

by Denise Myshko
and Taren Grom

The Changing Clinical **LANDSCAPE**



Companies are focusing energy and resources on those activities that most directly support the voice of the patient and are looking for the most relevant activities that ensure that they are gathering the right data to address the critical benefits and risks that the patient community has helped articulate and define.

KEN GETZ
Tufts CSDD

As clinical operations and development have become increasingly complex — from protocols to new science — sponsors, CROs, and sites need to manage a multitude of variables to meet the growing demand for new treatments.

Clinical operations — the department that manages the operational aspects of clinical studies — is facing increased challenges: compressed timelines; increased competition for sites and patients; more complex study protocols; increased regulatory expectations; and new technologies and industry standards.

Clinical operations is transitioning to align with innovative methodologies for faster and more efficient study start up, improved trial recruitment and retention, and to leverage technology to improve the productivity of collaborations through more efficient and effective oversight, says Mitchell Katz, Ph.D., head of clinical research and drug safety operations, Purdue Pharma.

One of the latest trends is patient-centric clinical development. Companies are piloting and integrating more patient-centric practices into clinical operations, including programs that aim to bring patient feedback to the protocols and study designs.

Patient-related challenges are among the top concerns of sponsors and CROs, according to a global survey conducted by eyeforpharma of biopharmaceutical companies, CROs, consultants, and others involved in the clinical research process. Patient-centricity is seen as a key factor in improving both the efficiency and the focus of clinical trials, although it also is perceived as being so important to the new pharma operating and commercial model that 21.24% of respondents reported it being a companywide imperative, according to eyeforpharma, which conducted the survey in the fall of 2014.

Patient-centric study teams are beginning to study real-time data to understand and adjust the patient recruitment process as it unfolds, according to a recent survey by Tufts Center for the Study of Drug Development. Engaging the patient — including soliciting patient input, using big data and new technologies such as social media for patient outreach — is a response to the growing pressures to

accelerate the pace at which new medicines are launched.

“This is in large part about applying a patient-focused approach to the clinical operations function,” says Ken Getz, director of sponsored research programs at Tufts CSDD and founder of CISCRP. “Companies are doing this for a couple of reasons: to focus energy and resources on those activities that most directly support the voice and needs of the patient and to gather the right data in the protocols to demonstrate clinically meaningful benefits as defined by the patient.”

Mr. Getz says there is an increasing focus on providing clinical trial results to patients in summaries that use lay language.

“CISCRP is working with more than three dozen companies that are implementing lay language trial results programs either within a given therapeutic area or across their portfolio,” he says.

Another growing effort is to solicit input up front from patients about the design of the protocol to ensure the protocol can be executed more feasibly. Patient advisory boards are helping to provide feedback on draft protocols and discuss how protocols can be simplified for the study volunteers.

Mr. Getz says some companies are also doing simulation exercises where they’ll ask

The Patient Experience



TOM AVERY
Senior VP of Business
Development, iCardiac
Technologies

The greatest opportunity we have to enhance the patient experience is to drive more clinical research into patients' homes, where data can be most credibly collected vs. the controlled, sterile site environment. The most accessible application of this concept appears to be patient reported outcomes. If we really want to enhance experience, what better way than to let patients stay at home with the right technological controls.



JOE BEDFORD
Corporate VP, Strategic
Marketing, Envigo

Patients report that enrolling and participating in a clinical trial can be disruptive to their lives. Hence clinicians are increasingly employing clinical technologies, such as interactive voice and web technologies to improve recruiting, scheduling, protocol compliance, patient reported outcomes data collection, adverse event reporting, patient randomization, drug management and other areas of the trial. These technologies enhance productivity by making it easier for patients to participate in a clinical trial and simpler for the clinician to manage the trial. Such technologies also provide data that helps support medical decisions aimed at protecting patient safety during the trial — one of the key areas of concern to patients. To date, many of these technologies have been employed to improve investigator performance and satisfaction during a trial. But moving forward I sense we will see technologies being used much more often to help im-

prove the patient experience. We've gotten started along that journey, but we have a lot more to do.



JOHN BLAKELEY
Chief Business Officer,
CRF Health

The patient-centric study has the potential to use technology to relieve the patient and site of a significant part of the burden of the clinical trial. Understanding how to mobilize new technologies can not only lead to better informed and more empowered patients, but can help ensure they remain engaged and compliant for the duration of a study.



LISA BOYETTE, M.D., PH.D.
CEO, Save Jon

There are few opportunities for patients to learn more about themselves or even the aggregate understanding generated when they participate in clinical trials. We should treat patients more like the stakeholders they are — like stockholders — by sending them quarterly reports or a summary of the knowledge to which they contributed.



BONNIE BRESCIA
Founding Principal,
BBK Worldwide

Only if we commit to knowing patients' experiences with their condition, their healthcare providers, and those that control access to their care and treatment, can we enhance the patient experience in clinical development. We will innovate in valuable ways and advance treatments faster if we keep the patient at the center of our work.



ADAM BUTLER
Senior VP, Strategic
Development,
Bracket

Everyone involved in the development lifecycle can do a better job of asking patients how they would like the research programs to work. In many cases, even minor adjustments to our processes and technology to accommodate patient's requirements, instead of data manager's requirements, would go a long way in bringing more patients to trials.



MARY CLEGG
Executive Director,
Clinical Operations,
SynteractHCR

The patient's experience is enhanced by limiting the impact that participation in a clinical trial has on their daily life. At-home visits, smartphone, and tablet technologies for patient reported outcomes improve a patient's experience and promote retention. Consulting patient advocacy groups during protocol development provides an opportunity for protocols to be designed with the patient in mind.



DOUG COOK
President, Global
Specialty Logistics,
AmerisourceBergen

At-home clinical trials will enhance the patient experience by minimizing the disruption to their lives, increasing the operational efficiency of the study, and allowing for faster completion times and more reliable results.

an investigator and a study coordinator to go through the motions of executing or administering the protocol.

"These efforts have helped companies identify areas where they need to shift or move procedures at a given visit and sponsors have been able to reduce the total number of procedures per visit to simplify and make the patient's participation more manageable," he says.

One example is Alnylam Pharmaceuticals, which holds meetings with investigative sites to understand the patients' perspective.

