

# How to Implement Investigator-Side Clinical Research Systems

## - Learning from the Mistakes Made With Clinical Information Systems –

July 2002

### About



### Author

[John S. McIlwain](#) is President and CEO of Velos and currently serves on management boards of several leading-edge software and healthcare-related companies.

[The Dilemma](#)

[The Challenge In Clinical Research](#)

[The Four Constituencies](#)

[Providers – The Opportunity for](#)

[Change](#)

[What about the Internet?](#)

[How Can Study Sponsors Help?](#)

[Those Information Systems Budgets!](#)

[The ROI Story – much easier than you think!](#)

### The Dilemma

In the early 1990s, McKinsey and Company, the highly respected management consulting firm, estimated that more than \$200 billion dollars could be saved per year in the U.S. through improved use of information in healthcare. That's an incredible figure, amounting to more than \$300 per person/per year in the U.S.

However, these savings are not quite so staggering when one considers that we spend about \$1.3 trillion dollars per year on healthcare – 15% of our Gross National Product. That's double the amount of money spent on healthcare by other westernized countries with mortality rates as low as ours. In short, there are huge opportunities for value improvement. After regulatory forces, information systems are among the most potent systemic tools we have for such improvements.

Much of what needs to be done involves getting clinical information systems into use by caregivers. Unfortunately, most information system innovations over the past few years were eliminated through a combination of issues:

- Implementation ineffectiveness by both software vendors and healthcare providers
- Some flawed ideas that spoiled some good ones

As a result, hospital CIOs are stuck with a handful of entrenched legacy vendors, cumbersome products, old, disintegrated, poorly designed software, high price points, and time-consuming implementation models. On average, if one aligns the enterprise clinical system implementation lifecycle with the CIO turnover, one clinical system will take three CIOs to implement. Obviously, something needs to change.

The lessons learned developing and implementing patient care information systems are largely applicable to the narrower, but equally available, opportunity of improving clinical research. Let's discuss the issues and then see how a solution can be implemented.

### The Challenge In Clinical Research

The benefits of implementing investigator-side clinical research systems are threefold:

- Facilitate and expedite discovery and development of new therapies, drugs, and devices
- Avoid wrongful death
- Save time and money

**Facilitating Discovery and Development.** In the January 2002 issue of R&D Directions, Styli Engel, Editor-in-Chief, opened with an update on the Tufts Center landmark work on Drug Development costs: \$802 million is what it costs now to develop one prescription drug. In just one decade, that's up from an already unbelievable \$231 million, or an inflation-adjusted 250%.

**Why is this important?** In a word — “economics.” Unlike much of the healthcare provider industry, the pharmaceutical and biotech industry has a refreshingly simple incentive: to make money. If their clinical study suppliers, the investigators, can get better studies done faster, there is great financial value to sponsors. Furthermore, because NIH-funded studies can also lead to product innovations, there's significant value improving efficiency in grant-related research execution.

Today, the inefficiencies in clinical trials are primarily the result of not having clinical information systems in use by providers/investigators. Were the drug industry to get together and decide to fund clinical systems for the entire U.S. healthcare industry, such investment could pay for itself within a few years in improved drug company profitability. It's unlikely that such a consensus could be formed or could be effectively implemented, but the point is: “That's gold in them hills.”

**Avoiding Wrongful Death.** The Leapfrog Group notes that up to 98,000 Americans die each year from preventable medical mistakes they experience during hospitalizations, according to the Institute of Medicine. Just as organizations like the Leapfrog Group are taking action on the issue of wrongful deaths on the patient care side, we in clinical research also have a compelling watchdog: the Federal government who funds about half the clinical research performed in the U.S. There have been some visible corrective actions initiated by the Federal government at some very reputable institutions. If these vaulted research institutions have compliance exposure, chances are you and your institution do as well.

The opportunity to save time and money is evident.

Fortunately, there are things we can do; and they are not nearly as difficult as one might think. Financially, they are a “drop in the bucket” relative to some of the potential consequences of inaction. Irrespective of the efficiency improvements, putting a system in place is a necessary insurance policy. You have to do the work, but we're going to provide some guidance later that will make it a lot easier.

