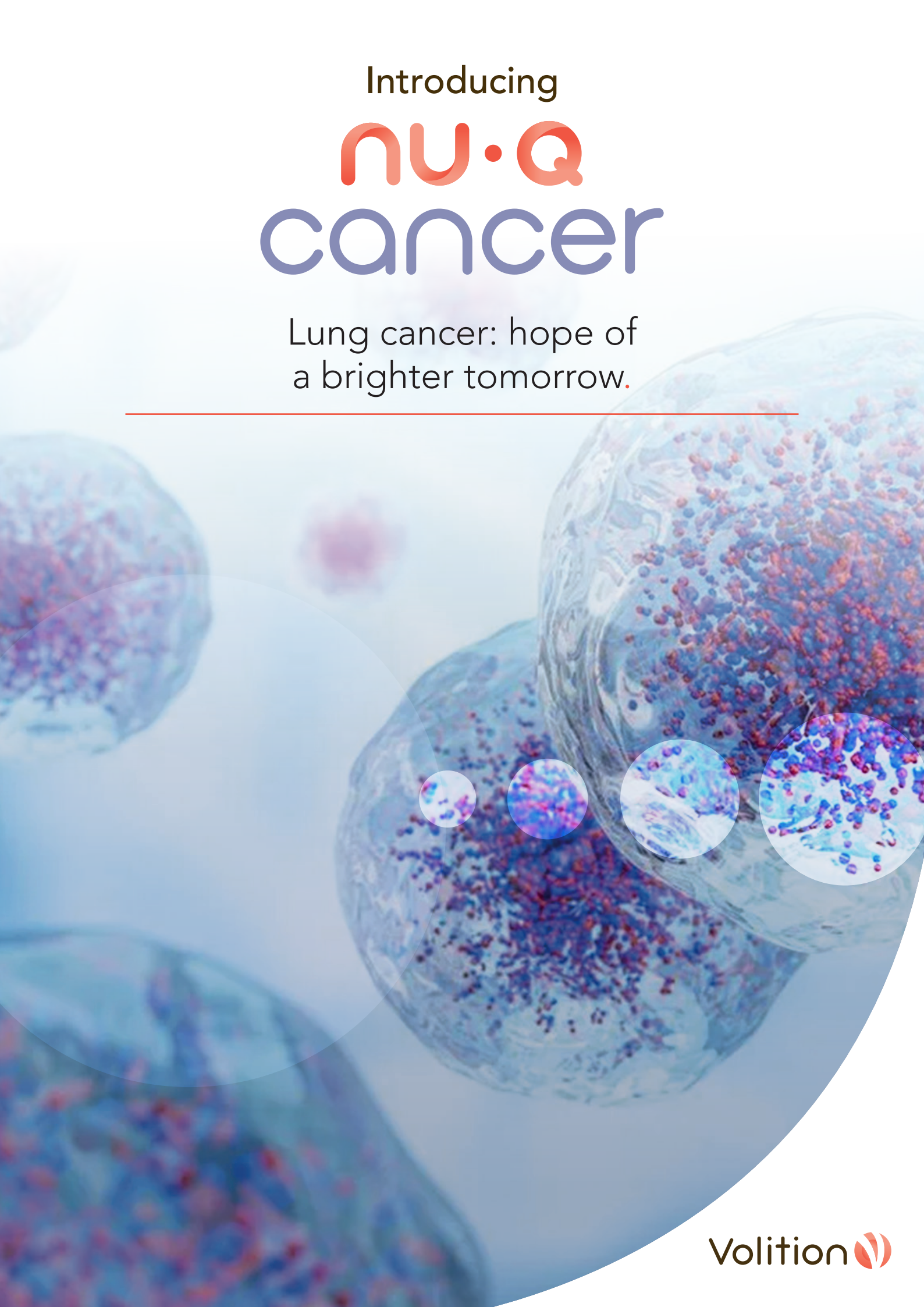
Introducing

nu·Q cancer

Lung cancer: hope of a brighter tomorrow.



Volition

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tomorrow.

