

IVRS

perceptive
INFORMATICS™

tcVisualize™: Supply Chain Simulation *with real-time integration*

Accurate prediction of clinical trial supply needs can have a significant impact on the cost of packaged supply, the cost of a study as a whole, and the total future revenue of pipeline drug. Only supply chain simulation makes such prediction possible.

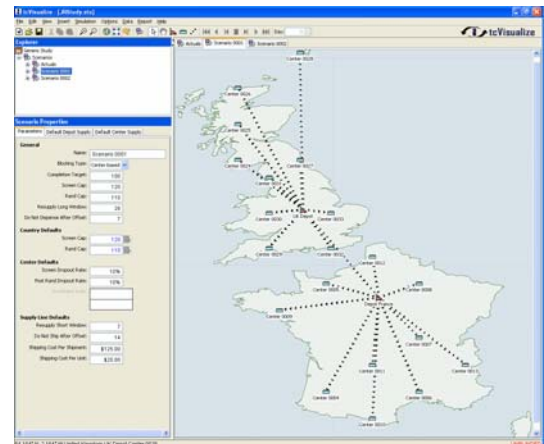
tcVisualize software can provide answers to critical supply questions – both before and during a trial – by quickly bringing the supply picture into view. A highly effective predictive tool for pharmacy, clinical, and support teams, tcVisualize scenario modeling allows full understanding of the impact of supply plans as early as the protocol design stage; integration of forecasting capabilities with actual trial data allows ongoing monitoring of global supply. The software can assist in answering important questions like, "How long will this current supply last?" – in an easy to use visual format right on your desktop. The tcVisualize software puts control in the hands of the supply team.

The Perceptive Solution

tcVisualize software allows easy supply study set up via its friendly user interface, its wizard-driven interface, or through XML study definition imports. The software imports study set up data from existing systems, and runs simulations over different supply chain scenarios. The tcVisualize solution allows users to vary blocking type, countries, number of sites, enrollment rates, dropout rates, supply lines, and a host of other parameters. The visualization feature allows quick set up of studies: key data can be entered directly, and the global supply picture can be drawn directly on a map.

tcVisualize software can run an entire study forward in time to its conclusion, virtually. A world map can display actual day-by-day conduct of the study, including subject enrollment and progress at sites, drug consumption, and resupply activity.

A blended resupply algorithm in the tcVisualize software allows simple floor/ceiling based resupply, and a consumption forecast algorithm covers all predictable dispensing visits.



One of the most useful attributes of the tcVisualize software is its simulation view. This view, which includes a Gaussian enrollment variance adjuster, and permits the user to turn off predictive algorithms, enables the modeling of a range of real-world specifics. Details such as the effect of sending partial shipments or of stopping patient enrolment for centers that fail to resupply fully are just a few of the things that can be modeled..

A range of scenarios can be created with varying parameters – such as supply at depots, placement of depots, blocking type, number of sites, enrollment rates – for use in the fine-tuning of re-supply settings. Since certain study designs naturally waste a lot of drug, and others are naturally efficient, modeling allows up-front knowledge of whether the amount of drug on hand is sufficient to support a planned study, or if a given number of sites and countries can be supported with the amount of drug planned.

It can also be beneficial to see the supply wastage impact of a seemingly small decision like whether to block randomizations purely at the center (site) level, or, instead, at some other level. Factors such as blocking type, number of dispensing visits, number of sites, length of supply lines, and positioning of sites can all have dramatic impacts on supply need and waste, and should be considered during study planning before the drug has been packaged.

Drug shortfalls during study conduct can cause unplanned lost subjects, health risks, closing of study centers,

unplanned drug wastage, and ultimately study delay. All of these factors are visible in a tcVisualize simulation, and all may be tuned out of your supply model – given expected enrollment rates – during the study planning phase.

Perceptive has all the data you need in its IVRS, including drug assignments, drug assignments, global stock (at sites, depots, and in transit), global population study progress, recruitment trends (including dropouts), and resupply configuration (including trends and dropouts). Real time integration is available.

Perceptive IVRS and tcVisualize give a combination of functionality unavailable anywhere else. Together they set a whole new standard of predictability and control for the clinical supply chain.

Features:

- Supports variable, fixed dose, dose escalation, crossover, double dummy, and other trial designs
- Easy trial set up via friendly user interface, wizard-driven interface, or XML import
- Easy to use : Average user productive in 1-2 weeks
- Wide variety of algorithm and simulation controls allow modeling of nearly any real world scenario
- Simulates combination of floor/ceiling and predictive algorithms for depots and sites
- Graphical rendering of simulation and summary stats
- Import and export capabilities
- Powerful scenario comparison reporting at all levels, including live trial data
- Encryption and blinded mode available for live study data Actuals data loading for on going supply chain monitoring and mid study simulations

tcVisualize Benefits:

- Baseline global supply for bolus packaging or initial expiry period
- Implications of planned overage, including for multiple countries, depots, and lots
- Effect of depot placement, resupply parameters, and shipping lead times
- Stockouts, lost subjects, overage, and waste
- Aggregate costs of drugs and shipments
- Actual global supply and subject population
- Projected end of enrollment, end of study
- How long current supply will last

tcVisualize software is produced by Tourtellotte Solutions, Inc., a strategic partner of Perceptive Informatics.

Perceptive at a Glance

Perceptive Informatics brings together comprehensive clinical knowledge, experience and leading-edge technology. We combine these qualities into a portfolio of business support applications and complementary services that optimize the process of product development and commercialization. Our customers are forward thinking pharmaceutical, biotechnology and medical device companies and associated service providers.

The product mix is built upon four key focus areas, each making extensive use of innovative technology:

IMAGING ▪ CTMS ▪ IVRS ▪ INTEGRATION

Each element is designed to deliver practical and tangible results, decreasing the time, cost and risk associated with the development and launching of new products.

It is reassuring to know that our professionals have a combined clinical and technology background. This means that, more than most, our products and services accommodate the needs of the regulated world (such as computer system validation and 21 CFR Part 11).

Our tried and tested solutions are used by many of the world's leading pharmaceutical companies.

perceptive
INFORMATICS™

A PAREXEL Company

For more information,

Call us at: +1 866 289 4464
Perceptive Informatics, Inc
200 West Street
Waltham, MA 02451, USA

Or at +44 (0)121 616 5600
Perceptive Informatics UK Ltd
Four Brindleyplace,
Birmingham, B1 2JB, UK

Or at +49 (0)30 30685 5075
Perceptive Informatics, Inc
Klinikum Westend, Haus 18
Spandauer Damm 130
14050 Berlin, Germany

Or email us at: info@perceptive.com
www.perceptive.com

Perceptive Informatics is a trademark of Perceptive Informatics, Inc. All other names or marks may be registered trademarks or trademarks of their respective owners and are hereby acknowledged.

Powering the pipeline through technology™