Press release – For immediate release
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Median Technologies announces onboarding of all academic sites involved in the pivotal validation plan for iBiopsy® LCS CADe/CADx SaMD

- Kick-off meetings have taken place in all academic sites that will be participating in the pivotal validation plan towards regulatory approvals of iBiopsy® LCS CADe/CADx SaMD.
- World-class academic healthcare institutions based in the United States and Europe will be involved in the pivotal validation plan.
- Median Technologies aims to obtain marketing authorizations of iBiopsy® LCS CADe/CADx SaMD on the US and European markets, in 2024.

Sophia Antipolis, France – Median Technologies (ALMDT) announces today that the Company has officially commenced operations with all investigator sites participating in the pivotal validation plan for its iBiopsy® Lung Cancer Screening (LCS) AI/ML tech-based CADe/CADx Software as Medical Device (SaMD). For the purposes of its pivotal validation plan, Median Technologies has signed clinical research agreements with world-class academic healthcare institutions, which are leading healthcare centers for the management of lung cancer patients.

Median's pivotal validation plan is composed of a pivotal standalone performance study (MT-LCS-002) and an international Multi-Reader Multi-Case (MRMC) pivotal clinical trial (MT-LCS-004). Both pivotal standalone study (MT-LCS-002) and pivotal clinical trial (MT-LCS-004) results will be respectively submitted to the FDA for obtaining the 510(k) clearance and to a European notified body for obtaining CE Marking.

The pivotal validation plan will mainly rely on the contributions from the sites listed below (by institution size):

US-based sites:

- The University of Texas MD Anderson Cancer Center, Houston, TX, USA,
- Hospital of the University of Pennsylvania (Penn Medicine), Philadelphia, PA, USA,
- Baptist Memorial Health Care and Baptist Clinical Research Institute, based in Memphis, TN, USA.

Europe-based sites:

- Clínica Universidad de Navarra, Departments of Respiratory Medicine and Radiology, Pamplona and Madrid, Spain,
- Instituto de Investigación Sanitaria de la Fundación Jiménez Díaz (IIS-FJD), Madrid, Spain.

"We are privileged and honored to have the opportunity to work together with these world-class academic healthcare institutions towards the validation and regulatory approval of our iBiopsy® LCS CADe/CADx SaMD. Both the large volume of lung cancer patients managed by these healthcare centers of excellence, as well as their world-class reputation are key to guarantee the quality of the imaging and clinical data we will be using in our pivotal validation plan. Data quality is compulsory for the proper conduct of our pivotal validation plan" said Fredrik Brag, CEO and Founder of Median Technologies. *"We started contracting with some of these academic sites during the year 2022, and started receiving data at the end of last year. Now that we have onboarded all the sites, we are on track for the launch of our iBiopsy® LCS CADe/CADx SaMD pivotal validation plan. We will carry out the pivotal standalone study and pivotal clinical trial according to the protocols discussed with the FDA during the Q-submission phase, which ended in February 2023,"* Brag added.

The international MRMC pivotal clinical trial Lead Principal Investigator will be Anil Vachani, MD, the director of Clinical Research for the Section of Interventional Pulmonary and Thoracic Oncology at Penn Medicine, and an associate professor of Pulmonary Medicine in the Perelman School of Medicine at University of Pennsylvania.

"Cutting-edge AI/ML tech-based Software as Medical Devices are paving the way for innovation in the field of lung cancer screening," Vachani said. *"The integration of these devices in evaluating low-dose CT scans shows considerable potential to improve the identification of abnormal findings, that if proven in clinical trials, could lead to improved diagnosis of lung cancer*."

Lung cancer has the highest mortality rate among all types of cancer worldwide. In 2020, approximately 1.8 million individuals died from lung cancer[1]. Early detection and diagnosis of the disease, when lung nodules are small and manageable plays a crucial role in drastically increasing the patient's 5-year and 15-year overall survival rates. In the US, the Centers for Medicare and Medicaid Services (CMS) have provided reimbursement for Low Dose Computed Tomography (LDCT) lung cancer screening since 2015 and the target population for lung cancer screening is about 14.5M people. Similarly, in Europe, more than 20 million individuals meet the eligibility criteria for lung cancer screening.

About iBiopsy®: Biopsy® is based on the most advanced technologies in Artificial Intelligence (AI) and Data Science (DS), benefiting from Median's expertise in medical image processing. iBiopsy® targets the development of AI/ML tech-based Software as Medical Devices (SaMD), to be used in several indications for which there are unmet needs regarding early diagnosis, prognosis and treatment selection in the context of precision medicine. iBiopsy® currently focuses on Lung Cancer, Liver Cancer (HCC) and Liver Disease (NAFLD/NASH).

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About Median Technologies: Median Technologies provides innovative imaging solutions and services to advance healthcare for everyone. We harness the power of medical images by using the most advanced Artificial Intelligence technologies, to increase the accuracy of diagnosis and treatment of many cancers and other metabolic diseases at their earliest stages and provide insights into novel therapies for patients. Our iCRO solutions for medical image analysis and management in oncology trials and iBiopsy®, our AI-powered imaging platform for the development of software as medical

[1] Global Cancer Observatory 2022 (GLOBOCAN)

devices (SaMD) help biopharmaceutical companies and clinicians to bring new treatments and diagnose patients earlier and more accurately. This is how we are helping to create a healthier world.

Founded in 2002, based in Sophia-Antipolis, France, with a subsidiary in the US and another one in Shanghai, Median has received the label “Innovative company” by the BPI and is listed on Euronext Growth market (Paris). FR0011049824– ticker: ALMDT. Median is eligible for the French SME equity savings plan scheme (PEA-PME). For more information: www.mediantechnologies.com

Contacts

Median Technologies	**Press - ALIZE RP**	**Investors - ACTIFIN**
Emmanuelle Leygues	Caroline Carmagnol	Ghislaine Gasparetto
Head of Corporate Marketing & Financial Communications	+33 6 64 18 99 59	+33 6 21 10 49 24
+33 6 10 93 58 88	median@alizerp.com	ggasparetto@actifin.fr
emmanuelle.leygues@mediantechnologies.com		