

ClinPhone® MedSim

Base your supply planning on reliable forecasts

Key features

- **Simulation of the clinical supply chain**
- **Calculation of clinical trial supply needs reducing unnecessary coverage**
- **Exploration of minimum supply requirements to commence study**
- **Determination of the timing and content of study production runs**
- **Mid-study simulation of clinical supplies using snapshots from the real-time trial supply management study database**
- **Estimation of an informative prediction range rather than simple “on average” forecasts**
- **Estimation of supply needs for adaptive trials**

Supply Chain Simulation

Clinical trials face increasing challenges as a result of the drive to bring new drugs to market faster. During clinical drug development, manufacture of bulk active ingredients and production of the clinical trials formulation is performed in parallel with the clinical trials program. Careful planning is required to ensure that sufficient medication is available and forecasted in the supply chain to meet the needs of ongoing and future studies. The acceleration of clinical research often means that studies must start with shorter lead times and with less raw material and therefore fewer supplies available.

The ability to conserve the quantity of medication required for clinical trials may be limited by the ability to estimate the amount required with any accuracy. Simulating the trial supply chain process enables the medication savings associated with the use of randomization and trial supply management systems to be calculated and realized.

ClinPhone® MedSim provides trial supply simulation and forecasting consulting services, performed by our in-house statisticians and technical consultants. Produced by statistical and medication management experts, our simulation model represents a state-of-the-art approach to supply chain forecasting.

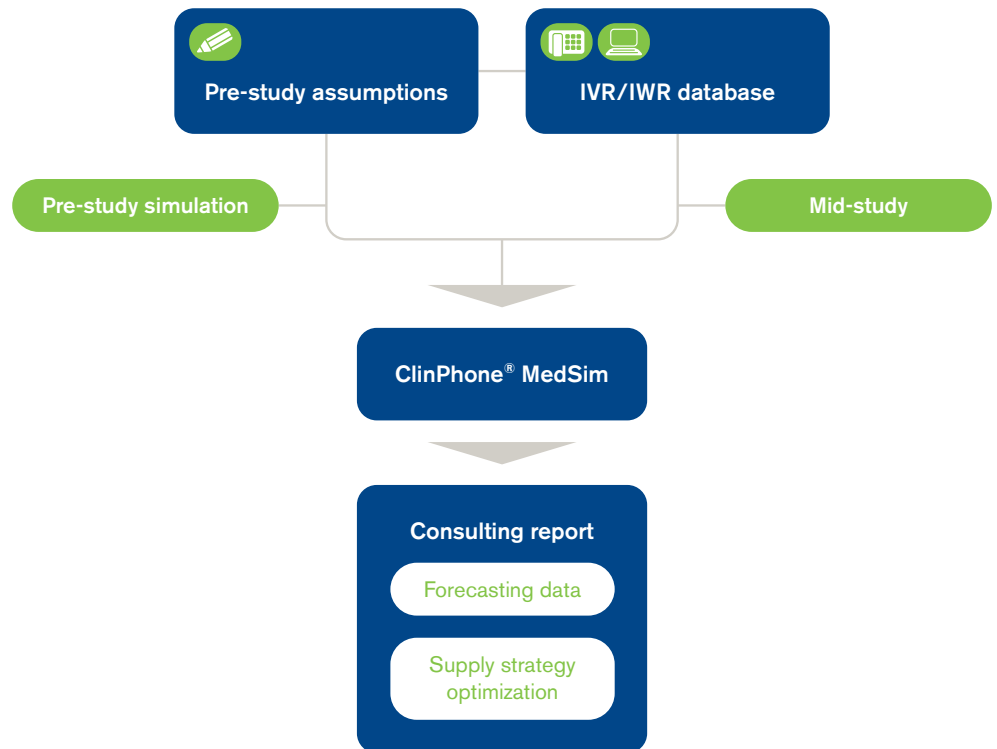
Solve Real-World Problems

Used in both study planning and ongoing study evaluation, ClinPhone MedSim yields expert advice on these important questions:

- What quantity of supplies does the study require?
- What minimum quantity of supplies is required to commence the study?
- What are optimal dispensing unit/medication kit sizes?
- What will happen if recruitment is faster or slower than anticipated?
- Is there enough drug available to complete the study?
- When should additional production runs be scheduled?

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- What is the impact of being unable to extend medication expiry dates?
- What is the impact of opening additional countries or centers?
- What should be the timing and content of the next mid-study production run?



Sophisticated Modeling

ClinPhone MedSim uses simulation modeling techniques to provide the answers to clinical supply chain quandaries. Our approach allows sponsors to create a variety of “what if” scenarios to optimize the supply chain. Using a Monte-Carlo simulation approach, we perform thousands of runs based on the scenarios we define with you. With this technique, our simulation model accounts for real-world randomness, such as variation in enrollment rates, to determine the range of possible outcomes and the likelihood of medication shortages. This is far more informative than a simple average projection which fails to account for chance events influencing the results such as slow recruitment.

Interpretation and expert advice is provided as part of our consulting service. We aim to provide your study team with the information needed to make informed decisions.

Key Benefits

- Measure the effectiveness of a supply strategy pre-study and understand the factors that put the strategy at most risk
- Optimize overage requirements so that drug supply savings associated with the use of randomization and trial supply management systems can be realized
- Calculate the timing and content of future production runs using all known information about the current and potential study performance
- Minimize risk of running out of study drug
- Solve complex problems such as medication estimation for titration studies and adaptive trial designs