# Pharma has the DATA but not the Information

WHY PROCESS MATTERS

Are you involved with clinical research?

If so, take a moment to imagine what if every clinical research assistant (CRA), monitor, and project manager working with a study were given a personal assistant to be at their sides at all times, watching everything, and keeping track of all the details of the study. Then, Michael Rosenberg, M.D., MPH, president and CEO of Health Decisions Inc., says, imagine that this assistant was able to write everything down at high speed and likewise was able to find anything required instantly. Furthermore, imagine if this assistant also communicated with everyone else's assistants so that there could be a single point of contact for all the study information. Continue to imagine that if the assistant was told something once, he or she not only remembered it, but also intercepted calls and answered the questions before going to the CRO or monitor or project manager, leaving them free to focus on the main purpose of their job. Daring to dream further, imagine that this assistant is also available to every site coordinator, then to every medical monitor, then to directors of clinical research, VPs, and so forth up the chain of command. And what if each personal assistant had a structure, a framework of sorts, that provided a starting point and allowed the assistant to flexibly adapt to different styles and those unforeseen twists and turns that are a hallmark of pharmaceutical development. At the end of the day, he says, most agree that would be one incredibly efficient personal assistant.

MICHAEL ROSENBERG, M.D., MPH, PRESIDENT AND CEO OF HEALTH DECISIONS INC., CHAPEL HILL, N.C., DISCUSSES WHY, COMPARED WITH OTHER LARGE INDUSTRIES, PHARMA'S AUTOMATION PROCESSES LAG BEHIND.
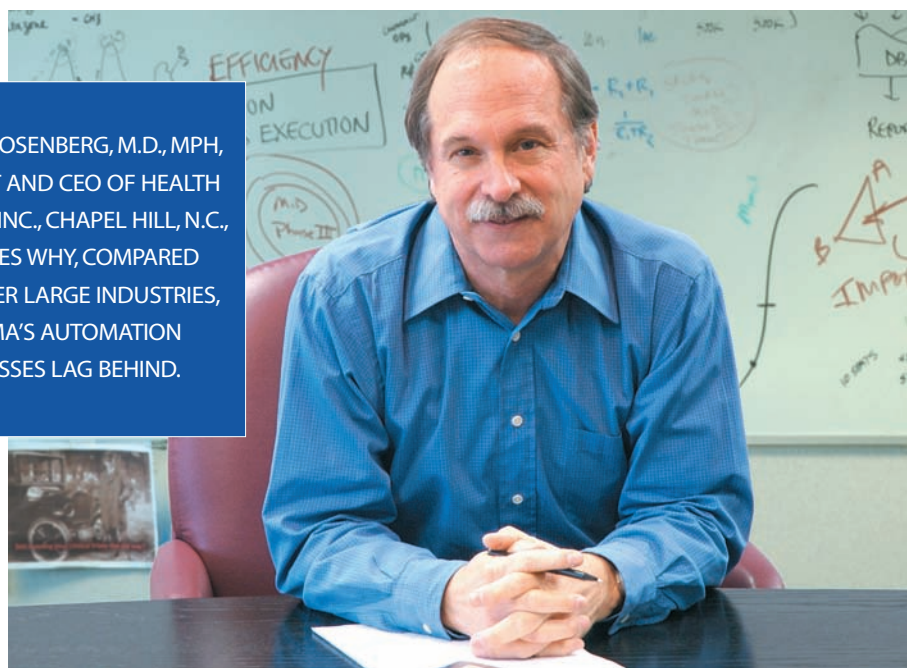
Borrowing Assistance from Other Industries

In effect, Dr. Rosenberg says, such a personal assistant has been around for a long time in other industries. One early example is the autombile industry. When automobiles first came into production, each was hand built by craftsmen. Each part was individually formed and fitted; no two cars were exactly alike. This slow, individualized process centrally depended on the expertise of highly skilled individuals. These craftsmen developed their capabilities over many years. Through apprenticeships new employees would learn a skill by watching what others did and gradually assuming a greater degree of responsibility.

Once Henry Ford developed the assembly line, which Dr. Rosenberg likens to a type of personal assistant, he was able to realize economies of scale that most thought could never be achieved.

"Notably, it was not the parts themselves but carefully designed processes that enabled an enormous leap forward in productivity," Dr. Rosenberg says. "Cars now could be defined and built with precision, because each element involved was predictably similar. Subsequent

WHY TECHNOLOGY MATTERS

development refinements led to the flexibility of individualizing automobiles through options, colors, equipment, and the like."

Pharma Needs an Assembly Line

According to Dr. Rosenberg, today pharma finds itself in a parallel position of doing development pretty much the same way early cars were assembled: each project is built by craftsmen who learned their trade largely through experience, with individual projects run differently by different individuals even within the same organization. Although some elements are standardized, many essential elements of what defines a strong clinical program still remain mostly manual.

"Without the help of something like a personal assistant to provide discipline, major repeatable benefits — a tightly run study with low outcome variance, good enrollment, consistency across multinational and multiyear efforts — are largely absent," he says.

The ability to change development timelines rests on the ability to effectively manage complex studies. Management does not mean transferring an onerous task, such as data entry to others, nor does it mean dutifully collecting and dumping data into a database. Every step is telling, but to be useful, it is the indicators of performance that enable management — what cannot be measured cannot be managed. The objective is to enable people to make faster, earlier decisions, about day-to-day study management and strategic decisions, and to be able to reduce between-study timelines.

