

BREASTAid™

Working to beat breast cancer



Pre-Screening Breast Cancer Risk Assessment

BREASTAid™ has developed the definitive Breast Cancer Risk Assessment to help women, of a pre-screening age, 25-49, categorise and understand their own risk of developing breast cancer at an early age.

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Our innovative Pre-Screening Breast Cancer Risk Assessment, known as The BREASTAid™ Platform, utilises clinically validated state-of-the-art risk modelling and intelligent analytics to determine, and monitor on an annual basis, the personal risk profile of a young woman, incorporating all the factors that can affect her chance of developing breast cancer at an early age, including demographics, clinical, family history, and genetic preconditioning.

Breast cancer screening is rapidly moving into an era of personalised care, where prevention, early detection, and treatment are guided by risk assessment, with the aim of increasing surveillance in High-Risk women, while sparing Lower-Risk women the burden of unnecessary imaging procedures (e.g., mammography, MRI, etc). Such risk assessment triaging also informs clinical care by refining screening recommendations for younger women, identifying women who should be referred to genetic counselling, and identifying candidates for risk-reducing medications, such as chemoprevention and prophylaxis treatment.

Some Background

Breast cancer is the most common cancer in women with 55,200 diagnosed every year in the UK alone (approx. 150 a day). Most women in the UK are offered initial breast screening at the age of 50. However, every year thousands of women die from undiagnosed breast cancer

at an earlier age, and before receiving an invitation for a screening mammogram. In many cases, these women could have been at a High-Risk of developing breast cancer through a family history, gene mutation or other epidemiological risk factors, but have no idea they are at risk, or any way of finding out.

Certain factors increase the risk of developing breast cancer, including advancing age, obesity, harmful use of alcohol, family history of breast cancer, early radiation exposure, reproduction (e.g., age menstrual periods began and age at first live pregnancy), tobacco use, and HRT. Some women have a Higher-Risk of developing breast cancer because certain family members have a history of cancer. Indeed, there can be an increased risk of developing various cancers if a woman has an inherited gene fault. High penetrance gene mutations can greatly increase the risk of developing breast and ovarian cancer, the most dominant ones being BRCA1 & 2.



The Platform

In a nutshell, The Platform collects detailed patient information through a secure and simple rapid data entry interface, including personal details, medical conditions and treatments, and family history, with which it evaluates a 10-year and Lifetime Risk of developing breast cancer, as well as a detailed Health Action Plan and Treatment Recommendations, if applicable. Individual BRCA1 & 2 mutation carrier probabilities are also reported to ascertain the likelihood of a gene mutation.

Although it is not common for younger women to get ovarian cancer, there are instances of ovarian cancer in premenopausal women; around 1,000 women under the age of 50 develop ovarian cancer every year. Additional risk factors, such as being overweight, use of HRT, endometriosis, smoking, and diabetes have all been shown to elevate the risk of

ovarian cancer. Moreover, known mutations in the BRCA1, 2 genes are highly probable of a High-Risk of developing ovarian cancer.

Information on personal and family history of cancer allows us to determine those individuals at a High-Risk of a genetic disorder that may be linked to a hereditary disease, such as breast or ovarian cancer. In this case, Genetic Counselling and Testing are recommended, according to established UK National Guidelines.

The Platform is offered to eligible women, between the ages of 25-49, on an annual subscription basis. Clearly, individual medical circumstances, conditions, and family history of cancer change over time so an annual Risk Assessment to continually monitor their breast cancer risk profile up until her screening age, is considered prudent.



“By educating and empowering women to manage and monitor their breast health, we are driven to a world where young women do not die from breast cancer as a result of early detection, diagnosis, and treatment.”

CEO, BREASTAid™ Ltd.



