tcVisualize™ General FAQ

Q: How does the per-protocol software license work?

The tcVisualize per-protocol license is controlled by a read-only setting which is applied to all "protocol definition" tabs in the application. This includes definitions such as kits, visit schedule and dosing.

Protocol level settings ("protocol setup") are created and configured by Tourtellotte resources, potentially along with an initial scenario if desired. Any required changes to protocol level settings may be communicated to the TS team and will be promptly turned made and sent back to the customer.

Although the protocol configuration is read-only, there is no limit on the number of scenarios, simulations, tcOptimizer runs, etc. that the customer may carry out. As always, there is also no limit on the number of installed copies (seats). Scenarios contain data such as countries, depots, sites, supply chain configuration, lead times, lots, enrollment curves, and resupply parameters. There is no limit on scenarios under the per-protocol license.

Q: Is there a per-seat license or other seat limit on number of users?

All current tcVisualize software licenses are unlimited-seat licenses, subject to the constraints of the licensing contract. Some licenses are restricted to particular protocols, others restricted in time, but there is generally no limit on how many users or machines may be installed with tcVisualize within a licensee company.

Q: How do you address manufacturing demand forecasting or enterprise forecasting?

TS has been moving towards an integrated demand forecast and plans ultimately to deploy a separate application (the Enterprise Demand Aggregator) for this purpose. In support of this, tcVisualize has the capability to model items at the sub-kit level, including API/dosage forms, kit materials, or anything else that is desired in terms of cost or output. All output can be rendered in terms of kits (dispensing units) or API (anything that goes into a kit).

It is also currently possible to model demand for multiple studies or even an entire program simultaneously by using tcVisualize pooling functionality.

Q: What training services are available?

A number days of training is typically bundled with the software license. This is usually provided in half-day session, one per week. However, any schedule within reason will be accommodated. Additional training can be provided at a rate of $1,200 per day.

Q: What application support is available?

Application support falls into two categories. First is trouble-shooting problems encountered running simulations. For example, a user is losing all subjects to stockout, or a simulation won't run. These are typically problems with the way certain entities are configured. It is expected that there will be issues of this sort, especially in the beginning, and that they will typically trail off over time. This support is included with the Software License at no additional charge.

Second is support in actually developing studies. Some clients prefer direct assistance in the development of tcVisualize study files in the early stages or for complex protocols. Tourtellotte Solutions provides this type of analysis on a fee basis. Current fees are $1,200 per day, once a pre-agreed number of hours are expended. Because TS is very interested in users successfully modeling studies in tcVisualize, our staff is very responsive in assisting customers with study modeling.

What has proven successful at some clients is developing a core of expertise in-house. These resources can then be used to assist others within the organization in addition to Tourtellotte Soultions provided support. TS is also willing to assign its own staff full or part time to a customer on a longer term consulting basis, or until customer staff are comfortable enough with the tool that TS is no longer needed.

Q: Do you have professional consulting services available? Do you have partners that support your consulting services?

Yes, consulting services are available. Tourtellotte Solutions maintains a substantial consulting organization representing more than half of its staff. We do not currently employ partners for consulting services.

Q: Is tcVisualize a validated application?

tcVisualize is a planning and forecasting tool, and does not store or manage any transactional data. Although tcVisualize is subject to a rigorous set of quality standards, it is not considered a validated application under 21 CFR part 11.

Q: What is tcOptimizer and how does it work?

tcOptimizer is the world's first site buffer stock optimizer, made available as a plug-in module for tcVisualize. Based on tcVisualize scenarios with or without actual data from IVRS, this tool can suggest appropriate resupply floor (safety stock) parameters to for use in simulations or in IVRS. Results are available at any degree of granularity in time and geography. tcOptimizer works by measuring "unpredictable" demand at sites over the shipping lead time, and gathering and compiling statistics over a series of tcVisualize Monte Carlo simulations.

