By Taren Grom

Outsourcing

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

NICK DEMLING

Executive VP
Planet Pharma

Opportunities: We have seen a significant undertaking from sponsors and CRO clients as it relates to supporting their clinical innovation teams geared at patient recruitment and retention. Much of the focus has been centered on bringing the trials to the patients.

Barriers: I believe that many barriers to innovation are coming down. My perception with many of our sponsor and CRO clients is that there is an industry-wide willingness to look at fresh ideas on multiple levels of service offerings e.g., staffing solutions, project based partnerships, patient recruitment, etc.

If they don't have that willingness, they may become irrelevant to varying degrees when it comes to submitting the NDA/PMA. Many of the innovations that are being offered from vendors are squarely geared at cost savings, more accountability, and more flexibility — all of which benefit the sponsor, and ultimately the patient the drug or device is intended for.

PATRICK LINDSAY

President
United BioSource Corporation (UBC)

Opportunities: A great opportunity for innovation lies in moving from multiple technology platforms to one integrated system. Using a single platform can automate workflow and ensure 100% compliance, eliminate redundant data entry leading to inconsistent reporting, provide data analytics that cut across multiple programs, and improve resource utilization through common training.

By working within a single source of technology, a manufacturer's programs can share patient information across patient services. This offers a holistic view of patient care and adherence, providing enhanced decision support to manufacturers, and ultimately leading to streamlined patient care. Integrating program platforms can allow patient-facing employees to develop customized outreach plans the fit each patient's communication preferences and avoid duplicative contacts.

Innovations: Social media and mobile health applications have significantly changed the way many patients approach healthcare decisions. Through social media and online sources, patients are doing a lot of research before meeting with their physician. For those diagnosed with a rare disease, online education, and support can truly provide connections that can save a patient time, resources, and even their life. Mobile health applications provide diagnostic and treatment support, remote monitoring, data collection, wellness, training and education, and tracking.

It's amazing what information patients now can access and how it can influence their decisions. Patient support programs, including REMS contact centers, reimbursement HUBs, and specialty pharmacy services need to recognize and understand the various tools patients may be using. Whether a patient has limited access to online resources and mobile health devices or has sought extensive education and support groups, programs need to be adept at guiding patients wherever they may be on their treatment journey.

MANISH SOMAN

President and CEO
Sciformix

Opportunities: The focus on safety and risk management has increased across all stakeholders — regulators, prescribers, and consumers. High volumes of safety data, more stringent regulations in developed regions, and evolving regulations in emerging markets, which have grown in their commercial relevance, make it difficult to consistently achieve compliance. Process excellence and technology innovation play a critical role in the outsourcing space, especially in the area of pharmacovigilance/product vigilance. The great opportunity lies in being able to use domain understanding to determine where and how much lean methodology and automation can be applied to deliver managed services in a way that ensures compliance, increases efficiencies and extends the life of the product on the market. What is certainly key here is that while you need the technology to enable and facilitate these advantages, human resources will also be required for not only implementation but for expert knowledge of the regulatory space.

Barriers: The greatest barriers that I find and hear most frequently across my network are also the key drivers for more technology and technology-based services. Regulations are increasingly tightening, and it is absolutely mandatory that compliance is maintained. From a global perspective, these compliance requirements are difficult to manage and not helped by the current fragmented state of the industry, for example in the areas of labeling and regulatory operations where multiple tools and technologies are available for different steps of the process, yet they are not integrated.

This fragmentation is caused partly by lack of technology and process standardization across the globe. Different regulatory requirements across different geographies typify this lack of standardization; for example the FDA is now mandating eCTD through the electronics submissions gateway (ESG), while the European Union accepts NeeS format, and some other regulatory agencies are still wanting submissions in paper format. What would certainly help this is an increase in the proliferation of global standards.

Innovations: The first innovation is the openFDA initiative announced by the FDA in January 2014, which made more than 3 million reports on adverse drug events and medication errors recorded between 2004 and 2013 readily available to the public and to researchers. These reports are available in their entirety and the data are organized in a manner that enables software developers to build tools to help signal potential safety issues, derive meaningful insights, and get information to consumers and healthcare professionals in a timely manner. Secondly, several large pharmaceutical companies have announced their commitment to being transparent regarding clinical trials they sponsor and have started sharing data and information about their clinical trials. They have acknowledged that there are important public health benefits in making these data available to healthcare providers, researchers, patients, and the general public. Both of these are significant developments in increasing data transparency giving researchers, innovators, healthcare practitioners, and patients access to more information for more informed and faster decisions. Making all of this data available improves the signal detection process and helps healthcare practitioners around the world prescribe the best therapy. PV