Collaborating to Transform the Industry: An Update from TransCelerate BioPharma Inc.

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Faculty Disclosure

In compliance with ANCC Guidelines, I hereby declare:

I do not have financial or other relationships with the manufacturer(s) of any commercial service(s) discussed in this educational activity.

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Presentation Objectives

• Provide an overview on TransCelerate along with a brief update on TransCelerate accomplishments and what’s next

• Discuss insights from 4 of our key site impacting initiatives:
  • Risk Based Monitoring
  • Site Qualification & Training
  • The Shared Investigator Platform & Investigator Registry
  • Answer any audience questions
Who is TransCelerate?

Non-profit organization, founded in 2012, comprised of the world’s leading biopharmaceutical companies committed to engaging in sharing outcomes that will increase quality and improve patient safety.

Our Vision
To improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.

Our Mission Statement
TransCelerate’s mission is to collaborate across the global biopharmaceutical research and development community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of new medicines.
Who is TransCelerate?

20+ Member Companies with the spirit of partnership, innovation, and collaboration on initiative goals.
TransCelerate Engages with Stakeholders

TransCelerate recognizes the need to collaborate not only across participating Member Companies, but also Investigator Sites, and Regulatory Authorities.
TransCelerate Engages with Stakeholders

We continue to strengthen our engagement with key industry groups, particularly CROs and Sites.

- A **CRO Forum under ACRO**, provides meaningful input on TransCelerate projects of interest to the CRO community
- Open to ACRO members and non-members

- The creation of **Site Advocacy Groups** with the Society for Clinical Research Sites provide a valuable feedback channel for interacting with Investigators and sites for select initiatives during solution development
- 20 meetings with SAGs held to date
Through collaboration across companies and within the industry, TransCelerate experiences significant growth in 3+ years.
Choosing Initiatives
We select new initiatives in line with our five Strategic Priorities.

**Improve the Site Investigator Experience**
Facilitate Information Sharing
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.

Enable Harmonization of Clinical Trial Processes
Enable the industry to move toward greater harmonization of clinical trial processes to facilitate the advancement of technologies and processes within the broader clinical ecosystem.

Enhance Sponsor Efficiencies
Through collaboration, streamline redundant sponsor activities to reduce investigator and Patient burden, while refocusing resources to drive and deliver innovative drugs to patients faster and safely.

Improve the Patient Experience
Improve the Patient Experience by enabling a better informed patient and improving study participation.

Improve the Site Investigator Experience as they work with Sponsors to execute Clinical Trials.
Our Initiatives

**Active**
- eConsent
- eLabels
- Placebo / Standard of Care Data Sharing
- Quality Management System
- Risk Based Monitoring
- Comparator Drugs

**Business Continuity Execution Phase**
- Common Protocol Template
- Clinical Data Standards
- Investigator Registry
- Shared Investigator Platform
- Site Qualification and Training
- Clinical Data Transparency

**Change Management Council**
**Technology Council**
**Regulatory Council**
Audience Questions…
Risk Based Monitoring
Model Framework
Approach for High-Quality, Risk-Based Monitoring

**Unmet Need:** No model framework existed that would have enabled organizations to successfully deploy and scale risk-based monitoring

**Objective:** Develop Guidelines for targeted, risk based clinical trial monitoring

**Benefits:** Improvement in data quality and patient safety for clinical trials; reduction in effort expended on low-value activities
Trial Oversight & Monitoring

• An adaptive approach to clinical trial monitoring that directs monitoring focus and activities to the evolving areas of greatest need which have the most potential to impact patient safety and data quality.
• The Approach is Changing / The Goal of Fit for Purpose Quality Has Not
Cross Functional Team Work Is KEY!

TransCelerate RBM Methodology

QbD is foundational to ensuring subject safety, data integrity and protocol compliance.

- Building QbD into design & planning of trial
- Conducting early and ongoing risk assessments
- Focusing on Critical Processes and Data
- Using Risk Indicators, Thresholds & Action Plans
- Monitoring Plans
- Adjusting monitoring activities based on risks

RCT

Critical Variables

Cross Functional Team Work Is KEY!
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<tr>
<th>Publications / Tools</th>
<th>Timeframe</th>
<th>Destination</th>
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<tr>
<td>Position Paper</td>
<td>May 2013</td>
<td>TransCelerate website</td>
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<td>RBM Update Volume I</td>
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<td>RBM Training Materials</td>
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<td>Risk Assessment and Categorization Tool (RACT) v2.0</td>
<td>April 2014</td>
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<td>RBM Update Volume II</td>
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<td>Defining a Central Monitoring Capability: Sharing the Experience of TransCelerate BioPharma’s Approach, Part I</td>
<td>September 2014</td>
<td>Therapeutic Innovation and Regulatory Science</td>
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<td>Technology Considerations to Enable the Risk-Based Monitoring Methodology</td>
<td>September 2014</td>
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<td>Evaluating Source Data Verification as a Quality Control Measure in Clinical Trials</td>
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Audience Questions…
Site Qualification & Training
Site Qualification and Training

What is the vision?
Evaluate approaches to improve start up activities, reduce administrative burden for sites to make participation in clinical trials more attractive, and provide support and information to less experienced site staff.

