The Latest

The Journey to Global eConsent Adoption

eConsent has the potential to improve the consent experience, increase regulatory compliance, and reduce quality risks. For patients specifically, it affords a more informed and tailored trial experience, helping to enhance enrollment and retention.

In the past few years, TransCelerate launched its eConsent Initiative and in 2017 it released the eConsent Implementation Guidance, which provides information on the various eConsent multimedia components available for use in an eConsent system, the external and internal processes to consider for implementation, and survey results regarding experiences with eConsent worldwide.

In this article, we catch up with Cassandra Smith, MBA, Associate Director, Clinical Insights and Experience at Janssen Research and Development, LLC., and a Leader for the TransCelerate eConsent Initiative, about the challenges to eConsent adoption and the insights the initiative team has gleaned over the last two years.

Technological innovation is ongoing and may impact all aspects of clinical studies. eConsent is one of many innovations that are part of the participant experience and, importantly, is often the first interaction the participant has with the clinical trial process. Involving study participants in their own care requires that they be fully informed. It is our hope that electronic, patient-guided technologies will have a significant and positive effect on overall outcomes.

Though the concept of eConsent is not new, its use today has an opportunity to grow tremendously. To understand more about the global experience with eConsent and where the technology can continue to evolve, we launched the eConsent Landscape Assessment.

The survey was distributed to pharmaceutical companies, clinical research organizations (CROs), and eConsent vendors in December 2016, and was later updated in the second half of 2018. Even with the limited industry experience of eConsent, the 2016 survey garnered data from 17 organizations, showing that eConsent was either submitted to Institutional Review Boards (IRBs) or Ethics...
Committees (ECs), or was used to consent patients in 29 countries. In 2018, an additional three respondents were recorded.

“From the results, we see a global uptick from industry sponsors actively piloting and implementing eConsent,” notes Cassandra, “and we only expect a better response for future assessments.”

While use of eConsent is on the rise, grassroots education efforts with all stakeholders could be of great use for further implementation globally. The Food and Drug Administration (FDA), Medicines & Healthcare products Regulatory Agency (MHRA) and the Health Research Authority (HRA) have issued guidance on the use of eConsent and, as a result, the industry has a roadmap of how to compliantly implement eConsent in countries covered by these regulators. Other countries may face complexities, such as concerns about the use of electronic signatures to document the informed consent vs. capturing consent using a wet-ink signature.

“Without broad adoption, regulators and IRBs/ECs may not have the chance to become familiar with eConsent and its use may not grow—ultimately hindering the opportunity for patients to receive an enhanced informed consent experience,” says Cassandra. “This means having informational conversations that outline the benefits of implementation while providing additional education to help encourage organizations to use eConsent and step outside their comfort zone,” she adds. “Only then will there be a rise in the global adoption of the technology.”

Although foundational efforts to get eConsent off the ground are still underway, clear progress is being made in terms of implementation. Looking toward the future of eConsent, Cassandra comments that we’re seeing a greater focus on enhancing the technology through integrations (with EDC, lab sample management, etc.), remote consenting capabilities (where patients can view and document consent outside of the study site), and the option that companies may have to self-author eConsent.

“It helps the patient navigate the consent process to enter studies sooner, allowing sponsors to save time and investment, which we hope will ultimately help deliver innovative therapies to patients sooner,” explains Cassandra.

Also, the use of remote consenting for virtual trials allows patients to use their own devices during the consenting process. Cassandra notes that while it may not be appropriate to use remote consenting in all types of studies, the technology exists, and she believes the industry will continue to progress toward broader adoption.

All stakeholders in the research and development ecosystem have a responsibility to continue to keep the eConsent adoption going for the benefit of the patient. Successful implementation of eConsent will not only help provide patients and the families that care for them with clear, easy-to-understand clinical trial-related information, but will also empower them to make better, informed decisions.

“Ultimately, patients are waiting for these kinds of technologies that make their lives as a trial participant easier, so we can’t rest until eConsent use is accepted by all regulators. The more eConsent submissions that generate easier, so we can’t rest until eConsent use is accepted by all regulators. The more eConsent submissions that generate globally, the greater chances we have of moving the needle on broader global adoption,” Cassandra concludes. “It’s truly up to us to make that change happen.”

Although patient technology has limited in the pharmaceutical realm, the clinical research tool remains a potential to serve a variety of functions in clinical studies, such as capturing clinical endpoints, engaging patients and facilitating remote study conduct, many trials continue to rely on manual or traditional methods. As a result, the lack of a clear vision of the opportunities, challenges and facilitators associated with PT implementation, has prevented the realization of benefits PT may bring.

