BY DENISE MYSHKO

The EVOLVING ROLE of the Clinical Project Manager

WITHIN THE PAST FIVE YEARS, THE **merging of the art and science** OF PROJECT MANAGEMENT HAS RECEIVED A GREAT DEAL OF EXPOSURE AS THIS ROLE IS ONE OF THE **core capabilities needed for drug development.**

Clinical studies have become more complicated. More studies are multinational, which means that projects must adhere to a variety of regulations and laws. Today's studies also require project managers to work across teams to manage a process that has become increasingly multifunctional. With this heavier workload, project managers are expected to take ownership of a project from the beginning and provide leadership through the development process and deliver studies on time and on budget.

THE CHANGING ROLE OF THE Project Manager

Experts agree that the project manager's role is broadening because of a need for efficiency in clinical development, the multinational scope of development, and new technologies that allow for faster communications.

CALLAHAN-SQUIRE. ASTRAZENECA. There is acknowledgement that project management is a core capability for the pharmaceutical industry. Project management, however, still has a way to go in terms of being a mature function, but the pace is certainly accelerating rapidly.

SMINK. CHILTERN. The role of project management in clinical research in general is less mature than in other industries that have a project management function. But this is changing, and increasing maturity is putting emphasis on planning, organization, and control.

RICHARDS. PFIZER. Within clinical project management at Pfizer, there is a much greater

THOUGHT LEADERS

JEROME BAILEY. Senior Project Director, Project Management, Omnicare Clinical Research, King of Prussia, Pa.; Omnicare Clinical Research is a Phase I to IV contract research organization providing drug development services to pharmaceutical, biotechnology, and medical-device companies in 30 countries. For more information, visit omnicarecr.com.

MAARTEN BEEKMAN, M.D. VP, Clinical Development, NicOx SA, Sophia Antipolis, France; NicOx is a product-driven biopharmaceutical company dedicated to the development of nitric oxide-donating drugs for unmet medical needs. For more information, visit nicox.com.

MICHAEL BILELLO. VP of Operations, Inclinix Inc., Wilmington, N.C.; Inclinix is an enrollment CRO offering customized trial recruitment services complemented with the power of technology to produce successful and timely study completion. For more information, visit inclinix.com.

MARY CALLAHAN-SQUIRE. Executive Director, U.S. Clinical Project Coordination, AstraZeneca US, Wilmington, Del.; AstraZeneca is an international healthcare business engaged in the research, development, manufacture, and marketing of prescription pharmaceuticals and the supply of healthcare services. For more information, visit astrazeneca-us.com.

DAVID DAMPHOUSSE. Manager, Clinical Operations, Idenix Pharmaceuticals Inc., Cambridge, Mass.; Idenix is a biopharmaceutical company engaged in the discovery, development, and commercialization of drugs for the treatment of human viral and other infectious diseases. For more information, visit idenix.com.

SHERI A. KOSTELNY. Senior Project Leader, Kendle, Cincinnati; Kendle is among the world's leading global clinical research organizations and is the fourth-largest provider of Phase II-IV clinical development services worldwide. For more information, visit kendle.com.

KEVIN MELVIN. Senior Project Manager, Covance Inc., Princeton, N.J.; Covance is one of the world's largest and most comprehensive drug development services

MICHAEL BILELLO
Inclinix

MARY CALLAHAN-SQUIRE
AstraZeneca

The ability of project managers to integrate the delivery of the trial across a number of boundaries **IS GOING TO BECOME MUCH MORE IMPORTANT.**

OUR PROJECT MANAGERS' SKILLS ARE EVOLVING; they are moving from being mostly clinically focused toward being more business oriented. The role is a balance of science and business.

level of accountability. The industry and environmental challenges are driving the need for greater levels of productivity and delivery against what the company has planned.

CALLAHAN-SQUIRE. ASTRAZENECA. There are so many pressures on the industry to deliver development projects in a timely and cost-effective fashion. Project management is focused on achieving that. That's why we are focusing on project management as a vehicle to achieve those goals.

BEEKMAN. NICOX. At our company, a project manager is similar to a very good conductor of an orchestra. In a way, this person wants to make sure all of the people involved play as well as possible to get a perfect piece of music. The role is less about directing operational work and more about managing remotely and understanding global needs.

VALANZOLA. SCHERING-PLOUGH. Project managers are taking more ownership of managing projects. In the past, it was a team management process. There was a lot of interaction between study managers and some of the project physicians driving the trials toward the end point. Now, the project manager is taking the lead in a lot of these roles.

PIERRE. ACRP. The project management role has become one of true management rather than one of implementation. Project managers appear to be more empowered than they were a decade ago; they now make decisions related to process efficiencies and budgets. They now

companies. For more information, visit covance.com.

