Volition

NYSE:VNRX

A Look to the Future of Cancer Diagnostics

April 2025

Forward Looking Statements and Disclaimer

Statements in this document may be “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. Words such as “expects,” “anticipates,” “intends,” “plans,” “aims,” “targets,” “believes,” “seeks,” “estimates,” “optimizing,” “potential,” “goal,” “suggests,” “could,” “would,” “should,” “may,” “will” and similar expressions identify forward-looking statements. These forward-looking statements relate to, among other topics, Volition's expectations related to the size of the market opportunity, the timing of product launches, the timing and success of clinical studies, the timing, completion, success and delivery of data from such studies, the timing of publications, the effectiveness and availability of Volition’s blood-based diagnostic, prognostic and disease monitoring tests, Volition’s ability to develop and successfully commercialize such test platforms for early detection of cancer and other diseases as well as serving as a diagnostic, prognostic or disease monitoring tool for such diseases, and Volition's success in securing licensing and/or distribution agreements with third parties for its products.Volition’s actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties, including, without limitation, results of studies testing the efficacy of its tests. For instance, if Volition fails to develop and commercialize diagnostic or prognostic products, it may be unable to execute its plan of operations. Other risks and uncertainties include Volition’s failure to obtain necessary regulatory clearances or approvals to distribute and market future products; a failure by the marketplace to accept the products in Volition’s development pipeline or any other diagnostic or prognostic products Volition might develop; Volition’s failure to secure adequate intellectual property protection; Volition will face fierce competition and Volition’s intended products may become obsolete due to the highly competitive nature of the diagnostics market and its rapid technological change; downturns in domestic and foreign economies; and other risks identified in Volition’s most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that Volition files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about Volition’s business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Forward-looking statements are made as of the date of this release, and, except as required by law, Volition does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

Speakers

Mr. Gael Forterre

MBA

Chief Commercial Officer

Dr. Andrew Retter

MBBS, MRCP, FRCPath (Haem), DICM, FFICM

Clinical Lead in Critical Care Medicine, ECMO and Thrombosis

Chief Medical Officer at VolitionRx, UK

Jake Micallef

PhD, MBA

Chief Scientific Officer

Investment Highlights

Vet Commercial Progress

- Nu.Q® Vet Cancer test now available in over 20 countries
- Sold ~120,000 tests and test components 2024
- Received $23 million in upfront and milestone payments to-date
  - Additional $5 million milestone payment (feline) anticipated 2025
  - Simple, low cost, recurring revenue generating tests performed on standard lab equipment
- **Multiple international partnerships launching**

Expansion into Human Diagnostics

- Same business model as Nu.Q® Vet; low capex/low opex, leveraging global base of established diagnostic and liquid biopsy companies
- **Clinical Partnering: multiple near-term licensing opportunities progressing**
- **Direct and Indirect sales of CE marked product(s) in Europe as hospitals evaluate for routine clinical use**

Large Unmet Needs

- **Lung Cancer** – screening, prognostics and MRD represent a $4B opportunity
- **MCED** - $20B opportunity of liquid biopsy market
- **Sepsis** – testing and monitoring ICU patients alone is a ~$1B+ opportunity
- **Other addressable markets** include Acute Kidney Injury (AKI), Acute Respiratory Distress Syndrome (ARDS) and use in the Emergency Department **>$10B** opportunity

Strong IP as of Feb 26, 2025

- 75 patents granted
- 128 pending internationally
- Patent coverage up to 2044

Derisked R&D and Commercial Strategy: Reported First $1+ million Revenue 2024

What sets us apart?

- **Our tests are *simple, low-cost* <u>*accessible*</u> routine blood tests**
  - Platform agnostic, can be adapted to any diagnostic workflow
    - Manual, Reference Lab, Specialist Lab and Point of Care

Six Hours

45 minutes

<10 minutes

<15 minutes

- **Our expanding *Intellectual Property* portfolio**
  - 75 patents granted, 128 pending, across 55 patent families[1]

1. IP as of February 26, 2025

Go-to-Market Strategy

Strategy implemented

- **Extensive product R&D conducted** by Volition and its research partners
- **Direct** and **Indirect sales** of CE Marked product(s) Europe as Centers of Excellence hospitals evaluate for routine clinical use
- **Monetize broad IP** through commercial contracts with upfront, milestone payments, royalties and sales of key components

Proven Commercial Model with Nu.Q® Vet

- Published canine clinical evidence in peer reviewed journals
- Launched early access program via Texas A&M GI lab
- Licensed the Vet product via a range of agreements, where partner does all lab, blood and sales work (global, regional and national with

Antech, IDEXX, FUJIFILM, NationWide Laboratories, VPG, vetlab, Vita Genomics

Go to Market Strategy - HUMAN

- **Drive adoption** in the EU working with KOLs and hospital networks for wide-ranging utility. Early revenue (pre-US FDA) clinical use in Europe.
- **Sign licensing deals** with partners to launch our Nu.Q® assays
  - On existing widely adopted current platforms,
  - Leveraging their sales teams, regulatory work and labs.

