



MAMMOSCREEN

Newsletter

ISSUE #1

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Introduction to the MammoScreen Project

The [MammoScreen Project](#) is a European funded project in which we are testing the ability of the MammoWave technology to detect breast tissue lesions. This technology has the potential to save lives, because breast cancer, the most common cancer in women (affecting 1 in 8 worldwide), still may go undetected due to the limitations of X-ray mammography, the gold standard for breast screening. In addition, some cancers may be too small or difficult to distinguish from the normal tissue, particularly in women with high density breast tissue.

If you are a woman under the age of 50, you may wish to keep a close look on our progress. In general, women are eligible for biannual screening only after the age of 50 (45 in some countries). However, recent studies from the [International Association of Cancer Registries \(IACR\)](#) show that 30% of breast cancers are now diagnosed in women under the age of 50. While early diagnosis is the only effective mean to tackle breast cancer, younger women are particularly impacted by the risks associated with repetitive exposure to X-rays and the low sensitivity of the mammography in dense breasts.

In a [pilot study](#), MammoWave demonstrated how it can detect breast tissue lesions. Now, we are recruiting 10.000 women undergoing regular screening to generate further evidence about the use of MammoWave in population-based screening programs.

We are harnessing the power of Artificial Intelligence (AI) to help in the detection of lesions. Not only does AI speed up the analysis of images, it also ensures independence from the operator, and these are enormous advantages for population screening programs. In a future issue

of the Newsletter, we will invite specialists to explain how AI works and how it helps to detect lesions in the context of this project.

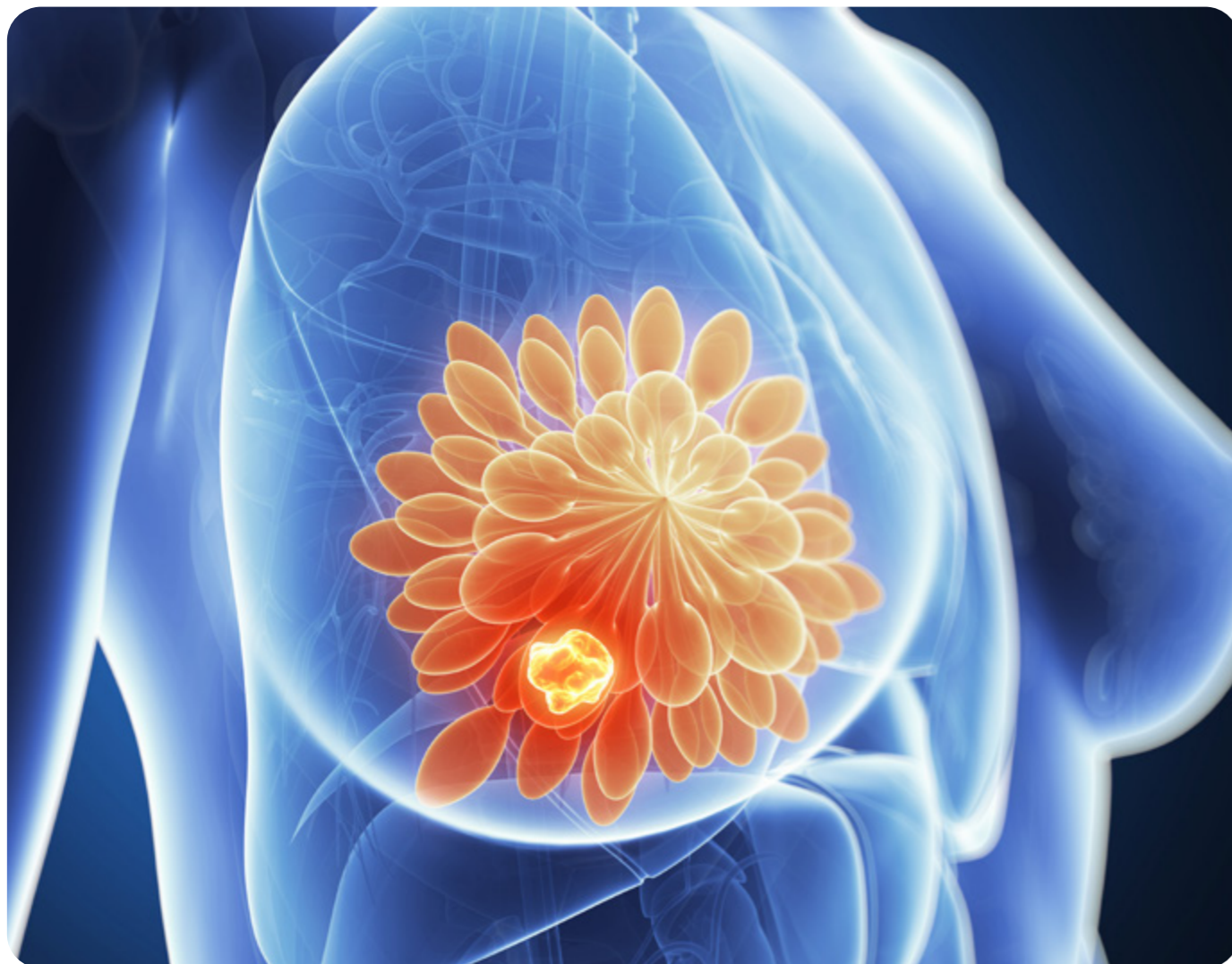
A digital platform will be developed to support the interaction between patients and clinicians with the technology, both pre-scan and post-scan. This initiative will include a web portal for clinicians and a user-facing App, which will have



