

FDA nod for GE's CT lung cancer screening device

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GE Healthcare has become the first company with a low dose computed tomography (CT) lung cancer screening option that is cleared by the US FDA (United States Food and Drug Administration) for lung cancer screening. Both the US Preventative Services Task Force (USPSTF) and the Centers for Medicare and Medicaid Services (CMS) recommend the use of low dose CT lung cancer screening for high-risk individuals.

Physicians using low dose CT for lung cancer screening will now have access to the benefits from a screening indication, including GE Healthcare's new low-dose screening reference protocols. These new protocols are tailored to the CT system, patient size, and the most current recommendations from a wide range of professional medical and governmental organizations.

GE Healthcare CT scanners can be confidently used by physicians within their FDA cleared indications for use, delivering low dose, short scan times, and clear and sharp images for the detection of small lung nodules. These nodules are critical in identifying lung cancer at its earliest stages when it is the most treatable and curable.

The landmark National Lung Screening Trial (NLST) was conducted at 33 medical institutions with over 53,000 older, otherwise healthy patients at high-risk due to smoking history. Half of the participants were screened using low dose CT, the other half were screened using chest X-ray. The trial demonstrated that the use of low dose CT screening decisively reduced the mortality rate from lung cancer by 20 percent compared to use of chest X-ray. The NLST also revealed a significant 6.7 percent reduction in the rate of death from any cause using low dose CT screening.

"This is the first time in history that any CT device has received FDA clearance for any screening indication," said Mr Henry Hummel, president and CEO of Molecular Imaging and CT at GE Healthcare. He added, "GE Healthcare is thrilled to be the first CT vendor who can help clinicians establish low dose CT lung screening programs in order to continue improving the health of their patients. Healthcare providers are looking for solutions beyond just imaging equipment; we look forward to

helping them establish low dose CT lung cancer screening programs that will inevitably save lives through earlier diagnosis and treatment for patients."