Efficiency Enhancing Collaboration in Clinical Trials

August 2014
Pharmaceutical R&D Leaders Identified Collaboration As A Key Opportunity For Generating Industry-wide Efficiencies

Conducted an industry survey on areas amenable to collaboration
To Drive Collaboration Opportunities Into Implementation, TransCelerate Was Incorporated

Existing collaboration organizations within the life sciences industry were evaluated for their ability to successfully execute the selected opportunities in clinical trial execution and it was determined that no existing vehicles met the necessary criteria. Therefore Transcelerate was formed to promote a high-level of member accountability and a results-driven approach.

**The new organization embodies the following defining characteristics:**

- Broad industry membership from Pharma and Biotech
- Lean, non-profit entity with sufficient funding by member companies
- High level of member company control and accountability
- Board of Directors composed of senior R&D leadership
- Member FTE contributions of experienced and skilled resources
Not For Profit Entity Created To Drive Collaboration As Means To Developing Solutions For Overcoming Inefficiencies

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
To collaborate across the global 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.

Our core values
+ Quality
+ Transparency & Openness
+ Trust & Integrity
+ Collaboration
+ Courage
An Entity That Engages With The Wider Clinical Ecosystem Globally

Strategically focusing engagement efforts with selected key stakeholder groups – the intent is not to recreate, but partner whenever feasible
10 Pharmaceutical Companies chartered TransCelerate and 9 additional companies joined in 2013

Charter Members
- Abbvie
- AstraZeneca
- Boehringer Ingelheim
- Bristol-Myers Squibb
- GlaxoSmithKline
- Johnson & Johnson
- Lilly
- Pfizer
- Roche
- Sanofi

2013 Members
- Allergan
- Astellas
- Biogen Idec
- Cubist
- EMD Serono
- Forest Laboratories, Inc.
- Medgenics
- Shionogi
- UCB
A Flat Organization Structure Has Been Developed To Manage Projects And Operational Activities

- **Board of Directors**
  - **CEO**
  - **Head of Delivery Excellence & Corp Affairs**

- **Clinical Operations Committee**
  - **Director of Projects**
  - **Finance Lead**
  - **Director of Operations**
  - **Director of Quality**

- **Sub-Committees**
  - Change Management
  - Communications
  - Regulatory
  - Technology
  - Future Initiatives Planning

- **Workstreams**
  - Clinical Data Standards
  - Clinical Data Transparency
  - Clinical Trial Diversification
  - Common Protocol Template
  - Comparator Drugs for Clinical Trials
  - Investigator Registry
  - Pediatric Trial Efficiencies
  - Quality Management System
  - Risk-Based Monitoring
  - Shared Investigator Platform
  - Site Qualification & Training
  - Exploratory Projects

- **Key:**
  - Retained Position
  - Contracted Resources
  - Member Representatives

**Instructions:** In Slide Show mode, hover over a box to view a description
TransCelerate currently has 11 projects which share the goals of increasing quality, patient safety & accelerating development timelines

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*Original initiative which began in 2012
Model Approach for High-Quality, Risk-Based Monitoring

**Unmet Need:** No model framework existed to provide implementation considerations for organizations to successfully adopt and scale the risk-based monitoring methodology.

**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.
Shared Site Qualification and Training

**Unmet Need:** Disparate and redundant GCP training, and collection of non-study specific information, are pain points for investigators and sites, as well as for biopharmaceutical companies.

**Objective:** Program established for mutual recognition of GCP training and site qualification credentials.

**Benefits:** Realization of improved quality of clinical sites and accelerated study start-up times.
Shared Investigator Platform

**Unmet Need:** Communication between sponsors and clinical trial sites are often cumbersome and difficult requiring investigator sites to use many different websites / login credentials to communicate with their sponsors.

**Objective:** Establish a single, intuitive interface for investigators to use across the industry.

**Benefits:** Ease of use and harmonized delivery of content and services for investigators and sponsor companies.
Clinical Data Standards - Efficacy (in partnership with CFAST)

Unmet Need: Clinical data is reported in individual trials in various ways, without benefit of an industry-wide set of standards

Objective: Accelerate current efforts underway through CFAST to establish therapeutic data standards

Benefits: Increased quality of clinical data and enablement of industry end-to-end data flow
Comparator Drugs for Clinical Trials

**Unmet Need:** Mechanisms to acquire clinical trial comparator drugs and co-therapy drugs were inefficient and unpredictable; supply chain intermediaries frequently decreased security, introduced delays, and couldn’t provide access to key drug documentation.

**Objective:** Establish a supply network to source comparator drugs between companies for use in clinical trials.

**Benefits:** Enhanced patient safety due to known product source and acceleration of study timelines.
Common Protocol Template

Unmet Need: There is increasing complexity in clinical protocols as well as a lack of consistency within and across sponsors

Objective: Create a common template for clinical protocols to ease interpretation & enable down-stream automation of many clinical processes; develop industry-wide & regulator accepted endpoint definitions

Benefits: Enhance quality of study conduct, facilitate data interpretation and enable down-stream automation of many clinical processes
Unmet Need: Sponsors invest resources, significant time and budget in identifying qualified investigators and setting up study sites

Objective: To create a shared repository of investigators

Benefits: Reduced cost and time of setting-up and running clinical trials
Pediatric Trial Efficiencies

**Unmet Need:** There are often an insufficient number of pediatric patients accessible to sponsors that can participate in clinical trials within the required timeframe.

