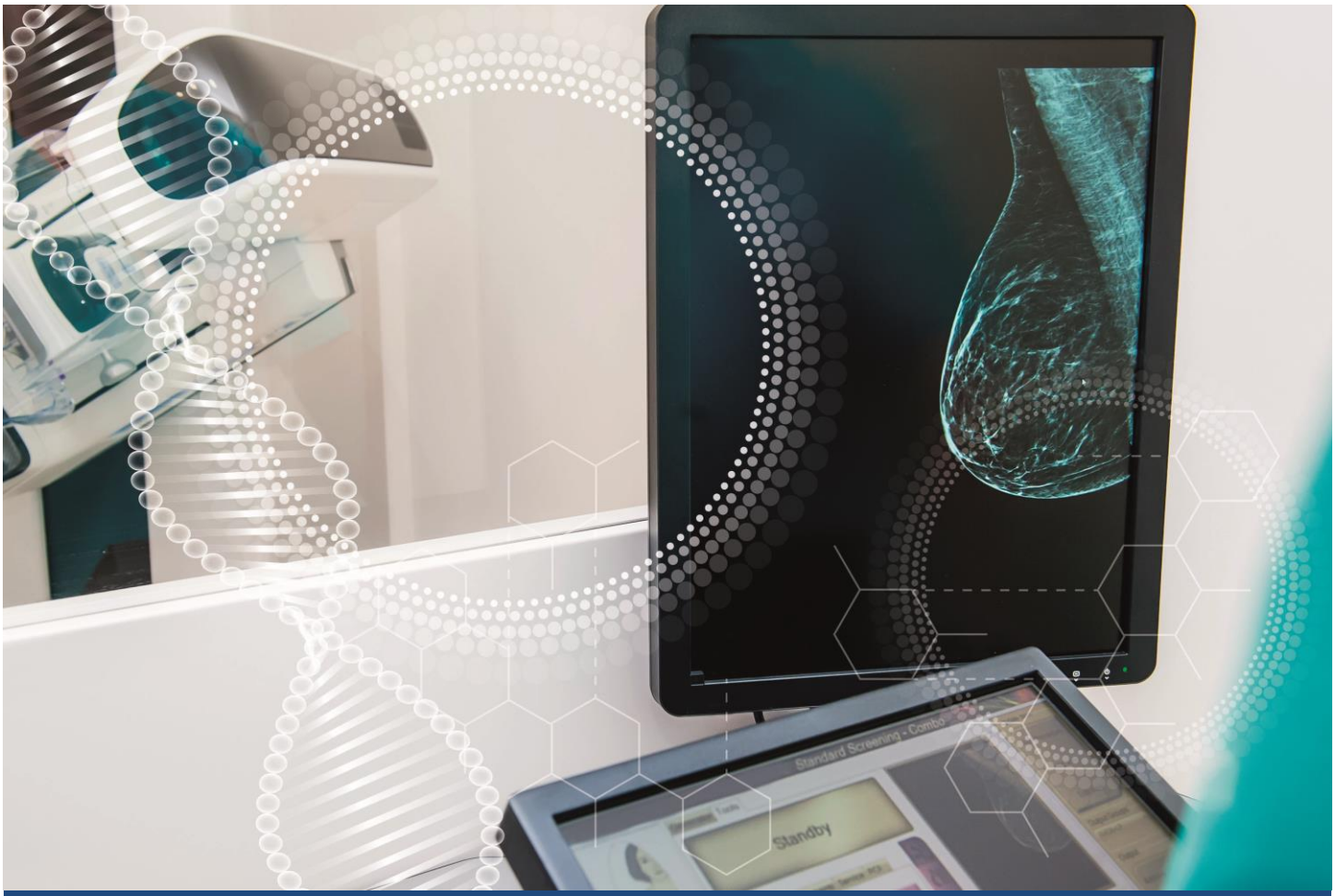

European Commission

Common
Dissemination
Booster

LUCA Policy Brief

Protecting society through innovative technologies for cancer screening

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Executive Summary

One of the most important weapons in the fight against cancer is timely screening. Countless lives have been saved through early detection and treatment. As successful as screening programs have been, however, one problem that has plagued screening techniques is the preponderance of so-called false positives, leading to unnecessary surgical intervention.