"Patients' voices are being incorporated with respect to how the disease impacts their lives the most," says Rick Falzone, senior director, clinical operations at Alnylam Pharmaceuticals.

In the company's lead Phase III program,

Alnylam incorporated sites' perspectives to understand how much is being asked of patients, and Mr. Falzone says the company is incorporating this feedback into how the study is being designed.

"We've been interacting with patient advocacy groups in preparation for these meetings," he says. "We have operationalized our clinical trials to help facilitate patients' par-



ERIK DALTON
Executive VP,
Healthcasts

Gaining insight and input from physician key opinion leaders early in the drug development process is critical to making strategic decisions on where to invest research dollars to discover innovative treatment options, and develop clinical trial design that not only ensures meeting FDA safety and efficacy standards, but measures the outcomes patients are looking for. In addition, once a treatment is newly approved, educating physicians directly impacts the patient experience — when physicians understand how a drug will positively impact QOL and the patient experience, it facilitates better patient/physician communication and speeds adoption.



TIM DAVIS
CEO and Founder,
Exco InTouch

Many of the clinical processes used today were developed before the digital revolution. The greatest opportunity we have today as an industry is to leverage technology to integrate clinical trial participation naturally into patients' lives. This will enable more aspects of a clinical trial to become connected and automated, provide patients with the interface they'd expect to use and give them feedback on the trial itself.



GLEN DE VRIES
President,
Medidata Solutions

Truly engaging patients — longitudinally, effectively, and salably — will have a dramatic impact on the value of the drugs in today's clinical development pipelines. The life-sciences companies that take a disciplined and scientific approach to developing those engagement strategies — the same way they develop the drugs themselves — will position themselves for success over the next decade and beyond.



DONALD DEIESO, PH.D.
Chairman
and CEO,
WIRB-Copernicus Group

The proliferation of personalized medicine holds great promise for those facing life-threatening diseases. Our understanding of the human genome and proteome has evolved to the point where therapies based on patients' omics and biology are a reality. The future lies in our ability to apply this to a larger cohort of patients.



DARCEE DUKE STRUBE
VP, Clinical Operations,
TKL Research

The biggest opportunity to enhance the patient experience is around the idea of patient centrality. The patient should be considered in all elements of the clinical development plan, including protocol design, trial objectives, recruitment messages and systems or tools used to facilitate and support patient participation in a trial.



JIM ESINHART, PH.D.
CEO, Chiltern

The advancements in wearable technology are positively impacting patient experience. Throughout the length of a trial we are performing more procedures and collecting more data over longer periods. Not only do wearables improve patient adherence to study medications and procedures, but also aid in capturing more real-world data less invasively.



CHERYLE EVANS
VP, Clinical Operations,
Advanced Clinical

Mobile and digital technologies within clinical development continue to expand, and communication through emails, text messages, and push notifications are overwhelmingly effective and well-received for those that opt in. However, a larger effort is needed to leverage the benefit and value of receiving messaging, like appointment and medication reminders, and mo-

bile-optimized study websites where the applications are streamlined, more clearly direct users to other resources with more information, and provide reliable user analytics to sponsors and CROs.



DAVE FITZHENRY
Managing Partner,
Trinity Partners

The biggest opportunity for enhancing patient experience is re-establishing trust between patients and innovators. This includes objective information on the treatment options — drug and non-drug — tradeoffs involved in managing the patient's disease, and disclosure of the study results. The patient's role in helping advance science needs to be recognized and honored.



PAM GARFIELD
Senior VP Strategy
& Innovation,
Patient Health
Perspectives

Co-creation can make magic happen between patients and healthcare organizations. Companies that bring patients and caregivers together in working co-creation sessions with key staff members can find solutions to challenges large and small together, ranging from improving participation and reaching underserved patients to best support for caregivers.



JENNIFER GOLDSMITH
Senior VP,
Veeva Vault,
Veeva Systems

As patients become more involved in their own treatment plans, clinical transparency can be vital. If an experimental new drug offers promise, right now there's no easy way for patients to access information about it. It's time to let patients know how to access information, and empower them to work with advocacy groups. Technology can give patients new visibility into crucial clinical development — a powerful level of patient-centricity.



LAURIE HALLORAN
President and CEO,
Halloran Consulting
Group

The biggest opportunity lies in public education on what clinical development is, and why a patient should participate. The nonprofit organization CISCRP has been making an impressive effort for a long time, but there is still little lay understanding beyond the idea of the human guinea pig fear. In addition, soliciting input from patients on protocol feasibility can be really valuable and is just beginning to gain some momentum in some innovative company settings, and would likely assist researchers in designing better studies.



JOHN HUBBARD, PH.D.
CEO, Bioclinica

Patient engagement is critical to the positive experience of participating in a clinical trial. Most studies screen a large number of patients, some who will screen-fail and not be randomized and benefit from the treatment. Likewise, the randomized patient may be part of the placebo group and thus not receive active treatment. Whether or not they are an active participant, feeling engaged with the study and its objectives is important. We must create an environment where the patient sees a trial as a continuum of care and treatment. Patient-centricity, a major focus of the FDA, allows patients greater involvement in the study and its objectives. In improving the patient experience, enhanced participation, as well as positive interaction about trials within social communities, is possible. New regulations and industry collaboration gives participants the ability to view the clinical trial results. One great example is Pfizer's Blue Button Project: Engaging Patients by Sharing Electronic Clinical Data. Launched in 2013, Pfizer's project enables trial participants to download their individual clinical data, which empowers patients to use the clinical data to enhance their overall health by sharing it with healthcare providers and, thus, moving the clinical trial experience to a mainstream healthcare option.



INDRANI KAKAIDE
Director-Clinical
Development,
Sciformix

Rapid penetration of technology across the globe provides better opportunities to use patient reported outcomes (PROs) to influence clinical development. As clinical data transparency extends to a greater number of clinical trials, it will provide a huge opportunity to enhance the patient experience since patients will have access to data generated from clinical trials.



DAVID LAKY
VP and General Manager,
Clinical Solutions,
ArisGlobal

Patient-centric clinical trials make the patient a true partner in clinical research. For pharmaceutical companies, this will help increase enrollment, decrease dropout rates, and reduce cost. For patients, the trial process becomes more convenient by eliminating intrusive site visits and procedures, and relying more on mobile devices and technology.



