The eLabels Initiative and the Art of the Possible

Jodi Smith-Gick, Senior Advisor, Product Delivery and Supply – Eli Lilly and Company and Initiative Lead for TransCelerate’s eLabels Initiative.

Technology has become a mainstay in the world around us, vastly improving our lives in areas such as medical advancements, entertainment and information access. As technology evolves and continues to make everyday tasks easier and more efficient, it is important and reasonable to consider the use of technology in the clinical research space. This could not only facilitate productivity within the clinical research process, but also enhance patient understanding, safety and clinical outcomes.

TransCelerate is working to enable technological innovation through the eLabels Initiative which is helping clinical trial sponsors progress on the journey to digitally supported, patient-centric clinical supply chains. The main output is not an eLabeling system, specifications or a standard, but an eLabels proof of concept and an implementation toolkit to facilitate voluntary, modular adoption of eLabels and to assist in Health Authority engagement. The eLabels initiative seeks to assist organizations in alleviating common pain points with the current booklet labeling systems. According to Jodi Smith-Gick, Senior Advisor, Product Delivery and Supply – Eli Lilly and Company and Initiative Lead for TransCelerate’s eLabels Initiative, “Biopharmaceutical companies employ the use of printed booklet labels that maximize the limited quantity of clinical trial material that can be used across multiple countries. The booklet labels typically have a long lead time, are expensive, and surveys show that they are infrequently utilized by the patient.” Overall, the current approach increases timelines and costs for clinical research, which boosts the expense of developing new medicines and delays patients from receiving their clinical trial material.

The eLabels Initiative is assisting with the implementation of eLabels by providing a Design and Delivery Toolkit, and a collection of feedback from external stakeholders, including commentary from patients and sites. Jodi goes on to mention, “The work of the eLabels Initiative through the toolkit and the proof of concept show the ‘Art of the Possible,’ and could relieve booklet label-related issues by providing patient-centric features such as text size modification, language selection, search functionality and the ability to quickly receive updates if the label content changes (i.e. expiry..."
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date, dosage modification and recall information). The patient could also have access to all information they need to aid them in adhering to the clinical trial regime and recording their information.”

To deliver additional efficiencies, the eLabel can be used in conjunction with what is called a “universal label.” While not yet accepted by all Health Authorities, the universal label concept is a physical paper label that contains limited, language neutral information and pictograms. Content on the universal label would include key information related to safety and dispensing medical information as well as trial specific information. The combination of the universal label and the eLabel could minimize the need for booklets thereby reducing the cost of development and aiding in the delivery of clinical trial materials faster to patients. To gain more broad Health Authority acceptance for the universal label concept, TransCelerate is continuing Health Authority discussions and pilots are underway to gather empirical data.

Regardless of whether a universal label concept is adopted in the future, “There are no regulatory requirements precluding the use of an eLabel in conjunction with the current printed label,” noted Jodi Smith-Gick.

Commenting on what Health Authorities should take away from the eLabels Initiative Implementation Toolkit, Jodi states, “eLabels offer the ability to engage the patient actively with their health care provider and their clinical trial materials, which could lead to improved outcomes for the patient and study. In addition, this technology reduces the cost for development, enabling investment in other promising research to find cures or treatments and help additional patients.”

Industry Lens

Five Opportunities to Improve Communication & Information Exchange with Clinical Research Participants

By Roslyn F. Schneider, MD, MSc, Global Patient Affairs Lead, Pfizer

The patient experience is an important aspect of a clinical trial, and yet, it is frequently either undervalued or is not fully recognized. This can be seen throughout the clinical trial continuum, where patients – a term which for me includes the person with a diagnosis, as well as care partners and family members – oftentimes do not have access to, or cannot clearly identify, personally relevant and meaningful information about clinical research.

