ALONG the Continuum

Taren Grom

The statistics on development to commercialization remain staggering, despite a decade marked by major technology improvements, process enhancements, and R&D realignment by most pharmaceutical companies. No doubt drug development is extremely complex, yet it is one of the most vital endeavors.

According to the most recent report from Tufts Center for the Study of Drug Development, it still takes about 10 to 15 years on average for an experimental drug to travel from the lab to U.S. patients. Only five in 5,000 compounds that enter preclinical testing make it to human testing. Only one of those five is approved. On average, it costs a company $1.3 billion to get one new medicine from the laboratory to the hands of the consumer; in 2003, the cost was $897 million. And once the product reaches the market, myriad factors impact adoption and use — from regulatory/legislative changes to patent life to a changing consumer world.

DR. ROSLYN SCHNEIDER ▪ *Pfizer*

"R&D productivity, while an important component, should not be viewed as equivalent to value delivered."

Ernst & Young (EY) analysts say companies will succeed or fail based not just on how many units of a product they sell, but rather increasingly on their ability to improve health outcomes, with patients and payers squarely in the middle. Pharma 3.0 does not replace Pharma 2.0 (the current model) as much as supplement the ongoing efforts to address unmet medical needs and expand access to products. EY has identified two trends that are driving the transformation of the industry: healthcare systems' lack of sustainability and the coming of age of several game-changing technological advances. In this special issue, we will seek to determine how these two trends as well as how many others are impacting the development timeline from the clinic through commercialization.

R&D Productivity

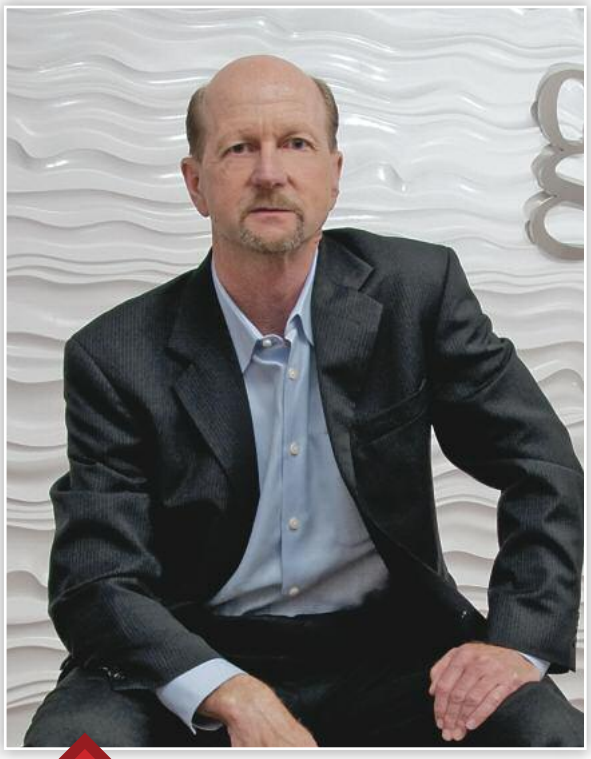
Historically, pharmaceutical companies relied on developing a few molecules and bringing a blockbuster to the market.

"However, the focus has now shifted to developing drugs for disease areas that are much more complex to treat," says Jennifer Brice, life sciences global program manager, Frost & Sullivan. "To improve this R&D deficit, pharma companies should develop concentrations and focus R&D efforts on a few core areas and exit areas of R&D that are not considered to be their core focus. Greater collaboration, including with academia, is one way to increase R&D productivity and improve the efficiency of trials."

Chris Garabedian, president and CEO, AVI BioPharma, agrees that the collaboration with academia, government funding agencies, and non-governmental organizations such as disease foundations, will need to be expanded and accelerated in a more comprehensive way to help address the R&D productivity question.

"If these collaborations can result in a more predictive, cost-efficient model of generating proof-of-concept to support clinical development, the programs may be more de-risked and funding may be easier to find," he says.

David Fishman, president of Snowfish, says there needs to be a stronger alignment between the industry and academic/research institutes.



STEVE WRAY ▪ *Cadient Group*

"The ability to provide on-demand product information is critical in reaching both professional and consumer audiences."

"Over the past five years, the number of BLAs per year has been averaging 22, almost a 50% decrease," he says. "Using a strategic partner identification and engagement strategy can significantly improve the chances of identifying promising approaches and bring products to market faster. The core emphasis is an approach that involves identifying, screening, and prioritizing research partners based on a multitude of factors. When unique weights and measures are added to further refine the top candidates, companies can significantly

increase the effectiveness of their collaborative research projects."

