Press Release
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ContextVision initiates the clinical phase of its point-of-care ultrasound innovation venture to advance liver disease diagnostics

ContextVision, a global leader in medical imaging software, today announced the first patient first visit in its clinical development program for liver disease diagnostics at the University of Washington (Seattle, USA). This marks a major milestone in the company's innovation program, following successful Institutional Review Board (IRB) approval, completion of technical setup, and validation of investigational ultrasound sequences.

The project, titled "Development of a Quantifiable Ultrasound Biomarker for Hepatic Steatosis (LYNX)"", aims to develop a novel ultrasound-based multiparametric biomarker for quantifying hepatic steatosis in patients with suspected metabolic dysfunction-associated steatotic liver disease (MASLD). The biomarker will be evaluated against the current gold standard – Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF) – to enable a non-invasive, quantitative, and accessible diagnostic tool.

The clinical phase will enroll 110 subjects over the next twelve months, including both healthy volunteers and patients across the MASLD disease spectrum. Each participant will undergo imaging using ContextVision's investigational ultrasound sequences deployed on a Verasonics Vantage NXT, alongside comparative imaging with EchoSense FibroScan, Philips EPIQ Elite Ultrasound device, as well as Philips 3T Ingenia Elition MRI system. The study is registered on ClinicalTrials.gov (https://clinicaltrials.gov/study/NCT07270601).

"The enrollment of the first patient marks the official start of clinical data collection and a major step toward developing new quantitative imaging biomarkers for liver disease," says Gerald Pötzsch, CEO of ContextVision. "We are proud to collaborate with the University of Washington and our partners, combining expertise across imaging physics, AI, and clinical research to drive innovation in non-invasive liver diagnostics."

The LYNX study at the University of Washington is part of ContextVision's Data Quality initiative, aimed at building AI-powered, organ-specific quantitative imaging solutions with the ultimate goal of developing digital biomarkers capable of assisting in early disease detection and monitoring. This program brings together a global network of partners, including AMRA Medical (Sweden), University of Waterloo's LITMUS Lab (Canada), and InPhase Solutions AS (Norway).

Addressing a growing global health challenge
MASLD affects approximately one in four people globally, representing an estimated 1.8 billion individuals. It is rapidly becoming one of the leading causes of chronic liver disease, and is strongly associated with obesity, diabetes, and metabolic syndrome. Despite its prevalence, early diagnosis remains limited due to reliance on invasive or costly diagnostic methods such as liver

biopsy and MRI. There is an urgent global need for non-invasive, cost-effective, and scalable imaging tools – a gap ContextVision aims to fill through its AI-based liver imaging program.

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About ContextVision
ContextVision is a software company specialized in image analysis and artificial intelligence. As the global market leader within image enhancement, we are a trusted partner to leading manufacturers of ultrasound, X-ray and MRI equipment around the world. Our expertise is to develop powerful software products, based on proprietary technology and artificial intelligence for image-based applications. Our cutting-edge technology helps clinicians accurately interpret medical images, a crucial foundation for better diagnosis and treatment. The company, established in 1983, is based in Sweden with local representation in the U.S., Japan, China and Korea. ContextVision is listed on the Oslo Stock Exchange under the ticker CONTX.