



BioClinica® Optimizer

Simulation, Optimization & Forecasting

WHY CLINICAL SUPPLY FORECASTING IS BENEFICIAL...

Avoid inadequate site buffers which can result in:

- Lost subjects (due to stock-out)
- Statistically questionable randomization techniques (skip, force, early rand)
- Emergency remediation such as site-to-site transfers
- Frustrated investigators and patients
- Sudden buffer increases which can empty the depot

Avoid depot stock-out which can result in:

- Inability to resupply sites
- Lost subjects on a large scale - even predictable (enrolled) subjects are at risk
- Extreme emergency remediation such as constant manual supply monitoring and very frequent site-to-site transfers
- Emergency packaging runs for replenishment
- Halt of enrollment or trial delay

Study dimensions supported by simulation:

- Variable Dosing
- Label Groups / Country Labels
- Dose Configuration
- Pooled Drug Studies
- Arbitrary Events

Modern clinical trial designs require sophisticated planning. Global logistics, complex designs and delicate biologics are just a few things found in modern trials. Methodologies of the past are incapable of applying the complex characteristics of today's trials to produce viable forecasts.

BioClinica Optimizer allows you to design unlimited supply chain scenarios and vary relevant study parameters – from a global level down to a site level. Simulated results can be analyzed and modified to create the ideal clinical supply chain.

BioClinica Optimizer is the world's foremost clinical trial supply forecasting solution.

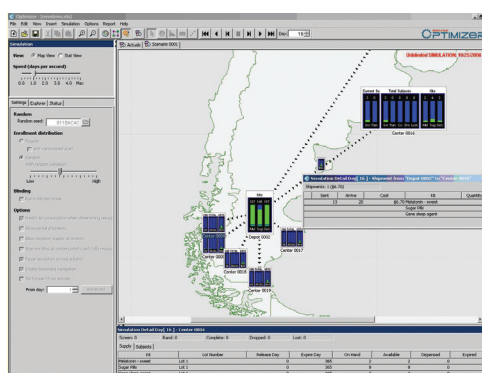
What is Simulation?

Simulation is a process that replicates a real-world system or environment in order to predict actual behavior. Simulating study scenarios can help identify and mitigate supply crisis, study delays and unnecessary overages.

What is Optimization?

Optimization helps define the minimum thresholds for site stock and local country depots using your specific shipping lead times. Finding your maximum unpredictable demand over time allows you to change your minimum stock levels as the study progresses, e.g. dropping off as enrollment or other unpredictable events become complete.

Forecasting & Simulation



Optimization

Update scenario

Initial: Initial = Floor % over floor qty over floor Other

Initial = Ceiling % over ceiling qty over ceiling

Ceiling: Ceiling = Floor % over floor qty over floor Other

Update country

Initial: Initial = Floor % over floor qty over floor Other

Initial = Ceiling % over ceiling qty over ceiling

Ceiling: Ceiling = Floor % over floor qty over floor Other

Update centers

Initial: Initial = Floor % over floor qty over floor Other

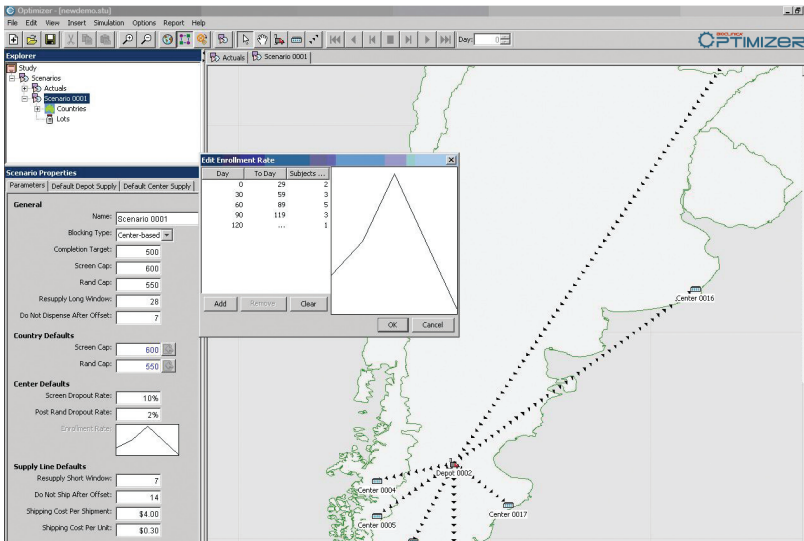
Initial = Ceiling % over ceiling qty over ceiling

Ceiling: Ceiling = Floor % over floor qty over floor Other

BIOCLINICA® OPTIMIZER

With BioClinica Optimizer

- Manage more variables and complexity with ease. Use the tool specifically designed for clinical supply coordinators.
- Power your clinical supply chain forecast with the most sophisticated optimization technology available.
- Communicate plans more effectively with stakeholders using clinical supply scenario visualization.



How to Eliminate Unnecessary Overage:

Minimize drug waste with the world's only buffer stock optimizer. By calculating the necessary and unnecessary Overage Thresholds, the Optimizer can determine minimum buffer stock required at sites and depots.

➔ Necessary Overage (site overage)?

- Supports enrollment and unpredictable dosing at sites
- Likely to be wasted at sites
- Important to understand how much is required to avoid crisis
- Planned site oversupply can be saved
- Site overage can be decreased over time in many cases

➔ Unnecessary Overage (primary depot overage)?

- Not required by reasonable range of scenarios
- Will never be shipped
- Planned primary depot oversupply can be saved

How to Fine Tune Costs:

BioClinica Optimizer helps to create multiple scenarios to illustrate cost trade-offs by comparing supply costs vs. shipping costs and supply costs vs. risk tolerance.

How to Manage Expiry:

BioClinica Optimizer provides the tools to plan drug lots more efficiently by considering expiry during supply planning and trial conduct.

How to Minimize Overage:

Minimize overage through accurate modeling of multi-depot supply chains by modeling required regional depots, optional country depots and 3+ level depot chains. BioClinica Optimizer helps minimize the overage required at depots.

About BioClinica

BioClinica, Inc. is a **leading global provider** of integrated, technology-enhanced clinical trial services. BioClinica supports pharmaceutical and medical device innovation with:

- Imaging core lab services
- Internet image transport
- Electronic data capture
- Interactive voice and web response
- Clinical supply chain design & optimization solutions
- Clinical Trial Management System (CTMS)

BioClinica services maximize efficiency and manageability throughout **all phases of the clinical trial process**. With more than 2,000 successful trials to date, BioClinica has supported the clinical development of many new products from early phase trials through final approval.

BioClinica operates **state-of-the-art**, regulatory compliant imaging core labs on two continents, and supports worldwide eClinical and data management services from offices in the United States and Europe.