



Tessella SFT:

Supply Forecasting Tool

Drug supply in clinical trials is an increasingly complex operation, trying to balance the conflicting requirements of:

- Ensuring there are always adequate supplies at centres to support recruitment and the re-supply of existing subjects
- Minimizing the amount of material required to run a trial
- Avoiding forced randomization of patients

These requirements have been made harder to achieve by the introduction of Adaptive Clinical Trial designs, which require central randomization, and vary the proportion of allocation of subjects to the different treatment arms during the trial in an unpredictable way.

Tessella has combined its extensive experience solving complex problems in the pharmaceutical and biotechnology industries with its experience in advanced statistical modelling and clinical trials to produce the Tessella Supply Forecasting Tool (SFT) allowing users:

During **Trial Planning** to:

- Forecast drug supply needs and costs based on study design, recruitment rates, drug formulation and packaging, and manufacturing and logistics
- Plan optimal production and delivery schedules
- Explore the possible consequences on supply and cost of different recruitment rates or delivery times
- Consider different packaging options
- Test the effects on both supply and cost of different re-supply algorithms and methodologies, including fixed ceiling/floor models as well as adaptive re-supply algorithms
- Explore stratification in treatment groups
- Consider the effects of changing relative allocations of treatment groups at pre-defined points in the trial
- Reduce unnecessary waste in production, distribution use and re-supply
- Optimize the drug supply chain, regardless of the number of 'arms'



And in the future, during **Trial Execution** to:

- Import current trial data to accurately forecast needs, based on up-to-the-minute supply inventory information
- Recommend shipments needed to ensure adequate supply at depots and centres
- Determine the amount of materials needed to reliably supply the remainder of the trial

Tessella SFT employs sophisticated statistical models to generate realistic and scientifically accurate forecasts of:

- The likelihood of losing subjects due to the lack of supply
- The number of subjects that can be recruited for a given amount of drug
- The amount of drug required to reliably recruit a given number of subjects

At the core of Tessella SFT is an advanced simulation engine, based on a mixture of statistics including the **Poisson distribution, Binomial distribution and Bayesian analysis techniques**.

SFT is the only tool in the marketplace to combine all of these techniques into a sophisticated simulation engine.

The result of this combination allows advanced modelling and multiple simulations therefore increasing the accuracy of **your results**.

Key features of Tessella SFT

Accurate forecasting ... hundreds of simulations in minutes

Adjustable re-supply algorithms

- Fixed regime with floor/ceiling levels set per location or location type
- Bayesian adaptive regime – you specify look ahead period and minimum and maximum tolerable probabilities for supply outage

Comprehensive coverage of factors that affect supply

- Trial sites, randomization, batch size, availability, expiry
- Probability of damage
- Drug expiry rates
- Uncontrollable factors such as delivery time, actual recruitment rates, titration
- Recruitment profiles

Explore and compare ...

- Multiple re-supply algorithms
- Treatment and distribution pack composition
- Trial site or shipping changes
- Protocol/re-supply algorithm changes

Support for site-based, central, stratified and adaptive randomization

Summary reports and graphs

- Fast, easy access to current reports and easy-to-understand graphs of the current state of supply, shipments, patient recruitment

User-defined report generation

Simple integration through our standard XML interfaces

Easy-to-use interface

Highly customizable providing **YOU** with the results that you need

To find out more about how the Tessella Supply Forecasting Tool can help your business please email info@tessella.com

Tessella plc 26 The Quadrant, Abingdon Science Park, Abingdon, Oxfordshire OX14 3YS, UK
T: +44 (0)1235 555511 | F: +44 (0)1235 553301 | E: info@tessella.com

Tessella Inc 233 Needham Street, Suite 300, Newton, MA 02464, USA
T: 1 617 454 1220 | F: 1 617 454 1001 | E: info@tessella.com

Tessella – successfully delivering IT and consulting services to world leaders in R&D, science and engineering.

For decades, Tessella has been successfully delivering IT and consulting services to world leaders in R&D, science, and engineering. Through the application of scientific methods and rigorous quality procedures, we enable clients in life sciences, energy, the public sector, and consumer industries to achieve a wide range of objectives, including, forecasting floods, developing fusion power, enhancing military sensor capability, increasing drug discovery and development efficiency, and reducing risk to health and the environment in the extraction and production of oil and gas. With offices in Europe and North America, global companies rely on Tessella for business critical assignments.

Copyright © Tessella plc 2009, all trademarks acknowledged. Issue: V1.R0.M0 | 18-Jan-2009



www.tessella.com