Carolyn Gretton

Trials Without TRIBULATIONS

As clinical studies become more global and increasingly complex, sponsors are striving to improve efficiencies, gain increased access to patients and investigators, and better integrate R&D competencies and solutions.

"Wireless technologies that streamline the process of swiftly and accurately identifying the best patients for clinical trial enrollment are another big advance in clinical trial management."

MARK JOHNSON *MediciNova*

There is a confluence of drivers that the industry needs to be mindful of if it is to realize innovation in clinical operations in the very near future: the empowered patient, the patient leader, mobile connectivity, mobile technology, social media, and electronic health records, according to Joseph Kim, clinical operations director at Shire.

He also notes that innovation is not always rooted purely in technology.

"People and process can be as much the source of innovation as technology," Mr. Kim says.

Mr. Kim adds that Shire is already leveraging various combinations of these drivers to enhance protocol development, patient recruitment, and informed consent.

"Together, these provide patients with the ability to quickly self-assemble across geography and time, as well as access and share data to enable more sophisticated decision-making, behavior change, and participation," he says.

Increased synergy and collaboration between healthcare and clinical research continues to be one of the greatest, albeit not yet fully realized, drivers of innovation in R&D, says Catherine Celingant, senior director, medical systems innovative technologies, for Millennium: The Takeda Oncology Company.

"Another key driver is personalized medicine, being able to pinpoint the subsets of patient populations most likely to benefit from specific treatments without wasting time, resources, and hopes on non-efficacious options," Ms. Celingant adds.

According to Adrian Harel, Ph.D., acting CEO and director of R&D for BrainStorm Cell Therapeutics, innovation in the biomedical field is being driven by breakthroughs in science and technology, as well as the need to find therapies to combat diseases with high morbidity or mortality rates for which no solution has been found.

"Either we don't yet understand the etiology of these diseases well enough, or we have not yet developed an effective treatment," Dr. Harel says. "For BrainStorm, a deeper understanding of cell cycles, combined with an innovative approach to differentiating autologous adult stem cells, allows us to re-establish the crosstalk between nerve and muscle fibers for a new level of treatment for diseases like ALS and MS."

Marc Gurwith, M.D., chief medical officer for PaxVax, says in his view, R&D innovation comes in large part from advances in recombinant science.

"From a vaccine perspective, there are going to be better monoclonals, better immunogens, and better assays to evaluate potential candidates," Dr. Gurwith says. "I foresee successes in difficult infections for which there aren't vaccines yet — malaria, HIV, and so forth — coming out of improvements in recombinant biology."

Eric Perakslis, Ph.D., chief information officer and chief scientist, informatics with the

FAST FACT

THE REVENUE FOR WORLDWIDE PHARMACEUTICAL CLINICAL TRIAL SERVICES TOTALED $21.69 BILLION IN 2010 AND IS EXPECTED TO REACH $32.73 BILLION IN 2015.

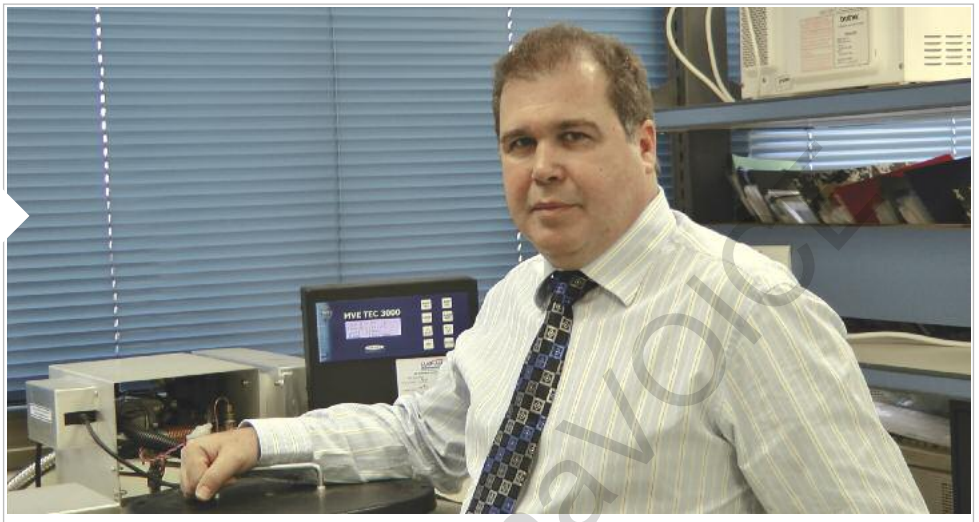
Source: Visiongain

Vendor Sponsored/Created Electronic Information

Electronic information used to support research/work

Source: BioInformatics, Ask-A-Scientist survey from April 2012.
For more information, visit gene2drug.com.

