The eConsent Initiative was established to create a practical guidance for the electronic consenting of patients using interactive multimedia components and internal/external process efficiencies related to eConsent. Implementing eConsent could help patients elevate their understanding of complex trial information become better informed when deciding to participate in clinical trials, as well as improve protocol compliance and reduce quality risks. eConsent processes could also benefit trial sites by offering the proper tools to gain insight into patient understanding and reduce complex and time-consuming explanations and paper work.

Recently, we spoke with Hilde Vanaken, PhD, Director of R&D Operations Innovation, Janssen, and the TransCelerate eConsent Initiative leader, to expand on the Initiative’s progress and the development of the eConsent Framework and Implementation Toolkit.

The eConsent Initiative is Addressing Patient Needs and Multiple Industry Pain Points

When asked to detail an immediate patient need that eConsent addresses, Vanaken explains, “It centers around one of the most critical elements to a clinical trial – the process for ensuring that patients understand and assent to the parameters for the particular clinical trial. It's extremely important that the materials used to convey that understanding to the patients are understood and filled out correctly, especially since it’s the first interaction patients are having with their clinical trial.”

Often, patients are left feeling overwhelmed by the informed consent process, and may not entirely understand the clinical trial information being presented to them prior to participation. As it stands now, the consenting process is not particularly patient-centric: it is carried out on paper forms that can run 20-30 pages long, and typically contains complex consent language and difficult-to-understand trial terminology. It's important that patients be educated and empowered as they embark on their clinical trial journey – and a revitalized approach to informed consent could be key to this. Thus, there will be great benefits to the patient to transform this process into a digital realm, with multimedia content and on-demand access to online consent tools, clear and easy-to-understand trial information for patients, and a consenting process that is tailored to the individual patient’s needs.

Although the implementation and adoption of eConsent cannot replace patient-site relationships in terms of ultimately deciding whether to participate or supporting the patient’s clinical trial experience, TransCelerate believes it will be an essential asset to improve communication and interaction between patient and the trial site.
Stakeholders in the Clinical Trial Ecosystem Recognize Inefficiencies in the Existing Consent Process

“The push for eConsent is strong: in recent years, we’ve observed health authorities such as the Food and Drug Administration, as well as many other industry organizations, issuing guidance to further refine the informed consent process,” states Vanaken. “TransCelerate has stepped up to focus on this area in part because we recognized that through collaboration we can multiply the benefits to the industry, and patients specifically, to create meaningful change relating to informed consent processes. In this and other areas in R&D, we’ve learned that working together on certain common pain points that have no bearing on the vibrant competition that takes place among members is much more efficient than trying to solve these problems in silos. Further, we recognized that the collective experience of the R&D professionals that comprise TransCelerate Member Companies could help us establish smart and innovative ways to improve the informed consent process for patients and all other affected stakeholders.”

Two key elements of TransCelerate’s eConsent Initiative are a Framework and an Implementation Toolkit. These elements, to be clear, are not building blocks to an eConsent platform, but are instead key resources to assist sponsors, CROs, sites and vendors in their journey to provide patients with clear and easy-to-understand clinical trial information.

“The Framework addresses the ‘what’ of eConsent. As in: What are the different multimedia components, what are the benefits and concerns for stakeholder use, and what are some of the options for using these multimedia components to achieve a more streamlined and efficient process?” Vanaken explains. “There are several components that can be used in a multimedia informed consent process – video, audio, comment boxes, electronic signatures – that TransCelerate believes would help eConsent reach its full industry potential.”

The Implementation Toolkit addresses the “how” of eConsent. “By this we mean, how can sponsors effectively use various multimedia options and related internal and external processes as the industry shifts from paper to digital, and what documents might sponsors need or want to consider submitting to external personnel, like health authorities?” posits Vanaken.

She continues, “What we’re focused on now is developing guidance on good and effective alternatives for merging the ‘what’ and ‘how’ together into a single combined work product that will aid organizations in moving towards that digital, advanced informed consent pathway with patients.”

