

## » Planning to Maximize the Economics of Clinical Trials

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New industry research indicates that conducting a clinical trial in the United States costs nearly twice as much as the same trial in other countries. Global competition for research funding has increased the pressure on United States cancer programs to successfully manage resources and processes to start trials in a timely fashion, meet participation targets, and limit financial risk to the organization.

### Best Practices in Research Program Planning

Planning plays a crucial role in the economics of clinical trials. Because the clinical trial type and funding source (industry vs. National Cancer Institute [NCI]) affect the finances of a clinical research program, trial selection must meet the cancer program's larger strategic and financial goals. To appropriately manage a cancer program's trial portfolio, senior management must consider the components of planning and implementation in Figure 1 that include...

### » DATA-DRIVEN SELECTION OF TRIALS

Understanding which types of trials have the highest probability of patient enrollment is the first step in appropriately managing research costs. Low-accruing research programs have higher per patient costs and a lesser chance of breaking even. Estimating patient accrual to a particular trial is critical and should be based on the following criteria:

- Congruity with patient population/needs.
  - » Analysis of the cancer program's patient volumes and community incidence rates.
  - » Historical accrual rates for the cancer type.
- Ability to accrue.
  - » Physician interest or ownership of the trial.
  - » Selection criteria that are reasonable and easy to screen for.

- Availability of resources (e.g., pharmacy staff, administrative staff, principal investigator [PI] time) in relation to the complexity of the protocol.

### » DEVELOPMENT OF A BUSINESS PLAN

Once specific research areas are determined and accruals are estimated, the next step is to formulate a business plan for the research program that will address the following key questions:

- What are the specific, mission-driven goals of the research program? How will these goals affect the program's overall financial targets?
- What are the total costs associated with the program of trials that will be offered?
- How will the financial merit of a proposed trial be evaluated?

The data that drives the business plan includes estimates of patient accrual, staffing, other expenses, and revenue. The resulting business plan should outline how the program will focus its resources by tumor site and sponsor type, as well as address the feasibility of meeting accrual targets. The plan should also identify metrics for performance evaluation. Structured performance monitoring will be required for the program to continually improve and achieve its business planning targets.

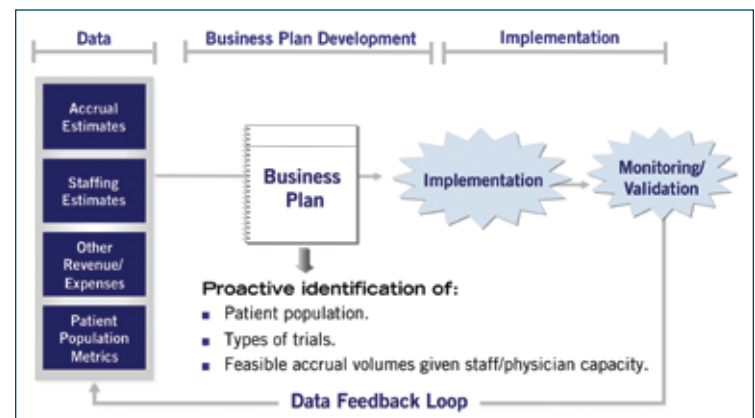


Figure 1. Clinical Trial Business Planning Source: ECG Management Consultants, Inc.

## » VOLUME PROJECTIONS AND CAPACITY PLANNING

Patient volumes should be projected based on study type. Table 1 represents patient and study projections by trial phase that underlie the financial estimates of the business plan. These projections are shown in aggregate and are estimated for each current and projected study. A similar table by cancer type should be developed to assess the cancer program's ability to meet aggregate accrual estimates given the patient population.

**Table 1. Patient and Study Volume Projections**

	2008	2009	2010	2011	2012
Patients by Type					
Phase I	102	98	98	97	96
Phase II	40	26	32	33	33
Phase II/III	10	11	16	16	18
Phase III	12	20	14	14	14
Other	63	74	68	70	70
<b>Total Patients</b>	<b>227</b>	<b>229</b>	<b>228</b>	<b>230</b>	<b>231</b>
Studies by Type					
Phase I	14	12	13	13	13
Phase I/II	3	4	3	3	3
Phase III	5	4	4	4	4
Phase II/III	1	–	1	1	1
Phase III	2	2	2	2	2
Other	5	8	7	7	7
<b>Total Studies</b>	<b>30</b>	<b>30</b>	<b>30</b>	<b>30</b>	<b>30</b>

Source: ECG Management Consultants, Inc.

It is also essential to model the total staffing requirements to determine if current resources are adequate to meet study needs. Administrative, physician, and RN/clinical research associate (CRA) capacity must be considered in these projections. Table 2 presents sample workloads for RNs and physicians calculated using benchmark ratios.

**Table 2. Capacity Planning**

Type of Trial	Protocols per RN	Patients per RN	Patients per Physician	Protocols per Physician
Any - Low/Average	3	36	105	–
Any - Max	8	96	–	–
Phase 1 - Low	2	20	–	3
Phase 1 - Max	5	60	–	6

### Actual workloads are dependent on trial complexity.

Note: These are general ECG benchmarks. Actual capacity will fluctuate by protocol.

