TATA CONSULTANCY SERVICES

Engaging and Empowering Patients for Effective Clinical Trials

Abstract

The biopharmaceutical industry considers a patient-driven approach to be vital in developing high quality healthcare solutions. Studies have recommended that a persistent patient-focused clinical trial can positively influence key health related outcomes. In turn, it helps patients develop a bond of trust with their healthcare providers, and they are less inclined to switch doctors or drop out of studies. For the sponsor and provider, engaged patients help derive better clinical outcomes. Within the industry, the observations suggest that improving patients' experience during their treatment in hospitals resulted in significantly improved recovery and survival rates.

A patient-driven healthcare services framework is not an idealistic pipe dream, especially given that the supporting tools and technologies for it are already available. This paper covers key industry challenges on the road to embracing a patient-centric approach to designing and delivering holistic healthcare.

Establishing Better Connect with Patients

Recent advances in drug development methodologies have enabled the biopharmaceutical industry to introduce new drugs and treatment modalities to the patient community faster than ever before. While the primary focus of pharma researchers continues to be on ensuring safety, improving clinical outcomes,[1] and ensuring data privacy,[2] patient inclusion in the drug development process is infrequent and inconsistent. Although its importance has been duly recognized, the present paternalistic approach to patient participation is instructive in nature, and often overburdens the patient with information.[3]

This is indicative of a significant disconnect between pharmas and their end-users, and is exemplified by the former's habitual dependence on social insurance experts as a proxy. Unless patients are considered central to the drug discovery process, researchers will find it difficult to deliver products truly capable of making a difference to their lives.

To this effect, drug manufacturers must focus on:

- Increasing patient access
- Improving awareness about clinical trials
- Monitoring diagnosis and treatment rates
- Enhancing adherence to study procedures and dosing schedules
- Reimagining point-of-care communication

Reimagining Clinical Trials – From Discovery to Enrollment

Traditionally, contract research organizations (CROs) and patient advocacy groups have served as a ready repository for pharmaceutical companies seeking candidates for their trials. Although this has proven itself to be a cost and effort efficient method, things are changing fast.

Before enrolling themselves in a clinical trial, today's digitally empowered patients prefer to spend time thoroughly researching and learning about diseases, drug mechanisms, and outcomes of similar studies – often responding to or sharing information they find useful on social media platforms.

In fact, over half of the 300,000 patient posts[i] pertaining to clinical trials that are available online have been published during the last six months. With 41% consumers[ii] reporting that such information affects their choice of physician or hospital, it is evident that social media platforms can help potential trial candidates identify the right study to enroll in at the right time. Once the patients choose to sign up for a particular study, they can be seamlessly qualified and on-boarded using a standard set of inclusion criteria and an electronic consent form accessible through their smartphones. Further details regarding schedules, procedures, and appointments can also be shared over the same channel.

At the other end of the spectrum, clinicians and pharmas also have much to gain if they can leverage patient information shared on social media effectively. Using artificial intelligence (AI) and machine learning (ML) algorithms to correlate patient information with electronic health records and predefined study enrollment criteria, researchers can quickly and accurately identify patient groups with the right set of attributes without having to rely on an intermediary.

Improving Outcomes – Keeping Patients Meaningfully Engaged

Even after patients are successfully enrolled into trials, they often tend to drop out, especially if the duration of a study is unusually long or if they have experienced adverse effects. This affects the trial's outcome, often delaying its conclusion with pharmas spending an enormous amount of resources to qualify new candidates to fill the gap. To counter such adverse events, the companies will need to analyze the situation from a patient's perspective. To facilitate this, pharmas operating trials can conduct patient experience surveys through smartphones at regular intervals over the course of the study. It will enable them to proactively identify reasons for non-compliance such as socio-economic factors or conflicts with doctors and hospital staff that eventually lead to loss of follow-up and end with patient dropouts. Exit surveys conducted at the end of the trials will also provide valuable insights which can be used to improve future study protocols and subsequently, their outcomes.

To further enhance the integrity of a clinical trial, patients can be equipped with smart medication kits capable of sending out alerts in case a dosage has been missed. It can also help the hospital staff track and monitor patient compliance in real time.

