



CASE STUDY: LEADING BIOSCIENCES

Creative Application of DFIN's Venue[®] Rescues Biopharma Research and Introduces A New Normal for Clinical Trials



Leading BioSciences, Inc. (LBS), a U.S. biopharmaceutical company focused on therapies that target serious diseases and conditions associated with the breakdown of the mucosal barrier protecting the gastrointestinal tract.

Carlsbad, CA

In early March 2020, when the first wave of COVID-19 rolled into the continental U.S., leaders from every industry were forced to abandon business as usual and embrace new strategies and operational practices. For some, these adjustments are stopgaps that will be dismissed when the pandemic subsides. For others, like Leading BioSciences, Inc. (LBS), an emergency pivot to a Donnelley Financial Solutions (DFIN) tool turned out to be a process game changer now here to stay.

A California-based biopharmaceutical company, LBS, was in the midst of a Phase 2 clinical trial to test the efficacy of their investigational drug in the U.S. when coronavirus infection rates and talk about potential non-essential lockdowns began to escalate. A shutdown likely would have forced a delay or even halted the study.

Having worked with the Venue virtual data room for other areas of the business, LBS approached DFIN to discover if the platform could also be used as a contingency plan to keep the study afloat. The temporary fix surpassed all expectations.

“Working with DFIN’s Venue left us questioning why we were doing things how we have always done them. Using the platform has certainly opened the eyes of our company and the industry in general. We found a new way to do business that offers efficiency and cost savings and is a long-term solution.”

**INGE BEAR MS, CCRA
LBS CHIEF DEVELOPMENT
OFFICER**



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A Surprising Study Outcome Reveals Cost and Time Savings

The alternative plan's first hurdle, data privacy, and patient confidentiality was easily met. Venue's rigorous encrypted security easily met these requirements, which left only one issue to be resolved – could the study's 11 trial sites and independent study monitors be trained on how to remotely log-in and properly upload data?

A new process had to be extremely easy for LBS to introduce and for trial sites to use. Venue came through again. Its highly intuitive user interface took minutes for study personnel to submit medical record data remotely.

Quick thinking and rapid implementation of the Venue solution enabled the LBS Phase 2 trial to remain on or even ahead of schedule. It also resulted in unexpected discoveries certain to impact clinical trials at LBS with broader application industry wide.

“History has shown us that times of crisis have often resulted in great innovation. We are proud to have been perfectly positioned to provide Leading BioSciences with a rapid response tool and guidance for an efficient and cost-saving solution that has revolutionized the way they will do business long after the COVID crisis has passed.”

CRAIG CLAY
DFIN PRESIDENT OF GLOBAL
CAPITAL MARKETS



“Managing clinical trials with the Venue data room is not just something to be used during a pandemic. DFIN will be the new normal for how we plan to monitor studies going forward. We’re talking about significant savings in upfront costs as well as huge gains in time and efficiency. When we move to Phase 3 and beyond, we will be using DFIN software again.”

BRIAN WENZEL
LBS SENIOR DIRECTOR,
PROJECT & VENDOR MANAGEMENT



While the DFIN solution prevented the LBS clinical trial from being stalled, remarkably, Venue's creative application also resulted in unanticipated and significant cost and time savings for LBS. The reliability and ease plus the upsides for budget and efficiency prompted LBS leadership to examine their clinical trial monitoring process going forward. While it is not possible to entirely remove in-person monitoring visits from a clinical trial, post-pandemic, LBS will continue to rely on the Venue virtual data room, including integrating Venue's redaction capability.

[More information about LeadingBiosciences.com](https://www.leadingbiosciences.com)

Learn about DFIN's end-to-end risk and compliance solutions.
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