**The Latest**

**Streamlining Study Startup with Structured Information and Automation**

In the current clinical research environment, there is an average lag time of four months between protocol completion and trial start, largely due to the manual study start-up system. While transforming to a more automated drug development process will reduce cycle times and improve data quality for sponsors, several key barriers have made true automation difficult to achieve. For example, due to issues such as technical solutions that lack interoperability and the need for consistent, comprehensive and fully usable data standards, it’s been challenging to implement automation across the biopharmaceutical industry.

TransCelerate is working to address these roadblocks through the **Digital Data Flow (DDF) Initiative**. The DDF concept was spurred by the Common Protocol Template (CPT) team who completed a proof-of-concept project whereby the results concluded that the biopharmaceutical industry has the building blocks necessary to enable end to end automation but currently lacks a common data model to enable true digital data flow while permitting different disconnected systems to “talk to one another.” Hence, TransCelerate launched the DDF Initiative to address this gap.

To learn the latest on TransCelerate’s efforts to streamline study start-up, we spoke with Co-Leaders of the Digital Data Flow Initiative, Bill Illis (Novartis) and Heidi Goldstein (J&J), about the value that structured information and automation will bring to clinical research and what it will take to get there.

The DDF Initiative aims to deliver an appropriate framework to enable the kind of automation that other industry sectors have achieved by focusing on study procedures and data elements that are routinely collected with a very high frequency. According to Bill, clinical data standards, developed by CDISC, are the foundational elements for building various pieces of the DDF solution. In fact, using existing and/or working with standards-setting bodies to establish new standards is a core component of a common data model.

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which Bill notes is a necessary, although not completely sufficient, component to implement what is needed in the digital data flow concept. It interprets moving data from a source to a target, thereby allowing us to build out a digital stream.

When it comes to value, Heidi says, “The common data model framework should help the industry move forward with automation, and ‘pull through’ all applicable documents and data sets, moving forward thus reducing study start up time, improving data quality and decreasing costs.”

Bill agreed, adding that a common data model would benefit investigator sites, patients, health authorities, software vendors and all stakeholders involved in study start-up activities by helping them review protocols, set up the study database and/or initiate sites.

In the case of the DDF Initiative, it’s proven difficult to develop an industry-wide solution due to the many different individual requirements of the relevant stakeholders.

However, Bill believes that TransCelerate provides the framework in which multiple companies can come together and collaborate with each other and other key stakeholders on initiatives like DDF. He says, “The reality is, it would be very difficult to get this type of initiative started and resourced without a foundational organization like TransCelerate to facilitate the process.”

The DDF Initiative is unique in the sense that it’s trying to help industry create solutions that brings value to all stakeholders in the clinical trial space. It reflects how close we are as an industry to moving from using a highly manual, document-based approach to study design, study planning and data collection, to one that relies on current and, ultimately, future technology for the purposes of realizing both efficiency and improving quality.

As the initiative continues to mature, the goal is to establish key stakeholder partnerships to create a neutral, agnostic, open-source framework that can be used across different biopharmaceutical companies and other stakeholders to achieve efficiencies across the industry.

Bill highlights, “While there are plenty of challenges and work ahead of us, we’re looking forward to creating something that’s never existed before.”

Adverse Event Reporting: Do Social Media Sources Matter?

By Jeremy Jokinen, PhD, MS, PSTAT, Senior Director, Pharmacovigilance and Patient Safety, AbbVie and Co-Leader of TransCelerate’s Advancing Safety Analytics & Value of Safety Information Data Sources Initiatives

The FDA Adverse Event Reporting System, or FAERS, a database of adverse event testimonials, medication error reports and product quality complaints (which resulted in adverse events), acknowledged 1.63 million adverse event reports from individual patients and health care providers in 2018.

An adverse event, or AE, is defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not it’s considered drug related. Official reports of these AEs, range in severity from life-threatening and severe to suspected and even unsuspected reactions to drug usage. The volume of spontaneous AE reporting data has increased 10-20 percent annually for the last five years thanks in part to the work of patient advocacy groups, patient support programs, online forums and discussion boards, and social media platforms like Facebook and Twitter that collect first-person reflections from patients about their experiences.

These newer information sources, coupled with traditional sources of safety data, have compounded the complexity of monitoring and reporting for regulatory authorities and ensuring the public health for those taking medicines globally.

Social Media as a Valued Safety Source?

