TransCelerate aspires for a future state where research and development is faster, more efficient, and harnesses all the available information. We envision this happening in 3 ways:

1. Full participation across all stakeholders — clinical trial sponsors, sites, investigators, patients and their healthcare providers
2. Information is fully used to improve the overall quality, design and development process. We protect patients through shared, proactive safety science
3. Improving the execution of research and development through greater harmonization with the potential to conduct collaborative trials

NEWEST RESOURCES

TransCelerate and BioCelerate launch new technology platform (DataCelerate™) to enable R&D data sharing
Information Sharing & Harmonization

Enable the industry to move toward greater harmonization of process and facilitate the sharing of information amongst industry stakeholders to enable the industry to capture, optimize and experience efficiencies.

• The Placebo and Standard of Care (PSoC) Initiative recently published a paper in the journal of Therapeutic Innovation & Regulatory Science, titled “Minimizing Patient Burden Through the Use of Historical Subject-Level Data in Innovative Confirmatory Clinical Trials: Review of Methods and Opportunities,” which provides a review for a regulatory and industry audience of the current state of relevant statistical methods and the opportunities for broader use of historical data in confirmatory clinical trials.

• Also, the PSoC Initiative held their first multi-stakeholder workshop in May with over 60 attendees from different stakeholder groups (health authorities, academia, patient advocates and clinical research sponsors) with a shared goal of solving challenges regarding the use of historical controls in confirmatory trials. The Initiative is exploring opportunities for future multi-stakeholder workshops in various geographic regions around the world to further the long-term goal of regulatory acceptance of historical controls in confirmatory trials as the norm and deemed scientifically appropriate.

• Recently, the eSource Initiative, in conjunction with the Common Protocol Template Initiative, held their fifth eSource Advancement Roundtable titled, “Clinical Trial Data Flow of the Future, The Influence of the Protocol on Data Collection,” which centered around the use of automation to:
  » Enable data flow to seamlessly occur across clinical trial processes from protocol to data collection
  » Ensure traceability from protocol to report, while accelerating study start-up
  » Improve quality and efficiency
Improve the patient and site experience by decreasing burden, enabling a better-informed patient and improving clinical research awareness, participation & engagement.

- The Clinical Research Access & Information Exchange Initiative released new communication templates that help share information with clinical trial participants after they have enrolled in a trial, completed their participation and when the full study has concluded, and study results are available. Download these helpful resources here.

- The Shared Investigator Platform (SIP) has reached key onboarding milestones, in addition to delivering the 25,000 users expected by years' end. To date:
  - Over 15,000 site users have been invited to join the platform and more than 13,000 users have been onboarded.
  - We have site users across 75 countries registered and seeing benefits in CV auto-generation, MRT GCP Training approvals, and more than 150 auto-generated FDA Form 1572s.
  - Currently, there are four sponsors utilizing SIP for approximately 100 active studies.

- The Shared Investigator Platform (SIP) Initiative has developed new educational videos around the SIP to help facilitate understanding of the platform’s key features and benefits. Click below to watch:
  - Site Capabilities Made Simple with SIP
  - Study Management Made Simple with SIP
  - The Shared Investigator Platform (SIP): From Concept to Reality

- In June, the Patient Technology initiative held a Novel Digital Endpoints (NDE) Roundtable that focused on identifying ways to accelerate the implementation of clinically meaningful digital measures in clinical trials. Stakeholders from industry, academia, and patient advocacy organizations discussed the challenges and opportunities posed by NDEs and explored solutions that could move the needle toward their use as primary or supportive outcome measures for clinical trials. This roundtable has and will continue to provide a forum for those at the center of the NDE revolution and interested in sharing best practices related to the discovery, development, validation and implementation of NDEs.
Enhance Sponsor Efficiencies & Drug Safety

Facilitate the advancement of innovative healthcare and clinical research through improved technologies, advanced data collection systems and simplified processes.

- The Value of Safety Information Data Sources Initiative recently met with the Food and Drug Administration (FDA) to present their hypothesis - safety information from patient support programs, market research programs, and social media is of low informative value - and demonstrate their findings which can be accessed here. The Initiative plans to keep in close contact with the FDA and engage in dialogue with additional global health authorities, as it seeks to identify sources of safety information for a single high value valid case and develops a proposed method for aggregate reporting of lower value cases.

- After a highly successful panel between the Pharmacovigilance Initiative teams and an FDA leader at the DIA Annual Meeting in June, Jose Vega, Vice President, Global Clinical Safety and Pharmacovigilance (GCS&PV) and Chief Safety Officer at Merck Research Laboratories was interviewed and discussed challenges biopharma companies face when evaluating drug safety. Click here to view the video interview!
Learn more about our Initiatives through our video overviews:

- Information Sharing & Harmonization
- Patients
- Sites
- Sponsors

Have Questions?

Please direct all inquiries as specified below:

**Membership:**
membership@transceleratebiopharmainc.com

**Events:**
events@transceleratebiopharmainc.com

**General:**
info@transceleratebiopharmainc.com

**Site Training & Qualification:**
SQT@transceleratebiopharmainc.com

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