the capacity to be configured to reflect regional variation in service delivery. We are organizing workshops and feedback sessions throughout the project, to obtain and integrate the feedback of patients, clinicians and regional healthcare decision-makers; these consistent opportunities for feedback from end-users will ensure that the final products are tailored to the specific needs of all users, keeping accessibility and functionality at the centre of the design.

Importantly, we will conduct an analysis of MammoWave's cost-effectiveness in breast cancer screening protocols. Our Health Technology Assessment (HTA) model will be calibrated with the results of the clinical trial to inform decision makers about the inclusion of MammoWave in different screening strategies, with a focus on young women and women with dense breasts.

The MammoScreen Project is supported by external advisors. We rely on the expertise of our advisory boards for data protection and ethics, independent scientific and strategic decisions, and patient advocacy. Together, we are committed to improve the standard of care for women at risk of breast cancer throughout the European space. In recognition of the potential impact of this initiative, the project is included in the Cancer Mission cluster of projects on "[Prevention and early detection \(Screening\)](#)" funded by Horizon Europe.



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Featured article

The MammoWave technology: how does it work?



The signals are analysed with a proprietary software that uses a novel, fast and accurate algorithm to highlight the lack of homogeneity in the breast. The software calculates certain parameters (such as the ratio between the maximum and the average intensity) and is augmented with Artificial Intelligence (AI) to help identify



MammoWave works differently from traditional methods that use X-rays. The device generates a qualitative representation of the breast tissues by processing very low power (<1 mW) electromagnetic signals in the microwave band (1-9 GHz). The ability to use this range of the electromagnetic spectrum for breast cancer detection is based on the difference in the dielectric properties of healthy and affected tissues. In simple terms, healthy and affected tissues respond differently to electromagnetic fields in the microwave band, which the MammoWave device is able to contrast and display. The exam takes a few minutes per breast and is performed with the patient lying in a comfortable facing-down position. MammoWave allows for a totally discreet examination, improving the compliance of patients when going for regular breast screening.

The results obtained using MammoWave are displayed as dielectric properties homogeneity maps shown in two dimensions, crossing a coronal plane (i.e., separating the front and back of the body in an imaginary plane that cuts through both shoulders).

suspected lesions.

MammoWave has several important advantages when compared to the classic X-ray mammography. One is that the microwave range used in the scan is completely safe. Another is that it does not require compression of the breast, which makes the process more comfortable for the person being examined.

Meet the Team: TLS

Coordination and Management Team at Fondazione Toscana Life Sciences (TLS).



Gianni D'Errico



Dr. Matteo Gentili



Dr. Letizia Pontoriero

[Fondazione Toscana Life Sciences](#) is a non-profit research organization based in Siena, Italy. Born as a business incubator, TLS has evolved to become a facilitator, by increasing the impact of projects related to biomedical research, drug development and health and wellbeing of citizens.