- **Gain adoption** in National Lung Cancer Screening Programs
- **Collaborate** with other liquid biopsy companies to incorporate our technologies to improve their performance
  - Nu.Q® and Capture™

Clinical Evidence

Dr. Andrew Retter

~1 in 6 deaths worldwide are caused by cancer

Almost **20 million NEW** diagnoses pa

~10 million deaths

1 in 5 people will develop cancer in their lifteime

Lung cancer is the **leading cause of cancer-related deaths...**

1.8 million deaths per annum (18.7% of all cancer-related deaths)

Lung cancer is typically diagnosed **at a late stage**…as yet a robust screening method for diagnosis is **not** available in routine practice.[1]

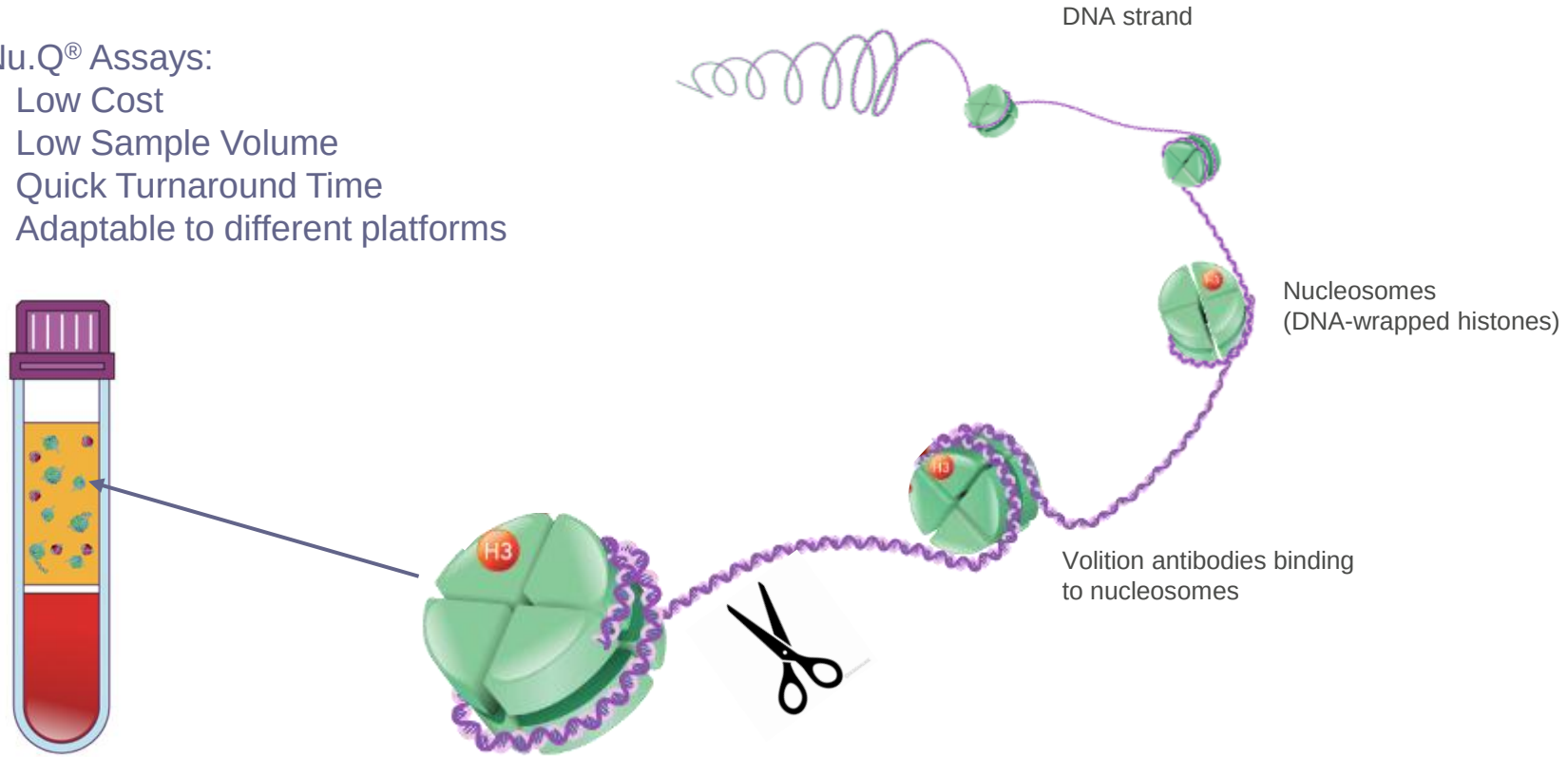
Statistics: https://gco.iarc.fr/en

1.Cassim, S., *et al. BMC Cancer*, 2019 https://doi.org/10.1186/s12885-018-5169-9