Successful industry adoption of eConsent will empower patients, the families that love them, the providers that care for them and the investigators conducting the trial they are enrolled in. As we collaborate across TransCelerate membership and with health authorities, sites, IRBs (independent ethics committees) to develop and refine the Framework and Toolkit, we will also work closely with patients, our most important partner, to integrate their unique insights into these important deliverables.

Industry Lens

A Patient’s Perspective: Finding a Clinical Trial

A Discussion between T.J. Sharpe and Dalvir Gill

In this piece, patient advocate and cancer survivor T.J. Sharpe sits down with TransCelerate CEO Dalvir Gill to talk about the clinical trial that saved his life, and his journey to find it.

Dalvir: Four years ago, you were diagnosed with stage 4 melanoma - and given a very upsetting prognosis. Can you talk about your initial experience with your illness?

T.J.: At the age of 37, I walked into the hospital with a spiking fever. After getting admitted, the ER doctor came up to me and told me he’d reviewed my x-rays, that there were spots on my lungs, and that I was having a recurrence of cancer. Cancer? My brain was flooded with negative thoughts, simultaneously, I was positive the doctor mixed up my file with someone else. Instead, I was diagnosed with stage 4 melanoma, and this is where my cancer story begins.

After receiving this world-shattering news, I immediately underwent surgery to remove one of my tumors. When it was time to sit down and talk about a post-surgery plan, a general oncologist on my case showed up with my tumor reports and started talking about the standard of care chemotherapy regimen. There was no mention of a clinical trial.

After he explained this care option, he told my wife and I that I’d be lucky if I was alive in two years. I knew how bad stage 4 melanoma was, I knew that it was not a good prognosis – less than 10% of patients with my condition had a five-year survival rate. But I had a four-week old son. “Maybe two years” wasn’t going to give him the chance to get to know me. It wasn’t good enough. So we started looking for other options.
Dalvir: So here you are today – healthy, energetic and with a story to tell. How did you come to find “other options”? Was that process cumbersome?

T.J.: Exploring and understanding my treatment options was an overwhelming process. With my late stage cancer diagnosis, I was at first simply trying to wrap my mind around the question: what is happening? But I knew I couldn’t be paralyzed by this question; I had to act – and fast. So, we went through a process of peeling apart some other questions: What is standard of care versus a trial drug? Am I eligible for a clinical trial? How does a clinical trial even work? What does it require from me?

I had worked in the pharmaceutical industry for a while as a consultant, and while I was involved in the IT side of things, I still had some knowledge on clinical trials, and knew that emerging medicine was discovered this way. I feel lucky to have had this basic knowledge, as it instilled in me a belief that I should consider clinical trials as an option. I was also fortunate to have friends that put in hours of research to uncover what the best melanoma treatments were, and it just so happened that at that time, immunotherapy drugs were taking off.

I had four “second opinions” before I finally found someone who spoke about clinical trials as a treatment possibility. But by the time I arrived in that doctor’s office I was pretty educated about my disease and potential treatments. I had an open, comfortable discussion about the current standard of care, what had recently been approved, and could point to specific clinical trials I had read about and inquire if they were right for me. This rich discussion led to me applying and being accepted into a clinical trial.

My evolution from being overwhelmed by what treatment option to pursue and feeling intimidated by the amount of information available about my disease, to showing up at that doctor’s office armed with the tools I needed to have a productive conversation, is evidence of how important it is that patients act as their own advocate, surround themselves with a community that will advocate for them, and be highly knowledgeable about their disease.

Dalvir: Can you describe your experience participating in a clinical trial? How did you come to access the one that saved your life?

T.J.: Our understanding of clinical trials totally changes when you’re looking at it through the lens of a potential participant – rather than a consumer who is tangentially aware of them. Before I was in the patient position, I didn’t understand that there are many different forces at play that make a clinical trial possible. I also didn’t realize that I would have to surmount some very real complexities to be a part of one. For example, the first trial I was in was delayed – and almost didn’t happen – because the contract hadn’t been signed. I was exasperated – my doctor and I believed this was the best shot I had at long-term health, and I didn’t want an opportunity taken away from me because a piece of paper was sitting on someone’s desk. To some, it may have just been a document, but to me, this was my life.

