

# ACCELERATE >>>>>> TO INNOVATE

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### TransCelerate Launches Technology Enabled Common Protocol Template

TransCelerate's Common Protocol Template (CPT) Initiative was established to address the increasing complexity of clinical trial protocol development through the development of practical solutions. This complexity – and lack of consistency among sponsor companies – has increasingly led to inefficiency and delays in the drug development process, delaying the delivery of quality medicines to patients. TransCelerate believes that the adoption of its common protocol template has the potential to integrate processes around protocol development, simplifying interpretation for trial sites, institutional review boards and regulators, and streamlining clinical trials.

What progress has this Initiative made in the two years since launch?

Thus far, the TransCelerate CPT Initiative has created the following tools:

- A single Common Protocol Template that can be used across all phases and study types
- A Microsoft Word-based tool to automate use of the Template
- An Implementation Toolkit to facilitate evaluation and implementation

For more thorough details, read on.

### [Common Protocol Template Educational Materials](#)

The CPT Initiative worked with industry stakeholders to create its first clinical

trial protocol template containing common structure and model language, as well as libraries containing common language specific to study populations and therapeutic areas. These materials were released in December 2015.

What does this collection of resources include?

- **CPT Core Template:** This is the content template for the protocol body and appendices, designed for use in all phases of a trial and disease areas. It includes a common structure, common text and suggested text that we recommend be used in a trial's protocol.
- **Population-Specific Libraries:** TransCelerate released four libraries containing recommended text specific for certain populations. Currently we have dedicated content for studies with healthy volunteers, with patients, and studies in asthma and diabetes.
- **The CPT Implementation Toolkit:** This toolkit includes Frequently Asked Questions, a mapping exercise worksheet and instructions, a tool that assesses the impact that implementation of CPT will have on different stakeholder groups, a text color guide that provides understanding of the meaning of color coding in the CPT, and PowerPoint presentations to facilitate communications within organizations evaluating or electing to implement the CPT.

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## Technology Enabled CPT Now Accessible to the Public

Recently, TransCelerate announced the availability of a Technology Enabled edition of the CPT. Our continued partnership with the Clinical Data Interchange Standards Consortium (CDISC) through our [Clinical Data Standards Initiative](#) paved the way for the new edition of the CPT. The Technology Enabled edition of the CPT differs from our original edition because of features such as point and click population of selected template sections from the accompanying libraries, content controls for selected protocol sections to enable automated re-use of protocol information. It also provides for an opportunity to introduce data standards up front, which is essential for end-to-end data flow, real-time data visualization and traceability of the data.

What are some distinct benefits of this new iteration?

- Accelerates the delivery of a high quality first draft protocol.
- Reduces human error thereby reducing avoidable amendments that invariably slow clinical trials.
- Links to objectives and endpoints with connectivity to CDISC therapeutic area standards.
- Enables automated reuse of selected protocol level information.
- The use of content controls assures that the same information is updated in any section it appears automatically during protocol editing.



- Decreases confusion for stakeholders and enables a simplified study start-up.
- Common approach for handling protocol amendments.

## Close Collaboration with FDA and NIH

Earlier this year, [the Food and Drug Administration \(FDA\)](#) announced that they were partnering with the National Institutes of Health (NIH) on a draft clinical trial protocol template. They, like TransCelerate, recognized that a clinical trial protocol is a critical component of any drug development program, and is deserving of attention - and modernization.

Peter Marks, Director of the FDA's Center for Biologics Evaluation and Research wrote, "We see the template as a way to facilitate creativity and innovation, not inhibit it." Many of

TransCelerate's efforts are grounded in the idea that when we streamline and harmonize processes, we reduce burden and free-up room for innovation.

The FDA and NIH's template will contain instructional and sample text for investigator sponsored studies. The hope is that better organized and high-quality protocols will accelerate the review process at both the FDA and NIH.

