

Making Accurate & Valuable Revenue Projections & Pipeline Forecasts

What is a pipeline?

This would be an estimate of the value of study revenue from studies not yet awarded to the site. When putting together the estimate, there is information that is routinely needed including:

- Study Budget (Estimated/Contracted)
- Randomized Subjects
- Duration of Enrollment Period
- Start Date
- Fixed Revenue (Invoiceables) & Variable Revenue (# Randomized x Per Subject Budget + SFs + Conditional Costs

Applying Discounts:

- 1) Interested / Submitted: 5%
- 2) CDA completed: 25%
- 3) Feasibility / Questionnaire 25%
- 4) PSV Stage: 90%
- 5) Awarded / CTA in Progress: 95%

Example: \$1,000,000 study value Factored at Questionnaire stage: \$250,000

Top-Down Conversion Method: determine probability of all study awards (20% or 1 in 5): Cumulative study values: $10,000,000 \times 0.2 = 2,000,000$

An overall discount may be considered for cancellations/delays and best to track on an annual basis to identify future discounts that are reasonable to the area in which you conduct clinical research.

What is Backlog?

This would be the value of study visits to be performed in the future entered into the CTMS for subjects screened into active trials.

You have to consider new subjects to be screened, randomized and those already randomized when pulling together your total backlog. Most often your CTMS can run reports to determine potential backlog, but you may need additional tools and/or systems to pull pipeline and backlog information together to determine your forecast.

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Factors to consider when determining both pipeline and backlog as it relates to recruitment and assigning risks or further discounts:

- Country Selection and Allocation
- Site Goals
- Site Intelligence Profile Questionnaire
- Diversity Targets
- Total # of Sites
- Competitive Enrollment
- Screen Fails

What are the unpredictable factors that can impact ability to meet recruitment goals?

- IP & Supplies Availability
- Sponsor/CRO Priorities
- Competitive Enrollment
- Enrollment Caps
- Monitoring Delays Site Initiation & Monitoring Requirements
- Protocol Amendments
- Cancellations
- Delays

What can be done to control these factors?

Consider a focused start up team, strengthening communication with sponsors and CROs to improve relationship/transparency, be flexible and agile with respect to monitor needs and timelines, and closely monitoring enrollment timelines and adjusting operations as needed.

Best practices in creating your yearly budget consisting of your pipeline and backlog is done in the third quarter. Each quarter, run an updated re-forecast to ensure you are in line with your budget. Note that study start dates can be a moving target and consistently change. Some larger studies can create significant volatility to overall budget.

As our pipeline and backlog is always changing, it is important to refresh on a continual basis. This will help your site evaluate what is needed in recruitment and/or go – get, which is identification of new trials to the site.

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