KARL METTINGER, M.D., PH.D. Chief Medical Officer, Oncolytics Biotech Inc., Calgary, Canada; Oncolytics Biotech is a biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics. For more information, visit oncolyticsbiotech.com.

CONNIE MOREADITH. Senior Director of Clinical Project Strategy and Start Up, North American Clinical Operations, AAIPharma, Wilmington, N.C.; AAIPharma is a global provider of product development and support services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit aaipharma.com.

CHRISTINE PIERRE. Chair of the Board of Trustees at the Association of Clinical Research Professionals (ACRP), Alexandria, Va.; the ACRP provides global leadership to promote integrity and excellence for the clinical research profession. For more information, visit acrpnet.org.

KAREN RICHARDS. Executive Director, Worldwide Project Management, New York Site Head, Pfizer Inc., New York; Pfizer is dedicated to better health and greater access to healthcare for people and their valued animals. For more information, visit pfizer.com.

AIZE SMINK. Global Head of Project Management, Chiltern International, Slough, United Kingdom; Chiltern is a global contract research organization with extensive experience with running and staffing international Phase I to Phase IV clinical trials across a broad therapeutic range. For more information, visit chiltern.com.

RICH VALANZOLA. Clinical Project Manager, Global Clinical Trial Management, Schering-Plough Corp., Kenilworth, N.J.; Schering-Plough is a global science-based healthcare company with leading prescription, consumer, and animal health products. For more information, visit schering-plough.com.

PROJECT MANAGERS ARE MANAGING A WIDER ARRAY OF SERVICES AND WORKING IN MULTIPLE COUNTRIES MORE THAN EVER. They are expected to take ownership of a clinical study from the beginning.


SHERI KOSTELNY
Kendle

have more divisions that report directly to them, including monitoring, education, budgets and contracts, and data management.

BILELLO. INCLINIX. Our project managers' skills are evolving; they are moving from being mostly clinically focused toward being more business oriented. The role is a balance of science and business. We were very concentrated on clinical know-how — the basics of clinical research, GCP, protocol knowledge, working with investigators, IRB relations, and recruiting patients. Now clients expect much more from our project managers than they did five years ago. They need to have a good financial understanding. They also have to measure things that we do.

RICHARDS. PFIZER. The matrix — the cross-functional components that are part of the clinical development team — has become more complex, and that impacts teams and how project managers lead and support those teams.

PIERRE. ACRP. The documentation and communication between the sites and project management are far more voluminous than they were years ago. This means the communications net is far more demanding to manage, and ultimately it is the responsibility of the project manager to ensure that deadlines and quality are adhered to. Providing project managers with the appropriate staff and technology resources can only strengthen this process, the efficiencies of which will be realized by sponsors, CROs, and the overall project.

FUTURE PROJECT Managers

Experts agree that project managers will continue to take on more responsibilities and handle a wider array of challenges.

CALLAHAN-SQUIRE. ASTRAZENECA. We're looking to groom the next generation of project managers within clinical development; their ability to integrate delivery across a number of boundaries is going to become much more important. Our project managers of the future will move from just overseeing projects delivered internally to also overseeing projects delivered by any number of external partners and alliance partners.

VALANZOLA. SCHERING-PLOUGH. Within Schering-Plough, the role will continue to encompass more responsibility. Project managers will have to continue to adjust to the trends and the environment, whether they are technological or otherwise, and we will have to provide additional training if needed. As project managers, we are beginning to manage CRO relationships because we're outsourcing more. We will have to manage key performance indicators and be very cognizant of how well we're performing. Many of our measures are centered on cycle times, but we're looking to move toward a more balanced scorecard that also includes quality and costs.

RICHARDS. PFIZER. In the past, there was an emphasis on the technical components of project management around delivery. Now there's a much broader emphasis on softer skills, the team dynamic components and the relationship pieces, which are really critical for the success of any project manager. Leadership qualities are extending beyond just technical attributes and skill sets that project managers bring to the table, such as costs, schedules, and quality.

KOSTELNY. KENDLE. Project managers in a CRO manage a wider array of services and work across continents and in multiple countries more than ever before. Each client and each trial has its own challenges. We're now responsible for managing everything from study start up to recruitment through to database lock and possibly writing the clinical-study report.

BEEKMAN. NICOX. Project managers in a CRO need to ensure that they bring the project in on time and manage the hours and costs. The tools that they have are, in general, much more sophisticated compared with those in biotech or pharma companies but they can be shared for tracking the progress and finances of a project.

SMINK. CHILTERN. The project manager is a key person in the execution of the clinical trial. In many cases, sponsors want to meet the project managers and assess their experience. In that sense, I think the project management function has matured, and, therefore, there is more formal empowerment of the project manager to make decisions that affect the study.