As you know, clinical trials have historically faced paper-based issues; I, too, was somewhat aware of this from my IT work in the pharma industry. But now I knew the implications of those paper-based inefficiencies. Fortunately, after connecting with some folks at the trial sponsor company, I was soon enrolled. Unfortunately, after my fight to get into that first trial, I was a non-responder. These things happen – it’s just part of science. And it’s an important part because even my “unsuccessful” experience can hopefully help provide answers to why this drug works for some and not others.

After that first trial, I was set on finding another. This time around, an extremely lucky cascade of events took place: I was blogging about my cancer experience and the clinical trial, and someone who worked at a melanoma advocacy organization happened to read it and called me. I told that person that I was a non-responder and seeking another trial, and they called me back shortly thereafter with information on a new trial. The trial was being conducted at a small, local cancer center, and though it was near my home, to my knowledge it had not been advertised. Also, I found navigating ClinicalTrials.gov to be challenging, so I likely would not have found out about this trial without the guidance of the advocacy group. To me this speaks volumes to how challenging it can be to match your disease with the right care option. It can take a village.

This is the trial that saved my life. In the years since I’ve been on this drug, I have been quite productive, enjoying life as a father, husband, blogger and a cancer and clinical research advocate. I even participated in a triathlon earlier this year – something I dreamt of since the age of 17.

When I speak to patients now, I say this: before you start the first treatment that your doctor prescribes you, look up all possible options, including clinical trials. Be armed with information and smart questions. Pepper your knowledge with as many smart sources and experiences as possible.

Dalvir: As a patient, what would you like to see changed in the clinical trial process?

T.J.: Based on my experience, I strongly believe in self-advocacy to better navigate our complex healthcare system. But I do think it begs the question, why do I have to worry about finding the right treatment on top of dealing with my disease? This is a huge disservice to patients, and a problem with our societal knowledge of and value around clinical trials as a care choice.

I think my “pie in the sky” answer of what I’d like to be changed in the clinical trial process would be that every physician is educated on clinical trial options, or at the very least, can point their patients in the right direction if it is something they want to pursue. This way, we can ease the burden patients can feel to set forth on this path on their own. Doctors can act as true partners on the journey to accessing clinical trials by empowering patients to make informed decisions.

I do realize that this would be a massive undertaking with many, many challenges. Short of that “perfect” solution, what I would like to see happen in the coming years is the development of better online tools that provide patients with clinical trial information.

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Important to this is a simple user journey, and easy-to-understand content. At this point in time, finding the right information from a massive amount of online resources is daunting, and can turn a lot of patients away from moving forward with accessing a trial. Having a common starting point, or a few known starting points, might streamline the process for patients and care providers.

As a patient who has been through it, I also believe there needs to be a focus on recruitment and engagement – two issues that, as you very well know, cause roadblocks in drug development. Central to improving process around this, I believe, is better communication to patients around the value of clinical trials. I think that patients may not be aware that when they join a trial, it’s not just that they’re getting a chance at improved outcomes for themselves, but are helping others as well. We need to enable them to see the big picture: that they are contributing to science and to the future. Perhaps making the connection that everyone is a patient might elevate the idea that trials don’t just help the individual, but help our community too.

I also feel that there needs to be better messaging around the clinical trial process as well, so patients can know, roughly, what to expect from day one. Springing information on them randomly during a trial, or in a complex way, deters patients.

Dalvir: What would you like to see from TransCelerate and other industry organizations to improve clinical trials for patients?

T.J.: TransCelerate is an organization of change agents. The leaders who are involved in TransCelerate can bring its initiatives and this innovative mindset back to their respective Member Companies, and push progress forward. You are creating meaningful change for clinical trials, and for patients.

I believe that bringing patients into the discussion is essential. Industry needs to continue to ask patients what it’s like out there navigating trials, what patients are talking to each other about when it comes to their diseases, and what messages they want to see delivered. As TransCelerate knows well, collaboration is so important to R&D. I would like to see these collaborative efforts extended to include patients.

Educational efforts are also key. Some patients don’t know where to look for trials, and some patients don’t even know to look at all. Industry need to help bridge this knowledge gap. It’s a shame that some people couldn’t get into the trial in time simply because they didn’t know it was an option.