SANDRA LOTTES, PHARM.D.
VP, Global Clinical
Development and
Operations, UBC: An
Express Scripts
Company

Immunotherapy can significantly enhance a patient's immune system to better respond to their disease, whether it's cancer or inflammation. Sponsors should partner with clinical trial nurses, who can be champions for patients during a sophisticated treatment process, to greatly improve the patient experience.



JEAN MCCOY
Senior VP Strategy and
Innovation, Health
Advocacy Strategies

Partnering with patients in an authentic and honest way can build trust as nothing else can. True engagement can show patients that not only is

a company making great products, but there are good people developing those products who care deeply about the well being of patients and seek their opinions to help that process.



ERIC MORRIE
Director of Product
Operations, ClinCapture

Facilitating patient recruitment, engagement, and retention are some of the most pressing issues in our industry. From a technology standpoint, eConsent and ePRO systems are being recognized and widely adopted to make patients' life easier, while streamlining the data collection process. A recent survey of the top 50 pharma companies shows that about 66% of them are either using eConsent or planning to in the near future. Another survey shows that 61% of companies implemented ePRO in the last five years, 28% in the last 10 years, and 11% over 10 years ago.



JIM MURPHY
CEO, Greenphire

An effort to provide a better patient experience cannot exclusively focus on the patient. It needs to also include efforts that empower sites and keep them focused on research. In our business, this comes with automating manual processes that can be time-consuming and resource-draining, distracting the research staff from focusing on the patient experience.



**MICHAEL MURPHY,
M.D., PH.D.**
Chief Medical and
Scientific Officer,
Worldwide Clinical
Trials

The opportunity lies with a participatory approach that leverages the patient perspective in the research experience to inform protocol design and the burden of proposed assessments. Early engagement helps to enhance the attractiveness of study participation, reflected in accrual/retention metrics and mea-

ticipation, whether it's understanding what to expect in a general clinical trial, why we do clinical research, and what to expect in this clinical trial, as well as how to help patients navigate through the challenges of participating in a clinical trial."

Outsourcing Trends

Experts agree there has been a push to outsource more clinical operations, especially by smaller biotech companies and among smaller companies that need capacity, infrastructure, and expertise.

Pharmaceutical and medical device teams plan to increasingly involve contract research organizations in their clinical trial planning processes. The largest projected change is the level of vendor involvement in trial design activities, according to a recent report issued by Cutting Edge Information.

Of the surveyed companies, 17% report that they currently share strategic planning duties with vendors. By 2020, the number of teams planning to share these trial design responsibilities with CROs is expected to increase to 52%. In 2014, no surveyed top 10 or top 50 team reported sharing trial design responsibilities with CROs or other third parties.

Mr. Getz says sponsor companies have shifted their operations to favor variable cost models, and the CRO has become integral to the clinical research enterprise.

"As sponsors have worked to reduce traditionally high fixed operating costs, the reliance on outsourcing has grown substantially," he says. "R&D pipelines continue to grow, requiring more capacity in order to manage all of the global R&D activity. There's a real need to supplement fixed headcount with expertise and capacity from outsourced personnel."

Dr. Katz says it's important for sponsors and CROs to align processes to generate a true value add.

"As an industry, we know how to run clinical trials, but we have a lot of experience doing it in what I call the 'fat way' — with bloated protocols, micromanagement to the point of duplication of efforts, and very broad blanket oversight that does not take into account the specific risks inherent in any given program," he says. "Our challenge is to get the same results more efficiently with smarter, more streamlined protocols; risk-based and metric-based models for more rational oversight; and strategic partnerships."

Dr. Katz says Purdue Pharma, as a smaller organization with a smaller pipeline, has found it is in his company's best interest to work with one CRO.

"Working with one CRO allows us to



Clinical operations is transitioning to align with innovative methodologies for faster and more efficient study start up, improved trial recruitment and retention, and to leverage technology to improve the productivity of collaborations through more efficient and effective oversight.

DR. MITCHELL KATZ
Purdue Pharma

efficiently align our processes with theirs," he says. "Over the years, we have been able to work with a CRO that meets the expectations of our data management, statistics, and other functional groups. For us that alignment makes both our work and the CRO's more efficient."

He also says Purdue works with a consultancy that does bidirectional surveys that ask team members and management at both Purdue and the CRO how the partnership is going.

"The results enable us to look at the trends, weaknesses, and opportunities we can work on together," Dr. Katz says. "Then, through the governance structure that we have in place, we work toward better alignment and on bolstering the weaker pieces of the relationship."

Mr. Getz says one of the reasons for inefficiencies and poor operating performance is that some companies often juggle multiple operational models.

"Even those companies that have the functional or strategic alliances in name are still very inconsistent in their implementation of their respective models," he says. "In many cases, they're managing and juggling multiple models at the same time and they're working with their partners inconsistently. This drives high levels of inefficiency, delays, and poor performance."

Traditionally, biopharma companies out-

sourced study monitoring, data management, statistical analyses, and medical writing, but now Mr. Getz says development planning and protocol design as well as the regulatory affairs management area, are seeing a growing involvement from the CROs.

"Companies are extending the role of the CRO into areas that used to be managed by internal teams," he says. "At the same time, we see a lot of companies rethinking whether they're going to outsource at the same level they did in the past and if they're going to use the same outsourcing models. Companies are always looking to tweak their approach to see if they can improve the economics and drive the cost down and at the same time improve efficiency and performance."

Dr. Katz sees some larger pharma companies starting to bring more activities back in-house.

"Some organizations that have been outsourcing using multiple providers have realized that there are certain functions they would prefer to have as key in-house operations and that they want to bring them back in," he says. "For this reason, fully outsourcing even to one CRO may not meet their expectations. It is about control and the way they would like to see certain elements handled within the conduct of the trial."

The move is counter to Purdue's strategy of maintaining a lean and nimble organization, however: "If we kept clinical operations in-house, we'd have to have a much larger infrastructure," Dr. Katz says.

The decision to use a lean outsourcing model has led to changes in how Purdue considers its staffing requirements for the future.

"Previously, the infrastructure was such that we looked at clinical operations in a particular way — a way that aligned with the traditional approach to getting the work done. Now, the competencies we need within clinical operations are changing," he says. "Much of this change has to do with technology, which is where the opportunities lie for us. We need to think about the roles technology and data are going to play in clinical operations, and about the competencies required to put them to optimal use."

