Cancer is a challenge best faced together
Dr Ines Gröner, MD
Senior VP Life Science
Sysmex Europe GmbH

Each day, over nine thousand people in Europe are newly diagnosed with cancer. The growing understanding of cancer pathophysiology, and the systematic development of diagnostic and therapeutic solutions are leading to longer survival rates and improved quality of life for many. To continue this trend, medical disciplines and specialists are merging expertise and experience. They are stronger together.

At Sysmex, we too contribute to improving patient care in cancer management. With profound scientific knowledge and an understanding of clinical needs, we work closely with our partners. Our aim is, together, to deliver innovative diagnostic solutions and therapeutic support that, wherever possible, address patients and their therapy individually.

Through greater efficiency in clinics, diagnostics that take into account patient wellbeing, and by reducing side- and post-effects, we are shaping advancements in cancer management.

Cancer management is classically defined in clear-cut steps. Screening to recognise cancer as early as possible. Diagnostics for therapy decisions. Surgical treatments. And support once therapy is underway.

Yet the knowledge of diagnosing and treating cancer continues to grow, and so do the synergies between the various product solutions. As a result, experts from a range of disciplines are cooperating to grasp and make best use of the emerging interdependencies. Experience shows that this is the most effective way to get the big picture from all the diagnostic information.

Simply put, we are all stronger when we bring our expertise and experience together – this is our approach at Sysmex.

Stronger Together…
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Breast Cancer

One in eight women in the EU will develop breast cancer at some stage in her life. New diagnostics and therapies offer fresh hope.

Thanks to new treatments, survival rates have improved significantly in recent years \[1, 2\]. As part of these treatments, patients’ quality of life is increasingly a focus \[3–5\]. Decisive progress has been made, for example, with the introduction of the sentinel lymph node biopsy (SNLB) concept, as a result of which patients benefit from tissue-saving operations and therefore from fewer long-term effects. With the Sentimag® system, which detects sentinel lymph nodes magnetically, you no longer need to use radioactive marker methods. Analysing lymph nodes molecularly using the OSNA® system provides reliable findings based on the entire lymph node – while operations are ongoing – so that surgeons can immediately perform the most appropriate surgical intervention. Importantly, the latest findings from research show that molecular lymph node analysis using OSNA® can also deliver valuable information for individualised therapy decisions.

Alongside these optimised diagnostics and therapies, using modern side-effect management can help you ensure your patients experience fewer limitations in their everyday life, despite the most essential, systemic cancer treatment. During and after chemotherapy, for example, many patients consider their loss of hair to be one of the most impactful and negative side-effects. Here, when choosing to use DigniLife®, many patients now have an opportunity to retain their hair and therefore greater normality and dignity in their everyday lives.

These developments in modern diagnostics and the new side-effect management methods are contributing to improved therapies and greater quality of life for breast cancer patients.

Best practice SLNB for more patients. At any hospital. At any time.

The method of ‘sentinel lymph node biopsy’, or SLNB, identifies the lymph nodes with the highest potential for harbouring metastases, helps to determine the stage of the cancer and make informed decisions for surgery and subsequent treatment.

Many treatments for early cancer, both breast and other cancers, involve SLNB. Standard SLNB uses radioisotopes for sentinel localisation, which can lead to challenges related to safety, workflow and availability associated with ionizing radiation. As a result, it cannot be offered at every hospital and is not available to all patients.

Radiation-free, best practice SLNB

In our diagnostics, we offer an easy-to-use, clinical solution that uses safe magnetic fields: the Sentimag® probe and the Sienna+® magnetic tracer. It offers clinical outcomes non-inferior to the current standard treatment.1

First, the tracer is injected into the interstitial tissue to provide a traceable signal. Next, using the Sentimag® probe, you locate the sentinel lymph nodes to determine how far the cancer has spread.