In a blog post detailing their protocol template, the FDA recognized TransCelerate's efforts on a common protocol template, and their plan to collaborate with TransCelerate to ensure consistency for the research and development community. We hope that by working together, we can ultimately generate even greater efficiencies for the entire clinical trial ecosystem. ●

## Industry Lens

### Data Transparency: Questions, Challenges & New Developments

By Benjamin Rotz, Director of Medical Transparency at Eli Lilly & Company and Co-Leader of the [Clinical Data Transparency Initiative](#)

"Data transparency" has gained a considerable amount of attention - and for good reason: transparency in research can drive scientific innovation at a faster pace and potentially lead to major discoveries. Over the last few years, stakeholders in clinical research - sponsor companies, investigators, regulators and patients

- have increasingly recognized the need for increased data transparency, specifically how data are reported and shared. Collaboration for data transparency and sharing is now at the core of many healthcare organizations' mission statements. Indeed, it was timely and relevant that TransCelerate put efforts behind an Initiative around clinical data transparency. We believe clinical data transparency is a key factor in enhancing the way we conduct trials, so we amassed our collective expertise behind an adoptable model approach that protects patient privacy, enables regulatory compliance and pools scientific knowledge.

### Questions to Consider as we Examine Data Transparency

At the start of our Clinical Data Transparency Initiative, we developed three guiding questions that we always consider as we try to achieve true data transparency:

1. *Most importantly, how do we protect the privacy of patients participating in a clinical trial while still providing useful information to the scientific community? Patients are participating in clinical trials recognizing the risks and potential benefits so that we can find new and*

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*better treatments for others with their condition. It's imperative that we acknowledge the time they dedicate and the chances they are taking by respecting their privacy. At the same time, we need a consistent way to anonymize data from numerous companies as this approach will allow researchers to take data from one or more companies and perform additional data analyses.*

**2. How we can improve upon processes so that they can be easily adopted by organizations interested in sharing data?**

*Change can be complex – there is definitely an adjustment period that we must recognize and address. Clinical trial sponsors who have historically not had a mechanism for sharing data, and did not have to traverse this world of redacting privacy information are in need of insights and in time, proven methods.*

**3. How do we adopt a model approach to information-sharing while taking trial and regulatory variables into consideration?**

*We're faced with determining the levels of information that can be made available for each clinical trial and how the data in different formats might be shared. The model approaches then have to be flexible so they can be adapted for different trial types.*

## Regulators Present New Challenge to Data Transparency

We simply cannot address data transparency without reflecting on the role of regulatory agencies, especially the latest shifts taking place in Europe, where many of TransCelerate's Member Companies have presence and conduct trials.

The European Medicines Agency (EMA) has issued guidance on publishing clinical data known as "Policy 0070."

EMA policy 0070 will be implemented in two phases, the first phase is the sharing of clinical documents from EU submission and the second phase will address sharing individual patient level data. Earlier this year, the EMA introduced changes and detailed requirements that expanded the policy's original use in some significant ways or

provided updated requirement: sponsors must redact or edit patient narratives which contain a considerable amount of patient information (rather than remove from clinical study reports); companies must identify "company confidential information" and provide justification for why they consider certain information confidential; and companies must provide a detailed anonymization report that explains how the sponsor company anonymized the submission to reduce the probability of patient re-identification.

So what does this mean for biopharma R&D, and for TransCelerate? Our three model approaches to protecting patient privacy will have to be reexamined and considered within the new framework shaped by Policy 70. We anticipate that we'll see specific and immediate impact on how we anonymize trial information and how sponsor companies conduct their medical writing, though more comprehensive guidance on how to interact with new Policy 70 provisions is still to come. See our [Initiative Assets](#) for more on our progress.