Source: ECG Management Consultants, Inc.

There are many variables in accurately assessing staffing needs; however, capacity planning is dependent on the type of trial and how much clinical management is required. Part of the feedback loop in the business planning process is to refine staffing benchmarks to your organization's research portfolio.

## » FINANCIAL PROJECTIONS

To build expense projections, total staffing requirements should also consider deployment of study coordinators and whether trials require RNs or if trained research coordinators, without clinical degrees, are sufficient. Depending on the type and scope of research to be performed, other personnel expenses may include physicians, pharmacists, data managers, statisticians, grant writers, and a director of research.

Revenue estimates for the business plan should incorporate grant and industry sponsor revenue for research activities, clinical revenue from patient care and ancillary services associated with the trial, and administrative revenue for standard program costs. Table 3 depicts a simplified example of financial projections for the business plan.



**Table 3. Business Plan Financial Projections**

	Historical 2007	2008	Projected 2010	2012
<b>Revenues</b>				
Clinical Trials	\$158	\$3,433	\$3,936	\$4,193
Other	224	1,726	2,386	2,656
<b>Total Revenues</b>	<b>\$382</b>	<b>\$5,159</b>	<b>\$6,322</b>	<b>\$6,849</b>
<b>Expenses</b>				
Personnel	\$2,004	\$3,758	\$4,238	\$4,188
Operating Expenses				
Purchased Services	\$877	\$1,474	\$1,625	\$1,790
Other	508	666	793	792
<b>Total Expenses</b>	<b>\$3,389</b>	<b>\$5,898</b>	<b>\$6,656</b>	<b>\$6,770</b>
<b>Excess/(Deficit)</b>	<b>\$(3,007)</b>	<b>\$(739)</b>	<b>\$(334)</b>	<b>\$79</b>

Source: ECG Management Consultants, Inc.

Once a financial model is developed, it can be used to determine the feasibility of new opportunities, and the management team can monitor the progress of the clinical trials program against the plan.

### »» IMPLEMENTATION: REDUCING ADMINISTRATIVE TIME

Inefficient trial operations result in significant financial risk. Cancer programs can mitigate this risk by closely monitoring operations through the following mechanisms:

- **Set Deadlines for Reviews**—Standardizing processes (e.g., signature appointments/deadlines, cost assignment to lab/pharmacy) and limiting the number of negotiating loops between parties greatly decreases administrative setup time. Table 4 presents sample guidelines for the budgeting and contracting processes.

**Table 4. Budgeting and Contracting Administrative Time Benchmarks**

Benchmark	Preferred	Acceptable	Unacceptable
Budget Creation	Within 3 days	Within a week	More than 1 week
Days for Contract Negotiation	Within 2 weeks	2 to 4 weeks	4 weeks

Source: ECG Management Consultants, Inc.

- **Evaluate the Use of External Versus Internal IRB**—The use of a local versus site-specific IRB may decrease costs and process time.
- **Use Administrative Staff Effectively**—Standardizing training and utilizing central resources reduces administrative labor costs.
- **Increase Transparency of Trial Approval and Setup**—IT and Web-based tracking mechanisms can be used to keep clinical trial staff informed of trial status, enabling them to prepare for trial setup and patient accrual on a real-time basis.

### »» THE FEEDBACK LOOP

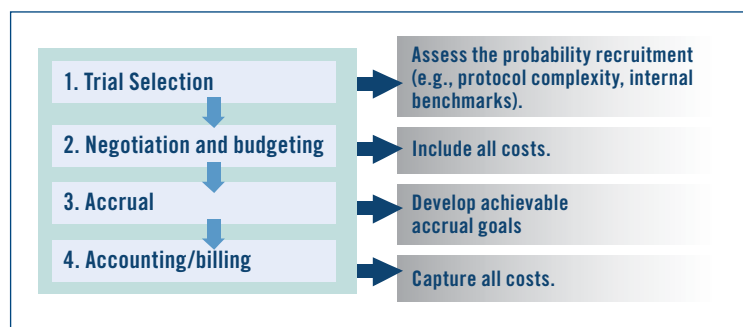
It is imperative to establish a plan with specific goals and build a process that supports the monitoring of targets for program improvement throughout the term of the business plan. The feedback loop should address questions such as:

- How well did the practice PI recruit to the trial?
- Is there an interested patient base?
- Were staffing and budget benchmarks met?
- Did the program receive all funding related to patient accruals?

The answers will be used to refine financial projections and performance metrics for future business planning.

## Conclusion

The best practices described can reduce costs, increase patient accrual, and ultimately enhance revenue for clinical trials. Figure 2 illustrates the elements of a financially successful trial.



**Figure 2. Elements of a Financially Successful Trial**

Source: ECG Management Consultants, Inc.

Achieving financial administration best practices centers on obtaining the highest-quality data for sound decision making, understanding and acting upon it, and then communicating the financial realities of clinical trial choices to physicians and leadership. Good business planning means that an organization can budget to support underfunded studies when deemed strategically important, such as increasing patient access to new treatments that are of clinical value. Deliberate and efficient allocation of available resources ensures that physicians and organizations can continue to fund the research that provides the most benefit to patients and the research community. **ECG**

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