Roslyn Schneider, M.D., senior director, medical affairs, Pfizer, says the healthcare community needs to take a more holistic view of the evolving healthcare system.

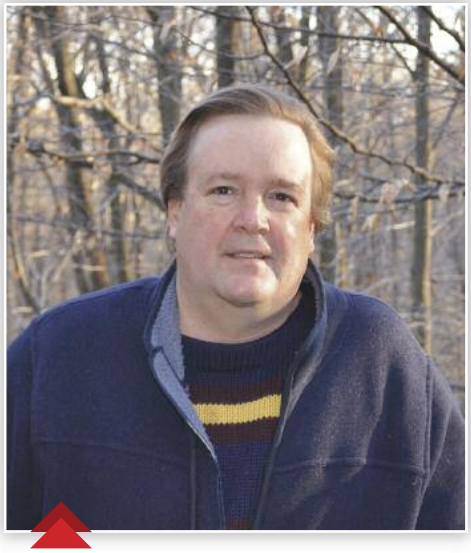
"R&D productivity, while an important component, should not be viewed as equivalent to value delivered," she says. "It is inadequate to measure progress across pharmaceutical companies by the launch of new molecular entities per dollar invested. Value may be seen differently whether it is from the vantage point of individuals, patient groups, physicians, other healthcare providers, scientists, payers, shareholders, and government. The qualitative measures of new or more efficient methods of discovery and development, the ability to identify more specific mechanisms of disease and new targets, and changing business models are recognized as important, but reports of innovation and productivity still seem to default to the quantity of new technologies and products. Companies are working in areas of disease prevention and management, which are increasingly complex, and require not only demonstration of safety, efficacy, effectiveness, but also that they are worth any incremental cost. Progressively rigorous decision-making, closer, appropriate collaboration between academia and industry, and other stakeholders, and partnerships to pool knowledge, investments, and share risk are what will propel the industry forward."

Dr. Schneider says stakeholder insights and modeling based on informed assumptions are strategically being incorporated in decision-making earlier in the drug development process. That information is then updated at each major development decision point and time of additional investment. Late-phase attrition is very costly and limits the resources available for new projects.

"The failures, however, may provide essential information in the pathogenesis of illness, and impact the plan for future development," she says. "Using different model-based drug development strategies by multidisciplinary teams enables certain programs to avoid investment, fail earlier, or provide confidence for further investment and development collaboration."

Mr. Garabedian says because the drug discovery process requires a large chemistry and biology effort, it does not conform to a predictable or robust return on investment.

"This is the reason many pharma and big biotech companies have streamlined their discovery efforts in fewer areas, and this has been exacerbated by venture capital and public equity investors who have de-emphasized drug discovery platforms or attached low valuations to new technologies that are unvalidated."



DAVID FISHMAN ▪ *Snowfish*

"Using a strategic partner identification and engagement strategy can significantly improve the chances of identifying promising approaches and bring products to market faster."

Ramana Reddy, practice leader — life sciences, at Cognizant Business Consulting, contends that life-sciences companies looking to improve the yield of the clinical development process, should prioritize more trials that can result in better business outcomes over trials that may result only in a better scientific outcome.

"To improve yield, life-sciences organizations need early intervention in the clinical process to either triage trials or move them aggressively through the clinical process to ensure successful submission," he says. "There are several strategies that can be leveraged to improve the yield, one of which is implementing concept trials to fill the pipeline with promising drug candidates."

A concept trial is not designed to establish the efficacy of a particular candidate, but rather to help researchers decide if a candidate is worth testing in larger Phase III trials.

"Another strategy is incorporating a comparative effectiveness approach early in the process," Mr. Reddy says. "Leveraging comparative effectiveness information ensures that the right types of trials are progressing through the clinical development process and triaging those trials that do not have improved health outcomes from existing treatment regimens."

Along a similar line, Phil Birch, D.Phil., corporate brand manager, Aptiv Solutions, says the design and implementation of adap-

tive clinical trials (ACTs) offer significant potential to improve the efficiency of trials.

"ACTs rely on the timely collection of data in defined interim analysis steps providing the opportunity for the trial to adapt to emerging data," he says. "For example, following an interim analysis, a decision may be made to re-estimate the size of the trial, stop the overall trial for futility, drop ineffective treatments, or change the randomization allocation in favor of more effective treatments in defined populations of patients. Importantly, these are not ad-hoc changes but are design changes that are prespecified and planned in advance, which is absolutely essential from a regulatory perspective. Adaptive design concepts are applicable from Phase I to Phase III and regulatory agencies have published specific guidance documents on adaptive trials that support the use of ACTs in both learn and confirm trials."