To help understand the factors affecting PT adoption, the

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TransCelerate Patient Technology Initiative conducted a series of surveys, interviews and focus groups with approximately 600 subject matter experts, including TransCelerate member companies representing sponsors, clinical trial investigational sites and clinical trial participants. Specifically, the results provided valuable insight into the unique challenges that are preventing wider implementation of PT in the clinical trial ecosystem and how we can overcome them.

Here are a few of the primary PT barriers we identified from the survey:

1. **Change Management:**

   A top-cited organizational challenge was related to a risk-averse corporate culture. Due to complexity and pressures to adhere to regulatory requirements, sponsor organizations have developed a general hesitancy to embrace change and implement PT. Survey respondents also mentioned that a lack of corporate strategy, leadership and vision, along with limited communication across functions, has hampered progress. Overall, there was consensus that a clear articulation of reason and a distinct plan-of-action are needed for corporations to be willing to accept change.

   **2. Risk of Investment**

   While the goal of PT deployment is to enhance the science-related conduct of clinical trials and facilitate patient recruitment and retention, those improvements require significant upfront investment. Consequently, technology cost was the most commonly cited business challenge amongst site and sponsor respondents, with interviewees also noting that the expected return on investment was relatively unclear. These financial implications make it difficult for senior leadership to see past the near-term impacts on budget and visualize the long-term ROI.

   To change the mindset from short-term return to long-term outcomes may take a multi-fold process, which could include: First, the timeline benefits of PT uptake need to be articulated, such as receiving a better signal that a trial will lead to a potentially good outcome. This speaks to the language of return for business leaders and can easily off-set the upfront investment. Second, inform leadership so they understand that PT implementation could help magnify the pool of potential trial participants, thereby increasing recruitment rate and helping patients benefit from a therapy more quickly. Third, take a pilot approach, and provide sponsors a framework for scaled deployment of technology implementation. This way, sponsor companies have the option to experiment with PT in a way that doesn’t impact a clinical trial team and can then progress to broader implementation.

   **3. User Experience:**

   The survey also provided insightful information regarding the site and patient willingness to use PT, as well as the primary barriers they face with adoption.

   **Sites:**

   From a site perspective, most reported that PT increased their desire to...
participate as a site (28.5%) or did not impact it (65.6%). Member company respondents also agreed or strongly agreed (61.1%) that sites were generally willing to use PT in clinical research.

Despite site willingness to use PT, several obstacles were cited, including difficulty managing patient training and experience and accessing the right tech support. Interviewees also noted that trial sponsors need to better understand the impact PT adoption may have on sites, suggesting they should engage with sites to manage expectations and ensure they understand the potential value of PT.

In light of this feedback, TransCelerate recently developed a **Patient Technology Implementation Framework** outlines a possible approach to Patient Technology implementation and encourages a mindset of strategic thinking, rapid learning, and patient-centric design.

**Patients:**

Comparatively, from a patient point of view, most felt there is no “one-size-fits-all” approach to the use of technology in clinical trials. Patient respondents suggested that the acceptability of and access to technology should be considered when designing a clinical study with PT, and that technology should not replace all in-person trial interactions.

Interestingly, site and sponsor participants had differing perspectives on the patient experience with, and willingness to use, PT. Although sponsor and sites respondents agreed that patients were ready to use PT, sponsors tended to believe that PT positively impacts the patient experience, while sites were more likely to report that PT use increased patient burden.

Sites and sponsors did agree on the key challenges that patients face with technology, such as access to connected devices, and the time, effort and complexity associated with learning to use the trial’s technology. In partnership with TransCelerate’s **Patient Experience Initiative**, we’re working to reduce these burdens, and develop tools that engage patients and increase patient centrality of study programs.

**4. Varied Regulation Interpretation**

Regulatory implications were reported as another major obstacle to PT adoption. One main challenge includes the lack of specific regulations or guidance around PT in clinical trials – both in the US and worldwide. Specifically, respondents mentioned that the absence of specificity as well as variable interpretation make it especially difficult. Moreover, for what regulation does exist, it is often misunderstood or over-estimated by sponsors.

To help sites and sponsors navigate this ambiguity pertaining to PT, we’ve developed a **Regulatory Landscape Tool**. We’re also actively identifying where additional regulatory gaps exist so we can engage regulators around those gaps and ultimately help with PT deployment.

While there’s a growing interest for using PT in clinical research, full implementation will not happen overnight. It’s going to require a cross-industry effort to advance awareness, but PT offers us an exciting opportunity to improve our understanding of investigational drugs, improve patient engagement and experience in the trial, and ultimately have a positive impact on all stakeholders in clinical trials. •
Todd Page, Director of Toxicology, Eli Lilly & Company and BioCelerate’s Common Templates for Nonclinical Studies Initiative Lead, provides an overview on the unmet need for the common template for nonclinical studies and what it will offer stakeholders.

