Q&A:

Ed Kellar, Astellas, and Brett Wilson, Pfizer, share recent advancements from the eSource Initiative

Q: What's the vision for the eSource Initiative?

This initiative aims to modernize the way clinical trial sponsors and other stakeholders in the clinical trial ecosystem collect data and to facilitate optimal use of electronic data sources to improve global clinical science and trial execution for patients, sites and sponsors. This involves:

- Improvement in data integrity and process efficiencies with reduction in data transcription and collateral errors, providing traceable end-to-end data flow.
- Real time or near real time data availability that facilitates quicker decision making.
- Building use cases that provide sponsors which facilitate demonstration projects to confirm viability of using eSource from multiple sources (e.g. wearables, Electronic Health Records) for regulated trials.

Q: What are the primary industry pain points that the eSource Initiative is looking to address?

Currently, clinical data capture requires extensive site effort for data transcription, along with high monitoring investments. Since the current clinical research approach relies heavily on transcribing clinical trial data from paper documents (or even Electronic Health Records) to electronic data capture (EDC) case report forms, the turn-around time for data access can be long. There is also a need to make better use of device data to enable more clinical trial applicable endpoints.

Our belief is that utilizing data in its original electronic format has the potential to:

- Streamline clinical research data collection.
- Simplify the clinical research process.
- Facilitate development of new objective measurements and endpoints.
- Increase frequency and level of data collection.
- Allow on-demand data availability.
- Increase data quality.
- Enhance patient engagement during the clinical research process, and in turn improve patient understanding of their medical condition.

In addition, lack of harmonization in the global regulatory environment creates additional burden for sites, CROs and sponsors. Interoperability, and scalability are all areas for improvement in the global clinical trial area.

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Q: What makes TransCelerate's eSource efforts unique, and what makes the non-profit particularly equipped to address this area?

We are well positioned based on collaborative industry model that brings human resources to bear to develop pharma solutions in collaboration with regulatory, standards, site, patient and technology stakeholder groups.

Q: For companies that are implementing eSource currently, what benefits should they expect?

For companies implementing a broad scope of solutions that leverage electronic sources of data, there is the possibility for overall reduction in Clinical Trial costs from study start-up, throughout study conduct and into the study closure phase. Some specific benefits may include:

- The potential for more efficient site and study feasibility processes.
- eSources of data like electronic health records (eHRs) can provide sponsors with the ability to develop optimized protocols more quickly and precisely based upon patient need and demographics.
- A reduction in data transcription which leads to efficiencies related to data monitoring, data entry and source data verification (SDV).
- The potential for reducing the number of protocol and Clinical Study Report (CSR) amendments by getting it right the first time.
- An overall improvement in more rapid decision making due to more available data availability.

Q: What developments can we expect from the eSource Initiative over the next year?

The work of the team has largely focused on building out the current landscape inclusive of identifying the key challenges that prevent broader adoption of various solutions that facilitate use of eSource. This landscape has included feedback from Health Authorities. The focus will shift in 2017 to more active projects including further development of use cases and demonstrations, as well as a broadening of stakeholder interactions, and the development of tools. Tools may include the following: A point of view which outlines the roadmap to better utilize eSource, non-CRF data best practices, Use Case library and corresponding lessons which are inclusive of stakeholder input.

We’re excited for what the future holds for this initiative, and for industry’s recognition and integration of eSource as a means to add important efficiencies to clinical research.

Industry Lens

Social Media, Patient Engagement and Clinical Research: 5 Things You Need to Know

The convergence of social media and clinical trials is a new story – but an exciting one. We are inching closer to an entirely connected digital age, and industries across the globe are embracing the sea change. While the world of R&D is still in the dawn of its social media embrace, there have been some substantial advancements over the last few years that warrant attention and discussion.

Today, patients around the world are using the internet and social media to find and share health information. There is significant opportunity for clinical trial sponsor companies to learn how they should be listening to and learning from these online conversations, and to form a thoughtful strategy that catalyzes their own participation in them.

In this piece, I’ll explore some key things that you should know about the connective points between social media, clinical trials, and patient engagement and empowerment, as well as what to expect of this phenomenon in the future.