From a systems perspective, the functional needs in clinical research are nearly identical to the functional needs of patient care. It just happens that we're dealing with a research subject versus a regular patient; a research protocol versus a care plan; and a case report form which is simply a specialized kind of medical record.

In this paper, we're going to spend quite a bit of time on clinical information systems. This is because the lessons we can draw from such initiatives give us a pretty clear picture of what we need to do in clinical research. We'll start with a review of all healthcare constituencies just to be sure we all agree that the provider constituency is where the biggest opportunity is. Then we'll look more closely at the provider side, considering two classes of information systems: back-office systems (financial and claims processing systems) and front-office systems (clinical information systems and related subsystems). Once we agree that the front-office (the clinicians and their support staff) is the place to focus, we'll learn how the front-office should be approached by examining common mistakes made implementing clinical information systems over the past decade or so.

Next, we'll go back to the research side and, drawing on an analogy to the automobile industry, demonstrate how the approach being taken by many clinical research software vendors today is, well, misguided; and at the same time show you why the challenges of clinical research systems is simply a subclass of the broader front-office challenge. Then, we'll give you a roadmap for implementing your clinical research system. We'll summarize by touching on a number of related points: the role industry sponsors can play; how the internet can help; and some tips on calculating a return on investment so you can acquire the budget and manpower you need to get the job done.

### **The Four Constituencies**

In 1999 alone, about \$1 billion was invested in more than 25 early-stage healthcare information technology companies focused on clinical information systems in one form or another – with zero return for investors.

There are a host of challenges peculiar to healthcare. For an industry with so much opportunity for improvement, we can ask: “What is the problem? Where can information technology help most? Where should the money be spent?”

First, let's clarify which healthcare constituency we're referencing: **"Who, what and where is the problem?"**

For purposes of this discussion, there are four major constituencies (the regulatory constituency is not included as it has little to do with the application of information technology):

- Patients
- Payers (employers, managed care, other insurers, the government)
- Suppliers (pharmaceutical, biotech, and medical device companies)
- Providers (hospitals and physicians)

Within these four segments, where are the most savings available through better use of information? Let's go by elimination . . .

**The Patient?** People can lead healthier lives and be more educated about healthcare-related issues. However, there's almost nothing a patient can do to improve information system inefficiencies.

**The Payers?** Payers have done quite a bit to slow the growth of healthcare costs. They can and have made structural changes in terms of incentives that can drive change, but they don't do the work.

**Suppliers and Pharmaceutical Companies?** This segment, along with non-government payers, is perhaps the most efficiently organized. This is not surprising in that the incentives are much more aligned. The job is to produce returns for investment, and to do so, generally one needs to provide measurably good products that deliver, or are perceived to deliver (i.e. well-marketed), value.

**Providers?** Industry study sponsors can be a big part of the solution, financially and otherwise, and industry sponsors arguably have the most to gain from improvements — but they are not a big part of the problem. The problem, without question, is among the providers and investigators. In fact, the entire \$200 billion savings per year that McKinsey references is provider-based.

[Top](#)

### **Providers – The Opportunity for Change**

So if the savings are so big and the needs so obvious, the questions are: "What's the big problem? Why can't we just go in and fix it?" First, let's orient ourselves within the provider settings. There are two general classes of information systems:

- **Financial, billing, and claims processing (back-office systems)** – these systems are in production in most provider settings. There is not a lot of additional value in improving these back-end systems. Close to 100% of the healthcare market have such systems in place.
- **Front line worker systems** – clinical and administrative systems for medical practitioners and their support teams (front office systems). Such systems support not just the physician but the entire team of people who most directly interact with the patients. These professionals are the source from which all information activities occur in healthcare. It is by far the group that needs the most support and can most impact the efficiency of clinical research and, for that matter, any other information function in healthcare. Less than 10% of the healthcare providers have front-office systems used in the care giving process.

**So why are front-office systems a problem?** To understand, you need to spend a few days at a hospital, for example, and watch how clinical professionals go about their business. It's an endless stream of forms, charts, prescriptions, and bits and pieces of paper – the heart of everything that occurs in our healthcare system. Dozens of patient interactions can occur in short spans of time, each of which adds to the information record. Data from one form might need to be entered into one system for billing purposes, another to order a lab, a third to order a prescription, a fourth to schedule a patient visit, and so forth. These pieces of paper are stored in walls full of medical records and related forms that are used to administer care. Changing these relatively complex, manual systems to an electronic medium is a major work habit transformation.