Introduction

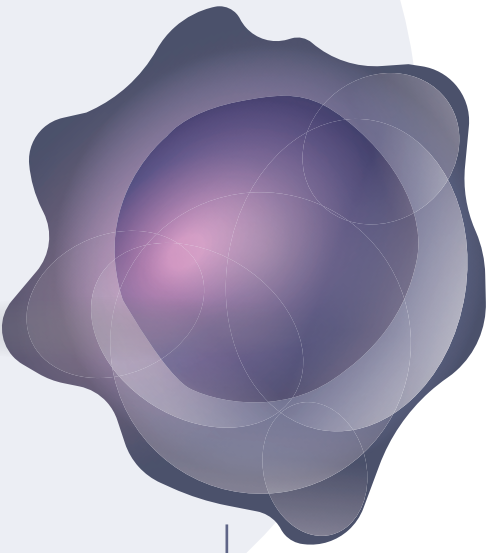
Lung cancer is the number one cause of cancer death worldwide. It kills an estimated 1.8 million people each year. That's more than die from colorectal and liver cancer, the two next biggest cancer killers, put together.[1]

Early detection and treatment save lives but people are often diagnosed with advanced disease when treatment options are limited and there is little chance of a cure.

"I see a lot of patients with lung cancer every week and we do everything we can for them but sometimes it is not enough. If a simple test allowed us to detect the lung cancer, then help us select the best treatment and monitor patients during and after treatment to help improve survival, we would use it."

Professor Sébastien Couraud,

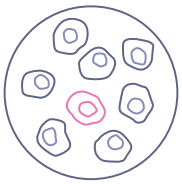
Head of Pulmonology and Thoracic Oncology Department,
Lyon Sud Hospital,
France



Once the disease is diagnosed, the techniques used to select treatment and monitor disease can lack sensitivity. This can lead to delays in starting more aggressive treatment – and even result in patients who could potentially be cured being sent down the palliative pathway.

Oncologists need a simple, reliable and rapid test to help them detect lung cancer, aid treatment selection and monitor the patient over the course of the disease.

That is why we've developed Nu.Q® Cancer.

Screening	Diagnosis & staging	Therapy decision, planning & treatment	Monitoring & follow-up
			
• In combination with LDCT	• In combination with NGS on tissue • Prognostic Value at diagnostic	• In combination with NGS on tissue • Prognostic Value at diagnostic	• In combination with NGS liquid biopsy • Treatment response monitoring • Minimal Residual Disease

Introducing Nu.Q® Cancer

Nu.Q® Cancer is a simple, reliable and rapid blood test that can easily be implemented in any hospital.

It is low-cost, uses a small sample of blood and takes just 45 minutes.

The latest research findings clearly show that it can enhance: screening for lung cancer, treatment selection and disease monitoring. In other words, wherever a patient is on their clinical course, Nu.Q® Cancer may help.

It does this by measuring levels of nucleosomes. These are small fragments of chromosomes that are released into the blood during cell death and consist of a section of DNA wrapped around a histone core.

High levels of histones, such as the histone H3.1, are a sign of the high cell turnover that occurs in cancer, while nucleosome-H3K27Me3 (an epigenetic modification of the histone H3) is a known biomarker of cancer.

How Nu.Q® Cancer could transform the diagnosis, treatment and monitoring of lung cancer: the research behind the claims

Studies carried out in Europe and Asia, including several at one of France's largest hospitals, show that when used alongside existing techniques, Nu.Q® Cancer can improve the specificity of lung cancer screening, assist with treatment selection and improve detection of minimal residual disease.

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Lung cancer screening

Screening programmes can detect cancer earlier, when it is easier to treat. Studies show that screening for lung cancer can reduce the death rate by 20%.[2]

Despite this, just a handful of countries screen for lung cancer. And, in those that do, uptake is often lower than for other screening programmes. In the US, for example, just 5.8% of the eligible population take up the offer of screening.[3]

One reason for this is that low-dose computed tomography (LDCT), the current gold standard for lung cancer screening, has a high false-positive rate. Around 20% of the nodules seen with LDCT are not cancerous.[4]

This leads to patients with benign modules undergoing biopsies, something expensive and time-consuming which can also be distressing for patients and put them at risk of infections and other complications.

