Clinical Trial Forecasting & Budgeting

Reforecasting Clinical Trial Budgets

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Reflex on Forecasting Clinical Trial Budgets

• Don Carlberg - Director, Business Planning & Analysis
  – Since joining Celgene in 2003, Don has held several positions in Celgene Finance and Information Technology most recently in FP&A supporting Clinical Research & Development and Clinical Operations for the last 3 years.

  – He has been a part of several key initiatives for Celgene including the launch of the Oracle E-Business Suite and development of the current Clinical Study Forecasting and Accrual Database Solution.

  – Don holds a Masters of Business Administration in Finance from Rutgers School of Business and previously worked in finance and accounting positions in publishing.
Reforecasting Clinical Trial Budgets

Who makes up this Group?

- Clinical Operations
- Finance
- Project Managers
- Other?

How many years dealing with Budget and Forecasts?

- 5+ years
- 2+ years
- 0-2 years
Develop a Unified Procedure to Dynamically Reforecast Clinical Trial Budgets

A central issue of clinical trial budgeting and forecasting is the challenge to reforecast when a study is not performing as planned. This session provides strategies to roll forecasts forward and realign projections to improve accuracy of both trial budgets and annual company budgets.

- Discover how to best track and update forecasts and accruals when trials are under or over performing
- Leverage forecasting tools to recalculate payments and budget reconciliation
- Discuss challenges of reforecasting future expenses based on often outdated study information to make real-time decisions and mitigate risk
Key Themes

- Planning and Assumptions
- The Value of Information and Business Partnership
- Understanding Drivers of Cost in Challenging Studies
- Optimize Tracking and Use of Tools
- Challenge of Real-Time Decision Making
Planning and Assumptions

Studies “not performing as planned” against baseline assumptions.

- Were the assumptions correct? What is correct?
- Carefully planned protocol and understanding of assumptions
- Budget and Governance
- Feasibility Review
- Understanding of Contract and Cost Drivers
“Go Slow to Go Fast”

– Planning, Feasibility and Protocol Development lead to better enrollment projections

– Realistic assumptions and reduced amendments / change orders which impact the forecast

– Use of data in feasibility and study design
  
  • Big Data’s impact on future studies
  • Finding patients more efficiently
  • Identifying challenged studies
“Transparency strategy (is there a perfect world where all relevant team members share knowledge and study status in order to allow the finance strategy to include all known and up-to-date assumptions)?

In a day-to-day business scenario, do we have enough transparency to the reality of the study that will allow the finance team to include all assumptions with cost impact in a time efficient manner?”

– Who has the information?

– Understanding the value of a piece of information
  ▪ What is relevant?

– Using the information in a forecasting model
Understanding Drivers of Cost in Challenging Studies

Major Cost Drivers

- Start Up - Work performed by vendor required to get study up and running
- Patients on study - Number of patients randomized/enrolled over the life of the study
- Patients on Follow Up - Number of patients on follow up over the life of the study
- Sites on Study - Number of active sites over the life of the study
- Monthly Professional Fees - Costs allocated across the contracted duration of the study
- Close Out - Work performed by vendor required to complete study
Understanding Drivers of Cost in Challenging Studies

Study Expense Percentage by Period

- **Oncology**
  - Enrollment / Treatment
  - Follow-Up / Closeout

- **Hematology**
  - Site Activation / Enrollment
  - Start-Up

<table>
<thead>
<tr>
<th>Period</th>
<th>Study Expense %</th>
</tr>
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<tbody>
<tr>
<td>6</td>
<td>0.5%</td>
</tr>
<tr>
<td>12</td>
<td>2.5%</td>
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<tr>
<td>36</td>
<td>1.0%</td>
</tr>
<tr>
<td>60</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
What was missing in a challenging study?

- Start Up
- Patients on study
- Patients on Follow Up
- Sites on Study
- Monthly Professional Fees
- Close Out

Screen Failures
Evaluation period between screening and randomization

Study was not enrolling → invoicing began to far exceed work performed calculation.
Leverage forecasting tools to recalculate payments and budget reconciliation

“Can we improve the current way of doing things? Probably any chosen forecast tool can do so much and then there is the business process that has a real impact on how accurate we can be in reconciling payments/contracts and forecasted values.

*Can we improve business processes and if yes, how do we prioritize which ones would be the high impact/easy to implement (according with the prioritization matrix)?*

— So we’re back here talking about forecasting tools again…

— Relevance and materiality

— Organizational objectives

— Tradeoff of complexity vs. accuracy

— Investment of resources
Developing Predictive Models

- Building cost elements into the forecasting model
  - Faster or slower enrollment period and/or changes in duration of treatment impacts monthly fees
  - Clinical Monitoring units increase with duration of treatment
  - Dynamically updates closeout period based on timeline shift

- Utilizing CRO Reporting to anticipate the need for change orders

- Modelling for sunk cost if a study will be terminated

- Does the use of vendor reporting for accrual improve predictability?
Challenge of Real-Time Decision Making

STUDY #1

2015-Q1_FC
2015-Q2.FC
2015-Q3.FC

Challenge of Real-Time Decision Making
Informing Strategic Decisions

- Timely notification to management of studies which are at risk
  - Shared responsibility
  - Straight-forward communication enables prompt decision-making
- Informed analysis of the cost impact of delays, challenges and/or mitigation strategies
- Awareness of the changing clinical landscape and thoughtful discussion between Finance and Clinical teams
- Risk Adjustments and Mitigation Strategies
- Portfolio Flexibility – How are teams and budgets structured?
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Questions / Further Discussion?

THANK YOU!