Once transformed, if done properly, clinical systems are of great value — this is an undisputed fact at this point. By way of empirical knowledge, we've had customers using our front office products who have undergone facility renovations during which time our systems were brought down for a period of time. In every such case, the staff

incurred significant labor increases to make up for the loss of their electronic system. When the system went back into production, labor time, charge capture, patient responsiveness once again improved.

### **Some Lessons Learned from Clinical Information Systems**

Armed with studies such as the McKinsey study, over the last ten years a large number of software companies built systems called electronic medical records (EMRs) to address huge inefficiencies surrounding patient care. Indeed, once installed, such systems are now proven to provide significant value and efficiency. But, the vast majority of these companies failed and lost hundreds of millions of dollars. Why? Well, because many such companies overlooked several issues:

- One . . . Putting EMRs in place involves a lot of change for a group of people that is extremely busy. A piece of paper, or a voice dictation machine, is faster and more efficient than typing into a computer terminal. Just converting paper to digits is not of sufficient value. What these systems should have done is use that data to solve all those other needs of the information: scheduling, lab order processing, pharmacy processing, regulatory reporting requirements. The need is not for an electronic medical record per se; the need is to fulfill the myriad of information demands a medical record supports.
- Two . . . Most vendors focused on getting the physician to enter the information. However, these are the highest value knowledge workers we have in any industry. Compare the physician to the senior business executive . . . neither one will walk into a meeting with their laptop and spend their time typing away on it. Instead they will discuss, evaluate, make decisions, educate. If there's a report to be written or notes to be taken, usually someone else does it. Take that situation and quadruple it in terms of the number of such patient interactions doctors must go through daily, and the quantity and specificity of the information that needs to be captured. People who thought they could force such a change in physician behavior, particularly in a single major stroke, were, in a word, "clueless." Also, consider the human issues. Most of our healthcare dollars go to treating seriously ill people. If you're a physician interacting with a patient on a very serious issue, it's downright rude to type and look at screens as you talk. What a physician does need, and can use, is the results of the information that is captured. And they do need and want the efficiencies that result from patient encounter data being used to address administrative needs, scheduling, lab and pharmacy orders, and ultimately the outcomes information that can improve their operational performance. Not the least of these positive results, by the way, is an increase in revenues for the same amount of work. Note: It's interesting to observe that the best way to improve revenue performance is not by improving the financial system, it's about capturing the necessary clinical information that drives, and substantiates, reimbursement. The same kinds of opportunities apply to clinical research.
- Three . . . The third challenge is a business model challenge. In addition to just looking at the problem as being a need for a digital record, which is wrong, vendors built relatively generic systems to solve diverse needs. Take a day and follow a cardiologist and their support staff around. Next, take a look at what an oncologist does. While there are many commonalities in the data, e.g. patients, heartbeats, blood readings, and so forth, there are also significant variances in what they do. The workflow, the kind of information captured, and the decision criteria are vastly different. These varying sets of information are, in hospital settings, captured today in what's called a "shadow chart." It's a little scary to think that of the small handful of electronic medical records projects that have succeeded, and the millions that have been invested in these systems, the front line workers in most specialty care settings continue to use a separate set of paper-based systems – shadow charts – to manage their daily affairs.

[↑](#)  
**Top**

**So there are three messages here:**

First, your medical record system should not be what's known as patient, or chart, centric; it needs to be process, or workflow, centric.

Second, the vendor's system needs to be adaptable to the needs of various medical specialties.

Third, the transformation is too big to be done in one stop. You need to have an incremental approach. Find a vendor with technology and implementation strategies that will allow you do that.

## **So What Does All This Have to do with Clinical Research Systems?**

### **An Analogy to Automobile Manufacturing Supply Chains**

A big problem in clinical research are the systemic inefficiencies in how studies are run. While there are opportunities for systemic improvement once clinical data is submitted back to the sponsor, those opportunities are internal to sponsors and dependent on the government. There are only so many moving parts and areas of opportunity there. Yet this area is the starting point for the strategies of the vast majority of software companies in the clinical research space.