"Innovation is being driven by breakthroughs in science and technology, as well as the need to find therapies to combat diseases with high morbidity or mortality rates for which no solution has been found."



DR. ADRIAN HAREL *BrainStorm Cell Therapeutics*

U.S. Food and Drug Administration (FDA), predicts the explosion and convergence of sociology around social networks will continue to shrink the world, propagate unlimited ideas, and drive the consumer healthcare experience.

"This opportunity clearly extends into the regulatory space with the recent Innovation 2.0 pilot campaign to solicit proposals for devices that can add meaningful benefit to patients with renal failure," Dr. Perakslis says. "This pilot program introduced three new communications, collaborations, and crowdsourcing approaches into the device regulatory submission process with impressive success."

Lynda Tussey, Ph.D., VP, research and development, at VaxInnate, says while innova-

tion relies on individual creativity, it also requires a certain amount of structure.

"In the end, talented people managed well by effective leaders who support innovative thinking and foster creativity are the major drivers of innovation," Dr. Tussey says.

Michael Coffee, chief business officer at MediciNova, cites three drivers of innovation in the life-sciences space: academic research, government and NGO research entities, and a healthy biotech/pharma environment where early-stage innovation is encouraged and supported.

"The improvements in technology are very important, but they aren't the only drivers for innovation," Mr. Coffee says. "There are development funding gaps, that tend to discourage risk-taking."

Data as Driver

Steven Sweeney, head of clinical technologies at Infinity Pharmaceuticals, identifies data integration and data visualization as critical drivers of innovation over the near and long term.

"We are continually looking for ways to make our data more accessible to and consum-

VIEWPOINTS

MARK ENGELHART
Chief Commercial Officer
ACM Global Central Laboratory

Collaborative Data

An increased emphasis on collaboration across partner companies, scientific disciplines, and global locations is driving innovation in the area of communications. In addition, having access to robust data, information, and ideas in real time is required for crucial decision-making. Lastly, the global scope and scale of R&D is driving the need for rapid collection and analysis of information from a variety of sources to enable the early identification of trends that resolve issues and capture opportunities.

Collective Knowledge

The scale of study, site, and patient information available today gives service providers an opportunity to leverage their collective knowledge and experience with sponsors to optimize study outcomes. Using innovative technologies and processes to rapidly integrate and analyze large volumes of information, identify study trends, and accurately forecast outcomes service providers can assist sponsors with R&D efforts by driving cost-efficiencies and improving outcomes.

SCOTT CONNOR
VP Marketing
Acurian

The Industry is Its Biggest Barrier

At a time when industry must shed its conservative cloak and embrace innovative change, too many people equate innovation with radical change and risk. They aren't synonymous. In patient enrollment, for example, innovation is as simple and safe as recognizing that fewer sites can fulfill the enrollment required when they are infused with external patients. To get pipelines to submission doesn't always require new technology. Sometimes it just takes new thinking.

MARK L. WEINSTEIN
President and CEO
BioClinica Inc.

A Cultural Revolution

In our industry science and technology rule, but the best driver of innovation is a culture that encourages employees to develop new products that supersede previous offerings. Quality is always essential but rather than focusing on filling gaps or correcting errors, this approach emphasizes an organization's strengths. That's usually a lot more productive. Such a culture wastes no fondness on the way it's always been done or too-big-to-fail and proactively supports new methods and systems.

A Unified Development Platform

There is widespread recognition that clinical research is too expensive and time-consuming. Technology hasn't more positively affected innovation largely because of the predominance of siloed technologies — a result of sponsors purchasing unrelated products to support separate job functions for each stage of a trial. Happily, there is a growing appreciation for the view that a unified clinical development platform will go a long way toward improving the overall process. At BioClinica, we think this is huge.

JOHN M. HUDAK
President and Founder
Criterium Inc.