– Craig Lipset, Head of Clinical Innovation, Pfizer

To learn more about TransCelerate’s eSource Initiative, visit our website at http://www.transceleratebiopharmainc.com/initiatives/esource

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1. Sponsor companies have a responsibility to pay attention and have plans around potential risks with social media sharing.

While we’re excited about the information explosion online and patients’ ability to discover and more meaningfully engage with clinical trials, there are a few issues that researchers and sponsors should be mindful of when it comes to online patient interaction while participating in a randomized clinical trial.

**Eligibility:**
With patients connecting with each other in online forums, in blogs and via social tools like Twitter, there could be chatter among individuals suffering from the same disease about clinical trials that some are enrolled in, or have heard about. This could lead some patients to believe they would be appropriate for a study – when eligibility criteria can be very specific. It’s also possible that caregivers or family members are participating in social discussions about their loved one’s disease, they might learn about a trial and then try to get their family member into a study that may not actually be a fit. Patients might feel disheartened or less hopeful if a situation like this occurs. In other instances, with significant unmet medical need, patients or caregivers may be sharing tips on how to respond to screening questions that help those who may be ineligible for a study to pass screening. This can also unlock the risk of potential misinformation or inappropriate treatment courses.

**Safety:**
There is considerable concern around amplifying certain safety events in a trial via social media. For example, if a patient has a substantial following on Twitter, including people who are enrolled in the same trial that they are, and they send a tweet out about how their last infusion gave them a bad headache, other patients in the trial may now perceive that they have that same symptom, and then share that on social as well as report it to their investigators. This could potentially transform a minor situation into a major one that warrants investigation (and thus, time and resources) by researchers. This also impacts data integrity through the false spike in safety reports.

**Blinding:**
It’s a reality that patients share their disease experience, as it can support information gathering and empowerment. But – there is a tipping point where information sharing among patients in a trial can become worrisome: the potential unblinding of a study. As many know, the “gold standard” of research studies are randomized controlled trials, where participants are randomly allocated to either the active group (receiving the investigational product), or the control groups (patients receiving the standard of care or a placebo). If patients share very explicit details with each other about the medicine they’re taking in the trial – for example, exchanging photos of pills, talking about side effects or ways to get and interpret diagnostic tests outside of the blinded trial – a patient might discover they are not in the active arm of the study, and end up dropping out. This is something we must keep in mind as patients increasingly connect online, as it can significantly impact a study’s integrity and success if one treatment arm is withdrawing with significantly greater frequency. Researchers must also be trained on the risk associated with maintaining blinding, given the new age of social networking.

It is growing increasingly important for study teams to develop a prospective strategy for engaging patients on their use of social media. Attempting to “block” social use by patients through strong language in the consent may be viewed harshly by the online patient community. Attempting to raise awareness and to educate on proper use of social media may help with some patients; such awareness efforts may also have a paradoxical effect if they are actually informing some patients who were previously unaware of these online clinical trial participant conversations.

By beginning with listening to social media, research sponsors can start to build insights that will inform their strategies for new studies.

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2. Collaborating with patient influencers can create a highway of information between patients and pharma.

Patients have entered a fantastic era of empowerment: social media and blogging are giving them tools to tell their stories and inspire others. Some patients are amassing sizeable followings – by other patients, caregivers, and everyday consumers as well as investors and pharma – becoming key opinion leaders (KOLs) on their specific disease experience. If these patient KOLs are disseminating healthcare information to their followers, sponsor companies have an opportunity to further empower these influencers and their communities by providing them with approved study participation information and materials, to help them and their followers make the best decisions for their health.

There are companies like WEGO Health that connect sponsors and other organizations with patient leaders to help them distribute information to other patients. Efforts like this also enable patients and pharma to have a more equitable relationship.

CISCRP (The Center for Information & Study on Clinical Research Participation), a group that TransCelerate is partnering with to gather feedback through Patient Advisory Boards, is also helping to inform patients about clinical research. In addition to working with patient ambassadors, CISCRP is leveraging interactive online content to connect with patients, such as distributing educational videos.

