The Clinical Research Access & Information Exchange (CRAIE) Initiative and the Registry of the Future

Paulo Moreira, Vice President, Global Clinical Operations – External Innovation at EMD Serono, Inc. and Initiative Lead for TransCelerate’s Clinical Research Awareness and Access & Information Exchange initiative and Roslyn F. Schneider, MD, MSc, Global Patient Affairs Lead at Pfizer, discuss new and exciting developments.

Patients are arguably the most important stakeholder in the clinical research system – without them clinical trials cannot occur. According to The Center for Information and Study on Clinical Research Participation (CISCRP), most patients (58%) aren’t fully aware of clinical trials. Thus, there is a critical need to create greater awareness and build an environment where physicians, patients, their care partners, and families know about clinical trials, have access to them and, once enrolled, have the information they need to remain engaged during and following the study.

“While there is a wealth of clinical trial information available, resources lack utility or ease for the uninformed patient. Existing platforms used to host information, such as clinical trial registries are often complex in readability and difficult to navigate,” noted Paulo Moreira. TransCelerate created the CRAIE Initiative to bridge the gap between available information about clinical trials and potential clinical trial participants. Further, this Initiative aims to facilitate a simpler, user-friendly information search for patients and guide government registries to provide patients with more meaningful clinical trial information.

Paulo goes on to share, “TransCelerate has also embarked on the Clinical Research Awareness (CRA) Initiative which is addressing a major educational need. If we’re able to increase clinical trial information awareness by as little as one percent amongst patients, that’s a big win. What makes this Initiative unique is that it not only focuses on general, public/patient awareness, but also awareness for health care professionals (HCPs). This is a critical component to the organization’s patient-centric initiatives; the combination of the CRA and CRAIE Initiatives have created an extremely comprehensive effort.”

“The problem is that there’s not much of a “next step” with other patient-focused initiatives: now that patients know about clinical trials, where do they go to obtain specific information? TransCelerate’s CRAIE Initiative is focused on creating that next step.”
One of the pragmatic solutions that TransCelerate is delivering as part of this Initiative is a proposal for those bodies that host and steer clinical trial registries to create what TransCelerate is calling the “Clinical Trial Registry of the Future.”

Roslyn F. Schneider states, “It’s been clear in listening to patients that when they look at registries such as Clinicaltrials.gov, they don’t view them as resources that serve patients. Instead, they see them as a mass of data that’s important, but at the same time impersonal and not as useful as it could be.”

Roslyn also discussed two recurring themes shared by patients:

- When entering personal information in a registry search query, the information received is either too much and overwhelming or disappointing from the lack of information relevant to them.
- Generally clinical trial sites are not as useful and easy to navigate as are other websites patients use in their everyday life and the bottom line is that patients may leave these registries feeling discouraged and without a path to help them consider participation in a clinical trial.

TransCelerate’s Clinical Trial Registry of the Future proposal lays the foundation to build a system that’s more connected and personal to the patient, physician or caregiver who’s searching for information. This proposal is based on a collection of input from focus groups which included patients, health care professionals, and research site professionals. The Registry of the Future proposal will soon be available on the TransCelerate website.

Commenting on the Registry of the Future proposal, Roslyn said, “Should key stakeholders align on the sequence of key registry improvement goals, this could allow for a methodical set of updates among publicly owned registries and help ensure that those who are key to implementation such as trial sponsors, are prepared to address the changes required to enable the future vision.”

**Key Ways that EHRs Might Positively Impact Clinical Research**

By Dalvir Gill Ph.D., CEO of TransCelerate

Electronic Health Records (EHRs) have significant potential for improving the way we conduct clinical trials. While many experts agree with this claim, the potential and application of this has yet to be fully realized.

EHRs, which were designed to support payers, providers and hospital systems, have proven to be quite valuable in the doctor’s office and hospital setting, adding important efficiencies in a space that was once inundated with paper and overflowing files. Clinical trials, too, have a history of paper-based inefficiencies. And the drug development world, much like the doctor’s office, is changing; we are re-examining historical practices through a digitized lens, we are searching for areas to innovate, modernize, improve. Leveraging EHRs, with their large repository of patient data that have yet to be tapped for research, could ultimately be an important part of this evolution in clinical research.

A few key ways that EHRs might positively impact clinical research include:

**Supporting trial feasibility and protocol optimization:**

Increasingly, access to insights derived from large and diverse data sets are critical to ensure a study is practical in design and that appropriate patients exist. EHR data today represent an important source for feasibility and optimization insights, as sponsors can access aggregated de-identified data that reflect eligibility criteria and other underlying patient population data. The successful use of EHR data for feasibility requires access to appropriate patient data that matches the study population and the geographies of a given protocol, along with an organization whose culture is supportive of data-driven decision making.