Although awareness is growing of the major health costs to European hospitals through unnecessary surgeries, the awareness has yet to be translated into policy – such as funding research on innovative approaches to improve screening. One particularly promising avenue is the use of photonics technologies in addition to conventional techniques, resulting in multi-modal imaging systems that enhance screening accuracy.

The projects LUCA, PAMMOTH and SOLUS are developing such multi-modal approaches that show great promise for the future of smart screening. Based upon the experience of these projects, this policy brief sets out a number of recommendations for strong policy formulation supporting the goals of improved screening and reducing costly unnecessary surgeries, and the promotion of innovation technologies for screening in the medical field and beyond.

These recommendations are the result of the direct experience of these projects, which are funded by the European Commission under the Horizon 2020 Framework Programme.

1 Topic Overview

1.1 Topic

One of the most important weapons in the fight against cancer is timely screening. Countless lives have been saved through early detection and treatment. As successful as screening programs have been, however, significant problems remain to be solved in order to maximize their effectiveness. Problems that have plagued screening techniques in many different domains, such as breast cancer and thyroid cancer, is the preponderance of false positives – indications of cancer when there is in fact none – and the characterization or staging of detected tumours.

For example, approximately 50% of positive breast cancer screening outcomes turn out to be false positives. Breast cancer is one of the most common cancers in the world. It is estimated that about one in eight women in Europe will develop breast cancer before the age of 85. Such a high number of false positives leads to a large number of additional examinations could have been avoided. At the same time, the chances for survival increase substantially upon early diagnosis of breast cancer, so the availability of diagnostic tools with a high sensitivity and specificity is vital.

Conventional screening methods for thyroid cancer lead to a large number of invasive procedures due to inaccurate screening results. Annually, about 750,000 patients in Europe receive non-diagnostic and/or false positives results due to poor specificity of current methods. This leads to about 150,000 unnecessary surgeries each year resulting in costs of more than €440m. These costs could be significantly reduced with improved screening methods.

Since conventional cancer screening methods lack the specificity to consistently differentiate between benign and malignant tumours, there still is a considerable need for invasive biopsy procedures to confirm the nature of the tumour.

It is recognized now that both the economic and emotional costs of unnecessary biopsies and treatment merit the full attention of the healthcare research community and policy makers. Photonics technologies have proven to be a highly promising avenue to tackle these healthcare issues.

In particular, the combination of photonics technologies with established imaging techniques yields multi-modal imaging systems – that is, where innovative photonics systems enhance the sensitivity and specificity of conventional methods, like ultrasound, and thereby improves the diagnostic information.

For example, the LUCA project combines near-infrared diffuse correlation spectroscopy and time-resolved spectroscopy with ultrasound for the screening of thyroid nodules.

Similarly, the SOLUS project combines diffuse optical tomography with both common and advanced ultrasound techniques to support the diagnosis of breast cancer.

Finally, the PAMMOTH project combines photoacoustic with ultrasound mammoscopy for evaluating screening-detected lesions in the breast.

These multi-modal approaches are showing great promise for the future of smart screening, which have the potential to go beyond breast and thyroid cancer screening as innovative tools for other types of cancer diagnoses, screening and therapy monitoring in areas of the body accessible to these techniques.

1.2 Policy challenges

Current European health policy is strongly oriented toward support for early screening, with governments supporting numerous programs offering free screening, e.g. for breast cancer or colorectal cancer.

Although awareness of major costs due to inaccurate screenings results and/or diagnoses is gradually growing, this awareness has yet to be translated into policy that supports initiatives or programmes to decrease such costs – such as funding research on innovative approaches to improve the sensitivity and specificity of screening, in particular exploring photonics as a means to enhance existing methods, and supporting clinical translation and market entry. This can significantly improve individual diagnoses and increase the cost-efficiency of large screening programmes.