CROs are often required to adhere to a variety of sponsor-specific protocol and/or reporting templates, often presenting information in different places and in different ways for each study. This has the potential to introduce inefficiencies: study errors, delays in drug development, inconsistency in study conduct and reduced quality of data being reported.

Q: Tell us about the unmet needs a nonclinical protocol template serves within the R&D ecosystem.

A: We understand most of the work sponsors and CROs are doing is similar in nature, but each operates under a protocol that is specific to their organization; each have slight deviations across their processes. BioCelerate’s Nonclinical Protocol Template addresses the increasing complexities of toxicology study execution. As it stands, these complexities and inconsistencies among CROs and sponsor companies have led to inefficiencies in drug development. A common template will increase efficiency for both CROs and sponsors resulting in toxicology study execution with fewer errors. It could be integral in driving quality, reducing costs and decreasing the time it takes to deliver new and innovative therapies to patients.

Q: From your perspective, what is most problematic about using multiple protocol templates or approaches across different Sponsors or studies?

A: Inefficiencies in study startup and errors during the study are the most common issues when using multiple protocol templates. Inconsistent forms may introduce room for error, impacting the quality and efficiency of a study. Frequently, template format changes are so subtle, laboratory technicians will overlook these modifications in an effort to seek out specific items or keywords/sections that are commonly included across toxicology protocols.

The adoption of a nonclinical common protocol template helps to promote data integrity, as well as simplify the interpretation and reuse of historical data.

Q: Who is the main beneficiary for this solution?

A: The Nonclinical Protocol Template will benefit a wide variety of stakeholders, with occasional areas of shared value. One opportunity that could benefit both sponsors and CROs would be the development of more automation and reuse of content in downstream processes.

On a more granular level, though, sponsors could potentially identify opportunities to condense existing templates, streamline protocol authoring and review, improve quality and reduce errors during study conduct. CROs might find more consistent expectations across clients, the ability to streamline protocol authoring and review, fewer protocol templates to manage, and greater efficiency in study start-up and conduct.

Lastly, health authorities could even see an increased consistency and ease of review around sponsor protocols due to streamlined data interpretation, greater ability to compare protocols and greater use of data standard enabling end-to-end traceability.

So, I wouldn’t venture to say the initiative benefits one [particular] stakeholder more than another in any way, since so many could be affected by its implementation. Rather, the drug development continuum could benefit from its implementation.

Q: Who did TransCelerate collaborate with to inform the first version of the template?

A: The Nonclinical Studies Initiative team leveraged TransCelerate Member Company and laboratory partner insights, as well as feedback from those involved in non-clinical protocol authoring/review and health authorities to inform Version 0.1 of the Protocol Template for Repeat-Dose Toxicology Studies. This is a draft document now available for review and feedback by interested stakeholders and the public. All stakeholders are encouraged to submit feedback on this first draft to help us improve the template in preparation for its first major release. Our hope is to launch our first in-use template by the end of the year.

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Q: Tell us about the Core Design Principles of the Template.

A: Our Initiative had a unanimous understanding that too much specificity in the template’s design would make it difficult to adopt. Therefore, we collectively chose four guiding principles to serve as our north star during the template’s design: Purpose, Scalability, Process and Structure.

Our Purpose is to simplify sponsor and CRO expectations; eliminating content better suited for inclusion in contracts and placing focus on increasing efficiency and quality during study execution and for study conduct. We then determined a need to provide Scalability to the template; to minimize the need for major customizations, allow for evolution, based on stakeholder need, enable flexibility across stakeholder types or geographies and create linkages to future templates or available standards like CDISC’s Standard for Exchange of Nonclinical Data (SEND).

Effectively aiding Processes was a huge driver as well. We wanted a template design that was fundamentally prescriptive where it counts, referencing OECD Principles of Good Laboratory Practice (GLP) as minimum baseline. We avoided process instructions where large variations in preferences exist and embraced the concept of a living protocol. To tie it all together, we built a Structure that would allow us to focus on layout and format, use of consistent terminology through sections ordered to intentionally ease reference and navigation through an electronic common technical document (eCTD) format and ensured OECD GLP-compliance.

Q: What type of feedback would be helpful as the Initiative looks to improve upon the first version?

A: BioCelerate has built a feedback mechanism on its website to support the release of the Nonclinical Protocol Template, Version 0.1. Our hope is to capture a broad overview of the thoughts, insights and reactions from stakeholders through their participation in a 10- to 15-minute survey.

Within the survey, stakeholders will be prompted to rate the potential value of the nonclinical studies common protocol/study plan template but are also afforded the opportunity to dissect sections of the protocol and share more extensive feedback with us.

We want to learn more on the areas to which we’ve hit the mark and identify areas of opportunity for the next version. Stakeholders will also have the opportunity to tell us about their barriers to implementation. This will be enormously helpful as we look to tailor and revise the sections of the protocol template.