At an Open Innovation Crossroads

The global pharma industry is at a very important crossroad when it comes to open innovation. For instance, the level of innovation — as defined by new drugs introduced into the market — continues to decline while innovation investment as defined by R&D spending continues to rise. When one considers the vast amounts of data that have been generated in the search for new drugs, it becomes clear that the ability to unlock these vast data sets can provide a much-needed spark. And while there are many examples of pharma embracing certain aspects of open innovation, this open-source view of data is relatively new. The best partnering will be to have transparent processes between pharma and service providers.

TOM AVERY
VP, Strategic Business Development
ERT

Technology-Supported Outcomes Research

Outcomes research is rapidly emerging as an es-

able by multiple key stakeholders, including our internal teams as well as our external collaborators and investigators," Mr. Sweeney says. "Through this shared access, our aim is to provide a decision-support and hypothesis-generation tool set that will lead to actionable scientific and operational insights and that will drive R&D and enhance value."

Greg Moody, director, clinical informatics, at Millennium: The Takeda Oncology Company, calls this a time of unprecedented opportunity for change and innovation in R&D. The convergence of business need and the growth of consumer connectivity and acceptance has enabled faster and less duplicative data collection, as well as the ability to better leverage the data over time as a community, he says.

"We made advances in efficiency and quality with EDC systems and ePRO systems, and there is an opportunity to feed these solutions from systems like EHRs and EMRs and possibly personal health records (PHR)," Mr. Moody says. "Patients and care providers can pick up a tablet or smartphone and be connected like never before, and they have shown their willingness to share information about

sential element of the clinical R&D process, while clinical outcomes assessments are increasingly becoming a vital part of regulatory requirements. One example of this is the 2010 FDA guidance for all developers of psychiatric — and some non-psychiatric — compounds to evaluate subjects for treatment emergent suicidal ideation or behavior. In line with emerging requirements, sponsors are looking for technologies that not only support their research, but also integrate effectively into their current processes. These companies are also looking for tools that support their need to make rapid decisions during trials accurately and consistently to enable better decision-making.

Complementary Assets

As the industry shifts toward strategic outsourcing, sponsors must begin evaluating their partnering strategies in more depth to develop complementary relationships. Clinical trial service providers must fully immerse themselves in the sponsor's business needs, goals, and objectives to ensure they gain a full understanding of the culture of the company. Entering into a strategic partnership with an expert vendor gives sponsors a higher quality of service due to a deep, mutual understanding of exactly what is required to ensure a smooth, cost-efficient process.

LAURIE HALLORAN
President and CEO
Halloran Consulting Group Inc.

Real-Time Data Key to Success

More technology isn't necessarily the solution. We have to use existing technology to provide real-time information about performance, so that management decisions can be based on clinical data and quality metrics. Management needs to be able to make value-based decisions on where to spend precious resources so that the products with highest potential are developed more quickly with built-in quality. Innovation drivers should be risk-based approaches and adaptive trial design. Neither is new, but it's the right regulatory time to maximize their innovative application.

Focus on Core Activities

Providers that lead the effort to reduce spending on non-value added activities will fare best. CROs work with sponsors to align goals more closely, prospectively evaluate risk, and build in quality, not maximize margin and expand scope. Pay-for-performance incentive programs in healthcare differentiate payment among providers based on performance of quality and efficiency measures so that desired outcomes occur through changed behavior. Perhaps studying how the pay-for-performance incentive programs could be applied in vendor relationships would be a start.

TED GASTINEAU
Global Data Technology
ICON Clinical Research

Innovation Equals Time Plus Money

I think the key drivers of innovation are time and money. The pharmaceutical industry is under pressure to find better ways to understand whether a drug demonstrates safety and efficacy and to make better informed and faster decision-making to improve time to market. This can be delivered through innovation.

Removing Innovation Barriers For Success

As an industry, we need to introduce more lateral thinking and learning. Most trials are transactional and don't necessarily inform the next trial. Innovations need to be shaped by informed prior experience and delivered by best-of-class processes. Personalized medicine is now driving drug development and biomarkers including laboratory test, imaging, and other indicators that show early efficacy are needed. However, regulatory approval of these markers is often challenging and this may delay wide-scale adoption.

JAMES C. WALKER
CEO and Chairman
Octagon Research Solutions Inc.

Clinical Data Standards

With the Food and Drug Administration embracing clinical data standards, sponsor companies that adopt standards will reap the benefits of more efficient clinical and regulatory information management, as well as improved product review timelines. Ultimately these efficiencies can improve time to market and speed innovative new therapeutics and devices to patient communities.