**Positively impacting clinical trial recruitment:**

Although a persistent challenge in clinical trials today, EHRs could help identify specific patients who may meet study criteria. Even where data may exist as unstructured free-text notes, natural language processing (NLP) technologies continue to mature allowing matches to occur even if the data is not tightly structured. The emerging use of artificial intelligence and cognitive computing will create even greater opportunities to match patients despite the density of free text notes. These technology improvements could create smarter EHRs, essential to elevating clinical research.

In fact, the EHR4CR project, which involved 35 academic and private partners and 11 hospital sites in France, continued on next page >
Germany, Poland, Switzerland and the United Kingdom, recently worked to develop a platform that can utilize de-identified data from hospital EHR systems, in full compliance with the ethical, regulatory and data protection policies and requirements of each participating country. EHR4CR reported that such a platform can significantly improve the efficiency of designing and conducting clinical trials, reducing time, costs and administrative burdens and enabling the participation of European hospitals in the more clinical trials.

The collection of patient data for prospective clinical trials:

This is perhaps the greatest use for EHRs in clinical research. While 21st Century Cures legislation charts pathways for the Food and Drug Administration (FDA) to support regulatory decision making based upon historical EHR data as real-world evidence (RWE), prospective trials will also benefit from electronic sourcing of study data (eSource). Last year, the FDA issued a notice expressing interest in demonstration projects to test the capability and evaluate performance of using an end-to-end EHR-to-Electronic Data Capture (EDC) single-point data capture approach signifying the importance and potential positive impact of data collection in clinical trials. It is considered that EHRs, with digital applications and monitoring tools, can help “improve reliability, quality, traceability, provenance and integrity of data from electronic source to regulatory submission,” as the FDA notice on EHRs states.

Sourcing electronic data for trials via EHRs may bring great efficiency for study conduct (including data management and monitoring), but the diversity of EHRs across the thousands of sites supporting trials around the world challenge the ability to consistently pull and map data for prospective trials. Data standard initiatives along with new platforms meant to work across different EHRs may create opportunities across this otherwise disconnected ecosystem.

To overcome current barriers to the effective use of EHRs in clinical research, TransCelerate has been partnering with Health Level 7 (HL7) International and other industry leaders. Through a series of co-sponsored eSource Advancement Roundtables, critical stakeholders are coming together to identify actionable tasks to overcome barriers to the effective use of EHRs. In addition to these roundtables, a series of public Connectathons are being held to develop use cases to motivate the clinical research community towards utilizing EHRs. Through these events, TransCelerate and its partners aim to enable the healthcare community to speak a common electronic language, which can help propel clinical research and ultimately benefit patients around the world.

Patients opting to contribute their personal health data to clinical research:

Meaningful use criteria contained with the Affordable Care Act and other legislation require that patients in the US can access their health data in the format in which it is acquired and maintained by their provider – if your doctor uses an EHR then you as a patient have a legal right to access your data electronically.

Multiple studies have found that over 90% of patients with access to their health data are willing to share that data to support research. With the launch of the Precision Medicine Initiative by the US National Institutes of Health, an expectation was set to enable over one million American to share their health data into a large cohort study. That Initiative brought together the country’s largest EHR vendors including Epic, Cerner, and Allscripts to work together to develop and pilot an application program interface (API) that will let patients share their health data for medical research in the “Sync for Science” Project. In addition, with clinical trials historically suffering from a lack of patient engagement in clinical trials, the API/Sync for Science program can get patients excited about clinical research as the industry moves to become more attuned to the needs of the patient. These programs contribute to the elimination of the silos that separate health data by EHR vendor and slow scientific progress. Activating EHRs in this collaborative manner and engaging patients to get involved can provide researchers with a mechanism to exchange data, and understand patient experiences with medical conditions, as well as clinical trial design. Ultimately, these advances will improve drug development inefficiencies, and deliver lifesaving drugs to patients faster.

Your Perspective

Your curiosity is important to us. In this section, we'll address questions from Academia, Sites, Technology Companies and CROs.

What's the latest around TransCelerate's work in pharmacovigilance?

The number of adverse events collected by biopharmaceutical companies and reported to regulatory authorities is increasing 10-20 percent per year. This increment in adverse events reporting is a result of several factors such as improved reporting measures and a massive proliferation in the identification of adverse events through patient support programs, social media, etc. However, the growth in volume of reports doesn’t equate to a faster signal detection or better protection of patients. Biopharmaceutical companies are still often uncertain on how they define these divergent data sources, and how they should be collected, processed and submitted to health authorities.