In addition, regulatory procedures for the approval of new medical devices in Europe can extend the approval process for innovations in the medical field into years. Recognizing the benefit of these innovations, developing innovative policies that fast-track such innovations into the clinics remains a challenge in the current regulatory landscape.

2 Recommendations

2.1 Enhanced Non-Invasive Breast and Thyroid Cancer Screening Programmes

The new photonics technologies being introduced in innovative projects like LUCA, SOLUS and PAMMOTH are making breast and thyroid cancer diagnosis and screening more sensitive and specific, and provides affordable, non-invasive, point-of-care solutions for health systems. In addition, these technologies provide better alternatives for treatment monitoring and follow-up due to their high sensitivity and specificity.

This is an area where policy makers can make a significant difference in making resources available for research and clinical translation to improve screening outcomes, reduce inaccurate results and thereby the financial burden of unnecessary invasive procedures.

2.2 Promotion of Innovative Photonics-based Technologies in Medicine and Beyond

The preliminary results from LUCA, SOLUS and PAMMOTH show the tremendous potential of photonics-based technologies for applications in a variety of medical fields: the potential in endocrinology has been confirmed, and considerable interest in the technology has been observed for the areas of head and neck oncology, rheumatology, paediatric neurology and nephrology, sports medicine and even clinical veterinary medicine.

Photonics technologies can also provide guidance during surgeries as innovative confirmatory or monitoring tools in areas of the body not accessible to these techniques outside surgery.

Monitoring and screening with devices based on photonics technology as means of quality control, e.g. for food or lumber, can extend quality improvements and cost-savings to fields beyond medicine.

Policy makers can ensure that funding initiatives for development and continuous improvement of these ground-breaking photonics technologies are on the political agenda.

2.3 Improving the Time-to-Market for Innovative Photonics-based Technologies

Policy makers could recognize the special characteristics of innovations in the reduction of medical false positive diagnoses to develop innovative policies that enables such innovations to be fast-tracked into clinics while safeguarding patient safety.

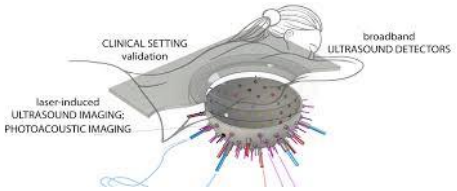
A short time-to-market of innovative photonics-based technologies leads to earlier significant cost-savings for the European healthcare systems.

Policy makers can take motivation from the substantial reduction of the financial burden as well as the enhancement of social and patient well-being through improvements in screening accuracy through the application of photonics technologies.

3 Project Group

The Horizon 2020 project Laser and Ultrasound Co-analyzer for Thyroid Nodules (LUCA) aims to develop an innovative technology for thyroid cancer screening that will provide doctors with enhanced information required to provide better and more specific results in thyroid nodule screening and enable better diagnosis.

http://luca-project.eu



PAMMOTH's objective is to **develop, validate and begin exploitation of a dedicated breast imaging device for a significant impact in breast cancer diagnosis.** The proposed device combines **non-invasive 3D photoacoustic imaging and ultrasound imaging.** The device will provide **near real-time, full-breast, multimodal images** to the radiologist. From the ultrasound mode, the radiologist will visualize **anatomical features and extent of tumors**, and from multiwavelength photoacoustics, she will see tumor vascularity. Quantitative spectroscopic photoacoustic images will be extracted off-line, providing the radiologist information relating to **tumor physiology and function such as angiogenesis and hypoxia.**

https://www.pammoth-2020.eu

SOLUS

The SOLUS project aims to develop a new multimodal imaging system which can classify breast cancer detected by mammography screening, in a non-invasive manner, and significantly improve the ability to differentiate between benign and malignant tumours. Invasive procedures, such as biopsies, are currently carried out in an unnecessarily high number of cases. SOLUS can help avoid such unnecessary biopsies by improving the characterisation of lesions in the breast.

http://www.solus-project.eu