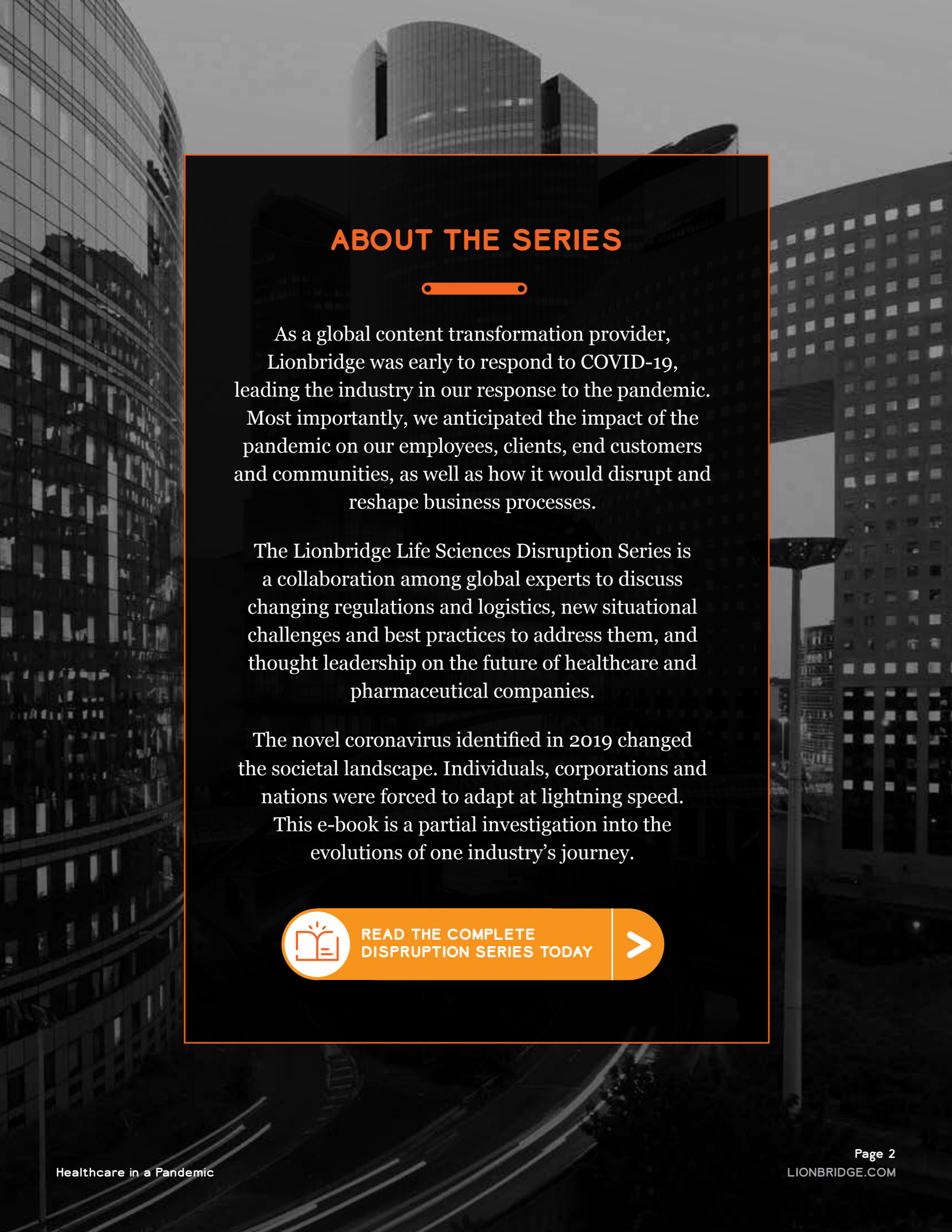
LIONBRIDGE

HEALTHCARE AND THE PHARMA PIPELINE IN A PANDEMIC

THE DISRUPTION SERIES



ABOUT THE SERIES

As a global content transformation provider, Lionbridge was early to respond to COVID-19, leading the industry in our response to the pandemic. Most importantly, we anticipated the impact of the pandemic on our employees, clients, end customers and communities, as well as how it would disrupt and reshape business processes.

The Lionbridge Life Sciences Disruption Series is a collaboration among global experts to discuss changing regulations and logistics, new situational challenges and best practices to address them, and thought leadership on the future of healthcare and pharmaceutical companies.

The novel coronavirus identified in 2019 changed the societal landscape. Individuals, corporations and nations were forced to adapt at lightning speed. This e-book is a partial investigation into the evolutions of one industry's journey.