The internet as a patient storytelling platform is here to stay, and R&D professionals must pay attention and strategically get involved.

3. Industry groups like TransCelerate can be a change agent for getting sponsor companies to consider social media as an important tool of influence for patients.

Patients are using social media and online spaces like forums and blogs to talk about disease and clinical studies at an increasingly rapid rate; sponsor companies must take this into serious consideration in their own trial strategies. It can be hard for sponsors and the research community to get on board with working with social media – but we must place our own assumptions and emotions about social media aside, and put in the work to understand how these tools are being used by patients.

There is a level of change management needed to get sponsor companies and R&D professionals thinking within this lens. Industry groups such as TransCelerate, whose bedrock is collaboration and the pooling of knowledge from multiple perspectives, have an opportunity to be the change agents for pushing our industry colleagues to consider social media as a powerful window into understanding patient preferences and behavior. We must closely examine and explore what changes need to be made to adapt, survive and thrive in the new age of continuous social connectivity.

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4. Some sponsor companies are beginning to use online patient engagement to inform clinical study planning

Clinical trial planning has been in a state of evolution for a long time, and is increasingly becoming more data-driven. The first step in this, which is already underway, is focusing on data collection that isn’t necessarily patient-owned – such as electronic health records (EHRs), investigator data banks, smarter use of ClinicalTrials.gov, and more. The next horizon is better use of patient reported data.

As sponsors are becoming increasingly familiar with channels for accessing patient insight during study planning, social media may prove to hold a wealth of information. Social analytics during study planning may help teams to understand patient priorities and burden, patient journey and options, and even experience considerations from those patients who have participated in studies within a given disease area.

Some study teams will be surprised to see that patients are reviewing investigator sites on sites such as Yelp, or finding other sites to post reviews of healthy volunteer protocols. At a time when consumers can post reviews of most anything, including their interactions in healthcare, one would expect that patients posting reviews related to study participation will only continue to increase.

Pharmacovigilance departments are becoming increasingly savvy in taking advantage of social media data, with the potential for earlier identification of potential signals. Shrewd study planners should be paying attention as well.

5. Social media and online interaction will shift patient participation from engagement and awareness to true immersion and empowerment.

Thanks to a number of forces – social media engagement, patient opinion leaders, sponsors investing more heft behind reaching out to patient communities and advocacy groups – patients have a seat at the table. But there’s still an inherent problem with this: there’s an implication that it’s our (sponsor companies’) table. Over the coming years, we expect a shift and need to anticipate truly sharing the table.

What might true immersion and ownership look like?

• Patients are consistently involved in co-designing studies – from endpoints that matter to operational considerations.
• Studies are designed with flexibility to accommodate individual participant needs – from home visits and travel support to visit schedules.
• Recruitment shifts from site- or sponsor-directed to patient-driven, akin to most all other types of user-generated content and social information sharing taking place online today.
• Patient access and control over their personal electronic health data becomes fuel for research studies with the rise of trusted systems that enable patients to choose to share their electronic health data with researchers.
• Trial participants come to expect “deliverables” from a study just like any other stakeholder – their study results and their data.
• Patients are able to make their personal data from the study portable, choosing not only to share it with one research sponsor but with any other research study that they wish to support.
TransCelerate’s Clinical Data Standards (CDS) Initiative collaborates with CDISC (Clinical Data Interchange Standards Consortium) and a number of other organizations to support the development of industry-wide clinical data standards in priority Therapeutic Areas (TAs), supporting the exchange and submission of clinical research data to health authorities.

**CDISC’s mission** is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. TransCelerate has collaborated with CDISC over the last four years through the Clinical Data Standards Initiative, elevating the industry-wide recognition and adoption of data standards into the clinical trial process.