Compliance & Regulation

As a technology, the portability, ubiquity, accessibility at point of care delivery, and processing power of mobile technology offer huge potential in the healthcare arena. The adoption and utilisation of such technology in the clinical context is expanding, bringing with it huge opportunities to improve efficiency within medical practice. These range from simple educational reference tools and glossaries to more complex applications, such as self-assessment through video tutorials, appointment management and reminders, and social networking tools allowing users to share their experiences of breast pathology with their peers. However, despite their huge potential, there is a concerning lack of evidence-based and medical professional involvement in application development resulting in concerns around their efficacy, safety, and reliability.

To address this, BREASTAid™ works closely with NHS England and Cancer Research UK to ensure The Platform meet both a high professional standard and offers trusted and reliable content. The Platform also adheres to the National Institute for Health and Clinical Excellence (NICE) recommendations on care pathways and treatment strategies for early-stage breast

cancer and those at a High-Risk of susceptibility to the disease. Moreover, to further safeguard consumers, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK has widened its public health responsibility for ensuring the safety of medical devices to include specific categories of mobile applications. The MHRA certifies applications to a set standard, stamping those that are compliant with a seal of approval through the UK Conformity Assessed (UKCA) mark, thus allowing consumers to be confident of their efficacy, trustworthiness, and reliability.

BREASTAid™ is very proud to announce that our Pre-Screening Breast Cancer Risk Assessment is the only UKCA medical device approved by the MHRA on the UK market.

Clearly, BREASTAid™ is not qualified to offer medical advice or counselling but acts as a post-Risk Assessment conduit to world-class Professional Healthcare Organisations that do offer such services. These Organisations are committed to providing the highest quality of care and have earned a reputation as leaders in their field.



