Why Patients Avoid Clinical Trials

And how big data, analytics, technology and domain expertise can help change the paradigm

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The pharma industry has a big challenge when it comes to clinical trials, one that continues to hinder the industry's approach to research. Sponsors want patients to enroll in their trials, but the clinical research environment can be so onerous and confusing that patients have little incentive or opportunities to sign up. Recent data suggest 82% of patients say they are not confident in their ability to identify clinical research opportunities on their own.[i] While most assume their physicians will steer them to trials, if appropriate, a mere 0.2% of patients in one survey said they were ever referred to a trial by their primary physician during standard care over a 12-month period.[ii]

These sobering statistics reflect a chronic problem. While clinical trials may offer innovative care solutions for patients and are the foundation upon which new treatments are created, the conduits meant to link patients to these opportunities are broken.

This is a big and expensive problem for sponsors. Almost 80% of trials face delays[iii], largely due to enrollment issues that can result in potential lost sales of $600,000 to $8 million per day.[iv] For sponsors developing precision therapies that require highly specific patient populations, the lack of engagement with the patient community will become an even more costly burden.

However, when pharma companies leverage big data analytics in combination with making their trial experience more patient-friendly and streamlined, they have a much better chance of engaging patients in the recruiting process.

Finding Patient Insights in the Data

To make a dent in leveraging big data, sponsors need to be able to assess multiple real-world and clinical data types from a variety of global sources. This isn't easy. These data sets can be difficult to access, curate, link and validate, and vary in reliability based on the maturity of the national healthcare system, local data privacy regulations and the granularity and consistency of the data captured.

When sponsors work with industry experts who have the data management knowledge and advanced analytics tools to analyze these data sets, they can uncover insights that will reshape their recruiting strategy and deliver better results. The more experience in analyzing data for recruiting, the better, faster and more reliable the results will be.

IQVIA has one of the largest curated repositories of of de-identified patient data in the world, which we have used for years to help clients find hidden patient populations and hone their recruiting strategies. Our advanced analytics experts build custom machine learning algorithms that are trained to locate targeted patient pools, as well as the research sites, healthcare facilities and physicians who treat them — even if those sites and physicians have never participated in clinical research. Proprietary machine learning algorithms predict and identify the top-tier global investigators to be selected for a specified protocol based on multiple key indicators (e.g., highest number of targeted patients, prior high performance and quality delivery, fewer concurrent competing clinical trials, etc.). The database also provides information as to which nearby community physicians are treating the patient population of interest and are within the same healthcare system as the top-tier investigators. These connections can help encourage patient referrals to investigators conducting clinical trials, especially in rare disease and oncology indications.

Sponsors leverage the data to identify the best countries to host their trials, vet trial sites and investigators, and identify the right combination of inclusion and exclusion criteria to speed recruiting and reduce screen failures while lowering avoidable protocol amendments and inefficiency costs.

Every time we train an algorithm to find a specific indication in a global patient population, we store that piece of software in our cloud, so we can reuse it anytime it's relevant to a new trial or development effort. That means the next time we need to search for a specific population, that algorithm that may have required weeks to originally develop and train can now uncover new populations in minutes. We currently have more than 1,000 of these algorithms in over 200 indications being deployed.

Big data-driven approaches have become essential to reduce time, cost and risk in recruiting, particularly for highly specific precision medicine trials.

Treating Patients as Partners

Until recently, most of the applications of big data analytics to improve recruiting focused on the perspective of the healthcare professional. The idea being that, if we can find the investigators treating these patients, we can get them into the trial.

But it's not enough to just identify the investigators. If we want to accelerate recruiting and improve retention, we need to rethink the entire trial experience through the eyes of the patient. If enrolling and participating in a trial is overly burdensome, confusing or lacks any positive feedback or engagement, patients have little incentive to participate. That lowers recruiting rates and increases the risk of attrition, which, on average, costs sponsors up to $36,000 for every patient who drops out.[v] Studies show an average of 18% of randomized patients drop out before a trial ends, which translates to hundreds of thousands of dollars lost.[vi]

No matter how much money sponsors spend to find these ideal trial candidates, until

we make the trial experience more patient-centric from first point of contact to close of trial, those investments won't fully pay off.

