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Healthcare Tech OUTLOOK

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ONCOLOGY EDITION

David Demanse, CSO

Wolfgang Hackl, CEO

USHERING-IN A NEW ERA IN BREAST CANCER TREATMENT

OncoGenomX

OncoGenomX

The annual listing of 10 companies in Europe that are at the forefront of providing Oncology solutions and impacting the marketplace

COVER STORY

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TOP 10
ONCOLOGY
SOLUTIONS PROVIDERS IN EUROPE - 2022

By Alex D'souza

It is estimated that 1 in 7 women in Europe and 1 in 8 in the U.S. will develop breast cancer in their lifetime. Despite these alarming numbers, the efficacy of breast cancer treatments has not yet reached the optimal level.

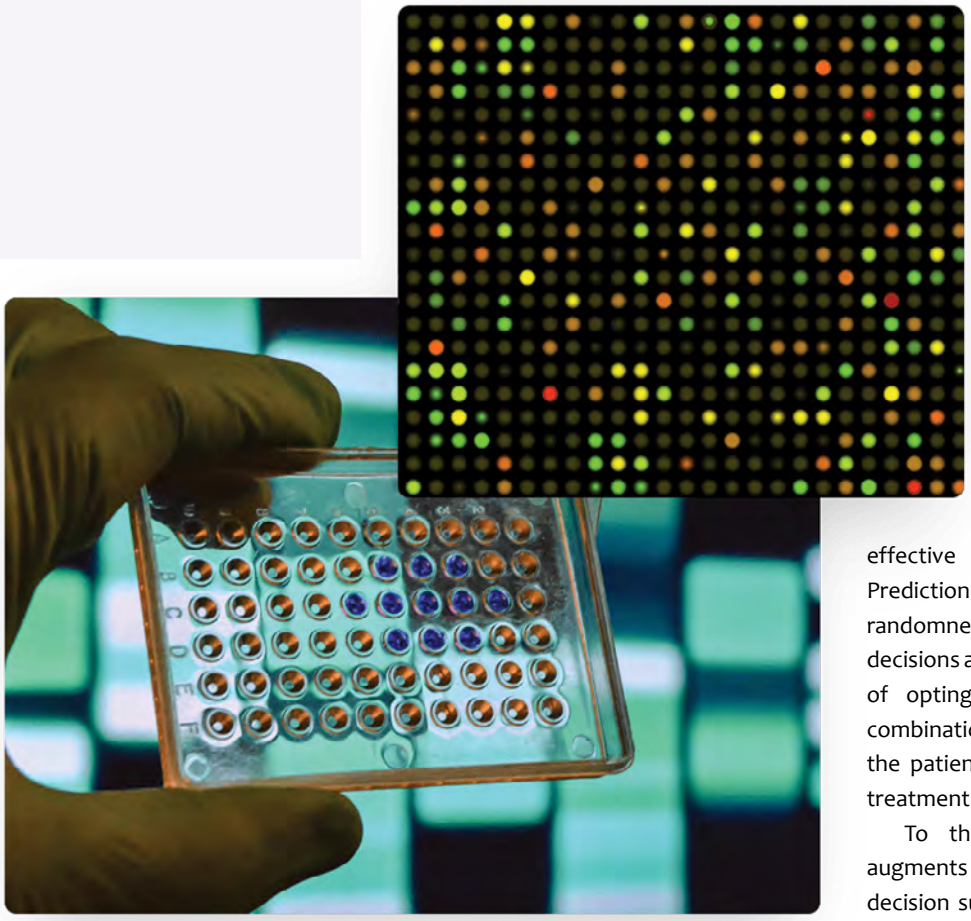
Breast cancer diagnostic methods have indeed come a long way in identifying a tumour's molecular profile. Relying on current, prominent genomic tests and clinical decision support tools, oncologists can determine the prognosis, patient risk, and eligibility of a patient and/or a tumour for specific treatment modalities (hormone, cytotoxic, or molecular targeted therapies). However, uncertainties persist in choosing the most effective treatment combination for a particular tumour or patient. Oncologists consider multiple factors to determine the treatment strategy: the patient profile, the clinical tumour stage, the pathological tumour grade, the molecular tumour profile, treatment guidelines and study results, and patient-specific contra-indications. But years must pass before oncologists and their patients can be certain that the treatment path chosen was the right one.

That is why oncologists largely resort to a risk-adapted approach in breast cancer treatment, extending moderate therapies for low-risk cancers and intensive therapies for high-risk cancers as well as during instances of clinical doubt regarding the accuracy of risk classification, putting more than half of the patients at risk of undertreatment or overtreatment. It is on this front that the Swiss-based startup, OncoGenomX, is set to revolutionise oncology care with its one-of-a-kind theragnostic decision support solution—PredictionStar.

