



Fujirebio Diagnostics Meets Immediate and Future Needs with LifeSphere Clinical Systems

Founded in Japan, Fujirebio has been in business for more than five decades. Their reputation for being innovative while developing, producing, and marketing high quality in vitro diagnostics (IVD) testing solutions worldwide, has made them a standout company in the marketplace.

LifeSphere Clinical systems provide speed and efficiency.

Eliminate delays caused by manual data production and review.

The Challenges

Fujirebio launched its first IVD test kit over 50 years ago and since then the company has seen steady growth over the years, including acquisitions of best-in-class IVD companies such as Centocor Diagnostics, which became Fujirebio Diagnostics, Inc. in 1998. As demand in this market segment began to rise, the company took its success to new levels. Led by Rachel Radwan, Director of Clinical R&D, the U.S. clinical operations and data management team doubled in size to accommodate an increasing volume of work.

Traditional data entry and review processes using spreadsheet trackers and paper were no longer sufficient to ensure fast and high-quality submissions to the FDA, Rachel said. Simultaneously, concerns grew about the increased risk of human error, quality issues, and delays as faster, shorter studies with higher complexity were planned. As a result of this, there was a need for faster, more accurate data, and a more streamlined data management process.

“Traditional data entry and review processes using spreadsheet trackers and paper were no longer sufficient to ensure fast and high-quality submissions to the FDA”

The Solution

Fujirebio Diagnostics next considered a Clinical Trial Management System (CTMS) and Electronic Data Capture (EDC) system for real time management of clinical operations and data. After assessing multiple software products, Fujirebio Diagnostics determined that ArisGlobal LifeSphere® CTMS and the unified LifeSphere Electronic Data Capture (EDC) system was the right solution.

LifeSphere was “the best overall product for now and where we are going,” Rachel said.

“ArisGlobal was willing to put in the effort with us and work toward the same goal. The entire group was amazing,” Rachel said.

The Results

The Fujirebio Diagnostics Clinical and Data Management team is now working in real time with unified LifeSphere CTMS and LifeSphere EDC. This will allow them to effectively eliminate delays caused by manual data production and review. Studies can now be launched much sooner, and the team will be able to look at data across studies. This includes visibility into site monitoring, an important benefit because clinical monitors were restricted from making site visits during the pandemic. The major achievement was moving beyond the manual process of reviewing reports and collating information manually across sites.

LifeSphere Clinical systems provide speed and efficiency.

For example, in one study that will collect samples from over 1,000 subjects, FDI quickly noticed an issue in the LifeSphere EDC case report form after enrolling 30 patients. It likely would have taken twice as long using traditional methods, Rachel said.

“LifeSphere makes us better and we are working with ArisGlobal to make the best system and improve study execution and data quality,” she concluded.

Benefits of LifeSphere Clinical

LifeSphere Clinical is a unified cloud platform for clinical operations and data management that accelerates studies, ensures transparency and streamlines collaboration across your organization.

It includes LifeSphere CTMS, LifeSphere electronic Trial Master File (eTMF) system, LifeSphere EDC, and LifeSphere electronic Clinical Outcomes Assessment (eCOA) system.

Share This



About Fujirebio Diagnostics, Inc.

Fujirebio Diagnostics, Inc., a wholly-owned subsidiary of H.U. Group Holdings, Inc. and Fujirebio Holdings, Inc., is the premier cancer diagnostics company and the industry leader in cancer biomarker assays. The company pioneered and introduced the CA125 test, the first FDA-approved ovarian cancer biomarker, over 25 years ago. Fujirebio Diagnostics specializes in the clinical development, manufacturing and commercialization of in-vitro diagnostic products for the management of human disease states, with an emphasis in oncology.



arisglobal.com