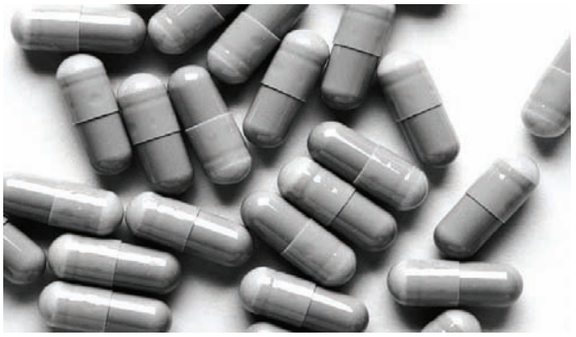
BEEKMAN. NICOX. The clinical project manager 20 years ago managed clinical projects, and that is still part of the role. In the end, they still have to make sure the study is delivered on time, on budget, and with high quality. What has changed are the tools that people can use to meet those goals.

KOSTELNY. KENDLE. Project managers are expected to take ownership of a clinical study from the beginning. Now, when we get a request to provide services to a client, the project leaders are brought in from the beginning. That wasn't the case five years ago.

AVERION

MILLENNIX ONCOLOGY

A Globally Preeminent
Clinical Research Organization



Averion International is a globally preeminent clinical research organization with a focus in oncology, dermatology, nephrology and medical devices. Through our Millennix Oncology branded service line, we provide specialized Oncology clinical research solutions. Averion International offers a comprehensive understanding of what it takes to efficiently manage clinical trials; from Phase I-IV through to post-marketing studies, safety surveillance and patient registries.

Our expertise assures quality, service and results. Our experience means your success.

www.averionintl.com

DAVID DAMPHOUSSE
Idenix Pharmaceuticals

THE ROLE OF THE PROJECT MANAGER WILL CONTINUE TO EVOLVE and it will encompass more collaboration with, and input to, other departments, such as regulatory and legal, on clinical trial-related matters.

TRENDS IMPACTING Project Managers

Regulatory issues, multinational studies, and technology are a few of the trends that are impacting the role of the clinical project manager.

METTINGER. ONCOLYTICS. There have been changes with the process, and these are stemming from the organization, such as collaborations and mergers and acquisitions. Regulations are changing, and in the last two years they have become much more complicated. All of these factors point to the need to have an extremely tight control of the project during the ramp-up process, as well as on a daily and weekly basis.

BAILEY. OMNICARE. Project managers are being asked to deal with multiple levels of complexity within a trial; this is the biggest change. There are no longer simple trials that look at one point of efficacy. There is a lot more analysis of subgroup enrollments so project managers have to deal with multiple potential issues about the compound.

KOSTELNY. KENDLE. The regulatory environment changes all the time, not just in the United States but globally. It's imperative that the project manager makes sure all of the team members are adequately trained and are aware of all the regulatory changes to ensure that we are compliant. For example, in the United States, there is increased scrutiny on how we approach potential investigators about participating in a clinical trial. There have been new regulations in the past several years, including HIPAA, which impact compliance and confidentiality during the participation of a clinical trial.

MOREADITH. AAIPHARMA. The need to assimilate data from more sources rather than fewer sources is going to continue to increase. The fundamental responsibilities of project managers won't change but how they get that job done may change as we see more and more data sources. Project managers also will need to be proactive thinkers and they will have to be able to manage large amounts of data and be able to turn the data into information, which will become critically important.

BEEKMAN. NICOX. Communication is much more streamlined, and there is more real-time data so project managers can act much faster and be more proactive to ensure that the study is delivered on time. Technology facilitates the communication and the data transferred; for example, electronic CRFs allow us to see trends, although the results will be blinded. We can see trends much faster than 10 years or 20 years ago when the CRFs needed to be brought in-house and the data entered by hand.

