Taren Grom

Clinical SERVICES

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

DR. MARTINE DEHLINGER-KREMER
Global VP, Medical and Regulatory Affairs
SynteractHCR

Opportunities: As we all are aware, developing new drugs is a long and complex process, not only because of the medical and scientific aspects but also because of the need to meet ever-increasing regulatory compliance and registration requirements. While it is good that these requirements are in place to ensure efficacy of the products and improve safety, the challenges increase exponentially in global drug development because each country has its own regulations and licensing requirements. I believe there is a great opportunity to improve the drug development process by finding ways to harmonize the regulatory landscape and streamline the licensing process.

While progress is being made through increased communications between the authorities worldwide and initiatives such as the ICH Guidelines, FDA-EMA collaboration (Transatlantic Trade and Investment Partnership), the international collaboration for pediatric developments (started between the United States and EU, expanded to Japan, Canada and now Latin America), Pan American Network for Drug Regulatory Harmonization (PANDRH), Association of South East Asian (ASEAN), and the new Clinical Trials Regulation in the EU, these are still limited. Joint advisory meetings with more countries in the discussion would help everyone. Yes, there are some regional or ethnic differences and some medical practice differences, but for the most part, patients are patients and we can assume that people's responses to various medicinal products would be about the same.

Greater cooperation among the various regulatory authorities across the world would better enable the scientific innovation already taking place in research and clinical processes. More commonality in regulations and guidelines would assist in streamlining the drug development process, as well as reduce expenses, and could aid in getting the drugs into the hands of those who need them worldwide much sooner.

Barriers: One of the greatest barriers to innovation is the limited funding available for innovative products. Frequently, innovative companies are small or midsize and have highly intelligent researchers but face a challenge in gaining access to funds.

A second barrier is the cost of drug development. We need to find ways to reduce these costs. New methods of evaluating products and data are essential in achieving this objective. The authorities are accepting novel methodologies and biomarkers in research and development and have qualification processes in place. Adaptive designs are a possibility. Modeling and simulations can be used as an "applied science" tool to provide answers on efficacy and safety of new drugs faster and at lower costs. All these approaches could help to streamline processes and perhaps even reduce the number of patients or trials needed, thereby reducing time schedules and costs. In addition to this, by better harmonizing the regulatory requirements we will see greater success in a faster timeframe.

ZAHER EL-ASSI
President
Merge eClinical

Opportunities: The mission of the drug development process — and the healthcare profession as a whole — is improving the human condition through safer and more effective medications and therapies. And the faster we as an industry can bring better medications and devices to market, the more we are able to fulfill that mission. In the life-sciences industry as in every industry, the biggest opportunity for innovation lies in transforming the power of information into the power of knowledge. That's the essence of the big data movement. The advent of EDC, cloud-based computing, mobile communications and wearable technology will have immeasurable positive impact on the conduct and results of trials. Beyond enhancing the speed and accuracy of studies, this can level the competitive playing field among all research organizations regardless of size and help bring better products and therapies to patients in need.

Barriers: From my experience, there is no primary barrier to innovation. As an evidence-based industry, clinical research is driven primarily by data. For something to win acceptance, it must be supported by data that clearly demonstrate success. Innovation, on the other hand, requires a leap of faith and a break with tradition. Some research organizations are prisoners of their past — and the more successful that past, the harder it is to make changes. Second, as a highly regulated industry, our sector by necessity is risk-averse. It's hard to be innovative when the rules that guide your work constrain individual initiative. And the final barrier is a lack of affordable alternatives. Simply put, the price of most innovations, such as end-to-end integrated solutions, the up front infrastructure and training investments required are too steep.

SANDI LOTTES
VP, Global Clinical Development and Operations
UBC: An Express Scripts Company

Opportunities: Technology combined with personalized medicine or a patient-centric approach to drug development is a tremendous opportunity to innovate and streamline the clinical development process. The ability to target specific genetic disorders and mutations that lead to various abnormalities and diseases, which are further exacerbated by environmental and lifestyle factors, has completely changed how

we develop drugs, conduct studies in patients and pharmacologically manage very complex and life-threatening illnesses.