### Progress on TA standards

Therapeutic Area (TA) standards are an extension of the CDISC foundational standards by representing data standards that pertain to specific disease areas, including disease-specific controlled terminology, data collection, tabulation, and analysis metadata. The Therapy Area User Guides provide examples and guidance on implementing CDISC TA standards. To date, CDISC has developed TA standards for over 25 different disease areas, most developed under the CFAST (Coalition For Accelerating Standards and Therapies), of which TransCelerate is a member. Indeed, in the last year, TransCelerate’s Clinical Data Standards Initiative has collaborated with CDISC to publish 10 new TA standards in areas such as breast cancer, kidney transplant, COPD, virology, and diabetes. We were proud to make such major progress in 2016 – helping to streamline the way clinical research is conducted so that data can be readily shared among clinicians, researchers and regulators around the world.

The development of TA standards is an important evolution from the state of data standards four years ago: we had data standards, but the collection wasn’t as robust – and more, specifically, we didn’t have many that supported TAs. Through our collaboration with CDISC, the breadth of available data standards is increasing, as is the predictability of when the standards will be available for use by sponsors and investigators.

**The partnership between TransCelerate and CDISC, and the unique role that TransCelerate has played in this effort, has created meaningful change for the clinical trial ecosystem over the last four years.**

### Impact on industry’s value of data standards

The partnership between TransCelerate and CDISC, and the unique role that TransCelerate has played in this effort, has created meaningful change for the clinical trial ecosystem over the last four years:

**There has been an increased awareness and understanding at the executive level of the important role that data standards play.** Previously, within many organizations data standards were being pushed from the bottom up and had to compete with a number of other sponsor company priorities, namely the drug pipeline.

Resources involved in data standards often participated in standards activities after their “day job” activities were completed. Through participation in TransCelerate, resource time is allocated to participate in standards activities as part of one’s the job responsibilities. What’s more, there were varying levels of maturity in terms of how standards were prioritized and put into operation. But in the last few years since our Initiative’s launch, thanks to TransCelerate role in facilitating and prioritizing data standards within Member Companies, there has been more of an appreciation of the essential enabling role of clinical data standards to information sharing, data exchange and the submission of study data to health authorities.

The importance of collaboration as a vehicle to efficient processes has been underscored. The ability for stakeholders to come together from many different biopharma companies and perspectives has created major productivity in moving the needle on data standards adoption. TransCelerate, specifically, is coalescing the perspective of our Member Companies into one body. Before our consortium launched, CDISC would go about a process of gathering feedback on standards from each individual TransCelerate Member Company; they then needed to make sense of each of those perspectives, understanding how they are valuing data standards in both different and similar ways, and needing to decipher how to weigh each of those individual perspectives against each other. With TransCelerate, we’ve fostered one focused, consolidated Member Company voice that can communicate a representative perspective to CDISC.

Taking that one step further, through the Clinical Data Standards Initiative we can harness a powerful network of subject matter experts (SMEs). In fact, our group of data standard SMEs from each Member Company are contributing to and helping define the future standard by providing reference materials, for example, when we are scope a TA standards development project with CDISC and/or identifying

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SMEs (e.g., from clinical or biostatistics) to participate in the development of the TA standard. The SMEs also have the opportunity to support the CDISC standards development process, which, once a standard is drafted, heavily relies on accumulating broader vetting across the industry. TransCelerate can facilitate some of that vetting through its Member Company SME network – which is enabling us to generate more confidence that Member Companies are engaging in and contributing to the data standards. This also helps ensure that the standards have meaningful input from relevant stakeholders and are well-defined, which leads to higher level of quality in the end deliverable.

The Clinical Data Standards Initiative is also helping to break down organizational silos within Member Companies. Data standards are an enabler of other operations within the clinical trial process. The integration of data standards experts with professionals from other areas, like protocol creation, is a tremendous opportunity that historically didn’t exist. In that way, the Clinical Data Standards Initiative isn’t just helping our Member Companies understand what data standards are – it’s helping them understand how they fit, alongside other functions, within the clinical trial ecosystem.

Data standards can support higher quality data and scientific discovery. Because data standards provide consistency in the structure and meaning of data, they can increase the data quality and confidence in the use of the data. For example, having standardized data facilitates the ability to combine data and harvest its value by using it for further exploration of safety and efficacy analysis and to test disease model hypotheses. Clinical data standards applied across sponsor companies facilitates health authorities’ ability to review standardized study data provided in regulatory submissions and to evaluate the safety and efficacy across products submitted by various sponsor companies.

