

# Automating Information Dissemination and Trials Management—Maximizing Efficiency and Recruitment by Publishing Protocol Information

Kimura, K (UCSF); Chahal, A S (Velos Inc.)



## Background

Organizations conducting clinical trials are finding increasing value in publishing trial protocols and results on the web<sup>1</sup>. Hundreds, even thousands, of trials may be ongoing in one organization, and regulatory scrutiny is intense. The traditional approach of updating the webmaster through a file output of a non-electronic internal process is fraught with omissions and risks. Wei et al, have suggested that the potential to use websites and related processes for recruitment is high<sup>2</sup>. We report here on processes entirely set up in an automated electronic loop from and to the clinical research staff, and some preliminary results.

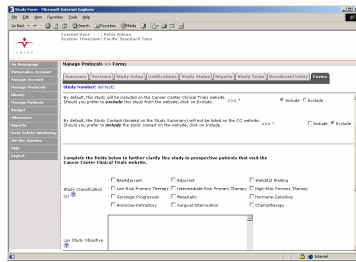


Figure 1. Trial 'Publish to Web' Form / Process in Velos

## Methods

An approach, currently being used at the University of California in San Francisco, is presented. Protocol information and updates, and regulatory permissions, which are normally managed in a clinical and trial management system, are part of a logical, automated throughput to the trials web site. Information entered by individual protocol managers and approved for external presentation and dissemination over the web is automatically handed on. Internal surveys and reports from the system itself were used to quantify results. The process behind this automation, which eliminates multiple levels of data entry, file management, and redundant information, is discussed and demonstrated.

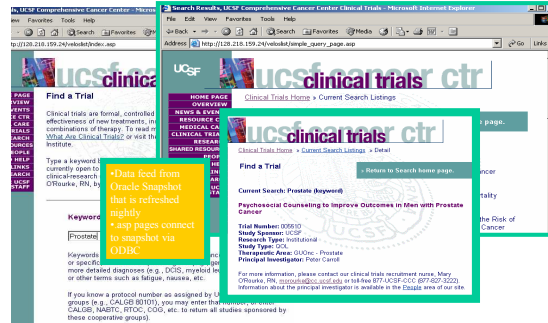


Figure 2. UCSF CC Clinical Trials Website

## Process

- Clinical research staff enter and manage the protocol/study in the system (Velos—a clinical trial information management system).
- A workflow configured by UCSF teams allows entry of a 'lay' summary for the protocol. Each form has a configurable workflow embedded. When the protocol is approved by the IRB, the status of the protocol is changed to 'Active/Enrolling'.
- At a configurable frequency (currently nightly at UCSF), the system updates a database snapshot with details for display on the site, and includes the 'lay' summary and eligibility criteria for the active trials.
- This information is displayed in a format that fits the general presentation in the website, independent of more specialized formats used in the system.
- If a protocol is completed or suspended, this is reflected by the omission of the protocol from the snapshot and hence the website.
- Prospective subjects review the protocol on the website, and contact the appropriate research RN listed on the site.
- A process created and configured in Velos to document answers to pre-screening questions is completed. This information is available for reporting, audit, and querying.

## Results

Though this automation is only part of the full enrollment process, internal reviews have since shown that 57% of all recommendations for possible trial enrollment were initiated by website lookups of trials and 52% of trial inquiries to the recruitment nurse were from the website. The protocol dissemination was timely, efficient, error-free, and recruitment efficiency increased with savings in staff time expended, while regulatory compliance was assured.

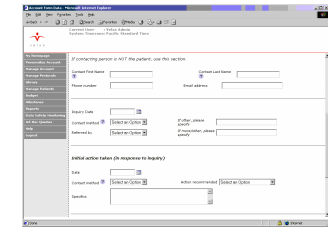


Figure 3. UCSF Clinical Trial Inquiry Form / Process

## Discussion

A systems infrastructure and configuration to manage several significant processes in clinical trials has been presented. The timely and efficient management of such distributed workflow in the clinical environment contributes significantly to enrollment, while ensuring compliance and enhancing good practice. The process outlined is relevant in information dissemination about protocols to:

1. websites for the lay public;
2. Journals for pre-publication registration;
3. research peers in controlled broadcasts of available protocols; and
4. Websites for pharmaceutical / biotech companies seeking controlled, transparent processes to publish trial results.

## References

1. Simon C, Hegedus S.: Contemp Clin Trials. 2005 Oct;26(5):530-3 Exploring websites on cancer clinical trials: an empirical review.
2. Wei SJ, Metz JM, Coyle C, Hampshire M, Jones HA, Markowitz S, Rustgi AK; J Clin Oncol. 2004 Dec 1;22(23):4730-6; Recruitment of patients into an internet-based clinical trials database: the experience of OncoLink and the National Colorectal Cancer Research Alliance.