(Viewpoints continued on next page)

"We are continually looking for ways to make our data more accessible to and consumable by multiple key stakeholders, including our internal teams as well as our external collaborators and investigators."

STEVEN SWEENEY *Infinity Pharmaceuticals*

themselves and their health to facilitate medical advances."

"Additionally, data in EHR systems can be mined to better understand unmet medical needs and target populations and refine clinical study protocols, thus increasing their chances of success," Ms. Celingant notes.

According to Ms. Celingant, pharmaceutical R&D organizations often have siloed systems, meaning that discovery, clinical pharmacology, toxicology, safety, and clinical data that could yield significant insights and opportunities remain only minimally tapped because the data cannot be mined in aggregate.

"As with EHR integration and personalized medicine, this is an area where technology, specifically having access to greatly en-

VIEWPOINTS

BILL GWINN
VP, Clinical Informatics Solutions
OptumInsight

Addressing Business Needs

The best innovators understand the business needs. Who will be purchasing new therapies? It is important to study disease prevalence patterns that include those who are currently uninsured. Healthcare reform legislation aims to extend access to health insurance to 32 million of the nation's 46 million uninsured by 2019. Expanded coverage starts in 2014, when new health insurance exchanges are expected to open. I expect that oncology/hematology, antibiotics/antivirals, and cardiovascular will dominate R&D activity.

Pharmacoeconomic Analysis

New breakthroughs are difficult to find, and R&D must overcome barriers to proving that something new is better. R&D will need pharmacoeconomic analysis, the scientific discipline that evaluates the clinical, economic, and humanistic aspects. There are tools, such as standardized questionnaires and benchmarks for patient reported outcomes. They can prove that a new therapy offers better quality of life.

BRIAN KELLY
Group President, Product Value Strategy
OptumInsight

Meeting Unmet Patient Needs

Technology has certainly driven R&D; however, the most inspiring and motivating driver has been and remains unmet patient needs and inefficiencies in the current health system. If novel technology does not serve patient needs or address inefficiencies, people won't pay for it.

Leveraging Technologies

Clinical trial services companies can help sponsors most by focusing on leveraging HIE and other platforms for healthcare providers that reduce the time and cost of data collection.

MIKE O'GORMAN
CEO
Sentrx

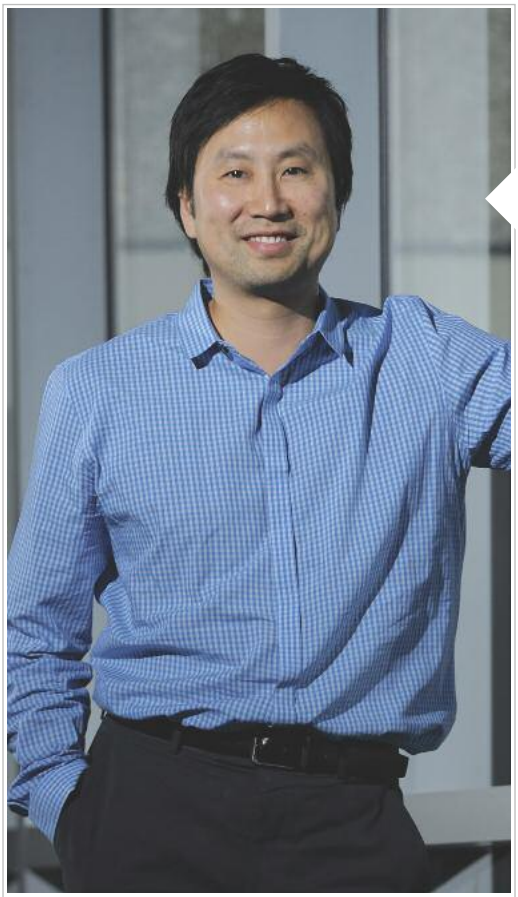
More Accessible Safety Data

Open innovation, which is the integration of internal and external technologies and expertise to address major challenges, has clearly made its way into the world of drug and device development. Computer-aided analysis and design, external collaboration, and partnering make it possible to develop new products quicker and cheaper than in the past. In our area of expertise, the use of internal and external safety data to detect signals has improved the sponsor company's ability to shift direction more rapidly or study potential adverse outcomes sooner during development, thus avoiding prolonged approvals due to lack of relational data, potential product recall costs, and/or avoiding potential costly lawsuits during commercialization.

