Join us on Thursday, June 16 for a call with TransCelerate and Member Company leaders when they recap recent significant accomplishments and highlight the progress of patient-centric initiatives.

We have scheduled two calls for this event, with identical content, although panelists may change. Click the link below to register for the session that works best for you.

**Session 1: 11 a.m.—noon EST**
**Session 2: 8—9 p.m. EST**

The Shared Investigator Platform Featured in Clinical Informatics News

In May, the Shared Investigator Platform (SIP) was the focus of a profile by Clinical Informatics News and Oversight Committee Member Jackie Kent (Lilly) provided an overview of the SIP, including how it works, the collaboration behind its creation and its goal of “revamping” the relationship between sites and participating sponsors.

Jackie speaks in particular about the changing landscape in the healthcare regulatory realm that has allowed the type of collaboration needed for the SIP. Jackie states, “The industry didn’t play this way in the past.” And, when describing the collaboration within SIP, Jackie states, “What you need to do is to be clear, concise, and effective, so it’s the perfect place to play together.”

To read the entire article, click [here](#).
TransCelerate In the News

CDISC and TransCelerate Announce Breast Cancer TA User Guide

Last month, the Clinical Data Interchange Standards Consortium (CDISC) and TransCelerate’s Clinical Data Standards initiative published the Breast Cancer Therapeutic Area User Guide. The User Guide will support clinical research and enable medical product development through the establishment and maintenance of data standards, tools and methods for conducting research in breast cancer. This project marks only the beginning for standards that will improve cancer research. In addition to breast cancer, the Data Standards team is working with CDISC on standards for prostate and colorectal cancer and will begin work on a standard for lung cancer by the end of the year. Developing standards for oncology is a priority for the team.

To read the entire press release, click here.

Conference Corner

PRISME Forum 18-May, 2016 - Prague, Czech Republic

Clinical Data Transparency team member Jason Coarse (UCB) spoke at the PRISME Forum Technical Meeting in Prague on the Anonymization and Sharing of Individual Patient Data from Clinical Studies. The presentation was viewed by over 50 members of the forum and spoke to the TransCelerate values, the Clinical Data Transparency workstream and in particular how the TransCelerate model approach to data anonymization is applied to UCB data. The session was well received by the group and tied in well with the “Understanding Disease through Mining Clinical Trial Data” theme of the meeting.

PSI Statisticians in the Pharma Industry 22-25, May 2016 - Berlin, Germany

Alun Bedding (AZ) spoke at the PSI (Statisticians in the Pharmaceutical Industry) annual conference in Berlin on Statistical Monitoring with a report on an Original TransCelerate Research Project. The session was attended by over 50 delegates of the conference. Other speakers on the same session included Marc Buyse from Cluepoints and Amy Kirkwood from UK Cancer Research. Participants expressed an opinion that statistical monitoring was needed, but as the field is still evolving some sponsors are reluctant to using it on all trials. The presentation did raise the awareness of TransCelerate work on Risk Based Monitoring (RBM) and the aspect of Statistical Monitoring.

Upcoming Conferences:

Eye For Pharma - Clinical Excellence Europe 14-June - London, UK
SCRS Asia-Pac Site Solutions Summit 14-15, July 2016—Melbourne, Australia

Join us at DIA 2016 in Philadelphia, PA

This year, TransCelerate is proud to be part of 10 sessions at DIA over the course of five days. This is a wonderful opportunity for TransCelerate to engage with the industry and for you to network with colleagues who are also part of TransCelerate. For a full list of TransCelerate presentations, check out the Events Calendar on SharePoint. Email us at Internal-News@TransCelerateBiopharmaInc.com if you’re able to join us Tuesday, June 28 for a special networking evening reception.
Regulatory Review

Upcoming Engagement with Health Authorities:

Upcoming meetings are listed below. For more on upcoming meetings with Regulatory Agencies, view the [Events Calendar](#).

EMA (EU) on 17-June

As part of an annual touchpoint with the EMA, leaders will be sharing significant accomplishments related to the Common Protocol Template, Quality Management System, and the Shared Investigator Platform. In addition, this meeting will also introduce the eLabels, eConsent, and eSource initiatives and gain feedback from the EMA on framework and deliverables.

TFDA (Taiwan) on 18-July

During this meeting, TransCelerate participants will provide an introduction to TransCelerate and an overview of the eConsent, eLabels, Risk Based Monitoring, and Site Qualification & Training initiatives.

Industry Engagement

TransCelerate Leaders Met with the AVOCA Group

In May, TransCelerate QMS initiative representatives met with leaders from The AVOCA Group, a consortium focused on the continuous improvement of outsourced clinical research.

The teams took the opportunity to reconnect and the QMS team provided an update on the initiative and TransCelerate.

Overall, the teams agreed they are aligned and have a synergy related to their goals and agreed to have continued meetings to share progress and gain feedback. Also, the teams will look for opportunities to align on talking points to differentiate the organizations and identify areas for collaborative presentations within the industry.
Industry Engagement

CPT Leaders Joined SCRS for a Webinar on 8-June

The TransCelerate Common Protocol Template (CPT) initiative represented by Workstream Leader Rob DiCicco (GSK), Oversight Committee Member Virginia Nido (Roche), and Rob Ferendo (Lilly) joined the Society for Clinical Research Sites President Christine Pierre for a webinar that reviewed how CPT and its accompanying authoring and editing tools will simplify the clinical trials enterprise for the benefit of all stakeholders.

The webinar was well-attended and there was a wonderful reception to the CPT by the audience. A recording of the webinar is available here.

Upcoming Engagement:

- TransCelerate Update to EFPIA Board of Directors 23-June
- TransCelerate Leaders to meet with the CRO Forum 23-June

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Key SharePoint Resources:

Overview deck
Member Contact List
Member Onboarding

What’s Tweeting?

Each month, we’ll take a look at our top Tweets that are generating buzz throughout the industry.

1,973 views!

1,923 views!

Don’t miss out — follow us @TransCelerate