The Way to High Returns on Systems for Clinical Trials

- Focus on Clinicians and Coordinators –

June 2003

About Author

Amar S. Chahal, M.D., M.B.A,

Director/co-founder Velos. Dr. Chahal has over 20 years experience in development of major clinical, financial, scheduling, and clinical research systems for large healthcare software providers and pharmaceutical companies.

Co-author Priti Sahai, M.D., M.P.H,

Dr. Sahai is currently Senior Product Manager of Velos eResearch and has been involved in all aspects of product design, development and project management since the inception of the product.

The Argument

This paper presents a simple and powerful change in the way technology infrastructure for clinical trials should be conceived and implemented. We argue that the workflow at research sites, and a systems build-out from that workflow, is at the heart of a systems model that will pervasively address the myriad issues in trial implementation, efficiency and safety. Current approaches to trials focus on functions, such as data collection, IRB management, or monitoring. By pivoting the entire clinical trial infrastructure around the workflow of the field workers and clinicians at the sites, the system provides pervasive returns to all participants in the trial, from patient to sponsor, and creates an infrastructure that allows clinicians and managers to methodically extend the depth and reach of good clinical practices.

A Traditional View

In the design and conduct of clinical trials, the Principal Investigator (PI) is the lead scientist or clinician responsible for the trial, and the Sponsor (an institution or a company) provides the money needed for the trial.

"To get returns from infrastructure, we need to reach beyond technology and beyond data-¦, back to the clear and fundamental principles of human engagement and management."

In view of the objective to obtain "good" data, and the significant funding needs, it is only natural that the needs and issues of the Sponsor receive the most attention. After all, they are paying for it. However, sponsor supplied software, focused on the needs to return data back to the sponsor, creates an exclusionary world where appropriate entry of data for a single protocol is the sole focus, and where multiple separate and distinct systems support trials for multiple sponsors. While marginal improvements for Sponsors are available through "Remote Data Capture", it's not a stretch, in our view, to suggest that Remote Data Capture is as much a solution to clinical trial process challenges as band-aid strips might be to a gun-shot wound.

A large team is involved in helping the Investigator and Sponsor achieve their aims through the conduct of a quality clinical study with an appropriate focus on safety and good practices. This team may include a design team of physicians, nurses, statisticians and scientists; an internal review board (IRB); clinicians (including physicians, nurses, technicians); patients or participants in the study; study coordinators; and research assistants, among others. A study involves the collection of data, usually in paper or electronic Case Report Forms (CRFs). But to deliver that quality data in time, with appropriate safety and reporting mechanisms, important steps are taken beyond simple data collection in what we call the current reality.

The Current Reality

The current reality in clinical trials encompasses all the actions, interactions, preparation, administration, and management that goes on around the CRF, which itself is relatively static.

These actions involve, but are not limited to pre-screening, screening, budgeting, IRB status management, inclusion/exclusion reviews, registration, scheduling, reminders, management of the clinical record, patient information delivery, tracking, coordination, reporting to various regulatory authorities (local, state, federal and sponsor related), and billing and financial management. And, there are more!

Except in studies that involve a very complicated or novel procedure, the actual clinician-patient or clinician-participant encounter is usually well-delineated and efficient. Inefficiencies occur mostly in the activities listed above– which are those other than the clinician/patient interaction. The single common thread in managing all these activities is the clinician, the clinical nurse or the coordinator. To create returns and efficiencies across the entire system, it is logical, therefore, to focus on creating returns and efficiencies for these field professionals.

Software – The traditional View

The systems approach to support clinical trials today is overly manager- and output-oriented– a model better suited to data entry clerks.

"Infrastructure has to adapt to the current reality. Software for clinical trials must focus on the users who are in a position to create the greatest benefit for the entire clinical trial process: the coordinators and the clinicians in the field."

It is insufficiently workflow oriented, failing to consider the day-to-day issues of the team involved in the actual 'execution' of a trial. This focus away from the field is the overwhelming limitation for system-based improvements in clinical trials. Without significant improvements here, once the relatively marginal improvements of Remote Data Capture are squeezed out, any gains come to an abrupt halt.