Nucleosomes and histones – altered in cancer and present in plasma

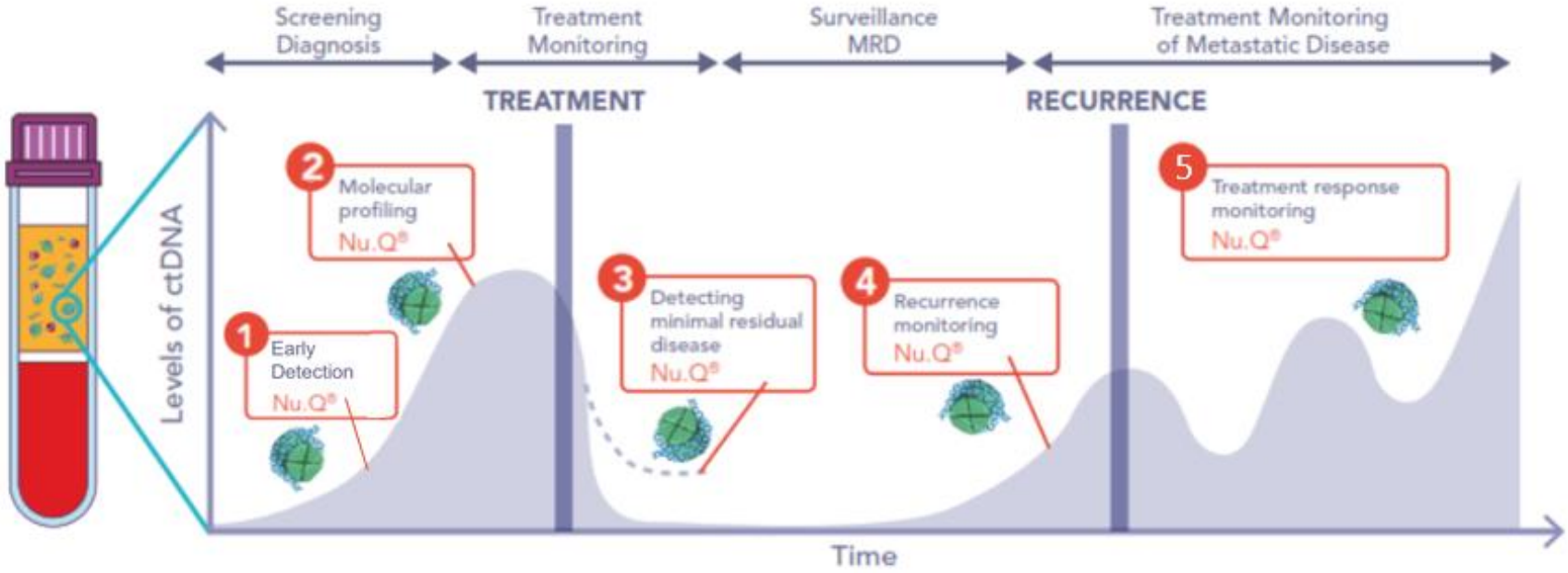
Nu.Q® Assays:

- Low Cost
- Low Sample Volume
- Quick Turnaround Time
- Adaptable to different platforms



Potential applications of a blood test in lung cancer: Nu.Q® addresses all five

nu·Q cancer
Lung



Peng Y, Mei W, Ma K and Zeng C (2021) Circulating Tumor DNA and Minimal Residual Disease (MRD) in Solid Tumors: Current Horizons and Future Perspectives. Front. Oncol. 11:763790. doi: 10.3389/fonc.2021.763790

Unmet needs in lung cancer disease management

nu·Q cancer Lung

- **Low-dose computed tomography (LDCT) recommended for screening BUT it often results in false-positives leading to further tests or unnecessary biopsies**
- **Cancer patient follow-up generally performed by imaging techniques**
  - However, limited sensitivity for MRD can lead to late detection of recurrence (>5 million Cancer cells in a 3mm metastases)
  - CfDNA analysis by NGS is expensive and sensitivity is limited by low mutant allele frequency

Grolleau et al, Biomolecules, Aug 2023, https://doi.org/10.3390/biom13081255

Unmet needs in lung cancer disease management

nu·Q cancer Lung

Oncologists need a reliable, simple, reproducible, fast, cost-effective test to:

- Help improve specificity for lung cancer screening
- Help provide tailored treatment
- Help detect disease recurrence early
- Help assess response to treatment
- Help support continued treatment decisions

Grolleau et al, Biomolecules, Aug 2023, https://doi.org/10.3390/biom13081255

Study Overviews

- Range of studies from prospective and retrospective, blinded, longitudinal studies of lung cancer.

