CASE STUDY

Successful Rapid Startup of a Psoriasis Study

BACKGROUND

The startup process for a clinical trial can be challenging and may impact the total cost of the study.

The median cycle time—the time between the final protocol received (FPR) and the first site active (FSA) or the first patient in (FSI)—is typically shorter for psoriasis studies compared to other clinical trials.

PPD® worked with the drug sponsor on the rapid startup of a phase II psoriasis clinical trial with 50 sites in North America, Europe, the Middle East, and Africa.

CHALLENGES

The rapid startup of this psoriasis study had several challenges, including:

- Short contracted cycle times
- United States (US) Food and Drug Administration (FDA) comments led to a delayed protocol amendment that further shortened cycle time, leaving only 54 days between FPR and FSA and only 68 days between FPR and FSI
- Some qualified sites had long historical cycle times
- Staff site training associated with the use of an electronic clinical outcome assessment (eCOA)
- Complex measurement of biomarkers
- Complicated recruitment and reimbursement process

SOLUTIONS

- **Smart site selection**—PPD identified six fast-track sites based on past responsiveness, feedback, and historical performance
- **Site engagement**—by engaging qualified sites early, we ensured all training and certifications were completed on time
- **Preparation**—the Start Up Team manager began the preparation of the central institutional review board (IRB) submission while the local team was being assigned
- **Streamlining**—early preparation of the master informed consent form (ICF) and US ICF allowed for only minor updates once the final protocol arrived
- **Experience**—to avoid delays with IRB approval, discussions about patient compensation with sites occurred early
- **Fostering relationships**—a close relationship with the central IRB allowed us to prioritize the fast-track site approvals
- **Anticipating risks**—an early vendor kick-off meeting helped to anticipate possible challenges such as translations, programming, and packaging

RESULTS

PPD and the sponsor worked as one seamless team to overcome the challenges of a short cycle time to achieve FSA and FSI well ahead of the contracted milestones and in less time than the average psoriasis study in the US.

Data	FPR-FSA (Days)	FPR-FSI (Days)
Case study	50	64
Contracted milestones	54	68
Psoriasis studies (US)	84.5*	113.5*

*Median number of days

© 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. 10.2023

www.ppd.com