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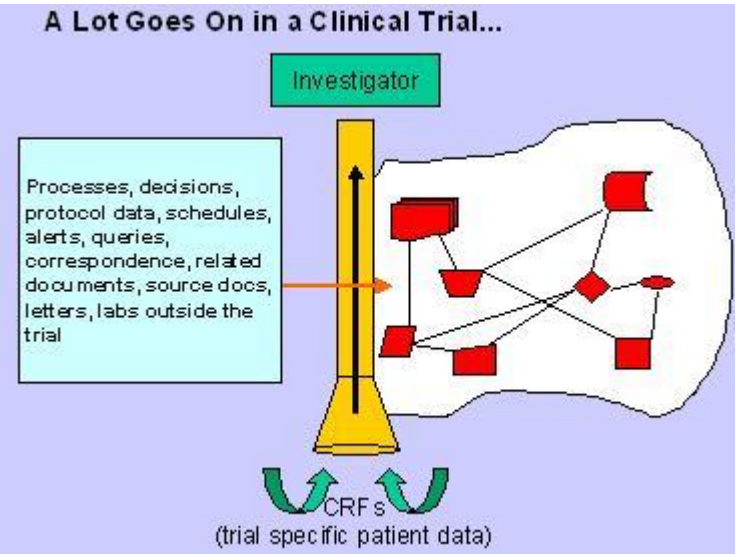
The end user in the clinical world–most often the clinician or coordinator–derives little benefit from such a system, as seen by the ratio of his or her interaction with the system when compared with returns. In such environments, managers "push" the system through threatened problems related to human resistance and non-compliance. As in many other instances where management is trying to deliver benefits that are not directly of interest to the people actually performing the task, the system has a high inherent risk of failure. There are innumerable examples of such sponsor- and site-initiated system failures over the last 5-10 years, some a good deal more visible than others.

Infrastructure has to adapt to the current reality, and software for clinical trials must focus on the users who are in a position to create the greatest benefit for the entire clinical trial process: the coordinators and the clinicians in the field.

Investing Instead in the Clinicians and Coordinators

The clinical research staff spend much of their time preparing for and managing critical interactions between the various groups. All information passes through, is stored by, or is acted upon by the coordinator and the clinical staff at the site. An infrastructure that looks to support their problems will provide benefits to them and other constituents in the team.



Provide a Return to the Coordinators and Clinicians

The clinicians on site must not only fill in case report forms, they have to log all interaction with monitors and patients; manage recruitment, screening and enrollment; manage schedules and reporting; track sub-investigators and sites; and fulfill reporting obligations internal to their organization: Data and Safety Monitoring, Audits, IRB status management, and NCI and institutional reporting. They must also manage Adverse Events, both clinically and on paper. Later, they often perform, help or advise on the billing, and sort out co-pay and other patient reimbursement issues.

By organizing, centralizing and automating many of these functions, or the infrastructure for these functions, a clear and significant incentive exists for the staff in the trenches of clinical research to use the system, and to make the human investment required to create an efficient infrastructure.

Understanding and supporting the essential and pivotal role of the clinician and coordinator in the execution of a clinical trial is central to the design of a system to manage studies and their execution. The deployment of such a system then provides immense benefits to the entire community involved in clinical research.

By delivering an infrastructure that provides near-term returns to the coordinators and clinicians, system designers should

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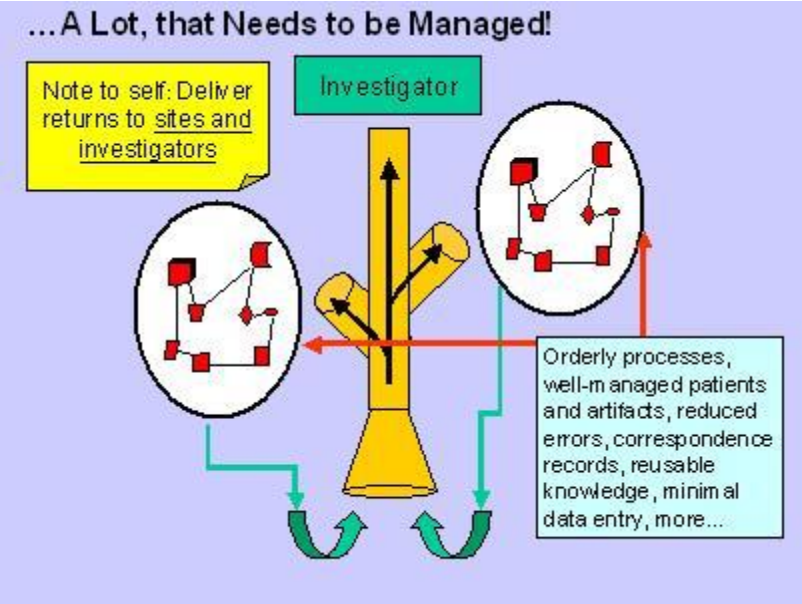
- **Automate Budgeting, Review and Billing**The coordinator logs events for each patient (with a single click!) and the financial managers and the billing office automatically have access to the information in a format friendly to their needs. While avoiding double entry of information is laudable, the larger benefit is the genuine numbers of dollars saved by appropriate and timely information collection, and milestone-based billing on complex contracts.
- **Centralize Correspondence and 'Notes to File'**The system should provide a methodology to allow storage, tracking and wide availability of correspondence and notes, which often are lost to multiple filing systems on multiple desks at multiple sites. The inability to centrally record and universally (for that team) view a simple explanatory sentence behind some patient or clinician action, often an administrative action, can create a significant issue at a later date. Clinicians and coordinators spend inordinate amounts of time responding to queries, and then keeping records of those queries.
- **Manage IRB status and Compliance**Automated, time or milestone based reminders to appropriate staff members allows centralized control and review of timely submissions and actions to ensure compliance with IRB directives and good standing with that office.