## What Developments Will Influence the Future of Data Transparency?

Beyond the EMA's Policy 70, there are other several other forces that could impact clinical data transparency in coming years:

- **Publishing Data in Peer-Reviewed Journals:** *The International Committee of Medical Journal Editors (ICMJE) earlier this year put forth a [proposal](#) for sharing*

*clinical trial data as a prerequisite for publication. The ICMJE is currently reviewing the comments that industry stakeholders shared in reaction to the proposal; therefore, specific provisions and impacts are largely unknown. What we do know is that authors, including those from companies or academic institutions, hoping to publish in one of their journals (which includes British Medical Journal, Journal of the American Medical Association, The Lancet and the New England Journal of Medicine) will have to adhere to the ICMJE's data-sharing requirements, and will thus have to acclimate to being more accountable and open. For these reputable medical journals to stand firmly in support of transparency means increasing normalization of clinical data transparency and sharing practices. The year after ICMJE formally puts out their proposal will definitely be one of major adjustment, but we welcome the spirit of this change, as it can contribute to better patient outcomes and elevated confidence in trial results.*

- **New EU Clinical Trial Directive:** *The EMA is scheduled to implement their new Clinical Trial Directive in 2018. This directive will include additional transparency requirements, including the requirement for clinical trial sponsors to post a summary written using plain language for the general public. Sponsor companies are working now to determine how to write such summaries and what is the important information to include while keeping the summary a manageable length. We welcome this change as it provides an approved mechanism for sharing information about the results of clinical trials in a way that previously had not been available for patients.*

With increased industry attention, regulatory guidance, it's a time of evolution for researchers and sponsor companies that's navigating data transparency and sharing. It is clear that more recognition around the importance of data transparency and sharing will enhance the work conducted within the clinical trial ecosystem. ●



## Deborah Driscoll from Merck Lists 5 Reasons Why Every Clinical Trial Sponsor Should Consider Building a Clinical Quality Management System (QMS)

Today, clinical trial sponsors lack cohesive regulatory guidance that defines a clinical Quality Management System (QMS). As a result, organizations continue to implement ICH Q10 guidance

or practice ISO methodology that ultimately are not tailored to the specific needs of a clinical trial and could lead to reduced quality and overall organization inefficiencies.

When asked why every clinical trial sponsor should consider building a clinical QMS, Deborah Driscoll, VP of Quality Assurance at Merck Research Laboratories and Lead of the TransCelerate [QMS Initiative](#) highlighted the value a clinical QMS can bring to organizations.

### Q: What are the key reasons every clinical trial sponsor should consider building a clinical QMS?

A: Our work through the QMS Initiative has largely focused on clinical quality —the complexity by which clinical trials are designed, performed and executed. The reasons every clinical trial sponsor should consider a clinical QMS are easy:

1. It sets the groundwork for good quality and requires an upfront setting of expectations that we hope will facilitate partnering and well run trials.
2. Involves interaction with leadership as a commitment that is needed for quality and a focus on continuous improvement, organizations should experience fewer quality-related delays in bringing needed safe and effective treatments to patients.
3. Ensures that there are adequate resources focused on quality at all times.
4. Drives an understanding of metrics and provides alerts when we're not meeting quality performance.
5. Most importantly, a clinical QMS should support expediting patients' access to medicines.

### Q. What is the hardest part of building awareness of the value of a QMS?

A: The hardest part is seeing immediate progress within individual companies. Within the member companies that have elected to develop quality management systems, we have seen great strides and early results. I think we've done a tremendous amount of work with the many TransCelerate Member Companies, but more broadly in the industry, we'd like to see an improvement in understanding what clinical quality management is, why it's important to have a focused system, and then feedback on implementation so there is a

mutual understanding of a clinical QMS and its role. A clinical QMS is not an add-on, instead it needs to be embedded in the culture of the organization and in the execution of work every day, 365 days of the year.

### Q: Are there specific details around how embedding a Clinical QMS can help drive meaningful change?

A: As we've described in our concept paper, published in Therapeutic Innovation & Regulatory Science and titled ["TransCelerate's Clinical Quality Management System: From a Vision to a Conceptual Framework,"](#) having efficient processes that people know well and are compliant with regulations internationally is essential to efficient drug

development. Ideally, every person working within a quality system is knowledgeable of their role, the importance of accountability and how their work supports quality is highly valued. A clinical QMS provides for an opportunity for knowledge sharing within sponsor companies so that good history repeats itself, lessons are learned, and quality is distributed across the organization.