Social media, as a tool for information gathering, has a complicated history. A decade ago, it was heralded as a resource with exponential growth capabilities that could one day eclipse all other AE reporting and monitoring services. Now, it’s maligned by some as inefficient in its ability to capture accurate data and therefore, a fundamentally unreliable information source.

In truth, social media is most helpful as a secondary source for specific safety issues, such as misuse or abuse, reports of which may be found on publicly available social media sites. However, it is not on par, let alone a substitute, for spontaneous (voluntary) reporting from patients and healthcare providers.

To learn more, visit our Digital Data Flow Initiative website.
Industry Lens

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providers. TransCelerate’s research ultimately concluded that despite the abundance of data, social media is not as valuable a source for obtaining data that will lead to a safety signal detection. Furthermore, the data from social sources should be reported to regulatory bodies more efficiently through aggregate reporting.

Progression of AE Capture, Analysis and Reporting

There is a lesson to be learned from the progression of perceived usefulness of social media data. For all sources of safety data, it would be incredibly valuable to understand the specific questions which types of data: spontaneous, patient support program, market research, and social media, may address.

Historically, regulators required that all captured safety data, regardless of the origin of the data point be gathered into industry and regulatory safety databases. Today, regulators and industry pharmacovigilance experts desire to reliably classify the various sources of safety data, social media included. This classification would enable regulators and industry safety experts to apply their limited resources to the right data to address the right questions. This is precisely the goal of research conducted by TransCelerate’s the Value of Safety Information Data Sources Initiative.

Given that pharmacovigilance is a critical function of the research and development process, there’s an opportunity for the pharma industry to identify and assign a weighted value to data sources that are valuable for safety surveillance. The development of this hierarchy together with continued engagement with health authorities may help to ensure a more accurate reporting and analysis of AEs and improved detection of safety signals.

Turning the Tide

The integration of technology, like artificial intelligence, augmented intelligence, and automation, provide an opportunity to further evolve AE reporting procedures and outputs. Specifically, it could improve efficiencies with processing a mass of information, but also allow companies to look more carefully at information sources being brought together through large cloud-based databases.

In order to collect, process, segment and record the copious amounts of information and cases made available, including social media, TransCelerate has established an Intelligent Automation Opportunities in Pharmacovigilance Initiative which lays the groundwork for how the industry might leverage technological advancements to assist their data gathering efforts.

With time, it will be technologically possible to analyze different data sources via a new meta-analytical layer that will appropriately link the value of these data sources simultaneously offering an unprecedented synergy and unburdening for key research and development stakeholders.
Biopharmaceutical companies are continuously challenged with the need for patients to want to participate in clinical trials: over 58 million patients are needed to fulfill and participate in studies on clinicaltrials.gov. Considering medicine can’t progress without clinical trials and without clinical trials, we can’t advance medicine; we seem to be left in a never-ending conundrum.

The 2015 CISCRP Perceptions & Insights Study indicated 80 percent of respondents would be willing to participate in a clinical trial. Additionally, if the respondent suffered from a health condition, their willingness to participate in a trial jumped somewhere between 93 to 96 percent, depending on the severity of their disease.

In this edition of Accelerate to Innovate, Christine discusses the recent headway the initiative has made since its launch in 2017.

Q: What were the challenges, inconsistencies and pain points that led to the development and/or ideation of this initiative?

A: The main challenge was sharing information on current clinical trials effectively. With the growing need for patients to enroll in clinical trials, we [the TransCelerate CRA&IE], commissioned a global survey that included over 3,000 patients across 36 countries; prompting participants to respond to one question: Why not?

The collective feedback informed us that respondents often use digital means to receive information about clinical trials. When asked about the type of online registries, respondents listed their most trusted source of clinical trial information as their government-owned registry; registries that place members of the scientific community as the end-audience and included scientific jargon and medical terminology within inclusion and exclusion criteria fields. Needless to say, the average person does not easily understand the information currently provided. This illustrated a fundamental lack of awareness among potential patients, preventing them from making an informed decision.

Patients also revealed, through focus groups, that a simple thank you would make them feel appreciated and more likely to participate and/or refer others to participate in future studies. As such, we’ve designed the TransCelerate CRA&IE Information Exchange templates to improve patient and site relations, along with a more satisfying clinical trial experience.