**Objective:** Lead the development and implementation of solutions which improve the operative feasibility and conduct of pediatric clinical trials.

**Benefits:** Faster access to new drugs for pediatric patients, reduce burden on patient, faster and more efficient site contracting and reduced trial costs.
Clinical Trial Diversification

**Unmet Need:** Ethnic minority representation in clinical trial populations is often not reflective of the prevalence of the disease being treated

**Objective:** To enhance the ability of sponsors and sites to achieve representative diversity within clinical trial populations

**Benefits:** Broader understanding of drug safety and effectiveness. Increased ability to access, recruit and retain patients in clinical trials. Greater number of effective and high quality minority serving sites
Clinical Data Transparency

**Unmet Need:** With increased transparency, there is a need to standardize the approach to protecting the privacy of individuals involved in clinical trials.

**Objective:** Develop a consistent approach for redacting privacy information found in clinical study reports and an approach for the anonymization of patient level data shared with the broader healthcare community.

**Benefits:** Enhance transparency and facilitate future research preserving the privacy of patients, investigators and clinical trial staff for operational transparency issues related to privacy.
Quality Management System

**Unmet Need:** Clinical QMS requirements are fragmented across multiple guidances contributing to quality issues

**Objective:** Identify ways to improve quality industry-wide through partnerships with regulatory agencies and other industry stakeholders

**Benefits:** Enhanced patient safety by improved quality, assure data integrity, minimize delays in clinical trials, and bring drugs to market more quickly
The Future - Our Roadmap With The Future State In Mind

**Current State**

- Disconnected interfaces
- Manual processes and interventions
- Limited standardization
- Lot of customization
- Rework
- Variable quality
- Wait time
- Missing information
- High costs
- Long cycle times

**Future State**

- Patient-centric clinical trial design
- End-to-end electronic data flow
- Seamless interfaces
- Automated
- Transparent
- Standardized
- Less rework
- Quality by design
- Shorter cycle times
- Cost efficient
- Integration of Regulatory, Safety, and Medical Sciences
- Conducting clinical trials together
- “Colossal Data Analytics”
In the first 2 years, TransCelerate accomplished the following:

+ Engaged Industry
+ Established Mutually Recognized GCP Training
+ Published Risk-Based Monitoring Position Paper
+ Launched SHARE Environment and Published Data Standards User Guides
+ Completed Numerous Comparator Product Transactions
+ Endorsed New Workstreams
+ Named Cognizant as Shared Investigator Platform Vendor
# Key Accomplishments

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<td>Engaged Industry</td>
<td>19 Member Companies and multiple external organizations (CTTI, SCRS, BIO, IOM, NIH, ACRO, IMI etc.) are engaged with TransCelerate.</td>
<td>+ The industry’s most talented individuals are collaborating to tackle R&amp;D’s biggest challenges. + Teamwork avoids duplication of effort so speedier timelines can deliver value for stakeholders.</td>
</tr>
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<td>Established Mutually Recognized GCP Training</td>
<td>The Site Qualification &amp; Training workstream published minimum criteria for mutual recognition of GCP training; 75 GCP training courses submitted by external training providers eligible for mutual recognition.</td>
<td>+ Repetitive training avoided. + Faster trial start-up times means focus sites can focus on conducting studies, rather than administrative tasks.</td>
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<td>Published Risk-Based Monitoring Position Paper</td>
<td>The Risk-Based Monitoring workstream posted a methodology which received 2,000+ downloads from the website, the RBM Framework is utilized by 6 member companies with 40+ ongoing studies identified and launched as pilots to submit to the FDA.</td>
<td>+ A potential industry shift in monitoring methodology that could result in better results for patient.</td>
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<td>Launched SHARE Environment and Published Data Standards User Guides</td>
<td>SHARE Environment (metadata repository, which will be a central place to store, manage, and govern data standards) deployed by the Clinical Data Standards workstream; published user guides for Asthma, Alzheimer’s and Multiple Sclerosis.</td>
<td>+ A potential industry shift towards common ways of tracking study data means improved accuracy and increased data integrity.</td>
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<td>Completed Numerous Comparator Product Transactions</td>
<td>Ten Member Companies who have signed the MSA in for the <strong>Comparator Drugs for Clinical Trials</strong> workstream have executed 20+ product transactions.</td>
<td>+ Easier access to and improved quality of comparator drugs means more effective studies with faster start up times for patients in trials.</td>
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<td><strong>Endorsed New Workstreams</strong></td>
<td>The board endorsed <strong>Quality Management System</strong> and <strong>Clinical Data Transparency</strong> workstreams.</td>
<td>+ The Quality Management System workstream will enhance patient safety by improved quality, assure data integrity, minimize delays in clinical trials, and bring drugs to market more quickly. + The Clinical Data Transparency workstream will meet industry, regulatory and patients needs, while preserving the privacy of patients, investigators and clinical trial staff.</td>
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<td>Named Cognizant as SI Vendor</td>
<td>The <strong>Shared Investigator Platform</strong> workstream has chosen Cognizant as their System Integration vendor.</td>
<td>+ Ease of communication with sites means sites can reduce administrative tasks and conduct faster trials.</td>
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ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

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