Biopharma companies continue to try to stay lean and flexible, says Robert Sorensen, associate director, clinical operations at Achillion Pharmaceuticals.

"There are pros to this approach and not having a huge dedicated infrastructure sometimes helps companies to be able to move and adapt quickly," he says.

Mr. Sorensen says Achillion Pharmaceuticals has a blended model of outsourcing.

"We have a mixed model, in some instances we outsource pieces of the clinical

asurable outcomes relevant to product adoption and compliance.



JUDITH NG-CASHIN, M.D.
Chief Scientific Officer,
INC Research

Listening to the patients and embedding their perspectives into all aspects of clinical development not only improves their experience, but also addresses tactical concerns, ensures meaningful clinical endpoints, and ultimately influences the types of medicines that are pursued, approved, and brought to market for others like them.



CHRIS PERKIN
CEO, Altasciences

The advent of wearable technology, mobile device applications, and the Internet of Things is starting to change the approach to clinical trials and improve both the patients' experiences and the quantity and quality of the data.



NINA PRUITT
Director, Global Product Marketing, Clinical Trial Optimization Solutions, IMS Health

We need to reduce the time and burden on patients to comply with the protocol through innovations such as remote or mobile technologies to alleviate unnecessary travel burdens and enable more efficient communications and adjusting protocols to be more patient-centric and targeted.



SY PRETORIUS, M.D.
Chief Scientific Officer,
Parexel

Listening to and connecting with patients — before, during, and after clinical trials is an area of opportunity for companies. If we can involve the patients earlier — and often — in the clinical trial process, we can help them be more dedicated participants, significantly improving the patient experience and the sponsor experience.



THOMAS SPROAT, PHARM.D.
Senior VP, Scientific Affairs, Clinical Mind

Patients do not have a voice when it comes to current clinical development of pharmaceutical products. If we can lobby for change to include PROs and other real-life experience in conjunction with rigorous scientific trial data as part of the overall review process, this would go a long way in involving patients in this process.



JAMES STREETER
Global VP,
Life Sciences,
Oracle Health Sciences

The Cloud provides a means of collecting professional grade data, IoT data, and patient-sourced data — on drug reactions and social commentary, easy sharing of data among clinicians, quickly identifying patients who might best benefit from a particular clinical trial, fast upgrading for solutions and lower costs for services. All of this will make patient experience easier, lower costs, and hopefully, provide better outcomes.



HUGO STEPHENSON, M.D.
Executive Chairman,
DrugDev

The biggest opportunity is to reduce the administrative burden on study coordinators, freeing up time to support patients. We need tools that allow sites to engage with patients with less effort, so they can use their limited time to support more patients.



CYNTHIA VERST, PHARM.D.
President, Clinical Operations, Quintiles

With the rise of mobile and wearable technologies and increasing availability of health data, new possibilities to digitally engage, recruit, and retain patients have emerged. We need to focus on developing novel technologies and patient-centric digital communities that capture patient-relevant outcomes and deliver benefits during the patient journey of standard treatment with minimum burden and intervention.



MICHAEL WOODS
President and CEO,
Schulman IRB

From a human subject protection perspective, eConsent offers an incredible improvement to the way we inform potential participants about a study. eConsent makes often complicated terms and information more accessible and useful, helping participants to make better, more informed choices about their research contributions.

study and match other things internally," he says. "The model is specific to our needs at the moment, but for the most part a lot of what we outsource to CROs or other niche providers is dependent upon resourcing."

He says Achillion looks to service providers to provide EDC, IWRS, and data repositories.

"With technology, we look for a service provider that's continually developing and perfecting the tools, which takes the onus off of us," Mr. Sorensen says.

Experts say there are many places where technology can play a greater role in supporting the clinical operations group, helping companies to use data more intelligently or lowering the cost of labor intensive activities such as risk-based monitoring for example or other types of risk assessment-oriented activities where more data are required and fewer people are needed to more smartly assess the various tasks that are being conducted.

"There's less paper being generated, but

more data being generated, so technology is absolutely paramount in what we do," Mr. Sorensen says. "There are so many different tools out there from a data collection, a data quality perspective, and a data monitoring perspective. I don't think most companies are dedicated to developing that expertise internally. To bring these functions in internally can be too costly and resource-centric for small companies especially as the technology can change so quickly."

The Changing Clinical Landscape

We asked experts across the clinical development ecosystem to identify what they think is the single biggest trend impacting companies' ability to discover, innovate, and advance science in the current clinical landscape and what they believe is the biggest challenge in the clinical arena today and why.



TOM AVERY
Senior VP of Business
Development, iCardiac
Technologies

TRENDING NOW: A pharmaceutical company's propensity for embracing technological innovation has the most immediate impact in advancing its research. As a recent example, international regulatory agencies, in collaboration with industry experts, have embraced new, more efficient ways to evaluate cardiac toxicity in drug development. Cardiac toxicity — or lack of — can now be evaluated much earlier in the clinical trial continuum, enabling faster, more informed decision making, and more effective pipeline management.

CLINICAL CHALLENGES: The greatest challenge is the sponsor community moving to new ways of outsourcing their R&D needs. While many appreciate the strategic need to leverage technology, this understanding has not fully translated to the tactical level, with access to technology mainly being through CROs. If an outsourcing department is charged with reducing short-term costs, and has no appreciation of early investment into innovation, then the traditional cycle of clinical research continues.



JOE BEDFORD
Corporate VP, Strategic
Marketing, Envigo

TRENDING NOW: The single biggest trend in preclinical development addresses a key challenge: how to best achieve a level of certainty that a molecule tested in a laboratory animal will be predictive of what happens when tested in humans during clinical trials. This is an age-old challenge, but one in which we are making some progress. Beyond the variety of exciting technologies that are now being routinely employed in preclinical development (e.g. biomarkers, im-

aging technologies, genetic testing, etc.), scientists are increasingly using "precision" laboratory animals, which often involve the manipulation of genes in rodents or human genes, tissues and cells in "humanized" models. Such research models allow researchers to test human cancer tissues, for example, by engrafting them on to mouse models, such as the NSG or the NOG. Such advancements are attempts to improve the predictability of the human response to a molecule following testing in laboratory animals. Exciting work is being done in oncology, immunology, and other therapeutic areas with precision models, but we still have to advance the science to close that gap of predictability between preclinical and clinical development testing.