Data Traceability

One of the primary benefits of Clinical Data Standards is the traceability of data across the clinical lifecycle stages. When creating a submission package for a health authority, you are providing a large amount of information – such as insights from your clinical development plan, and an explanation for why you have decided to explore these specific compounds. Sponsors have to show the health authority that they worked toward what they set out to achieve or explore. Traceability of data, supported by data standards, is a thread that health authorities can follow.

Clinical trial information isn’t just collected and reported – there’s a lot that happens in between, and sponsors must have a clear story of that “in between.” Health authorities must see that information can be traced backwards and forward – like vertebrae on a spine. Use of agreed upon data standards can help answer some key questions from health authorities, such as:

• How did you collect the data? What was the source? If it was an eSource, was it an electronic patient diary, an EKG machine, imaging, etc.?

• What transformations did you apply post collection? How did you represent the collected data in tabulation format?

• How did you use the tabulation data to generate your analysis datasets?

Health authorities want to see that you collected the data you said you would per the protocol, each source and format of data captured, how that information was transformed and represented in tabulation format, and ultimately used to generate analysis datasets and submission deliverables that support the Clinical Study Report. Clear data traceability helps ensure that the data integrity and quality isn’t compromised, and that nothing is going to get muddled in the translation from data collection and cleaning, post-processing, analysis and reporting, to the submission of clinical data sets and supporting submission deliverables. Implementing the CDISC data standards elevates the chance that the data will be understood, which will give health authorities more confidence in the data, and ultimately enable them to make better decisions.

Connectivity to the Common Protocol Template

The Common Protocol Template (CPT) Initiative creates a model clinical trial protocol template containing common structure and model language, and sets the stage for the data that are collected based on the trial goals. It supports the primary and secondary objectives of a trial, and the statistical analysis plan. If a trial has a lot of variability around protocols, it can be hard to have stability around some of the data collected. The CPT has leveraged disease areas where the Clinical Data Standards and CDISC team have already defined TA standards. Asthma and diabetes were selected as the first disease areas for which CPT created libraries. The CPT endpoints and their objectives are actually metadata that are directly tied to the data collection standards, and the terminology around TAs. Defined data standards also help support the CPT initiative goal of harmonizing controlled terminology as much as possible.
Data standards might also, in the future, support a more seamless information exchange within the protocol template.

Essentially, the CPT and Clinical Data Standards build off one another – and it’s a bi-directional relationship. These two initiatives have direct highways of connectivity, from the TA standard that is used, to what is documented in the protocol, to the data that is ultimately collected, analyzed, and reported.

The evolving state of data standards

Last year, data standards reached a very important turning point: FDA and PMDA Binding Guidance regarding the submission of standardized study data went into effect on December 17, 2016 and October 1, 2016, respectively. What this means is that sponsors whose studies start after the December date must submit data in FDA-supported formats, as listed in the FDA Data Standards Catalog, which specifies the use of CDISC standards. For submission to PMDA after the October date, standardized study data must be provided in CDISC format in accordance with the PMDA Data Standards catalog. We are transitioning to a period where sponsor companies must deliver their study data in accordance with clinical data standards in order for a submission to be evaluated by the health authorities.

Binding Guidance being issued by health authorities represents a shift away from data standards as something that was a “nice to have” to something sponsor companies must do. Soon, data standards are going to be business as usual in R&D – and if companies don’t have solidified processes and roles around data standards, the clinical trial process will be more complicated. It could even become a barrier to getting medicine to patients. TransCelerate is proud to support CDISC increasing the breadth and depth of available clinical data standards: our ability to facilitate more efficient clinical trials, and information exchange with partners and health authorities, is why we got involved in supporting data standards at the outset of our founding.

To learn more about TransCelerate’s Clinical Data Standards initiative, visit our website at: http://www.transceleratebiopharmainc.com/initiatives/clinical-data-standards/.
Your Perspective

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

What has the Risk Based Monitoring Initiative accomplished since launch, and why did TransCelerate create an interactive guide dedicated to it?