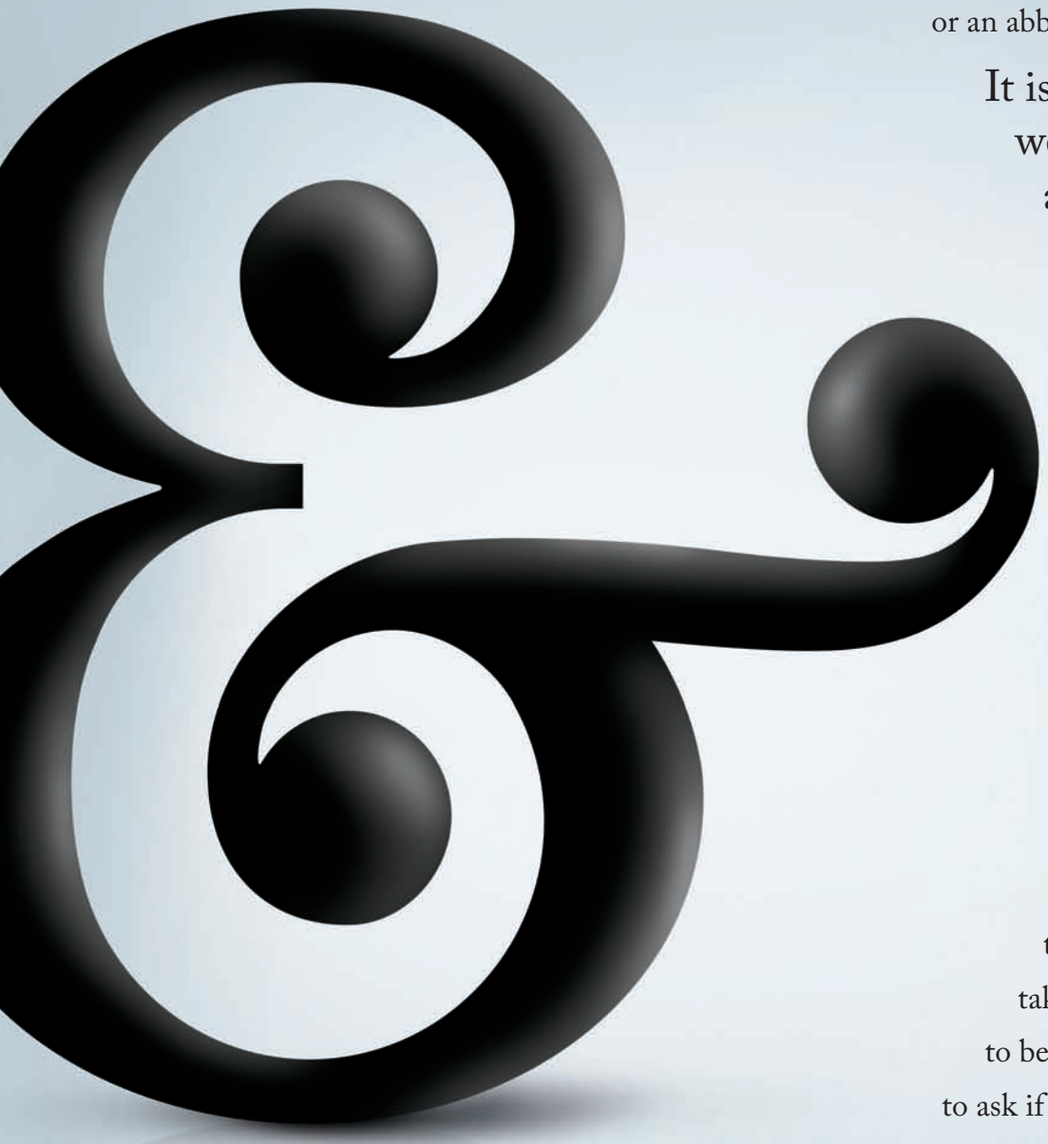
DR. MAARTEN BEEKMAN
NicOx

Our clinical project manager **GOES OVER THE TASK ORDER, INDICATING THE CRO SERVICES, LINE BY LINE WITH ALL OF THE INVOLVED FUNCTIONAL AREAS** so that everybody is completely aware of the expectations and deliverables.

PROJECT MANAGEMENT BEST PRACTICES

1. Clarify and make a commitment to roles: this can provide the most dramatic step change in project team work; it can also happen very quickly, but it's not always so easy to achieve.
2. Establish a clear, agreed upon vision and purpose: in a matrix project environment, this can be the only real source of power and authority.
3. Adopt open, questioning behaviors: expert scientists and commercial executives often seem driven to debate and prove they are right rather than collaborate to reach consensus.
4. Empower team members: people perform best if goals are clarified, and then they can do their own jobs without micro-management.
5. Check information and stakeholder views: check, rather than make, assumptions and guesses.
6. Make regular reviews: teams discuss what went well, what didn't, why, and what must change in future.

Source: Pharmaceutical Industry Project Management Group, Berks, United Kingdom. For more information, visit pipmg.org.



The distinctive symbol that joins the names of Art Sudler and Matt Hennessey in our logo is an ampersand.

Beyond simply being a striking piece of design or an abbreviated "and," it also says a lot about us.

It is a symbol of who we are, what we value, and how we think.

It's our assurance to S&H employees, stakeholders, and customers.

It simply says we add.

We add outcomes to ideas, add insights to information, add beliefs to inspiration, and add understanding to issues.

Our ampersand is a promise to go the extra distance, reach higher, take more chances, do whatever it takes to become greater, and never be afraid to ask if anything more can be done.