Working with an individual patient's genomic profile and focusing drug treatment to this degree of specificity, essentially gives us the opportunity in drug discovery for a myriad of approaches to receptor-targeting. Additionally, clinical trials in patients with a range of mutations that confer specific types of cancer or clinical disorders allows the individual patient to serve as his or her own control such that the outcome of treatment is more likely to be successful.

Compiling multiple "n of one" experiments in this fashion helps to inform the study design and treatments that are more probable to have a beneficial result on an even broader population with similar conditions. To have the technology platforms to facilitate the discovery, development, and medical management on a more personalized level will hopefully lead to improved quality of life, and possibly a cure for many currently intractable diseases.

Barriers: Success, along with the status quo, has led to inertia, lest we tip the balance of the accomplishments we have achieved in drug development and drug product management. This state can apply to any number of the processes and services engaged in the healthcare and biopharmaceutical industry. Because we have reasonably mastered managing the increasingly complex process of developing new molecules, as well as navigating the ever greater regulatory demands to meet market approval for our drug products, we have become averse to any type of risk to those achievements, and to what we perceive as the ultimate formula to attaining those goals and maintaining our considerable successes. Disrupting the status quo will lead to even bigger success.

Innovation: Similar to the concept of personalized drug development, the discovery of tests and assays to measure the appropriate biomarkers needed to quantify our progress is a remarkable innovation. Tools that are ultra-sensitive at the molecular level ensure that we can accurately evaluate breakthrough treatments and better assess the benefits as well as potential risks and adverse events, while stabilizing and possibly stunting or reversing the progress of disease.

BRADLEY VINCE, D.O.
CEO and Medical Director
Vince & Associates Clinical Research

Opportunities: Regulatory authorities and IRBs continue to support the recruitment of disease state populations earlier in the drug development process for certain indications provided appropriate safety measures are incorporated into the study design. As the industry becomes more innovative with the enrollment of specific patient populations in Phase I trials, there continues to be an opportunity to obtain an earlier read on the potential efficacy of a compound. While the adaptive design model that often incorporates patient populations is being used by some companies, it has yet to become a requirement for certain types of drugs/indications in early development studies. The ability to obtain efficacy data for the intended disease state population earlier in the clinical trial process can be essential for a go or no-go decision, which in turn enables companies to effectively manage their drug development pipeline.

Barriers: Too often we become fixated on what has been done historically in drug development and thus the willingness to be innovative is shied away from to avoid culpability if the trial does not go as planned. Many become comfortable with the status quo and allow the opportunity to become innovative pass them by. The study design process within specific disease state populations can be a make or break for a small biopharmaceutical company, and with heightened risk comes a heightened hesitancy toward innovation. With the increasing support of both regulatory agencies and IRBs, companies are becoming more comfortable with making the change to use patient populations in early phase clinical trials for certain types of drugs/indications; but it is not yet the standard. As an industry, we need to encourage companies from large pharma to small biotech to embrace the addition of patient populations whenever possible earlier in the development process.

Innovations: Currently, nearly all drugs in development require evaluation for potential QT/QTc prolongation. This is accomplished through a dedicated Thorough QT study to assess drug-induced QTc prolongation, a major consideration in the development process. In 2012, the Cardiac Safety Research Consortium held a public meeting at the FDA to discuss the results for an improved technique to reliably assess QT/QTc from data already being routinely captured during Phase I trials. Discussions are currently ongoing between regulators and the pharma industry to consider implementation of this new methodology. If the FDA supports this change, a substantial percentage of cases will use "Early QT Assessment" as an alternative to the TQT study. This innovation has the potential to save pharmaceutical companies significant time and money while at the same time providing them information and certainty about the cardiac safety profile earlier in the drug development process. PV