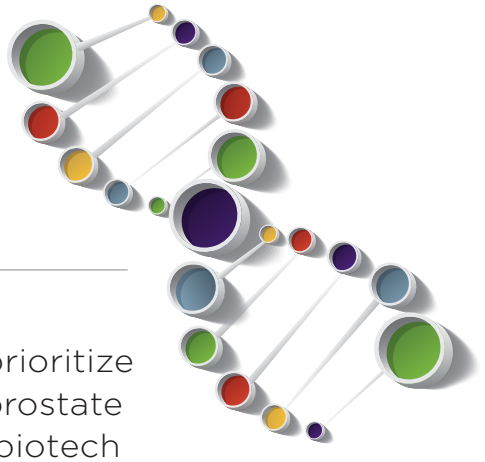
CASE STUDY

Rapid Site Activation in Prostate Cancer Study

Early Approval Triggered Mobilization of Resources



BACKGROUND

PPD Biotech's quick strategic planning and ability to rapidly prioritize needs and mobilize resources during a large global Phase III prostate cancer study resulted in unexpected time savings for a small biotech client when country-level approval times came in faster than expected.

OBJECTIVE

PPD Biotech began this study with extremely aggressive timelines due to a competitive recruitment environment. Earlier-than-expected approvals from a handful of countries presented an excellent opportunity to front-load additional work on the study. We targeted reducing risks for future milestones by activating sites earlier and increasing the number of active site months, giving the client a bigger site pool and bigger patient pool to recruit ahead of the curve.

CLOSED THE GAP UNDER TIGHT RECRUITMENT TIMELINES

CHALLENGES

Capitalizing on these early approvals required immediate rethinking of strategy and accounting for specific challenges.

- Accelerating startup timelines required complex coordination with key stakeholders, the client and vendors.
- The early approvals came in at the start of the summer months, so holidays both at sites and with the wider PPD team had to be taken into consideration and managed accordingly.
- The nine-hour time zone difference needed to be factored in for all communication between PPD Biotech executive leadership, local operations teams and the client.

STRATEGY

PPD Biotech's oversight director and project manager reacted quickly to adjust execution strategy.

Successful site activiation driven by project team with

FLEXIBILITY, CLIENT ADVOCACY & CAREFUL PLANNING

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They immediately revised the custom communication and action plans and tackled challenges by:

- Holding daily calls between the project manager, clinical team manager and start-up manager to review site-by-site results and adaptplans as needed to advance activation.
- Increasing schedule accountability through shared, daily to-do lists and timely follow-up between PPD and the client.
- Engaging PPD's executive leadership to advocate for the client and highlight the value of the opportunity, gaining buy-in for flexible and rapid mobilization of the resources needed to accelerate startup.
- Ensuring close cross-functional coordination with all internal and external key stakeholders, which included:
  - clinical management, site startup and legal teams involved with contracts and budgets
  - vendors
  - the client and global clinical supply teams responsible for getting the drug to sites on time for site initiation visits.
- Implementing a team training plan during the holiday period, ensuring the remote site monitoring process effectively supported CRAs.
- Reaching out to all sites for their vacation schedules to book initiation visits and manage any timeline changes.

THE RESULTS

Because the PPD Biotech team was empowered to take action cross-functionally and work to development creative, rapidly-adaptable solutions, we were able to exceed already-tight site activation targets for the quarter and through to the end of the nine-month site activation plan. This time savings cascaded to subsequent milestones.

- We activated 84 sites globally between June and September, exceeding our target by 20 sites, which is remarkable for the summer holiday season.
- Our activation times for this study have been 25% faster than our normal median timelines for oncology studies across 90% of the countries.

ACTIVATION EXCEEDED BY

20 SITES

90% OF COUNTRIES ACHIEVED

25% FASTER ACTIVATION

than median times for oncology studies

PPD® Biotech Partnering to Drive Innovation

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