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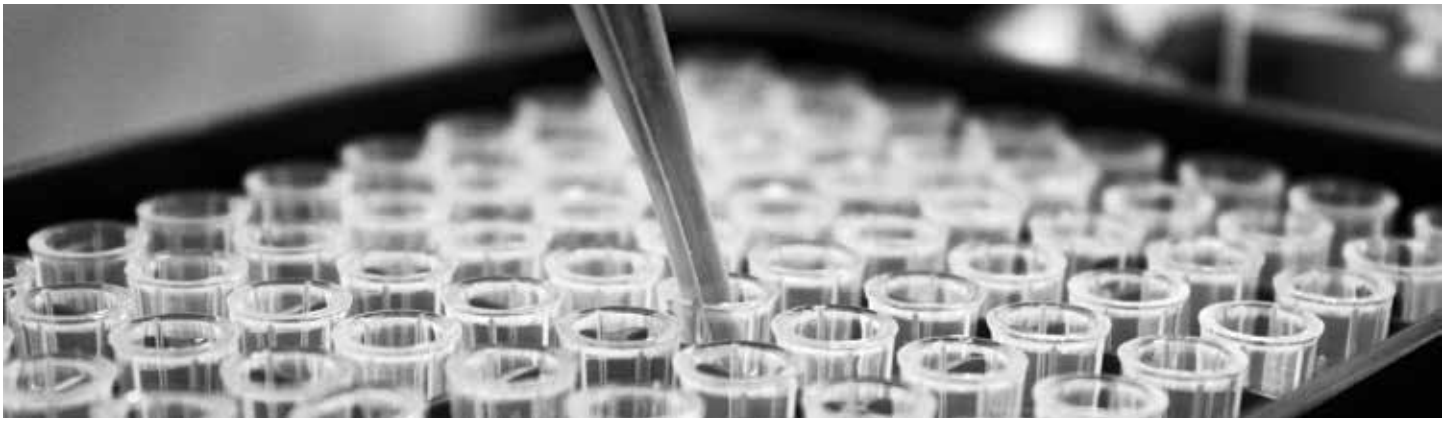


THE DISRUPTION

The COVID-19 pandemic impacted every industry in every corner of the globe, but perhaps no industry felt the disruption more deeply than healthcare. In addition to the plummeting demand many industries faced for elective or non-emergent services, healthcare, and specifically pharma, has seen a massive upswing in need for treatment and prevention of the illness.