Some of the initiatives that TransCelerate is working on can be complicated to explain to people unfamiliar with clinical research. But you are working on enormously important areas that have an impact on us, the patients. Distributing information on your work only increases the knowledge pool and lets them know that you are truly working for them.

You can check on T.J.’s progress and research at his Patient #1 blog.

Afterword from Dalvir Gill

I had the pleasure of meeting T.J. Sharpe earlier this year at a conference; since that first encounter, we have had multiple conversations about his experience with cancer, clinical research and survivorship, and he has reminded me time and again of how critical it is that we make patients centric to our work. We appreciate T.J. allowing us to share his story, and hope that through sharing it, we can bring to light the challenges that so many patients face in navigating the complex world of clinical trials.

TransCelerate Member Companies believe that there is an enormous opportunity to improve the patient experience in clinical research. Enhancing patients’ ability to find and enroll in trials, elevating patient understanding of how a clinical trial works and its broader contributions to medical science, technological solutions to ease patient burden and improve their trial experience, educational initiatives that ensure clinical research is offered as a viable care option, and process efficiencies to make recruitment and participation in clinical research streamlined and simplified – these are among our priorities in our initiatives dedicated to the patient.

We’ve also begun an exciting new pursuit: working with Patient Advisory Boards to gather feedback directly from patients on various areas related to clinical research.

We look forward to embarking on this journey, together with patients, to advance clinical research and help improve the health of people around the world.
Sanjay Jalota of Member Company Johnson & Johnson

Sanjay shares insights on TransCelerate’s Regulatory Council

TransCelerate is known for its ability to work harmoniously with various stakeholder groups within the clinical ecosystem and this is central to the organization’s strategy. We collaborate across Member Companies, with investigator sites, with patients, with CROs, and many more organizations involved in drug development. One important group that we also engage with is Global Health Authorities. Working in tandem with this important stakeholder is critical to building innovative, industry-transforming solutions. With this belief in mind, TransCelerate established a Regulatory Council to help advise TransCelerate Initiatives on how to productively engage with Health Authorities around the world. Taking their feedback and experience into account can ultimately bring medicines to patients quickly and more efficiently, without compromising safety and efficacy.

To learn more about the Regulatory Council and its value to TransCelerate and industry, we sat down with Sanjay Jalota, Senior Director, Global Regulatory Affairs at Johnson & Johnson and the lead of TransCelerate’s Regulatory Council.

Q: Can you give us some background on the TransCelerate Regulatory Council? Why was it formed?

A: The Regulatory Council was formed in early 2013, not long after TransCelerate was formed. Representatives from each Member Company were asked to form a council, which ultimately turned into the Regulatory Council that we know today. The mission of the Council was to advise the TransCelerate Initiatives and the Oversight Committee (the primary governing body for decisions related to the operational direction of TransCelerate) on regulatory strategies and processes, and deliver engagement approaches for collaborating with Health Authorities around the world. Importantly, we wanted to optimize the best way to obtain feedback to inform our initiatives for a successful path forward.

Q: Why is it important that TransCelerate collaborate with and gather feedback from global health authorities?

A: In my opinion, health authorities are an important stakeholder, so it absolutely makes sense for us as an organization to strive to understand what they’re looking for and to make their involvement in clinical research easier. At the end of the day our job is to get medicine to patients faster; collaborating with global health authorities enables us to have more efficient internal processes in regards to developing and refining initiative tools, which in turn can lead industry who are implementing our solutions to complete studies quickly and safely.

When we first began engaging with health authorities our key purpose was to provide information to them about TransCelerate, and the initiatives we were working on. Now, several years later, with health authority relationships as a central tenet of our work, the pendulum has swung the other way: agencies have begun scheduling meetings with us, are consistently requesting updates on our work, and in general have started to more proactively engage with us. We’ve found that health authorities have grown more comfortable in the last few years speaking to TransCelerate as a body that represents some of the world’s most successful sponsor companies. They are recognizing that we have a common goal, and if we work towards that goal collaboratively, we can all be more efficient, effective and successful. This is a major proof point to the evolution of TransCelerate’s work and our value to the industry.