TLS is supporting researchers as host institution for carrying out their projects, as well as working as incubator for startups and small companies that are investing on the development of new therapeutic biotechnological approaches. TLS is actively involved in many European funded projects dealing with healthcare and Precision Medicine, such as Regions4PerMed, SINO-EU PerMed and EP PerMed, working to transform standard clinical practices into personalized solutions for patients.

Another important task of TLS is to keep decision makers and health systems stakeholders informed about the latest technological developments on a regional, national and European scale, to promote the development and the adoption of state of the art therapeutic options for patients.

As coordinator of the MammoScreen Project, TLS oversees project management activities,

monitors the implementation of ethical and data protection principles, and implements best practices for dissemination, communication and business development.

There is a lot going on daily at TLS's project management office: advancing the agenda of the monthly MammoScreen Consortium meetings, seeking consensus among partners, preparing and revising project deliverables, monitoring expenditure and preparing financial reports.

The TLS team is also the contact point for European Commission officers. The team works together with all the partners to ensure that the implementation of the project is as effective and efficient as possible. Building a good relationship with partners and finding synergies within the consortium is a key part of their work.

Together, we all play to our strengths towards the success of the project, and project managers are like the Maestro of a fine-tuned orchestra, guiding the MammoScreen partnership towards a possible game-changing solution for the early detection of breast cancer.

You can follow TLS's activities on [LinkedIn](#), [Twitter](#) and [Facebook](#).

Under the Spotlight

Let's discover how patients are recruited for the MAMMOSCREEN clinical trial!

The MammoScreen clinical study involves 9 centres in five different European countries – Italy, Poland, Portugal, Spain and Switzerland – and will recruit 10.000 women volunteers aged between 45 and 74 years of age with an average risk of cancer. Women will be recruited by the clinicians of each centre when they attend a scheduled breast cancer screening session and, therefore, it is not possible to submit applications to join the study. However, there are other ways of getting involved, for instance, by keeping informed about [breast cancer prevention](#), learning about the risk of [hereditary breast cancer](#), or by reaching out to a [patient advocacy group](#) in your country of residence.

The main aim of the trial is to confirm that MammoWave, augmented by AI, reaches high sensitivity (the ability to correctly identify women with breast cancer) and specificity (the ability to correctly identify women without breast cancer). The study will be managed by a specialist third party (the Contract Research Organization, or CRO), who will work together with the clinical investigators and a medical statistician. All the details of the study will need to be approved by the various national Ethical Committees and regulatory authorities prior to recruitment, and participants will be informed about the risks, benefits, and alternatives of the procedure in order to be able to give their informed consent.



The outcomes of the study have the potential to improve the early diagnosis of breast cancer for all women and to help promote the quality of life and health in breast cancer patients. Our communication and dissemination activities will ensure that the relevant stakeholders are informed of the outcomes of this study, so please keep in touch through our website and social media.

In the clinical trial, the MammoWave technology is being investigated to confirm its ability to reach a sensibility >75% and a specificity >90%. This trial will be an open, multicentric, interventional, prospective, non-randomized clinical investigation. A dedicated electronic report form (e-CRF) was developed to optimize data acquisition and analysis in a non-biased way.

Breast Cancer UK's 25 tips to reduce breast cancer risk (and we select our top 3)

According to [Breast Cancer UK](#), around 30% of breast cancer cases are preventable. This means that by making simple changes to our lifestyle, we can help reduce our risk of breast cancer (and cancer in general). We have followed [this link](#) to learn 25 ways to reduce the risk of breast cancer and here are our top three choices:

1. Get moving!
2. Live like and Italian.
3. Avoid packaged food: buy fresh food and have fewer takeaways.

Patient's Perspective

Interview with Siobhán Freaney

Siobhán Freaney is the coordinator of the MammoScreen Project Patient Advisory Group (PAG). She was diagnosed with stage 3 Invasive Lobular Carcinoma (ILC) in December 2015 and, following extensive treatment and surgery in 2016, she became a patient advocate. Siobhán set up Ireland's first [Breast Density patient advocacy blog](#) and passionately campaigns to raise awareness about ILC and how it can escape early detection with X-ray mammography in women with high density breast tissue.