OncoGenomX's PredictionStar breaks new ground in breast cancer drug development, diagnosis and therapeutic outcomes with its biologically, pharmacologically, and clinically framed, evidence-based guidance, aiming at targeting the entire cancer—eradicating it completely and preventing metastasis

Wolfgang Hackl, CEO

"PredictionStar enables accurate, actionable, and comprehensive matching of therapies and tumours to facilitate individualised therapeutic decisions at any stage of the disease trajectory



permanently. According to NCI's Surveillance, Epidemiology, and End Results (SEER) program, 50 percent of the women with breast cancer are affected by metastasis, despite five years of consequent treatment. That's 1.4 million women worldwide. Honing in on biological defects shared between the cancer cells of a given tumour, the genetic mechanisms applied to compensate for these defects, and leveraging the two by patented artificial intelligence (AI) and machine learning algorithms, PredictionStar is extending an optimal solution to largely avoid this grave problem. For each candidate drug, PredictionStar finds precisely the target tumour type on whose tumour cells the treatment with the candidate drug has an absolutely lethal effect. For each patient's tumour, PredictionStar finds the treatments proven to be the most effective according to current real-world outcome data from comparison collectives, enabling clinically efficient therapeutic decisions, for any patient, at any stage of the disease trajectory.

PredictionStar does not require invasive measures, extra tests, or shipment of samples. The only requirement is to enhance a hospital's smart IT system by its smart IT module that gives temporary access to the anonymised patient-level diagnostic data. As far as tumour gene tests are concerned, PredictionStar works with standard, unsupervised, or commercial target gene panels, not only expanding their scope but also raising the applicability of test results from an average 65 percent to more than 80 percent. For the first time, oncologists can understand which treatment type will work the best for a patient. For instance, in the case of hormonal treatments, PredictionStar offers insights to determine if estrogen receptor or estrogen synthesis blockade is more effective. The cytotoxic therapy will similarly be augmented by distinguishing between antiproliferative and DNA-damaging cytotoxic treatments. PredictionStar can also predict which molecularly targeted treatment mechanisms will be effective for different tumours or patients. PredictionStar takes away the uncertainty and randomness surrounding breast cancer treatment decisions and substantially increases the likelihood of opting for the most effective treatment combination without delay and without exposing the patient to the side effects of an ineffective treatment.

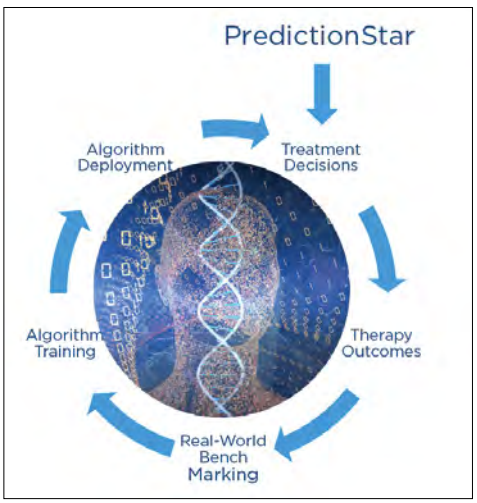
To that end, PredictionStar considerably augments five current-day cancer tests and clinical decision support tools. The molecular diagnotics tests have a 55 percent accuracy rate. But once these tests are complemented with PredictionStar, the correlation between the predicted treatment and the achieved beneficial patient outcomes reaches 85 percent, significantly improving care delivery.

PredictionStar achieves this with a three-pronged approach. It first comprehends the underlying complexity of a given cancer. The platform analyses tumour-specific genomic, biological, and pathological, and patient-specific clinical information routinely collected for breast cancer diagnosis. PredictionStar then identifies the biological defect shared between the cancer cells of a tumour and the bypass mechanisms they apply to compensate for the defect. Specially developed precision gene sets help to determine a tumour's 'sweet spots' for an efficacious pharmacological intervention. In the next stage, PredictionStar applies two AI-based software routines; the first to achieve individualised drug-tumour matching for efficient pharmacological intervention, and the second is to make outcome predictions. But PredictionStar doesn't leave things at forecasting. It also has a feedback learning solution for

continuous refining of its therapy guidance. The platform also offers decision-makers supportive real-world outcome data from relevant patient collectives.

"Our users have the unique opportunity to garner insights, learn, and benefit, not just from their own and institutional therapy decisions. PredictionStar also factors in the decisions, and clinical experiences made elsewhere," states Wolfgang Hackl, Founder and CEO of OncoGenomX.

OncoGenomX has already analysed the data of more than 4,500 breast cancer patients from 3 different cancer genome databases. OncoGenomX's development support service becomes available in fall 2023. In addition, the company aims for market authorization in the U.S. and Europe in 2027. Once brought to market, OncoGenomX's PredictionStar can offer clinically actionable direction for targeted treatment of patients as early as two weeks after the presumptive cancer diagnosis. As the battle against cancer is a race against time, PredictionStar can indeed bring path-breaking advancements in oncology care.



