# COVID-19
## *Industry Challenges and Opportunities*

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# 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

# TransCelerate's Modernization of Clinical Trial Conduct Initiative

## *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**

# TransCelerate's Modernization of Clinical Trial Conduct Initiative
*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

# TransCelerate's Modernization of Clinical Trial Conduct Initiative
## *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**