Transforming clinical trials

Bringing life-changing drugs to people faster, at less cost

It's an exciting time in medicine. As our understanding of the causes and complexities of disease has grown, so too have the approaches to treating them. Thanks, in part, to medications developed in recent years, we've seen a dramatic decrease in overall mortality from common health problems such as heart disease and cancer.[1,2] Drug advances have even drastically changed the prognosis for people with less common conditions, such as HIV/AIDS, which once had no effective treatments.[3]

The future may be even brighter. There are close to 7,000 new medications in development worldwide, most of which could be first-in-class treatments.[4] These drugs hold the potential to cure diseases, improve quality of life and lower economic costs by reducing the need for medical care and hospitalizations and improving personal productivity. Research has estimated, for example, that a new type of medication for migraines could save $396 billion over 10 years by reducing the number of migraines people experience, helping them continue to raise a family, work and remain productive without disruption.[5]

With benefits like these, it's clear that getting new drugs to market as quickly as possible is a priority. Data and analytics can help make it happen. Recent advances in artificial intelligence-enabled analytics and technologies create the foundation of breakthrough drugs.

~7,000

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Drug development: The trials of clinical trials

It's often reported that it takes 10 to 15 years for a newly discovered drug to enter the marketplace — the true number may be closer to 30 years.[6] The average cost is $2.7 billion.[7] Clinical trials and the time to recruit qualified patients are behind most of that expense.

Clinical trials typically proceed in four phases:

Phase I
Phase I trials focus on testing a new drug on people for the first time to learn about safety and side effects. They usually involve fewer than 100 people and are often completed in less than one year.

Phase II
Phase II trials typically involve up to several hundred people. They look at safety and efficacy and are generally completed in several months to two years.

Phase III
Phase III trials provide more statistically valid information regarding safety and efficacy because they include several hundred to 3,000 participants and may last several years. Their larger, longer nature provides more insight into long-term effectiveness and makes these trials more likely to identify rare problems associated with the drug. Phase III trials may compare a new treatment to existing therapies, when available.

Phase IV
Phase IV trials track information about the drug or treatment after it's been approved by the Food and Drug Administration (FDA) and is available for general use.

A new medication must successfully complete each phase before advancing to the next. Unfortunately, nine of every 10 drugs in clinical trials fail.[8]

Recruitment at each phase poses a challenge

Locating and enrolling people to participate can often be challenging, especially if the study involves an uncommon medical condition. Investigators must frequently double the enrollment period to reach recruitment targets, and sometimes, they never do meet their goals. One study found that nearly one-fifth of cancer-related clinical trials failed because they didn't recruit enough participants.[9]

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Average time for a new drug to enter the marketplace — the true number may be closer to 30 years[6]

$2,700,000,000
Average cost to go to market, primarily spent on clinical trials and the time to recruit qualified patients

Barriers to recruitment may include:

The **extensive number of clinical trials** that exist

Lack of recommendation from providers

Potential time burdens for participants

Lack of desire to participate if other previously approved treatments are available

Costs associated with finding participants[10]

Issues may also arise after participants enroll. One study found trial outcomes were missing from almost 90% of reviewed clinical trials.[11] Participants who fail to adhere to study protocols or who drop out are among the biggest problems.[12] Recruiting additional study participants may be necessary in order to collect complete, accurate data.

Tackling the cost and time of conducting clinical trials

Optum has developed a process for identifying and contacting those who qualify and alerting them to the trial's existence. It streamlines the recruitment and enrollment process and, just as importantly, offers hope to people who previously had no treatment options — and may not have otherwise heard of the trial.

The Optum Digital Research Network (DRN) is an example of a new way pharmaceutical companies recruit patients and conduct clinical trials. Working with preapproved site partners, the DRN captures research-ready patients by prescreening for eligibility through 91 million unique electronic health records.

People who meet a trial's inclusion and exclusion criteria are identified using a variety of data including ICD-10 codes, pharmacy claims, lab tests and other data tools as screening filters. This means what could take years to do manually in some cases, could potentially be accomplished in weeks. Faster enrollment translates into trials being conducted faster. This can reduce development costs and/or time to market for successfully tested products by 20% to 30%.

91 million

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Using data and analytics to address barriers

Time to market and recruitment come at a high cost. And while we should not cut trials where efficacy and quality are primary objectives, advancements in available data and technology offer hope to improve some challenging areas in the process.

Apellis Pharmaceuticals, a biotech company, illustrates how DRN is being used to help in the development of a first-ever treatment for geographic atrophy (GA). GA is a form of late-stage, age-related macular degeneration (AMD), a progressive eye disorder that leads to vision loss. According to the BrightFocus Foundation, there are no proven ways to prevent or slow down the progression of AMD.

Apellis explored new ways to recruit for their phase III trial. On their own, it was difficult to find people with GA to take part in their phase II trial. With Optum DRN, Apellis was able to identify and locate potential trial participants. Using data and analytics, the DRN searched health care claims and electronic health record data, working with physicians. Potential participants were identified for the larger phase III trials in a fraction of the time it would have otherwise taken.

Advanced analytics and technology create additional benefits

Improve study design

The benefits of advanced analytics extend beyond clinical trial enrollment, creating additional opportunities to cut down on time and costs. By identifying potential trial participants through registries, it becomes possible to determine the feasibility of a proposed trial and design it around people who meet established protocols, rather than first designing the study and then looking for participants.

Follow trial participants through the study's completion

Medical and pharmacy claims data, as well as data available through implantable and wearable devices, makes it possible to better track individuals through their real-world medical care. This leads to a better understanding of disease progression and how people respond to experimental treatments.

Build the case for prescribing and reimbursement

The ability to gather off-protocol data on participants before and after FDA approval helps drug developers demonstrate to doctors why they should consider prescribing new drugs to help improve quality of life. This helps health plans see value in new medications.

Lead to further medical advances

Saving time and expense on one trial allows pharmaceutical companies to more quickly shift focus to additional products and projects that could improve quality of life or help save lives for other conditions and illnesses.

Looking to the future

The Apellis trial is ongoing, but already the company is recognizing how data and analytics are helping transform the drug development process to one that contains costs and responsibly brings new drugs to market faster. While this is important, there are additional benefits that can be seen that also deliver high value, such as having a better understanding about the disease progression and improving the design of a clinical study so that people struggling with diseases are given more hope for the future.

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