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tcVisualize™ Technical FAQ

Q: What hardware does tcVisualize run on?

tcVisualize is available as both a desktop and a client-server based application. The J2EE server option is available, but not required. The same desktop application is used with the server-based option – thus it is required in either case. Client communication to the server is via Web Services.

...more: although a server option is available, tcVisualize is primarily a desktop application and thus there are no out of the box requirements for application servers, web servers, database servers, etc. The standard desktop installation is a java/swing application with an internal database, which runs entirely on the client machine. Data storage is achieved using standard local or shared file systems.

Q: What are the desktop system requirements?

Tourtellotte recommends a desktop or laptop with 2G RAM and a 2GhZ processor, if possible. However, tcVisualize is known to run on as little as 700M RAM and 1.3GHz machines. tcVisualize performance is a function of the size and complexity of the study being modeled (as well as other background processes running on the machine in question). For example, a 5 country study with 100 sites, 600 randomized subjects, and a medium duration visit schedule can run at speeds exceeding 1 Monte Carlo simulation (end to end) per second. We have found that performance is linear with processor power.

Q: Is there a server version of tcVisualize? Why / what does it do?

Yes. Occasionally, tcVisualize users need to process very large studies (e.g. 20K subjects in 40 countries over 5 years) or pools of studies all operating together, or would simply like to offload simulation processing from the desktop. One option in these cases is to ship off the studies to a server-mounted simulation engine (essentially the same tcVisualize engine that exists on the desktop, but on a bigger machine somewhere else) for processing. The results can then be pulled back to the client whenever the user wishes. The server-based implementation is merely a way to put the simulation engine on larger hardware, and not in any way a transactional or validated system nor does it control any operational data.

Q: What are the server system requirements?

The tcVisualize server based implementation can run on either Weblogic or JBoss application servers, with Oracle as the RDBMS. As with the client, a minimum of 2G RAM and 2GHZ processing power are recommended. We have found that given adequate RAM, study processing speed will scale linearly with processing power. Additional details can be found in the tcVisualize server based architecture document.

Q: What version of the Java virtual machine is required?

tcVisualize requires JVM version 1.6, which is bundled with the installation.

Q: What external integration points are available for tcVisualize?

tcVisualize is built around an XML schema which allows for import and export of study and scenario design, as well as import of actual live data from IVRS. tcVisualize also has the capability to import data such as site definitions, center activations and enrollment rates through .csv. Also, all tcVisualize statistical result tables are one click exportable to Excel (.csv). Finally, tcVisualize is able to export its relational data store for external analysis. tcVisualize does not currently integrate directly with MRP or other systems to reference kit or material definitions, but this level of integration is planned for the future.

Q: How does "actuals integration" work?

Actual trial data defining live lots/kits at depots and in the field, subjects, and visit histories is usually available from IVRS, or other sources. If this data can be extracted from the source and placed into the proper XML format, then tcVisualize can read current state from a running protocol. Alternatively, if the data is available in .csv format, TS can develop translators to convert the data to XML, and we have done so for several customers.

Each data file is a full snapshot of all relevant data for the running protocol. Actual data feeds may be performed as often as once per day, or as infrequently as desired by the customer. With actual data in tcVisualize, it is possible to browse and monitor global disposition of all sites, subjects and supply. It is also possible to "sim forward" – take the current state in the field and play it forward to its conclusion. Finally, if any future issues are detected, it is possible to "test drive" study or scenario modifications such as adding more centers to increase enrollment.

tcVisualize also contains tools to analyze actual data around subject enrollment and variable dosing probabilities, with the ability to overlay assumptions with data derived from the running study.

Q: What backup and recovery models are supported?

There are no recovery models specific to the product itself. it is compliant with models typical of an n-tier, J2EE implementation.

Q: Does the system maintain an audit trail?

The models that are developed within tcVisualize are file based and there are no central audit trails maintained.

Q: Describe security model for users and data objects.

The system uses LDAP for user Authentication. The system also employs Role Based Access Controls (RBAC) to enforce blinding of data as required.

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