CLINICAL CHALLENGES: Identifying the single greatest challenge in drug development is quite difficult, but if I had to select one it would be minimizing failures in later phases of drug development by gaining more insights on drugs in preclinical and early clinical development. Fortunately, in the past decade or so the industry has made significant progress in this regard by using a variety of technologies, for example biomarkers, imaging, and precision research models in early development to gain as much knowledge as possible before Phase IIa proof-of-concept clinical trials. New methodologies of managing drug development, such as learn and confirm, translational medicine, and adaptive trials have also contributed to better assessing molecules earlier in development, hence reducing failures in late-stage clinical development. Together, these new technologies and methods of conducting R&D are helping the industry overcome some of the productivity issues that we encountered 10 to 20 years ago and reducing failure rates in clinical development.



JOHN BLAKELEY
Chief Business Officer,
CRF Health

TRENDING NOW: New technology that improves connectivity between patients and clinical

trials, as well as instant access to real-time data, will have a far-reaching impact on clinical trials. The need for more data, and then figuring out what to do with all the data once you have it, will require significant focus from the industry.

CLINICAL CHALLENGES: The consumer-based trend of wearable technology in the clinical trial setting is a challenge. The rise of the technology-savvy ePatient brings new opportunities to empower patients in clinical trials to play a more active role in study design, their enrollment, consent and participation. Harnessing the potential of these technologies will be challenging for sponsors, but will reap huge rewards.



LISA BOYETTE, M.D., PH.D.
CEO, Save Jon

TRENDING NOW: Big data generation and mining are the biggest trends driving innovation in the clinical landscape. The next generation of meaningful therapies will come from understanding complex and interacting biologic circuits, and understanding which of those circuits are disrupted in a particular disease and how we can restore equilibrium.

CLINICAL CHALLENGES: The diseases we must cure are complex. Capturing big data during drug development and using it to understand multifactorial diseases means getting just as comfortable understanding how thousands of factors fit together in one patient as we are with studying one factor in thousands of patients.



BONNIE BRESCIA
Founding Principal,
BBK Worldwide

TRENDING NOW: Two equally important trends are pushing at the clinical

development enterprise. Breakthroughs in biometrics and genomics, among others, are opening new avenues of discovery and innovation, often at significant cost. In counterpoint, governments, employers, and patient advocates worldwide are pressing industry to keep or bring prices down. We are just beginning to move the discourse from price to value, from science to wellness — driven by the shift to see patients as partners.

CLINICAL CHALLENGES: One of the biggest challenges remains the absence of best practices across study disciplines. As pharma, researchers, regulators, patients, physicians, and payers become increasingly comfortable with the ways in which new technologies can help improve engagement, real-time and meaningful data collection, and ultimately improved outcomes, I believe we'll see big, positive shifts. Is good clinical practice enough? Wouldn't best clinical practice be better?



ADAM BUTLER
Senior VP, Strategic Development, Bracket

TRENDING NOW: There is a rapid adoption cycle bringing new technology to people all over the world. Pharma is behind making these technologies — smartphones, activity monitors, social networks — a part of clinical research and all will become standard components of all clinical trials in a very short amount of time.

CLINICAL CHALLENGES: Increasingly, investigators and the other research study staff are left out of the innovation process. Pharma, CROs, and especially technology providers, are developing new tools and systems to help harness the data from clinical trials. We need them more involved in the design process if we want these to work.



MARY CLEGG
Executive Director, Clinical Operations, SynteractHCR

TRENDING NOW: New therapies such as immunothera-

pies and biologics provide great promise to health-care and science. However, the cost and complexity of these treatments also provide challenges, not just in development, but also in processing, storage, and handling. It requires specialized expertise and special equipment to handle them in the clinical setting.

CLINICAL CHALLENGES: As always, subject recruitment and retention present big challenges in clinical research. It is important to think through both recruitment strategies and retention from the outset when designing the specific protocol to increase the likelihood of being able to find and retain the best possible subjects for a study.



DOUG COOK
President, Global Specialty Logistics, AmerisourceBergen

TRENDING NOW: The biggest trend is the shift to a patient-centric approach to increase recruitment and retention, which drives trials faster and gets products to market quicker. Home-care trials are making participation more attractive and increasing retention rates but also driving the need to ensure integrity of time- and temperature-sensitive products are maintained throughout the global supply chain.

CLINICAL CHALLENGES: The biggest challenge is pre-empting issues that may slow a trial. With the rise of complex treatments requiring specialized logistics and administration, solutions that facilitate easy access for patients, such as in-home trials or sophisticated time and temperature controls, are critical. Packaging solutions that require no external power, like World Courier's Cocoon, minimize the loss of product along the cold chain, which can add significant reassurance to a manufacturer needing to ship valuable API or study supplies.



ERIK DALTON
Executive VP, Healthcasts

TRENDING NOW: For the industry to be successful in innovation and discovery of new compounds and treatment

options, collaboration across stakeholders is increasingly important earlier in the drug discovery process — in particular with physicians who are on the frontlines of treating patients. We have seen first hand the significant benefit of seeking early collaboration with physicians.

CLINICAL CHALLENGES: This is an exciting time for advancing medicine, especially for rare diseases given the rich pipeline of specialty therapies. Given the deeper knowledge required by physicians to administer new drugs, there's a barrier for quick uptake of newly approved drugs caused by limited time and easily accessible educational resources when a drug is first approved, or when a label is updated.



TIM DAVIS
CEO and Founder, Exco InTouch

TRENDING NOW: Many of the processes used today were developed before the digital revolution. The greatest opportunity we have today is to leverage technology to integrate trial participation naturally into patients' lives. This will enable more aspects of a trial to become connected and automated, provide patients with the interface they'd expect to use, and give them feedback on the trial itself.

CLINICAL CHALLENGES: The greatest challenge we face is how to help the pharma sector embrace change. Although historically risk adverse, the desire to adapt is now there within the industry and we must all contribute to this culture change by demonstrating the immense benefits and value it can bring to everyone involved.



