Case study

Dermatology clinical research

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.

The PPD™ clinical research business of Thermo Fisher Scientific 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 — our experts 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

Our team 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

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