While adaptive design concepts have been available for some time, Dr. Birch says only recently has implementation, especially for complex design trials, been achievable.

"This breakthrough has been possible because of the development of integrated technologies specifically designed to support the execution of ACTs," he says.

Expertise in this area has grown steadily over the last decade not only within pharma companies, but also through the emergence of certain service providers that have specific expertise in adaptive trial design and execution, all of which is enabling sponsor companies to implement complex design trials that were once thought too difficult to achieve.

"The integrated execution environment required to support adaptive designs will also increase the number and complexity of designs, leading to trials that more robustly identify critical components of success," Dr. Birch says.

Beyond the Blockbusters

The patent cliff story is familiar to most in the industry as is the dearth of blockbusters in the pipeline, which has shifted the focus to specialty pharmaceuticals, including therapies for rare diseases, as well as compounds that include a companion diagnostic.

"The current circumstances have contributed to pharma looking more strategically at the business case for investing in rare disease therapies," says Wendy White, founder and president, Siren Interactive.

Financial incentives from The Orphan Drug Act of 1983 have resulted in the development and commercialization of more than 350 orphan drugs to date. Some of these incentives include tax credits, selective grants, and financial assistance that can reduce up to 50% of the cost of clinical trials for orphan drugs.

In addition, according to Ms. White, the review process for FDA approval is expedited and provides flexibility on the quantity and quality of the evidence required.

"This fast-tracked approval process is critical for attracting potential venture capital investors who typically wouldn't consider investing because of the standard protracted timeline associated with bringing a drug to market," she says. "Once approved, the orphan drug receives market exclusivity for seven years in the United States and six to 10 years in the EU."

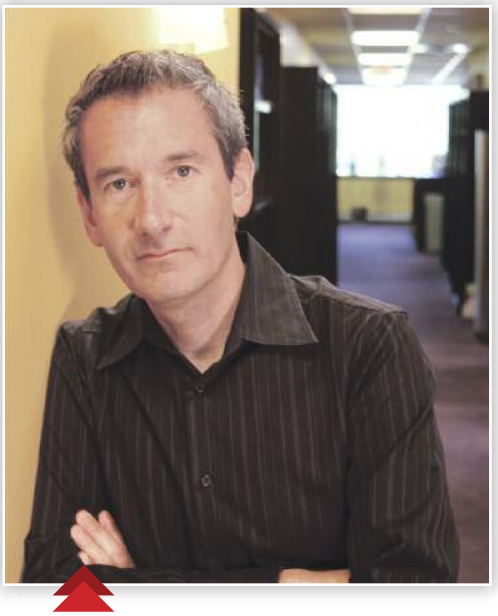
Several other factors also contribute to the current business climate being conducive to pharma investing in rare disease therapies.

"As patents expire on many blockbuster drugs, pharma companies are searching for new products to generate future revenue," Ms. White says. "Me-too drugs fall flat as payers scrutinize new drugs more carefully and only reimburse for those that demonstrate a better value than what's currently available. Conversely, therapies that target a smaller patient population and deliver the greatest benefit can justify a premium price. Therapies developed for rare diseases often have a positive impact on advancing established treatments for more mainstream diseases that affect larger numbers of the general population. While improving the quality of life for more patients, this also generates a much greater return on investment for the pharmaceutical company. And there are plenty of opportunities for pharma to evaluate since only about 5% of all rare diseases have an FDA-approved treatment."

Michael Whitworth, head of centralized clinical data sciences at Quanticate, says making the best use of all the clinical and healthcare data available for a product is bringing about advances in personalized healthcare.

"We are being asked to standardize huge amounts of legacy data so that companies can mine the data to look for improvements in personal healthcare and new indications for a product," he says. "This means that patients can be targeted with the right dose and healthcare package, enabling the provision of optimum efficiency, care, and safety for the patient. The increased use of biomarkers and better access to big healthcare data will also mean more emphasis on larger scale meta analysis and simulations of real-world data. This trend is starting to change the emphasis from running large clinical trials to deliver big blockbuster drugs to more targeted clinical trials that rely on maximizing the use of data from translational science through to real-world evidence."

Another growing sector of the industry is the area of therapeutics combined with a diagnostic component. According to Ron Ellis, CEO and president, Endocyte, co-developing a companion diagnostic with a personalized therapeutic provides answers to key questions that guide decision-making.



DR. KEN KRAMER ▪ *Alpha & Omega*

"A higher level of clinical evidence will become the new cost of entry for products entering established therapeutic areas."

