

PharmaReady™



PharmaReady Case Study Submitted by Conatus Pharmaceuticals

PharmaReady has proven to significantly decrease time and effort in locating legacy documents and study-related materials.

COMPANY PROFILE

Conatus Pharmaceuticals Inc. is a privately-held specialty pharmaceutical company engaged in the development of innovative human therapeutics to treat liver disease. Chronic liver disease affects tens of millions of people worldwide and can be caused by many different conditions or “insults” to the liver including Hepatitis C and other viral infections, obesity, chronic alcohol abuse or autoimmune diseases. Conatus was founded by the executive management team of Idun Pharmaceuticals in July 2005 following the successful sale of Idun to Pfizer.

Our lead drug candidate, CTS-1027, is an oral small molecule that is being studied in a Phase 2 trial as a treatment for the inflammatory damage to the liver resulting from infection by HCV. CTS-1027 has been shown to be effective in multiple preclinical models of liver disease.

Conatus Pharmaceuticals is a “virtual” business model based in San Diego. We currently have 11 full time and 2 part time employees. We expect the headcount will remain below 20 people.

BUSINESS PROBLEM

CTS-1027 was in-licensed from a major pharmaceutical company after it had been tested in Phase 2 trials in a different clinical indication. Because so much work had been performed with the drug, there were hundreds of legacy documents that were part of our technical transfer. We evaluated electronic data management systems (eDMS) prior to the finalization of the licensing agreement. The plan was to implement a solution around the time of tech transfer, as we were also preparing our initial IND for filing with the FDA.

We gathered input from colleagues who were going through a similar selection process or who were going through implementation of an eDMS. We spoke with regulatory affairs, quality assurance and IT experts. We eliminated a number of solutions early on as not appropriate for our needs, and selected PharmaReady and LiveLink as the solutions we were most interested in pursuing. We had demonstrations and spoke

with users of both products. While we were very impressed with the functionality of the LiveLink product, PharmaReady had a number of key advantages:

- + Total cost was almost an order of magnitude less
- + Implementation was much simpler because it is designed for the pharmaceutical industry
- + A hosted solution was feasible
- + The implementation of an eDMS solution was essential before our successful entry into the clinic.

BUSINESS DRIVERS

The objective for Conatus Pharmaceuticals is to build a specialty pharmaceutical company focused in the area of liver disease. As a virtual company, we utilize a minimum number of employees while maximizing our reliance on key outside vendors to provide scalable resources for our business needs. We acquired the lead development asset, CTS-1027, and have recently initiated a Phase 2 clinical trial in HCV-infected patients. We plan to supplement this lead compound through the acquisition of complementary molecules targeted at different mechanisms in order to build an attractive portfolio of drug candidates for liver disease. Our goal is to add value by confirming efficacy in preclinical studies and demonstrating activity in human clinical trials in a defined patient population.



PharmaReady Case Study Submitted by
Conatus Pharmaceuticals

SOLUTION

To meet our business needs, we decided to purchase PharmaReady version 3.0. We have been able to use PharmaReady's shell to develop an eDMS that effectively manages both the legacy documents and the clinical trial records from our Phase II study. Through discussions with our Take Solutions Support Team, we decided that remotely hosting the system was the best option for a company of our size. We have recently upgraded to PharmaReady version 4.0 because of its more user-friendly interface and higher processing efficiency.

We designed our PharmaReady system so that documents could be easily coded for searches at a later date. In doing so, we brainstormed the types of documents to be included in the system, the areas or "libraries" that needed to be created, and the ideal sub-categories to help sort these documents. We decided to use the system for the following types of documents:

- + SOPs and Work Instructions
- + Clinical Study Documents (e.g. Protocol, Investigators Brochure)
- + Clinical Trial Records (Site-Specific Regulatory Documents, e.g. CVs, IRB Approval Letters)
- + Legacy Reports on Preclinical and Clinical Studies
- + Chemistry and Manufacturing Documents (e.g. Specifications, Stability Data)

As a result of numerous discussions with our Take Solutions Support Team, as well as our work customizing the system, our Regulatory Department was already fluent with PharmaReady. We therefore provided our own group training to the remainder of our office and to our off-site Clinical Research Monitors (CRMs). The system proved very userfriendly, and our core users quickly learned the system. For less frequent users, we provide training on an as-needed basis through our Quality Assurance group.

BUSINESS VALUE

PharmaReady has proven to significantly decrease time and effort in locating legacy documents and study-related materials. Previously, a very limited number of personnel were able to access these documents from our file room, but now all "need to know" personnel are able to view each of these materials online by logging into PharmaReady. For example, we collect all site regulatory documents in-house and subsequently post the documents on the PharmaReady system. Since PharmaReady can be accessed from anywhere, our off-site CRMs can view the information at the touch of a finger twenty-four hours a day. This allows for a complete and up-to-date exchange of information, resulting in a higher level of site monitoring.

In terms of managing our IND, PharmaReady has proven invaluable for organizing and storing our 16,000 page submission. In addition, PharmaReady's "virtual document" functionality has allowed us to combine already uploaded documents into a composite file. This has increased efficiency in filing amendments to our IND.

As an added bonus, PharmaReady has significantly reduced the burden of tracking the training requirements for members of our staff. Previously, we worked with numerous spreadsheets to ensure that all appropriate training was conducted. With the addition of PharmaReady, we are able to use the system to send reminder emails to our staff when a training need arises, as well as to generate reports to ensure that the training has been completed. Finally, since we have already customized the PharmaReady system for our current clinical trial, the system is ready-to-go for future studies. The start-up time will be significantly reduced, and we will be able to

Ready for more?

Visit www.pharmaready.com to take a look at PharmaReady. If you've looked at other regulatory information management products, we think you'll like what you see.

Learn how your organization can benefit from the most cost-effective, EDMS solution on the market today by calling: **877-320-3626** or visit: www.pharmaready.com.



PharmaReady™ is an exclusive brand of
TAKE Solutions Inc., Global Life Sciences
502 Carnegie Center, Suite 100
Princeton, NJ 08540
contact@Pharmaready.com
Tel: 877-320-3626