Wearable devices fitted with sensors can help both patients and researchers track and analyze data related to electrocardiogram, respiratory rate, ambulatory blood pressure, glucose levels, skin temperature, and heart rate among others. Not only does this simplify the process of tracing an experimental drug's side effects but also provides the patient with insights about his or her own health – making the wearable devices an integral contributor to the study. By providing features such as dosage reminders, real-time connectivity with hospital staff, AI-driven self-service helpdesks, and informative how-to nano videos, pharmas can hope to engage patients meaningfully and improve their overall experience. An integrated knowledge library linked to key sites like HealthIT.gov can further complement the usefulness of such devices. After the study is complete, concise summaries explaining the results and outcome shared electronically can create a much more conducive and transparent environment within the patient community.

Restructuring Legacy Practices

Adopting a patient-centric approach towards drug development will require implementing changes at multiple levels of the process – from discovery and R&D stages to regulatory approval and postmarketing surveillance.

Engaging the patient community right from protocol development can provide meaningful insights and practical requirements for eligibility and endpoints that are deeply significant from a patient's perspective.

By collaborating with an external technology partner to deploy these solutions, pharmas can significantly improve patient experience, in turn reducing dropout rates and improving data quality critical for shortening the lifecycle of a clinical trial. Ideally, a set of well-defined policies and procedures should be in place to ensure solutions meet not just the anticipated regulations around general data protection regulation (GDPR) but also existing regulatory requirements as defined by the Health Insurance Portability and Accountability Act (HIPPA).

Setting the Foundation for Patient-centric Healthcare

For pharmaceutical companies, patient centricity is quickly becoming a vital guiding principle for their drug development process. To this effect, multiple initiatives have been undertaken by not just drug makers but also governments, regulatory authorities, and even patient advocacy groups. Their efforts, however, will need to be translated using cutting-edge technology to achieve the ultimate goal of improving the patient's experience over the course of a clinical trial. Smart devices will help eliminate convoluted processes and make it significantly easier for patients to adhere to study procedures. Once it matures as a practice, a technology driven patient centric approach will create an environment wherein the pharma industry will begin to see a more seamless participation from the patient community driving innovations in drug development.

References

i   http://www.picronline.org/article.asp?issn=2229-3485;year=2017;volume=8;issue=2;spage=73;epage=78;aulast=Ray

ii   http://blog.medicalgps.com/social-media-and-healthcare-10-insightful-statistics

[1] International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use 2015 http://www.ich.org/home (accessed Nov 2017) Google Scholar

[2] Health Insurance Portability and Accountability. Standards for privacy of individually identifiable health information DHHS [45 CFR Parts 160, 162 & 164 (HIPAA)]. 2016 http://www.hhs.gov/hipaa/for-professionals/privacy/ (accessed Nov 2017).Google Scholar

[3] European Medicines Agency. The patient's voice in the evaluation of medicines. How patients can contribute to the assessment of benefit and risk. 18th October 2013

About The Authors

Dr. Niraj Vyas

Dr. Niraj Vyas is the Assistant General Manager, Life Sciences at TCS. He has 16 years of experience in the biopharmaceutical industry, managing cardiac safety and centralized clinical monitoring operations. He has graduated in medicine from Seth GS Medical College and KEM Hospital in Mumbai. He also has a PG diploma in clinical research from Bombay College of Pharmacy and a Masters in Business Administration from Indira Gandhi National University.

Bharat Shukla

Bharat Shukla is currently working as Assistant Manager, Clinical Operations - Risk Based Monitoring at TCS and has 12 years of experience in Contract Research Organization (CRO) and Biopharmaceutical industry. He has graduated in Science (B.Sc) from Mumbai University and holds a Masters degree in Clinical Research from ICRI (Cranfield University, UK).

Contact

Visit the Life Sciences & Healthcare page on www.tcs.com

Email: lshcip.pmo@tcs.com

Subscribe to TCS White Papers

TCS.com RSS: http://www.tcs.com/rss_feeds/Pages/feed.aspx?f=w
Feedburner: http://feeds2.feedburner.com/tcswhitepapers

About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is an IT services, consulting and business solutions organization that delivers real results to global business, ensuring a level of certainty no other firm can match. TCS offers a consulting-led, integrated portfolio of IT and IT-enabled, infrastructure, engineering and assurance services. This is delivered through its unique Global Network Delivery Model™, recognized as the benchmark of excellence in software development. A part of the Tata Group, India's largest industrial conglomerate, TCS has a global footprint and is listed on the National Stock Exchange and Bombay Stock Exchange in India.

For more information, visit us at www.tcs.com

Experience certainty.   IT Services
Business Solutions
Consulting