

Virtual Clinical Adjudication System

Increasing speed and efficiency of endpoint adjudication

Key features

- **Web-based distribution of clinical documents and collection of independent assessments**
- **Workflow and query management for streamlining the review process**
- **Adjudication logic to trigger a tiebreaker review**
- **Reports to give sponsors immediate access to view adjudication findings**
- **Central document storage for all types of clinical data, including medical images**
- **Secure electronic environment that is regulatory compliant (21 CFR Part 11)**

Key Benefits

- Alleviates the need for committee members to meet in person, saving time and cost
- Enables international review committees utilizing the best doctors for a therapeutic area
- Eliminates costs for printing and shipping of source documents to committee members
- Reduces cycle time for review committee to perform assessments
- Improves data quality through use of eCRFs and online edit checks

Clinical endpoint adjudication, the assessment of patient events or outcomes, by an independent committee – whether for randomization, efficacy or safety – is increasingly common in today's clinical trials. Clinical Endpoint Committees (CEC) are formed for a study, consisting primarily of physicians, to review all relevant documents and provide adjudication. Performing these reviews in a paper environment is challenged by the logistics of scheduling committee members to gather in a central location, as well as the collection and printing of all relevant documents to be delivered to that location, affecting the timely completion of assessments.

The Perceptive Solution

Perceptive's Virtual Clinical Adjudication System (VCAS) is a web-based application that facilitates central management of adjudication activities in a paperless, collaborative and auditable environment.

When an event or endpoint occurs for a subject, relevant clinical documents such as ECGs, labs or radiology reports are collected in VCAS to create an electronic dossier. Once a dossier is complete, VCAS automatically notifies reviewers via email and allows easy access to the secure website where reviewers can analyze the appropriate dossier, and record their assessments. Built-in edit checks help ensure that clean data is collected at the time of entry. The completed reviewers' assessments are compared by the system, and if discordance is found, the dossier is automatically reassigned for tiebreaker review. The application incorporates sophisticated workflow management based on a CEC Medical Charter. The electronic query tools available within the VCAS are able to manage the

Virtual Clinical Adjudication System

real-time nature of the review cycle between sites and investigators, enabling the overall workflow to be highly efficient.

The system is designed with flexibility in mind. The VCAS is role-based and can accommodate any number of users and reviewers with specific privileges based on their role. Depending on the needs of the specific trial, it is possible for the various tasks of collecting clinical data and creating patient dossiers to be performed centrally, or by users located at different organizations, such as a trial sponsor, CRO or an independent review facility.

Suggested/Example

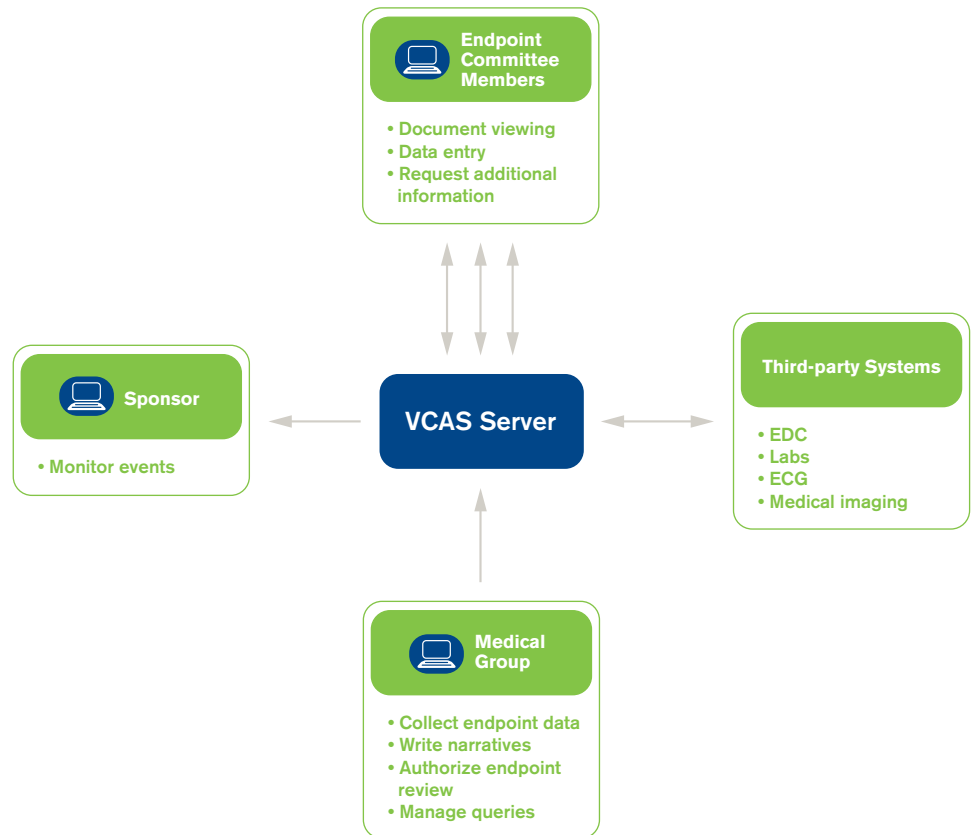
Therapeutic Applications:

- Cardiovascular disease
- Oncology
- CNS disorders
- Anti-Infectives (HIV)
- Inclusion/Exclusion, Enrollment, Randomization

Types of Independent

Review Committees:

- Clinical Endpoint Committees
- Clinical Event Committees
- Data Safety Monitoring Boards



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