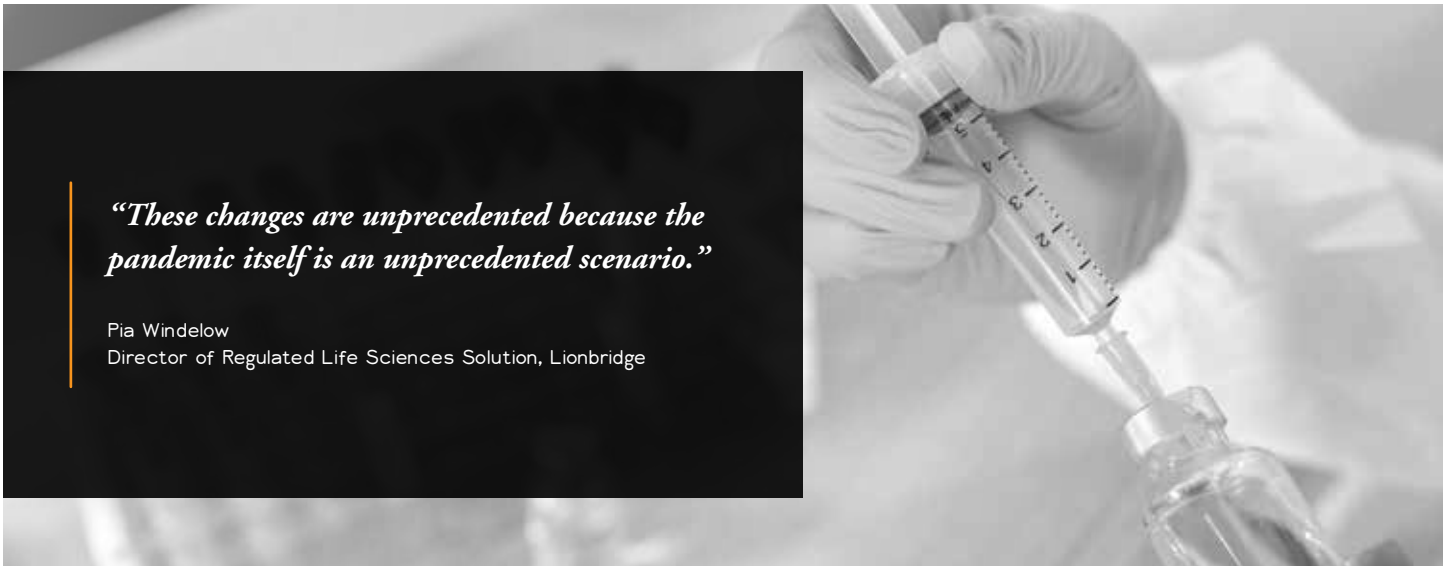
Applying the Brakes

On March 26, DIA moderated a panel discussion of experts from China who represented the full spectrum of the clinical trial process. Participants shared their findings on the impact that the coronavirus pandemic in China had on clinical trials being conducted there. As one would expect, the disruption to clinical trials was significant. Approximately 70 percent of ongoing trials were suspended or stalled during the height of the outbreak in China.

Within trials that continued throughout the outbreak, approximately 80 percent of study participants declined to travel to study sites, even if the government granted them an exception to any quarantine transportation restrictions.

On March 18, the American Food and Drug Administration (FDA) published a guidance for industry on how to conduct clinical trials during the COVID-19 pandemic and to minimize the disruption of ongoing clinical programs. The European Medicines Agency (EMA) followed on March 20 with a similar guidance for trial sponsors conducting clinical trials in Europe. The intent of the guidances is to minimize the interruption of important ongoing clinical programs, but first and foremost to protect the safety of trial participants without compromising the quality of the data obtained in clinical trials.

With the restrictions enforced on both infrastructure and personal mobility, it is very difficult to carry out trial procedures, site visits, monitoring, consent procedures and physical examinations. Both FDA and EMA have therefore encouraged trial sponsors to find alternatives to physical trial visits for non-critical procedures, e.g. by use of phone or video visits. Also, the regulators have warmed to the option for monitoring to be replaced by remote source data verification to reduce onsite visits.



> *"These changes are unprecedented because the pandemic itself is an unprecedented scenario."*
>
> Pia Windelow
> Director of Regulated Life Sciences Solution, Lionbridge

Speeding Forward

Regulatory agencies including the FDA and the EMA have modified policies to accelerate the fight against the coronavirus. As new trials to fight and prevent COVID-19 start up on an accelerated timeline, regulatory agencies are encouraging international partnerships.

On March 19, the EMA published a statement urging the E.U. research community to prioritize large scale controlled clinical studies for potential treatments for COVID-19. In the same statement, trial sponsors were encouraged to include all E.U. countries in these trials to speed up drug development. The clinical trial geographic footprint is likely to expand as a result.

The classical phase III trial often enrolls only a handful of countries in Europe including Member States in the "big five;" also known as the EU5 (Germany, France, Italy and Spain, now excluding the UK) and a couple of countries in Eastern Europe or the Nordic region. Conducting trials in all E.U. Member States within the same protocol will be a significant expansion and require effective communication across 24 different languages.

In March, the FDA released a policy for diagnostic tests for coronavirus to guide clinical laboratories, commercial manufacturers and FDA staff during the COVID-19 pandemic. Diagnostic tests for detection or diagnosis of the novel coronavirus (SARS-CoV-2) can be granted an Emergency Use Authorization (EUA) by the FDA.

This enables rapid development, manufacturing and distribution of tests under a public health emergency. Section 564 under the Federal Food, Drug and Cosmetic Act allows the use of unapproved medicinal drugs and devices under specific circumstances during emergencies; the pandemic certainly qualifies as such.

While the FDA has not waived test validation, the policy does allow manufacturers to develop and distribute SARS-CoV-2 test kits before submission to the agency. (That submission is expected within 15 business days after validation of the test.) The submission of the EUA request to the FDA should include fact sheets for healthcare providers and patients, as well as instructions for use and proposed labeling/package inserts. Test kits that have received a Letter of Authorization under the EUA program will then be listed on the FDA webpage, along with both fact sheets and Instructions for Use.

Further Implementation Delays

In addition to the changes due directly to COVID-19, the planned timeline for a series of regulatory updates also changed. The E.U. again delayed the upcoming Medical Device Regulation (MDR) and although the In Vitro Diagnostic Medical Device Regulation remains on track for 2022, MedTech Europe has called for its delay as well.

The Medical Device Coordination Group (MDCG) released new guidances along with the delays. Previous critiques of both sets of regulations included complaints of too little information for manufacturers and a shortage of Notified Bodies. The global pandemic coincided with intended implementation of MDR, but addressing the impact of the coronavirus has taken precedence over regulatory changes.