It acknowledges that two heads are better than one, and that no matter how much things change, there will always be greater opportunity by adding one idea to another.

This is our Sudler and Hennessey.

S&H

www.sudler.com

CALLAHAN-SQUIRE. ASTRAZENECA. We want our project managers to become more effective communicators in a global world. We want to make sure they can use the most effective technologies — audio conferences, WebEx meetings, video conferences, virtual team meetings.

KOSTELNY. KENDLE. New technologies can help us manage a clinical trial. Technology has changed the way in which we communicate with study sites, clinical sponsors, and even study subjects. Now instead of commu-

Sound Bites from the Field

PHARMAVOICE ASKED THOUGHT LEADERS FROM COMPANIES SERVING THE PHARMACEUTICAL INDUSTRY TO ADDRESS HOW THE ROLE OF THE CLINICAL PROJECT MANAGER HAS CHANGED OVER THE LAST FIVE YEARS.

MICHAEL GAMBLE is Group Manager, Yoh Scientific and Yoh Clinical, Philadelphia, a provider of talent and outsourcing services. For more information, visit yohclinical.com.

"There have been several changes that have impacted the role of the project manager. One is technology. There is more use of electronic data capture and electronic submissions, more widespread use of project management specific software, etc. A project manager must stay current with technology.

Another change is resource management and the diverse set of resources. The project manager must manage internal and external resources in the United States and abroad. They must manage consultants and contractors, as well as their own employees, with some being local and some at remote locations. All of these resources must work together for a successful project. The use of many different types of resources continues to grow.

A third change involves talent. Key issues project managers face include the competition for talent and attrition of crucial staff members. Drug-development professionals are in high demand and are constantly presented with opportunities. Staff retention is key to a successful project.

Project managers will continue to be affected greatly by these issues. They will need to continue to stay current with technology, juggle many different resources, and work with their companies to find creative ways to keep talented staff in place."

MELYNDA GEURTS, M.S., is the Chief Operating Officer for D. Anderson & Co., Dallas, a provider of patient recruitment and retention services for the clinical-trials industry. For more information, visit dandersoncompany.com.

"The role of the clinical project manager in patient recruitment has changed significantly in the past five years. Patient recruitment is frequently defined as a delicate blend between art and science. But the science aspect of patient recruitment is the trend leader.

Project managers' responsibilities have evolved whereby ingenuity in capturing and reporting metrics to define customers' return on investment is pivotal.

This is not an easy task, as there are many uncontrollable variables that impact patient-recruitment programs.

In addition to metric collection, project managers are responsible for referral-management programs and quality control measures.

Lastly, and probably most importantly, project managers are becoming defined as the key liaison between sites and the pharmaceutical companies."

JASON TIBBS is Director of Project Management in the Victoria, British Columbia, office of PRA International, a global clinical research organization with corporate headquarters in Reston, Va. For more information, visit praintl.com.

"In the past five years, several factors have caused a major shift in the way clinical project management is conducted, notably the increased internationalization of trials, rapid introduction and adoption of new technologies, regulatory changes, a move toward regionalized staff, and operational efficiency and resource management.

These dynamics are likely to accelerate over the next five years, requiring greater adaptability on the part of clinical project managers.

Because of the increased cost of drug development in recent years and the consequent critical issue of cutting time to market, the global project manager has come under increased pressure to lead by operational excellence and in particular have experience in developing cohesive management plans that are focused on contingency plans for dealing with the unexpected.

Implementation of proactive recruitment strategies and solutions has been an area of critical importance.

Applying standardization and best practices is an area of critical import as project managers seek consistency of approach across regions and across programs."

JIM ZUFFOLETTI is President and Cofounder of openQ, Charlottesville, Va., which develops and delivers solutions for the strategic management of key relationships and compliance in life-sciences and other industries. For more information, visit openq.com.

"The globalization of trials always has been a consideration in the industry, but now we are hitting a tipping point. It's not possible to manage a global trial by getting on a plane anymore.

Working with clinicians requires coordination and planning. This has become its own business process with its own resources and technology needs to support management and compliance.

The pharmaceutical industry also is coming to appreciate the fact that today's clinicians are tomorrow's opinion leaders. As a company's mindset shifts in this direction, it begins to take the development of the life cycle of its relationships with clinicians more seriously.

