Green light from FDA for CT lung-imaging software

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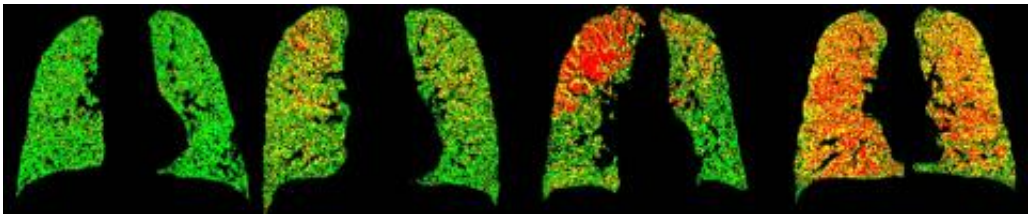

This is a comparison of different patients' lungs, imaged using the U-M/Imbio technique. The red and yellow areas show reduced ability to push out air. Credit: University of Michigan Center for Molecular Imaging

A technology that started in a University of Michigan Medical School lab may soon help lung disease patients around the world breathe a little easier, by helping their doctors make a clearer diagnosis and more individualized treatment plan.

Imbio, a startup launched from the University of Michigan in 2007, has just received clearance from the U.S. Food and Drug Administration to sell its software platform based on U-M research. Called Lung Density Analysis or LDA, it analyzes images of patients' lungs with detailed precision.

The new FDA 510(K) clearance allows doctors to use Imbio's LDA system in patients with chronic obstructive pulmonary disease or COPD, which affects over 60 million people worldwide.

The software allows doctors to carefully analyze a patient's CT (computed tomography) lung scan and look at how their disease is affecting their ability to fill their lungs with air and to push it out when they exhale. The company is also developing techniques for analyzing other lung images, and images of cancerous tumors, to guide treatment using variations of the same technology.

Not only does the technology have its roots in the U-M Department of Radiology's Center for Molecular Imaging, it was also tested thoroughly by a separate team of U-M Health System lung-imaging experts.

Together, they published the results of their in-depth testing in the prestigious journal *Nature Medicine* in 2012. For more on that study, and the concept first created at U-M, visit http://umhealth.me/copdprm .

The technology grew out of basic laboratory research at U-M by the company's co-founders, Brian Ross, Ph.D., and Alnawaz Rehemtulla, Ph.D. Both now act as scientific advisors to Imbio.

"It's incredibly gratifying to see this concept grow from an idea in our lab, to a product ready for market," says Ross. "We look forward to seeing how clinicians worldwide can use the LDA approach to benefit patients, and we're grateful to all who have helped this concept reach this exciting point through many years of research and product development." He credited the university's research and technology transfer environment for helping the concept reach the marketable stage.

Ella Kazerooni, M.D., chief of cardiothoracic imaging at UMHS, led the clinical evaluation of the technology, using images from the COPDGene trial that involved thousands of COPD patients around the country.

"This groundbreaking technique reveals functional information about the lung's performance that is not available through other means and will

allow us to tailor more individualized treatment for these patients," says Kazerooni. "We are very excited to see the technique launched as a commercial product, after years of development in our image processing lab and extensive clinical research in thousands of COPD patients."

The LDA approach uses powerful computer techniques to overlay the CT scan taken during a full inhalation with an image taken during a full exhalation. The overlaid, or registered, CT images share the same geometric space, so that the lung tissue in the inflated and deflated lungs aligns. The density of healthy lung tissue will change more between the two images than the density of diseased lung, allowing researchers to create a three-dimensional "map" of the patient's lung function

The software assigns colors to each small 3-D area, called a voxel, according to the difference in signal changes within each of the areas between the two scans. Green means healthy, yellow means a reduced ability to push air out of the lung's small air sacs, and red means severely reduced ability.

Ross is the Roger A. Berg Research Professor of radiology and professor of biological chemistry at the U-M Medical School, while Rehemtulla is the Ruth Tuttle Freeman Research Professor of Radiation Oncology. Kazerooni is a professor of radiology and member of the Institute for Healthcare Policy and Innovation.

Ross and Rehemtulla have a financial interest in the company, but do not receive salary or consulting income. Kazerooni has no financial interest in the company or involvement in its operations. The University has a financial interest in the company via its licensing agreement.

Provided by University of Michigan Health System