- Perform best practice SLNB in any clinical setting, available to all patients
- Eliminate issues with radioactive materials
- As a surgeon, retain full control of the SLNB procedure
- Inject the tracer when it is best for you and your patient, up to seven days in advance

Dr Cem Yılmaz  
Breast Surgeon  
Istanbul, Turkey

“Now that we have Sentimag® in our breast surgery practice, we save time and offer more comfort for our patients with a clinically proven technology. The new approach means our staff are not anxious about radiation any more either.”


Magnetic sentinel node localisation: as effective as the radiotracer, as easy as blue dye
The nodal status matters.  
More information.  
Better treatment decisions.

When diagnosed with breast cancer, metastatic spread to axillary lymph nodes is an important prognostic factor. Sentinel lymph node (SLN) analysis shows whether axillary lymph nodes are affected or not.

Should no metastases or only very low tumour loads be found, further dissections can be avoided. Classical histopathology used to determine SLN status does not generally analyse the full lymph node, thus providing limited, non-standardised information to clinicians.

From diagnostics to treatment

OSNA®, or One Step Nucleic Acid Amplification, is a more precise, more comprehensive method for determining the tumour burden in SLN. By analysing whole lymph nodes, it provides all the information and confidence clinicians need to select the most appropriate surgical and non-surgical treatment for individual patients.

- Analyses entire lymph nodes to more accurately determine the tumour load
- Better predicts the risk of non-sentinel node involvement
- Provides staging information relevant for therapy decision-making, even if no axillary dissection is performed

Recent studies also indicate a prognostic value that enables patients to be categorised into high/low risk groups. As such, the OSNA® result provides predictive and prognostic information to support personalised treatment decisions for early stage breast cancer patients.

Molecular analysis of sentinel node metastases to fine tune treatment decisions

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Dr Vicente Peg  
Pathologist  
Barcelona, Spain

“Sentinel Lymph Node Total Tumour Load (TTL) allows clinicians to know the likelihood for further axillary involvement and, from now on, for recurrence, too.”

Prof Antonio Rulli  
Breast Surgeon and President of the Italian OSNA User Society  
Perugia, Italy

“Various European studies are looking to find methods to avoid ALND with one or two macrometastatic lymph nodes. Using the OSNA Nomogram calculator (www.osnauser.it), as predictive tool, we gain reliable information as to whether or not ALND is necessary.”
Spare your patients the most visible side-effect of chemotherapy

Chemotherapy is the standard of care for treating breast cancer patients. In many cases, this systemic treatment results in partial or complete hair loss – for many the most distressing side-effect of cancer therapy.

Besides the obvious change in the way one looks, chemotherapy induced hair loss is often associated with a poorer image of oneself. In some cases, this self-image does not recover, even when hair has regrown, chemotherapy has ended, and the outer appearance returns to normal. If this negative self-perception remains, it often leads to deterioration in other areas in patients’ lives.

DigniLife® – a new perspective for cancer patients

Scalp cooling with DigniLife® can help your patients retain their hair and so improve the quality of life during and beyond chemotherapy. The DigniLife® solution covers both hardware (DigniCap® scalp cooling system), service and consultancy. The DigniCap® System is the latest generation in scalp cooling and the only solution cleared by the FDA. To simplify its introduction, we take into account the details of your individual practice, and therefore offer a custom-made solution:

- Interactive planning, ensuring it is easy to use in your routine, including staff training
- Sensor controlled cooling – not too cold but cold enough for effective therapy
- Scientific support and user networking
- Help with communications: step-by-step explanations for patients and external promotion

After six cycles of chemotherapy with F500E100C500.

Hair preservation: 70%.
Colorectal Cancer


Colorectal cancer is the second most common cancer in Europe, with over 400,000 new cases diagnosed each year. Great progress has been made in recent years in terms of patient survival and quality of life. Identifying colorectal cancer early on is especially important for therapeutic success, whereby screening – both symptomatic and especially large-scale – is essential.