Catering to the Complete Oncology Care Value Chain

PredictionStar caters to all the stakeholders in the oncology care value chain, from drug developers and laboratories to cancer hospitals and oncologists.

For drug developers, PredictionStar offers an innovative platform to develop highly effective treatments that will succeed in clinical trials as well as in everyday clinical practice. Today, the most promising treatment candidates fail in clinical studies or do not prevail in the clinic, despite having achieved health authority approval and market authorisation. FDA approval currently has a staggering 97 percent failure rate in clinical oncology trials, typically due to drug efficacy or toxicity issues. But PredictionStar's holistic approach can be a game-changer for pharmaceutical companies on that front.

Unlike conventional anti-cancer combination regimens that target specific tumour cell populations, PredictionStar considers the biological properties shared between all cells of a given tumour and helps drug manufacturers target cancer as a whole. By leveraging PredictionStar, the drug developers can comprehensively understand the ideal target tumour/patient, the biological markers to identify them, the most promising mechanistic drugging approach (LMW-inhibitors or biologics), and the additively or synergistically acting combination treatments. The result is a treatment candidate with a higher chance of succeeding in clinical tests, achieving market authorisation, and stepping up to the expectations of physicians and patients.

Similarly, by adding the granularity required for evidence-based clinical decision-making and enabling clinically relevant and accurate predictions, PredictionStar is uniquely positioned to augment and complement cancer tests and clinical decision tools. Be it immunologic receptor testing, multigene tumour assaying, tumour sequencing, or liquid biopsy testing, molecular diagnostics laboratories have the most reliable guidance tool in PredictionStar.

Despite all these diagnostics and care delivery advancements, what makes PredictionStar all the more remarkable for cancer hospitals is its significant cost-saving opportunity. It is estimated that by avoiding overtreatment, cancer hospitals can save up to a third of cancer treatment costs incurred by today's decision-making and treatment practices. PredictionStar achieves just that with its precise tumour and patient profiling.

A Secure End-to-End IT Solution for Hospitals

PredictionStar will be made available to hospitals as an end-to-end IT solution with numerous core features and functionalities, which can be easily integrated with the hospital's health IT and EHR systems. The portals and services PredictionStar offer include a personalised identity provider, test ordering and purchase transaction portal, EHR/IHS input/output portal, laboratory data input/output portal, cybersecure data analysis room, cybersecure data store, 24/7 support service platform, and an intuitive mobile application for end-users to access the test reporting portal.

What's more exceptional is PredictionStar's data security. Its security architecture can be adapted and expanded in coordination with the security architecture of the hospital's local health IT system, to achieve maximum data security. For analysis, interpretation, and update, anonymised patient diagnostics data is temporarily loaded into the cybersecure data analysis room. Hospitals can rest assured that their sensitive health data doesn't leave their own IT environment.

David Demanse, CSO

Wolfgang Hackl, CEO

Leaning on Vast Industry Expertise

At the core of such extensive competencies is a broadly experienced team of industry experts. Hackl has quite an accomplished career as an esteemed oncologist and an R&D scientist in drug development. Over the course of his expansive career, Hackl has been in leadership roles in strategic target and investigational new drug (IND) positioning, translational oncology, and clinical research. Meanwhile, Co-Founder David Demanse is a pioneer in predictive modelling. Demanse brings a wealth of experience working in the AI and machine learning domains.

Complementing the founders is a team of skilled professionals with expertise in different fields, like in vitro diagnostics/molecular diagnostics and platform engineering. The hands-on experience that the team has in their respective sectors and their appreciation for the real hurdles in the oncology field have propelled OncoGenomX to come up with a revolutionary platform.

Paving the Future for Oncology Care

AI-based computer programs have been used for decades to aid doctors in interpreting mammograms. But the research in the field is swiftly advancing, bringing forth a new era, and PredictionStar exemplifies it. For example, AI-enhanced analysis of digital tumour images (clinical or microscopic) is currently conducted to avoid misdiagnosis or to prevent overlooking borderline cases. But PredictionStar takes it up a notch and guarantees to guide personalised follow-up testing with the analysis.

Leaning on such capabilities of its platform and driven by the Swiss tradition of precision and craftsmanship, OncoGenomX is set to revolutionise complete oncology care. It is only a matter of time before the availability of mature and robust patient data sets extends the scope of PredictionStar to other cancer types. But for now, Hackl reiterates that the company's primary focus is to commercialise PredictionStar for breast cancer treatment in the U.S. and European markets.

> **Its security architecture can be adapted and expanded in coordination with the security architecture of the hospital's local health IT system, to achieve maximum data security**

"To make the endeavour successful, strong collaboration partners are instrumental," says Hackl. In that regard, discussions are already underway for OncoGenomX with various cancer clinics, diagnostic laboratories, study consortia, and industry representatives from the fields of molecular and in vitro diagnostics, clinical and histologic image analysis, and pharmaceuticals. By forging such a strong alliance, OncoGenomX promises to bring a new era to oncology care. HT

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