### Q: Do you think the biopharma industry as a whole agrees that a Clinical QMS is needed?

A: My hope is that people who execute clinical trials believe that quality is a major differentiator in effective clinical trial operations. To

prevent delays in submissions, reviews or approvals, you have to plan upfront – quality measures can save time and keep clinical trials on schedule. ●

*Deborah Driscoll joined Merck as the head of Quality Assurance in July 2015, assuming responsibilities for GCP, GLP, GPvP in addition to Animal Welfare oversight within Merck Research Laboratories. In 2014 Deborah assumed the leadership role for TransCelerate BioPharma's Clinical Quality Management System Team working with 20+ member companies to develop and advance a clinical quality framework to enable consistent and timely delivery of reliable data that may be used by an organization, its partners, regulators, clinicians, and patients to make informed decisions. Deborah holds a B.S. in Animal Science and an M.S. in Biology.*

To learn more about the TransCelerate QMS Initiative, visit our website at <http://www.transceleratebiopharmainc.com/initiatives/quality-management-system/>.

## » Your Perspective

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

**In your last newsletter, you focused on your new Clinical Research Awareness & Access Initiative that “taps” into a new stakeholder: patients. Why did you determine this to be a space to focus on, and how are you planning to integrate the perspectives of patients into the Initiative?**

At TransCelerate, we believe that patients are the single most important stakeholder in the R&D ecosystem, so it was a natural progression that we launch an Initiative that specifically focuses on better informing and engaging the patient. The Clinical Research Awareness & Access Initiative couldn't come at a better time: Memorial Sloan Kettering Cancer Center in New York recently [conducted a survey](#) that revealed only 40 percent of Americans have a positive overall impression of clinical trials, and merely 35 percent would be likely to enroll in one. This is an important issue that TransCelerate is focused on addressing. We're fortunate to have a unique opportunity to truly make an impact on engaging with patients before, during and after participating in a clinical trial.

The patient perspective is critical to helping us think through the tangible solutions and recommendations that come from this Initiative. We're examining ways to tangibly capture and measure the patient experience throughout a clinical trial, and then deliver that information to the teams running the trials so that they can make the trial more attentive and mindful of patient needs.

We're also excited to be working with the Center for Information and Study on Clinical Research Participation (CISCRP), an organization dedicated to activating the public and patients as partners in the clinical research process. CISCRP will be establishing Patient Advisory Boards with the Clinical Research Awareness & Access Initiative and a few of our other Initiatives focused on the patient experience. This effort will enable interaction between TransCelerate and patients, and integrate their perspectives and needs into our work.

**Companies within this industry are known for having their own processes, terminology and culture. What have you observed in how peers in TransCelerate operate together that can be leveraged across the industry?**

Biopharma companies harbor unique processes, terminology and cultures; however, we've learned at TransCelerate that these factors are not a barrier to success. The solutions we've established and shared with many stakeholders involved in research and development are a testament to the realized possibility that a group of differentiated organizations can identify a common goal and efficiently meet that goal. In reality, we're all working towards the same outcome - bringing lifesaving medicines to patients.

In the few years since TransCelerate was founded, we've identified important lessons learned that can be leveraged across other industry groups and biopharmaceutical organizations:

**Have something you want to ask us? Submit it [here!](#) We will continue answering your questions in future newsletters.**

1. Keeping the “big picture” in sight. It's about diagnosing a shared end goal, which for all of us at TransCelerate, is developing drugs to extend and improve human life.
2. Uncover where you and others have commonality. For TransCelerate, that was looking at common issues and inefficiencies that we're all experiencing and trying to figure out.
3. Recognize where it is more impactful to work as a collective force rather than in siloes. For some critical clinical trial processes (like risk assessment and protocol development), the only way to generate meaningful benefits for patients, sites, and sponsors was to create common solutions that not only TransCelerate Member Companies, but the entire industry could leverage. In order to move the needle on scientific innovation, some of our initiatives focus on knowledge sharing such as the [Placebo and Standard of Care Data Sharing Initiative](#), where participating Member Companies are pooling data in order to propel each other - in our individual research - forward.

