

Frontline Experience: A Road Already Traveled

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MAY 11, 2021





TransCelerate is a Not-for-Profit Entity Created to Foster Collaboration

Our mission is to improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.

TransCelerate : A Catalyst For Industry-Wide Collaboration

1,000+

Contributing
Member Company
Experts

20

Member
Companies

70+

Solutions Available
for Adoption

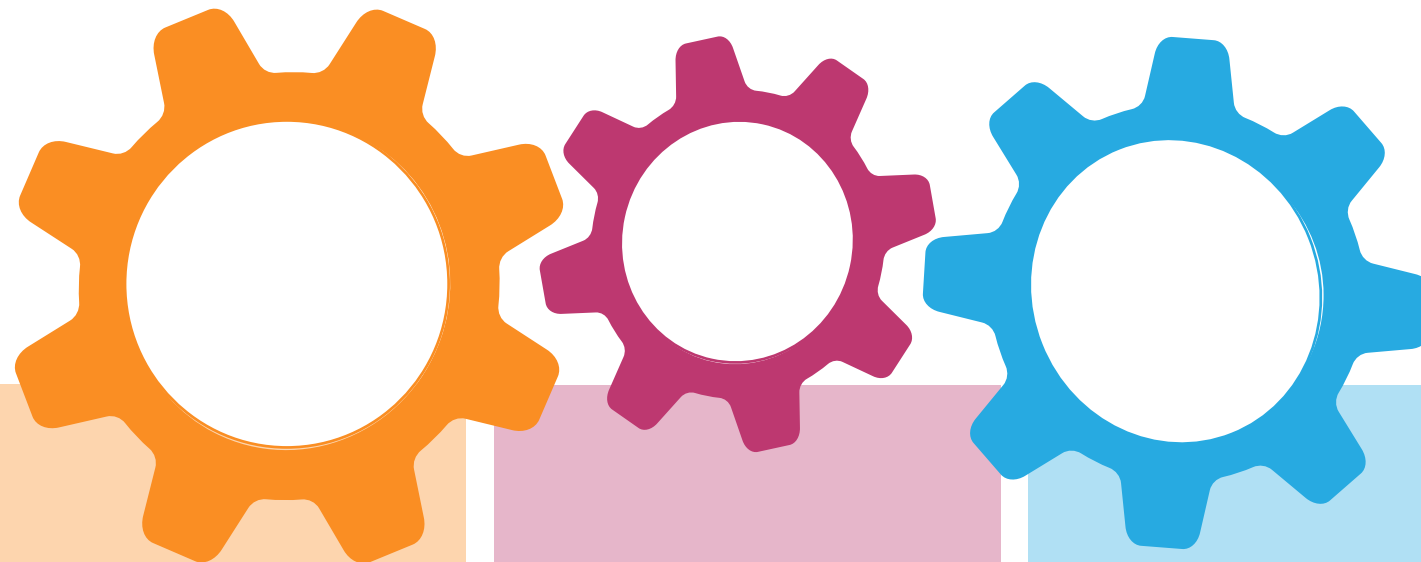


Focus on Preclinical
Research



Our Commitment to
Data Sharing

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Our Strategic Priorities Guide Us In Achieving Our Goals

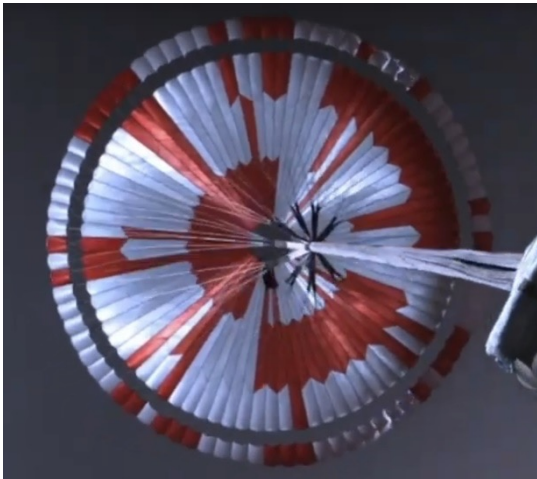
Harmonize Process
& Share Information

Improve the Patient
& Site Experience

Enhance Sponsor
Efficiencies & Drug
Safety



COVID-19 - Pivoting to the Future



“Dare Mighty Things”

The Future is Here

- Unprecedented degree of sharing, collaborating, and learning happened throughout 2020 and there's no going back
- Evaluate which continuity solutions are appropriate post-pandemic
- Ecosystem to come together to proactively **pandemic proof** ourselves



Sponsors



Sites



Patients



Regulators



Industry
Organizations

In utilize Continuity Tools & Technologies....

- Must consider patient & site experiences—Reducing patient burden shouldn't result in increase of site burden
- Data integrity & privacy requirements cannot be compromised
- Implementing continuity solutions reactively and during a crisis inherently poses challenges (see “Catalyst Paper”)

We Are in This Together

- The entire ecosystem have an opportunity to “co-learn” together—sponsors, sites, regulators & patients
- Real, lasting change is only possible through a mindset shift
- **“To go fast, go alone. To go far, we have to go together”**



Collaboration In Action: TransCelerate's COVID-19 Response

Enabled Best Practice Sharing amongst Members. Published a catalyst paper and case studies.

