By Taren Grom

Clinical Services

We asked C-suite executives throughout the clinical services ecosystem to provide their insights on where the biggest opportunities for innovation for improving the drug development process lie, what the biggest barriers are, and identify a recent innovation that is improving the process.

WENDEL BARR

CEO
SynteractHCR

Opportunities: I think there are several areas in which processes must be continually assessed and improved to streamline the drug development process. Integration of technology via a common platform that allows data to be delivered to the client in a timely manner is a critical component for innovation. Feasibility is important to select the right sites, and thoughtful monitoring and project management to proactively manage any issues that might come up are the keys.

From the CRO perspective, maintaining a dedicated focus on quality and adherence to harmonized global operating procedures means we ensure consistent trial conduct regardless of where the trial is placed. And that dedication to quality also means we are always working to improve.

Barriers: The greatest barrier to innovation is taking the time to do it. The importance of early study planning in running a complex global study efficiently cannot be stressed enough. Sufficient time for planning must include time allotted for regulatory feedback, questions, and responses, as well as time to solicit feedback from thought leaders and operational staff in each country/region prior to protocol finalization. Without taking the time to plan properly at the outset, we jeopardize our final outcomes.

PETER BENTON

Executive VP and President, eClinical Solutions
BioClinica

Opportunities: Mobility and connectivity will play a greater role in drug development as new technologies and processes integrate with the tools we already use such as SharePoint and Microsoft office (email etc). This will help us bring new therapies and devices to market even faster in the future. As our "office" becomes more mobile and cloud-connected, devices such as tablets, slates, and the Microsoft Surface will bring true office capabilities to everywhere we go. Clinicians and site monitors will be free to interact with patients while capturing and reviewing vital clinical data in an easy-to-use format such as eClinical apps that provide both simple and sophisticated data capture forms and cloud-based analytical solutions. And with the proliferation of consumer tablets and mobile devices, subjects will have personal mobile devices that allow for patient-reported outcomes directly into an EDC system without the need for additional hardware and complexity.

Barriers: This story remains the same: adoption, either through software or hardware. Industry demands for standards have pushed the industry in the right direction, but not nearly fast enough to take advantage of all the amazing technology that is available. Siloed decision-making and outdated perspectives lead to sponsors choosing single solutions that do not integrate well and do not optimize the entire platform. Life-sciences technology companies have to be conscious of the entire development spectrum and use of their solutions. You don't want a market leader in EDC trying to determine supply chain and clinical operations on your trial; you want a comprehensive clinical platform provider to deliver a comprehensive solution, with improved power and easy-to-use common interfaces. With the right tools, the industry is poised to spur even great rates of innovation from new leaders.

DOREEN LECHNER, PH.D.

VP, Service Delivery — Pharmacovigilance Healthcare
ConneXions

Opportunities: Tailoring therapeutics to the individual as is done in the personalized medicine initiative is one of the greatest areas for innovation to improve the drug development process. Optimizing dosage regimens and mechanism of delivery will allow sponsors to delicately balance the risk-benefit paradigm associated with drugs thereby reducing the challenges associated with determination of the appropriate drug dosage regimen.

Barriers: The current regulatory system has its challenges since it has not evolved to allow a simpler approach to drug development in a cost-effective manner. The current regulations are inefficient, burdensome, and not harmonized globally.

PATRICK LINDSAY

President
UBC

Opportunities: A great opportunity for innovation in this process lies in moving from a linear view to a 360-degree view that brings information around the drug, mechanism, disease patterns/episodes of care, outcomes of therapy, and intervention in a manner that is more efficient and offers more depth than current approaches. We are still witnessing too much sequential thinking with not enough focus on maximizing clinical and other drug development insights toward commercial strategies.

We are in a highly regulated industry and most organizations address the components of the drug development process as separate systems to navigate. We need to be looking at the process in a more holistic manner — as all one system from development through commercialization. This will get therapies to market faster and more efficiently and allow for better outcomes for patients.

Barriers: The number of stakeholders who need to be satisfied is challenging to pharma. We have government and regulatory agencies, payers, prescribers, patients, and caregivers. Each requires different types of information, and each exerts a different level and nature of influence on the successful regulatory acceptance, approval, adoption, and adherence to therapy. While we work hard to

satisfy each and every one of the stakeholders along the development continuum, the number, nature, and complexity of requirements that need to be successfully navigated by pharma is intense and complex.

Add to that increasing pressure to demonstrate financial value of a product and too often the time and attention needed to really innovate is placed on the back burner.

KATRINA RICE
VP Professional Services
eClinical Solutions

Opportunities: The use of genomics in clinical research appears to be the greatest opportunity for innovating the drug development process. Although all human beings have a common set of traits needed for growth, development, and maintenance of their body, there is a variety of individual characteristics that influence how a person's body reacts to a particular drug treatment. The idea of giving patients tailored treatments based on their specific genotype should be more effective than the existing trial-and-error approach (e.g. trying drugs with a defined population and hoping for safety and efficacy across the larger public). This leads to the personalization of clinical trials embracing the power of pharmacogenomics reducing overall costs and increased success with drug development.