- **Review and Act Upon Issues in Patient Compliance**In a complex world with multiple studies and varying degrees of latitude toward patient schedules, the system provides the sponsors and the clinicians with warnings and connectivity to recruit appropriately, track needs and close without needless recruitment and disappointment.
- **Easily Manage Regulatory Reporting**The system eases the burden of regulatory reporting, which sometimes takes weeks of effort in record review and report compilation. It also provides easier audits, controls, and audit trails on the events, the information and the management of trials.

  The benefits accrue to these various constituencies from a clear objective of enabling the coordinators. Excluding CRFs, almost no data entry occurs outside "check-offs" in a sound basic infrastructure for the trials deployed for the coordinator. Yet, even in a system of paper case report forms, monitoring can be extended worldwide, and all the way to the sponsor's desktop! And the IRB, the DSM committee, the clinicians involved with the patient directly, and the billing and financial staff can all receive reports, manage functions, and avoid multiple entry and management of the same information. What's more, addressing these needs is less expensive, required less behavior change, and involves lower project risk than many sponsor-driven initiatives.

  Deliver Returns to the Principal Investigator

  The infrastructure should focus further on the needs of the Principal Investigator (PI).
- **Provide a "Single Sign-on" Environment**The PI may be involved in multiple studies, and the systems infrastructure needs to give him or her the environment for a single login to access all protocols, data and teams within his or her purview. This results in an ability to track patient recruitment by site, compliance and adverse events. It gives the PI an ability to manage many trials authoritatively and efficiently. None of this is possible in the systems paradigm currently envisioned by many.
- **Allow Instant Network and Site Creation**Staff for a PI on one study should be able to create sites and teams for a study in real time, and store (centrally with 'from-anywhere' retrieval) the documents needed for that protocol. Thus, a site that has some familiarity with the system should be able to "switch-on" with just one outgoing message. A significant problem currently dogging the world of electronic infrastructure is the cost of training staff for electronic management of any given protocol. Recurrent use of a single infrastructure will go a long way to reduce that cost, as measured in time, quality, and cash outlay.
- **Allow Sponsors to track Progress**The PI needs to allow some sponsors to 'see' how the trial is progressing in administrative terms. The technology needs to give the PI the ability to easily create access for a sponsor team member, who can then see relevant reports.
- **Connect Through Messaging and Alerts**With a well-designed infrastructure, the PI is 'connected' through alerts, messages, and broadcasting abilities that provide efficiency and support urgency. By designing processes and protocols for a network with this messaging infrastructure, the PI has available all necessary information with appropriate safeguards for information access and hiding in place. This minimizes or avoids ad hoc, undocumented messaging and querying–a constant source of administrative and communication issues.

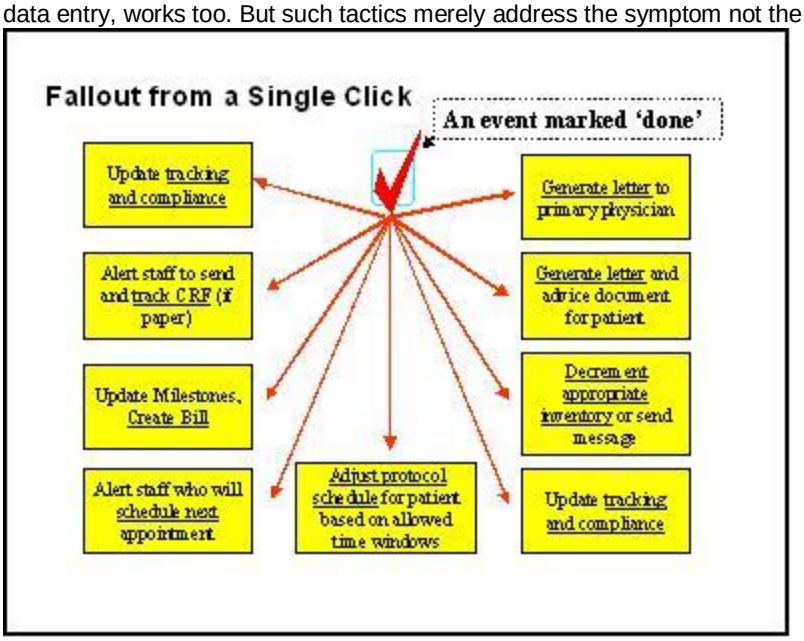


Be Inclusive of Patients and Sponsors

The investment in this kind of infrastructure also provides an environment that is inclusive; it provides benefits for, and interaction with, both patients and sponsors.