Questions:

MammoScreen (MS): Siobhán, in your blog you mention that 40% of women have dense breasts. Can a woman know if she has dense breasts without undergoing a mammography?

Siobhán Freaney (SF): The experts say that 43% of women have dense breasts. Breast density is

not palpable, so women cannot know by feeling their own breasts. Having a mammogram is, at the moment, the only imaging tool routinely available to women to determine if they have dense breasts. Unfortunately, the [ECIBC \(European Commission Initiative on Breast Cancer\)](#) have not issued specific guidelines to mandate for women to be notified about their breast density. There are recommendations from [EUSOBI \(European Society of Breast Imaging\)](#) that all women should be notified about their breast density. Quoting [them](#) "After careful consideration of the evidence, particularly the results of the Dutch DENSE trial, EUSOBI now recommends that women with extremely dense breast tissue are offered screening with breast MRI. In these women, breast MRI can reduce the mortality from breast cancer and is highly cost-effective". Read the full article [here](#).

MS: In a rough estimate, from your patient contacts, what is the percentage of women that are not aware of the relative breast density and how much can it hinder the early detection of breast cancer?

SF: Approximately 7 out of 10 women do not know about their breast density. There are studies to indicate that 50% of breast cancers are missed on screening mammograms of women with dense breasts. As women, we rely on our screening programmes for early detection of cancer. For almost half of women within a breast cancer screening programme, a mammogram alone is not enough. Breast cancer early detection is all about finding cancers when they're small and node negative; that is really important. In my experience, there are way too many cancers being missed as a direct result of breast density. There is a lack of shared informed decision making and I would also add that the introduction of a standardized breast density notification with additional essential imaging is crucial.

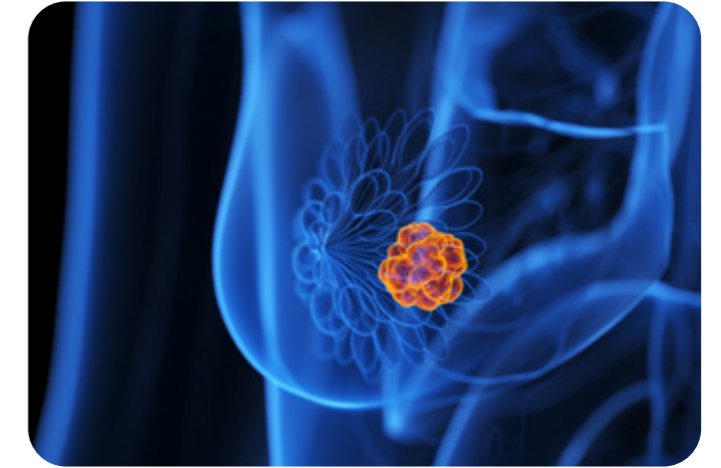
MS: Why do you think women are still unaware of their relative breast density and the limitations of X-ray mammography?

SF: Women are still unaware because nobody is telling them. When a woman receives her letter telling her that her mammogram is clear, she has no reason to believe otherwise. When a radiologist looks at a mammogram of a woman with dense breasts, the level of breast density is clearly visible, but this information is not disseminated. There are specific limitations of X-ray mammography. Breast density appears as white and bright regions on a mammogram, cancer also appears as white. In non-dense breasts, a cancer will be visible to the radiologist. However, in dense breasts, small cancers can be "masked". This is often referred to as looking for a snowball in a snowstorm.

MS: Tell us one interesting fact about invasive lobular carcinoma (ILC).

SF: ILC is a unique histological subtype and it is different to other types of breast cancer. It's the

second most common subtype of breast cancer and accounts for 15% of all breast cancer diagnosis. ILC originates in the lobules, whereas the more common ductal breast cancer (80%) originates in the milk ducts. Across Europe, approximately 86,500 women are diagnosed with ILC every year. Upwards of 30% of lobular breast cancers are missed on screening mammograms.