"Our findings so far indicate that Nu.Q® Cancer can accurately identify malignant nodules, including small ones, with high sensitivity. We are now conducting a large, prospective validation study, the results of which could lead to the test being included in Taiwan's national lung cancer screening programme."

Professor Jin-Shing Chen,

Department Chief, Department of Surgery,
National Taiwan University Hospital,
Taiwan

A recent large-scale study has demonstrated that Nu.Q® Cancer can differentiate between malignant and benign pulmonary nodules found by LDCT, improving the specificity of the results.[5]

The test had an AUC of 79% and accurately identified lung cancer in different types of nodules, including part-solid and non-solid nodules, as well as small nodules, which can be challenging to biopsy.

*Nu.Q® Cancer reduces the false positive rate of LDCT. This could more than **halve** the number of unnecessary biopsies.*

Nu.Q® Cancer also performed accurately and consistently across different Lung Imaging Reporting and Data Systems (RADS) categories.

The researchers calculated that, used alongside LDCT, the blood test could reduce the number of unnecessary biopsies by more than 50%.

The 800-patient retrospective study was carried out in Taiwan, the first country to set up a national screening programme for lung cancer. It is now considering adding Nu.Q® Cancer to that programme, pending the results of a validation study which is under way.

Aid treatment selection

Research shows that Nu.Q® Cancer can assist with treatment selection by prognosticating patients who may benefit from different treatment strategies.

"Our results indicate that measuring nucleosome levels at NSCLC diagnosis can provide valuable information about survival, progression-free survival and, crucially, enhance the identification of patients who may benefit from curative care."

Professor Léa Payen,

Professor in Toxicology and Biochemistry,
Claude Bernard University of Lyon I and Hospices Civils de Lyon, France

The OncoProLung study at Hospices Civils de Lyon, the second largest university hospital in France, examined the prognostic value of measuring levels of the histone H3K27Me3 at diagnosis of non-small cell lung cancer (NSCLC).

The small retrospective study found that levels of H3K27Me3 correlated with progression-free survival and overall survival independently of treatment type and Circulating tumor DNA (CtDNA) mutational status.[6]

Nu.Q® H3K27Me3 correlated with progression-free survival and overall survival independently of treatment type and CtDNA mutational status.

The test also identified "long survivors" – a subset of palliative care patients who live many months longer than other palliative patients and so might benefit from being treated curatively. No other test is able to identify this subgroup.[6]

Nu.Q® Cancer was also able to identify patients who might benefit from immunotherapy.[6]

Monitoring disease

Studies indicate that Nu.Q® Cancer could also play a pivotal role in identifying minimal residual disease (MRD) – cancer cells that are left in the body after treatment and have the potential to cause relapse. This is normally done with imaging however, it is known to have some limitations – by the time an abnormality shows up on a scan, there are already more than three million cancer cells present.[7]

CtDNA analysis by Next Generation Sequencing (NGS) can detect MRD earlier, but it is expensive and may not be cost-effective for multiple use in the same patient. In addition, sensitivity is limited not only by low mutant allele frequency but also subject to variations in technique meaning residual cancer can be missed.

"Minimal residual disease (MRD) is missed in a significant number of patients, leading to delays in treatment or sub-optimal treatment selection. Nucleosomic quantification may be a simple – and much-needed – new method of MRD monitoring."

Dr Andrew Retter,

Chief Medical Officer,
Volition

A proof-of-concept study carried out at Hospices Civils de Lyon shows that Nu.Q® Cancer identified MRD that was not detected by NGS, increasing the diagnostic yield.[8] The study of blood samples from 600 individuals found that NSCLC patients had higher levels of Nu.Q® H3K27Me3 than healthy controls. Using Nu.Q® Cancer in combination with NGS revealed that 27% of CtDNA negative patients during treatment were Nu.Q® H3K27Me3 positive and had MRD.