"In the development of small molecule drug conjugates (SMDCs) we start with the companion diagnostic in order to select the right molecular targets and then select the most promising indications," he says. "Valuable targets are those that are highly specific to diseased cells. Before we invest aggressively in a therapeutic agent, we have already confirmed the ability to target diseased cells in specific indications. This process dramatically changes development risk. As a result, there is a higher rate of clinical success per research dollar."

Data are King

The need for different and more accurate data related to patient care — from clinical trials through outcomes — is growing. EMR and EHR systems are gaining traction, the cloud is providing a safe harbor for clinical and other data, and instant patient feedback technologies are driving researchers, developers, and marketers to re-evaulate the status quo.

Jae Chung, CEO and founder of goBalto, says there is a trend toward the "consumerization" of enterprise software, which is increas-

ing the focus on user friendliness and elegant design in corporate enterprise applications.

"Unfortunately, consumerization has made little headway in the life-sciences because of regulatory complexities and the need to build an organization familiar with this industry and technology," Mr. Chung says.

He adds in the clinical trials arena, R&D professionals still make do with clunky user interfaces and complex legacy systems for study start-up and monitoring — manual, tedious, and inefficient methods from which it is difficult to extract data.

"Over the long haul, such methods can affect a company's bottom line," Mr. Chung says. "Each day that a clinical trial sponsor is in development potentially translates into millions of dollars in lost revenue. However, new, cloud-based technologies are helping pharmaceutical companies and CROs to better collaborate, and the ones that incorporate the best practice principles advocated by design research firms will become the norm. People who believe such friendly interfaces are nothing more than a pretty wrapper are completely missing the point: new user interfaces will encourage users to interact with a system in a manner that captures meaningful and actionable data and reports it to end users in real-time to impact outcomes and improve predictability."

WENDY WHITE ▪ *Siren Interactive*

"Therapies developed for rare diseases often have a positive impact on advancing established treatments for more mainstream diseases that affect larger numbers of the general population."

"We can no longer make assumptions around technology and its use in the clinical environment," says Tim Davis, CEO of Exco InTouch. "Being complacent around the end-users' perception of technology reduces engagement and ultimately has a negative influence on the success of our work. Mobile technologies in all their forms — smartphones, tablet PCs, and laptops — along with the accessibility of the Web are empowering today's super consumers and we must adapt to accommodate their expectations. But the adoption within the clinical arena is in its infancy and the industry needs to change to adopt these methodologies to meet the end users' expectations."

Ron Marks, Ph.D., chief scientific officer, Clinipace Worldwide, says technologies exist to integrate trial data in a single system that can maximize transparency of study information for all interested parties from investigators to monitors to sponsor management, as appropriate.

"Such integration allows the sponsor to keep enrollment on target, investigators to enter clinical data more accurately and timely, monitors to more expeditiously check and validate clinical data, and data managers and biostatisticians to efficiently produce clean and

complete data for analysis," Mr. Marks says.

Daniel Chapple, Ph.D., commercial VP, Quanticate, says the intelligent use of new technologies is already helping to improve the quality of clinical data collection and starting to substantially reduce the cost of monitoring clinical trials.

"It is now possible for more data to be verified remotely from the investigator sites while still being compliant with regulatory requirements," he says. "Advanced methods are starting to be used in conjunction with the development of new technologies and processes to maintain source records. With real-time data becoming more accessible when using technologies such as tablet/handheld devices, there is faster access to data with the ability to visualize at a high level and drill down to the source data if required. The collaboration at the reporting level can be controlled through portals to virtual teams throughout the world allowing faster review cycles through improved workflow and notification. Such portals are also facilitating the training and support of investigators during the start-up and conduct of a trial, delivering improvements in quality and compliance. Future integration with EHR will continue to provide increased efficiencies in clinical development."

At the end of the day, or decade in the case of drug development, it's all about the product and its safe use to help meet a unmet demand.

"The ability to provide on-demand product information is critical in reaching both professional and consumer audiences, so that the product can more readily establish its position around ease of use and high-value customer service, in a manner that creates meaningful brand differentiation," says Steve Wray, president and CEO, Cadient.

Because product positioning in the marketplace is more critical than ever, one of the biggest factors moving forward will be the need to provide clinical outcomes to both patients and providers in marketing materials.