GLEN DEVRIES
President, Medidata Solutions

TRENDING NOW: Patient-centricity is typically listed as a goal for most clinical development programs, but to date, there haven't been great ways to achieve it — at least

scientifically. However, looking at objective endpoints related to quality of life, leveraging sensors and mobile connectivity to patients, changes that.

CLINICAL CHALLENGES: Collaboration is a huge opportunity, but also a big challenge. Sharing information — for example, about which drugs work best together, or what sites are best to work with in a particular study — is an important and worthy endeavor. However there is tremendous naiveté in the industry that sharing raw data is the equivalent of sharing actionable information.



DONALD DEIESO, PH.D.
Chairman and CEO,
WIRB-Copernicus Group

TRENDING NOW: In health-care delivery, general practitioners were succeeded by specialists and subspecialists. We see the same trend in drug development; the intricacy and complexity of today's clinical trials demand greater expertise and more sophisticated, more highly specialized solutions. That is the natural evolution of an increasing knowledge base.

CLINICAL CHALLENGES: As we begin to address more orphan and rare diseases, our approach to clinical trials must become more tailored and more efficient. From protocol design to technology implementation, from site selection to subject solicitation, each and every step of the process must be optimized for success



DARCEE DUKE STRUBE
VP, Clinical Operations,
TKL Research

TRENDING NOW: A lack of funding is the biggest trend impacting discovery, innovation, and advancement in today's clinical landscape. As profit margins continue to shrink, and mergers and consolidations are on the rise, sponsor companies are focusing on strategic, core competencies and are less likely to assume the risk associated with expanded R&D and innovation efforts.

CLINICAL CHALLENGES: Patient recruitment is the biggest challenge and usually the biggest cause in clinical trial delay. Effective patient recruitment requires proactive planning, forecasting, and accurate feasibility to ensure access to the appropriate, and interested, patient population. If recruitment is lagging behind, study delays can significantly impact trial costs.



JIM ESINHART, PH.D.
CEO, Chiltern

TRENDING NOW: We are entering an era of personalized medicine and individualized care. As a result, we are seeing a rise of special designations and expedited pathways granted by the FDA for new product approvals. In 2015 alone, more than half the products approved received special status or accelerated review.

CLINICAL CHALLENGES: Many products with special designation and expedited pathways involve rare diseases — making patient recruitment challenging. In turn, feasibility assessments for site and country selection, well-planned recruitment strategies, global technology platforms, and most importantly, good relationships with investigators, patients, and patient advocacy organizations are becoming increasingly more essential to trial success.



CHERYLE EVANS
VP, Clinical Operations,
Advanced Clinical

TRENDING NOW: The cloud-based technology trend continues to impact the abilities of both sponsors and providers to efficiently share and aggregate audit-ready, quality-driven data. Service offerings using cloud technology, such as risk-based monitoring and eTMF, are examples of streamlined communication platforms that offer complete visibility and create operational efficiencies.

CLINICAL CHALLENGES: To meet the growing demand for highly trained and motivated clinical research associates, especially now with competencies required in analytics and sophisticated centralized

monitoring (RBM) procedures, the industry needs to tap into the skill sets of more entry level staff with advanced degrees to enter the clinical research workforce.



DAVE FITZHENRY
Managing Partner,
Trinity Partners

TRENDING NOW: The rise of the specialty product is evident in new drug approvals and clinical development trends overall. A company's ability to target a very specific mechanism known to be implicated in the disease, combined with the advancement of basic science of several areas including oncology, autoimmune, orphan/genetic based disease and diabetes has led to an explosion in innovation in these fields.

CLINICAL CHALLENGES: One of the biggest challenges in clinical development is the disconnected needs of the regulators, the payers, and the innovator company stakeholders: patients, treaters, and investors. Walking the tightrope between demonstration of safety — placebo control, efficacy — comparative effectiveness, and cost-effectiveness is a challenge every clinical program faces.



PAM GARFIELD
Senior VP Strategy &
Innovation, Patient
Health Perspectives

TRENDING NOW: The seismic shift is that drug developers and FDA are asking the question, "What would patients define as success?" and then incorporating patient perspective and preference into drug development and clinical trial protocols, from the endpoints to the tools and services that wrap around the trial.

CLINICAL CHALLENGES: Every healthcare company we talk to wants to embrace the patient perspective, but they face the very real challenge of how to adapt their structure to operationalize

this approach. How do departments need to function differently? How do teams need to work together across department lines? How are budgets carved out for these initiatives?



JENNIFER GOLDSMITH
Senior VP of Veeva
Vault, Veeva Systems

TRENDING NOW: A company's ability to leverage information across an increasingly broad ecosystem of internal and external stakeholders is critical today. Connections between data, and between partners, patients, providers, and payers are key in clinical discovery. They enable richer, data-driven insights that speed the process of bringing drugs to market. The companies that focus on combining data-driven insights with stronger human connections will drive new ways of thinking in product development.

CLINICAL CHALLENGES: The increasing complexity of clinical trials will be a significant challenge. As more data are collected from a wide variety of sources, it becomes more difficult to analyze, leverage strategically, and measure. Compounding this challenge is the lack of consistency — different stakeholders have different taxonomies. New cloud solutions address these complexities to enable greater collaboration across parties, emphasize metrics early, and standardize taxonomies — to make data a strategic asset.



LAURIE HALLORAN
President and CEO,
Halloran Consulting
Group

TRENDING NOW: People love to talk about being innovative, but they are not inclined to try something new first. They cannot think through what new would be like, to champion it, and forge new ground. It's easier to stay stuck in the old, tried-and-true methods of doing things. Ultimately, risk aversion stems from individual motivation for self-preservation, and I see this as a pervasive issue in the industry. Big company culture and small company fear of

failure can impact everything from regulatory strategy to trial design and it seeps into the inefficiencies in trial operations and technology adoption. It expands to attrition within the investigator landscape, and subject engagement in daunting clinical studies.

CLINICAL CHALLENGES: The biggest challenge in the clinical landscape I see today is complexity without a rationale. There are a million examples of this, from a protocol design that can't really be executed, to quality systems that are redundant while being conflicting and bloated, to numerous vendors that seem to offer a solution, but really create more moving parts where something can and will go wrong. When this complexity is combined with a lack of ability to problem solve caused either by risk aversion or inexperience it's a combination that can breed at worst compliance disasters, and at best lumbering progress through a development program.



