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# Leveraging Patient Health Data to Drive Clinical Trial Feasibility and Recruitment Improvements

By Ann Dokus

It has been nearly ten years since President Barack Obama signed the American Recovery and Reinvestment Act (ARRA) into law. Though the belief that computing power could significantly enhance the delivery of medical care had been widely held since the 1970's, it wasn't until the ARRA helped fund the purchase of Electronic Health Records (EHR) systems that provider adoption finally moved from pure early adopter territory into mainstream clinical practice.

The digital data that has amassed over the last decade is significant; the potential of said data to radically re-engineer front-end clinical trial processes around participant engagement is nearly limitless. It is widely reported that today, 90% of physician group practices have implemented an EHR system, replacing cabinets of paper charts with cloud-based storage of data that is scalable, portable and easily accessible.

Though the adoption curve of technology within the clinical research space is expanding, paper-based and manual processes still play a major role in the execution of trials. Fortunately for all stakeholders, this is all about to change thanks to progressive medical practitioners that now understand the value of the clinical data they have collected: the massive digital repositories that for many years were viewed as administrative in nature and overlooked for the applicability to accelerate clinical research.

## Seamless Patient Identification and Recruitment

The vast majority of research protocols are complex in design, yet core eligibility criteria are typically based on patient factors well documented in every certified EHR system. Patient problem lists, medication and procedural history, lab values, demographics and increasingly genetic data all form the basis of whether a patient is appropriate to enroll into a study. The pervasive challenge has been how to mine this data in an efficient manner since most native EHR reporting capabilities have tended to focus on reimbursement, logistic and quality issues.

However, as analytical and business intelligence platforms evolve to make the premise of 'big data' actionable, clinical research leaders now have tools that can be applied to EHR datasets to identify potential participants from large cohorts of diabetic patients down to a single patient with a rare disease.

## Near-time Data for Feasibility Due Diligence

The identification of patients for an open, IRB-approved study is only half the battle. With access to patient data sets, even those that have been completely de-identified

via the removal of any patient health information (PHI), researchers can ensure that the design of a study is feasible and that patients actually exist fitting the ideal profile. The benefit of EHR data in this realm is not trivial because downstream amendments and the activation of sites that ultimately under-perform hurt sponsors by way of protracted timelines and increased cost.

## The Source of Patient Truth

One of the greatest challenges for the widespread acceptance of EHR data and processing engines for the purposes of clinical trial matching is the fact that a good amount of data within a patient's record is currently unstructured. Even as natural language processing technologies evolve and interoperability standards improve, the EHR remains the strongest foundation to build from. Electronic prescriptions, medication reconciliation, imaging reports, orders, referrals and so forth all emanate from the hospital and/or clinic EHR. As such, clinical research entities are wise to continuously refine their digital health strategy with the goal of creating and augmenting a longitudinal patient record. What happened to a patient today or five years ago is of less value without the entire context just as a lab value cannot be completely understood without its reference range and more importantly, how the result fits within a historical trend.

And while its hard to argue with the desire for a fully informed patient record that is comprehensive and fully searchable – think about a holy grail where a patient's pharmacy, claims, clinical, behavioral and even wearable data come together – due to ongoing privacy concerns and pervasive data entry (human) errors, the realization of such a record is still years off. But the value of pure, structured EHR data for trial feasibility and recruitment efforts has been well established by countless medical journals and as such, is the best path forward until the ancillary data is made available and easily transmittable (not to mention can be appended to an existing patient profile with little margin for error).

## Achieving True Patient Centricity

With 200,000 plus active trials underway in the US, the need for effective, efficient identification has never been more evident. Interestingly, the majority of adults have never been asked to participate in a single trial. There are millions of patients receiving care at small practices that fit trial eligibility criteria from studies that range from interventional to more passive in nature. Yet because most small groups lack the resources, human and financial, to implement an investigational research capability, their patients are continuously overlooked.

But by applying the latest in de-identification standards to datasets in order to remove patient personal information, the remaining data suffices to surface what is an (essentially) anonymous patient record for evaluation against study criteria, communicated solely by patient's own provider. Under this model, the approach has created no additional overhead for the physician and has in fact opened a new line of communication between the patient and his/her provider, reinforcing a relationship that must be grounded in trust and the patient's steadfast belief that the caregiver has his/her best interests in mind. Moreover, if a patient has confidence that the office five miles from home with easy parking and a friendly staff can offer what the academic medical center 40 miles away and with a large ramp garage can offer, the independent group will improve its overall retention capabilities.

## How Do We Get There?

Every stakeholder – the doctor, patient, researcher, sponsor and technology vendor – has a role to play in successfully operationalizing the application of EHR data to clinical research as the first step in a long term digital health data strategy. So what can different parties do today to help drive this approach forward?

Taking the physician aspect into consideration, many opportunities exist to optimize EHR workflow and standardization. It is true that old habits die hard, but unless there is a focused approach on ensuring a standard approach to clinical documentation across a practice entity, the variability in diagnosis coding via ICD-10 can ultimately hurt if a patient fails to surface for a study. Now that ICD-10 is entering its third year of adoption, there have been improvements in coding and consistency (in part thanks to claims denials), but this really must be an ongoing quality program so that the US can reap the benefits of the headache that the transition brought to many.

Sponsors and CROs are at the core of the issue and must make every effort to set the expectation that

near-time EHR data be leveraged for a first-cut patient cohort. This can be executed in minutes and not hours or days. And with the IT resources and budgets at the sponsor's disposal, educating the greater public about privacy safeguards can help win over anxious patient and providers over in this era of breaches and ransomware. Our industry has a great opportunity to demonstrate a position of leadership in this area since so many other organizations allied to the field have suffered with security issues hurting overall patient/consumer confidence.

EHR vendors should be seeking to establish trusted partnerships with synergistic technology platforms that will leverage and extend the value of the data they have helped providers aggregate and store. As quality and billing requirements continue to evolve, and complexly so, finding complementary solutions that can make patient data actionable for research initiatives is a much better application of resources than trying to build a new analytics offering and for purposes that lie outside of traditional EHR core competencies.

It's the year 2017 and EHR systems are here to stay. But in the context of disruptive and yet highly adopted consumer applications – think Uber, Netflix, Amazon – we are a society that craves better, faster and less expensive ways of getting the things we want. So why should medical research be any different – except that when it comes to finding those who researchers think can be helped (and may indeed want the help), the terabytes of informative data that exist have yet to be fully maximized.

## About the Author

**Ann Dokus** is an executive leader with extensive experience in the pharmaceutical and medical device industries. She has held management positions at Pfizer Inc., Bausch & Lomb and Fisons Pharmaceuticals. Her broad expertise includes information technology, regulatory affairs, quality management, medical affairs, identity management and strategic operations. In her role as Chief Information & Compliance Officer at Patient iP, Ann is responsible for software development, deployment and integration, and oversees every facet of compliance.