"Back in the day, a statin could just demonstrate that it produced a significant reduction in cholesterol endpoints, which was sufficient to get the point across that the mediation worked," says Ken Kramer, Ph.D., senior VP and medical director, Alpha & Omega Worldwide, part of The Core Nation. "Consumers are now looking for outcomes, such as reductions in first or second heart attacks when it comes to choosing a cholesterol-lowering drug. This links the drug's mechanism of action to tangible health benefits. This will certainly come with a cost, literally and figuratively. This translates into tougher, perhaps more extensive clinical trials, which we know can run into the billions of dollars. However, this level of evidence will become the new cost of entry for products entering established therapeutic areas." PV

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WHITE PAPER

IDENTIFYING STRATEGIC PARTNERS FOR PRODUCT DEVELOPMENT

David Fishman, Snowfish LLC

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EXPERTS

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JAE CHUNG. CEO and Founder, goBalto, a developer of new generation Web-based clinical research solutions. For more information, visit gobalto.com.

TIM DAVIS. CEO, Exco InTouch, a provider of regulatory compliant patient management solutions. For more information, visit excointouch.com.

RON ELLIS. CEO and President, Endocyte, is a biopharmaceutical company developing targeted therapies for the treatment of cancer and other serious diseases. For more information, visit endocyte.com.

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ROSLYN F. SCHNEIDER, M.D. Senior Director, Medical Affairs, Pfizer Inc., a biopharmaceutical company committed to helping people improve their health by discovering and developing medicines. For more information, visit pfizer.com. (The statements and opinions expressed by Dr. Schneider are her own and do not necessarily represent those of Pfizer Inc.)

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MICHAEL WHITWORTH. Head, Centralized Clinical Data Sciences, Quanticate, a global biometrics contract research organization. For more information, visit quanticate.com.

STEVE WRAY. President and CEO, Cadient Group, a digital healthcare marketing agency serving a range of industry markets and stakeholders. For more information, visit cadient.com.

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MONDAY, APRIL 23

KEYNOTE PANEL:
Communicating in the Real World

William Hoffman, Partner and Co-Chairman of the Food and Drug Practice Group, Kaye Scholer LLP

Mariam Koohdary, Senior Counsel, AstraZeneca

TUESDAY, APRIL 24

KEYNOTE SPEAKER:
Understanding Stakeholders: Beyond the Usual Suspects

J. Russell Teagarden
Vice President, Scientific Affairs
Advanced Clinical Science & Research
Medco Health Solutions, Inc.

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- **Day–2 Stakeholders:** Be prepared to hear from 'not the usual suspects,' with an emphasis on what end users want from medical publications
- **Day–3 Medical publications–capturing the change:** Tips to help us manage in a 'doing-more-with-less' environment and the latest in technologies beyond the printed page

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- Evolution of pubs from print to new media
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Taren Grom

THE ERA of Superconsumers

Information transparency, technology-enabled processes, and community engagement are some of the central drivers within the Pharma 3.0 ecosystem space, which is shifting the concentration from products to patients and in essence creating superconsumers.

The paradigm shift to placing the patient at the center means pharmaceutical companies will have to develop and implement new processes and ideologies to respond accordingly.

"Pharma companies have the opportunity to conduct online intelligence to identify the unmet needs of patients and caregivers along with the language they use in their conversations," says Wendy White, founder and president, Siren Interactive. "Armed with that insight, pharma companies can engage key stakeholders with relevant content. By focusing on a relationship marketing approach that educates patients before selling the brand, companies provide value and earn acceptance and trust from patients, which is critical to initiating new patient starts and maintaining adherence to therapies."

JAE CHUNG ▪ *goBalto*

"New cloud-based technologies are helping pharmaceutical companies and CROs to better collaborate, and the ones that incorporate the best practice principles advocated by design research firms will become the norm."

Social media and open innovation are blurring the lines of how companies need to communicate with their stakeholders. This new and open environment is shaping how pharma companies and their partners communicate with these various groups.

"Effective communication through social media begins with conducting online listening, which, for example, AEs are being monitored on social media and reported as with any other channel to make sure they are," Ms. White says. "It's critical to understand what stakeholders need and to provide value by addressing their unmet needs through relevant information, targeted resources, and specialized tools."

Consumers are able to use a variety of ever-improving technologies in their daily life. These same consumers then expect to see these technologies transition into their patient life.

Ms. White says there's an opportunity for pharma to establish a two-way conversation with these superconsumers, who are hyper-connected through the Internet.

"Game-changing technology includes video sharing channels, in particular on YouTube," she says. "Video will play an increasingly important role in pharmaceutical marketing since it's a persuasive medium that provides a unique opportunity for brands to tell their stories."

Manhattan Research found that one in two e-pharma consumers prefers video to text due to his or her learning style.

"This study shows that online health videos result in consumers following up on the call-to-action, with three-quarters of viewers doing additional research," she says. "Plus, YouTube provides a safe way for biopharma companies to interact with consumers. Comments on a single video or a channel on YouTube can be turned off, allowed to go live immediately, or sent for approval via email."

