Clinical Trials SIMULATOR

Reduce risk and accurately forecast recruitment with Clinical Trials Simulator

pain

Clinical studies account for almost half of the over one billion dollar cost of drug development. More than 80% of all clinical trials experience significant delays, the cost of which can exceed $35,000 a day. Patient recruitment and retention in clinical trials are widely recognized as the leading clog in the new drug development pipeline. The unfortunate result of this problem is that pharmaceutical, biotech, and medical device companies spend millions in additional development costs – and lose hundreds of millions in revenue.

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Clinical Trials Simulator is a user friendly decision support technology that takes into account all the inherent variability in Clinical Trials and generates realistic data on how patient recruitment will perform so you can make better decisions, faster.

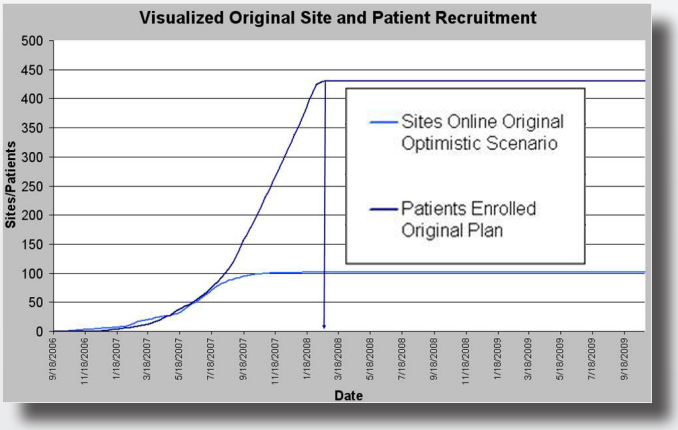
Clinical Trials Simulator's design and easy to use interface gives you the power to:

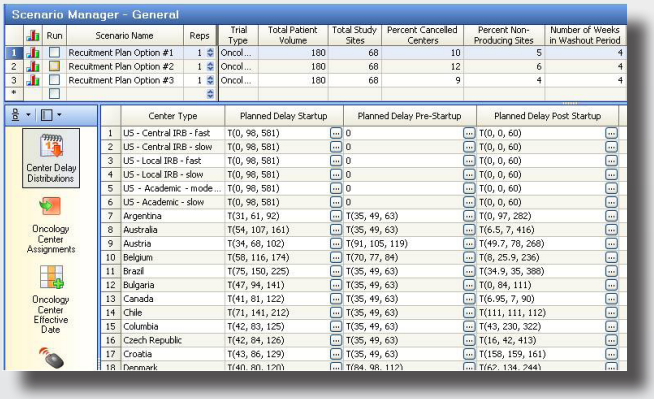
- Experiment with and optimize the number of sites any trial will require.
- Mitigate risk around recruitment by accurately projecting "True" patient enrollment and retention.
- Accurately project trial milestone dates such as FSFV, LSLV or close out.
- Accurately forecast the cost of the optimal trial solution.

methodology

1 Visualize

Determine how your current site and patient recruitment plans will realistically perform.





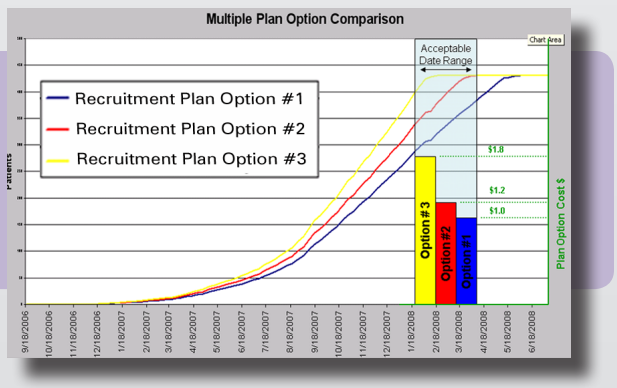
2 Analyze

Define study plan options such as:

- Number of sites per country
- Site schedules
- Patient enrollment rates
- Site recruitment rates
- Protocol modification

3 Optimize – New True Optimization!

CTS can now automatically find the optimized site selection combination and patient recruitment plan at the lowest cost AND closest to the clinical trial milestone delivery dates.



