exploratory sub-study performed at approximately 20 sites
4. Retention of adolescents flagged as risk
5. primary endpoint analyzed within three months of last patient enrolled
6. Lock for CSR added – submitted after continued exposure mid-study during COVID
7. COVID-19 impact including PPD/ Sponsor engagement approach and data cleaning efforts
8. 5 DBLs with interim analysis – three within five months during COVID pandemic

PPD STRATEGIES

1. Fast activation of high enrolling US sites driving enrollment
2. Implementation of a multi tactic campaign comprised of Direct Mail, e-Recruitment, study specific web landing page with pre-screener and a live call center to boost adolescent recruitment
3. Highly collaborative approach with Sponsor
4. Best recruiting sites in the first study ramped up to support recruitment of second study, heavily supported adolescent recruitment
5. Retention champion put in place
6. COVID-19 Impact Analysis developed and report shared with Sponsor weekly
7. Enhanced RBM strategy implemented
8. Once study had met primary endpoint overall SDV was maintained at 25%
9. PPD pivoted approach to ensure KPI and program updates reached the Sponsor without interruption

RESULTS

1. PPD was able to get initial site activated within two days of study approval with subsequent rapid site activations across regions
2. PPD's recruitment engine exceeded time adjusted goal and delivered 94% of recruitment in 66% of time
3. US sites exceeded contractual number of patients
4. Primary endpoint met with database delivered following condensed recruitment period for EMEA
5. Client had confidence in the quality of the data to publish topline results during active participation of subjects
6. Two interim analysis and five locks achieved – pulling in timelines by four months
7. Revised monitoring strategy enabled the team to deliver interim hard-lock for submission during COVID