DeepTrace Technologies Announces CE Mark and European Launch of TRACE4OC™: the medical device for predicting the risk of ovarian cancer

MILAN, December 06, 2021 - **DeepTrace Technologies**, the Italian spin-off of the University School for Advanced Studies IUSS Pavia, that has recently secured a seed funding round of 1,7M euros by **Progress Tech Transfer**, announces the launch in Europe of the CE marked **TRACE4OC™**, a vertical AI-powered tool developed with the proprietary, patented-protected AI platform TRACE4™, able to select women with high-risk of ovarian cancer by a simple automatic reading of transvaginal ultrasound scan and serum level of CA 125.

"The tool shows a very-high ability in selecting the patients with ovarian cancer and high specificity in avoiding treatments to very-low risk patients representing a valid decision support system to gynecologists. We are pleased to offer TRACE4OC™ to European hospitals and medical clinics" said Christian Salvatore, CEO of DeepTrace.

"Although the subjective impression of an experienced pelvic ultrasound examiner in ovarian cancer masses can perform well in defining the malignant masses to be surgically treated, the lack of reproducibility among examiners with different expertise represents one of the highest clinical unmet needs in gynecologic oncology ultrasonography. Our tool aims to close this gap providing a fair, accurate and reliable approach" commented Prof. Isabella Castiglioni, Scientific Advisor and Honorary President of DeepTrace. "The tool is very simple to be used by gynecologists".

About TRACE4OC™

TRACE4OC™ is indicated for women at risk of ovarian cancer under the recommendation of gynecology specialists. Physicians with expertise in pelvic ultrasonography (US) can use TRACE4OC™ to support the reporting of US-detected adnexal masses investigations. Specialists in gynecology can use TRACE4OC™ as an aid to diagnosis.
TRACE4OC™ software provides the subject level of risk (very-low-risk or medium/high risk) of being affected with ovarian cancer at the date of the TRACE4OC™-processed US investigation of an adnexal mass, combined with the serum level test for Cancer Antigen 125 (CA-125), performed no earlier than and no later than one month from the US study, and with the current woman's menopausal state (premenopause or

postmenopause). TRACE4OC™ showed sensitivity >97%, specificity >75%, PPV >86%, NPV >97%, moreover its performance improves with time, as the training of the tool progresses. DeepTrace Technologies considers TRACE4OC™ as a support to gynecology specialists in their diagnosis, and as a support to physicians with expertise in pelvic US in their reporting of adnexal masses. These medical professionals retain the final decision-making responsibility.

About DeepTrace Technologies

DeepTrace Technologies S.r.l. (www.deeptracetech.com) develops and delivers cutting-edge software technologies that augment human capabilities to early detect and predict effects of severe changes in global assets impacting society. Healthcare is the main one. Based on AI-data driven analyses, DeepTrace Technologies provides low-cost, time-saving solutions for predictive personalized medicine. These technologies are non-invasive, scalable, replicable, sustainable, and support users' engagement in the decision management by providing understandable outputs. Software-as-medical-device is delivered to the healthcare providers with highly competitive time-to-market.

About Ovarian Cancer

Ovarian cancer is one of the most lethal cancers in women, with over 300,000 cases diagnosed worldwide and 200,000 deaths per year. The lack of accurate screening and diagnostic tools, the scarce symptomatology, abnormal cell metabolism, and the rapid spread of disease are the main causes of such lethality. For medical specialists, current diagnostic classifications are helpful in high- and low-risk groups but most of them require the knowledge of a specific terminology and a certain level of experience by the examiner in assigning echogenic and structural features to ovarian masses being inconclusive for lesions assigned with an intermediate risk.

About Progress Tech Transfer and MITO Technology

The Progress Tech Transfer fund was launched in January 2019, with a total endowment of 42 million euros, jointly subscribed by the European Investment Fund (Fei) and by Cassa Depositi e Prestiti (Cdp), ENPAIA and other private limited partners.

MITO Technology is the leading Italian technology transfer company that for over a decade has been dealing with the enhancement of research results in support of universities and public bodies and is the strategic advisor of the Progress Tech Transfer fund ensuring the connection with the world of research in Italy for the scouting of technologies and start-ups.

References

1. A decision support system based on radiomics and machine learning to predict the risk of malignancy of ovarian masses from transvaginal ultrasonography and serum CA-125. Chiappa V, Interlenghi M, Bogani G, Salvatore C, Bertolina F, Sarpietro G, Signorelli M, Ronzulli D, Castiglioni I, Raspagliesi F.Eur Radiol Exp. 2021 Jul 26;5(1):28. doi: 10.1186/s41747-021-00226-0.PMID: 34308487
2. The Adoption of Radiomics and machine learning improves the diagnostic processes of women with Ovarian MAsses (the AROMA pilot study).

3. Chiappa V, Bogani G, Interlenghi M, Salvatore C, Bertolina F, Sarpietro G, Signorelli M, Castiglioni I, Raspagliesi F.J Ultrasound. 2021 Dec;24(4):429-437. doi: 10.1007/s40477-020-00503-5. Epub 2020 Jul 21.PMID: 32696414

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