ubuntu Research
Transforming science to medicines

Cell Therapy Company's Clinical Development Program Rescued from Missing Critical Milestone

Ubuntu's Clinical Development as a Service Model Accelerates Phase 2 Transition by Three Months, Driving Cost Savings of $2.5 Million

CHALLENGE

Ubuntu was working with a mid-stage oncology cell therapy company transitioning its first ever clinical asset into Phase 2 development.

The organization was facing several challenges, including limited in-house clinical expertise, frequent leadership changes, and underdeveloped clinical infrastructure. These dynamics created a labyrinth of obstacles, putting clinical development timelines at risk and leaving the organization ill-prepared for the asset's Phase 2 transition.

Ubuntu helped the organization identify several critical problem areas, including:

- Clinical planning and project delivery bottlenecks
- Good clinical practice (GCP) non-compliance issues
- Ineffective team composition and role responsibilities
- Communication gaps within the project team and with external stakeholders

> " The probability of missing the Phase 2 submission deadline was greater than 95% and we were able to reduce that to less than 30%. Ultimately, we helped them not only meet their deadline, but get there three months ahead of schedule."
>
> **- Ataali Shaikh**
> Clinical Development Strategy & Solutions, Ubuntu Research

SOLUTION

Ubuntu got to work right away implementing its Clinical Development as a Service (CDaaS) model.

- *Optimized CRO Operations:* Revisited and revised the contractual scope and delivery timelines, ensuring the clinical operations team and vendors were aligned for efficient delivery.

- *Delivered Project Planning & Governance Models:* Introduced effective trial methodologies using robust governance frameworks (e.g. CTS governance) to streamline planning and execution.

- *Deployed Regulatory-Compliant Processes:* Implemented clear standard operating procedures and process maps to ensure full compliance with GCP and regulatory requirements, reducing future risks.

- *Launched Knowledge- and Data-Driven Processes:* Enabled new processes for evidence generation by leveraging insights from comprehensive data collection, setting the foundation for improved decision making.

RESULTS

Over the course of the three-month project, **Ubuntu implemented several fundamental changes:**

Improved collaboration and communication

Ubuntu's CDaaS approach to drug development led to a new level of trust and collaboration between the Ubuntu and biotech teams as well as between, within, and across the clinical operations, trial site, and CRO teams.

Increased big-picture thinking

Transformed team behaviors to focus on outcomes rather than tasks and helped company embed accountability and patient-centric decision making across the clinical organization.

Enhanced integration

Integrated siloed clinical datasets and locations into one unified dataset view, giving all team stakeholders a "single source of truth" regarding the status of the clinical development program and necessary next steps, actions, and corrections.

Outcome:

- 3-month acceleration of clinical program timeline
- 15% (~$2.5M) cost savings

> " Ubuntu helped us implement much-needed processes to run our clinical operations more efficiently & effectively, including better managment of our CRO. Our SOPs and vendor management plans are now complete and up to date, and our study management teams are run much more smoothly, empowered with accountability and ownership. **Ubuntu's top-notch subject matter expert team is very client-focused, available, and responsive** and I was grateful they were able to immediately step in and help us during a particularly vulnerable period."
>
> – Chief Medical Officer, Cell Therapy Client

For more information about how Ubuntu's Clinical Development as a Service model can help you bring clinical assets to market efficiently and successfully, reach out for a complimentary consultation today: info@ubunturesearch.life