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UniConnect Inks First Clinical MDx Deal in Europe with Vivia Biotech

UNICONNECT, a laboratory information management system software company, announced recently that personalized medicine firm Vivia Biotech will use its UniFlow software to manage patient samples and drug compounds.

Segovia, Spain-based Vivia, which screens drugs in blood samples in order to determine the most effective treatments for individual patients, will use the system to manage data and samples for hematological cancers including leukemia, multiple myeloma, and lymphoma.

UniConnect has historically focused on biotech and diagnostics companies as its primary customers and is looking to make a move into clinics and hospitals. The agreement with Vivia marks its first deal with a clinical diagnostics company in the European Union, though other diagnostics firms, including Axial Biotech and Clariant, are UniFlow users.

Vivia selected UniFlow following a 10-week pilot project to validate the system's ability to meet its current and future requirements.

Teresa Bennett, vice president of research at Vivia, told BioInform that the company considered offerings from competing vendors such as Oracle, IDBS, and Lab-Vantage during the pilot.

Prior to purchasing the new LIMS, Vivia used IBDS' ActivityBase and Excel spreadsheets to manage and track its data, Bennett said.

Vivia determined that it needed a compound-management system, but also wanted "something that we could integrate into managing our patient samples," she said.

This was particularly challenging because the company currently collects samples from 25 hospitals in Spain and expects that number to rise to 70 by the end of this year.

The company has developed a technology called ExviTech that uses flow cytometry to assess the effectiveness of therapies in specific patients.

"We do patient sample testing and look at functional assays based on the blood samples and bone marrow samples of patients," Bennett explained. Currently, the company offers a test for hematologic malignancies that identifies the most effective multi-drug treatment for individual patients.

"We [needed] to be able to track samples from when [they are] extracted from the patients until we get it into our laboratory," Bennett said. "Our results need to be correlated with information we receive from the hospital; we need to track the workflow of the sample and ... be able to generate [internal] reports ... [and] supply a report to physicians."

Coyt Jackson, Vivia's IT engineering director and lead project engineer, told BioInform that the company compared the available systems and found that most failed to address all of Vivia's needs, although some systems could do "thirty, forty, or sixty percent of it."

PROCESS-ORIENTED LIMS

UniFlow, which UniConnect describes as a "laboratory process management system," is a customized offering that delivers benefits that off-the-shelf LIMS software can't, according to the company.

"We do LIMS but we do LIMS through a process-



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oriented platform that takes into account LIMS requirements but a lot more than just [that]," William Harten, founder and CEO, told *BioInform*. "It is a platform for defining and implementing any kind of process."

Among other capabilities, the tool tracks and manages processes involving multiple steps and information types, such as samples, outputs, instruments, reagents, worker responsibilities, and requests and it lets users customize the system to their needs and modify them as their requirements change.

"We track product units moving through work units in a generic data-driven way so that we can create new processes very quickly without programming," Harten explained.

The company defines each work product, work unit, data to be recorded, and required validations in a "high-level, executable process-specification language," he said. "Defining requirements this way makes them rigorous and complete, and enables the UniFlow engine to execute the specification directly."

The language is built on top of Java and XML and provides a way to capture information that "drives the user interface, the business logic, and data recorded in the database," he said.

These three layers are woven together into the fabric of the UniFlow specification language, yet they remain accessible for customization when needed, Harten explained.

He likened the system to Excel, which offers formulas that enable users to analyze data without programming. The UniFlow equivalents of Excel's formulas, called tags, "make it possible to completely and unambiguously define complex processes," he said.

These tags are defined in terms of "process concepts" — for example, what product units need to be built; what components comprise the product units; and what other information must be captured and validated as well as what controls are needed to prevent mistakes.

UniConnect trains clients to use the language to make additional customizations to the system as well as implement changes as they arise.

The company counts among its customers Myriad Genetics, Celera Genomics, Illumina, Pioneer Hi-Bred,

Sorenson Genomics, Southern Research Institute, Nelson Labs, and ARUP Labs. These groups are using UniFlow in molecular laboratories as well as for high-throughput screening and proteomics applications.

UniFlow is priced between \$200,000 and \$400,000 for a license. Carl Hull, UniConnect's vice president of sales and project manager, told *BioInform* that the cost is based on whether the customer wants to purchase a perpetual license to the software or opt for a software-as-a-service model.

He said that the price is also based on the amount of configuration and customization that needs to be done upfront.

EXPERIENCED CUSTOMERS

UniConnect's primary clients are labs that have had at least one experience with commercial LIMS software or homegrown solutions and are looking for an alternative.

Rick Mandahl, UniConnect's vice president of business development, explained to *BioInform* via e-mail that the company typically encounters two types of customers.

"Those without LIMS experience shop for a specific set of features they need today. They assume others' needs are the same, and evaluate products based on 'feature fit,'" he said. Those with prior LIMS experience, on the other hand, "have painfully discovered that off-the-shelf features don't fit their situation [and] that labs optimize processes differently."

These customers, he said "demand the ability to change the process quickly and economically as their primary requirement."

Harten explained that novice clients typically run into problems with off-the-shelf solutions because they aren't comprehensive enough to meet all their requirements and using a combination of two solutions "doesn't work."

"The real LIMS need ... is not this or that specific solution, it is the capacity to address any solution, to meet any changing LIMS requirement, he said. "That is what we deliver, and that is what makes us different."

He noted that most LIMS aren't flexible enough to account for changing lab requirements as companies

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make adjustments to their businesses to optimize value and minimize costs.

“The areas where you make adjustments are usually the risk factors that you want to track and control,” he said. “No two labs are optimizing the same variables. So although it may be the same science, what you track and control is completely different.”

IN THE BEGINNING

Headquartered in Sandy, Utah, UniConnect began in 1998 as a one-man consultancy when Harten was hired by Myriad Genetics to build a laboratory-tracking system for its protein-interaction research pipeline. Myriad later contracted a similar system for a whole-genome sequencing project.

Prior to starting the company, Harten developed the FamilySearch genealogical database for the Church of Jesus Christ of Latter-day Saints, and he applied the same principles to Myriad’s projects.

“We view tracking and controlling a complex process as a genealogical problem,” he explained. “We need to know the descendants of a given sample down through all of its generations; or, coming the other way, we need

to know all the ancestors that resulted in a particular outcome.”

At each step of the process, Harten continued, researchers capture information and procedures as they happen, which affords the opportunity “to apply controls” along the way and maintain detailed records of samples, instruments, and processes.

“By being able to track every event, every activity that people did, every relationship from a mother tube or plate to a daughter tube or plate, we are able to reconstruct the complete genealogy in both directions in a generic and uniform way,” he said. “And this information allows us to apply controls to prevent mistakes as we went along.”

In 2006, UniConnect switched from a consultancy business model to a venture start-up model and expanded its employee headcount. Currently, the firm has 12 employees and a series of outsource groups based in the US and Western Europe. It also has offices in San Diego, Calif., and Minneapolis, Minn.

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