Barriers: The greatest barriers to the above mentioned innovation are cost and unreliability of the DNA sequencing technology to support the drug development process. Even when costs come down, there are still resource costs and talent needed to utilize/integrate these technologies into the drug development process. There will be a huge learning curve on incorporating genome-based strategies as this disrupts the way clinical trials are currently designed and implemented. The life-sciences organizations will have to collaborate with other companies and academia to re-design the existing inefficient processes and modernize the overall clinical trial process to leverage these technological advances.

SHEILA ROCCHIO
VP, Marketing and Product Management
PHT Corp.

Opportunities: Since the late 1990s, numerous companies and industries have transformed or have been transformed by using technology to connect customers directly to the products, services, and information they need and want. Amazon, Google, SF.com, LinkedIn, and NetFlix are just a few of the many examples. In clinical trials, Phase Forward, Medidata, eRT, and others have delivered value to sponsors and shareholders by simply removing paper from the clinical trial collection system. There is still a tremendous opportunity to use technology to transform drug development and healthcare to provide greater value and less error to the key stakeholders: physicians and patients.

Barriers: The use of precedence to drive business strategy is a tremendous barrier to innovation. There is so much financial risk in drug development that there is little incentive to try something new and innovative because the stakes are so high. I have often heard, "no one loses their job for choosing XXX" where X is the status quo. That mindset is a barrier to innovation.

BHASKAR SAMBASIVAN
VP and Head of Life Sciences
Cognizant

Opportunities: Today, drug development efforts should begin and end with the patient. This requires innovation and the advancement of new strategies to speed the delivery of healthcare, whichever form that is for the individual. We are finding the greatest opportunity to improve drug development lies in three areas. The first is a better understanding of patients and engagement with them to increase participation in clinical trials and help develop targeted treatments and personalized medicine. The second is the adoption of new technologies — social, mobile, and analytics — across various phases of drug development to help accelerate clinical trials, reduce errors, and increase productivity. The third opportunity is collaborating and sharing among companies through industry consortiums and group initiatives that enable sharing of risks and failures that others can learn from.

Barriers: The greatest barrier to innovation is the traditional ways of doing everything in-house and a reluctance to look outside and collaborate. With new business models and technologies evolving rapidly, every organization should take a hard look internally to see how it can adopt these elements to have a more profound impact on modern healthcare. This is especially important in an environment when companies need to demonstrate greater value and outcomes from their products through close working relationships with academia, payers, providers, patients, and other internal functional groups. The future is about coming together for the betterment of the patient.

MARK WHEELDON
CEO
Formedix

Opportunities: Standardization offers real innovation opportunities within the end-to-end drug development process. It brings the promise of faster time to market with reduced costs and increased quality, both of which are compelling reasons for using Clinical Data Interchange Standards (CDISC) now and in the future.

CDISC allows for the ability to reuse content end-to-end, streamline study set-up, automate study build, as well as optimize study conduct and analysis. New external content standards from TransCelerate, CDISC, FDA, and NCI will see innovation in the form of content compliance tools that will work hand-in-hand with dataset validators to enhance the quality of regulatory submissions.

Therapeutic content standardization and CSHARE will increase patient safety by allowing regulators to integrate data and look across multiple submissions from sponsors in the same therapeutic areas and see key safety signals for a new class of compounds.

Barriers: Like all major industries, the life-sciences industry is very conservative and there is a resistance to embrace new, innovative information technology solutions. In addition, life-science companies have been accustomed to buying from large "established" vendors and an environment for truly disruptive companies such as Google and Amazon, in their respective industries, does not really exist today.

Amazon, in particular, has shown the effect this can have; imagine such a disruptive influence in clinical trial informatics and the opportunities this would bring to streamlining trials and propelling drugs faster and cheaper to the market.

With the cost of developing drugs rising annually and fewer drugs being approved every year, it is essential that our industry begins to embrace new options and increasingly adopt modern technology.

SAMUEL WHITAKER
Founder and CEO
Greenphire

Opportunities: Drug development is going to evolve more quickly, when we, as an indus-

try, can transform the data that are gathered by the multitude of systems from "data" to "information." With the increased attention to "personalized medicine," the specificity of a disease state targeted by any single NCE will change the nature of Phase II and III trials. The inclusion/exclusion criteria will include new, more objective identifiers, and the nature of subject recruitment will change from being relationship-based — subjects known to a physician — to being data-driven. This will require new paradigms in patient recruitment, access to information, and protection of patient confidentiality regarding access to automated records.