Mobile technology, which is helping to fuel the superconsumer movement, will take on more importance with the global expansion of pharma marketing.

"In many developing countries, people are leapfrogging over owning a desktop or laptop and are accessing the Web via a mobile device," Ms. White says. "This trend is expected to continue as costs come down and networks expand. Patients increasingly rely on their mobile devices to access healthcare information. Google estimates that 26% of all U.S. prescription searches this year have been done via mobile devices. Some people

Lessons Learned

During his almost 25 years in the industry — in both a large pharma company and a startup organization — Mike Clayman, M.D., CEO of Flexion Therapeutics, has learned a few things about drug development that align around two major challenges, which he says if addressed could enhance the efficiency and effectiveness of advancing a new medicine to patients in need.

"The first relates to integrating as early as possible the science with the views of the many stakeholders who will be involved in the success of the new medicine," Dr. Clayman says. "The second is even more thoughtful design of clinical development programs. So the two big challenges are integration and design."

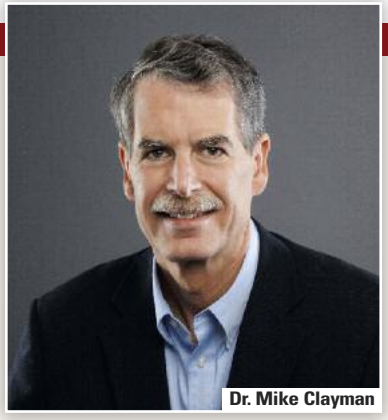
Dr. Clayman spent 20 years at Lilly, where he says when it came to integration, he and his team aggressively pursued clarity of new medicine performance at the very earliest time points. "When project teams came forward to gain approval for their new compound from the Candidate Selection Committee, an integral part of the presentation was the draft launch label," he says. "And we required those labels to be as clear and quantitative as possible. It was not enough to say that product X must perform better than standard of care. We mandated a statement of how much better and on what specific measure. That information allowed us to meaningfully test validity with regulators — would this likely stand as an adequate difference in an approval endpoint — as well as with other stakeholders."

By determining if the data would resonate with prescribers and payers, it allowed the Lilly teams to begin to construct the clinical development program and to design specific protocols.

"A clear and quantitative draft launch label can serve many useful purposes and it helps to organize development," he says. "And while it should be obvious, we took the word draft quite seriously. No one assumed that the first version of a draft launch label would be its final version. Rather it served the purpose of challenging the regulatory, medical, and marketing groups within the company to begin talking in specific terms of what they needed and what was feasible. With additional data, including input from external stakeholders, the draft launch label was refined. It was a living document, an evolving blueprint for the construction of the development program."

During his time at Flexion, he has taken the integration piece to another level.

"Having constructed the draft launch label for our compounds, we've done formal marketing analyses with thought leaders, prescribers, and payers to be sure we understand what they need in terms of product performance and the elements of the value proposition from their perspectives," Dr. Clayman says. "And because reimbursement has emerged as such a powerful ingredient in the ultimate success of a new medicine, we are undertaking formal reimbursement analyses with external expert consulting groups, in parallel with our first in man, Phase Ib/II studies. By doing that work now, we afford ourselves the opportunity to integrate the perspective of payers into our clinical trial designs, well before we ever finalize a Phase III protocol."



Dr. Mike Clayman

Moving from integration to design, Dr. Clayman believes there are certain principles worth embracing as teams architect their overall clinical development program and specific study protocols.

"It's a big, expensive, and disappointing problem when promising early clinical data are not replicated in downstream studies," he says. "We don't declare perfect insight here, but we do think there are specific considerations that can help."

Best Practices

» Avoid underpowered "hint of efficacy" studies.

Because hint of efficacy trials are underpowered — and often use a surrogate endpoint — they have great potential to generate data that will mislead.

"We know of recent studies in pain where cohorts as small as five or six patients were used to assess efficacy and while a signal was declared in these early studies, subsequent larger studies failed to confirm the observation," he says. "When we advanced our first drug into clinical testing, we began with a study that had two phases. The first phase was a single ascending dose, where we focused on safety and pharmacokinetic data, and purposely did not collect efficacy data. Following that we did proof of concept studies, which were appropriately powered to determine efficacy."

» As early as possible, use efficacy endpoints that are registration quality.

"One reason why so many promising early studies are not confirmed with subsequent clinical trial data is that early studies use unvalidated end points, including pharmacodynamic surrogates that are more likely to be positive but may unreliably predict clinical outcome data," he says.

» Pursue clinically meaningful differences in efficacy.