Currently, patients receive little information on what trials they are eligible for, how to facilitate enrollment and general inquiries, such as the typical trial experience and expectations. TransCelerate conducted a global survey of patients with the support of the Center for Information and Study on Clinical Research Participation (CISCRP), Clariness, CenterWatch, featured in “Improving Information Exchange with Clinical Trial Participants: A Proposal for Industry”. In that survey 94 percent of respondents felt it was “somewhat” to “very important” to be aware of trials conducted in their community; however, 79 percent were unaware of clinical trials recruiting for their condition of interest.

For people who move along the continuum and begin participation, information exchange is often limited to the informed consent process, sponsors’ trial websites, trial sponsor information submitted to patient advocacy groups, brochures/leaflets in clinical trial site settings and discussions with clinical trial site staff. Patients have cited a desire for more information during

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and after a trial. For example, 91 percent of participants have expressed the importance of receiving a study summary following participation, however, according to the 2017 CISCRP Perceptions & Insights Study: The Participation Experience, 53 percent of patients did not receive an update or summary after they finished their study.²

When evaluating current information exchange practices, the clinical trial community must understand that a patient’s experience does not start on their first day of trial participation and end upon trial completion. Rather, the moment when a person is diagnosed and first begins consulting with doctors and health care teams on a treatment plan is the first moment when a broad set of options may be considered. Early in those conversations are opportunities for clinical trial information exchange to begin. Further, researchers must consider participants’ needs throughout the duration of a trial and as they continue their healthcare journey beyond the trial. Patients who have accurate information about clinical trials at their disposal and who can speak about their experiences with others, can spread the message about the importance and potential benefits of clinical trials.

The clinical research community has an opportunity to enhance patient engagement, participation, retention and experience for participants and those involved in their care through a variety of communication methods.

1. Publicly accessible information about clinical research

81 percent of patients reported that it was important to know the potential risks and benefits of a specific study before considering participation.³ However, early in a journey, clinical trial information – active trials, benefits and risks, trial requirements and educational resources – can be difficult to find and decipher for both patients and their healthcare professionals (HCPs), which can be a barrier to participation.

It is essential that patients and HCPs have the tools to facilitate decision-making processes and answer potential questions either party might have. One method to help alleviate this issue is the development of improved public clinical trial registries including site contact information. This is critical in this day and age, as the TransCelerate survey published in “Improving Investigative Site Contact Options on Clinical Trial Registries: Making It Easier for Patients to Find Clinical Trials,” showed that 50 percent of potential clinical trial participants indicated they would find information on trials through a general internet search.⁴

To help facilitate these search efforts, TransCelerate, in consultation with patients, has developed a Clinical Trial Registry of the Future concept that highlights challenges patients and HCPs face when navigating the complex clinical research information available online through government-sponsored registries and proposes potential improvements to these registries.

2. Discussions with primary care providers and other members of the health care team

Studies have shown that patients are most likely to begin their clinical trial search by asking their primary care provider about trial options.⁵ Not only may patients first ask their HCPs about what trials are available, most (56 percent) expect to discuss the full breadth of participation with their HCP before contacting a clinical trial location.⁶

While trial participants expressed the expectation of discussing trial participation with their primary care provider, this expectation often was not met in practice. Clinical trial researchers should place an emphasis on ongoing discussions with HCPs around clinical trial awareness, participation and results, if applicable. In fact, following patient enrollment, HCPs have indicated that (1) determination of patient’s eligibility,
3. Multimedia informed consent

All communication methods between investigators, site staff and patients should be clear and easily digestible for potential participants. So, once a person has selected the clinical trial that may be right for him or her and the process of informed consent begins, investigators should consider channels that would help streamline consent processes such as multimedia informed consent.

Should the clinical research community transition to user-friendly, patient-focused multimedia components, patients and their care partners may feel more empowered to make more informed, better, shared decisions with their healthcare teams. Instead of only paper handouts about study visit procedures, invest in developing audio, video, pictures/diagrams, summary boxes, etc., to help patients better understand the purpose of the trial, the potential risks and the procedures they will be involved in. As technology evolves, so is the exploration of other multimedia components, such as virtual reality, to implement during the informed consent process.