Since patient deficits in clinical trials ultimately serve as roadblocks to the delivery of new and innovative drugs or therapies and, the quality of life and outcomes of patients suffering from illnesses, our Initiative looks to build upon the current state of affairs/perception of clinical trials.

Q: Where does this Initiative deliver the most benefits? Is the highest impact on the industry or for patients?

A: The Initiative is patient-centric and aims to empower patients, and the public, with critical pieces of information because not only are patients searching for trials, but their caregivers and physicians are as well. Increased awareness inspires patients.

For example, a patient recently attended one of our patient advisory board meetings and expressed her interest in participating in a clinical trial but lived in an area where there were none accessible to her. She went on to share with us that being aware of studies focusing on her disease state and the thought of a potential cure gave her hope – even though the studies were not easily accessible to her.

So, while the patient has been placed at the center of our work, the value of this Initiative is twofold: 1.) Increased awareness of clinical trials among the general public cascade into participation and 2.) More patient participation results in more executed trials that could bring about new and quality medicines faster.

Q: What makes this Initiative unique compared to other patient-focused initiatives within TransCelerate or across the industry?

A: This effort is rooted in the essence of TransCelerate’s mission to improve upon the clinical trial process, and while all of the initiatives work together to produce a better and more efficient experience for those participating, our initiative hones in on one of the most critical steps at the beginning of the clinical trial process. A large piece of the puzzle surrounds reframing the connotations associated with clinical trials and helping patients get the information they need to make informed decisions.

Imagine designing and building a beautiful restaurant at the perfect location, but no one knows about it or can find it. We’ve taken a huge leap with an effort that will significantly move the needle with government agencies through the Registry of the Future concept and proposal which calls for the delivery of relevant and applicable information that is patient-centric and easily digestible; and that’s our differentiator.

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it, how successful will that restaurant be? It is the same case for clinical trials, if a clinical researcher writes the best clinical trial design and sets up a clinical site in an area where patients are suffering from the disease under investigation, but no one knows the trial is taking place or the location of that site, how successful will that clinical trial be?

We’ve taken a huge leap with an effort that will significantly move the needle with government agencies through the Registry of the Future concept and proposal which calls for the delivery of relevant and applicable information that is patient-centric and easily digestible; and that’s our differentiator.

Q: What progress has the Initiative seen thus far?
A: We’ve done our due diligence. We’ve consistently met with our patient advisory boards and conducted many patient focus groups to develop the Clinical Trial Registry of the Future Concept and Proposal as well as marketed the concept through the development of an e-book and concept videos to communicate our vision to government registries.

More recently, we’ve opened discussions with the National Institutes of Health (NIH) as our primary stakeholder – sharing our patient feedback, assets and implementation goals. Our conversations center around the potential implementation of the Registry of the Future design and the specific areas that could draw the most benefits. Our next step for the Initiative is to focus on how the industry can ensure the quality of the information being shared with patients through registries is effective and reliable.

To learn more about TransCelerate’s Clinical Research Access and Information Exchange Initiative, visit our website at: http://www.transceleratebiopharmainc.com/initiatives/clinical-research-access-information-exchange/

Mark Your Calendars

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.

SCOPE Summit
February 18 – 21, 2019
Orlando, FL

Clinical Trials Congress
March 4 – 5, 2019
San Diego, CA

Patients as Partners Europe
January 28 – 29, 2019
London, UK

Global Oncology Site Solutions Summit
February 2 – 3, 2019
Austin, TX

DIA Europe
February 5 – 7, 2019
Vienna, Austria

Patients as Partners U.S.
March 11 – 12, 2019
Philadelphia, PA

European Site Solutions Summit
March 18 – 19, 2019
London, UK
Your Perspectives

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

TransCelerate has stated that the Shared Investigator Platform (SIP) creates and develops synergies with sites and sponsors. What are the benefits to sites, and what are the benefits to sponsors?

A: SIP users are experiencing tangible results in alleviating a shared burden while conducting trials: administrative tasks. SIP allows site investigators to dedicate more time to patient care, and sponsors the opportunity to seamlessly run feasibility surveys, access study documents and manage clinical trials through one platform, instead of many.

Rather than utilizing multiple, disparate processes and tools across studies within a company, sites can use the same processes and tools across participating sponsors’ trials. Sponsors can rely on SIP as the master source for user and facility profile information, potentially increasing quality within their company. APIs and integrations have been developed to allow sponsors to migrate their full portfolio of studies onto the platform, compounding the value and benefits realized.