JOHN HUBBARD, PH.D.
CEO, Bioclinica

TRENDING NOW: The ability to use multi-source data — a.k.a. big data — across the R&D continuum is a big trend today. In personalized medicine we've seen targeted therapies in oncology, for example HER2+ breast cancer and Herceptin or ALK+ NSCL cancer and Xalkori, where development was accelerated using molecular data, genomic, and imaging biomarkers to show an impact on objective response rate and progression free survival. Such drugs positively impacted patient survival and achieved accelerated approval based on endpoints and molecular targets validated with clinical data and outcomes. Integration of this type of data is key to innovation in the development of targeted medications for a variety of other diseases.

CLINICAL CHALLENGES: A major challenge is also an opportunity to improve the clinical development process. With rising development costs, difficulty in finding patients, delays due to protocol amendments and other challenges impacting study feasibility and recruitment, the industry must become more efficient in conducting clinical trials. As we move to a precision-based approach, clinical trials

will likely be smaller and focus on patient subgroups, similar to orphan disease trials. Moving from a mass to a targeted approach for patient identification, screening, enrollment, and retention will emphasize the need for data, digital marketing, and patient communities, ultimately leading to efficiencies in patient recruitment and better engagement.



INDRANI KAKADE
Director-Clinical
Development,
Sciformix

TRENDING NOW: Companies' willingness to share data and collaborate, as evidenced through the high adoption rate of the initiatives of TransCelerate, is the single biggest trend that will positively impact their ability to advance clinical development. This collaboration extends to initiatives around clinical data standards, shared investigator platform, common protocol templates, etc.

CLINICAL CHALLENGES: New medicines increasingly being developed through acquisitions and innovative collaborations are leading to a major challenge in the clinical landscape of a fragmented R&D process. Multiple organizations and outsourcing partners follow different processes and standards. This is compounded by the need to achieve more with less through the use of efficient but complex study designs, leaner processes, and new technology platforms to reduce the time to regulatory submissions and approvals.



DAVID LAKY
VP and General
Manager, Clinical
Solutions, ArisGlobal

TRENDING NOW: One of the trends is companies moving to technology vendors that allow them to consolidate the use of various eClinical applications into one unified technology platform. This limits the multiple eClinical vendors and systems that a company has to deploy and manage, saving

time, money and resources that can be refocused on actual clinical research.

CLINICAL CHALLENGES: Leveling the playing field for organizations of all sizes is the biggest challenge in the clinical landscape. Small to medium pharma, biotech, and CROs should have the same opportunity to take advantage of the same eClinical technologies as the larger organizations in order to maximize efficiencies and improve their capabilities.



SANDRA LOTTES, PHARM.D.
VP, Global Clinical Development and Operations, UBC: An Express Scripts Company

TRENDING NOW: Managing the full economic cycle of products is essential to investing in innovative therapies. Our industry is developing more effective therapies through personalized medicine, yet the cost of developing therapies like these has never been higher. Through mergers and partnerships, sponsors are sharing costs while also consulting stakeholders before setting pricing on approved products.

CLINICAL CHALLENGES: The greatest challenge has moved to include not only recruiting and retaining patients to also recruiting and retaining qualified clinical data monitoring professionals. Only with experienced CRAs and a well-developed overall data monitoring/management strategy — e.g., RBM approach — can we meet the need to obtain data quickly and accurately and efficiently manage the reporting process.



JEAN MCCOY
Senior VP Strategy and Innovation, Health Advocacy Strategies

TRENDING NOW: If you haven't started engaging patients yet, it's not too late. Though it may seem like everyone else is ahead with patient engagement, the fact is that due to compliance and operational challenges, many healthcare organizations are still

working out how to engage patients in development and clinical trials. Now is the perfect time to get serious about patient engagement.

CLINICAL CHALLENGES: Creativity and compliance do not have to be mutually exclusive. Healthcare companies are working hard to figure out how much room to give employees to spread their wings while remaining compliant to build authentic relationships instead of interactions that could feel forced or formulaic.



ERIC MORRIE
Director of Product Operations, ClinCapture

TRENDING NOW: Cloud-based eClinical systems are disrupting our industry by reducing the friction to adopt data collection and data management technologies. It changes the game when all sponsors can afford to collect and submit data electronically. Cloud-based systems have the unmatched benefits of being on demand, pay-as-you-go, and scalable. They empower small, mid-sized and large drug developers to quickly and nimbly open, or close, new clinical studies.

CLINICAL CHALLENGES: Clinical data interoperability is one of the next frontiers for our industry. We need to continue to work on harmonizing systems and data standards across sponsors, CROs, payers, physicians, and regulators. In particular, the enormous potential cost- and time-savings of leveraging EHR data in clinical trials makes it well worth the effort.



EDMUNDO MUNIZ, M.D., PH.D.
CEO, Certara

TRENDING NOW: Pharma companies and regulatory agencies are increasingly embracing physiologically based pharmacokinetic and pharmacodynamic modeling because it can be used to determine appropriate drug doses or identify potential drug-drug interactions in untestable population.

CLINICAL CHALLENGES: About 80% of the drug candidates entering Phase II trials fail, often due to lack of efficacy. Quantitative systems pharmacology, which

uses computer modeling and experiments to examine relationships between the drug, biological system, and disease process, can help to identify those drugs earlier, thus saving time and money.



JIM MURPHY
CEO, Greenphire

TRENDING NOW: The clinical trial industry has traditionally been slow to adopt new technologies and processes. However, we are now entering a period where sponsors, solution providers, and clinicians are increasingly open to change, especially changed aimed at improving the site and patient experience.

CLINICAL CHALLENGES: The biggest challenges we hear about from our prospective clients are compliance, trial efficiency, and site engagement. We have seen steadily increasing interest from sponsors and CROs looking to leverage our specialized expertise and technology to successfully manage the complexities of funding research across different regions, cultures, workflows and regulations; and increase visibility, control, compliance, and accuracy in the movement of money for patient and site reimbursement.



MICHAEL MURPHY, M.D., PH.D.
Chief Medical and Scientific Officer, Worldwide Clinical Trials

TRENDING NOW: One trend is the need for collaboration across the enterprise. Discovery and development are coordinated through a complex stakeholder matrix. Success requires facilitation of contact points across disciplines; critique of pipeline attractiveness when both value and novelty are mandated; global clinical research dynamics; and access to services mirroring the sophisticated science, supporting products even within niche indications.

