



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

“Clinical Trials Eligibility Database (CTED) – Automated Assessment of Patients for Inclusion in Trials”

VCU #07-011

Applications

- Drug developers may use CTED to enhance patient recruitment and reduce costs
- Clinicians may use CTED to increase their level of participation in clinical trials
- Provides notification to the clinical staff regarding the patient's potential eligibility

Advantages

- Reduced cost and increased efficiency
- Assures that all patients are evaluated
- May be adapted and used with many different electronic data formats
- Patients with an appointment or change in clinical status are evaluated for eligibility
- Allows for better targeting of clinical trials by the clinical practice

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Market Need

Clinical trials for new therapeutic compounds are costly and time consuming endeavor. Patient recruitment is an increasing challenge. Pharmaceutical and biotechnology companies as well as clinical research organizations wish to quickly recruit patients eligible to participate in each trial. Community physician practices and hospitals also participate and enroll patients in clinical trials. Ideally, physicians will introduce their patients to the relevant trials and will be able to educate those patients on the merits of participating in the trial. However, only 14% of patients participating in clinical trials were actually informed of their trial by their doctor first (Thompson CenterWatch). The high patient volume, limited visit time and the large number of clinical trials available make it difficult for clinicians to identify and discuss appropriate trials with their patients. Further, the clinical inclusion and exclusion criteria for each trial are typically very specific, further complicating the process by which clinicians match a patient to a trial.

Technology Summary

To address these issues, VCU researchers have developed the Clinical Trials Eligibility Database (CTED) as an automated tool for use by clinical staff to prescreen patients before their office visit for eligibility in clinical trials. CTED uses information from multiple electronic in-house sources including historical billing and clinical test results to build an eligibility profile for each patient. The consolidated longitudinal profile of clinical information captured through these electronic sources contains sufficient clinical detail to permit accurate eligibility assessment of every patient for every clinical trial in the system. As a visit is scheduled, the patient's eligibility profile is automatically screened against the selection criteria for each clinical trial in CTED. When a match occurs both the clinician and the research nurse are informed prior to the visit, giving them an opportunity to discuss the trial with the patient and make a determination if there are other barriers to participation (such as patient emotional state etc.).

Technology Status

CTED is being implemented at the VCU Medical Center

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This technology is available for licensing to industry for further development and commercialization.