Data-Driven Patient Recruitment
to Deliver Qualified Patients, Faster

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EXECUTIVE SUMMARY

The biopharmaceutical industry is at an important crossroads in medical innovation. Drug developers must seize opportunity to find a more efficient, scalable way to recruit patients for clinical trials, or face costly delays in bringing new medicines to market. Amid increasing costs, declining productivity, decreasing pipelines and a host of other challenges plaguing the industry, the most significant problem in conducting clinical trials in the New Health is well documented: Sponsors and clinical research organizations (CROs) cannot recruit qualified patients fast enough.

This white paper examines the extraordinary opportunity for the biopharmaceutical industry in using data to drive more efficient patient recruitment strategies. In the paper, Dr. Cabell issues a challenge to the industry, government, technology providers, patients, payers and health care providers to collaborate and seize the opportunity that electronic health data holds for transforming patient recruitment. Topics discussed include:

- The optimal state of patient recruitment, enabled by a world of readily available health data;
- The current state of data-driven patient recruitment, and how progressive companies are using data to streamline certain aspects of clinical research;
- The future of data-driven patient recruitment, and what could be possible with the growth and exchange of electronic health records; and
- The need for greater collaboration between key stakeholders to realize the full potential of data on patient recruitment, and science.
A New Way to Recruit

Almost 80% of clinical trials fail to meet their patient enrollment quotas on time, causing delays in bringing new drugs to market and costing the biopharmaceutical industry up to $8 million in revenue for each day a drug is delayed. Traditional patient recruitment methods are inadequate and do not scale to reach the entire populace. And although Web-based methods may hold promise for the future, today’s competitive market for clinical trial participants necessitates a new approach.

Only 8% to 10% of the general public has ever participated in a clinical trial. The vast majority of eligible candidates are either unaware of available trials or have a poor perception of clinical research.

Fortunately, the growth of electronic health data is paving the way for a more efficient, scalable method to recruit patients for clinical trials. Data-driven patient recruitment can enable greater reach and efficiency, reduce trial delays and save valuable resources. And it’s within our grasp.

Innovative companies are already dialing-in data to increase the speed, number and quality of patients recruited for clinical trials. With the continued growth of electronic health data, and plans for interconnected health records systems on the horizon, possibilities could dramatically increase for clinical research. As an industry, we must collaborate on a greater scale to realize the full potential that data holds for patient recruitment. We must work with government, technology providers, patients, payers and health care providers to encourage the responsible use of electronic health data to advance clinical research and serve tomorrow’s patients.

The Optimal State of Data-Driven Patient Recruitment

Imagine a world of readily available health data in which eligible trial participants could be identified and automatically alerted to clinical trials that could benefit them. For example, a sponsor launches a clinical trial for type II diabetes to test the efficacy and safety of a promising investigational therapy over the current standard of care. With access to basic, anonymized health data – gender, age, location, condition, medication and primary care physician – clinical researchers conducting such a trial could conceivably scan a database to:

• Identify patients who meet the protocol’s inclusion/exclusion criteria;

• Engage clinical trial sites based on patient populations; and

• Alert eligible patients of the trial, directly through their primary care physician.

A comprehensive database containing anonymized health records of individuals from a region, country or continent could dramatically streamline patient recruitment for clinical trials by alerting physicians whose patients might be eligible for a study. Such data has potential to expand the patient universe, alerting more people to available clinical trials and locking patient enrollment quotas in weeks instead of years. With patient recruitment consuming 30% of the trial process, such data could significantly cut the drug development process, decreasing costs and increasing the pace at which new medicines become available to patients.

Patients Inform Study Design & Recruitment Strategy in Alzheimer’s Trial

When a sponsor turned to Quintiles for help in executing a Phase II protocol for patients with mild-to-moderate Alzheimer’s disease, Quintiles reached out to real-life patients and caregivers enrolled in iGuard.org, a social networking site, to pre-test the protocol. Feedback from iGuard.org members proved tremendously valuable in informing protocol design and recruitment strategy before the protocol was launched into study sites.

Created in 2007 as a start-up venture with funds from Quintiles, iGuard.org is currently tracking over 10,000 people in the United States who take medication approved for the treatment of Alzheimer’s disease. Upon receiving the sponsor’s protocol, Quintiles worked with iGuard.org to conduct a blinded survey of Alzheimer’s patients and their caregivers.