Dr. Rosenberg defines the "personal assistant" as a combination of processes — a series of operations performed in the making or treatment of a product — and tools — the assistance required to get the operations done.
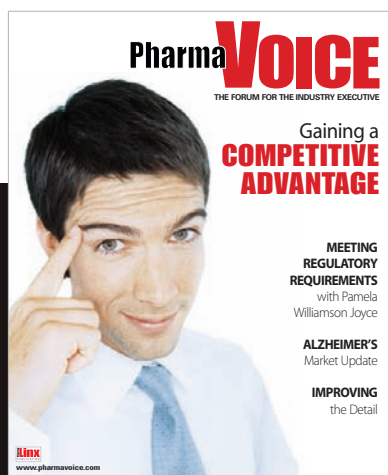
In an industry where each project manager tends to do things a bit differently, even within the same company, neither of these items is fully obtainable.

"One cannot leverage past experience because it is not codified nor can tools be developed to assist future tasks," he says. "A personal assistant needs to provide structure and process, to a much greater degree than currently exists in pharma. And this is a problem that can be addressed."

Putting the Electronic Assistant into Action

Trials need to get off the ground more quickly. All the paperwork, changes, scheduling, and planning have to be sent and resent as the study takes shape. What if an electronic assistant were able to provide the essential building blocks — a guide that, even when some element arose that was unfamiliar, there was somewhere to access the collected experience from several hundred studies? This elec-

tronic assistant tool could provide instructions on what makes an IRB submission pass the first time or how to design CRFs to minimize queries. Obtaining this information would not depend on the "right" person being available — the data would be available 24/7. Further, every answer would be consistent every time from the study's inception right through to completion.

These actions are achievable right now. Every study has certain requisite building blocks. For example, we all know that data will have to be collected and processed, IRBs have to be dealt with, source documents need to be checked, DMGs must be written, and so on. Although the challenge often lies in the fact that every study is different in details, certain building blocks are always necessary. In this case, an electronic assistant allows one to draw on the collective wisdom of many hundreds of

uously recording all along — then the project manager would know exactly what data were provided to the sites. Not only would that information be available to every site, 24/7, it would be the first place to check — not the monitor or the study physician, but a dedicated Website.

This capability, too, is well within a good end-to-end system today. The result is a codification of knowledge, easy access to it by all members of the study team, less reliance on people for the critical aspect of consistency across a long and complex study and, best of all, less concern about the inevitable turnover among key study staff.

A side benefit is fewer questions from sites. The focus shifts from, "I have to know what the information is," to "I have to know where the information is." This is a much more manageable proposition.

fact, that the head of data management actually knows immediately when the study coordinator goes on vacation, just on the basis of the data.

Such a system could reduce CRA requirements by about 40% and site costs by 5% over a traditional model.

This is obtainable with today's technology. Because real-time information about site performance is available, CRAs can be sent out on a schedule according to when and where they are most needed. The result is a 50% reduction in the number of field visits required and a reduction of 50% time on site when they do.

Dr. Rosenberg says each of the examples cited, and many others, have one thing in common: they are based on actual circumstances, real trials that occurred in a broad variety of settings. In each case, substantial time and money were saved by implementing a system that leveraged technology and process — in essence an electronic assistant — to address predictable, repetitive study components and to provide a degree of timely knowledge about performance that enable personnel to focus on what is important — managing a study. In short, technology was applied to remove the dull, repetitive background work in providing a range of performance indica-

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start-up studies and facilitates implementation and communication. The result is a faster study start up, an adaptive approach to responsibilities (between CRO and sponsor, CRA and manager), and a highly adaptable approach that provides a framework but also allows individualization, including the flexibility to change as the study progresses.

Imagine that a CNS drug, with difficult-to-measure cognitive endpoints, is in the clinic. These studies are expensive and long. Six months into the study, the medical monitor for the study leaves the company for personal reasons. As the project manager there is no way of knowing everything that was in his head, most notably the subtle details that determine how a patient will be treated in regard to items such as concomitant medications. What is more worrisome is the fact that many aspects of the medical treatment that the study monitor has been advising site on are unknown.

But if the electronic assistant had been assid-

Imagine that the task is managing a proof-of-concept study for an emerging biotech company. Finances are tight and the study is critical for the company. Further, while every penny must be watched, assuring a well-done study is essential. Considerable discussion takes place deciding on how large the study can be, tradeoffs of number of sites, and the number of staff members it will take to reassure all that the study is being run tightly enough to have the results be sufficiently reliable to progress the drug into pivotal testing. As the project manager, the biggest concern is the expensive CRAs.

Today's electronic assistant capabilities enable an extraordinarily tight degree of management by providing real-time tracking of site performance. Further, the entire study team can closely monitor field events from their computers. The study Web pages reveal which sites are enrolling and why. Site query rates and response times are available at all times, including comparison of sites overall and individually, as well as trends for each. These are so well tuned, in

tors as well as data to let people focus on what they are truly needed for — interpreting and acting.

According to Dr. Rosenberg, automation has been both oversold and overimplemented, complicating studies to the point where legitimate skepticism has kept pharma from taking proper benefit. Much of what is involved in clinical testing is a people business and needs to take advantage of what people have to offer. Technology is just one component of success. It must be combined with the people and the processes.

Michael Rosenberg, M.D., MPH, is President and CEO of Health Decisions Inc., Chapel Hill, N.C., a full-service, globally capable CRO that leverages technology to simplify and improve processes for rapid, effective clinical evaluation of pharmaceutical products. For more information, visit healthdec.com.◆