The SIP integrates assets developed by the TransCelerate Site Qualification & Training (SQT) Team, including collection and capture of a single User & Facility Profile, which are then re-used to auto-generate CV templates and 1572s.

As training providers continue to submit GCP training that meets the TransCelerate minimum criteria for Mutual Recognition, the courses are available within SIP. So, sites can choose their training, upload their certificates onto the platform and sponsors can self-serve and retrieve as part of start-up activities. Due to the integration between SIP and the Investigator Registry (IR), a collaborative registry for site selection, consenting site investigators are now visible to participating sponsors for study opportunities.

SIP continues to evolve as a multi-tenant, multi-vendor platform to strengthen Sponsor-Site relationship globally. To learn more, check out our videos on the impact SIP has on sites and how SIP makes study management simpler.

What steps is TransCelerate making to address challenges with recruiting Data Monitoring Committee (DMC) members?

A: Considering the complexity of trial designs and the steady increase of clinical trials that are occurring, TransCelerate is working to develop and expand the DMC candidate pool by offering a solution that could democratize the recruitment process to more easily connect DMC candidates with critical resources.

To help improve communication between research professionals and DMC organizers, we are working closely with both candidates and organizers to build a searchable, centralized and publicly available online registry prototype.

Those interested in serving on or organizing a DMC could join the registry by creating an account and personal profile detailing their relevant skills, areas of interest and experience.

Within the registry, we’ve identified two concepts for those interested in learning more about DMCs: an apprenticeship model framework and a resource list. The apprenticeship model framework aims to connect individuals new to the DMC process with experienced members through a mentoring relationship. Potential apprentices and mentors can indicate interest by checking a box on their profiles. We encourage DMC organizers to include apprentice/mentor pairs on the DMCs they are convening. For those who prefer self-study, the registry could include a resource section on various topics available for perusal at any time.

To learn more, visit our Data Monitoring Committee Initiative webpage.

I’d like to learn more about the Common Protocol Template (CPT) and the recent release. Where do I start?

A: TransCelerate’s CPT initiative provides a solution to the increasing complexity and lack of consistency within clinical trial protocols. We believe the adoption of a common protocol template by companies will continue to streamline and add efficiencies to the research and development (R&D) process, simplifying interpretation for trial sites, institutional review boards and regulators.

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Check Out Our Top Social Mentions from the last three months

@transcelerate: Thanks to all the TransCelerate & Member Company executives that took part in our FDA Annual Update on Nov. 1! The FDA expressed significant interest in the presented topics & raised opportunities for continued collaboration in #clinicalresearch. We’re excited by this progress.

@MySCRS: With input from the SCRS Site Advocacy Groups (SAGs), @transcelerate has been able to get critical site feedback early and often in the development of solutions designed to simplify and accelerate the development of new medicines. [link]

@ACROhealth: #RiskBasedMonitoring is the future of patient safety & data quality in #clinicalresearch. Learn from the experts @transcelerate & @PAREXEL in their free webinar expert panel. Today at 11am ET [link]

@transcelerate: New study alert! We recently presented our findings on the impact of patient support programs (PSPs) to the European Medicines Agency. Find out what the results may mean for handling safety data from PSPs: [link]

@JillNotte: Thanks to all the Investigators and site managers that took the time to talk to the @Cognizant team about @joinSIP at the @MySCRS Global Site Solutions Summit. We appreciate your enthusiastic support for the Shared Investigator Platform! #SCRS2018

@transcelerate: Looking for industry-wide clinical data standards in disease areas like #diabetes and #influenza? Search no more! View a full list of the therapeutic areas on the @CDISC website here: [link]

Your Perspectives
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Since the last release in December 2017, we have collected feedback to further improve the utility and sustainability of the CPT. We’ve aligned our recent November 2018 release with the EU Clinical Trial Regulations and recent updates to ICH regulations (E6 and E9) and continue to align with the Protocol Template developed by the National Institutes of Health (NIH) and US Food and Drug Administration (FDA).

For the first time, we’ve released a Common Statistical Analysis Plan (SAP) and Common Clinical Study Report (CSR) Basic Word Edition templates. This release is the first step towards enabling greater automation of downstream processes and improved reuse of content.

Visit our Common Protocol Template webpage to read more about the newest materials and access the latest protocol templates.