The survey results were astounding. For example, 30% of survey respondents failed to meet the protocol’s inclusion criteria because they consumed three or more cups of coffee each day. Furthermore, the survey identified time commitment as a primary barrier to participation, with more than one-third of respondents unlikely to participate in a study that required overnight stays.

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Dialing-in Data
There is one obstacle standing in the way of an optimal state of patient recruitment – we do not live in a world of readily available health data. A health records system that covers the entire health care continuum and populace does not exist today. Finding a usable health records system at a regional, let alone country-level, is next to impossible. In lieu of a comprehensive data source, innovative companies are culling data from multiple sources to streamline certain aspects of clinical research.

As the world’s largest CRO, Quintiles was founded on using biostatistical data to optimize the drug development process. Today, we leverage historical data from our clinical trials in 59 countries, laboratory test results, secondary data, opt-in patient databases and our network of physician investigators and sites to refine clinical trial conduct and increase the speed, number and quality of patients recruited for clinical research.

Data can expedite patient recruitment in the following ways:

- **Data-Driven Feasibility and Protocol Design.** Today, feasibility is largely determined using surveys filled out by prospective sites. This approach is inefficient and largely inaccurate. Quintiles is streamlining feasibility by dialing-in data from multiple sources, including site surveys, historical site performance, patient data and secondary data to determine if, how many and where patients exist. This data is then used to recommend optimal protocol design, ensuring that inclusion/exclusion criteria maps to an existing patient population. This rigorous approach to feasibility means that patient recruitment estimates can be more accurately predicted, and therefore more accurately met.

- **Data-Driven Site Selection.** Identifying sites with a large number of potentially eligible patients is paramount, as is selecting quality sites that meet patient recruitment goals on time and execute the protocol successfully. By combining patient data with historical site performance data, it is possible to select the right sites for the right protocol. Quintiles has more site relationships in more countries for more disease areas than any other CRO, making finding sites and patients much easier.

- **Data-Driven Patient Communication.** Understanding patient motivations and barriers to participation in a clinical trial can dramatically expedite the recruitment process. Rising internet penetration, and the growth of social networking sites, makes direct communication with potential patients possible. Quintiles has direct access to more than two million patients through our opt-in social networking sites, iGuard.org and ClinicalResearch.com. We communicate directly with this highly motivated, highly responsive group to obtain their feedback on study-specific recruitment material, and identify potential barriers to study participation. We use this feedback to recommend protocol design, and create tailored, targeted recruitment material. (See sidebar: “Patients Inform Study Design & Recruitment Strategy in Alzheimer’s Trial”).

- **Data-Driven Patient Referral.** With direct access to the patient population via iGuard.org and ClinicalResearch.com, it is possible to test clinical trial inclusion/exclusion criteria in real-world patients, and pre-screen patients for referral to clinical trial sites. Quintiles’ extensive patient database, paired with our coordinated network of physician investigators, makes it possible to refer qualified patients to study sites in the first, critical weeks following site initiation.

In addition, many respondents said they would not participate because of other lifestyle restrictions in the protocol, such as refraining from smoking, consuming grapefruit juice or consuming alcohol.

Using iGuard.org to get real-world feedback from patients or their caregivers before launching the protocol saved time and money; normally, issues with protocol design or lagging enrollment are discovered months after a study is launched. Armed with data, Quintiles worked with the sponsor to modify protocol design where possible and implement key strategies to enhance patient recruitment, such as ensuring an appropriate approach to subject compensation or allowing caregivers to stay overnight with their loved ones suffering from Alzheimer’s disease.

Obtaining patient feedback on protocols through social networking sites such as iGuard.org can dramatically expedite the patient recruitment process, and ensure that new medicines move to market more quickly. To obtain a free example of an iGuard Patient Protocol Assessment or to request that Quintiles and iGuard.org evaluate your protocol, please contact support@iguard.org.
Turbo-Charging Data-Driven Patient Recruitment

In the not-so-distant future, data-driven patient recruitment could reach new heights. The rapid growth of electronic health data – electronic medical records (EMRs), personal health records (PHRs), electronic health records (EHRs), electronic prescribing (e-prescribing) and electronic laboratory test results – and the arrival of Health Information Exchanges (HIEs) or “highways” to share data within regions, has potential to turbo-charge patient recruitment by introducing the most comprehensive health records database available. With it, clinical researchers could finally move closer to patient recruitment nirvana.

