Oncology Clinical Trials RFP Planning Guide

This eBook will help oncology sponsors plan clinical studies with key cost drivers in mind.

Planning clinical studies: Identifying cost drivers upfront

Understanding the primary cost drivers for oncology clinical studies can be daunting. IQVIA™ Biotech developed this guide to help oncology sponsors prepare for clinical outsourcing from a financial perspective.

HIGH
MEDIUM
LOW

Throughout this guide you will see a cost impact key to indicate financial significance as you are planning a clinical study.

Use these arrows → to easily navigate through the guide.

Get started →

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STUDY PHASE

MEDIUM

REQUIRED SUPPORT

Different studies require various levels of clinical development support. For example, an early phase oncology trial with a complex dose escalation component will require more intense monitoring of data than a post-approval study.

TIMELINES & MILESTONES

MEDIUM

KEY DATES

When a trial includes long-term follow-up, it is imperative the sponsor and Contract Research Organization (CRO) understand not only the subject engagement during that portion of the trial but also what data will be collected/monitored. In some cases, if the subjects are being followed by site phone calls, the sponsor may desire to manage the clinical monitoring component of the trial in-house as a cost savings approach.

Sponsors should outline a preferred timeline of critical dates including first subject in (FSI), last subject in (LSI), last subject out (LSO), long-term follow-up, final deliverable and interim data results.

Understanding of the goals of any interim data cuts is also imperative. For example, will the sponsor only be looking for a basic set of Tables, Listings & Figures (TLFs) to review for an interim data cut or would a formal analysis be required? Would unique TLFs be warranted or could programmed TLFs be reused?

TIP

Inflation is applied generally starting in year two of the study. Shifting a start date out will generally increase your rates by nomimal amounts.

HIGH

TIMELINE IMPACT

Timelines are perhaps the largest driver of budget, and can impact the number of full-time employees (FTE) needed. Timelines also impact site management and trial master file (TMF) maintenance.

HIGH

PM COST DRIVERS

Project Management (PM) is the most often discussed line item cost in a CRO budget. Some CROs include hours from other functional areas within the PM scope of services (TMF, sponsor communication time for the entire study team, all team/customer meetings, admin support, etc.).

Project management costs are driven by the number of full-time employees required to manage the study. This number is calculated based on factors including:

GEOGRAPHY

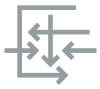
- Determines the number of staff and hours required per project.

SCOPE OF SERVICES

- More services in the scope of the CRO means more PM FTE will be needed to manage the study.

PATIENT INVOLVEMENT

- For example, slow enrollment will generally mean a lower PM FTE per month than a trial with fast enrollment.



COMPLEXITY OF STUDY

- Studies with multiple protocol amendments or rare patient populations may drive project management costs.

NUMBER OF EXTERNAL VENDORS THAT WILL BE MANAGED BY THE CRO

TIP

Ensure CRO bids are accurate by understanding what each bid includes in the overall PM scope of services.

GEOGRAPHY

MEDIUM

NUMBER OF COUNTRIES/REGIONS

Each region across the globe presents a unique financial impact based on varying costs associated with CRO resources (such as CRA and PM rates), site contracting, and institutional review board (IRB) and ethics committee (EC) submissions. Adding countries to your program will impact the overall cost, regardless of the number of sites per country. For each country, Competent Authority and EC submissions must be made, country specific document templates must be created for many essential documents and in-country resources must be trained.

NUMBER OF SITES AND RESPONSIBILITIES

Sponsors may choose to perform functions internally for some or all sites and outsource the rest to the CRO.

The cost impact is tied directly to the number of services managed by the sponsor. For example, if the sponsor only maintains the site identification work for some sites, this is much less of a cost savings than if the sponsor manages Clinical Monitoring.

LOW

CHANGING COUNTRIES/REGIONS

The cost of replacing one country with another in the same region is not significant outside of rate variation.

TIP

The largest financial factors of adding new regions are resourcing and legal/local representation services.

SUBJECTS

HIGH

NUMBER OF SCREENED AND ENROLLED SUBJECTS

The number of patients impacts several areas of the budget including:

Number of monitoring visits required

Site management

Data to be reviewed by CRA/DM

MEDIUM

SITE VISITS PER SUBJECT

The total number of subject visits drives both site payments and payment report programming. The required number of CRFs is impacted as well.

ADVERSE EVENTS

A CRO may engage a medical monitor to help estimate the serious adverse events (SAE) rate based on their review of the protocol.

TIP

SAEs are a cost driver, specifically reportable events as those must be reported to all sites, EC, central IRB and Competent Authorities.

DATA MANAGEMENT

HIGH

CASE REPORT FORM (CRF) COUNT

The number of CRFs per patient impacts several areas of the budget including:

- Data listings
- The number of data review cycles needed
- Monitoring visits
- Remote review time (by CRA or in-house resource)
- Query volume/reconciliation
- Programming and biostats (affected by unique forms)
- Electronic data capture (EDC) hosting costs

DATA MANAGEMENT

HIGH

DATA MANAGEMENT AND ELECTRONIC DATA CAPTURE (EDC)

Data management and EDC costs will be driven primarily by the complexity of the CRF and associated edit checks, page/data volume, and variables such as data import/export volumes, and analysis numbers.

MEDIUM

ESTIMATE OF TABLES, LISTINGS & FIGURES (TLFS)

Generally the TLFs are tied to the number of unique eCRFs as well as the number of external data sources.

TIP

Including a Schedule of Events at the time a bid is requested will give the CRO the information needed to estimate the casebook size more accurately.

COMMITTEES

MEDIUM

INCLUSION OF COMMITTEES (E.G., DSMB, CEC)

Some CROs offer in-house management of committees which may include the identification, contracting and payment of committee members.

Should you need assistance in planning your next oncologic study, IQVIA Biotech is here to help. Contact us at iqviabiotech.com

YOUR TRUSTED PARTNER

At IQVIA™ Biotech, our extensive oncology expertise, coupled with the ability to leverage IQVIA's vast data, technology and analytics resources, creates a clinical development partner perfect for you.

Our dedicated oncology teams have the global experience, knowledgeable staff and robust infrastructure to effectively guide your study to the next milestone. You want to get the right treatments to the right patients. We want to help you pave a more predictable path to get there.