

# Mitigating study start-up risks in a biotech's early phase immuno-oncology study

## A KEY QUESTION



How can a study get back on track and keep sites engaged after an unforeseen manufacturing issue threatens start-up timelines?

## KEYWORDS

Immuno-oncology, Gene Therapy, Study Start-up, Site Strategy, Phase I, Regulatory Support, Product Manufacturing, Genetically Modified Organisms



## Confronting an unexpected challenge

A biotech sponsor was developing a treatment targeting people with advanced solid tumors who are beyond the standard of care. They selected Fortrea to run their Phase I/Ib open-label study of its genetically modified organism (GMO). The sponsor had selected a manufacturing vendor for its investigational medicinal product (IMP), but its regulatory submission was rejected due to insufficient testing, setting the study timeline back by five and a half months.

This case study shares how Fortrea addressed this unexpected manufacturing delay by providing regulatory guidance, keeping sites engaged, aligning expectations and quickly enrolling patients after an approved re-submission.

### Providing regulatory alignment

To set expectations and develop a new plan of action, Fortrea:

- Established a close collaboration with the sponsor to develop a strong working relationship
- Provided clear guidance on the resubmission pathway
- Defined realistic regulatory approval timelines

### Result:

Re-submission was achieved within ~3 months, followed by regulatory approval ~2.5 months later.

### **Defining responsibilities and supporting sub-contractor management**

Understanding that GMO manufacturing processes involve uniquely complex regulatory requirements, Fortrea defined a robust scope of responsibilities and tracked deliverables across all vendors as they:

- Prepared the vendor's subcontractors to be ready before regulatory approval
- Supported time-sensitive, complex negotiations and aligned the qualified persons (QPs)

#### **Result:**

Fortrea rapidly secured cross-stakeholder alignment and implemented an effective quality technical agreement ahead of regulatory approval.

### **Reducing whitespace with parallel workflows and proactive planning**

While the regulatory approval was pending, Fortrea recognized that the delay could reduce site engagement and slow momentum toward first site activation and patient enrollment in a competitive immuno-oncology landscape. To address this, they:

- Negotiated and finalized the budgets and contracts with sites
- Conducted an initial site initiation visit (SIV), followed by a refresher visit post-approval
- Promoted transparent communication to keep sites informed on the anticipated approval timelines
- Obtained details on potential participants as part of the pre-screening activities

#### **Result:**

Fortrea achieved site activation within a week of regulatory approval and two weeks ahead of the sponsor's planned timeline.

## Recognizing the collaborative efforts

Fortrea efficiently navigated uncertainty and anticipated the next steps to reduce risk while optimizing costs. Through proactive planning and parallel workflows, the study progressed with a clear, achievable path forward.

As a result, the study reached first patient in (FPI) less than two weeks after site activation and one week ahead of the initial projections. Enrollment continues to outperform expectations in this study, demonstrating how Fortrea's biotech-dedicated delivery culture embraces urgency to reach critical milestones.



Learn how Fortrea helps sponsors reduce risk, maintain site engagement and support early phase oncology milestones faster.

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