Ultimately, multimedia informed consent will help in reducing complex and time-consuming explanations and paperwork, potentially improving patient adherence and recruitment, among others.

4. Updates on the status and progression of the overall trial and access to trial results after completion

Patients have reported a desire for greater transparency regarding data sharing. This disconnect between patients and sponsors is illustrated in the TransCelerate survey previously mentioned—81 percent of patients reported wanting their own test or lab results during the clinical trial, while 64 percent of sponsor respondents indicated that their companies do not share this information during a trial. Further, 79 percent of sponsor respondents said they do not share patient-level data even after a study is complete—compare that to the 83 percent of patients who want that information.

Information exchange should continue after the end of a person’s clinical trial journey, particularly around the sharing of general trial results. According to the same survey, 80 percent of participants want access to the general results of the clinical trial. How these results are communicated is a topic of other work within and outside of TransCelerate.

5. Invitation for participants to provide feedback on experience

The clinical trial community should aim to provide an inclusive environment, both while the patient is participating in the clinical trial and after they have completed participation. It’s crucial that patients are empowered to express their feedback on their experience and leverage that information to inform the design and logistics of future trials. TransCelerate and CISCRP have partnered to convene Patient Advisory Boards that help streamline two-way communication between sponsors and patients to gain feedback and help educate patients about clinical research; and we’ve seen other key stakeholders take a proactive step toward greater patient engagement.

The observations and opportunities noted do not minimize the great progress in the R&D industry. A well-informed, activated, and empowered patient community will complement that progress and benefit the clinical trial community and healthcare as a whole.
The procurement of comparator medicines required for use in clinical trials has historically posed a formidable challenge for supply chain professionals within biopharmaceutical research and development. The TransCelerate Comparator Network, a forum that facilitates access to comparator medicines and the exchange of related documentation between participating TransCelerate Member Companies, has been a game changer by increasing supply efficiency, enhancing process integrity and mitigating the risk to the continuity of clinical trials.

To learn more, we sat down with Erica Drew and Nish Chudasama on the Comparator Network Initiative.

Q: Erica, Could You Tell Us Why a Comparator Network is Needed in the industry?

A: The use of comparator medicines for clinical trials is challenging for biopharmaceutical companies both in terms of cost and availability. In research and development, it is necessary to assure supply of product in large quantities for clinical trials and eliminate the risk of using counterfeit drugs which could jeopardize patient safety and the integrity of the clinical trial data. This Network enables supply chain integrity by allowing the innovator and manufacturer to work directly with one another.

The Comparator Network allows membership to access documentation for comparator products that enables quick and efficient release of comparators for use in clinical trials. In addition, the Comparator Network helps foster collaborative relationships that move the industry clinical trial process along and deliver new medicines to patients faster.

Q: Nish, What Are the Benefits of the Comparator Network for TransCelerate Member Companies?

A: First, membership in the TransCelerate Comparator Network provides more direct access to comparator medicines in the US and EU, and access to other markets if the buying and selling Member Companies agree. When it comes to benefits for TransCelerate Member Companies, there are two perspectives to consider -- there’s a buying Member Company and then there’s a selling Member Company.

As Erica alluded to earlier, from the point of view of the buyer (or the innovator), the largest fundamental benefit is the ability to buy directly from the manufacturer of the product with no middlemen involved. By doing so, the buying Member Company significantly reduces, if not eliminates, the risk of the introduction of counterfeit drugs. By procuring product directly from the manufacturer, there’s an enhanced supply chain integrity leading to enhanced patient safety -- that’s the most fundamental benefit.

In addition, there’s flexibility in scheduling periodic purchases in smaller quantities and with desirable expiry. Through this approach, buying Member Companies can avoid stockpiling large quantities of expensive comparator medicines, leading to a reduced risk of medicines expiring, as well as obsolescence risk in case a clinical study is discontinued ahead of schedule. For the seller, there’s also a reduced risk of potential outages, especially in smaller or regional markets.