"This may seem obvious but we are aware of clinical development programs that demonstrated statistically significant differences that were a fraction of the generally acknowledged threshold for clinical meaningfulness," he says. "And while they ultimately gained regulatory approval, it has left many to ponder the value of the therapy."

» Have a low threshold for performing head to head, active comparator studies using the current standard of care.

"These data are often at the heart of the value proposition and provide data that can be most meaningful to prescribing physicians and payers," Dr. Clayman says. "In one of our development programs, the initial efficacy study compares our product, at three different doses, the current standard of care, and is powered to determine superiority."

» Use adaptive design as a tool in the clinical trial design toolkit.

"We used adaptive design to excellent benefit at Lilly and always actively consider it during the planning of specific studies," he says. "Ultimately, the choice to use adaptive design should reflect a holistic consideration of whether the clinical development program needs are met most efficiently and effectively with an adaptive design or a more standard design."

may correlate mobile with apps, but the functional focus of mobile is actually on search and websites."

Physicians are also increasingly relying on mobile devices. According to the latest Manhattan Research survey, an estimated 81% of physicians use smartphones. In its report on ePharma Physicians that focused on the 87% who use digital channels for pharma resources and connecting with reps, Manhattan Research analysts found that 45% would like to access pharma product information on their smartphone or iPad. Furthermore, 36% of physicians surveyed found the use of iPads or other tablets more beneficial than speaking with reps bearing printed materials or devices such as laptops.

Mobile marketing solutions are becoming part of everyday life for the consumer.

With 77% of the world's population having access to mobile technology in one form or another, Tim Davis, CEO of Exco InTouch, says the ubiquitous nature of this technology overcomes cultural and educational barriers.

"We are already seeing the positive deployment of mobile technology within the clinical arena," he says. "The use of the ubiquitous technology is powering the patient-centric approach to clinical studies. The recent REMOTE study revealed how mobile technology can be used to reduce costs and drive patient access."

Bringing EMR/EHR to the Party

According to Ramana Reddy, practice leader — life sciences, at Cognizant Business Consulting, life-sciences companies are evaluating each process and looking at how they can leverage mobile technology to better deliver value through the process.

"Mobile technology is being leveraged to give patients better access to interact with life-sciences organizations, both through the clinical process and post clinical process," he says. "Mobile technology can help patient/physician interactions, deliver dynamic and context-specific content through the channel interactions with both patients and physicians, and help educate the patients and physicians on drug and treatment information."

Mr. Reddy believes that EMR/EHR data and information are going to be the cornerstone of life-sciences organizations' foray into personalized medicine and developing drugs that are more targeted to specific patient population.

"More and more life-sciences organizations are going to develop models based on EHR/EMR to prove that their drugs are comparatively better than others already in the market for specific patient populations," he says. "In the future, close integration with EHR/EMR systems used by the providers will change the model of how clinical systems in life-sciences companies integrate with provider systems. Close access to this information will significantly reduce the cost of monitoring and also replace multiple different systems that providers have to access and interact with."

Ron Marks, Ph.D., chief scientific officer, Clinipace Worldwide, agrees that there is a need to better integrate EMR and HMR systems into the clinical research process.

"Improved integration can provide access to more patient information that can shorten and simplify the clinical trial process and provide more study information to enhance investigational product evaluation," he says. "Data from EMR and HMR systems, as well as from postmarketing research studies, provide a valuable opportunity for companies and physicians to mine rich clinical data to learn more about the true efficacy and safety of a drug of interest. Such information is more relevant in that it represents the real world of clinical use, rather than from the more controlled world of clinical trials. Technology to summarize and report these data provides unparalleled opportunity to document any true areas of concern with a newly marketed drug, especially if they occur in any specific population cohorts."

The Cloud

Anytime the word technology is mentioned today, inevitably the next two words are the cloud, and appropriately so. Cloud technology is changing how companies do business along the entire drug development continuum.

"Drug development can be dramatically improved by using easy-to-use yet powerful cloud-based technologies, which leverage the collaborative nature of the Internet and improve workflow and processes," says Jae Chung, CEO and founder of goBalto. "Leveraging network effects between sponsors, sites, and CROs can generate actionable data and

TIM DAVIS ▪ *Exco InTouch*

"Mobile technologies in all their forms — smartphones, tablet PCs, and laptops — along with the accessibility of mobile Web are empowering today's superconsumers and we must adapt to accommodate their expectations."

metrics, which can then be aggregated anonymously and reported on to improve transparency and benchmarking. For example, a cloud-based collaboration platform can facilitate the tracking of the time it takes between tasks to complete clinical research tasks. Such data can be aggregated and displayed to study managers to identify where bottlenecks exist and resolve them in real time. In a nutshell, by enabling clinical trials sponsors to collaborate with multiple partners directly from the Web in a transparent and regulatory compliant manner, cloud technologies allow for quicker decisions on expensive protocols and faster time to market."