Overall, Nu.Q® identifies an additional 15% of lung cancer patients who may have MRD. These patients could then be switched to more aggressive therapy to prevent relapse. No other marker is able to identify such patients.

The test may also be more sensitive than imaging and, therefore, could be used to monitor treatment response and recurrence. Research into this is under way at Europe's largest cancer centre, Gustave Roussy, France.

Excitingly, the relatively low cost of Nu.Q® Cancer would allow patients to be tested more often than with NGS, which may help improve outcomes.

Used with CtDNA analysis, Nu.Q® Cancer could enhance the detection of minimal residual disease, allowing patients to be changed to a new line of treatment sooner.

Conclusions and next steps

It is clear that no matter where a patient is on their clinical course, Nu.Q® Cancer may help. Simple, reliable and low-cost, the test requires a small amount of blood and can be done on equipment found in most hospital labs in approximately 45 minutes. Several large studies are now under way to confirm that Nu.Q® Cancer adds value to the existing techniques used in lung cancer screening, treatment selection and disease monitoring.

These include:

- A 500-patient prospective validation study at the National Taiwan University Hospital and National Taiwan University Hospital Cancer Centre. Due for completion in 2025, it could lead to the test being included in Taiwan's national screening program for lung cancer.
- A 1050-patient retrospective study of treatment-naïve NSCLC associated with NGS Hospices Civils de Lyon.
- ULYSEES Map - a prospective study of 100 patients at Hospices Civils de Lyon exploring the use of tests in assisting treatment selection and disease monitoring.
- REVEAL - a study involving about 2,000 patients, which is being financed by the French government and conducted at the biggest cancer centre in Europe, Gustave Roussy. The study, which has retrospective and prospective arms, focuses on treatment selection and MRD detection.

The results of these and other studies could lead to our ground-breaking nucleosome quantification test being used routinely in lung cancer screening, treatment selection and disease monitoring, improving survival and giving patients a brighter tomorrow.

"The data included in this report demonstrates a compelling case for the use of Nu.Q® Cancer at multiple points in the patient journey. From screening and aiding treatment selection, to monitoring patients during and after treatment, using Nu.Q® Cancer alongside existing methods such as Low Dose Computed Tomography and/or Next Generation Sequencing (NGS) could significantly improve survival from this deadly disease."

Dr Andrew Retter,

Chief Medical Officer,
Volition

References

1. Cancer. Accessed March 3, 2025. https://www.who.int/news-room/fact-sheets/detail/cancer
2. Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. New England Journal of Medicine. 2011;365(5):395-409. https://www.nejm.org/doi/full/10.1056/NEJMoa1102873
3. Poon C, Wilsdon T, Sarwar I, et al. Why is the screening rate in lung cancer still low? A seven-country analysis of the factors affecting adoption. Front Public Health. 2023;11. https://doi.org/10.3389/fpubh.2023.1264342
4. Pinsky PF. Assessing the benefits and harms of low-dose computed tomography screening for lung cancer. Lung Cancer Manag. 2014;3(6):491-498. https://doi.org/10.2217/LMT.14.41
5. Chen, P.-H. et al. Accurate Diagnosis of High-Risk Pulmonary Nodules Using a Non-Invasive Epigenetic Biomarker Test. Cancers 2025, 17, 916. https://doi.org/10.3390/cancers17060916
6. ELCC 2024 Baseline values of circulating nucleosomes in Lung Cancer: NUCLEO-LUNG study. Accessed March 3, 2025. https://volition.com/elcc-2024-baseline-values-of-circulating-nucleosomes-in-lung-cancer/
7. Narod SA. Countercurrents series; Disappearing breast cancers. Curr Oncol. 2012 Apr;19(2):59-60. https://doi.org/10.3747/co.19.1037
8. Grolleau E, Candiracci J, Lescuyer G, et al. Circulating H3K27 Methylated Nucleosome Plasma Concentration: Synergistic Information with Circulating Tumor DNA Molecular Profiling. Biomolecules. 2023;13(8):1255. https://doi.org/10.3390/biom13081255