At this point, we're going to make a comparison between the clinical research industry and the automobile industry. In clinical research, the thinking seems to have been: "drug companies have piles of money, so let's design a solution for them and sell it to them." This is a little like saying, "Let's build a company around creating a supply chain management system for Chrysler, Ford, and GM that they'll pay for and hand out to their parts suppliers to use." If I were Ford, why would I pay for a system if GM will take advantage of it? I wouldn't, and I didn't. Or, by contrast, as an automotive software supplier, I say, "I'm going to make my money selling Ford the same system a dozen times (the per study pricing model in clinical research)." How long am I going to put up with that if I'm Ford?

What I did do, at Ford, was tell my network of suppliers (in our analogy the investigators) that they needed to be compliant with Ford's system and if they were, the suppliers would get more business and be better off in the long run. They did, and they were. No software company made a fortune building Ford, GM, and Chrysler's supply chain system. Indeed, each of the big three automakers built their own big system, comparable in concept to the mostly proprietary systems Eli Lilly, Merck, and Novartis are on their way to completing for clinical research today. (Note: We use the term "in concept" because the notion of getting automobile parts suppliers to be compliant as compared to medical professionals are entirely different matters.)

In automotive and other similar manufacturing supply chain industries, software companies were successful:

- Providing applications to the thousands of suppliers in the market, and
- Supplying "the network", or integration software, that connected the suppliers and manufacturers.

The same is true for clinical research. And it's an approach that's entirely distinct from the approach being taken by the majority of clinical research software companies today. With this new approach, there is opportunity for major efficiency improvements. Right now, 'the cart is trying to pull the horse.'

### **" So, how does one do it? "**

Above, we mentioned that medical professionals (the clinical study "suppliers") are not like automobile suppliers. Medical professionals have far more complex daily routines, time pressures, and challenges. Over the next five years, sponsors will be able to compel many investigators to adopt sponsor-supplied systems for electronic study data submission. However, that's not going to make a world of difference in study efficiency for a number of reasons: First, most investigators have numerous studies in progress, some industry-sponsored, some investigator- or NIH-sponsored. If each system requires different procedural activities, which they do, the industry sponsors are not going to get major efficiency improvements from their suppliers by putting in remote data capture systems.

And second, if the study suppliers have not already standardized on a system of their own, the activities that lead up to submission data, which are in the greatest need of improvement, remain unsolved. The right set of core competencies have to do entirely with workflow of the medical provider and investigators, not that of sponsor-side clinical research. Very few competitors in this market have these competencies.

While the market dynamics and economics of clinical research adoption issues are largely identical. We've spent quite a bit of time working with patient care systems (that's why we know so much about the mistakes made). Indeed, Velos built an integrated system that supports patient care and clinical research in one system architecture.

Actually, this is the 'Holy Grail', as any expert in the area will acknowledge, and is also very difficult to do from a systems design perspective. However, it's an impractical business model in that, for a particular study, every investigator would need to be standardized on the same front-office system. Here again, the cart is trying to pull the horse—the same 'horse' but a different 'cart.' We'll come back to a practical alternative in a moment. The essential point is that the lessons learned, technology, and domain expertise in patient care systems have substantial application to research systems.

From a systems perspective, the modules required for clinical research are identical, in construct, to the systems required for patient care:

<u>Name of Patient Care Module</u>	<u>Name of Clinical Research Module</u>
Treatment or Careplan Design	Protocol Design
Patient Scheduling	Study Subject Scheduling
Electronic Medical Record	Case Report Form
Clinical Compliance System	Query Management System
HIPAA-Compliant Security and Audit trail	HIPAA-Compliant Security and Audit trail & 21 CFR Part 11
Data Interface Engine	Data Interface Engine
JAHCO and other Compliance Reporting	IRB and other Compliance Reporting
Budgeting and Billing	Budgeting and Billing

This is not difficult to understand if one takes the simple perspective of a patient undergoing medical therapy and a research subject participating in a study. In each case, there is the patient visit; tests; diagnoses; treatments; follow-ups to be scheduled; services billed; and so forth. The system constructs to support these functions are the same.

