Article

Bio.logis Readies New Clinical Genetic Data Interpretation Tools Amid Growing Customer Interest

NEW YORK (GenomeWeb) – Bio.logis, a Frankfurt, Germany-based informatics company, is planning multiple upgrades to its flagship clinical genetic data interpretation tool as it continues to win new customers across Europe.

CMO Maike Post said that the firm will launch two new analysis modules for its Genetic Information Management Suite next year, in addition to a new pharmacogenomics mobile application.

The activity is synchronous with uptake of Bio.logis' analytical tools at a number of laboratories. Last week the firm announced that Laboratoires Réunis, a medical analysis laboratory based in Luxembourg, had adopted GIMS to automate the creation of diagnostic reports. The firm's tools are also being used within the Ubiquitous Pharmacogenomics Consortium, a multinational, EU-funded project for the clinical implementation of pharmacogenetics.

"Our goal is to support and drive the adoption of human genetic diagnostics into clinical practice," said Post. "In the process chain of genetic diagnostics, we go beyond bioinformatic output and focus on the last mile ... by merging genetic raw data with actionable clinical knowledge for direct application," she said.

Established by CEO Daniela Steinberger as Bio.logis Genetic Information Management GmbH (Bio.logis GIM) in 2013, the company is a spinout of the Bio.logis Center for Human Genetics, a Frankfurt-based clinic that offers human genetic diagnostics and genetic counseling. Bio.logis currently employs 25 specialists in bioinformatics, IT, and human genetics, Post said. It develops its software using open source tools, and its core business is software development and services for diagnostic labs.

Bio.logis commenced commercial operations last year when it rolled out its Diagnostic Report Module (DRM), which has since been certified as a Class 1 medical device in line with European directives. Advertised as a "fully functional content management system for diagnostic content," the module consists of a genetic report engine for the automated production of diagnostic reports with direct connectivity to laboratory information management systems or other informatics platforms through standard interfaces.

According to Post, Bio.logis is now preparing two additional modules to build out its offering, both of which will launch during 2018. These include its Knowledge Management Module (KMM) and Delivery Module (DM).

The first, KMM, supports a structured documentation process for the review and approval of expert content. This includes the provision of curated information for diagnostic decision support and automated report production through a direct interface to DRM.

The second, DM, provides results in formats that enable better access and usability, such as web portals and mobile applications. The module supports the real-time generation of diagnostic reports within genetic health records, and alerts users when new data becomes available. There is also the option to integrate the module into electronic health records, according to the company.

Both modules will be ready for market introduction in 2018, she said. These new tools will "further streamline the process of clinically enhanced diagnostic report formats," she said.

The company views its products as serving an unmet need in the market, replacing current processes, which Post described as "highly manual, fragmented, and heterogeneous," rather than competing with other informatics tools.

"They replace procedures that are sensitive to erroneous decisions based on incomplete information and knowledge gaps," said Post.

One of the first customers using Bio.logis' offering outside of Germany is Laboratoires Réunis.

Post said the lab had "very specific requirements" given its test portfolio, which runs the gamut from oncology to infectious disease testing. Laboratoires Réunis currently maintains 50 blood sampling locations, as well as sites at Trier, Germany, and Fléron, Belgium. As such, Post described the lab's adoption of Bio.logis' tools as a "milestone" for the company.

Martin Schöndorf, director of preventive medicine at Laboratoires Réunis, said that the lab selected GIMS because it's a "good tool for clinical decision making." He also praised Bio.logis for understanding the complexity of genetic analysis and how to deal with medical algorithms, noting that the company was "very supportive" in customizing the system for his lab.

In addition to Laboratoires Réunis, Post said that GIMS is installed in five European countries where it serves as the backbone for the U-PGx project. Backed by €15 million ($16.1 million) in EU Horizon 2020 funding, the U-PGx project aims to implement preemptive pharmacogenomic testing at seven healthcare systems across the continent by 2020. Bio.logis reported in April 2016 that it received €2.4 million ($2.8 million) in connection with the project.

As part of the effort, U-PGx members will genotype 8,100 patients at sites in Austria, Greece, Italy, the Netherlands, Slovenia, Spain, and the UK with a panel of 84 genes relevant to drug dosage. The members hope to show a decline in adverse drug reactions and improvement in drug efficacy among genotyped participants. They also hope the results will encourage healthcare systems across Europe to adopt pharmacogenetic testing as part of routine care.

Post called Bio.logis' participation a "milestone" for the company as "pharmacogenetics experts with highest international reputation are applying its products in a clinical context." As a result, "high-ranking international institutions" have shown interest in the firm's products, she said.

Participants are using GIMS to create customized reports with "easily understood pharmacogenetics recommendations," according to Post. GIMS will therefore enable automated

production of diagnostic reports as well as the digital delivery of results and information to physicians and patients, in the local language, she said.

Mobile application

Bio.logis also recently launched an initial version of a mobile application called pharma.sensor that can be used to identify if genotyping a patient for certain variants might be useful prior to administering a particular therapy.

"The drug check is performed by simply entering a drug name or scanning the barcode on the packaging," Post said. She noted that while a "huge amount of information about genetic variants" exists, it has been difficult for clinicians to access that data because no supporting tools have been available. Bio.logis therefore developed pharma.sensor to check whether relevant DNA information is available for the efficacy or tolerance of different drugs.

If a genetic test is deemed to be necessary, users can then order one via the Bio.logis Center for Human Genetics, Post added. Other testing partners will be added in the future, she said.

The app is available in German and English via the Apple store and is free of charge, and a version for Android will soon be available.

According to Post, the availability of pharma.sensor is part of a trend towards developing mobile applications for the healthcare sector.

"The amount and complexity of information that has to be handled by a medical doctor for decision making is a challenge;" said Post. "These challenges easily exceed individual capacities and can be better managed by trustworthy, certified smart mobile solutions;" she said. "It can be assumed that these [mobile] solutions will become more popular in the healthcare industry."