Risk Based Monitoring (RBM) was one of TransCelerate’s first five initiatives when the organization launched in 2012. There had been a movement within the industry, driven by health authorities and, as a result, championed by TransCelerate, to develop a novel risk-based approach focused on risks and errors that matter. Because clinical trial monitoring approaches historically did not account for the varying levels of experience and quality at clinical trial sites, and due to inefficiencies and high costs associated with traditional On-Site monitoring and Source Data Verification (SDV) practices, TransCelerate determined that this was an important area to tackle, where we could create meaningful change.

We were right. Through collaboration across Member Companies, TransCelerate developed a model approach for risk based monitoring that would more efficiently and effectively identify risks to patient safety and data integrity in clinical trials across the globe. Over the last five years since its launch, our team has developed a collection of guidance papers, risk planning and assessment tools and templates, and articles focusing on data quality, technology and metrics. Those Member Companies who have voluntarily adopted the approach to risk-based planning and management have seen a significant impact in data quality and patient safety for clinical trials, as well as more focused centralized monitoring activity and targeted on-site monitoring topic.

We also developed the Risk Based Monitoring Interactive Guide that summarizes the RBM Initiative’s methodology and includes assets, key learnings, potential applications and our vision for the future. By aggregating the RBM Initiative’s assets and insights in a way that is easy to navigate (and interactive!), the guide can serve as an educational tool for organizations and individuals eager to explore our research and deliverables, or serve as a guide for those considering implementing proactive risk monitoring into their clinical trial operations. Our hope is that it lives on as a central knowledge portal on all things RBM. We believe that the RBM Interactive Guide will teach readers why and how a holistic RBM approach is helping to modernize drug development, deliver improved effectiveness and efficiency to the R&D ecosystem and, ultimately, bring lifesaving medicines to patients faster.

Want to help support the RBM Interactive Guide and honor the hard work of the TransCelerate team on this initiative? Below are some suggested social posts that we encourage you to share with your networks:

For Twitter:
• The @TransCelerate #RBM Interactive Guide is live! Follow the link to see what this initiative has accomplished http://bit.ly/2JsuDvJ
• Proud to announce that @TransCelerate has launched an interactive digital guide on the RBM Initiative http://bit.ly/2JsuDvJ
• How much do you know about Risk-Based Monitoring? Check out @TransCelerate’s digital interactive guide to learn more http://bit.ly/2JsuDvJ

For LinkedIn:
• TransCelerate BioPharma created a digital interactive guide about the Risk-Based Monitoring (RBM) Initiative. The guide focuses on our accomplishments and outputs, as well as a vision for the future. Follow the link to learn more about this important work. http://bit.ly/2JsuDvJ
• Risk-Based Monitoring (RBM) is an adaptive method of clinical trial monitoring that directs monitoring focus and activities to the evolving areas of greatest need, and which have the most potential to impact patient safety and data quality. Explore TransCelerate’s newly launched RBM Interactive Guide to learn more http://bit.ly/2JsuDvJ
• The Risk Based Monitoring Initiative was established in 2012 as one of the five initial goals created by TransCelerate to drive efficient and effective solutions into the R&D industry. Today you can explore a digital, interactive guide that coalesces research and insights into one place. Check it out! http://bit.ly/2JsuDvJ

Have something you want to ask us? Submit it here! We will continue answering your questions in future newsletters.

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Last year, TransCelerate launched a subsidiary named BioCelerate, whose first initiative is sharing toxicology data across participating members. Can you explain why the industry needs this data sharing platform, and what unmet need this effort addresses?

Most high-quality toxicology data is confined to internal member company archives, often lacking a defined structure and housed within multiple repositories. Paired with the reality that this data is rarely published, there is limited understanding of target-related toxicity across the industry. An incomplete view of the toxicology data landscape hinders the ability of researchers to make data-driven decisions regarding compound progression, potentially resulting in advancement of nonviable compounds, or termination of viable compound. Development of a centralized, searchable repository storing data in a standard format could mitigate these common challenges and help companies identify fatally flawed compounds earlier in the drug development process.

