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Electronic Health Data Holds Potential to Hasten NDRs

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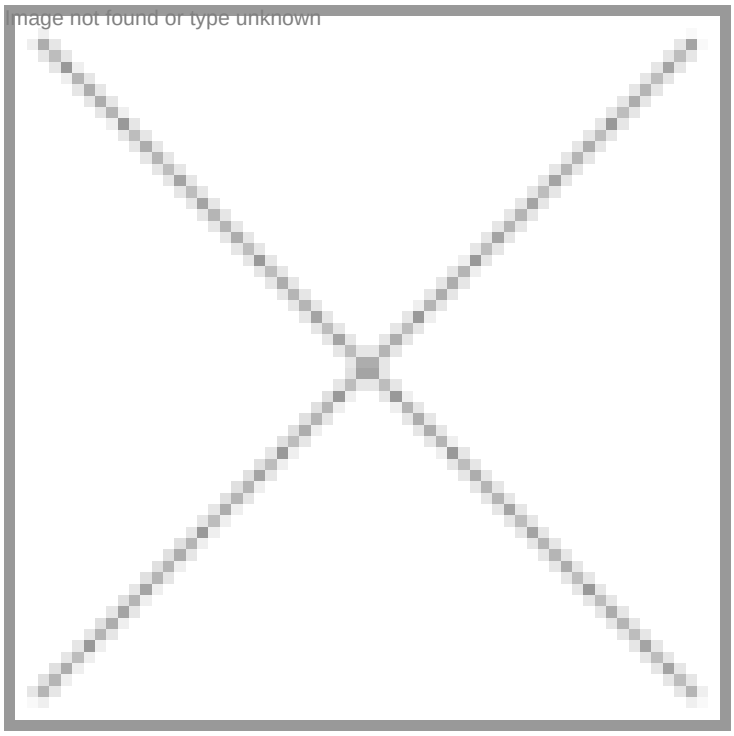

Electronic Health Data Holds Potential to Hasten NDRs

EMR can help pharmaceutical companies reduce research costs and accelerate time to market for new drugs.

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Electronic Medical Records (EMR), software that allows the creation, storage, editing and retrieval of a patient's data on a computer, and to a lesser extent Electronic/Personal Health Records (EHR/PHR) have been making strides around the world. Many hospitals or hospital clusters have to some extent either implemented EMRs or are in the process of doing so. Many countries around the region are also looking at putting in place the infrastructure that would support EHR/PHR as well. Countries like Singapore, Australia, Taiwan, Malaysia and Hong Kong have made significant progress in both these areas and there will be more to come.

As exciting, but often less reported, however, are the potential benefits such initiatives can deliver to the life sciences and biomedical industry. There are significant crossover benefits that take aim at some of the industry's most vexing challenges- more effective and efficient identification and recruitment of clinical trial participants and the ability to simultaneously capture clinical trial data from the electronic health record to decrease the costs of clinical trials, resulting in faster time-to-market for new drugs.

Wanted faster, more cost-effective clinical trial recruitment

With the average cost of developing a new prescription drug creeping toward US$1 billion and the process often spanning more than a decade, pharmaceutical manufacturers are continually searching for ways to extend efficiencies at all stages of the development continuum, allowing them to bring safe products to market faster and at a lower cost.

Clinical trials, which average $124 million per drug candidate after accounting for drug failure rates (Di Masi, JA, Hansen, R.W., Grabowski, H.G. "The Price of Innovation: New Estimates of Drug Development Costs," Journal of Health Economics, 2003) and whose costs are rising faster than pre-clinical research and development activities-are a prime target for scrutiny. Rising clinical trial costs can be attributed to several factors, including new challenges related to trial candidate identification and recruitment.

Clinical trial patient recruitment is also an increasingly time-consuming process. One study, which looked at 4,000 clinical trials over five years, discovered that nearly half of the time spent on the trial process involved patient, site and investigator recruitment. On average, difficulties in patient enrollment delay 81 percent of all clinical trials from one to six months, costing pharmaceutical companies as much as $8 million each day. This figure does not take into account the human costs of such delays in terms of the inevitable morbidity and mortality when promising new drugs are delayed in reaching the market.

Connecting EMR and clinical trials

Today, initiatives at individual investigation sites in the United States, Europe and Asia are revealing glimpses into the potential of patient's EMR data to transform clinical trial recruitment.

This will require biomedical and life sciences to work together in terms of information exchange. The pharmaceutical company will provide physicians, in both the public and the private sector, with information on the clinical trials currently being conducted, as well as the selection criteria for the trials. The physicians, on the other hand, could reference a patient's EMR during a routine examination to determine if the patient meets eligibility requirement for a particular clinical trial based on the record and the trial requirements. If a patient matches the criteria for any study, the physician could immediately collect the additional information required for the trial from the patient, record the data in the EMR and send an electronic notification to the relevant party. At that point, screening for the trial is completed--within a matter of minutes.

By combining electronic health records with data mining tools, pharmaceutical companies can also have the potential to quickly query the EMR database to determine the number of potential candidates for a specific study and to assess the viability of candidates for a specific trial. They can also potentially and quickly screen large numbers of anonymized electronic records for potential trial candidates using any number of factors, including age, sex, co-morbidities, lab results etc.In this way, pharmaceutical companies could efficiently approach physician groups that they know treat significant numbers of patients matching a specific trial candidate profile. This method could be particularly useful when recruiting for trials for drugs intended to treat rare conditions, as the trial sponsor from the pharmaceutical or biomedical company could efficiently search for specific criteria. The end result could be faster and more cost-effective trial participant identification and recruitment-ultimately accelerating time-to-market.

While the approach outlined above would enable more effective targeting of physician practices that treat viable candidates, another approach being advanced would take information on clinical trials directly to the potential candidates. It would involve the creation of a patient opt-in mechanism, in which individuals would grant permission to have life sciences organizations access their health information via the EMR and when launching a clinical trial, to contact them directly. This approach could go a long way toward empowering patients to take charge of key health decisions, as well as streamlining the participant recruitment process. To optimize the success of this approach, physicians would also need to be notified, in tandem, when trial sponsor contacts their patients.

Once a patient is enrolled in a trial, researchers could then incorporate data captured from a specific study as part of the EMR and routine clinical care by physicians. Automating these processes can help accelerate clinical trials by streamlining patient enrollment and documentation. If all the relevant trial and medical information is available to the doctor in the form of EMR, the physicians are able to make accurate and correct diagnosis 80% of the time.

Electronic records, an imperative need to overcome hurdles

The conversion from paper records to electronic records in the healthcare system will be a complex one. Issues such as data privacy, data protection, regulation and audit have to be addressed. Having said that, the healthcare and life sciences industries are optimistic about the potential of electronic health data to transform the delivery of healthcare as well as the

drug development process, including spurring advances in the quest for personalized and translational treatments and therapies. The critical technology components needed to enable meaningful exchange of information between the healthcare and life sciences industry exist today-as do the data mining and analytical tools needed to interpret data and drive incisive action. By combining these core technologies with proper planning and vision, electronic health records offer one of the brightest hopes for the future of the healthcare and life sciences industries and their quest to save and enhance the quality of lives.

The views expressed herein are the personal views of the authors and do not necessarily represent the views of the company they represent or any of its member firms.