Patients Feel Neglected

There are many reasons patients don't participate in trials — confusion about how to identify the right clinical trial, trial burden and schedule conflicts, misconceptions about trial safety, scheduling and transportation challenges and quality of life issues that make participation feel overly burdensome. Couple that with confusing paperwork and a lack of any real feedback about the value their participation brings to the research, and it's no surprise that recruiting and retention are so complicated and often ineffective.

IQVIA's 2019 patient community survey found patients are no longer satisfied to be passive participants in the trial experience. If they are going to be a part of clinical research, they want feedback, including access to their own trial data (89%), updates about upcoming trials (81%), study statistics (78%), and reminders and calendar tools (52%) to make participation easier.

While some of this data is difficult to share due to statistical integrity of protocol and regulatory and intellectual property issues, in other cases, the value of treating patients as active stakeholders in the research process has not been embraced. In our survey, patients reported struggling to find even basic data, such as when the study will start, how many visits are required and when it will end. And they are often surprised by how little information they receive about the trial's progress and their own healthcare data.

We must demystify the clinical trial process for patients to improve their recruiting efforts. If we are going to ask patients to make such a big commitment of their time — and their healthcare — to research, we need to make it worth their while.

A Portal for Patient Engagement

In response to this gap in the marketplace, IQVIA created a platform designed to make patient access and engagement much easier to deliver.

The IQVIA Patient Portal takes a human-centered design approach to patient recruiting and retention by giving patients a direct connection to the clinical research environment — and the sponsors hosting these trials. This global, web-based solution, built on the Salesforce Health Cloud platform, enables transparency and collaboration between sponsors, sites and the patient community. The portal supports the site-patient relationship through enabling patient retention without increasing site burden. Patients and their caregivers can join the portal from anywhere in the world through a mobile device and use it to learn about their disease, get alerts about trials and enroll where appropriate. Post-trial, it facilitates sponsors' ability to continue to interact with their alumni patient community.

From the moment of enrollment, patients gain value through access to information, education and healthcare resources. The platform uses transformative technology and analytics tools of the IQVIA CORE to scour the patient community and to alert trial alumni when upcoming trials may fit their needs, creating a more direct-to-patient proactive recruiting channel.

If a patient chooses to enroll in a trial, the portal becomes their one-stop direct access for trial information, patient-reported outcomes, trial support requests and planning. Using patient-friendly language and intuitive icons, they can learn about the study and what to expect at individual appointments and track study progress. They can also complete electronic paperwork, sign up for reminders and alerts, and review their healthcare data where appropriate. In collaboration with the site, the sponsor determines how and when medical data is delivered, ensuring patients get the value of seeing their personal benchmarks after the investigator provides meaningful context and without risk of biasing trial results. The portal has also been designed to satisfy upcoming mandates from the EU Directive to provide plain language summaries and FDA patient experience data to patients at the end of the trial.

The features built into the portal address the many complaints patients have had about the clinical research experience while providing a transparent platform. It also takes much of the retention burden off of investigators, who can then dedicate more of their time to clinical research and care activities, rather than trying to track down patients.

By designing a patient-centric platform, sponsors will be able to bolster recruitment for upcoming studies, collect patient experience data and inform future study design, while patients and their caregivers get a more positive trial experience and access to information before, during and after a trial that affirms their critical value and importance in the research process.

To learn more the IQVIA Patient Portal, and other ways that IQVIA is leveraging big data to accelerate recruiting, go to https://www.iqvia.com/solutions/research-and-development/patient-retention. PV

Editor's Notes:

[i] Center for Information & Study on Clinical Research Participation, 2017

[ii] Getz, K. Changing Drug Development Landscape and its Anticipated Impact on R&D Operations. http://csdd.tufts.edu/files/uploads/Outlook-2014.pdf

[iii] https://www.drugdevelopment-technology.com/features/featureclinical-trial-patient-recruitment/

[iv] http://isrreports.com/wp-content/uploads/2014/04/ISR-The-Expanding-Web-of-Clinical-Trial-Patient-Recruitment-Whitepaper.pdf

[v] "Biopharmaceutical Industry Sponsored Clinical Trials: Impact on State Economies," Battelle Technology Partnership Practice for PhRMA. March 2015.

[vi] https://forteresearch.com/news/infographic/infographic-retention-in-clinical-trials-keeping-patients-on-protocols/