



# Electronic Data Capture in Clinical Trials Management Challenges in Deployment at an NCI Comprehensive Cancer Center

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## BACKGROUND

Internal discussions identified three **key issues** in research operations at our center: excessive duplication of effort, too much paper, and data latency in critical operations, such as, protocol patient accrual reports, and protocol status.

The deployment of Velos™ eResearch (a Clinical Trial Management System (CTMS) by the UCSF Cancer Center Clinical Research Support Services (CRSS) office allows both the office and Clinical Research Coordinators (CRCs) to enter and manage protocol and patient information. Investigators, PRC members, and CRCs are assigned permissions based on their program role and their signed "Sensitive Data" request form. While training and support is provided by the CRSS, our model suggests developing a "super-user" within each program.

## IMPLEMENTATION AND BUY-IN

Specific strategies were used to ensure key players became supportive users of the new systems infrastructure.

- Implementation goals focused on:
  - Protocol Review Committee (PRC)
  - Pharmacy Rollout
  - NCI Data Reports

Based on our 2 year experience with 200 plus users and over ten thousand protocols, we report a successful major institutional transition from a paper based system to an entirely web-based infrastructure.

## Protocol Review Committee (PRC)

Encouraging full electronic data entry to minimize multiple paper copies, and ensuring faculty compliance by an electronic signature requirement.



**PRC Application** – The first part of the form is completed using lookups to pull data already entered on other pages

**PRC Full Committee Review** – The PRC Reviewer uses this form to complete their review of the protocol. Selecting their role on the form determines which fields will be completed

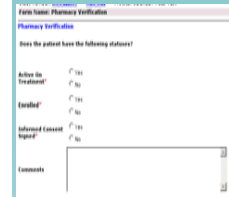


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## PRC Cost Metrics

## Pharmacy Rollout

Allows pharmacists to have access to protocol and patient data to verify compliance regulations and ensures CRC data entry into CTMS.



**Pharmacy Verification form** – The pharmacist uses this form to verify that the patients have met the requirements to receive the therapeutic agent

**Pharmacy Verification AHQ** – The Velos analyst runs the ad-hoc query (AHQ) to monitor which patients do not meet the patient status requirements.

## NCI Data Reports –

Encouraging clean and timely patient accrual for both therapeutic and non-therapeutic cancer studies.

## CONCLUSION AND RECOMMENDATIONS

Clearly articulate operational and human benefit in the project, and ensure systems are seen as part of that plan;

Ensure definition of the metrics of success are defined and measured;

Decide and pursue common research processes that are of primary interest to the research team—such as, consolidating entry on one electronic form that will be utilized for multiple reporting agencies, saving time by eliminating duplication of effort.

Solicit and incorporate ongoing feedback from end-users in an effort to focus on harmonizing the goals of the user and the applications, and ultimately the organization.

## ACKNOWLEDGEMENTS

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