The question becomes: **“How does one implement the research system?”**

The short answer is that the clinical functions are the most intrusive, take the longest to implement, and are the most expensive. This becomes very understandable and obvious after you've followed that nurse or doctor around for a couple of hours. What the clinical research industry needs is . . .

- A vendor who can provide a basic, easy-to-use administrative solution that begins with everything but the clinical part, and
- A vendor who focuses on solving problems from the study coordinator perspective.

For the foreseeable future, the study sponsors will supply their own paper- and electronic-based clinical systems, anyway. As such, systems that are actually used by study coordinators and investigators will still not be in place. This is a critical distinction. Even when the Remote Data Entry (RDE) system is electronic, the sponsor only sees study activities on a post-facto basis — and that information is basically a duplication of the manual efforts at the study sites.

What will help sponsors, for paper-based and electronic-based studies alike, is

- A system that is actually used by investigators in the study process, and

- At early stages, chronologically, systems and tools that can be used to mine for patients who might be suitable for trials. These much more nimble application sets can then be integrated with what will ultimately be proprietary internal sponsor systems (the ones Novartis, et al., are now building) for data collection and regulatory study submissions. Together, they form the “collaborative” solutions so many experts talk about today that are now available in industries such as automobile manufacturing.

[Top](#)

### **A Roadmap for Investigator-side Research System Implementation**

What’s true for patient care is also true for clinical research. So here’s how to proceed on your research systems implementation project.

- **Focus on the needs of the front line professionals** Within that group, address the needs of clinical coordinators and administrators first. Just give investigators the results. They’ll come along as the benefits of ready information access and labor efficiencies become manifest. Gradually, as the clinical coordinators, and related administrative and management staff, use information system tools, the investigators will use the electronic capabilities more and more in the patient encounter, and the quality of the encounter will improve.
- **“Don’t try to do the ‘whole enchilada’ in a single stroke. It won’t work.** Your internal customers are far too diverse and far too busy to make such a massive transition. In a major hospital system, it will take two years or more if you’re really good, by which time the technology will have changed. More likely, it will take longer or won’t happen at all. Take things in steps. Look for a vendor that thinks the same way and has designed their software that way.
- **“A front-office system is not an island.”** Look for systems that support workflow and use information captured in the patient encounter to solve related information problems, such as financial performance, outcomes, scheduling, and regulatory compliance. If such needs are not addressed as a by-product of the system you implement, you’re not getting the value you need. Again, evaluate a vendor in terms of how well he or she supports the clinical coordinators — and how naturally the system mirrors their work practices.
- **“You’ve got to ‘step up to the plate’ on budget and implementation.”** Even after you drill down to a department, or a single function like scheduling, these systems don’t just walk in and start working. It takes time and focus getting started. Even if these systems were free, it takes effort and leadership to get the job done. To justify that, you have to be able to justify your ROI. We’ll help you with that in a moment. If you’ve acquired systems as described here, you will have an ROI. Here again, make your vendor talk to you about their product in terms of how it provides a return on investment. If they can’t help you there, chances are they haven’t focused on the right issues.
- **“Use a stick, but mostly use carrots.”** The “stick” is the rules central managers, such as Clinical trial Offices and IRBs, set that investigators must follow if they want to do clinical research. These rules, considered necessary but burdensome by most investigators, are going to increase. For obvious reasons, central clinical research management functions – such as the IRB, Budget/Grant contract managers, and administrative executives have considerable power when it comes to investigators. As central study managers implement your controls, you should give the coordinators software tools that make their lives easier, both from the perspective of complying with your rules as well as facilitating day-to-day study coordination. Harnessed effectively, central study managers can have a favorable impact on clinical research efficiency, particularly as relates to compliance. As an aside—Your institution could be taking significant risks in the area of compliance right now. In most research settings today, central managers have almost no idea what’s going on in a study between the time it leaves the IRB and comes back for periodic review.
- What one needs is a means to stay in touch with the investigators – a better way to monitor research activities. This is entirely an information systems, incentive, and SOP issue. The easiest way to have positive results is to give the front line professionals something in return, i.e., “If you use this system, it will also make life easy for you in these

other ways; and we'll be in a position to give you a faster turnaround on your approval requests and help keep you out of trouble.”