Companies can work to be more transparent and more focused on helping the clinician develop new capabilities over time."

inVentiv health

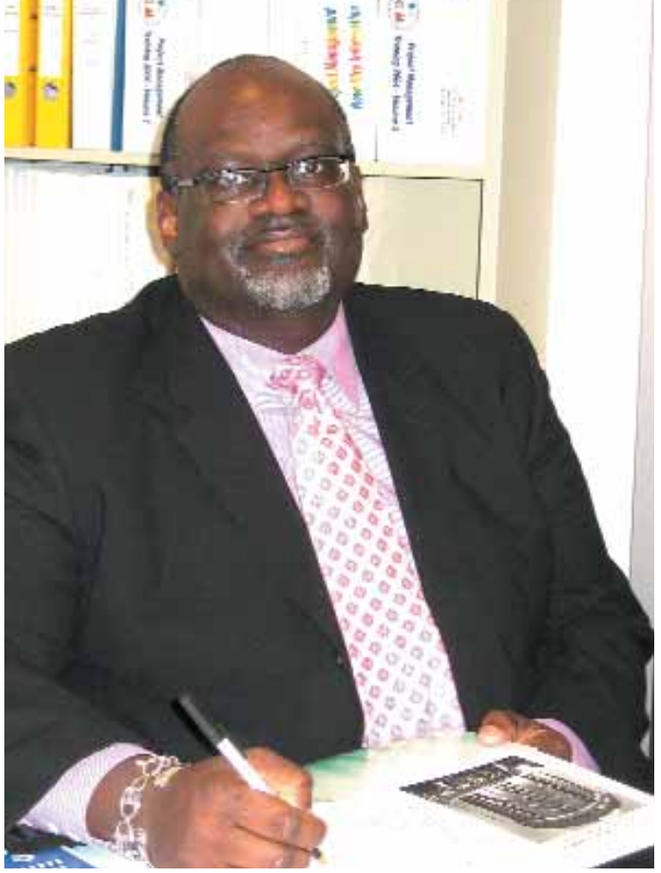
accelerate your vision

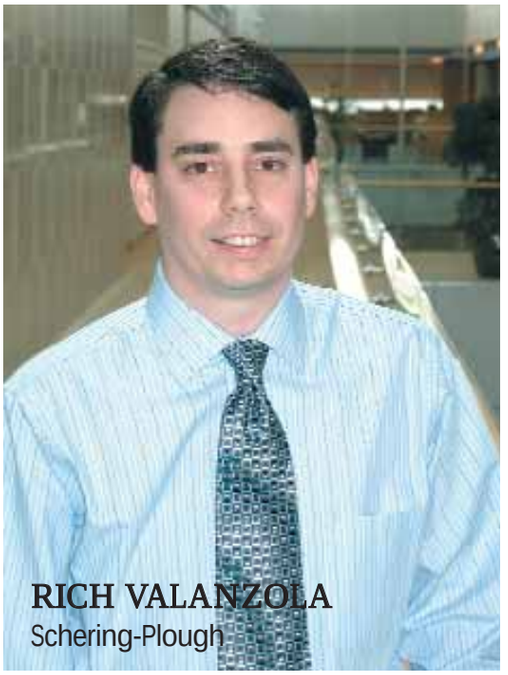
Welcome to inVentiv Health

A whole new way of thinking about your business

Everyone's moving fast these days. But speed alone is not enough to take your pharma product from development to commercial success. You need your own formula for acceleration and a partner like none other to help you find it. With three client-focused service divisions—**Clinical, Communications, and Commercial**—inVentiv Health smoothly integrates a full range of services across the product lifecycle. Move ahead with inVentiv Health.

To achieve the quality growth your business demands, visit us at ***www.inventivhealth.com***





RICH VALANZOLA
Schering-Plough

When I interview project managers, I look at the challenges they have encountered with a study **TO SEE WHETHER THEY HAVE THE SKILLS TO MANAGE ISSUES THAT MAY COME UP IN THE FUTURE.**

JEROME BAILEY
Omnicare

IN THE FUTURE, THE PROJECT MANAGER IS GOING TO NEED THE SKILLS TO MULTITASK and look at cross-functional areas of protocols that have multiphase processes.

nicating via a fax, regular mail, or FedEx, we have secure Web portals where we can upload information, and this information can be viewed whenever and wherever it is convenient.

MANAGING CHALLENGES in Trial Studies

Timelines, recruitment, and cost overruns are a few of the challenges that project managers face.

MELVIN. COVANCE. My role as a project manager is to provide a quality deliverable on time and on budget. Risks can come in all forms that may impact these goals, which could lead to delays of the study or impact quality. For example, a few years ago a truck with lab samples was hijacked. This is not something that one normally thinks about, but it can happen and it can impact the study.

RICHARDS. PFIZER. The biggest impacts that project managers can have on a trial are ensuring that all of the people on the team have clear and aligned goals with clear roles and responsibilities, have the information that's needed, understand and proactively manage risks across several studies within and across TAs, have contingency plans in place, are proactively communicating and sharing the progress of the project, and are working effectively as a team.

METTINGER. ONCOLYTICS. Risk is a corporate challenge across the organization, and this is even more so in a small company. We always have to watch out for red flags and have systems in place to track those warning signals early on in terms of adverse events, which are probably the most dangerous risks in clinical trials.