ProModel

VISUALIZE ANALYZE OPTIMIZE VAO

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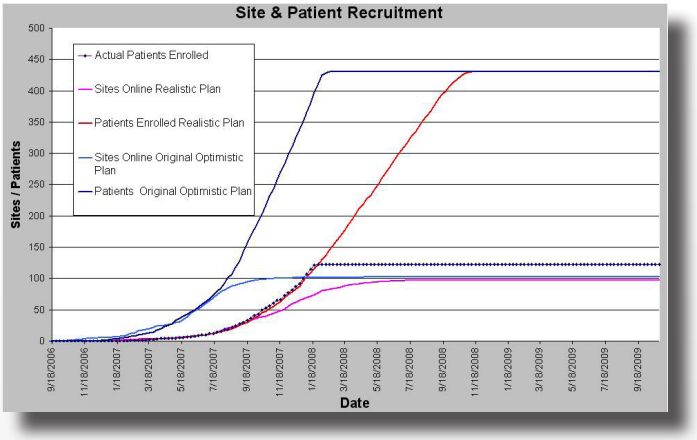
CLINICAL TRIALS SIMULATOR ADVANTAGE

Designed for clinical trials likely to exhibit uncertain recruitment performance, ProModel's Clinical Trials Simulator will help you mitigate risk during planning and execution of clinical trials by:

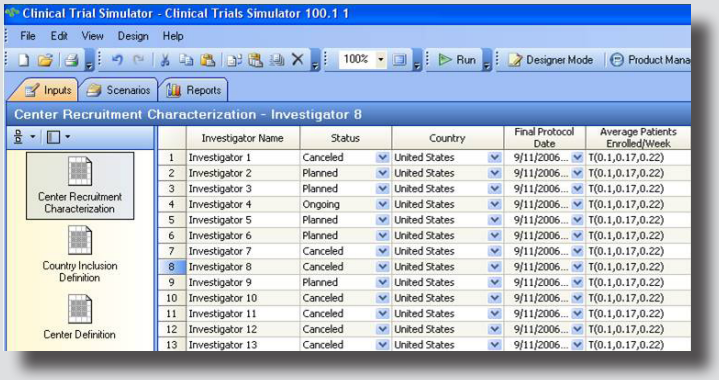
- Predicting accurate site and patient recruitment.
- Selecting the optimal list of test centers from a known list of centers using the optimization feature.
- Reducing the risk around projecting study milestones, fulfillment and completion.
- Reliably predict the resources, money, and API requirement times to execute a trial.
- Providing a profile of FTE requirements that will be required to coordinate study activity.
- Enabling decision makers to manage and adjust to events of the actual trial while it's being conducted.



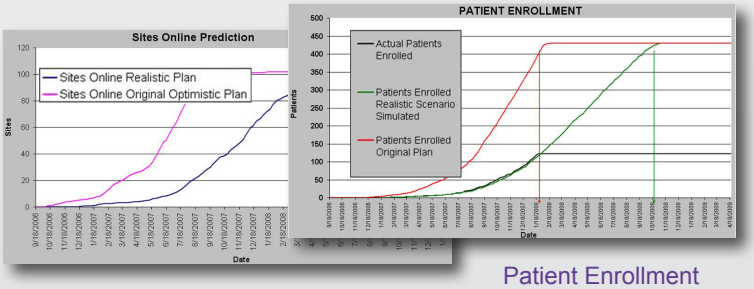
Site and Patient Enrollment Prediction Compared to Actuals helps Manage the Trial while its Underway.

Inputs

- Center Recruitment Characterization (or estimates)
- Country Inclusion Definition
- Center List & Definition
- Qualification delays
- Costs
- Recruitment Protocol Definition
- Number of patients required
- Diversity requirements
- Pharm Sci Requirements
- Forecasted Trial Milestones and Completion Timing



Center Recruitment Characterization Input



Site On-Line Timing Prediction Scenarios

Patient Enrollment Prediction Scenarios

Outputs

- Accurate projection for protocol completion date and cumulative cost
- Accurate projection of site and patient recruitment rates
- Ongoing trial monitoring (compare actual vs. projected)
- Optimized list of "Best Choice" test centers for use in the clinical trial

Clinical Trial Simulator ***Milestone Summary Table***

Designed to give the user an easy to read single table for examining system performance ac

Scenario Update Completed; Click to Reset

Number of Reps	Scen	Description	FSFV	Elapsed Time (Weeks)	FSFD	Elapsed Time (Weeks)	LSFV	Interim Assess 1	Interim Assess 2	Endpoint Event
50	1	Realistic Scenario	02/05/07	2.60	02/23/07	89.31	11/09/08	05/16/08	08/10/08	11/30/08
50	2	Optimistic Scenario	11/06/06	2.86	11/26/06	60.09	01/20/08	11/21/07	01/22/08	04/07/08

tech specs

Hardware Requirements	Minimum	Recommended
Processor	Pentium 4 – 1.2 MHz	Pentium 4 – 2.4 GHz or Faster
Memory	512 MB RAM	2 GB RAM
Operating System	Windows 2000 Service Pack 2	Windows XP Service Pack 2
Video	SVGA Monitor (1024 x 768 x 16 bit color)	SVGA Monitor (1280 x 1024 x 32 bit color)
Other Hardware	3 GB Available Hard Drive Space CD ROM Mouse	3 GB Available Hard Drive Space CD ROM Mouse Internet access
Optional Software	ProModel Project Simulator	

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