

Virtual Panel System

Web-based Technology to Help Manage Independent Review Panels

Clinical trials are relying upon independent event and data review committees with increasing frequency. Clinical Endpoint Committees and Clinical Event Committees play important roles in monitoring patient safety. However, the timely collection of data from such committees is frequently challenged by the logistics of having to bring committee members together. This challenge is heightened by the use of thought leaders on committees, whose busy schedules may inhibit the review process. While it is possible to distribute copies of information to decentralized reviewers for some programs, data can be difficult to copy or the quality may be inadequate, such as with medical images.

A lengthy panel process limits the ability for Sponsors to make timely decisions based upon review committee findings.

The Perceptive Solution

Perceptive's Virtual Panel System (VPS) is a web-based application that combines the functionality of a document repository with electronic data capture. The VPS distributes clinical endpoint data electronically to virtual panel members for review and then collects their assessments using electronic data capture forms. The application incorporates sophisticated workflow management and query management tools to make the process highly efficient. The system is developed, validated, hosted and managed by Perceptive Informatics.

When an event or endpoint occurs, clinical data is collected and scanned, or uploaded, to a document repository to create an electronic dossier for the subject. Once a dossier is complete, it is placed in a work queue for one or more of the virtual panel members. Each reviewer accesses the secure website, reviews the case and completes the data capture form online. Built-in edit checks help ensure that clean data is collected at the time of entry. System logic can check for concordance between reviewers and schedule tiebreaker or further reviews of an event if necessary.

The system was designed with flexibility in mind. The VPS can accommodate any number of users and reviewers and users are defined with specific privileges based on their role. Depending on the needs of the specific trial, the various tasks of collecting clinical data and creating patient dossiers can be performed by users located at different organizations, such as a trial Sponsor, CRO or an independent review facility.

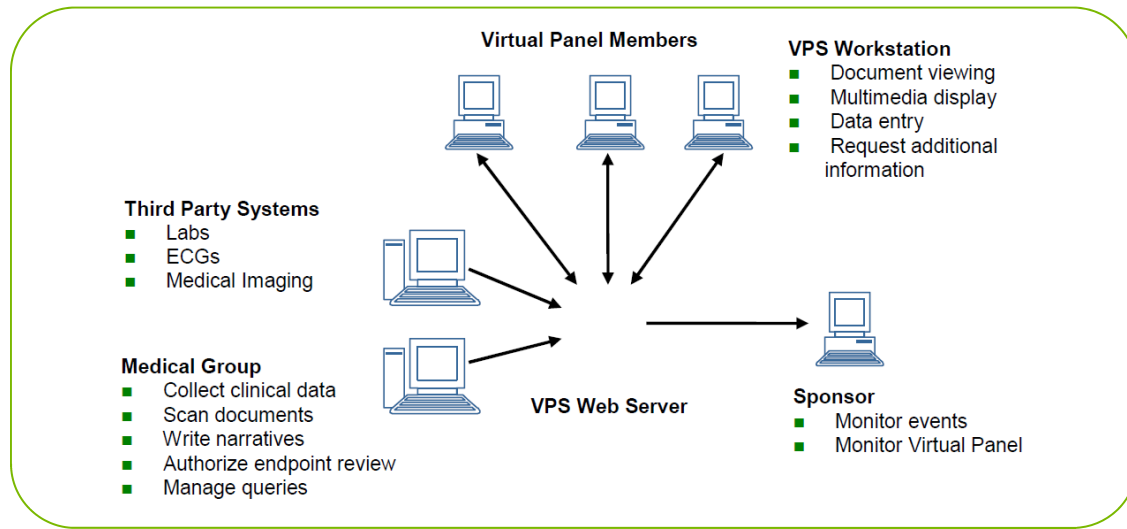
Features

- Web-based distribution of clinical data to virtual panel members
- Workflow management tool for streamlining the review process
- Sophisticated query generation and management tool
- Electronic data capture of panel member findings
- Adjudication logic to trigger a tiebreaker review
- VPS reports for Sponsor
- Support for virtually any type of clinical data, including medical images, to be uploaded into the document repository
- Regulatory compliant (21 CFR Part 11), validated and secure system

Benefits

- Alleviates the need for panel members to meet in person, saving the time, cost and logistical challenge of getting everyone together
- Permits international review panels to be more easily employed for your clinical trial
- Eliminates cost of shipping paper CRFs to panel members
- Reduces the cycle time for the review panel to perform its assessments
- Provides cleaner data through the use of electronic data capture and online edit checks
- Performs concordance checks and triggers tiebreaker reviews automatically
- Gives Sponsors immediate access to review findings through VPS reports

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The diagram above illustrates how the application operates in either a hosted or licensed environment.

Suggested/Example Therapeutic Applications

- Cardiovascular disease
- Oncology
- CNS disorders
- Anti-Infectives (HIV)

Types of Independent Review Panels

- Clinical Endpoint Committees
- Clinical Event Committees

Perceptive at a Glance

Perceptive Informatics brings together exceptional clinical knowledge, experience and leading-edge technology. As the industry's leading eClinical solutions provider, 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, CROs and associated service providers.

Our versatile, comprehensive eClinical suite is built upon six areas, each of which makes extensive use of innovative technology:

ClinPhone RTSM ■ Imaging ■ CTMS
EDC ■ ePRO ■ Solutions

Each element of our eClinical suite 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 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.

To learn more about how our solutions can help you, please contact us at info@perceptive.com.