CALLAHAN-SQUIRE. ASTRAZENECA. We have a corporate methodology for risk management. It's called integrated risk management, and this strategy has been rolled out from the highest levels of AstraZeneca on down. We train people on the methodology, and we have people who go to our project teams to assist them with learning the methodology.

MELVIN. COVANCE. One of the philosophies that Covance employs is engaging in continuous risk management. As such, we take predictive and proactive measures toward prevention. What it boils down to is that we look at contingency planning up front, and we look at all aspects of a study and identify any areas of risk where something could go awry or amiss. We then rate each of these risks individually and their probability and potential impact. We also try to identify predetermined trigger points when we would put our contingency plans into motion. This is more of an upfront investment in a program than we traditionally use to do.

SMINK. CHILTERN. We create a project plan in which we document how we are going to implement a clinical study. We do feasibility studies to check if our initial assumptions make sense or whether we should modify them. We also look at contingency plans so that, if we deviate from the plan, we have backup plans in place that can be implemented immediately.

DAMPHOUSSE. IDENIX. From day one, project managers need to build bridges where bridges — internally and externally — have not been built before. For example, they need to understand the CRO they are working with and get to know the project leader as well as the CRAs. They should continue that relationship throughout the entire trial to build that bridge.

MELVIN. COVANCE. The project manager's biggest impact is to bring out the best in each of the individuals on the team. The project manager is there to promote a collaborative atmosphere and a team environment. We can't expect the project manager to be the expert in every discipline; there is a core team of statisticians, data managers, medics, regulatory, and safety folks, among others. Project managers have to engage all members and gather what is needed from each of these individuals to facilitate the project and make sure that the information meets the study's and the clients' needs.

MOREADITH. AAIPHARMA. We've just implemented a new standard for all of our clinical trials that includes a discussion about risk man-

Our mission is to disseminate medical and scientific data to advance the educational, commercial, and regulatory objectives of the healthcare industry.

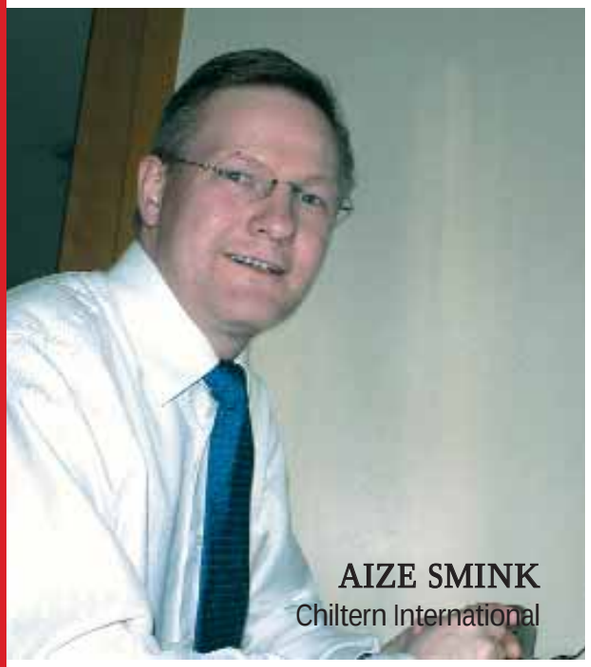
Kevin Flynn, Managing Director 781-246-6646

Core Skills

- Medical writing
- Editorial services
- Meetings logistics
- Client service
- Graphic design

Services

- Publication planning
- Publication writing (abstracts, clinical papers, monographs)
- Poster writing, design, and printing
- Advisory boards with full slide support and executive summaries
- Investigator meetings
- Sales training
- Interactive programming
- Live promotional events
- Animation production
- Video production



AIZE SMINK
Chiltern International

Project managers have been given formal responsibilities; **THIS EMPOWERMENT MEANS THEY CAN MAKE DECISIONS THAT AFFECT THE STUDY.**

agement as an ongoing part of our project reviews. In any clinical trial, just as there are critical success factors, there are potential risks. We look at current risks, as well as potential high, medium, and low risks, and what contingency plans we might need. Risk management has to be individually built in for each project.

DAMPHOUSSE. IDENIX. The biggest risk that every company encounters is enrollment and meeting timelines. When we think this may be an issue, we try to think outside the box and look to see if there is something we can do while developing the protocol in terms of inclusion/exclusion criteria that will enhance enrollment. Once the protocol is in place, we look for other ways to recruit sites, such as attending a scientific meeting where we can talk to potential investigators.