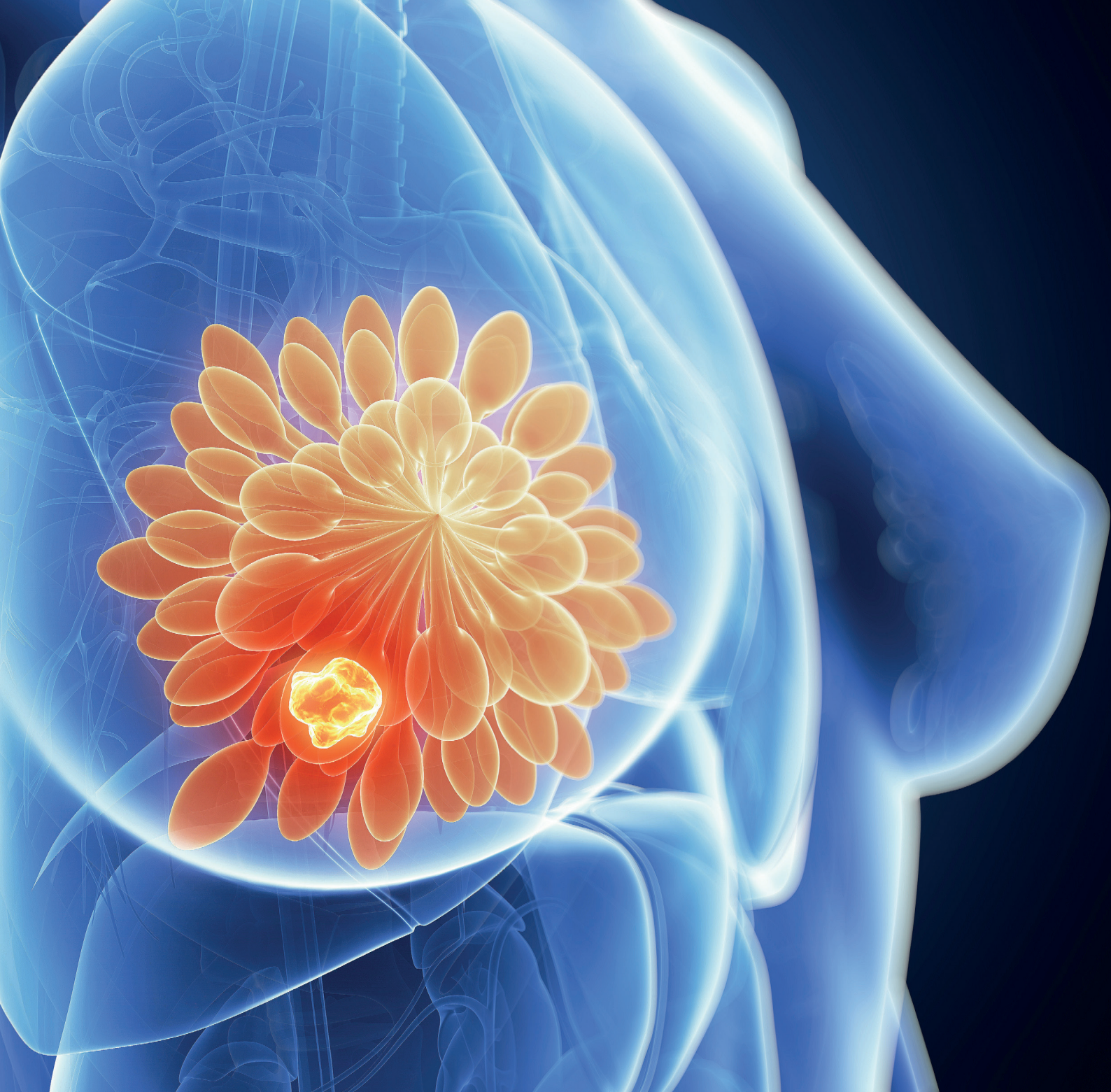
Cloud Infrastructure

Over the past several years, technological advancements have highlighted the benefits of shifting healthcare processes from a fully managed server-based setup to a more efficient and manageable cloud solution, underpinned by a serverless infrastructure. BREASTAid™ has brought The Platform to the mainstream utilising advances in cloud architecture and serverless software as a service (SaaS) framework. With SaaS, the entire application (or service) is delivered over the web through a browser, making it accessible on any device, including mobile, tablet, laptop, and desktop. SaaS models offer lower upfront costs over traditional software downloads and installation, and provides availability to a wider range of users, making it easier for smaller companies to disrupt existing markets. This is our preferred route to market.

Amazon Web Services (AWS) is the trusted technology partner for the global healthcare and life sciences industry in the cloud. As the most mature and reliable cloud platform, with an extensive portfolio of healthcare and life sciences solutions, AWS provides the security and privacy to operate in a highly regulated industry,

including effective handling and de-identification of protected health information (PHI) whilst adhering to the standards for General Data Protection Regulation (GDPR) across jurisdictions. Through our AWS Partner Program, BREASTAid™ works closely with a dedicated team to ensure that our Platform conforms to the AWS Well-Architected Framework and adheres to the principles of operational excellence, security, reliability, performance efficiency, and cost optimisation.

Health Level 7 International (HL7) recently made liberating and sharing data easier with the development of Fast Healthcare Interoperability Resources (FHIR), a new standard protocol for health data exchange. FHIR Works on AWS is a new product with an open-source software toolkit that can be used to create an FHIR interface for data sharing across organisations and clinics. The FHIR specification is expected to become the next-generation standard for inter-organisational health information exchange and BREASTAid™ will be poised to take advantage of the commercial opportunities available for The Platform.



Ground-breaking Discoveries

The Platform uses the clinically validated and world-renowned IBIS breast cancer risk model for which we have a Software Licence Agreement from Cancer Research UK. However, the extended question sets allow the intelligent use of Machine Learning (ML) algorithms, running in parallel in the background, to identify and uncover new patterns and correlations potentially leading to ground-breaking discoveries, as well as a more accurate and improved model over time. For example, knowing the ethnicity, nationality, and country will allow us to explore new demographic relationships for breast and

ovarian cancer. Age, height, weight, bra cup, and band size will expose a more informed analysis of obesity and BMI trends and may lead to a new method of extracting estimated breast density measures on a pre-screening basis. This alone would have a profound impact on the early treatment of breast cancer for those of a younger age and at a higher risk, due to having dense breasts, which will ultimately result in saved lives.



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