ELLEN LEINFUSS
Senior VP, Life Sciences
UL EduNeering

Cloud Solution Improvements

Cloud-computing solutions are making it easier to capture and reuse knowledge, which accelerates development of new products. Similar holistic knowledge approaches are improving clinical trial effectiveness. Investigator meetings are recorded and made available for retraining, leading to more accurate trial data and improved patient safety. Training records are embedded into the e-clinical infrastructure, so researchers and site personnel can focus on product innovation and recruitment rather than on administrative tasks.



JOSEPH KIM *Shire*

"There is a confluence of drivers needed to realize innovation in clinical operations in the very near future: the empowered patient, the patient leader, mobile connectivity, mobile technology, social media, and electronic health records."

GREG MOODY
Millennium: The Takeda Oncology Company

"The convergence of business needs and the growth of consumer connectivity and acceptance has enabled faster and less duplicative data collection, as well as the ability to better leverage the data over time as a community."

hanced computing and analysis power, can make all the difference," she says.

To help promote intensive knowledge-sharing, Mr. Sweeney says that Infinity Pharmaceuticals builds its systems with an eye toward integration.

"Currently, all of our clinical trials are using EDC, and the data are warehoused in a system we developed internally," he explains. "Additionally, we are in the process of developing a data warehouse that will be populated with data from our internal research teams as well as external collaborators such as specialty academic labs. The ongoing development of these warehouses is being done with the goal of making it easy for our R&D teams to mine and analyze these complex clinical data sets."

Mark Johnson, director of investor relations and corporate development at MediciNova, views wireless technologies that streamline the process of swiftly and accurately identifying the best patients for clinical trial enrollment as another big advance in clinical trial management.

"With MediciNova's recent acute asthma exacerbation trial, it was very important to reach patients as soon as they came into the emergency room of a hospital," Mr. Johnson notes. "When I was on site last time, I noticed that the residents conducting the trial for us were getting direct alerts on their pagers when patients would come in with a preselected chief complaint like shortness of breath. There are technologies such as this that are being developed and standardized for use across all clinical trial sites, and the incorporation of technology will be a huge help with clinical trial enrollment."

Scaling the Barriers

Mr. Sweeney observes that today's increasingly sophisticated and accessible technology platforms — such as genetics, genomics, proteomics, and metabolomics — are enabling pharmaceutical companies to amass data at an unprecedented rate, helping to shift the focus of R&D, and medicine in general, toward more personalized, targeted approaches to treating disease.

"Yet, standing between us and personalized medicine is the mind-boggling onslaught of data: how to make sense of it all and, most importantly, harness its clinical relevance," he says. "Advancing innovative methods and standards to find, mine, connect, visualize, and analyze complex data sets and quickly transition to developing and testing hypotheses in the clinic will be critical elements in making the promise of personalized therapies a reality for patients."

"In the context of informatics and technology, I believe better knowledge management is key," Mr. Moody says. "Industrywide, we could make great advancements if we could share negative results in a more complete and timely manner so each biotech/pharma company didn't spend time and resources going down a path that may have been already identified as a dead end."

Ms. Celingant agrees that there is an urgent need — and encouragingly, a few ongoing initiatives — for a framework that would allow pharma and biotech organizations to share precompetitive data and that would be acceptable to all stakeholders, including regulators.

"In the same vein, we see that therapeutic solutions for the most challenging and urgent unmet medical needs often involve combinations of drugs, some of which may still be in development, by different organizations," she says. "Some companies, Millennium being one, are challenging traditional sequential development models and exploring private/private as well as private/public partnerships to accelerate the testing of potential beneficial combinations. Regulatory authorities need to continue to be open to such efforts."

Dr. Perakslis believes that despite all its technological advances, the industry is still experiencing a lack of validated biological targets, and that there is a knowledge and information gap that's yet to be filled despite global efforts.

"Data density in specific areas of biology is also an unmet need," he adds. "There are so many partnerships on the cusp of forming that could have a positive effect, but the incentive system is still lacking. We have to cross the threshold and begin to address this." PV

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MARK JOHNSON. Director of Investor Relations and Corporate Development, MediciNova Inc., a biopharmaceutical company focused on acquiring and developing novel small-molecule therapeutics for the treatment of diseases with unmet need. For more information, visit medicinova.com.