BioCelerate’s first initiative, Toxicology Data Sharing, is focused on enabling access to a broader cross-company set of toxicology and background control data. The initiative is motivated in part by the Food and Drug Administration’s (FDA) 2011 Strategic Plan for Regulatory Science, which includes objectives to modernize toxicology data to enhance product safety. The FDA also issued binding guidance at the end of 2014 requiring standardized SEND-formatted data submissions for all new studies starting after December 18, 2016.

TransCelerate launched BioCelerate with the vision of creating a ‘one-stop’ data sharing platform that is capable of storing, visualizing, analyzing, and linking preclinical and, ultimately, clinical data. The platform will have the flexibility to share a multitude of future preclinical and clinical data types, such as clinical placebo data and preclinical omics data, to facilitate the discovery of translational insights and outcomes.

The ultimate goal of this initiative, like many TransCelerate projects, is to enable member companies to make confident and informed decisions. Starting with a robust data sharing platform for toxicology, BioCelerate strives to help preclinical researchers close critical gaps in understanding the relationship between preclinical findings and clinical response, which will ultimately benefit the patient community.

What’s the latest update on TransCelerate’s Shared Investigator Platform Initiative?

TransCelerate’s Shared Investigator Platform (SIP) Initiative created a central platform to deliver content and services to investigator sites, and provide a single point of access for interaction with participating clinical trial sponsors. TransCelerate Member Companies that voluntarily adopt the SIP can increase engagement with investigative sites and eliminate company-specific portal development and maintenance costs.

We proudly launched the SIP in January of 2016, and have since been working on advancements to increase efficiency, reduce administrative burden and streamline interactions between investigators and participating sponsors. In 2017, we’re focusing on two primary areas:

- **Outreach:** We will send messages to Investigators with data in the Investigator Registry (IR) to encourage registration in the SIP so Sponsor users are able to access the full potential of both tools. In addition, we’ll be presenting at several site-facing conferences globally and meeting with stakeholder groups to not only educate about the SIP, but guide potential users on the abilities of the tool.

- **Improving the user interface:** There will be several important updates to the SIP this year, but the one that excites us and our users is improving the user interface. This enhancement will be available in Release 2.0 later this year.

And speaking of Release 2.0, here are some significant changes users can expect:

a. Document Management (e.g., versioning, workflow, e-signatures, ability to integrate to sponsor eTMF)
b. Safety Letters
c. Surveys and analysis
d. Enhanced functionality
e. Expanded Reporting
On Your Newsstands

Check Out Our Greatest Hits from the last six months

@ClinicalLeader: News: TransCelerate BioPharma Reports Impact In The Way Clinical Trial Information Was Shared In 2016 okt.to/H1Al2u

@ACRPDP: Cool interactive RBM guide here from @transcelerate if you missed it: bit.ly/2irUISV

@Clin_Trials: Justin Stark of @ucb_news discusses advancements in #RBM and @transcelerate’s Quantitative #Metrics Toolkit #pharma bit.ly/2izTJeY

@LillyTrials: Survey says: Digital tech helps “demonstrate the real-world value of an intervention.” eli.ly/qzwp h/t @transcelerate

@TransCelerate: We recently launched a new assets page for our #Clinical #Data #Transparency Initiative. Explore here: bit.ly/2gdM7Qe

@Clinical_Trial: TransCelerate BioPharma Reports Impact in the Way Clinical Trial ... - Yahoo Finance: dlvr.it/NZzI9 #clinicaltrials

@TransCelerate: #ICYMI last week we introduced 2 new #pharmacovigilance initiatives that address #AE reporting & more: bit.ly/2oaWibj

@TransCelerate: Check out our #eSource landscape paper recently published in the journal TIRS & learn more about this initiative: bit.ly/2dt94it

@washingtonpost: People susceptible to the placebo effect may be keeping us from getting new drugs t.co/DAkOlt32I

@TransCelerate: #ClinicalTrials

@ TransCelerate: #ICYMI last week we introduced 2 new #pharmacovigilance initiatives that address #AE reporting & more: bit.ly/2oaWibj

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