The Clinical Trials Eligibility Database: tools and functionality.

Software system developed to assist in quickly and efficiently screening and identifying potentially eligible patients for Clinical Trials (CT) or other research studies. The system integrates four key areas of the clinical trials recruitment process- automated matching, screening, notification of providers and tracking of eligibility status over time. There are 3 integrated components of CTED that were created to perform these functions:

- Automated Matching Tool
- MD Alert
- Tracking system

**CTED Automated Tool**

Offers an automated electronic solution to enhance efficiency in screening patients for CT eligibility. Queries are developed specific to each clinical trial, and validated prior to completing production scheduling. The use of scheduled automation assures that all patients are screened for eligibility (based on current clinical status for each patient). This means that each patient seen anywhere within the VCU Health Care System is screened for eligibility for each CT specific query that is in production on a regular basis as established by the scheduling process. As a patient’s clinical status changes they are automatically screened to re-assess eligibility over time. The list of potentially eligible patients is available with linked documentation to the research staff and/or PI. The list may also be sent through the MD Alert system as described below.

The AutoMatch system selects patients based on combinations of discrete variables as well as easily customizable searching of free text including the following sets of patient characteristics:

- Demographics
- Diagnoses
- Treatments
- Clinical Laboratory test results
- Text strings/terms unique to each study
- Algorithm-derived complex clinical concepts (e.g. Newly diagnosed metastatic disease from radiologic dictations)

**CTED MD Alert**

The alert tool links output data from Automatch (patients matching study specific eligibility criteria) with the VCU scheduling system each night. If a patient on a list from the Automatch query is scheduled for a next day visit, then designated personnel (research nurse, treating physician etc) receive an email alert directing them to a secure website 24 hours prior to the scheduled visit. These information may be accessed at any time (even at the point of care). The alert has a live link with Oncore, where a trial icon can be clicked to obtain more detail on the study protocol for which the patient is eligible. The alerts identify patients who are potentially eligible for specific trials and provide an opportunity for the provider to refer that patient to the appropriate research group with a single click. If a patient is referred, an email notification is sent to the research staff, and an evaluation is created in CTED Tracking.

**CTED Tracking**

This tool was the original system developed to track eligibility screening of cancer patients prior to entry in clinical trials. The system tracks:

- ongoing eligibility status of patients (outcomes and details of eligibility screening)
- research staff workload associated with eligibility determination
- physician clinical trial behaviors (referrals/discussions with patients about trials)
It provides information to the administration to direct interventions that directly target accrual barriers in OUR patient population. It is integrated with the Clinical Trials Management System (ONCORE) and auto-populates data fields for enrolled patients. It provides ongoing access to clinical data for enrolled patients and has a real time link with clinical trial menu information. Similar to the AutoMatch tool, the Tracking tool provides linked, longitudinal clinical information on all patients for more detailed manual eligibility screening by research staff including the following:

- Demographics
- Diagnoses
- Treatment
- Clinical notes from all providers (dc summaries, radiology notes etc.)
- Pathology (surgical and clinical)

CTED is maintained under an IRB approved protocol as a “registry” used for “preparatory to research” evaluations.

To request data or access to the CTED system or to request the development of a query to identify potentially eligible patients for your study, please click on the following link [http://www.massey.vcu.edu/online%20service%20request%20form.htm](http://www.massey.vcu.edu/online%20service%20request%20form.htm) and submit a request using the fillable pdf.