At the simplest level, patients can see and read about protocols on the Internet, be provided with relevant email alerts about new protocols, and, where such interaction is permissible, receive email reminders on schedules and reading materials. Alternatively, messaging for patients can be sent to a central resource that can then use these messages to remind or inform patients telephonically.

Sponsors benefit both directly and indirectly. They benefit directly by access to good tracking, workflow and messaging mechanisms. They benefit indirectly by knowing in advance the kind of infrastructure a site will provide, the mechanisms the site will use, and by being able to ensure protocol-specific good practices are incorporated into real workflows that real research professionals use from day to day. These are really very basic capabilities for which system support is only feasible if clinicians and coordinators use systems — which in turn will only happen if they see there is benefit to system use. Admittedly, “bribing” sites to use Remote Data Capture systems, by tying payments to data entry, works too. But such tactics merely address the symptom not the cause.



Invest in People for Returns

Investing in an infrastructure that focuses on the problems of the clinical and site staff in the world of clinical trials creates an environment where:

- Protocols are better managed
- Recruitment and retention are easier
- Practices and processes are embedded for and visible to all participants
- Document, Process and Communication errors are minimized or avoided
- Billing is efficient and timely
- Direct benefits accrue to all participants

The 'Single Click Fallout'

The example of events that are generated in and around a protocol from a single click by a clinician or coordinator marking a given event as "done" provides a striking review of efficiencies, automation, and communication derived from the infrastructure concepts expressed here.

When such an example is interpreted at a multi-site level in a large trial, or in multiple instances for trials at the same site, the advantages are multiplied significantly for the investing institution, PI or sponsor.

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In Summary – Steps to High Returns

The returns from investing in an infrastructure for clinicians and coordinators, helping them manage their workload and problems, are immense.

> "The high return proposition is a system that creates an infrastructure and provides returns to all participants in a trial by supporting the workflow of the research staff in the field."

The investment for such returns should look for a systems infrastructure that

- Is workflow, not function, oriented
- Focuses on the clinician and the coordinator
- Is ubiquitously available
- Allows for a gradual implementation (from patient or protocol registry to scheduling to document repository to other functions including electronic data capture), in any order for a given department or institution

By tailoring initial rollout to local needs, and growing with a simple plan that avoids long training sessions that clinicians cannot find time to attend, the clinical trials team can create an environment with a clear return on investment, together with significant quality of life and quality of work improvements. The high return proposition is a system that creates an infrastructure and provides returns to all participants in the trial by supporting the workflow of the research staff in the field. . By addressing the entire issue of clinical trials from the perspective of the teams on the front lines of trial execution, and executing to that objective, a wealth of value will emerge.

About Velos

Velos is a leading designer and developer of next-generation healthcare information systems. Velos develops, markets, and supports an integrated suite of clinical, administrative, and financial products. Velos' internet services and turnkey solutions address the information needs of healthcare providers and investigators in clinical research and medical specialties. Velos is privately held with headquarters in Silicon Valley.

About Amar S. Chahal, M.D., M.B.A.

Director/co-founder, served Velos from September 1996 to Present as a Director and from September, 1996 to November 2000 in the capacity of Executive Vice President and Chief Technology Officer. Dr. Chahal is the original visionary behind the Velos product lines. From 1992 to 1996, Dr. Chahal oversaw the healthcare business unit of Software Services International, Inc, now Aithent, of which was also a co-founder. It that role, Dr. Chahal oversaw development of major clinical, financial, scheduling, and clinical research systems for large healthcare software providers and pharmaceutical companies. From 1990 to 1992, Dr. Chahal provided consulting services to Merck.

From 1983 to 1989, Dr. Chahal practiced orthopedic medicine for the National Health Service in England. In 1982, Dr. Chahal directed a primary care hospital in Punjab, India. Dr. Chahal holds an MBA from Columbia University; Fellow, Royal College of Surgeons, Scotland; MD, Armed Forces Medical College, India.

About Priti Sahai, M.D., M.P.H.

Senior Director, eResearch, joined Velos in April 2000 and brings to Velos extensive expertise in the Internet and healthcare industry. Dr. Sahai is currently Senior Product Manager of Velos eResearch. She has been involved in all aspects of product design, development and project management since the inception of the product. Prior to Velos, Dr. Sahai worked in the field of Public Health where she successfully combined her medical and computer skills to design, develop and implement health programs for AIDS, womens health and health education. She was a key member of the professional team at Indian Society of Health Administrators (ISHA) that provided analysis of policy-changing healthcare data to the Government of India. Dr. Sahai holds an MBBS (MD) from Lady Hardinge Medical College, Delhi, India and a Master of Science in Community Health and Health Administration.