MAINTENANCE AND PROGRESS

To preserve scientific and medical research, investigations and treatments, the world's health care providers, CROs and pharma companies have needed to expand their toolboxes.

READ THE FULL POST ABOUT VIRTUAL CLINICAL TRIALS >

Telehealth use has skyrocketed due to the desire for less in-person interaction (to minimize disease spread) as well as a sudden willingness from insurance companies to cover virtual visits. For those enrolled in clinical studies, video conferences and patient portals have provided a way to continue communication with participants. This change provided an opportunity for CROs and participants alike to experience hybridization in trial design.

Hybridization

A virtual trial is defined by where and how the trial data are captured. They can be captured at a trial site, remotely, or as a hybrid of both. Because clinical trials vary widely in complexity, it is difficult to define the ideal remote model. Hybridization allows some on-site and some remote activities.

READ THE FULL POST ABOUT MAINTAINING STUDY PARTICIPANTS >

Hybrid trials offer decreased need for travel and in-person contact. They lessen the load on participants and can increase patient retention as a result. While patients appreciate decreased time and expense in any scenario, during the pandemic the improved safety has been especially important.

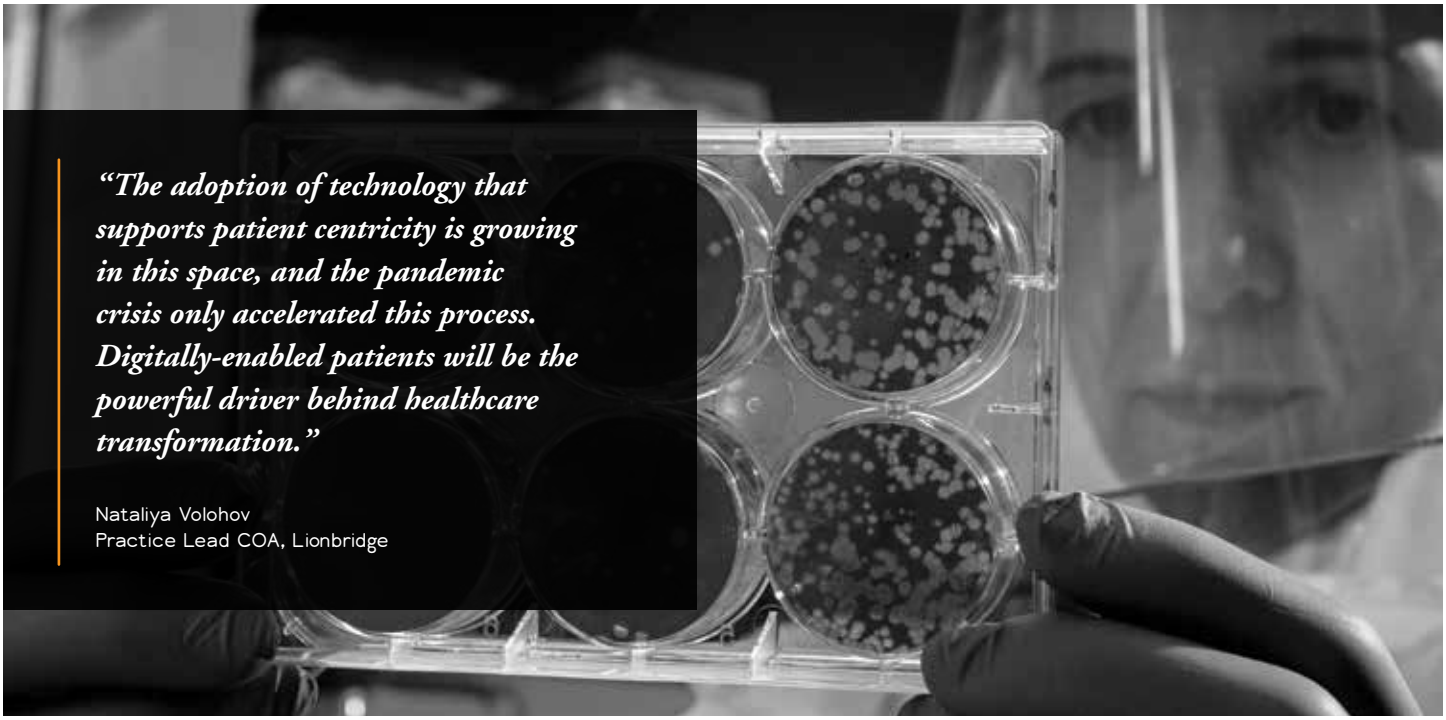
Many trials have needed to suddenly pivot to hybrid formats to follow regional and national restrictions on travel. Going forward, hybridization (particularly in phase two through four) is an increasingly attractive option for trial organizers.

