Clinical Leader Interview with Jonathan Zung (UCB) on Trends Impacting Clinical Trials in 2016

In the article, Jonathan Zung talks about technology and advancements in clinical trials, and covers how TransCelerate will play a role. Jonathan cites the Risk Based Monitoring (RBM) work as an example of an approach that will simplify clinical trials, and both the author and Jonathan agree that guidance produced by TransCelerate has been instrumental in getting companies on board with work done by TransCelerate. Jonathan also discusses wearable devices and mentions eConsent as an example of an approach that uses technology to enhance the efficiency of clinical trials and the patient experience.

To read the complete article, click here.

Also in Clinical Leader, TransCelerate noted for Collaboration

In an interview between author Ed Miseta and James Gillespie, CEO of the Center for Healthcare Innovation, James Gillespie provides his predictions and insights on the healthcare industry trends in 2016, with a nice nod to TransCelerate’s work. Gillespie states, “...collaborations are one of the most exciting trends occurring in our industry. With initiatives like TransCelerate and PACeR, the number of collaborations between CROs and pharma will continue to grow and get deeper.”

Read the full article here.

“The trial of the future will be more patient centric. It will utilize technologies and approaches that will minimize the burden for patients.”

- Jonathan Zung (UCB)
TransCelerate Applauded for Collaboration and Initiatives

In the Applied Clinical Trials article, 2015 a year in Review: The Year of Clinical Trial Innovation, changes and innovation that took place in 2015 are explored, as well as predictions for the future. The author identifies trends including patient centricity, RBM, and data quality.

The author dives further into non-profit organizations introducing collaborative initiatives, and cites TransCelerate and others are spearheading new initiatives that are bringing together study sites, sponsors, and regulators to streamline clinical operations. He further goes on to call out specific initiatives including the Quality Management System framework, Clinical Data Transparency, e-Labels, and Placebo/Standard of Care.

Click here for the full article.

An article in PMLiVE, explores Risk Based monitoring (RBM) and how it’s changing clinical trials while referencing TransCelerate’s work in the space.

In the article, the author states, “Companies wishing to take the plunge in RBM can get a leg-up thanks to work being carried out by TransCelerate.” The article continues by stating that RBM was one of the first initiatives tackled by TransCelerate and that TransCelerate has been working on models of adoption like a review of technological considerations.

Click here to read the full article.

TransCelerate RBM Paper Mentioned by CluePoints

CluePoints—a company that creates central statistical monitoring solutions—posted a blog in which TransCelerate’s RBM work is mentioned, in particular, the recent paper, Detecting Data Quality Issues in Clinical Trials: Current Practices and Recommendations. The post discusses the pressure on sponsors to implement controls to identify data quality issues that impact trial outcomes.

CluePoint’s stance on the identification and mitigation of data quality issues in clinical trials echoes that of TransCelerate’s.

To read the full blog post, click here.
2016 Regulatory Council Meetings

During the TransCelerate Town Hall, Regulatory Council Lead Sanjay Jalota (J&J) gave an overview of the Regulatory Council, its structure and its plan for 2016. This year, the Council seeks to hold even more meetings with an ever increasing number of regulatory agencies.

Upcoming Meetings

The Regulatory Council is working together with Regulatory Authorities around the globe, along with TransCelerate Country Leads and Workstream Leads to schedule activities in the upcoming months. Planned engagements in Q1 2016 include:

- **Canada—Health Canada (15 Jan):** A Health Canada Informational Session will be held that includes a Risk Based Monitoring training forum opportunity for all of Health Canada and will also serve to introduce TransCelerate and review TransCelerate initiatives.
- **Germany—BfArM (15 Jan):** QMS will present the QMS workstream, gain feedback and determine interest in the Concept Paper, and confirm interest and identify next steps for Issue Management and Knowledge Management Frameworks.
- **Spain—AEMPS (21 Jan):** TransCelerate will be meeting with the AEMPS for the first time to introduce TransCelerate initiatives. Additional detail will be shared on the Site Qualification and Training, Shared Investigator Platform, Common Protocol Template, Data Standards, and Risk Based Monitoring initiatives.
- **USA—FDA (1 Feb):** The Quality Management System (QMS) team will provide work-to-date on QMS Issue Management and Knowledge Management Frameworks and will also provide an update on the Concept Paper.
- **Brazil—ANVISA (3 Feb):** TransCelerate will be meeting with ANVISA for the first time to introduce TransCelerate initiatives. Additional detail will be shared on the Site Qualification and Training, Shared Investigator Platform and QMS initiatives.

Be sure to check back to this section in the coming months to see a high-level debrief on these planned engagements.

Conference Corner

Upcoming Conferences:

- **Dpharm 2016 EU** 9-10, Feb 2016 - London, UK
- **SCOPE Summit** 23-25, Feb 2016 - Miami, US
- **Clinical Innovation Congress** 9-10, Mar 2016 - London, UK
- **Clinical Trial Collaboration Summit** 21-22, Mar 2016 - Boston, US

In 2016, conferences will continue to be an important part of TransCelerate engagement with industry leaders. If you have suggestions for future conferences at which TransCelerate should participate, or are interested in getting involved, contact Internal News.
Industry Engagement

Upcoming Industry Engagement:

- **TransCelerate Leaders meeting with Pistoia Alliance 25 Jan**
  Leaders from TransCelerate will meet with the Pistoia Alliance in order to discuss each organization’s portfolio of projects and identify if there are any current or future areas for collaboration.

- **FasterCures Webinar: Collaboration 2.0: Exploring the Future of Research-by-Collaboration in Medical R & D 28 Jan**
  TransCelerate CEO Dalvir Gill joins leadership from the FDA, the Critical Path Institute and FasterCures. The panel will discuss considerations for starting a new medical R&D collaboration/consortium, principles for successful collaborations, how to position the outputs to facilitate both the regulatory process and transition to use and more. To register, click [here](#).

- **RBM to meet with representatives from Cancer Research UK 1 Feb 2016**

- **Representatives from QMS, RBM, and SQT to meet with Society of Quality Assurance 5-7, Apr 2016 – Grapevine, TX, US**

Enhancement to the TransCelerate Homepage

After receiving feedback on our website, we are proud to announce we have a new solution in place to easily post news coverage, announcements, and upcoming events.

Now in the middle of the page, you’ll see three boxes that contain announcements and events, making it easier to share the latest information with both internal and external stakeholders.

We hope you’ll find this a great upgrade as we continue to maximize the efficiency of our site.