Typically, pharmacovigilance -- the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem -- has been viewed as a time-consuming challenge, burdened by ambiguity and misalignment on industry approaches for reporting to health authorities. Through our Patient Safety Initiatives we aim to introduce harmonization into a process historically marked by disparate efforts and opinions by introducing the following initiatives:

- Our Value of Safety Information Data Sources Initiative seeks to identify sources of safety information for single high value valid cases and develop a proposed method to streamline reporting of lower value cases. This hierarchy of values will be based on the evidence derived from the collective experience of drug companies and other stakeholders.
- Another one of our latest initiatives, Interpretation of Pharmacovigilance Regulations provides a framework and process to pool expertise for interacting with regulators when it comes to pharmacovigilance – with the aim of more efficiently and effectively meeting the intent of requirements that have in the past been considered ambiguous. The initiative hopes to proactively collaborate with health authorities to better align on this important component of protecting patient safety. The long-term benefits of having the industry to harmonize its interpretation of current global pharmacovigilance regulations and guidance, will influence better harmonization of pharmacovigilance regulations among global regulatory agencies.

How does TransCelerate work with the patient community?

We believe that patients are the single most significant stakeholder in the R&D ecosystem, so developing initiatives that focus on better engaging and informing the patient is of utmost importance. To enable deeper interaction with patients, and integrate their perspectives and needs into our work, we’ve been collaborating with Center for Information and Study on Clinical Research Participation (CISCRP), an organization dedicated to activating the public and patients as partners in the clinical research process.

Through our partnership with CISCRP, we’ve been able to actively integrate the valuable insights gleaned from patient advisory boards on a variety of critical clinical research areas:

- Improving patient experience by better informing patients about available clinical trial information
- Educating the public about clinical research and encouraging conversations about clinical trials between patients and their health care providers
- Creating a common approach for the electronic consenting of patients by using process efficiencies and incorporating an array of digital and multimedia elements that provide insight into patients’ understanding, increase regulatory compliance, and reduce quality risks
- Helping the industry progress on the journey to digitally supported, patient-centric clinical supply chains
- Facilitating and accelerating the industry’s progression towards effortless accessibility to innovative technologies that enhance patient experience and reduce patient burden in clinical trials

How do you become a TransCelerate Member Company?

Most recently, TransCelerate announced the addition of Novartis to the biopharmaceutical non-profit organization, growing the consortium to 19 biopharmaceutical companies. We’re excited to onboard Novartis as we feel this will further advance the adoption of tangible improvements that foster more efficient and accessible clinical research environments for key stakeholders. Our member companies, like Novartis, are at the forefront of improving drug development efficiency, and can both contribute to and benefit from the collaborative power of our industry-wide organization. To see if your organization qualifies for membership, check out our Meet the Members page and review the applications.

Have something you want to ask us? Submit it here! We will continue answering your questions in future newsletters.
TransCelerate leaders and Member Companies are invited to participate and present at many biopharmaceutical research industry conferences and meetings across the globe to provide a perspective on industry challenges and clinical trial issues. Take a peek at a few places we will be presenting this year. For detailed information on speaker presentations, visit the events page on the TransCelerate website.

15th Annual Clinical Trial Supply East Coast 2017
October 18, 2017
Princeton, NJ

Patient Summit Europe
October 19, 2017
London, England, UK

2017 AIChE Annual Meeting
October 29, 2017
Minneapolis, MN

2017 KoNECT International Conference
November 1, 2017
Seoul, SK

Eyeforpharma Patient Summit USA 2017
November 2, 2017
Philadelphia, PA

2017 CDISC International Interchange
November 13, 2017
Austin, TX

Partnering for Cures
November 14, 2017
San Francisco, CA

Partnerships on Clinical Trials Europe
November 28, 2017
Amsterdam, NL

Forbes Health Summit
November 29, 2017
New York, NY
Check Out Our Best Highlights from Q3 2017

@LillyTrials: Patient advisory boards + focus groups + crowdsourcing + technology = ways to include patients in research elil.ly/y7Ik via @transcelerate

@transcelerate: Learn how we’re working to facilitate optimal use of electronic data sources in research in our new position paper bit.ly/2vE1F2t

@transcelerate: Global Operations VP Janice Chang discusses why clinical trial info sharing is a driving force in the R&D industry. Read more: http://bit.ly/2u4FQo

@transcelerate: View our new @Storify for a recap of DIA2017 and the topics TransCelerate leaders covered: bit.ly/2uPWjAd

@transcelerate: #ICYMI our leader Ulo Palm discussed the importance of clinical trial data sharing among key stakeholders: http://bit.ly/2r1JcKk

@fastercures: @deacstephen recognizes @transcelerate as an example of an effective collaboration facilitator #FCWebinar

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