Breakthrough Drug Development Innovations: Increasing the Likelihood of Market Launch

By: Sy Pretorius, Chief Scientific & Medical Officer, PAREXEL

Drug development today is facing serious challenges. The way new treatments are brought to market has become increasingly inefficient, lengthy and costly, with a high likelihood of failure. Meanwhile, pressures are mounting on companies to bring therapies to patients more quickly and cost effectively than ever before.

Fortunately, innovations exist that can light a path to a more productive, sustainable future.

The Innovation Imperative: The Future of Drug Development, a recent data-driven report conducted by The Economist Intelligence Unit and commissioned by PAREXEL, analyzed the future sustainability of drug development and its current trajectory, and identified promising innovations to improve efficiencies, rekindle productivity and restore sustainability. Specifically, the report unveiled four key areas of innovation that can lead to the improved success in bringing a drug to market, including: patient-centric trials, adaptive trial designs, precision medicine trials, and real-world data trials.

Impact of Patient-Centric Designs

Patient-centric trials are clinical trials co-designed or designed specifically around patients' needs and seek to make it as easy and as convenient as possible to participate in research. A key component is direct involvement of patients and/or their caregivers and/or patient advocacy groups in the initial design of the study. Convenience can also be achieved through technology, such as with the ability to capture data in the comfort of the patient's home via wearable sensors and other virtual approaches.

Enrolling patients in clinical trials is a challenge; only about a third of clinical trial sites meet their accrual enrollment targets and about half of clinical trial sites are forced to extend their enrollment periods beyond their original estimates to complete enrollment. There are several reasons why sites struggle, including overly restrictive inclusion/ exclusion criteria, overly optimistic enrollment projections, and heavy patient burden (i.e. several visits, numerous study procedures etc.) that make trials less attractive to patients to participate in. Convenience alone reduced patient burden and increased perceived patient benefit.

Importantly, being more patient-centric also holds tremendous potential to improve drug development. The recent research findings showed that patient centric trials enrolled patients faster and are more likely to succeed. It took an average of four months to enroll 100 patients in patient-centric trials versus seven months for non-patient-centric trials, and, these trials had a higher probability of success as defined by progressing from Phase II and III to market launch.

Barriers to Innovation Adoption

Despite the positive overall impact to clinical trial success that the data show, there is evidence of low adoption rates of innovations like patient-centric trials. Over the five-year period covered by the EIU report, only about 5% of Phase II and Phase III trials included patient-centric themes – a surprisingly low figure given the general buzz and attention around patient-centricity across the healthcare ecosystem.

Many organizations are aligned on the concept that patient-centricity is important and holds great potential. But many often do not know where to start when it comes to implementing patient-centric processes. The research identified key barriers to innovation:

1. One barrier to adoption of patient-centricity, as well as some of the other innovations highlighted in the EIU report, is the vast volume of new and fragmented data that we, as an industry, are currently dealing with. While there has been exponential growth in the amount and types of data used in healthcare research, there is an uncoordinated approach to its collection and storage, often leading to data silos.
2. Small or inadequately prepared workforces is another barrier. Drug development of the future requires teams who are skilled and knowledgeable in handing and interpreting medical data.
3. Another barrier to adoption of these innovations is the negative perception of the pharmaceutical industry. It is our responsibility to instill and foster trust in pharma as a key player in connecting payers and patients across drug development.
4. Lastly, cultural barriers are preventing people who work in an already high-risk industry from feeling empowered to taking on additional risk through innovation.

The research also found that adoption rates of patient-centric trials can be addressed through four enabling factors: advanced data analytics, workforce readiness, collaborative partnerships, and early payer and patient involvement.

Advanced data analytics: We must develop more industry-wide data standards and integrate data capture and analytics across the entire drug development and market access continuum. This will require implementing mechanisms for data sharing and interoperability, data prioritization, integration of alternative data sources, and predictive analytics. Bridging data silos can enable greater data sharing and transparency across the industry, potentially driving efficiencies as suitable data can be shared and re-used.

Workforce readiness: We need to better prepare our workforces and train them adequately. Without sufficient workers involved in drug development who have a deep understanding of data as a science, barriers to data usage will continue to exist. Workforce readiness includes the collection and management of unconventional data and continual improvement.

Collaborative partnerships: It's important that we begin looking at our industrywide relationships and identifying potential collaborations. Well-defined partnerships will lead to organizations working together and learning from each other without permanently altering the competitive landscape. Along similar lines, "co-opetition" has gained traction as a way for multiple potential competitors to collaborate with each other.

Early payer and patient involvement: Ensuring a shared set of objectives among regulators, payers and patients early on has a critical impact on the speed and success of drug development and market access. Engagement among stakeholders builds trust and emphasizes the importance of collaboration to drug developers. Perhaps most critical, though, is early engagement with patients. Patient engagement can provide insight into clinical manifestation of disease as well as provide drug developers with feedback on

treatment options, such as standard of care and effectiveness of existing therapies and improvement of patient retention in trials.

Conclusion

As an industry, we are dependent on patients to advance new therapies. We need patients to be interested in clinical trials, to participate in and be invested in clinical trials. Ultimately, it is their lives that all in the healthcare ecosystem work each day to impact.

Clinical trials should be as attractive and as convenient as possible for patients to participate in. We must adopt new ways of working and researching that support this focus, including use of patient-centric trial designs. In turn, we can do more to improve patients' lives and help accelerate clinical trial timelines and the likelihood of drug launch.

For more findings on patient centricity trial designs, visit: https://druginnovation.eiu.com/.

About the Author

Sy Pretorius is the Chief Medical & Scientific Officer at PAREXEL and has been with PAREXEL for more than two decades in a variety of roles and countries. On a day-to-day basis, Sy collaborates closely with biopharmaceutical and medical device clients in designing and optimizing drug / device development strategies and plans, as well as finding, evaluating and purchasing assets. As a member of the PAREXEL executive leadership team, Sy is responsible for the overall leadership of a number of PAREXEL service lines & business units – these include Global Medical Services, Translational Medicine (includes Genomics, Modeling & simulation and Biomarkers, Real World Data Services, Real World Evidence, Safety Services, Regulatory Outsourcing and The Medical Affairs Company (Medical Science Liaisons). Sy is absolutely passionate about drug development and leads several company-wide forums and initiatives focused on clinical trial innovation and further expanding PAREXEL's capabilities and service offerings. Sy is a Medical Doctor (M.B.,Ch.B) with Masters degrees in Clinical Pharmacology (M.Med.Sc), Business Administration (MBA) and, most recently in the Management of Drug Development (MS) from the University of Southern California (USC). Sy has and continues to publish and present extensively.