VALANZOLA. SCHERING-PLOUGH. One of the biggest challenges is meeting the timeline. To overcome this, we identify where the slippage in time might occur, what impact this could have on our broader timelines, and what corrective actions need to be taken to address what has occurred. Then after assessing these factors, we'll look at whether there is a place to gain back the time that we lost, whether we need to adjust our timelines, and what can we do to prevent such an instance in the future.

CONNIE MOREADITH
AAIPharma

MELVIN. COVANCE. To counter risk factors, we do a lot of informatics modeling; we have a group that is strictly dedicated to this purpose. Based upon the history that we have, and our experience in the field, we come up with initial assumptions and apply these assumptions to a statistical model. The beauty is that we can take real-time data and input our assumptions to customize the information. We can use this information for everything from predicting our resource needs to predicting site activations. We also can use it to forecast study supplies, taking into account items that impact a study's drug supply needs and run models around different what-if scenarios. So there is much more going on behind the scenes than in years past.

PROJECT MANAGEMENT Skills

All of the experts interviewed pointed to communication and the ability to lead as critical skills that project managers need now and in the future.

RICHARDS. PFIZER. When I look for project managers, I want someone who has strategic thinking and leadership capabilities, who does not have a problem having the hard conversations with people, someone who has good judgment, someone who clearly has a project management background, someone who has strong problem-solving skills, and someone who has relationship management and strong communications skills.

COMMUNICATION IS ONE OF THE KEY ROLES AND RESPONSIBILITIES OF A PROJECT MANAGER; he or she must be able to communicate in many different directions and sometimes in all directions at once.

CALLAHAN-SQUIRE. ASTRAZENECA. We look for people who have very good interpersonal skills. We look for people who are excellent relationship managers. In the United States, we look for people who have a PMP certification from the Project Management Institute. We look for people who have an average of 10 years to 15 years of clinical drug-development experience, preferably in a number of therapeutic areas. A nice-to-have quality is experience in a number of different companies.

SMINK. CHILTERN. We are working more and more with virtual teams; location is becoming less important than the actual expertise project managers bring to the team. We look for people who have a scientific background and ideally a clinical background or someone who has been doing data management at a senior level, preferably at a CRO.

KOSTELNY. KENDLE. A project manager has to be able to work independently as well as with a multidisciplinary team. We look for someone who can work with study sites directly and who may also be involved in a subject recruitment campaign while managing an internal team. They have to be able to put on multiple hats. And since we're expanding into multinational studies, it's good to have global experience.

MOREADITH. AAIPHARMA. Outside of the core knowledge and experience that a good project manager should have, I'm looking for people who are creative problem solvers, who are lead-

ers, who can work within a team environment, and who can understand the team motivation.

BILELLO. INCLINIX. We look for a clinical research background, meaning they should have experience working for a pharmaceutical company or a large CRO. Many of our project managers had been project managers in the pharma industry environment or had been CRAs at one time in their career. We have some people with nursing backgrounds, those who have Pharm.D.s, and other types of clinical/medical backgrounds.

VALANZOLA. SCHERING-PLOUGH. One of the most important skills is the ability to communicate among various cross-functional teams, whether the teams are within Schering-Plough, such as data management, or at a vendor, such as a central lab or a CRO. When hiring, I look at what challenges people have encountered with a study, such as a missed timeline, and how they've responded to those situations to see if they have the skills to manage issues.

BEEKMAN. NICOX. Communication from the beginning is key. As soon as we have selected a CRO, our clinical project manager who leads the study goes over the task order, indicating the CRO services, line by line with all of the functions involved — biostatistics, data management, regulatory, drug safety, clinical supplies — so that everyone at NicOx and the CRO is completely aware of the expectations and deliverables, avoiding unnecessary change orders.

METTINGER. ONCOLYTICS. Another important skill is the ability to manage and motivate other people in a matrix organization across corporate and cultural borders. This is very much a challenge within the industry because of mergers and acquisitions.

BEEKMAN. NICOX. Clinical project managers, especially in small biotech companies, have to have the ability to manage remotely. The last thing we want to do is hire someone who wants to micromanage a project. We have full-service contracts, which means that we contract with a CRO to deliver the entire study using their standard operational procedures and their logistics. The role of our project managers is to help the CRO to deliver on time with high quality.

KOSTELNY. KENDLE. A few years ago, we made a decision to change the title to "project leader" to reflect the responsibility this person has for a study from the beginning all the way through to the end. This is not just someone who manages a project but someone who takes ownership of the study from the beginning.

METTINGER. ONCOLYTICS. Project management is not a matter of leading from the top down; it's a matter of leading in a matrix system, which means that sometimes they have to lead side by side. This is a special skill set that needs to be nurtured and developed.

MELVIN. COVANCE. Clinical trials are all about people, so people skills are important. Project managers have to be able to communicate on the proper level and ensure that the message is being heard correctly. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.