CLINICAL CHALLENGES: Elegant technology and fractionated clinical indications require that product attributes be compatible with the standards of care of patients with unique phenotypes and difficult-to-treat conditions. Evidentiary standards for product approval are evolving, while a value proposition must be developed sampling endpoints beyond those required for registration.



JUDITH NG-CASHIN, M.D.
Chief Scientific Officer,
INC Research

CLINICAL CHALLENGES: As patients, prescribers, regulators, and payers insist on clear evidence of not only safety and efficacy, but also significant improvement over current options, positive impact on quality of life, and healthcare cost savings, the data demands in clinical drug development continue to expand, putting additional demands on sponsors and researchers.



CHRIS PERKIN
CEO, Altasciences

TRENDING NOW: The increasingly complex drug and drug combination studies have put a lot of pressure on systems and processes to deal with recruiting, safety and outcomes, particularly in early stage trials. Although these changes will lead to innovation and advancement, in the short term the priority is the need to adapt to a new market very quickly.

CLINICAL CHALLENGES: The proliferation of new immunoactive therapies and the gradually increasing number of biosimilars are challenging current protocols in the absence of reliable and predictive animal models.



NINA PRUITT
Director, Global Product
Marketing, Clinical Trial
Optimization Solutions,
IMS Health

TRENDING NOW: Reductions

in R&D budgets and government agency grants negatively impact the innovation pipeline for new treatment discovery and development. Simultaneously, commercial returns are not fueling the reinvestment in research as in the blockbuster era.

CLINICAL CHALLENGES: Finding patients that meet the most feasible and scientifically reasonable I/E criteria in proximity to experienced, high-performing investigators — globally.



SY PRETORIUS, M.D.
Chief Scientific
Officer, Parexel

TRENDING NOW: Prescription drugs as a percentage of healthcare spending has increased over time driven by the enormous cost of innovation in the biopharma space. To prepare for commercial needs, it is important to keep a focus on market access and payer/provider considerations throughout development, specifically during Phase II and III.

CLINICAL CHALLENGES: The high failure rate in drug development is one factor that limits access to therapies for patients. Although failures cannot be eliminated, the risk of failures can be reduced through a variety of innovative tactics such as leveraging data from a variety of sources.



THOMAS SPROAT, PHARM.D.
Senior VP, Scientific
Affairs, Clinical Mind

TRENDING NOW: It is more cost-effective for big pharma to allow start-up biotechnology companies and their investors to assume the economic risk of drug discovery and early clinical experience. The R&D pipeline process for large companies consists more now of due diligence for M&A activity rather than having their own scientists in-house.

CLINICAL CHALLENGES: The biggest challenge also presents a huge opportunity — and that is the rapid pace of change in our industry — scientifically, economically, and socio-politically. The confluence of these forces are opening doors to new medicines,

novel partnerships, and an evolving desire to broaden access to those who are in most need.



JAMES STREETER
Global VP of Life
Sciences,
Oracle Health Sciences

TRENDING NOW: Our ability to enhance the patient experience by bringing together all kinds of real world data via the cloud from myriad sources — IoT, mHealth devices, clinical trials — results in more individualized interactions and better targeted treatments for each patient.

CLINICAL CHALLENGES: Collecting, aggregating, normalizing, and managing data for the most accurate analysis and the most precise trial results is a challenge. These results can produce actionable patient treatments.

RICHARD STAUB
President, Novella Clinical

TRENDING NOW: Immuno-oncology has emerged as one of the most promising subsets of cancer research with immunotherapy drugs generating \$41 billion in sales in 2014, almost half of the overall cancer therapeutics market. It's exciting to see the shift away from the concept of oncology being only tissue specific, and trials are beginning to treat patients with drugs that address the genetic profile of cancer, as well as looking to reengage the immune system to fight cancer on its own.

CLINICAL CHALLENGES: Patient enrollment is one of the biggest challenges within immuno-oncology studies. Subjects must meet a narrow set of inclusion and exclusion criteria for specific genetic markers, and that can make finding the right patients more difficult. But, the potential benefits for those patients are tremendous.

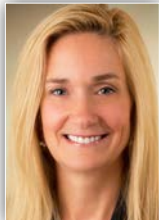
HUGO STEPHENSON, M.D.
Executive Chairman, DrugDev

TRENDING NOW: The extraordinary expense



of the clinical development pathway is a massive barrier to scientific innovation. First, this long and expensive process makes it harder to justify the development of treatments with novel mechanisms of action and unproven commercial application. Second, given how much time and money is at stake during this process, sponsors are reluctant to take risks in the way they operationalize their trials.

CLINICAL CHALLENGES: The biggest challenge in the current clinical landscape is the mismatch of perceived fair market value payments to sites — i.e., constantly decreasing, versus the increase in administrative and burden — i.e., EDC data entry) being demanded. As this mismatch gets bigger, and sites either leave the industry or drag their heels, the whole site-based clinical trial model breaks down.



CYNTHIA VERST, PHARM.D.
President, Clinical
Operations, Quintiles

TRENDING NOW: Leveraging real-world and secondary data evidence to power up clinical development in earlier phases is becoming more pervasive as sponsors demand smarter, faster, and more cost-sensitive approaches to product development. Real-world evidence can be used for earlier or conditional approvals by way of adaptive licensing and breakthrough therapies, as well as to inform investigator and patient feasibility and smarter trial design that accelerates recruitment timelines.

CLINICAL CHALLENGES: Patient recruitment remains a challenge and often leads to delays in drug development timelines — not to mention adding considerably to project costs. Recent research estimates that more than 10% of sites fail to enroll a single patient in a trial.



MICHAEL WOODS
President and CEO,
Schulman IRB

TRENDING NOW: Data sharing and digital collaboration have forever changed the way we conduct clinical research. New technology lets us use information to make faster and better informed decisions during drug development, and this increased access leads to increased transparency, lending credibility to research innovation.

CLINICAL CHALLENGES: Clinical study start-up continues to be the most challenging part of the research process. The choices made in this short timeframe have a profound impact on the entire clinical study. From my point of view, regular communication and informed decision-making are the keys to finding success in this critical start-up phase.



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