Of importance, through the Comparator Network, TransCelerate Member Companies have achieved an aggregate savings of roughly $20 million annually. There are multiple avenues that enable the buyer to realize savings. Firstly, buying directly from the manufacturer at wholesale pricing or equivalent means sourcing comparator medicines at a lower expense than alternate channels. Secondly, the ability to purchase in smaller quantities with desired expiry dates, leads to reduced inventory carrying costs, as well as reduced waste due to expiry and obsolescence. Additionally, access to allowable temperature excursion data enables the buyer to rescue product that has encountered acceptable temperature excursions, which would have otherwise been discarded due to lack of data. Critical to this process, avoiding drug loss due to potential temperature excursions has prevented delays in getting lifesaving products to patients who participate in clinical trials.

From the seller’s standpoint, the Network provides greater demand visibility and can help prevent inventories from suddenly being siphoned out, especially in smaller regional markets.

Q: Nish, Can You Describe How Comparator Network Members Request Comparators?

A: In the Network, buying companies can anonymously share forecasts with the selling member company, and once the selling member company receives that forecast, they’re able to review their inventory and confirm that they will be able to fulfill that forecast.

As a result, there is usually an assurance of supply for the manufacturer. There’s always that rare instance where a seller may not be able to supply the full quantity in the requested timeframe, but in most cases, sellers are able to deliver the desired product in the requested time and that leads to what is an assured supply.

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With this transformative approach, the buying company avoids the traditional supply chain model where the organization stockpiles safety stock for a product and run the risk of expiry, or if a study is discontinued, the buying company is left with unexpired product that it is unable to use. With the TransCelerate Comparator Network approach, the buying company purchases the appropriate quantities in a shorter period.

Q: Erica, Could You Describe the Comparator Network’s Evolution?

A: Starting in 2014 with just six TransCelerate Member Companies, the original intent for the Comparator Network was designed around buying and selling comparator products to one another. When the Network started to see signs of success (efficiencies created) in 2015, the TransCelerate membership proposed bulk exchanges, as well incorporating placebo products, to its model.

The benefit of bulk drug product exchanges is the ability to use repackaging formats that are easier to include in a clinical trial, such as bottles. The real benefit of being able to buy and sell placebos is the reduction of time and effort for a member company in not having to developing their own placebo for a commercial product for use in a clinical trial. Both benefit patients by reducing study start up times, and ensuring studies go forward.

As a result of this creative solution that has worked to simplify the supply chain and increase efficiency, boost resilience, enhance integrity and reduce operating costs, TransCelerate was presented the 2017 Supply Chain Innovation Award at CSCMP’s EDGE Conference for the Comparator Network approach.

To learn more about TransCelerate’s Comparator Network, visit our website at: http://www.transceleratebiopharmainc.com/initiatives/comparator-drugs/
What is TransCelerate doing to help move the industry forward in terms of eConsent?

TransCelerate’s eConsent Initiative seeks to create general awareness and enable broad, voluntary implementation of electronic informed consent (eConsent). The use of eConsent may help boost patients’ understanding of clinical trial study objectives and design, increase regulatory compliance and reduce quality risks. To empower patients to make more informed decisions, eConsent consists of various multimedia components which can be used to develop an interactive and engaging informed consent experience. Some of the tools and resources sponsors can implement during eConsent design include images, audio, video, diagrams, reports, call out boxes and a digital signature. A detailed list of these multimedia elements can be found on TransCelerate’s eConsent Assets Page.

To facilitate a more effective and efficient implementation of eConsent, TransCelerate developed the eConsent Implementation Guidance. This tool provides sponsors and other interested stakeholders with information about how to determine whether eConsent is a feasible approach, which eConsent multimedia components are a good fit for a specific study and the external and internal processes to consider when implementing. The Implementation Guidance allows for a more holistic adoption of health literacy approaches and alignment across platforms, thereby improving the quality of clinical trials and the patient experience.