You asked, we answer (Q&A)

Q: Can the technology used in MammoWave be adapted to detect other types of cancer?

A: The technology can be extended to other diagnostic scenarios, including the detection of other types of lesions. UBT, the company that developed MammoWave, is adapting the technology for the detection of brain cancer and lung cancer.



MammoScreen News

Our promotion video is out: [watch it here.](#)



The [MammoScreen Webinar with Patient Advocacy Groups](#) took place via Zoom on 4 September 2023. This event was organized by the partners EVITA and ELAROS, in anticipation of another Workshop held on 2nd of October, entitled “EVITA and ELAROS App co-creation Workshop under MammoScreen Project”. In the latter, we listened to women (some of them breast cancer patients), gathering insights into the development of a user-facing App that will support the use of the MammoWave technology.

The ELAROS-EVITA synergy is key for the development of a Patient and Public Involvement and Engagement (PPIE) framework within the MammoScreen Project. Together, they launched the [Hereditary Breast Cancer Questionnaire](#) in August of 2023, which gathered more than 400 participants during the limited time it was opened for participation. The Questionnaire responses are being analysed carefully by ELAROS and EVITA and the results will be presented in relevant Conferences throughout 2024.

The MammoScreen Project is one of 12 research projects selected to support the EU Mission on Cancer, sponsored with a budget of €125.6 million under Horizon Europe. The Consortium integrates the [Cancer Mission Cluster for “Prevention and early detection \(Screening\)”](#), together with six other initiatives. In the [first Annual Meeting of the Cluster](#), held on 7 September 2023 in San Sebastian, Spain, project managers worked together to address common challenges and discussed the organization of joint activities aimed at creating added value and increasing the impact of EU funding.

The MammoScreen Consortium got together for the 3rd in-person Consortium Meeting in Toledo, Spain, in 22-23 November 2023. Our partner SESCOAM was the host and organizer of the meeting. All partners were delighted to meet the Regional Minister of Health of the Government of Castilla-La Mancha, who renovated his unconditional support for the project. You can read more about it [here](#).

Our partner UBT and the sponsor of the clinical trial, hosted by the Italian Trade Agency (ITA), attended the [MEDICA trade fair](#), held between 13 and 16 November 2023, in Dusseldorf, Germany. UBT took the opportunity to present MammoWave during this event, which is one of the largest medical B2B (business-to-business) trade fairs in the world.

On November 27, 2023, the [Colegio de Ingeniería Informática de Castilla-La Mancha](#), Spain, awarded the prize of [Proyecto Público Más Destacado](#) (Most Outstanding Public Project) to Dr Cristina Romero (SESCAM) for her work with MammoWave. This recognition comes at a time when the public sector in Spain is supporting initiatives that improve services to citizens.

In December 2023, EVITA became a member of [ECHAlliance](#) (European Connected Health Alliance), a global community of companies, entrepreneurs and public sector and charitable organisations. ECHAlliance promotes a network of Ecosystems designed to bring together key stakeholders across specific geographic regions or thematic areas, with the aim of transforming healthcare and creating opportunities by matching needs with solutions.

At the time of this edition, the MammoScreen project has secured the approvals from the ethics committee and the national competent authority in Italy and Portugal and is well under way to secure the necessary authorizations in Spain, Switzerland and Poland. We are pleased to communicate that the first MammoScreen patient will be enrolled in Italy at the end of January! Enrolment in other centres will soon follow, pending the installation of the respective MammoWave devices. Congratulations to all the regional teams for their hard work in making this possible.

Upcoming Events

February

The [European Society of Radiology](#) organizes the European Congress of Radiology, ECR 2024, in Viena, Austria, from the 28th of February to the 3rd of March. Artificial Intelligence, one of the hottest topics in radiology right now, will be one of the highlights of the event.

The 14th [World Congress on Breast Cancer Research & Therapies](#) will be organized in Rome, Italy, on 15 and 16 February. This event will focus on the theme “Breaking Barriers: Equity, Access, and Inclusivity in Breast Cancer Care”, offering keynote and speaker sessions on various topics related to breast cancer, including one specifically dedicated to mammography. Late registrations are accepted until the 15th of February.

