

Imbio secures research agreement with U.S. Dept of Veteran Affairs

27 February 2024

Highlights

- This project will use Imbio's Lung Texture Analysis (LTA) to assess the CT scans of a cohort of Veterans that underwent Lung Cancer Screening (LCS) between 2014 and 2017 to determine the prevalence of interstitial lung disease (ILD)
- The U.S. Veteran population suffers from ILD at a rate of 10 times the civilian population, with a 260% growth in the incidence of this debilitating condition since 2010
- Distinct from the Company's ongoing efforts to diagnose Veterans with deployment related respiratory disease, this project broadens and accelerates 4DMedical's engagement with the VA

Melbourne, Australia, 27 February 2024: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", or the "Company") today announces the signing of a research agreement with the U.S. Department of Veterans Affairs (VA).

VA research agreement

4DMedical's wholly owned subsidiary, Imbio, has secured a research agreement with the VA Center for Innovations in Quality, Effectiveness and Safety (IQuESt). The research project will use Imbio's Lung Texture Analysis (LTA) to retrospectively assess the CT scans of a cohort of Veterans that underwent Lung Cancer Screening (LCS) between 2014 and 2017 to determine the prevalence, diagnostic delay, and mortality associated with interstitial lung abnormalities (ILA) and interstitial lung disease (ILD).

The U.S. Veteran population suffers from ILD at a rate of 10 times the civilian population, with a 260% growth in the incidence of this debilitating condition since 2010. Approximately 1 million Veterans are eligible for lung cancer screening (LCS), and up to 25% of these patients are projected to have findings of ILA/ILD based on lung cancer screening demonstration project data.

While the prevalence of high-risk features for ILA progression are not well characterised, lung texture analysis is effective in the classification of normal versus abnormal tissue, and performs well in distinguishing typical pathologies present in lungs with fibrotic disease. Imbio's LTA product will be utilised to retrospectively assess a random sample of 2,000 patients with ILA/ILD from the national cohort, in the project titled, "Novel Machine Learning Tools to Reduce Diagnostic Delays Among Veterans with Pulmonary Fibrosis".

Principal investigator from the Michael E. DeBakey Department of Veterans Affairs Medical Center, Houston, Texas, Prof. Kaul, MD, stated in the research outline: "Our central hypothesis is that [Imbio] LTA can identify Veterans with fibrosis early in their disease process and expedite access to subspecialty care...Partnering with the VA's national LCS program thus has the potential to improve early pulmonary fibrosis diagnosis as there are 900,000 Veterans eligible for lung cancer screening".



Scientific aims of the project

The project will describe the prevalence of ILA and ILD among a national cohort of Veterans undergoing lung cancer screening. Because lung cancer screening is often led by primary care, under-reporting of radiographic abnormalities on CT may contribute to delays in pulmonary subspecialty referral, and subsequent initiation of appropriate therapy.

The project will quantify the delay between acquisition of the lung cancer screening CT and diagnosis of pulmonary fibrosis. Additionally, the project will quantify the degree of radiographic progression (change in percentage of fibrosis) between lung cancer CTs with evidence of fibrosis, and a 5-year follow up CT.

Additional baseline demographic, comorbidity and 5-year outcome data will be extracted from the electronic health record. This additional data is important, as quantifying disease progression and mortality associated with ILA/ILD detected during lung cancer screening will help inform future risk prediction models and care for Veterans with these incidental findings.

4DMedical MD/CEO and Founder Andreas Fouras said:

4DMedical's transformational acquisition of Imbio is already yielding results with an additional pathway to supporting lung health in the Veteran community. This research agreement is a major milestone in adding value to lung cancer screening programs in the VA and elsewhere, as we progress our LTA product to FDA approval later this year. 4DMedical's demonstrated work to date with Veterans has been focussed on exposures to airborne hazards during deployment and I look forward to sharing further progress on this over the coming weeks and months.

-ENDS-

Authorised by the 4DMedical Board of Directors.

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About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company that has created a step change in the capacity to accurately and quickly understand the lung function of patients with respiratory diseases.

Through its flagship patented XV Technology®, 4DMedical enables physicians to understand regional airflow in the lungs and identify respiratory deficiencies earlier and with greater sensitivity as they breathe. This technology powers 4DMedical's FDA-cleared XV Lung Ventilation Analysis Software (XV LVAS®) – the first modality to dynamically quantify ventilation throughout the lungs, and its Computed Tomography-enabled counterpart software, CT LVAS™.

XV LVAS® and CT LVAS™ reports are prepared using 4DMedical's Software as a Service delivery model using existing hospital imaging equipment or the Company's revolutionary XV Scanner.



In December 2023, 4DMedical acquired Imbio, a leader in artificial intelligence medical imaging solutions for chronic lung and cardiothoracic diseases. Imbio's regulatory-cleared solutions transform the way patients are discovered, diagnosed, and treated, enabling physician productivity and more personalised care for patients.

To learn more, please visit <u>www.4dmedical.com</u> and <u>www.imbio.com</u>.