Upcoming Plans
- Deliver an Informational Program for Site Staff Less Experienced.
- Produce a Mutual Recognition Process of Electronic Data Capture (eDC) training.

Accomplishments
- Operationalized an effective Good Clinical Practice (GCP) mutual recognition program to save time & avoid duplicative GCP training.
- 12 Member Companies & 140+ external training providers have attested their GCP training courses meet the mutually recognized criteria (~7% increase since June 2015)
- 113,000+ GCP training completion certificates issued by 9 Member Companies* (~7% increase since June 2015).
- Developed & implemented forms for Investigator Sites to create value and streamline processes. The Site Profile Form data is consistent with the Shared Investigator Platform (SIP) data fields; Site Users can upload a completed Site Profile into SIP to reduce data entry.
- Created an informational program on the basic components of PI oversight of clinical trials.
Benefit to Sites

1. Reduced study start up times.
2. Reduced administrative burden as sites no longer have to repeat the same information in different formats.
3. Less redundancy in GCP re-training, as participating Sponsors accept completion credit.
4. You have more time to focus on protocol.
Site Qualification and Training:

**Informational Program for Site Staff Less Experienced in Conducting Clinical Trials**

1. Describes basic concepts of Clinical Research in accordance with the ICH Guidance for Good Clinical Practice: Consolidated Guidance (E6).

2. Offers readily available topics in key areas which can be used as a source of basic information for less experienced investigators and their staff.

3. Completion certificate available at conclusion of each topic. Certificates can be provided upon request.
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<th>Available Now:</th>
<th>Arriving by Q1 2016:</th>
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<td>• Adverse Events and Safety</td>
<td>• Conducting a Study</td>
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<td>• Clinical Research Overview</td>
<td>• IRB/IEC Responsibilities and Informed Consent</td>
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<td>• Facilities and Equipment</td>
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Each topic, when available, can be accessed at transceleratebiopharmainc.com under the Site Qualification and Training Initiative.
Audience Questions...
Investigator Registry & Shared Investigator Registry
The Shared Investigator Platform (SIP) will facilitate interaction between investigators and multiple clinical trial sponsors, enabling study planning, study start-up, and study conduct activities while reducing the administrative burden on site staff.

What is the vision?
Reduce the burden on investigative sites by providing them with a single point of access, harmonized content and services, and streamlined interaction with participating clinical trial Sponsors.

Accomplishments
- Selected and contracted with Systems Integration partner.
- Engaged external site users (SCRS Site Advocacy Group)
- to partner in solution design and testing.

Upcoming Plans
- First release to be adopted by some Member Companies on a rolling basis.
- Enhancements and new functionality in Release 2 and future releases.
Benefit to Sites

1. The Shared Investigator Platform was developed with sites, for sites.
2. The Platform increases efficiency, reduces burden on investigators and site personnel in planning and conduct of clinical studies.
3. The Platform streamlines interactions and data exchange with participating Study Sponsors through a single application with centralized access.
4. Aligns and harmonizes data and processes for interacting with participating Study Sponsors.
SIP Highlights

Selected, Licensed Key Service Components

Selected Member Companies Decided to Adopt

Selected Cognizant as SI Partner

Finalized R1 Requirement - working on R2 concurrently

Partnered with SCRS SAG to Design SIP

Integrated Investigator Registry (IR) Solution

Investigator Registry (IR)
Master data for SIP profiles are assigned unique identifiers & stored in the IR.

PRESS RELEASE
24 July

[Logo images of sumtotal, EXOSTAR, LIFERAY, DrugDev, Cognizant]
SIP Roadmap – www.SharedInvestigator.com

Release 1
- Single Sign On
- User Profile
- Facility Profile
- Training
- Feasibility Surveys
- Study Workspace
- Document Exchange
- Tasks, Alerts & Notifications
- Dashboards and Reporting
- Search capabilities

Release 2
(Proposed functionality)
- Document Management (e.g., versioning, workflow, e-signatures, Integration to sponsor eTMF)
- Safety Letters
- Surveys - new types, analysis
- Enhanced functionality
- Expanded Reporting

Release 3
(Future proposed features)
- PI/Sponsor Collaboration
- Online FAQ
- Discussion Boards
- Online Meeting
- Investigator Payments
- Non-drug supply ordering
- Drug supply ordering/IWRS

The Shared Investigator Platform - developed with sites, for sites
Audience Questions…
Thank you!