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Holistic Approach Needed to Transform R&D Process, ICON Says

Thought Leadership in Association with ICON

by

Pharma is at a most critical point in its evolution. It is being held back by a lack of flexibility, speed and mastery of analytical power. The R&D process that has been its foundation now underpins an inefficient clinical trial process that is costly, often unprofitable and which makes it harder to successfully meet the changing and challenging demands of disease in the 21st century. The model of three fixed study phases is no longer viable to produce the therapeutic solutions that are required to meet increasingly complex healthcare demands dominated by an aging population with multiple health needs. ICON has undertaken research, assisted by ISR Research, and conducted an industry survey with Informa's Pharma Intelligence, to examine the challenges facing pharma and find solutions.

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The reality of the industry's position is that to gain approval in the US for a new pharmaceutical product costs more than $2.5 billion, representing an increase of 145% in just 15 years, according to the Tufts Center for Drug Development. Furthermore, the stakes are high risk as only 7% of first-in-human drugs receive regulatory approval.

Holistic approach

ICON has undertaken research, assisted by ISR Research, and conducted an industry survey with Informa's Pharma Intelligence, to examine the challenges facing pharma and find solutions. This includes a holistic approach to transforming the clinical trial process. The top three challenges identified by respondents in ICON-Pharma Intelligence's survey were patient enrolment, site start up and regulatory approval delays/changes.

Interestingly, respondents also identified study start up, patient recruitment and retention and product development as three key areas with the most potential for generating savings and efficiencies. It is clear from the survey that those who participated have a growing understanding that to really gain traction and change, a holistic approach must be adopted to secure trial transformation. New trial design is essential, along with the adoption of a new corporate and scientific approach that supports the clinical trial process throughout the enterprise from the ground up.

We have now entered a healthcare era that requires more targeted therapies, more orphan indications and personalised medicines – with opportunities for enhancement and integrated support via disruptive technologies, powerful statistical analysis, and artificial intelligence (AI). However, the ICON-Pharma Intelligence survey showed that despite the recognition of the need for a holistic approach, only one in five respondents indicated they have a holistic/integrated initiative to drive clinical trial transformation.

Including data from its survey, ICON has published a white paper on how to improve R&D efficiency. Patient centricity needs to be at the heart of new strategies as the pharmaceutical industry works to move away from its traditionally disease-focused approach to R&D. ICON demonstrates that pragmatic trials with real-world data generating evidence to guide recruitment, shorten start-up times, and expand indications, are key. Furthermore, expanding recruitment pools is one way of addressing the need to include traditionally underrepresented patient groups such as the elderly, children and ethnic minority populations.

In the 21st century, the power of the internet has dramatically empowered patients to become knowledgeable about health and disease and to share knowledge with each other. One in 20 Google searches are for health-related information. There are also technological developments and devices that are enablers in gathering real-world data.

E-health

27% of survey respondents said that using smart phones, developing novel outcome measures and remotely collecting data will improve operations. ICON emphasises that big data, new

outcome measures and endpoints generated from mobile devices, sensors and wearables supplied to patients need to be rigorously validated. The challenge is to establish and structure data, from a range of diverse technologies, that can be understood and interpreted to gain meaningful patient and scientific insights. Outcomes need to be modelled and validated. "Although people can access a lot of data, making it talk to one another is an unsexy but really important piece of work that needs to be done," commented Rob MacKenzie, Executive Vice-President and Chief Development Officer at Pfizer, speaking at the 2017 FT Global Pharmaceutical and Biotech Conference.

Statistical analysis and AI can be harnessed for managing data integration and interpretation. These tools can lead to improvement in trial performance at every level, including modelling investment return. AI, big data and risk-based monitoring were among the top technologies recognised in the survey.

There is now evidence building that using these new technologies and approaches in clinical trials can save millions in development costs. Case studies by ICON have shown that applying adaptive design can accelerate time to market and eliminate $5 million in expenditure.

Another new approach thanks to technological advances is siteless trials. The virtual trial alleviates the sometimes unmanageable burden on patients of frequent clinic visits for monitoring when participating in clinical studies. CentreWatch, which provides clinical trial information to trial professionals and patients, has found that 18% of clinical trial patients drop out of trials after they have enrolled and that difficulty reaching clinic locations is a negative factor.

The adoption of e-visits and telemedicine can reduce trial costs considerably. Sanofi's tie-up with Science 37 in 2017 to allow patients to be monitored from home, is one example. Patients were equipped with a smart phone to be monitored via a cloud-based research platform. Science 37 suggested that such technology could reduce typical trial time by at least 30% and that virtual clinical trials could reduce trial time by as much as two years.

Collaboration

Taking a holistic approach to trial transformation is not just about adopting new technology, gathering and interpreting big data and applying new resulting strategies. It also requires internal, external and interdisciplinary collaboration.

There needs to be collaboration between sites, investigators and also internal corporate functions such as clinical development teams and commercial teams. And externally, a critical element is strategic partnerships. Tufts advocates that the role of contract research organisations

is becoming increasingly significant as these businesses become more involved in clinical research and are recognised as strategic partners. Many CROS have already adopted the technologies discussed. For example, ICON has incorporated various technologies such as electronic data capture, real-time analytics and data apps into its programmes, including partnerships with Intel. McKinsey & Co believes that with the growth in specialisation of clinical research, partnerships between sponsors and CROS are likely to grow in value.

This holistic approach, if diligently embraced and applied, will transform the clinical trial process and the way the pharmaceutical industry operates so that it will ultimately produce more effective therapeutic products, increasingly address patient unmet need and achieve higher returns on investment.

To receive ICON's White Paper. "Improving R&D Efficiency: The Case for a Holistic Approach to Transforming Clinical Trials register at *www.iconplc.com/pharma*