Is there a difference between the CPT delivered by the FDA/NIH and TransCelerate?

TransCelerate’s Common Protocol Template (CPT) is a harmonized and streamlined approach to the format and content of clinical trial protocols. It’s designed to reduce complexity by making reporting and implementation easier for sponsors, sites, regulators and, most importantly, patients. The TransCelerate CPT was developed in alignment with the common protocol template launched by the US Food and Drug Administration (FDA) and National Institutes of Health (NIH). Although the two templates are similar, the FDA and NIH CPT was created with single-center NIH sponsored trials in mind. Comparatively, the TransCelerate CPT includes additional text to support global, multicenter trials and supports re-use of protocol level information for other clinical trial requirements, such as analysis plans and clinical trial registry posting. This collaborative effort has the potential to reduce confusion for stakeholders and allow benefits such as simplified start-up and execution as well as faster review time by global health authorities.

TransCelerate is excited to release its latest version of the CPT which incorporates stakeholder feedback to further improve the utility and sustainability of the template. The most recent updates include content changes, newly added libraries, enhancements for the Technology-Enabled Edition of the CPT and how TransCelerate is supporting disclosure data uploads into clinical trial registries. A high-level overview of the CPT changes and additions can be found on the CPT Assets Page.

What is TransCelerate’s presence globally?

With more than 1,000 colleagues from our Member Companies across 35+ countries working on TransCelerate Initiatives and councils, TransCelerate has a very broad global presence. To develop an even more impactful presence, TransCelerate has a Country Network of 22 countries, each led by 1-2 Member Company Country Leads who act as local ambassadors for TransCelerate within a particular country or region. Leads work to increase TransCelerate engagement and knowledge amongst the members in these locations through regular meetings called Country Meetings. These meetings offer a great avenue for TransCelerate Initiatives to introduce or share best practices of implementation to the local audience, while also giving local experts the opportunity to provide feedback back to the initiative. Furthermore, the Leads boost TransCelerate’s global presence through appearances at local conferences, meeting with local and regional industry stakeholders and identifying publication opportunities in trade journals.

TransCelerate’s global presence has also increased because of their engagement with Regulatory Authorities. To ensure that TransCelerate is aligned on the approach for engagement with each Regulatory Authority, TransCelerate established the Regulatory Council. Equipped with a robust understanding of the regulatory landscape and agency priorities, the Regulatory Council can align with the agencies on their priorities as well as match the priorities of the TransCelerate portfolio, expand and enrich current relationships and help identify regulatory barriers. As a result of their efforts, TransCelerate has engaged with 14 Regulatory Authorities around the globe and in 2018 will prioritize engagement with global Regulatory Authorities based on initiative-driven needs.
Check Out Our Top Hits from the last three months

@LillyTrials: Another great idea from the @transcelerate communications survey: Create a #clinicalresearch alumni community.  
http://ell.ly/c4dk

@transcelerate: TransCelerate leader @CraigLipset @ #SCRS17: “Site Advocacy Groups have been so important to TransCelerate. We have a lot of SAG-love”  

@transcelerate: Our #clinicaltrial #RegistryoftheFuture concept was designed with #patients, for #patients! Check out this video which demonstrates how searching for a clinical trial could be improved  
http://bit.ly/2ieTQiD

@MySCRS: The #ClinicalTrials Registry of the Future (ROTF) is designed to improve the #patientexperience, from @TransCelerate [2 min video]  
http://ow.ly/HjAb30qZfie

@CRO_Forum: @dave_muoio reports on @transcelerate’s mission to investigate how digital technology can improve #clinicaltrial efficiency for @MobiHealthNews. Get the full story here:  
http://bit.ly/2iB5WPG

@transcelerate: TransCelerate’s eConsent solutions! Click on the link below to explore various eConsent assets and learn what supporting tools and resources are available:  

@transcelerate: Our team hosted an #eSource Connectathon Challenge – click below for a recap of the exciting event & winning case!  
http://bit.ly/2yXq2oV

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