### **What about the Internet?**

Internet technology is ideal for supporting clinical research. The Internet's particular power lies in two areas. One is its ubiquity – the Internet can be used to exchange information across researcher and organizational boundaries – this is very different from the closed systems of the past and, indeed, the present. Today the vast majority of our healthcare information is locked away in closed systems, most frequently on paper somewhere. Simple activities like sharing protocols, reminding physicians and patients of appointments, searching databases for eligible patients, accessing information from different physical locations, and communicating with sponsors can all be time savers that also shorten study turnaround time.

The second advantage that Internet technology brings is a much lower cost structure for vendors to deliver “services.” This lower cost structure is the result of lower selling costs, as the Internet provides a new, low cost distribution channel. Also, the cost of supporting systems on the Internet is far lower. One update supports all customers. Effectively, in Internet architecture, one “virtual” user shares support and infrastructure costs with all the users. As a result, Internet services can cross organizational, geographical, and even cultural boundaries at a far lower cost than traditional platforms. And one can expect to see entirely new, innovative business models introduced using the Internet that can break the mold and overcome some of the barriers and challenges we face in healthcare. They will be a little slower in coming than they might have been before the Internet market fell, and venture investors lost all that money; but there is no question that the innovation will come from the Internet.

### **How Can Study Sponsors Help?**

It's interesting that healthcare suppliers, particularly pharmaceutical companies, are by far the most profitable industry in the United States. Their customers/distributors – the providers – are by contrast among the least profitable and least efficiently run. There are reasons for the huge margins of drug companies:

- Patent law,
- The clear profit incentives drug companies have – compared to other healthcare constituencies, and
- The huge risks drug companies take – as evidenced by the newly-released drug development figures above, which merit comparable rewards in a free market economic system.

**Patent Law.** Some time ago, our patent laws were revised to be quite favorable in supporting drug discovery. These laws give drug makers significant means to maintain huge margins on their products. What is important about this is that funds are available from study sponsors if their suppliers, the investigators, deliver increased efficiency and value. There is no place that this is more evident than in clinical trials, the most costly and time-consuming aspect of drug development.

Pharmaceutical, biotechnology, and medical device companies have a lot to gain through improved information efficiency. The amount of money required to solve some of our information problems on the provider side is far less than the amount of additional revenues and profits drug companies will gain through those same information improvements. As a result, there is a significant opportunity to create efficiencies that shift the allocation of the clinical research economic pie to benefit all interested parties. In this sense, the gains that drug developers can achieve far exceed the gains automobile suppliers achieved.

Some of this is already happening as some drug companies supply the equipment, computer, modems, etc. for a single trial. Given the low unit cost of each such equipment configuration, and the fast devaluation of computer technology, it's cheaper for them to simply leave the equipment behind which can be of some help. But only modest help — investigators are then often left with a hodge-podge of equipment provided by each sponsor. The software left behind is usually licensed for use on only the one trial and was probably customized for that one trial.

**Incentives/Opportunities.** The bigger opportunity, as relates to sponsor-driven systems support, is what in software parlance is called a “side effect.” One example is in the area of patient recruitment. Let's suppose that a sponsor finds it worthwhile to provide tools that facilitate patient recruitment; a search engine, for example, that can be used to identify patients that might be suitable for a clinical trial, or for refining a protocol. This involves provided technology



that can interface with lab systems, ADT systems, pharmacy, and other provider-side devices and systems. As we noted earlier, the technology required here is nearly identical to technology that can be very helpful in supporting patient care. As such, sponsors can help drive positive change for investigators and for clinical research, as well as other uses.

The most obvious opportunity is even more basic. If investigators can find cost-effective tools that will enable them to be better suppliers, they're going to receive more business from the drug company and may, over time, also justify higher fees. The main reason so much industry-sponsored research has moved away from the major academic health centers is due to the huge system inefficiencies that prevail in most AHC settings. It follows that those who can deliver efficient research service will get a larger piece of the pie.

One more aside-!So far we've discussed industry-sponsored trials. Yet, nearly half the funds allocated to clinical research in the U.S. are investigator-sponsored, funded predominantly by the NIH. To address the efficiency and compliance needs for industry-sponsored trials, most major research centers have established separate clinical trial offices over the last five years. There's a risk of thinking that industry-sponsor trials require a separate systems infrastructure.