- Cohort sizes – ranging from 70 to 1000+ patients.
- Covering detection of lung cancer at diagnosis and during treatment

- KEY Outcome measures to demonstrate CLINICAL UTILITY (correlation with):
  - Sensitivity and specificity
  - Positive Predictive Value (PPV) – aiding rule-in/rule-out
  - Overall Survival (OS)
  - Minimal Residual Disease (MRD)
  - Recurrence Prediction

Study	Country	Cohort Size	Key Results	Status
NTU Lung	Taiwan	806 patients	• improve specificity of LDCT • avoid up to 50% of unnecessary biopsies	Published
NTU V	Taiwan	500 patients	• prospective study "Epigenetic Nucleosomes in Plasma for Pulmonary Nodule Differentiation"	Ongoing. Due Q4 25
OncoProLung	Lyon, France	64 patients	• identify a subset of patients who may benefit from immunotherapy • identify a subset of patients who can be cured instead of palliative care • predictive of Overall Survival and Progression Free Survival	**Completed**. Target Sub Q2 25
CircanBis	Lyon, France	1050 patients	• detecting tumor burden to complement the current ctDNA gold standard at diagnosis • when combined with ctDNA, H3K27Me3 levels improve the prognostic value for overall survival and could help inform treatment decisions.	**Completed**. Target submission Q2 2025
ULYSEE Map	Lyon, France	100 patients	• prospective study for Prognostication and MRD detection	Ongoing. Due Q4 25
NucleoCircan	Lyon, France	628 subjects 319 LC 309 Healthy	• identify additional 23% of patients that have MRD over ctDNA alone • Supports clinical decision to continue first line treatment (-ve MRD) or change treatment (+ve MRD)	Published
REVEAL	Paris, France	800 subjects	• retrospective study for treatment selection and MRD detection	Analysis Q2 25
REVEAL	Paris, France	2000 subjects	• prospective study for treatment selection and MRD detection	Ongoing to 2026

Lung Cancer Package Summary

- Answer clear clinical question with direct impact on patient management
- No existing solution

Product #1 : Screening - H3.1/H3K27Me3 in combination with LDCT to

- improve specificity of LDCT
- **avoid up to 50% of unnecessary biopsies**

Product #2 : Prognostic value - Baseline Nu.Q® level as prognostic factor to

- Identify a subset of patients who may benefit from immunotherapy
- **Identify a subset of patients who can be cured instead of palliative care**

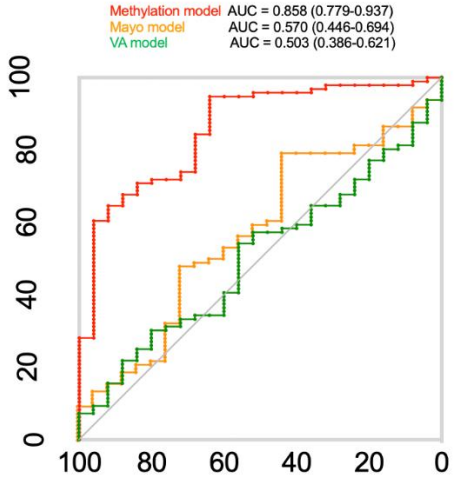
Product #3 : Recurrence detection - Nu.Q® level During Treatment to

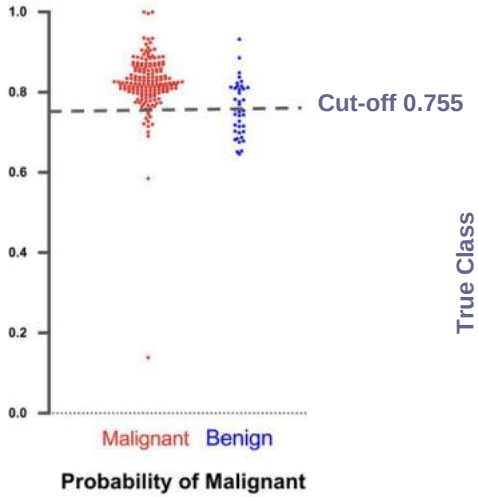
- **identify additional 25% of patients that have MRD over ctDNA alone.**
- Supports clinical decision to continue first line treatment (-ve MRD) or change treatment (+ve MRD)

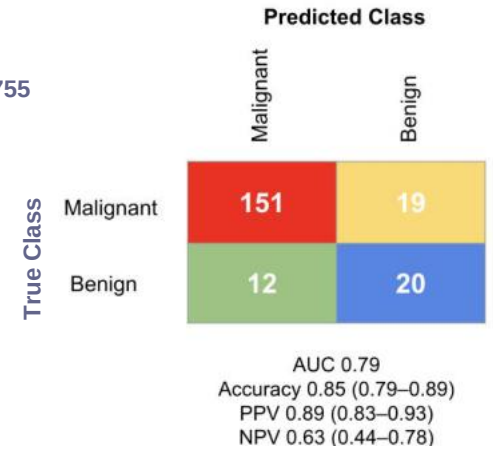
Product #1 : Accurate diagnosis of high-risk pulmonary nodules using a non-invasive epigenetic biomarker test