Barriers: The inertia that comes from being part of a herd is a big barrier. In the competitive environment, the one who breaks away either becomes the new leader or journeys alone. There is safety in the herd, but limited rewards. Our challenge is how to provide change, but at the same time to limit the downside risk. PV

INNOVATION CORNER

WENDEL BARR
CEO, SynteractHCR

Crowdsourcing

One recent innovation that has been successfully used in other industries includes open collaboration through crowdsourcing, where experts in fields other than our own, such as academia or technology, can be invited to participate in an open forum that allows colleagues at all levels to put forward innovative ideas. While this is not broadly used yet, it is an interesting idea. Ideas such as these shift the paradigm of the manner in which we conduct drug development. I think we all recognize that the current processes cost too much and take too long, so we are looking for new innovations for assessment and collaboration. Ultimately, new solutions, and maybe better ones, can be found.

DOREEN LECHNER, PH.D.
VP, Service Delivery — Pharmacovigilance, Healthcare ConneXions

Adverse Events Consortium

The FDA initiative of working alongside the International Serious Adverse Events Consortium to identify genetic markers that may be useful in predicting the risk of serious adverse events. Their early studies have identified genetic variants associated with various toxicities with specific drugs. This will hopefully lead to the emergence of the underlying pharmacologic mechanism leading to a drug-induced serious adverse event.

PATRICK LINDSAY
President, UBC

Breakthrough Therapy Designation and PfizerLink

From a regulatory perspective, the FDA's breakthrough therapy designation within the Safety and Innovation Act can have a real impact on speeding product approvals. The collaboration among the FDA, patient organizations, academics, and industry leaders was notably impressive. (Editor's Note: See related article in this issue: Breakthrough Therapies Become a Priority)

From a collaborative perspective, UBC supports PfizerLink, an opt-in, online community for graduated Pfizer clinical trial participants. The digital platform allows Pfizer and clinical trial participants to maintain contact, build closer relationships, and share data after the trial has ended. PfizerLink serves as a database, allowing Pfizer researchers to re-engage with participants and recruit for future studies, outcomes research, and market research.

Pfizer has partnered with the VA and Blue Button Plus to provide clinical trial results back to patients. PfizerLink is the patient-facing interface/platform in which patients will access this data. During the pilot phase, this data would include demographics, ConDrug, ConMed, ECG, drug treatment, lab, medical history, and vitals.

These types of cross-disciplinary connections are vital to the process and ultimately to patients.

SHEILA ROCCHIO
VP, Marketing and Product Management, PHT Corp.

Crowdsourcing

The use of crowdsourcing by the disease community to develop protocols by Transparency Life Sciences is notable both for its openness and economy. It's a way to connect and engage the entire disease community and customers — both physicians and patients —with the therapy early in the development process through simple technology. This is an example of a DTC model for drug development that may deliver significant cycle time and cost benefits. Similarly, the movement to leverage patients' own mobile devices for data collection in clinical trials (BYOD) is creating interesting opportunities to make clinical trials more convenient and safer for patients and more economical for sponsors.

BHASKAR SAMBASIVAN
VP and Head of Life sciences, Cognizant

Data Analytics

One of the most notable innovations is the rapid advancement of data processing and analytics technologies ranging from big data, social data, semantic data, data appliances, and in-memory data processing. All of these technological advancements have made possible solutions that were unsolved for many years, for example, full genome sequencing, personalized medicine, etc., which have now the promise of finding an antidote to what many thought were incurable diseases.

MARK WHEELDON
CEO, Formedix

Cloud Technologies

Consumers have seen an explosion of cloud technologies in the market from providers such as Amazon, Google, and Apple, which have changed the way they access, distribute, and utilize content on any connected device. By contrast, in the world of e-clinical technologies, we have silos of content for the reuse and the development of each deliverable within the trial process: protocol content, database design content in proprietary global EDC libraries, and dataset design libraries managed in statistical computing environments. Furthermore, the world of drug development is changing with ever-increasing reliance on the sharing of this content with CRO partners.

The solution is an "iTunes of clinical trials" with all manner of media — eCRF designs, submission and analysis dataset designs, controlled terminology, etc. available for consumption and reuse across multiple platforms, systems, and vendors throughout the clinical trial process. This can be achieved with the use of standardized content stored in a vendor neutral model.

SAMUEL WHITAKER
Founder and CEO, Greenphire

Optical Glasses

Liquid-filled optical glasses by Joshua Silver. The ultimate in personalized medicine, produced cheaply, that can be implemented cheaply, without medical training, around the world for people who could not otherwise see. It improves quality of life, opens the door to enhanced literacy, and answers an unmet need in places where access to finished eye glasses would be unavailable otherwise. (For more information, visit http://www.ted.com/talks/josh_silver_demos_adjustable_liquid_filled_eyeglasses.html)