**Note:** While there are differences, it is a mistake to create yet another information system "island". The reasons for this are simple: heavy-user investigators, the people most in need of systems support, do both investigator- and industry-sponsored trials. One system should support all studies involving human subjects. Further, from a technology perspective, while the processes for investigator- and industry-sponsored trials are different, a well-designed system can easily support both.

#### **"Those Information Systems Budgets!"**

The good news on budgets is that once your more manual systems are replaced, a very powerful ROI emerges. Your upfront challenge is . . .

#### **"How do I get budget approval?"**

First, let's once again broaden the context from which you can make your pitch. For a long time, it didn't make sense to invest in the front line worker. Efficiency didn't really matter. Healthcare was a cost-driven incentive system. Supply and labor costs went up, fees went up, insurance and national healthcare costs went up. That continued for about 50 years. We all know that's changed now.

Those of us who can influence healthcare investment allocation, which most of us can, must champion a change in perspective. Let's briefly evaluate why . . .

#### **What are the major components and investments required to deliver healthcare?**

- First are certainly the **professionals** – we need great caregivers, support staff, and managers.
- The second is **medical technology** – not information technology but medical technology. New, better drugs, medical devices, and so forth. Lots of advancements have occurred here and lots more will come.
- Third, there are the **physical facilities** – buildings, operating rooms, offices, desks, chairs, and so forth. For some reason, charitable sources like to support building construction. Each of these three major cost components has natural champions.
- The fourth is **information** – Information is the lynchpin and a huge component of our care delivery capabilities. There is no fifth area of investment. Yet, if we look at how money is spent, in hospitals for example, millions of dollars are spent on new buildings, piles of money on drugs, and hospitals routinely cough up \$500,000 or more for the latest devices. But when it comes to information systems, the silo of funds allocated is relatively paltry, and a major reason taxpayers spend so much more on healthcare than is necessary.

So, we must champion the need to invest more in information systems. One of the best ways to do that is to first prove it works.

Now, back to the task at hand. You need to justify a return on their investment. Here's how . . .

#### **The ROI Story – much easier than you think!**

Accountants often make the mistake of thinking about Return on Investment (ROI) in terms of cost reductions: “If I spend X, I’ll reduce my costs by Y, which yields an ROI of Z.” These basic returns can be significant in clinical research. However, the vast majority of the return, as is usually the case in ROI opportunities, is in such areas as increased revenue, better quality, less elapsed time.

“Indirect” advantages include the ability to attract more research opportunities, finding more suitable patients for clinical trials; doing safer trials; and reducing the risk of non-compliance. One can prevent an adverse drug reaction, for example, which in turn prevents unnecessary hospitalization (not to mention the patient benefits). One can provide better service to research subjects and sponsors by having information at hand (which also saves time). One can report successes that help win more study opportunities, or perhaps more favorable terms, from sponsors.

There are also numerous compliance issues that will be solved once research systems are in place. This is like an insurance policy – one adverse episode might be prevented. Putting in systemic precautions around compliance alone can justify your entire investment.

In information technology, ROI is a funny thing: on the one hand elusive, and at the same time painful. How does one measure the ROI of e-mail, for example? Hard to do but it’s abundantly clear that e-mail is of tremendous value, right? The same is true for front-office applications that support clinical research.

In short, there are many different ways to demonstrate an ROI. So let’s get out there and “just do it!”

#### **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 John McIlwain**

John S. McIlwain is co-founder, President and CEO of Velos. Prior to Velos, Mr. McIlwain served as President and Chief Executive Officer of Software Services International, Inc. (renamed Aithent), a software development services company focused in part on healthcare. Aithent is a 300 person company today. Prior to Aithent, Mr. McIlwain held sales, consulting, and software design positions at Sun Microsystems and Price Waterhouse. Mr. McIlwain also served as Adjunct Professor of Management and Operations Science at Columbia University Graduate School of Business and currently serves on management boards for a number of early-stage software and healthcare-related companies. Mr. McIlwain holds an MBA from the Columbia Graduate School of Business, and a BA in English and Economics from Middlebury College.