Q: How have regulatory experts from TransCelerate Member Companies provided strategic expertise to the Initiatives?

A: TransCelerate’s initiatives have a regulatory council liaison and that person’s role is to provide regulatory advice/guidance the team as they develop tailored solutions. We have seen the value of and impact of this role across TransCelerate; however, the Placebo and Standard of Care (PSoC) and Risk Based Monitoring (RBM) Initiatives are two great examples that I’ll share. Both the PSoC and RBM Initiatives were influenced by regulatory feedback. The PSoC Initiative enables the sharing of data collected historically in the placebo and standard of care control arms of clinical trials, with the goal of reducing the number of patients enrolled in clinical trials due to this reuse of previous study data. One of our Regulatory Council members had previously championed the Critical Path Initiative, which is a method of gathering feedback from the Food and Drug Administration (FDA). This experience was critical as we defined how this Initiative could achieve its goals.

With RBM, the initiative was prompted by the FDA suggesting that companies should turn towards a more risk-based monitoring approach. Our Regulatory Council Liaison regularly communicated updates on the team’s strategy and progress. This relationship resulted in the FDA requesting that member companies engage in nonbinding RBM pilots,

“At the end of the day our job is to get medicine to patients faster; collaborating with global health authorities enables us to have more efficient internal processes...”

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and provide the agency with metrics from those pilots. Not only does it allow us to integrate FDA feedback into our initiative’s goals and outputs, but having the FDA recognize and familiarize itself with RBM enables it to be more successful and supported by the biopharma industry at large. Further, with clinical development bodies adopting our RBM guidelines and framework, we want them to be as successful as possible. FDA feedback that we have integrated into RBM propels our methodology forward.

Similarly, the team took a proactive approach in securing feedback from other Health Authorities across the globe. Through interactions with the European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA), China Food and Drug Administration (CFDA), Health Canada, Mexico COFEPRIS, Korea MFDS, and other Asia Pacific and South American Health Authorities, we’ve expanded our global reach and engagement with Health Authorities.

Q: Can you talk about some key successes so far in 2016?

A: 2016 was a milestone year for the Regulatory Council. Here are a few highlights:

- We engaged in nearly 15 Health Authority face-to-face meetings around the world.
- We continued the expansion of our initiative connections with Health Authorities.
- We’ve visited Brazil, Spain and Taiwan for the first time to meet with their regulatory agencies.
- Our meeting with the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) was highly productive. For us to engage further with the MHRA was a major success.
- Further, we had a very positive meeting with European Medicines Agency (EMA), which indicated that in the future they may want to work with us in a more collaborative way, including regular meetings over the next few years.
- We also had a very positive annual touchpoint meeting with FDA sharing significant accomplishments and an update on current initiatives. There was a high level of engagement and FDA highlighted the meaningful contributions that TransCelerate has made.

In general, we have experienced many “firsts” this year – which is exciting for the Council. As for what’s next, we anticipate that we will expand our focus to patient awareness and access. TransCelerate is making progress on how best to integrate the patient perspective into clinical research, and working on historical pain points such as education and engagement. To support this, the Regulatory Council has started setting up specific strategies for engagement with health authorities for initiatives such as eConsent, eLabels, and Clinical Research Awareness & Access.
Your Perspective

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

What are the Key Factors Used to Determine Priorities for TransCelerate’s Initiatives?

Since its launch in 2012, TransCelerate BioPharma has focused on improving the health of people around the world by accelerating and enhancing the research and development of innovative new therapies. Our Member Companies share this vision, and are listening to pain points that are common across the industry and finding ways to solve them together. One of TransCelerate’s greatest strengths is the collective experience, knowledge and passion not only given to the execution of each initiative, but to the careful ideation that goes into which challenges we choose to tackle. Our portfolio of initiatives is guided by our strategic priorities:

- **Improving the site investigator experience** as they work with sponsors to execute clinical trials.
- **Facilitate the sharing of clinical trial related information** -- as appropriate -- amongst industry stakeholders, focused on exchanges of information that would enable the industry to capture efficiencies.
- **Enabling the industry to move toward greater harmonization of clinical trial processes** to facilitate the advancement of technologies and processes within the broader clinical ecosystem.
- **Through collaboration, streamlining redundant sponsor activities** to reduce investigator and patient burden, while refocusing resources to drive and deliver innovative drugs to patients quickly and safely.
- **Enhancing the patient experience** by decreasing patient burden, enabling a better-informed patient and improving clinical research awareness, study participation and engagement.