nu·Q cancer Lung

Epigenetic Model of Nu.Q® H3K27Me3 and Nu.Q® H3.1

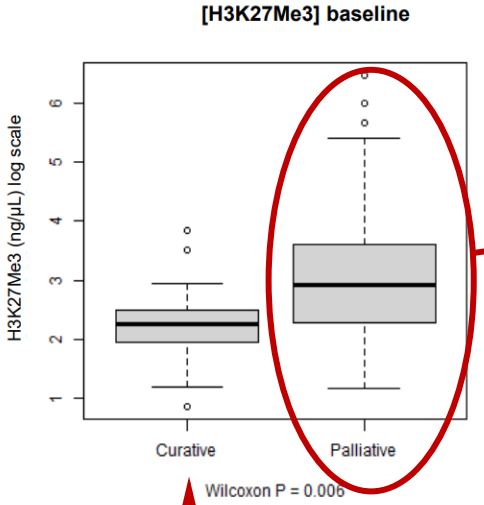




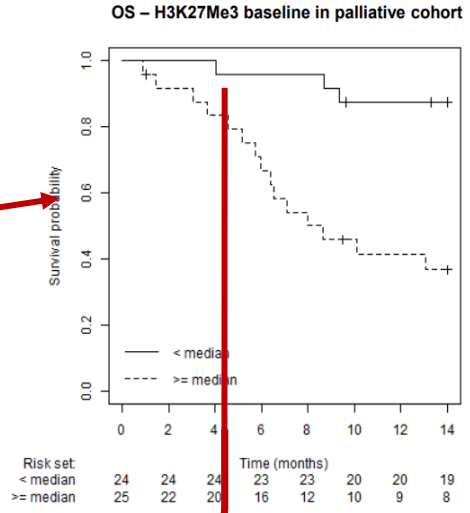


Pei-Hsing Chen et al, Paper published

Product #2 : Baseline values of plasma H3K27Me3 predict survival in NSCLC patients in palliative care



Plasma Nu.Q® H3K27Me3 at diagnosis in curative (n=19) and palliative (n=30) cohorts.



Survival analysis by plasma Nu.Q® H3K27Me3 at diagnosis

Key findings

Nu.Q® at diagnosis predicts survival among NSCLC patients selected for palliative care.

Identifies "long survivors" as a subset of patients who may benefit from curative care

No other marker

Next step: ULYSEEs study

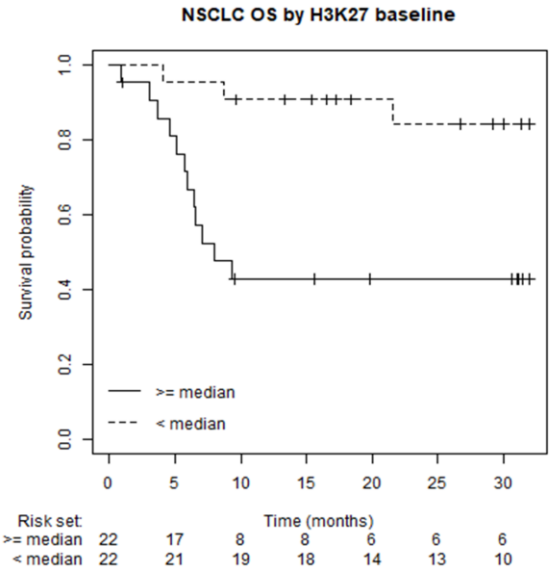
Fundings: AstraZeneca Volition CLARA

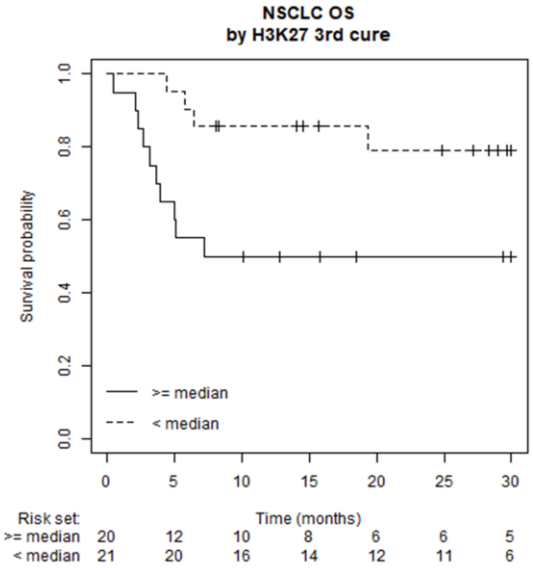
235P - Baseline values of circulating nucleosomes in Lung Cancer: NUCLEO-LUNG study
Manuscript in preparation

elcc European Lung Cancer Congress 2024

Product #2 :Prognostic value of plasma Nu.Q® H3K27Me3 during treatment of stage IV Non-Small Cell Lung Cancer

nu·Q cancer Lung





Key findings

- Nu.Q® is **predictive** of survival independently of treatment and mutational status
- Alerts on the risk of early progression
- Identifies a subset of patients who may benefit from immunotherapy
- No other marker

Study sponsored by:

Volition CLARA AstraZeneca

1333P - Prognostic value of circulating nucleosomes during treatment with or without immunotherapy in Non-Small Cell Lung Cancer: results from Nucleo-Lung study

