

## Molecular Insight's Value-Driven Focus Excels with Hosted Drug Safety Solution



### **Molecular Insight Pharmaceuticals Inc.**

Cambridge, Massachusetts  
[www.molecularinsight.com](http://www.molecularinsight.com)

**Industry:** Pharmaceutical

**Employees:** 92

**Aris Global® Product:**  
agOnDemand™

### **Key Benefits:**

- Managed, hosted solution for drug safety and pharmacovigilance
- Configured to Molecular Insight's unique SOP for handling of serious adverse events
- Eliminated the upfront and ongoing costs of new software, hardware and support staff
- Demonstrated SoX compliance with sustainable, proactive drug safety processes

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### **Diane Dahill**

**Pharm D Associate Director,  
Drug Safety and Pharmacovigilance, Molecular Insight Pharmaceuticals Inc.**

Cambridge, Massachusetts-based Molecular Insight Pharmaceuticals is a growing, publicly held biopharmaceutical company specializing in the emerging field of molecular medicine. The small, 90-person company works under a mission to lead the way in the discovery, development and commercialization of innovative and targeted radiotherapeutics and molecular imaging pharmaceuticals that improve the diagnosis, treatment and monitoring of patients with life-threatening heart disease, cancer and neurological disease. As it expands its value-driven pipeline of product candidates, Molecular Insight Pharmaceuticals consistently places patient safety at the forefront of all its R&D efforts.

### **Taking Back Control of Drug Safety and Pharmacovigilance**

Molecular Insight Pharmaceuticals had been outsourcing its drug safety to several contract research organizations (CROs) and incurring sizeable costs in the process. The company began to realize it wanted more control, security and support to ensure compliance with the regulatory authorities. In its attempt to reconcile the safety information it was receiving from various systems and sources—the pharma decided it wanted a more concise reporting process with enhanced tracking ability. The pharma wanted to take back the narrative writing of serious adverse events from the outside CRO so that important medical history and prior cancer treatment would be incorporated into the text to give a broader account of the patients that were enrolled within the Molecular Insight Pharmaceutical studies. Additionally, they wanted to review these serious adverse events directly with the sites rather than go through a third party to obtain and discuss pertinent information regarding these patients.

Based on these decisions, Molecular Insight Pharmaceuticals decided it was time to take control of its pharmacovigilance and safety process.



## The Challenge

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### **Making Sound Business Sense with a SaaS Solution**

Molecular Insight Pharmaceuticals' advancement of pre-clinical product candidates is partly based on proprietary platform technologies, which requires the ongoing support of its small information technology (IT) team. Without wanting to place any greater burden on IT, the small pharma company considered but quickly realized that the length of time required and the total cost of ownership necessary to implement and support an in-house pharmacovigilance system were more than it wanted to manage or invest in. Instead, the search for a hosted solution began in earnest.

“Because we are a small company, a hosted safety solution made perfect business sense for us,” says Diane Dahill, MS, Pharm D Associate Director of Drug Safety and Pharmacovigilance at Molecular Insight Pharmaceuticals. “We could eliminate the upfront and ongoing expenses of new software, and hardware, as well as the overhead of hiring additional staff to provide training and support.”

### **Selecting a Solution Backed by Strong Vendor Reputation**

As the company began its search for a solution, Dahill collaborated with a core team of professionals from Drug Safety, Regulatory Affairs, Quality Assurance, IT, Operations and Data Management to ensure that key areas of the company would contribute to making the best choice. A number of meetings and lively discussions culminated with a detailed list of necessary requirements from which each vendor's hosted safety solution would be evaluated.

After some initial research, a short list of five possible major vendors, including Aris Global, was determined. Given that five users across the organization would use the selected system, ease of use, quality training and 24x7x365 support were seen as key criteria. It was also critical that the company receive a pre-validated system—one that could handle its IQs, PQs and OQs.

Following an extensive, five-month review period in which all five vendors were invited in for demonstrations and meetings, the pharma ultimately selected Aris Global and the agOnDemand solution. While some of the other vendors met the company's core functional requirements, their pricing model was significantly more expensive than Aris Global's and included hidden fees and other charges that drove the costs even higher. The company also felt comfortable with choosing Aris Global because of its solid reputation and long-term commitment

## The Solution

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to providing future updates—something that came into question for some of the vendors being evaluated.

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### **Ensuring Regulatory and Sarbanes-Oxley Compliance**

“Pioneers in Medicine. Partners in Care.” is the mission behind Molecular Insight Pharmaceuticals' every activity. R&D programs need to remain on track, and the company recognizes that it can better meet clinical and developmental milestones by reducing regulatory risks.

In choosing agOnDemand, the company took the opportunity to improve its internal processes, data quality and reporting to the FDA. The ability to now attach source documents with any reported adverse event, especially helpful for medical reviewers residing outside the U.S., is just one example that is helping ensure its compliance.

Just as important, the company's compliance to the Sarbanes-Oxley (SOx) Act of 2002, which is U.S.-based legislation, is vital to ensuring shareholder confidence and value.

### **Achieving Support for Non-Standard Workflows**

Molecular Insight has an all-encompassing standard operating procedure (SOP) for handling SAEs, involving many departments such as Safety, Regulatory and Medical Monitoring. Being a small pharma, many of the individuals in these departments wear multiple hats in the SAE process. While the agOnDemand is delivered as an out-of-the-box solution and is based on industry best practices, Aris Global's development team quickly configured the hosted solution to meet the company's unique SOP workflow and process requirements.

## The Result

Via an intuitive user interface, each user has web-based, remote access to agOnDemand. The company's Regulatory team can easily pull reports on whatever statistics and information it needs to prepare for regulatory submissions. Moreover, ARISg's integration with SAP<sup>®</sup> BusinessObjects<sup>™</sup>, allows users the ability to create ad hoc reports as well as execute the standard out-of-the-box reports contained in the system. Molecular Insight Pharmaceuticals is also taking advantage of the SAP BusinessObjects integration to run reports to reconcile data between their clinical and safety system.

### **Security, Availability and Support that Never Quits**

The company's IT department, headed by Peter Sebilian, Director of IT, is also very satisfied with agOnDemand. Sebilian conducted an onsite audit at the Navisite data center in Andover, MA, where agOnDemand is hosted, to ensure SAS 70 certification and ISO 9001 compliance. Sebilian and his team also audited Aris Global's QA documentation via an online portal and were pleased by what they read. The IT team further appreciates that patches and upgrades are automatically applied by Aris Global without any burden on them.

"Based on all that we have seen and from the ongoing discussions we have with Aris Global, we are completely confident that Aris Global's system provides us with the responsive support, maximum system availability and data security we need," says Sebilian."

### **The Future Looks Promising**

As Dahill looks to the future, she is optimistic that Molecular Insight Pharmaceuticals' drug safety needs will be easily met with agOnDemand. While the company is still in the early throes of working with agOnDemand, she is excited by the possibilities of how the hosted solution will enhance its safety processes and case handling.

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### **About Aris Global**

For more than 20 years, Aris Global has been a trusted and reliable partner of many of the world's leading pharmaceutical, device, biotechnology and clinical research organizations. More than 300 life sciences companies rely on our innovation and advanced technology solutions in pharmacovigilance and safety, regulatory affairs, clinical research and medical information.

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