With our strategic priorities as our guide, we continuously identify and assess potential initiatives based on three criteria:

1. **Impact**: The value to our mission and future state of clinical trials, as well as suitability.
2. **Effort**: The feasibility, time to completion and use of innovative approaches.
3. **Risk**: The external acceptance, adoption risk and availability of appropriate resources.

Our strategic priorities and assessment framework are considered at the concept period, as we build our deliverables for the new initiative and as we distribute our findings within clinical trial ecosystem.

Has TransCelerate Elevated the Role of Collaboration as it Works to Simplify and Accelerate Research and Development?

Our challenge as an organization and as an industry is not to recognize that there are many areas in clinical development that have opportunities for improvement, but rather to examine in which specific areas we can truly make a positive impact.

One example where we have made significant progress is alleviating duplicative burdens on clinical trial sites and their patients, most noticeably through our site-focused initiatives. Although TransCelerate does not represent the entire biopharmaceutical industry, we feel that we can make valuable contributions to resolving these key pain points given the vast array of expertise, practical experience, and knowledge derived from the number of clinical trials our collective membership has conducted.

Another area our collaboration has been focused on are our data sharing initiatives, such as the Placebo and Standard of Care (PSoC) Data Sharing Initiative, where participating Member Companies are pooling historical control arm data in order to propel each other forward and improve the trial experience for patients. The Initiative is already seeing a reduction in the number of patients in the control arms of some studies, and in one case we observed the need for a planned observational study was negated entirely. The shareable data and knowledge transfer that comes with the adoption of the PSOc database, has the potential to alter burdensome clinical trial processes for patients, sponsors, sites and regulators.

Have something you want to ask us? Submit it here! We will continue answering your questions in future newsletters.
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
January 25, 2017
Miami, Florida

Patients as Partners
February 2, 2017
London

Patients as Partners
March 2, 2017
Philadelphia

Clinical Trial R&D Leadership Summit
March 9, 2017
Miami, FL

SCRS EU Summit
March 19, 2017
Barcelona, Spain

Asia R&D Summit
March 21, 2017
Shanghai

DIA Euro Meeting
March 29, 2017
Glasgow, Scotland
Check Out Our Greatest Hits from Q3 2016

@Clin_Info_News: @TransCelerate’s SQT Initiative introduces new solutions supporting R&D of new therapies. bit.ly/2aMtY3B

@Clin_Trials: Discussion on @TransCelerate’s QMS Initiative bit.ly/2bV1ZpR: Interview w. initiative lead, Deb Driscoll

@LillyTrials: Insights from @LillyPad’s Ben Rotz on considerations for #clinicaltrial data transparency: ell.ly/pcy4

@DrugInfoAssn: From a Vision to a Conceptual Framework; Hear @transcelerate’s #ClinicalQMS team’s journey in our new podcast: ow.ly/27Mf30ZhKZT

@Clin_Trials: Update from SQT Initiative Lead, Katerina Hugeneck about informational programs bit.ly/2aV97yp @moealsumidae

@TransCelerate: Thanks @EdClinical for this Q&A detailing the benefits of a QMS framework in clinical trials bit.ly/2d279P9U

@MySCRS: The collaboration to partner with & share SQT Informational Modules was a success! prn.to/2dSVqER

@TransCelerate: Thanks to @ZacharyBrennan for this article on our progress on trial efficiencies in @RAPSorg: bit.ly/2963lXq

Inquiries

Please direct all inquiries as specified below:

Membership:
  membership@transceleratebiopharmainc.com

Conference and Participation
  conferences@transceleratebiopharmainc.com

Media:
  media@transceleratebiopharmainc.com

General:
  info@transceleratebiopharmainc.com

Site Training & Qualification:
  sqt@transceleratebiopharmainc.onmicrosoft.com

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