Manuscript in preparation

BARCELONA 2024 ESMO congress

elcc 395P — European Lung Cancer Conference

H3K27Me3-nucleosome is a strong prognostic biomarker in Non-Small Cell Lung Cancer: interim results from the analysis of up to 832 patients at baseline

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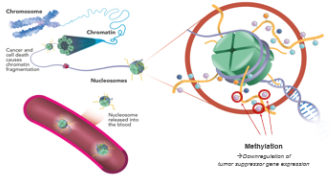
7. Hospices Civils de Lyon, Department of Acute Respiratory Disease and Thoracic Oncology, Lyon Nord Hospital, 69004, Lyon, France
8. Belgian Volition SRL, 22 Rue Phocas Lejeune, Parc Scientifique Créalys, 5032 Isnes, Belgium

CONTEXT

- Molecular profiling of somatic tissue and circulating tumor DNA (**ctDNA**) is critical for personalizing **lung cancer** treatment. Yet, all tumors do not harbor targetable mutations.
- Epigenetic modifications of nucleosomes play a crucial role in gene expression and are commonly dysregulated in tumors *(Scheme 1)*. **Aberrant levels of methylated nucleosomes in plasma** have already been reported in lung cancer *(Grolleau et al., 2023)*



Scheme 1: Methylated nucleosomes (DNA wound around histone proteins carrying methylation marks) are released by cancer cells in bloodstream after cell death and can be detected in patients' plasma (figure from Volition®).

OBJECTIVE:

To evaluate the **complementarity of ctDNA molecular profiling and H3K27Me3-nucleosome titers** in the prediction of NSCLC patients' outcome at diagnosis.

MATERIALS & METHODS

- Interim analysis relies on plasma samples from **832 patients with NSCLC (from cohort n=1050)** collected at diagnosis in the University Hospital of Lyon in between 2022-2024.
- **ctDNA molecular profiling by NGS** was performed using either PlasmaSeqSensei (4 genes, 0.2% sensitivity – Sysmex, Japan), a custom comprehensive panel (77 genes, 1% sensitivity – SOPHiA Genetics, Switzerland), or a custom targeted ultra-deep technique (33 genes, 0.2% sensitivity – SOPHiA Genetics, Switzerland).
- **H3K27Me3-nucleosome** titers were measured by the Nu.Q® immunoassay (Volition SRL, Belgium) on IDS i10 automated immunoanalyzer (Immunodiagnostic Systems Ltd, UK) .
- Statistical analyses were performed using R software (version 4.4.1). Associations with survival and relapse were quantified using Hazard Ratios (HR) using "survival" package.

RESULTS

❶ H3K27Me3-nucleosome titers are increased in ctDNA positive samples

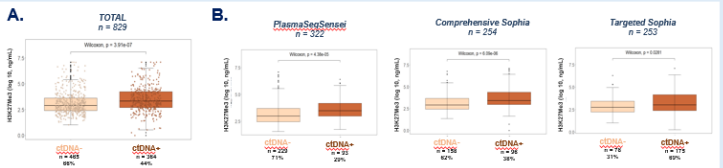


Figure 1
H3K27Me3-nucleosome titers at diagnosis according to molecular profile on ctDNA *(without mutation = ctDNA-, with mutation = ctDNA+)* (A) in the global cohort (median 18,2 vs 27,8 ng/mL) and (B) according to NGS techniques *(median PlasmaSeqSensei 19.8 vs 32.1, Comprehensive Sophia 18.2 vs 30.4 Targeted Sophia 15.6 vs 20.6ng/mL)*.

❷ H3K27Me3-nucleosome titers are increased in patients with low survival probability, independently of molecular profiling results on ctDNA

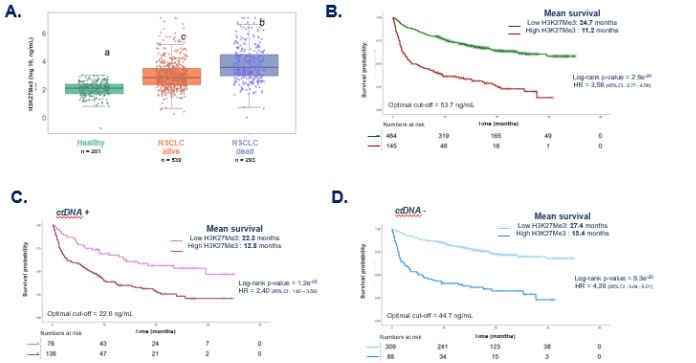


Figure 2
(A) H3K27Me3-nucleosome blood titers in cancer patients at diagnosis according to survival status (orange = alive, median 17.03 ng/mL vs blue = dead, median 35.49 ng/mL) compared to a healthy cohort (green, median 8.0 ng/mL). (B) Survival analysis according H3K27Me3-nucleosomes titers at diagnosis (optimal cut-off 53.7 ng/mL). (C) Overall survival according to H3K27Me3-nucleosomes titers in patients with at least one somatic mutation detected on ctDNA (ctDNA+, optimal cut-off = 22.6 ng/mL). (D) Overall survival of patients with negative molecular profiling (ctDNA-) according to H3K27Me3-nucleosomes titers (optimal cut-off = 44.7 ng/mL).