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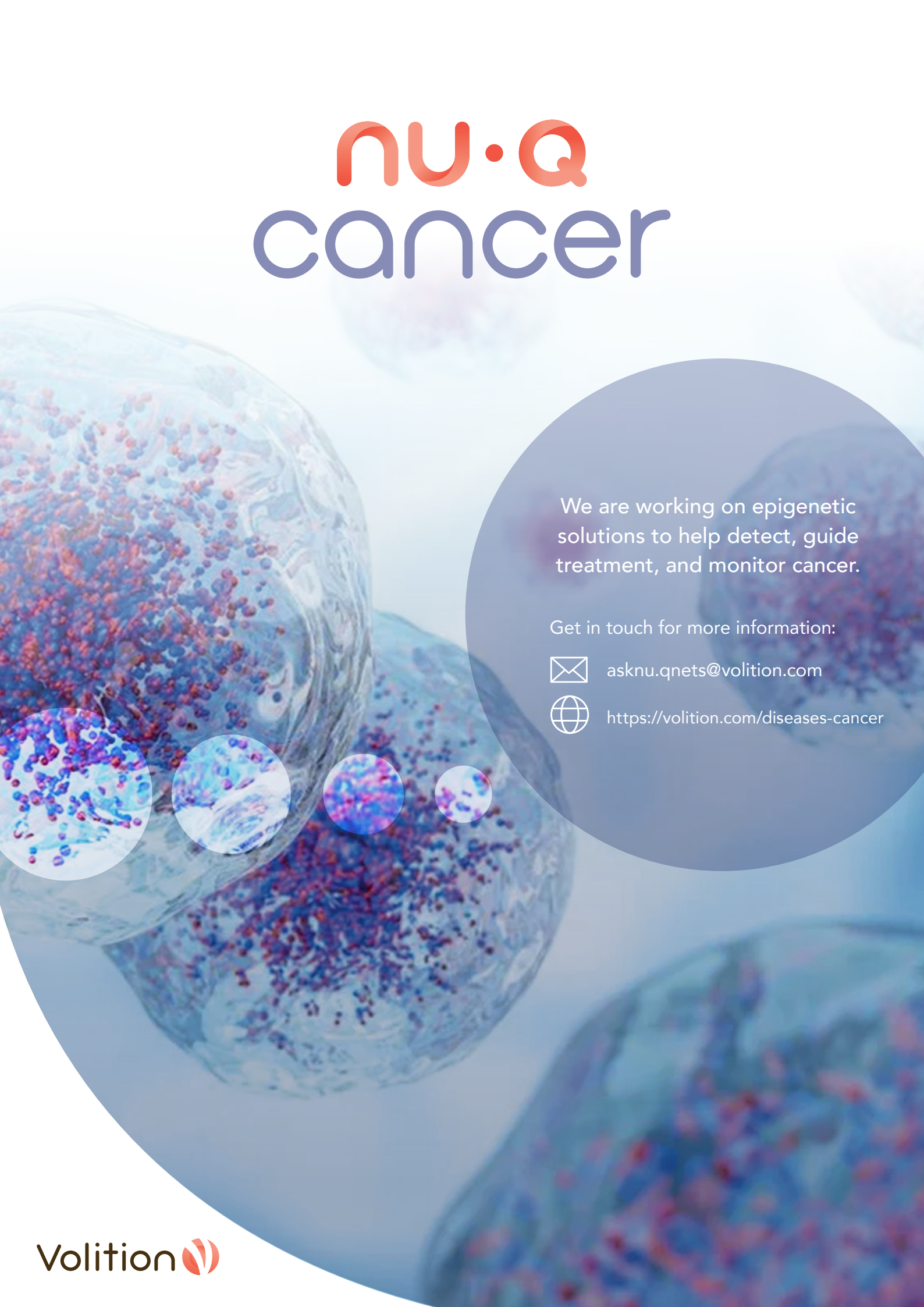

We are working on epigenetic solutions to help detect, guide treatment, and monitor cancer.

Get in touch for more information:

asknu.qnets@volition.com

https://volition.com/diseases-cancer

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