March

The European Society of Breast Imaging (EUSOBI) will organise [a new course](#) designed to meet the needs of professionals in the field. With an immersive and comprehensive programme, the Breast Imaging Research Course – from basics to changing practice will take place in Milan, Italy, February the 19th, ahead of the 14th European Breast Cancer Conference. The program combines theoretical lectures with panel discussions and the deadline for early registration is 19 February.

[The 14th European Breast Cancer Conference \(EBCC\)](#) will take place in Milan, Italy, on 20-22 March, under the theme of Research & Innovation in the Multidisciplinary Management of Breast Cancer. EBCC’s mission is to promote truly multidisciplinary collaboration and education in breast cancer, with an approach to provide equality across borders. Regular registration closes on the 24th of January, but onsite registrations are accepted until the 7th of March.

April

The 2024 [SBI Breast Imaging Symposium](#) will take place in Montréal, Canada, on 11-14 April. This meeting is in-person only and will feature four afternoons dedicated to hot topics, including clinical implementation of AI systems.

[Younger Women Together](#) – London 20 April 2024 is a one-day meeting aimed at women aged 20-45 that have a diagnosis of primary breast cancer. Organized by Breast Cancer Now, a research and support charity in the UK, these events include small group discussions, with support from expert facilitators and trained volunteers who have all experienced breast cancer.

May

The European Society for Medical Oncology (ESMO) will organise its 2024 congress in Berlin, Germany, on 15-17 May. The [ESMO Breast Cancer 2024](#) aims to deliver a comprehensive overview of all the practice-changing new data and to make sure it has a clear roadmap to the clinic. The event will take place onsite as well as online through a dedicated virtual platform. [Early registration](#) ends on 6 March 2024.

The next in-person MammoScreen Project Consortium meeting will be held in Lisbon, on 22-23 May. EVITA is organising this event in the beautiful [Champalimaud Foundation Research and Clinical Centre](#). The meeting will be followed by the first MammoScreen Stakeholders Workshop, in the afternoon of 23 May. We will be sharing MammoScreen’s progress with top healthcare officials and policy makers representing the healthcare systems of several European countries.

The EVITA & ELAROS “Workshop Unveiling Progress - MammoScreen Updates and Demonstration of the Beta Co-Created App” will take place on the 24th of May. This event will have an in-person and online participation format and will gather insights of breast cancer patients and healthy women about the features of the app being developed by ELAROS.

June

The 29th edition of the European Health Management Conference, [EHMA 2024](#) will take place in Bucharest, Romania, on 5-7 June under the theme “Shaping and managing innovative health ecosystems”. The Conference is co-hosted by the Ministry of Health of Romania and the National Institute of Health Services Management.

The 5th Edition of the Global Summit on Breast and Women’s Cancer will be held during 24-25 June in Rome, Italy. The main theme of the conference is “Frontiers in Breast and Women’s Cancer Research and Therapy”. This event brings together global and regional experts in the field of breast and women’s cancer including clinicians, policy makers, patient advocates and care partners. [Follow this link](#) for more information, including abstract submission and registration.

July

This year’s [IEEE International Symposium on Antennas and Propagation and ITNC-USNC-URSI Radio Science Meeting](#) will be held in Florence, Italy, on 14-19 July. Our LSBU partners will present their promising results on the Artificial Intelligence model that supports the interpretation of MammoWave signals.

Ongoing

We plan to release a series of video interviews, featuring the experience of breast cancer patients and non-affected women. We are very grateful to all those that accepted the challenge of sharing their experience of breast cancer through screening, diagnosis and treatment.

Stay Connected



Top Post



[MAMMOSCREEN launches the Hereditary Breast Cancer Questionnaire](#)



[MAMMOSCREEN joins the cancer “Prevention and early detection \(Screening\)” cluster of EU funded projects](#)



[The 2nd in person MAMMOSCREEN Consortium Meeting will be held in Toledo \(Spain\) on November 22 and 23, organized by SESCAM](#)



[MAMMOSCREEN takes part to the first Annual Meeting of the Cancer Mission Cluster “Prevention and early detection \(Screening\)”](#)

Stay tuned for the next issue!



MAMMOSCREEN