CONCLUSION

H3K27Me3-nucleosome is a **non-invasive biomarker,** that **complements ctDNA** and **predicts survival** regardless of mutation status

PERSPECTIVES

H3K27Me3-nucleosome titers at diagnosis could help inform treatment decisions and patients' monitoring thereby facilitating *personalized care.*

- Prognostic value of H3K27Me3-nucleosomes titers was assessed across different **cancer stages.**
- Evaluating the predictive value of H3K27Me3-nucleosomes titers for **treatment response** and disease progression may be valuable for patients undergoing treatment.

NEXT STEPS

- Survival analysis to be reviewed according to the **cut-off of 22,5 ng/mL** previously determined in Grolleau et al,2023.
- The H3K27Me3-nucleosomes titers according to the **type of somatic mutation detected on ctDNA** to be investigated.

Study sponsored by:

CONTACT: Lea.payen-gay@chu-lyon.fr

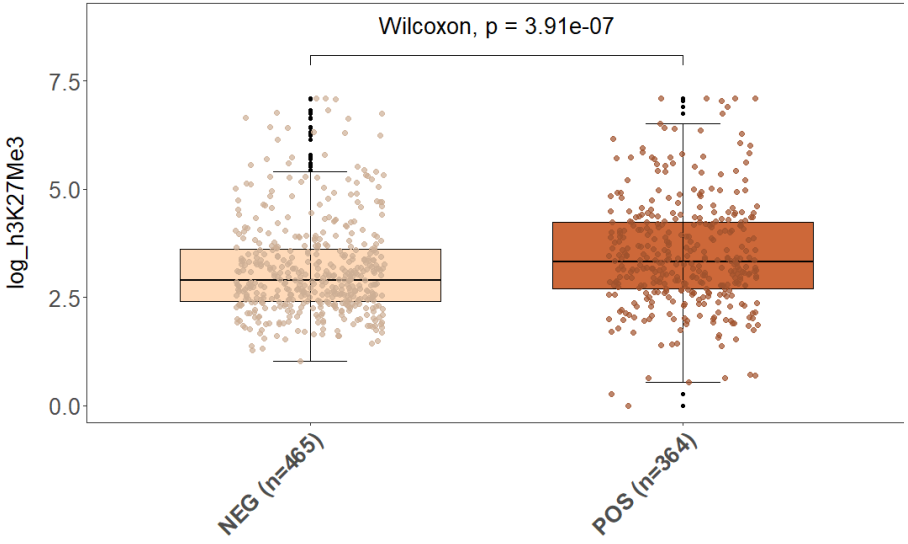
nu·Q cancer Lung

NEW Poster March 2025

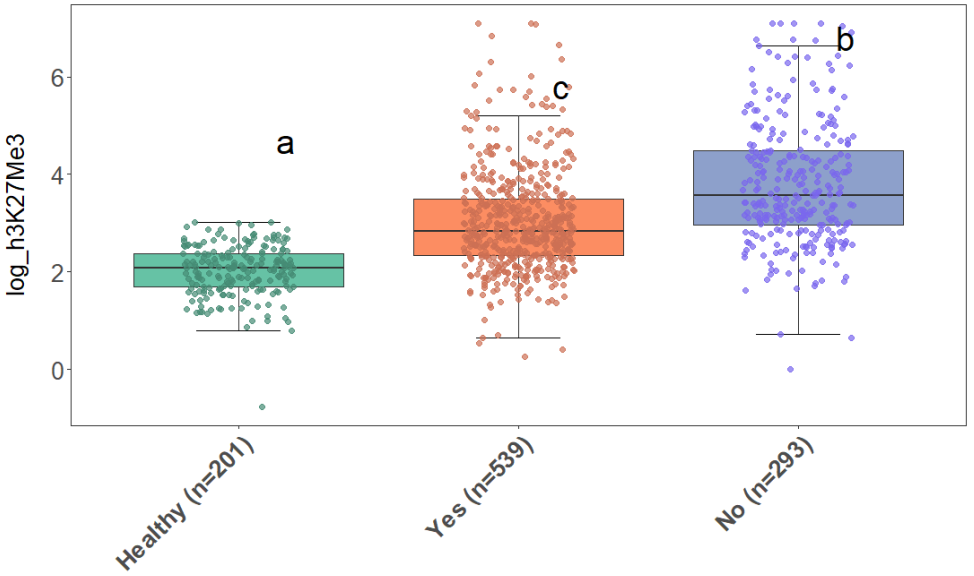
Interim analysis of CircanBis Cohort

nu·Q cancer Lung

H3K27Me3-nucleosome titers are increased in ctDNA positive samples



H3K27Me3-nucleosome titers are increased in patients with low survival probability



H3K27Me3-nucleosome is a strong prognostic biomarker in Non-Small Cell Lung Cancer: interim results from the analysis of up to 832 patients at baseline ELCC Poster 2025