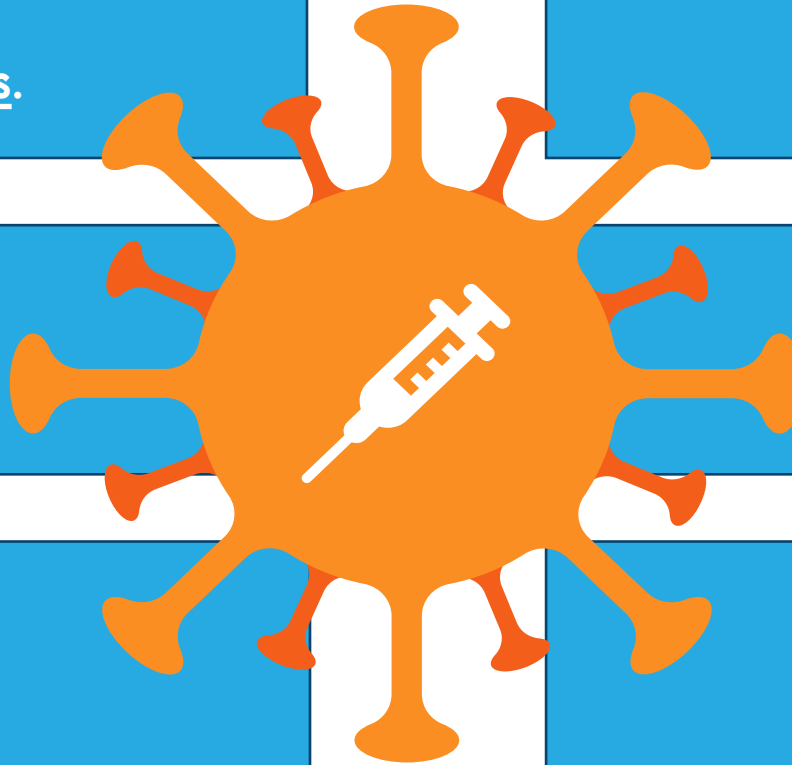
Launched a technology module to enable COVID-19 Data Sharing in DataCelerate®.

Published Clinical Study Report (CSR) Considerations related to COVID-19 disruption.

Launched a new initiative focused on innovative efforts that evolve and modernize clinical research.

Early release of tools to manage anticipated Protocol Deviations.

Assisted NIH and Operation Warp Speed on various operational matters related to ongoing ACTIV master protocols.



For all publicly available resources, visit www.transceleratebiopharmainc.com



Turning Disruptions into Opportunities Leaping into the Future

The pandemic has catalyzed immense changes and TransCelerate's ongoing initiatives have been reprioritized to focus on two main themes:

Modernization

Evolve clinical research to include a broad range of innovative technologies and business processes to simplify, modernize, improve patient experience while maintaining patient safety and data reliability.



The COVID-19 Pandemic presented TransCelerate with new opportunities to accelerate select areas of our portfolio, pivoting to two key themes: Modernization and Dynamic Data



Dynamic Data

Amplify the power of data to inform and accelerate research and development through a connected, holistic approach focusing on data usage, accessibility and versatility.



Enabling a More Dynamic Data Ecosystem

Foundational building blocks necessary to support novel technologies

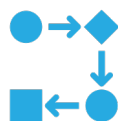


Model Language

- Templates
- Semantics, syntax
- Metadata
- Proposed Data Model*



Data Versatility



Connected Process

- Fluid data exchange
- Provenance and lineage
- Cross-sponsor data sharing



Data Accessibility



Better, Faster Insights

- Routine re-use of data
- Right information/right time
- Readily available context
- Broader evidence base



Data Applications

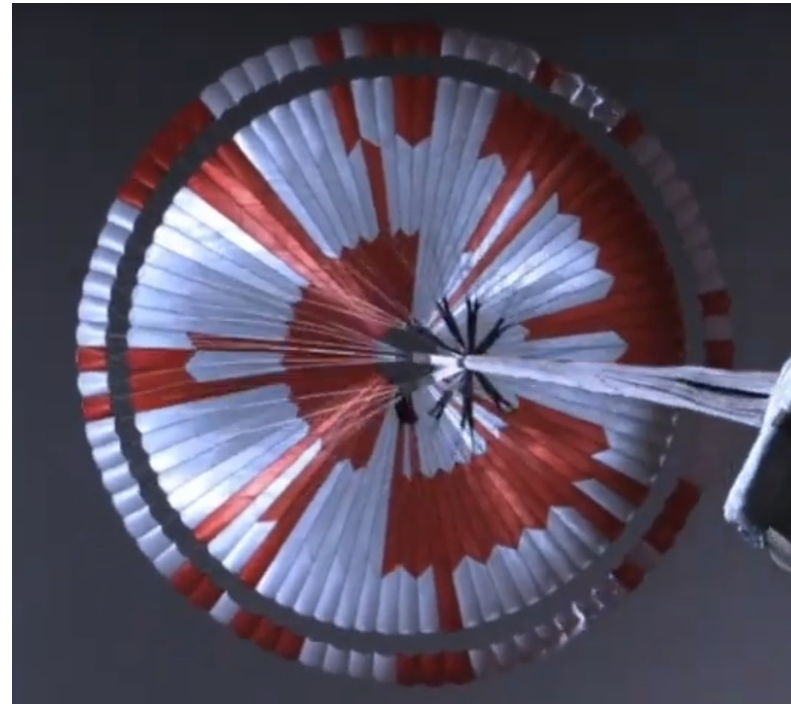
Related TransCelerate Initiatives

- Clinical Content & Reuse
- eSource / Project Vulcan
- SEND Data Implementation
- Digital Data Flow
- Patient Technology
- DataCelerate® – a data sharing platform
- Clinical Trial Data Sharing
- Pre-clinical Data Sharing
- GDPR Data Reuse Framework
- Privacy Methodology for Data Sharing
- Real World Data



Looking ahead to 2030....

“Dare Mighty Things”



Questions?