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### What do sites think about TransCelerate's efforts? Can you give perspective on the sites' thoughts?

One of TransCelerate's key areas of focus is improving the site investigator experience. This was an early priority for TransCelerate, as we recognized that there have been many historical burdens on clinical investigator sites such as completing multiple forms and trainings for several companies for different trials. We've developed tools and resources to improve the qualification and training process, while freeing up time and resources for investigators and sponsors alike, to focus on study-specific and value-added activities.

Indeed, in May of this year, Dr. Christophe Berthoux, CEO of Synexus, a leading site management organization, [\*penned a piece for CenterWatch\*](#) on industry efforts dedicated to reducing the burden of sites around the globe. Dr. Berthoux cites TransCelerate as one such effort, and spotlights how our site-focused initiatives, like our Investigator Registry and Shared Investigator Platform, are helping to reinvent clinical trials.

Through our partnership with the Society of Clinical Research Sites (SCRS) – an organization whose mission is to represent global research sites and work towards site sustainability – we've conducted multiple SCRS Site Advocacy Groups (SAGs) in order to facilitate meaningful dialogue between site professionals and industry leaders. These programs ensure that our sites focused initiatives are truly aligned with their needs, and that we can work together to enhance overall clinical trial efficiency and effectiveness. In a recent [\*press release\*](#) detailing our partnership, Christine Pierre, SCRS president, stated "On behalf of all sites, SCRS is deeply appreciative and applauds TransCelerate and other industry organizations committed to site engagement through the SAG program." We believe that as a result of our collaboration with SCRS, we are in possession of invaluable insights that can be used to create the needed solutions for site staff such as our [\*EDC System Training and GCP Mutual Recognition Programs\*](#). ●

## » Mark Your Calendar

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.



### Clinical Trials Asia

**August 2, 2016**

*Singapore*



### Disruptive Innovations US

**September 20, 2016**

*Boston, MA*



### Partnerships in Clinical Trials

**October 05, 2016**

*Boston, MA*



### 2016 Global Site Solutions Summit

**October 13, 2016**

*Boca Raton, FL*

## Check Out Our Greatest Hits from Q2 2016

@Medicine\_Maker:  
Congratulations Dalvir Gill  
of @TransCelerate for making  
our 2016 #PowerList!  
<http://ow.ly/4npVtV>

@RfwrightLSL: @Roche  
Combines Analytics + Clinical  
Operations = Better Feasibility  
Plans <https://shar.es/1ehWjQ>  
@TransCelerate @EdClinical  
@DrugInfoAssn

@pharmaphorum: "New  
monitoring methods can  
provide a more holistic  
& proactive approach to  
#clinicaltrial monitoring"  
@TransCelerate [bit.ly/1NRzy7F](http://bit.ly/1NRzy7F)

@TransCelerate: Janice Chang,  
our SVP of Global Operations,  
speaks to @eyeforpharma  
about streamlining drug  
development. See it here:  
[bit.ly/1qERnwd](http://bit.ly/1qERnwd)

@HealthBizBlog: Collaboration  
in pre-clinical & clinical dev:  
My interview with Dalvir Gill  
of TransCelerate  
<https://t.co/myATDdf9vF>

@TransCelerate: Thank  
you @NicolausWriting for  
this great article on our  
#SharedInvestigatorPlatform,  
feat. our leader @JackieKent19  
[bit.ly/1XtTsrw](http://bit.ly/1XtTsrw)

@MySCRS: Announcing  
@TransCelerate's Ongoing  
Commitment to Partnership  
with SCRS #ClinicalResearch  
Site Advocacy Groups  
<http://ow.ly/4mYVWT>

@CDISC: #CDISC &  
@TransCelerate Announce New  
Standard for #BreastCancer  
to Support Data Sharing for  
#Oncology Research  
<http://ow.ly/ko62300kMHF>

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