

ASX RELEASE

FDA Launches “Enhancing Quality Using the Inspection Program (EQUIP)”

- ***New requirements emphasize ongoing clinical image quality review in the ~8,744 US breast screening clinics***
- ***Automated quality assurance features in VolparaEnterprise will assist clinics in complying with new requirements***

Wellington, NZ, 3rd November 2016: Volpara Health Technologies (“Volpara”; ASX: VHT), a digital health company focused on early detection of breast cancer by improving quality of screening, has today advised that the United States Food and Drug Administration has launched the EQUIP initiative, “Enhancing Quality Using the Inspection Program”.

The program, which was launched on 27th October 2016 to coincide with the 25th anniversary of the passage of the Mammography Quality Standards Act (MQSA), is designed to emphasise “the need for ongoing facility review of clinical image quality”. From 1st January 2017, three new questions to ensure compliance with regulations relating to quality assurance will be addressed in the FDA’s annual facility inspections of the approximately 8,744 accredited breast screening providers across the United States.

The three new questions will assess:

- Facility procedures to ensure that clinical images comply with the agreed-upon quality standards, including quality attributes such as positioning, and include regular reviews of sample images from each technologist and each interpreting physician;
- The use of corrective procedures when clinical images are of poor quality, including a mechanism for ongoing feedback from the interpreting physician to the technologist and other designated personnel;
- The procedures in place for the lead interpreting physician’s oversight of quality assurance and quality control records—including the frequency of performance of all required tests and appropriate adoption of corrective actions when needed to amend images of poor quality.

Dr Ralph Highnam, CEO of Volpara Health Technologies, said the new requirements were highly relevant to Volpara’s business, and the recently launched cloud-based quality assurance solution, **VolparaEnterprise™**.

“These new requirements are placing a greater onus on the lead interpreting physician to ensure they have procedures in place to constantly assess image quality and take appropriate corrective actions.

“They also reflect the growing body of evidence demonstrating that factors such as positioning and compression of the breast impact the quality of the image, and could impair a radiologist’s ability to detect breast cancer in a screening mammogram.

“VolparaEnterprise is the only solution currently available that provides a comprehensive assessment of image quality on every screening mammogram. Our dialogue with our existing and prospective customers is now very much focused on how our suite of solutions

can assist in the early detection of breast cancer not only through assessment of image quality, but also the measurement of breast density and comfort factors such as compression pressure. The wide array of quality control features and data we provide enhance quality and productivity, and ensure facilities are compliant with the new EQUIP initiative.”

Further information from the FDA regarding the EQUIP initiative can be found here:

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm526238.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

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About Volpara Health Technologies Limited (ASX: VHT)

Founded in 2009 from research originally conducted at Oxford University, VHT is based in Wellington, New Zealand and facilitates the early detection of breast cancer through its digital health solutions to enable personalised, high-quality breast cancer screening based on objective measurements of breast density.

VHT has a number of patents and trademarks and regulatory clearances, including FDA and CE, supporting its technology and services. It launched its cloud based **VolparaEnterprise™** solution which incorporate breast density screening with a range of automated quality control features focused on improving quality and productivity in July 2016.

VHT listed on ASX in April 2016 after a \$10m IPO and has customers and/or research projects in 35 countries.

www.volparasolutions.com