The quantitative FOB Gold® FIT (Faecal immunological testing) solution, a screening test for recognising colorectal cancer, delivers more reliable results than the standard qualitative test. It is extremely flexible and can be adapted to screening programmes of any size and to laboratories with all throughputs.

When determining the appropriate therapy, the stage of the cancer is decisive. Here, nodal status is an important parameter and determinant as to whether chemotherapy is needed or not. Sensitive, standardised lymph node diagnostics are essential. OSNA® delivers both the sensitivity and standardisation required. Clinical studies show that this molecular testing reduces the number of false-negatives compared to classic histopathology.

In recent years, the use of antibodies alongside chemotherapy improved the overall survival of CRC patients.[1] Clinicians must, however, test stringently which patients are eligible for this type of therapy. Thanks to the OncoBEAM™ RAS CRC test, this decision is now possible with a mere blood test instead of surgical intervention. Without the need for tumour tissue.

Bringing together innovation for early recognition, individualising cancer therapy, and using less invasive diagnostics are leading to improved prognoses and greater quality of life for colorectal cancer patients.

Because detecting colorectal cancer early on saves lives

With almost 1.5 million new cases diagnosed each year, colorectal cancer (CRC) is second only to lung cancer in terms of deaths around the world.

Yet since CRC takes many years to develop, implementing screening programmes can be particularly effective for both preventing and diagnosing CRC early on. Quite simply: CRC screening can save lives.

In contrast to older, non-invasive methods for CRC screening, the quantitative faecal immunochemical test, or FIT, is currently considered the best choice in terms of its simplicity and proven superior performance.

Since FIT-based screening manages to attract high participation rates, the main challenges labs face are processing samples quickly, cost efficiently and especially without the loss of standardised analytical quality.

Sysmex and CRC screening: A perfect FIT

The Sysmex FIT solution is designed to perfectly fit all lab screening settings. The universal patented FOB Gold® Tube enables:

- Customised screening solutions
- Easy, safe and hygienic testing
- Dedicated stand-alone or walk-away configurations for most throughput needs
- High quality standards, while keeping a lid on costs

FOB Gold® – The perfect FIT for all lab testing settings

Colorectal cancer (CRC) is most frequently diagnosed in the later stages, which correlates with decreasing survival rates. FOB-based (Faecal Occult Blood) screening contributes to early detection of CRC. This decreases the risk of dying from CRC by up to 30%.[1]


W.W.J. Spijker
CEO Screening Organisation Netherlands

“The FIT Test has a major advantage as it is quantitative so that no interpretation from the doctor is required. Another benefit is you can perform it in high volume because the throughput is fast: you can easily analyse a few thousand tests per day.”

Lizet Bosman-Weijzen
Analyst
Geleen, Netherlands

“With simple lab testing you can help save lives.”

Survival 5 years after treatment:

- Polyp

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<thead>
<tr>
<th>Diagnosis</th>
<th>37%</th>
<th>63%</th>
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> 50-years-old 1 in 4 have polyps

> 1 in 10 change to invasive cancer

Survival 5 years after treatment:

93% 77% 48% 7%

W.W.J. Spijker
CEO Screening Organisation Netherlands

“The FIT Test has a major advantage as it is quantitative so that no interpretation from the doctor is required. Another benefit is you can perform it in high volume because the throughput is fast: you can easily analyse a few thousand tests per day.”
Diagnostics

In colorectal cancer, determining lymph node status is an important and independent prognostic factor. Metastatic lymph node involvement is the most important criterion for adjuvant chemotherapy.

Normally, lymph node analysis is performed using classical histopathology. In doing so, the lymph node is only analysed on one level, leaving a large amount of tissue unanalysed. The risk is that some metastases remain undetected.

Analysing the whole node is the key

OSNA®, or One Step Nucleic Acid Amplification, is a sensitive, accurate method for identifying metastases in lymph nodes. By analysing whole lymph nodes, it enables more precise staging and provides the reliable basis clinicians need to select the most appropriate treatment for each individual patient. This relates in particular to whether or not patients have to undergo chemotherapy.