JOSEPH KIM. Clinical Operations Director, Shire, a global specialty biopharmaceutical company. For more information, visit shire.com.

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LYNDA TUSSEY, PH.D. VP, Research & Development, VaxInnate Corp., a privately held biotechnology company developing novel, proprietary vaccines for pandemic and seasonal influenza. For more information, visit vaxinnate.com.

Carolyn Gretton

Picking PARTNERS

With sponsors constantly seeking efficiency in the execution of clinical trials, there is a growing demand for partners that provide lean, efficient processes and high-quality, effective clinical supply and data management.

Lynda Tussey, Ph.D., VP, research & development, at VaxInnate, says clinical trial service providers can best partner with sponsors by introducing innovation into trial design and services.

"One way they can do this is through innovative trial designs that optimize efficiency, increase the chance for success, and enable projects to move forward more quickly," Dr. Tussey says.

Adrian Harel, Ph.D., acting CEO and director of R&D for BrainStorm Cell Therapeutics, notes that at an early stage, BrainStorm decided to implement its R&D activities in collaboration with medical institutions.

"For example, in the design of our currently running Phase I/II trial at Hadassah Medical Center in Jerusalem, the medical staff teamed up with company scientists to develop the clinical treatment and monitoring protocols," Dr. Harel says. "For our next clinical trial, planned for the end of this year in Boston, there is an open dialogue between the principal investigators and BrainStorm. Good collaboration between the medical and commercial teams has enabled us to develop a clinical protocol that is highly beneficial for the patient."

PaxVax Chief Medical Officer Marc Gurwith, M.D., says his company tends to select service providers that specialize in a particular aspect of clinical trial management.

"We'll use one CRO for data management and a different consultant for statistics or clinical monitoring, rather than just turning over an entire project to a single CRO," Dr. Gurwith says. "It's more flexible, user-friendly, and cost-efficient."

Steven Sweeney, head of clinical technologies at Infinity Pharmaceuticals, says the ability of a CRO to integrate well with his company's processes and systems has become a major selection criterion, as has the ability to offer near real-time transfer of data and Web services/APIs that streamline data transfer.

"I believe that clinical trial service providers need to recognize that they cannot be all things to all people," Mr. Sweeney says. "For example, we have outsourced the management of our clinical trial specimen bank to a specialty vendor that operates both on site and at external facilities. Using custom-built Web services, we manage everything from requesting specimens through managing custom workflows, labeling processes, and reporting that make the work of both our scientists and project managers more efficient and decrease the chance for error. These Web services also enable us to connect users with the relevant information regardless of their vantage point."

But Eric Perakslis, Ph.D., chief information officer and chief scientist, informatics with the U.S. Food and Drug Administration (FDA), says the piecemeal outsourcing approach can be risky.

"Current approaches can be a mixed bag of many partners each doing a partial bit of the process, and the resulting patchwork can be complex and even error-prone," he explains. "Thorough process analysis can help in identifying the optimal value processes and partial processes to partner."

Greg Moody, director, clinical informatics, at Millennium: The Takeda Oncology Company, says he would like to see service providers proactively invest in solutions that

EXPERTS

CATHERINE CELINGANT. Senior Director, Medical Systems Innovative Technologies, Millennium: The Takeda Oncology Company, a biopharmaceutical company focused on delivering medicines to patients with cancer worldwide. For more information, visit millennium.com.

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drive standardization and operational efficiencies.

"Our best outcomes usually come as a result of an open and honest dialogue, which allows the team to work in that spirit of open innovation," Mr. Moody says. "But it's hard sometimes to keep from slipping back into the old customer/provider relationship where the provider waits for direction from the sponsor instead of creating a true collaboration."

Michael Coffee, chief business officer at MediciNova, considers shared risk a key component of a good service partner.

"If clinical trial organizations only play the role of service provider, they don't get as integrated into the operation as they would if they had a shared risk/reward stake in the trial's success," Mr. Coffee says. "As we go forward we're looking for partners in development that have a shared interest in making sure things run efficiently and effectively all the way through the end of the program."

"For service providers to be true partners, they need to look beyond the statement of work and seek to truly understand their sponsor's business model and strategy," says Catherine Celingant, senior director, medical systems innovative technologies, for Millennium: The Takeda Oncology Company. "This will allow them to be more effective partners with sponsors, making day-to-day decisions, as well as suggestions for improvement, in the spirit of the agreement, rather than its letter." PV