Most interesting is the creation of a Nationwide Health Information Network (NHIN) led by the U.S. Department of Health and Human Services. This so-called “network of networks” proposes to link regional HIEs to create a master exchange of health data. Similar programs are under way in the United Kingdom, France, Singapore and Austria, promising a country-wide health records system that covers the entire health care continuum and populace.

Interconnected health data could finally provide clinical researchers with a comprehensive view of the patient universe. Armed with a robust understanding of the patient population, clinical researchers could streamline many aspects of the patient recruitment process, including trial feasibility, protocol design, site selection and patient referral. Very futuristically, such data could even reduce the number of trials and patients required to test new medicines.

Quintiles recognizes the extraordinary opportunity that electronic health data and interconnected records systems hold for patient recruitment. We are working with government agencies and leading technology vendors to seize the opportunity at hand for clinical research (see sidebar: “Piloting Patient Recruitment via Health Records”). Quintiles is also at the forefront of health care reform, working with regulators and industry associations to encourage the responsible use of health data for clinical research, and set global standards for information sharing. But there are still obstacles that stand in the way. Clinical researchers are unable to fully leverage the power of today’s health records systems due to technology limitations; regulatory hurdles; ethical considerations; and industry reluctance to a new approach. Furthermore, electronic health records must become widely adopted by providers, and widely embraced by patients, in order to be useful for clinical research. Fortunately, many of these challenges are already being addressed by key stakeholders.

Collaboration on the Path to an Optimal State of Patient Recruitment

With the continued growth of electronic health data, and plans for interconnected health records systems under way, possibilities could dramatically expand for clinical research. Data-driven patient recruitment is the way of the future, and is already being pioneered by progressive companies like Quintiles. We as an industry must encourage the continued use of health data to advance patient recruitment and serve tomorrow’s patients. We must be good stewards of personal health data, working closely with regulators and patients to establish policies and guidelines that protect the security and confidentiality of personal health information at all times.

We must also work with technology providers to realize the full potential of data-driven patient recruitment. A health information highway is on the horizon, but will require the support and collaboration of the biopharmaceutical industry, government, technology providers, payers and health care providers to determine how to best use it to advance clinical research. Patients also...
All parties who have a vested interest in the journey to the New Health must come to the realization that sharing health data is better for everyone, and could eventually lead to the promise of healthier humans.

After coding an appropriate query, Quintiles ran it in the database. The query quickly produced a list of over 150 “potentially eligible” patients, which was sent directly to the two study sites. A study coordinator at each site then conducted a full chart review of the “potentially eligible” candidates to confirm eligibility. Upon full chart review, only six of those identified by the query were in fact eligible, and of those six, one was interested and enrolled in the trial.

The pilot program identified several areas for improvement. First, Quintiles helped the EHR vendor realize that its querying capabilities must be improved to better navigate the patient database. Next, the vendor’s health records must contain more fields to make them useful for clinical research. Finally, and most importantly, Quintiles determined that the patient recruitment strategy must lead with using the EHR system to identify eligible patients. Once patients are identified, research sites should be engaged based on patient populations, not vice versa.

Quintiles is currently evaluating a next generation pilot program, taking into account key lessons learned and challenges identified.
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Christopher Cabell
Senior Vice President of Global Access to Patients at Quintiles

Christopher Cabell, MD, MHS, FACC is the Senior Vice President of Global Access to Patients at Quintiles. In his current role, Dr. Cabell addresses the increasingly critical challenge of recruiting patients for clinical trials, and developing a more efficient site infrastructure.

Prior to joining Quintiles, Dr. Cabell was on faculty at Duke University School of Medicine and the Duke Clinical Research Institute in Durham, N.C., where he was director of the echocardiography core lab, associate director of the ECG core laboratory, co-chair of the cardiac safety research consortium and director of the international collaboration on endocarditic.

Dr. Cabell is an honors graduate of Pennsylvania State University and the Duke University School of Medicine. He completed his internship and residency in internal medicine at Duke as well as a chief residency year. He completed a fellowship in cardiology at Duke and a master’s in health sciences. He is board certified in both internal medicine and cardiovascular diseases.

Dr. Cabell has over 75 original articles, reviews, editorials, book chapters and electronic publications. He has received numerous awards and recognition including the Greenfield Scholar in Cardiology Award, induction into the Four School Physician/Scientist Training Program, and was a Howard Hughes Medical Student Research Training Fellow. In addition, Dr. Cabell helped to found the Cardiac Safety Research Consortium, which is a public-private partnership between academia, FDA and industry expressly designed to answer pragmatic questions regarding cardiac safety and therapeutic drug development.
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