Lymph node analysis using OSNA®:
- Analyses entire lymph nodes to more accurately identify the presence of lymph node metastases, even very small metastases
- Provides observer-independent and standardised diagnostic information
- Delivers results quickly and reduces waiting time for further treatment decisions

More confidence staging colorectal cancer patients

In colorectal cancer, determining lymph node status is an important and independent prognostic factor. Metastatic lymph node involvement is the most important criterion for adjuvant chemotherapy.

Classical histopathology analyses only a single slice of lymph node tissue. Metastases can be overseen.

Accurate, standardised lymph node analysis for reliable staging and improved basis for treatment decisions

Dr Bruno Märkl
Pathologist
Augsburg, Germany

“OSNA® was astonishingly easy and fast to establish in our histology lab. Even our technicians, with no previous experience in molecular techniques were able to perform the analyses after a very short training phase. It has proven to be very sensitive and specific in detecting lymph node metastases of colon cancers. Initial data indicate higher sensitivity compared to conventional histology.”

Dr Miriam Cuatrecasas
Pathologist
Barcelona, Spain

“Molecular positivity in lymph nodes correlates with other classical high-risk factors of early-stage CRC.”
Antibody-based therapy against EGFR has become a standard of care for treating patients with metastatic colorectal cancer (mCRC). To select those who will benefit from this therapy, you have to analyse the tumours for mutations in the RAS genes.

Tissue-based biopsy has been commonly used to determine the RAS mutation status in mCRC patients. This has significant limitations, however.

... An additional, invasive biopsy may be required.
... Tumour tissue is heterogeneous. For almost 50% of patients with primary mCRC, RAS mutations are present in only a very small portion of the tumour\(^{[1]}\); RAS mutations may therefore be missed when analysing the tissue.
... There may be differences in RAS status between the primary tumour and the metastases. Here too, it is therefore easy to oversee RAS mutations when analysing only a single tumour.

Blood, not biopsy.
Targeted therapy based on the current mutation status.
It has been shown that tumour cells deposit small fragments of DNA in the bloodstream. This circulating tumour DNA (ctDNA) can be detected from a blood sample (liquid biopsy, LB) and can provide an alternative to invasive tissue biopsy. The OncoBEAM\textsuperscript{TM} RAS CRC test is based on such a LB – with many benefits for your patients:

✓ You can determine RAS status in patients for whom biopsies are contraindicated or those who refuse an invasive diagnostic method.
✓ Because there is no selection bias with a blood sample, the test lets one assess both the primary tumour and metastases. This delivers a complete, current picture of all of a patient’s lesions.
✓ The test can be performed at any time. This means that the current mutation status can be obtained at any phase during therapy\(^{[2]}\).
✓ Test results are available in less than seven days so that anti-EGFR therapy can be started quickly.

\(^{[1]}\) Grasselli J, et al. (2016): Circulating tumor DNA extended RAS mutational analysis as a surrogate of mutational status of tumor samples in metastatic colorectal cancer and it impact on patient selection for anti-EGFR therapy. Study presented at the meeting of ESMO 18th World Congress on Gastrointestinal Cancer, Barcelona, Spain.
Tackling cancer in new ways

In the new age of cancer diagnostics and therapy, the ‘blanket treatment principle’ is increasingly being replaced by personalised and targeted therapies. This calls for diagnostics that look at tumours from multiple perspectives and so create a holistic picture of all the information available for a particular patient.

In doing so, experts from various fields of expertise merge their professional knowledge and skills. So that they can choose the best possible therapy. Together. Individually for each patient.

Pathology continues to play an essential role in this process. It includes histological findings, such as tumours’ growth, invasion and malignancy types, as well as molecular-genetic aspects. Collecting and classifying this information represent a decisive knowledge base for further treatment options for interdisciplinary tumour boards.