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.

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PCI Conference
June 2-5, 2019
London, UK

DIA China 2019
May 20-23, 2019
Beijing, China

DIA 2019 Global Annual Meeting
June 23, 2019
San Diego, CA

To learn more about BioCelerate’s Nonclinical Studies and provide feedback on the Nonclinical Protocol Template, visit our website at: https://www.transceleratebiopharmainc.com/biocelerate/nonclinical-protocol-template-feedback-form/
Your Perspectives

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

Q: How is TransCelerate playing a role in R&D automation and analytics?

A: In 2018, we launched three new initiatives that leverage advancements in automation and analytics and focus on data quality, safety and integrity so that we can help achieve meaningful change for patients, sites and other R&D stakeholders. These initiatives include:

**Intelligent Automation Opportunities in Pharmacovigilance**
Given the breadth of global regulatory requirements and the repetitive nature of clinical trial operations, the Intelligent Automation Opportunities in Pharmacovigilance initiative seeks to identify the ways intelligent automation technologies can better support the execution of pharmacovigilance processes. These include limiting the errors commonly associated with manual data processing, increased consistency within a sponsor’s case processing and enhanced speed through automation. The Intelligent Automation initiative is slated to release a whitepaper on its research later this year.

**Digital Data Flow**
Four months is the average period between protocol completion and study start. The Digital Data Flow (DDF) initiative is focused on helping reduce that time interval. The goal of this initiative is to facilitate movement of the drug development process from a current state of manual, study start-up asset creation (i.e. Case Report Forms, Procedure Manuals, Statistical Analysis Plans and Schedule of Activities) to a future state of fully-automated, dynamic, study start-up readiness via a vendor-agnostic solution that will reduce cycle times and improve data quality for sponsors, third-party providers, sites and regulators.

**Advancing Safety Analytics**
The power of analytics is enabling the pharmaceutical industry to improve insights on drug safety and strengthen patient care at large. But limited data exists on the effectiveness of these various methodologies. In addition, there is an opportunity to identify new data sources and / or novel methodologies which could drive further understanding of product profiles and support product development. This initiative aims to develop best practices and guidance around the application of interrogative methods towards various safety data sources.

Q: What is the latest with TransCelerate’s Clinical Trial Registry of the Future concept and prototype?

A: Upon launching the Clinical Trial Registry of the Future concept and engaging with government registry owners, we received great feedback on our concept and framework. 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 is to focus on how the industry can ensure the quality of the information being shared with patients through registries is effective and reliable. TransCelerate is working to release a Common Registry Data Packet within 2019.

Q: What’s the typical outcome of TransCelerate’s engagement with global health authorities?

A: Global health authorities are one of the many stakeholders TransCelerate engages across the biopharmaceutical R&D ecosystem. Our work with health authorities helps to foster collaboration and informs our solutions at various stages of development and deployment.

Recently, we launched the Interpretation of Guidelines & Regulations initiative that aims to, along with actively engaging health authorities, share expertise to more efficiently and effectively meet the intent of pharmacovigilance requirements that may seem ambiguous. The initial focus will be on recent measures such as the IND safety reporting requirements, but over time the initiative hopes to work proactively with health authorities toward modernized and internationally harmonized pharmacovigilance.

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

Check out our top social mentions from the last three months

@ucb_news: In order to accelerate innovation, UCB partners with @transcelerate to implement solutions to drive efficient, effective and high-quality delivery of new medicines, improving the health of people around the world. http://bit.ly/2JipmsO

#Innovation #UCB90

#Partnership

@transcelerate: Have you explored our Integrated Quality and Risk Management Plan? This tool helps provide a tailored & integrated plan for collecting, analyzing & reporting clinical trial data. Download it here: http://bit.ly/2A3DBLt

@lanikashimoto: Thanks @deacstephen for sharing the @transcelerate PE toolkits that are in Pilot now and coming to the public later in 2019

#Patients2019 #collaboration

@transcelerate: How can real world data bridge the gaps in clinical trial access? Give this article a read to uncover the answer! http://bit.ly/2EonIa9

@CraigLipset: Calling All Patients as Partners! #Patients2019. Our friends at @transcelerate need your help completing a survey to inform recommendations to make clinical trial registry websites more patient friendly. Appreciate your sharing insights at http://bit.ly/2IAGucQ

@transcelerate: Wrapping up SCOPE2019 on a high note with Lisa Moneymaker (@Amgen) & Cassandra Smith (@JanssenGlobal)! pic.twitter.com/sew7HvedH6

@transcelerate: Have you explored our Integrated Quality and Risk Management Plan? This tool helps provide a tailored & integrated plan for collecting, analyzing & reporting clinical trial data. Download it here: http://bit.ly/2A3DBLr

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