

# CHAPTER

# 9

## Budgeting and Contracting in Patient Recruitment

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### Objectives

- Budgeting and contracting that incorporates patient realities during the earliest stages is essential to the success of clinical trials.
  - Developing distinct strategies and understanding budget variables and components leads to effective patient recruitment budgets.
  - Understanding and identifying a company's values are key parts of the budget process.
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### Introduction

In the field of patient recruitment for clinical trials, considerations of budgeting and contracting are becoming increasingly essential to success. This chapter challenges clinicians, administrators, sponsors and others involved in clinical trials to think more strategically in deciding when, where, how and why to budget and contract for patient recruitment.

Until recently, patient recruitment was exclusive to the principal investigator's role in a clinical trial. Patients for clinical trials were largely drawn from the physician's practice, and the sponsor paid for that access as part of the physician's total compensation. A separate budget for centralized patient recruitment was rare.

As the number of clinical trials increased and competition grew among companies testing similar compounds and procedures, recruiting patients from physician practices was not enough. It became necessary to find new

methods for attracting participants. Individual study sites began spending money on promotional campaigns with widely varying degrees of success. For every success there were more failures, and the duplication among sites of effort was inefficient and wasteful.

Management within sponsor organizations soon began analyzing the return on investment for patient recruitment efforts, challenging the marketplace to re-evaluate the concept of decentralized versus centralized campaigns and budgets. The first organizations to attempt centralized programs were contract research organizations (CROs). However, CROs lacked expertise in direct-to-consumer promotions, and soon it was necessary to find others that could analyze the process and develop a marketing communications strategy for patient recruitment as a distinct effort. Many early, centralized recruitment budgets were often inflated, even exorbitant. More recently, the pooling of patient recruitment expertise distributed throughout the clinical trial community—sponsors, sites, CROs, site management organizations (SMOs) and communications agencies—has resulted in a more strategic approach to budgeting for patient recruitment.

This need for achieving recruitment success in an efficient, cost-effective and process-oriented manner has led to the growth of strategic contracting as a budget management tool. Performance-based contracting among sponsors, sites, CROs and communications specialists is an effective method for distributing the risks and rewards—without unduly influencing the informed consent process involved in the increasingly competitive field of clinical trial recruitment.

Every protocol demands its own budgeting strategy. What follows is a process to assist project leaders in understanding the variables that affect the recruitment budget, which, when evaluated, lead to a comprehensive patient recruitment budget.

## **Before Budgeting**

In one successful study after another, a commitment to investing in patient recruitment at the onset has achieved demonstrable results: expenses can be anticipated, allocated and contained. Furthermore, patient involvement and retention in these studies have increased. Rather than planning protocol design, investigator recruitment or patient recruitment as sequential steps in a process over time, when all elements are considered early and concurrently, a study can be more effectively managed. Ultimately, this mindset shift from linear to dynamic planning has proven effective in avoiding the recurring problem of under-enrolled studies. This section provides an overview of key questions to ask about the trial, specifically:

- Is there a method for estimating numbers of patients needed at each recruitment stage to fulfill the final randomized requirement?