Mr. Reddy says in his experience life-sciences organizations are looking to variabilize and virtualize their operating costs for clinical systems.

"To drive virtualization and variabilization, life-sciences companies are adopting SaaS models and cloud computing across the clinical development process," he says. "We are seeing a significant proliferation of SaaS and cloud computing in the clinical development space. SaaS models have evolved in many areas including EDC, IVRS, CTMS, investigator portals, clinical data repositories,

and other business intelligence and reporting platforms, e-clinical portals, pharmacovigilance, and regulatory submission systems."

As with all technologies, their effective use is determined by ensuring the correct deployment.

"When study leaders are looking for technology solutions, they should work with their vendors to ensure that the correct mix of technology is made for the individual protocol requirements," Mr. Davis says. "By working in partnership with the vendor, the correct technology mix can be achieved to ensure patient engagement and study success."

The key to the implementation of technology in these areas is price and accessibility as study budgets are more restricted in late-phase studies. As a rule, traditional technology solutions used in early phase studies are price prohibitive for late phase.

"Hence there has been a move for the deployment of mobile, Web-based, and 'lite' EDC solutions to try and meet the technology demands at an acceptable price point," Mr. Davis says. "However, a number of these technologies have been developed to enable site-based data capture that may not be addressing the real-world data collection requirements of Phase IV and registry studies. Real-world studies are by nature global and as such must employ a technology that is global and assessable by all and this is where mobile technology is the ideal fit. Mobile solutions can be developed that are cost-effective and readily deployable, thus ensuring the collection of the required real-world data."

Cost-Reduction Strategies

The need to reduce the cost of clinical development has been an ongoing mantra for years, and is more important than ever given the current financial environment. Our experts say there are ways to trim budgets without sacrificing quality or safety.

"To manage the holistic costs of the clinical development process and to have better and safer drugs, life-sciences organizations need to have a better understanding of personalized medicine and the comparative effectiveness of their drugs for specific patient populations," Mr. Reddy says. "Efforts are under way to integrate multiple entities across the full ecosystem of personalized medicine, which includes researchers, physicians, and consumers as participants."

Clinical development costs can be measured and managed in many different ways. There are many benchmarks and metrics to make sure that the time it takes to move the drug through the clinical development process continues to be reduced and thereby reduce the costs. For example, there are strategies to reduce the cycle time from 1,000 days to 700 days.

Mr. Reddy suggests evaluating every aspect of the clinical process to identify the core activities that life-sciences companies need to retain and what can be outsourced.

"The outsourced activities are being sourced on a per-outcome model that will provide greater predictability of cost and effort in the clinical process," Mr. Reddy says.

Another strategy is leveraging technology to measure and manage metrics and cycle times.

"Life-sciences organizations are developing decision and information dashboards that give greater transparency to all of the aspects of clinical development process," he says. "Life-sciences companies are using IT systems to have more integrated metrics that allow them to monitor and intervene proactively to manage not only cycle time activities but also cost-related components. In addition to having a real-time view of information, life-sciences organizations are developing better decision infrastructures, such as data repositories and dashboards to bring past and present clinical trial information to the forefront, all of which proactively integrate safety and efficacy information upfront in the clinical process to ensure that historic data and real-time information can be leveraged to make better decisions on reducing cycle times and costs."

Finally, life-sciences companies are getting internal and external data in terms of how they manage their costs in terms of patient recruitment, site selection, and ability to get the right investigators.

"There are cost-benefit models that are evolving in terms of all aspects of the clinical development process to make sure that new trials are adhering to the right benchmarks in terms of cycle time and costs," Mr. Reddy says.

"Pharmacovigilance teams should be participating in the clinical trial design to provide better context to the safety and efficacy of the product," Mr. Reddy says. "This will ensure that the right type of products with the right safety profiles are progressed and prevent efforts on trials that have a low probability to succeed because the products lack the appropriate safety profiles and will not lead to better drugs in the market. It is also important to leverage patient reported outcomes early on in the drug development process. This will ensure that the relevant patient feedback is available to ensure the right targets are identified to move forward in the drug development process."

Finally, he says, leveraging new technology can reduce the cost and improve the approval success rate of drugs.

"Life-sciences companies should look to use more molecular diagnostics and simulation and modeling, which will enable them to clearly determine the benefits of the drug candidates early in the drug life cycle and improve the overall R&D throughput," Mr. Reddy says. PV

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