> *"The goal of virtual trials should be to aim for the low risk trials where there is a high return on virtual trial execution."*
>
> Pia Windelow
> Director of Regulated Life Sciences Solution, Lionbridge

Patient Engagement and Tracking

As a result of more remote data collection and virtual site visits, study administrators have needed to focus on patient engagement more than usual. Multimedia tools to instruct participants on regimen adherence or data collection are increasingly popular because of the option to replay them. Even augmented reality can be of use for partially remote trials—the more interesting and informative patients find the process the more likely they are to correctly follow instructions and remain with the study to completion.

> *"Social media listening is another extraordinarily useful source of information. While medical device manufacturers conduct post-market surveillance on their products, clinicians and patients often discuss their experiences and opinions in online forums, creating a channel of informal feedback that manufacturers can also monitor."*
>
> Mark Aiello
> Vice President of Sales, Lionbridge



"The adoption of technology that supports patient centricity is growing in this space, and the pandemic crisis only accelerated this process. Digitally-enabled patients will be the powerful driver behind healthcare transformation."

Nataliya Volohov
Practice Lead COA, Lionbridge

RECOVERY

As some regions return to a semblance of normalcy, the clinical research space is moving out of crisis mode. Tools for eCOA, ePRO and any digital versions of once analog elements of the trial process are permanent fixtures in the trial space.

READ THE FULL POST ABOUT CHALLENGES IN MOVING CLINICAL TRIALS OFF SITE >

The Role of AI

Artificial intelligence applications have expanded and gained more acceptance due to the urgency of the situation. Data scientists and public health experts tracked patterns to predict new outbreaks and estimate unreported infections. New programs like a proximity-sensing app are in development to ideally notify anyone exposed to the virus and improve contact tracing.

Chatbots (as well as patient portals) are likely to continue growing as foundational tools for reducing face-to-face interaction and fast-tracking potential coronavirus cases. Decreasing the load on medical professionals as waves of infection come and go will, ideally, stabilize demand, allowing the return to clinical trials abandoned or slowed down during the worst of the pandemic.

Disaster Preparedness

The pandemic demanded a sudden flexibility that some trial sponsors were unprepared to meet. The solutions deployed to keep trials on track and the tools to accelerate COVID-related work are likely to move into the permanent toolbox of CROs.

Cross-border cooperation and regulatory flexibility were key to launching efforts to fight the spread of coronavirus. Just as with the pandemic itself, the future of those elements is unclear. If organizations and governments can maintain them, the same interconnectedness that spread COVID-19 so quickly could be the key to stopping it.

"The threat of the pandemic is not just its immediate effect on populations but the long-term implications for clinical trials."

Dan Herron
Global Director of Clinical Outcomes, Lionbridge

As medical and scientific experts have responded to the disruption from COVID-19, clear communication has continued to be key. From regulatory changes to patient engagement, comprehensible content is central to maintaining relationships and compliance. Lionbridge's decades of experience in multilingual content transformation support every project we complete. Whether you need fast-turn one-time help or a long-term on-going partnership, we can deliver quality language services anywhere in the world.

Learn more today by visiting
LIONBRIDGE.COM/GET-IN-TOUCH

MEET THE AUTHORS OF THE DISRUPTION SERIES

These Lionbridge Life Sciences experts have decades of experience with pharmaceutical companies, clinical research, regulatory agencies and medtech innovation around the globe. Together they lead a dedicated team that melds linguistic excellence with deep scientific and medical understanding.

MARK AIELLO

With an extensive regulatory background, Mark partners with customers to bring life-saving products to market while meeting and exceeding regulatory standards.

DAN HERRON

As Global Director, Clinical Outcomes for Lionbridge Life Sciences, Dan brings 12 years' experience in project management and account management supporting eCOA and Sponsor clients.

NATALIYA VOLOHOV

As the Practice Lead COA, Nataliya draws on her extensive experience within the clinical research industry to develop and support the delivery of Lionbridge Life Sciences' product strategies.

PIA WINDELOV

As the Director of Product Strategy for Lionbridge Life Sciences, Pia brings 15 years' experience in R&D in the pharmaceutical, CRO and MedTech sectors.

About Lionbridge

Lionbridge partners with brands to break barriers and build bridges all over the world. For more than 20 years, we have helped companies connect with global customers and employees by delivering localization and training data services in 350+ languages. Through our world-class platform, we orchestrate a network of one million passionate experts in 5000+ cities, who partner with brands to create culturally rich experiences. Relentless in our love of linguistics, we use the best of human and machine intelligence to forge understanding that resonates with our customers' customers. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 26 countries.

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