

Paragon Biosciences unveils Qlarity Imaging to advance Quantx system

By Liz Hollis, Staff Writer

Chicago-based Paragon Biosciences LLC has launched its seventh portfolio company, Qlarity Imaging LLC, which will focus on further developing Quantx, an FDA-cleared, computer-aided breast cancer diagnosis system.

“By driving innovation across life sciences, Paragon fulfills its mission of improving outcomes for patients with severe medical conditions,” said Paragon Biosciences Chairman and CEO Jeff Aronin. He added that his company was enthusiastic about helping advance this artificial intelligence (AI)-enabled diagnostic software for breast cancer magnetic resonance imaging (MRI).

Quantx was developed at the University of Chicago based on research led by Maryellen Giger, who will serve as an advisor to Qlarity Imaging. She has conducted more than 30 years of research in computer-aided diagnosis, including computer vision and machine learning for cancers of the breast, lung, prostate, as well as lupus and bone disease. She also had high praise for Paragon Biosciences. “When we looked at how to best commercialize and scale Quantx . . . Paragon Biosciences was the perfect partner,” Giger said.

Quantx, which was incubated at Quantitative Insights Inc., is powered by machine learning AI and trained by a large reference database of abnormalities. It includes a display of similar cases and the histogram of known lesions for various analytic features.

The Quantx Advanced won its nod through the FDA’s de novo pathway, with Quantitative Insights reporting its clearance in July 2017. “In our FDA clinical study, Quantx was shown to improve the diagnostic performance of radiologists, enabling faster and more accurate diagnosis, more personalized treatments and better outcomes for patients,” Keith Tipton, CEO of Quantitative Insights, said at the time.

A couple of months prior to the de novo win, the company reported that it had won 510(k) clearance for the Quantx SE system, a quantitative imaging based analysis platform for the evaluation of breast lesions. Quantx SE is the basis for Quantx Advanced, with the latter adding on a QI Score, similar case compare, 4D lesion segmentation, real-time analytics and graphical tools to visualize all radiomic features.

The QI Score is a metric computed by an AI algorithm

“

In our FDA clinical study, Quantx was shown to improve the diagnostic performance of radiologists, enabling faster and more accurate diagnosis, more personalized treatments and better outcomes for patients.

Keith Tipton
CEO, Quantitative Insights

synthesis of certain imaging features. “[It] is related to the likelihood of malignancy,” Meghan Harrison, Chicago-based Qlarity Imaging’s head of product and COO, told *BioWorld MedTech*. “Quantx extracts image data from radiologist-selected regions of interest to provide volumetric analysis and computer analytics based on morphological and enhancement characteristics. These imaging [or radiomic] features are synthesized by an [AI] algorithm into a single value, the QI Score.”

Looking ahead

Harrison noted that physician feedback thus far has been positive. “The results of our FDA-clearance study demonstrated a 20% overall diagnostic improvement and a 39% reduction in missed breast cancers when radiologists used our software,” she added.

“The patents and key intellectual property developed by Quantitative Insights have been acquired by Qlarity Imaging. The core leadership team and clinical advisors formerly at Quantitative Insights have joined Qlarity Imaging as well,” Harrison responded when asked whether Qlarity Imaging would continue work with the other company.

Qlarity Imaging is in the early phases of rolling out Quantx as its gains more feedback from radiologists at the University of Chicago and the MD Anderson Cancer Center at the University of Texas, Harrison added. “We will use that feedback to further optimize the product in preparation for a broader rollout.”

Continues on next page

Continued from previous page

For now, the company will focus on optimizing Quantx. “We are also exploring how it can be expanded to other imaging modalities beyond MRI and additional medical conditions.” She added that Paragon Biosciences’ support should boost the company’s “active program to expand AI-enabled diagnostic insights to multiple imaging modalities and additional types of cancer.”

AI making strides

A number of companies have been using AI to help identify breast cancer. Last year, for example, Nashua, N.H.-based Icad Inc. received clearance from the U.S. FDA for a cancer detection software solution for digital breast tomosynthesis (DBT), known as Profound AI. (See *BioWorld MedTech*, Dec. 10, 2018.)

Profound AI is a deep-learning, cancer detection and workflow solution for DBT. It aims to deliver benefits via the improvement of cancer detection rates by an average of 8% and decreasing unnecessary patient recall rates by an average

of 7%. The aims to detect malignant soft-tissue densities and calcifications and provides scoring information. That information relates to the likelihood that a detection or case is malignant based on the large dataset of clinical images used to train the algorithm.

In addition, Wellington, New Zealand-based Volpara Health Technologies Ltd. has said that its AI algorithm Volparadensity provides additional evidence of the significance of breast density as a risk factor for missed cancer. (See *BioWorld MedTech*, March 11, 2019.) Early trial results of its Volparadensity clinical application showed a dramatic drop in interval cancers in women with extremely dense breasts when using X-ray, Volparadensity and then MRI.

In early June, Volpara reported that it had signed a binding agreement to acquire U.S.-based MRS Systems Inc. The move aimed to allow Volpara to expand its product portfolio and apply its experience in AI and machine learning to improve personalized breast care through new technology development. ♦