

COVID-19

Industry Challenges and Opportunities

JULY 2021

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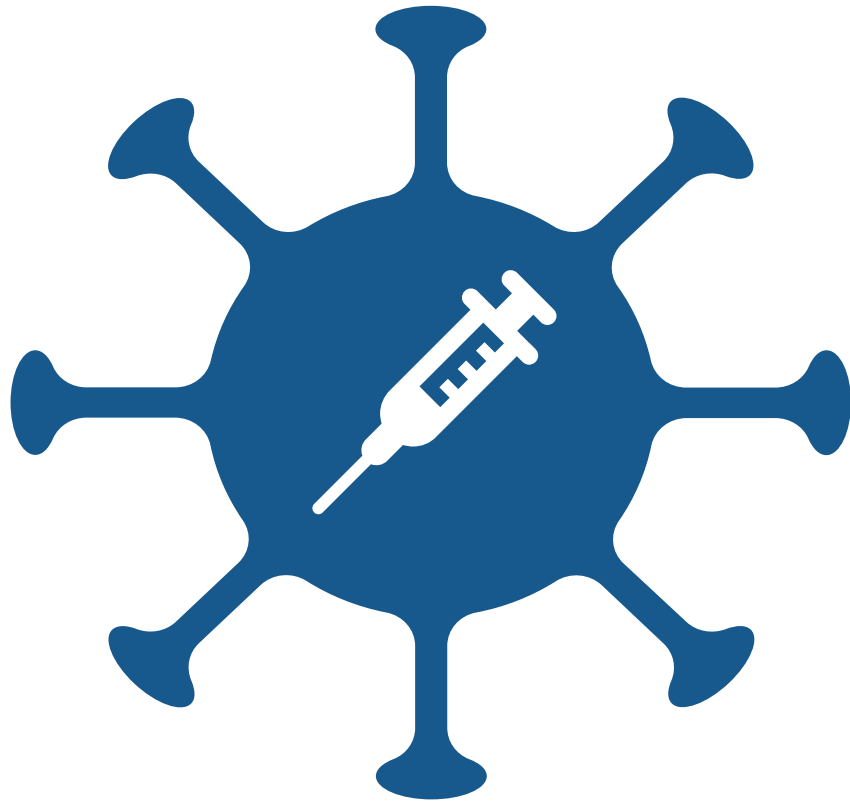
Board of Directors

TransCelerate BioPharma, Inc.



COVID-19 : Industry Challenges and Opportunities

Overview



The COVID-19 pandemic challenged the way that healthcare and pharmaceutical industries deliver care to patients.



The disruption required both health authorities and industry to think progressively about how to enable and execute new methods for delivering care to patients.



As a result, there are numerous lessons learned, including both challenges and opportunities.



These learnings can be used to inform future ways of working for the industry and future policy by health authorities.





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

In April 2020, TransCelerate Member Companies mobilized a working group to **explore the use of modern solutions and approaches** as permitted by health authorities globally

TransCelerate's Modernization of Clinical Trial Conduct Initiative

Identified Challenges



There is a **lack of harmonization** of global **regulatory policy** and Health authority acceptance of data from modern solutions is unclear



Connectivity and integration of technology solutions and platforms is not standard



Global **privacy** laws and ethical considerations prevent the use of modern solutions in every country



Patient preference and **burden** when using modern solutions/approaches needs to be better understood



Use of modern solutions requires a **cultural shift** among all stakeholders



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Lessons Learned



Build flexibility (e.g., pandemic preparedness) into protocols



Prospectively discuss digital data collection tool(s) with health authorities



Create plans to ensure that sponsor systems (e.g., EDC) can accept data from planned sources.



Consider the pertinent and critical data that is required to be collected



Design future protocols to include the option to use modern solutions



Incorporate time to provide training for study teams, sites, participants, and others as needed



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Success Factors

Change the Mindset

- Have a willingness to be **creative and/or flexible** without one size fits all solutions
- Foster a desire to **work together** and prevent increased burdens for key stakeholders
- Recognize the **potential benefits** and consideration of the work required to implement continuity solutions

Focus on Continuous Execution

- Continue ongoing research/consideration of **digital data collection tools** and other technology platforms
- Continue ongoing research/consideration of other **possible continuity solutions**
- Establish **RBM principles** to identify the appropriate approach for monitoring critical data



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Conclusions

- COVID-19 had a catalyzing effect on industry and forced us to think about ways to **improve/enhance trial conduct**, not only for operating during the pandemic, but for the future
- We previously asked ourselves the question of 'why change' but are now asking ourselves '**why go back**,' if there is no additional risk to data integrity and patient safety
- The need for **global regulatory uniformity** is as strong as ever as we change and challenge many of our traditional ways of working
- Industry has undergone a forced **change in risk perspective**. Companies have been forced to innovate. A failure to learn and change as a result of this experience would represent a retrograde step for clinical trial conduct.
- **Change must be driven** not just by regulatory policy but also by industry broadly (as evidenced by the experiences and use cases in our paper) **with the complete ecosystem working in partnership**