Digital pathology offers doctors real progress in this respect by, for example, making it easier to get second opinions and facilitating interdisciplinary therapy decision making.

Liquid biopsy is opening new opportunities in tumour analytics. With OncoBEAM™, blood is used for these tests instead of tissue. This form of analytics is easier on the patient and can also be performed when biopsies are counter-indicated.

Digital pathology and highly-sensitive, blood-based detection methods offer new perspectives for treating all manner of cancer entities, such as colorectal, breast, lung cancer and melanoma. The most effective results are achieved when disciplines work together closely – bringing together expertise, hardware and data. This is our approach at Sysmex.
Digital pathology. See more. Do more.

As we slowly unravel the mysteries of tumour biology, we are finding new ways to address cancer patients on an individual basis – with far higher levels of success.

The associated diagnostics are extremely complex, however. Quantitative analysis of tissue samples, standardisation of findings, quality assurance, archiving of slides and the merging of records for individual patients to name just a few of the challenges. In addition, costs rise with the increased use of molecular diagnostics.

With the increasing influx of information in pathology, keeping track of all your patient data may be a challenge. Holistic digital pathology can help you manage this complexity, even at this cutting edge. It significantly simplifies your workflow and increases efficiency by addressing matters such as sample type and sample throughput, staining, digitisation and interpretation of samples.

Manage even the most complex pathology data

Our digital pathology covers every step and more – perfectly aligned so you can see more and do more. Starting with tissue microarrays for efficiency purposes all the way to archiving your findings and samples, you need just one point of call.

✔ Time-saving, simplified sample interpretation for pathologists thanks to, for example, automated biomarker quantification
✔ Remote access to all samples, thereby simplifying collection of second opinions and enabling pathologists to compile diagnoses at any place and at any time
✔ Significantly improved laboratory efficiency with tissue microarrays, digital sample management, etc.
✔ Modern quality assurance and easier adherence to accreditation / certification guidelines
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Fast and accurate: From first impressions to your second opinion. Digital pathology as it should be.
Use blood, not tissue, to determine your patient’s mutation status

Only a portion of patients benefit from targeted cancer therapies. To find out who can benefit, you first need to determine the mutation status of a patient’s tumours.

Common mutation testing is performed with tumour tissue, which for patients is often associated with an invasive intervention. Moreover, mutation analysis using tissue cannot take into account the heterogeneity within a tumour or between a patient’s lesions. And tumour tissue is sometimes not available.

Therapy selection – based on a simple blood sample

For many patients, it’s now possible to replace tissue-based mutation analytics. To go beyond biopsy with blood.

OncoBEAM™ tests require no more than a simple blood sample (liquid biopsy) to determine a tumour’s mutation status. It is used within clinical studies for breast cancer, colorectal carcinoma, lung cancer as well as melanoma. OncoBEAM™ tests offer:

- Minimally invasive diagnostics, independent of the tumour’s location
- Determination of a mutation status that represents the totality of a patient’s lesions
- Early recognition of progressive disease
- A solution for patients for whom representative tumour tissue is unavailable

New study data show that OncoBEAM™ RAS CRC tests can be used for monitoring of acquired resistance to therapy in colorectal carcinoma:[1],[2]. Another important area of application for OncoBEAM™ tests is cancer drug development and the related clinical studies.


Comprehensive, patient-friendlier tumour mutation analysis using a simple blood sample
Cancer is a challenge best faced together

Experts in a wide range of specialities have known it for years: to arrive at the best decisions in terms of therapy, it’s best if you work together.

On Tumour Boards, which focus on patients and their individual illnesses, this system of cooperation has proven itself time and time again as a platform for developing successful treatment strategies and sharing essential feedback. The overall picture, including all relevant patient information, is important for everyone involved across the various phases of cancer management. For this reason, we at Sysmex also stress the importance of sharing information; quite simply, it helps us to better solve your challenges.