Interim analysis of CircanBis Cohort

nu·Q cancer Lung

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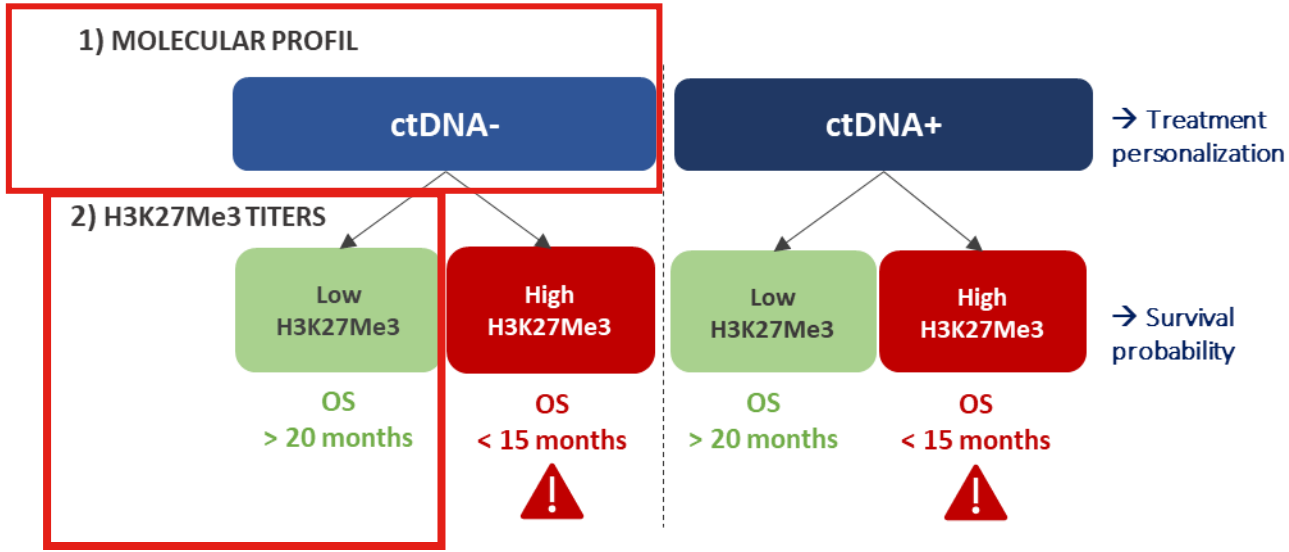

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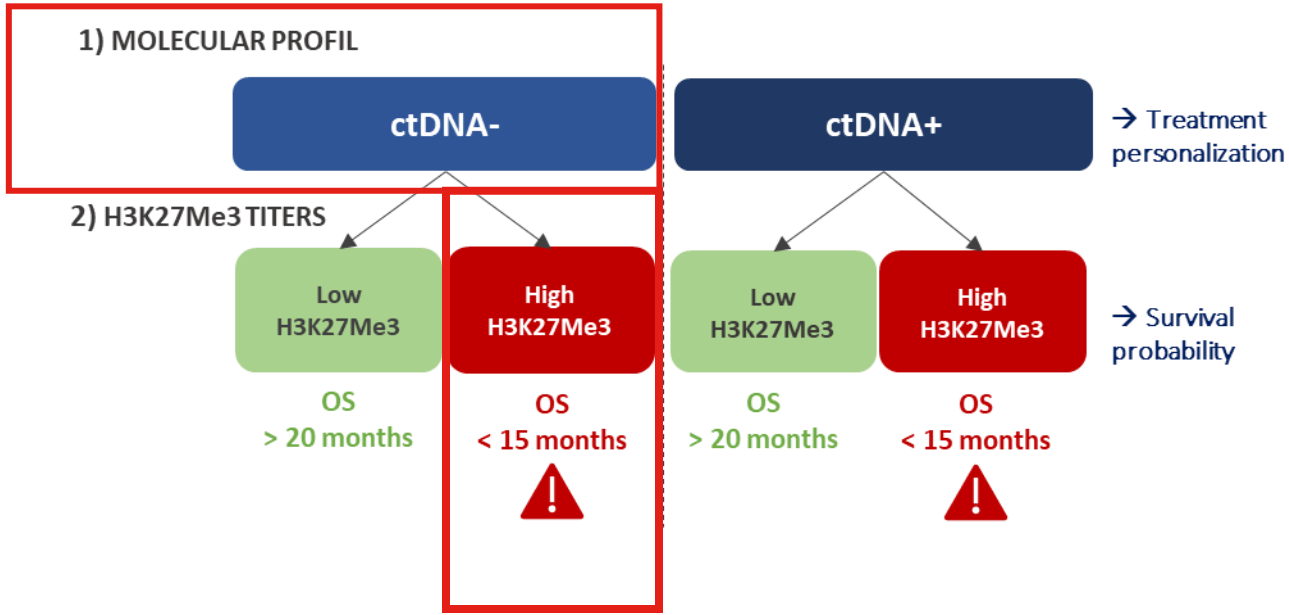

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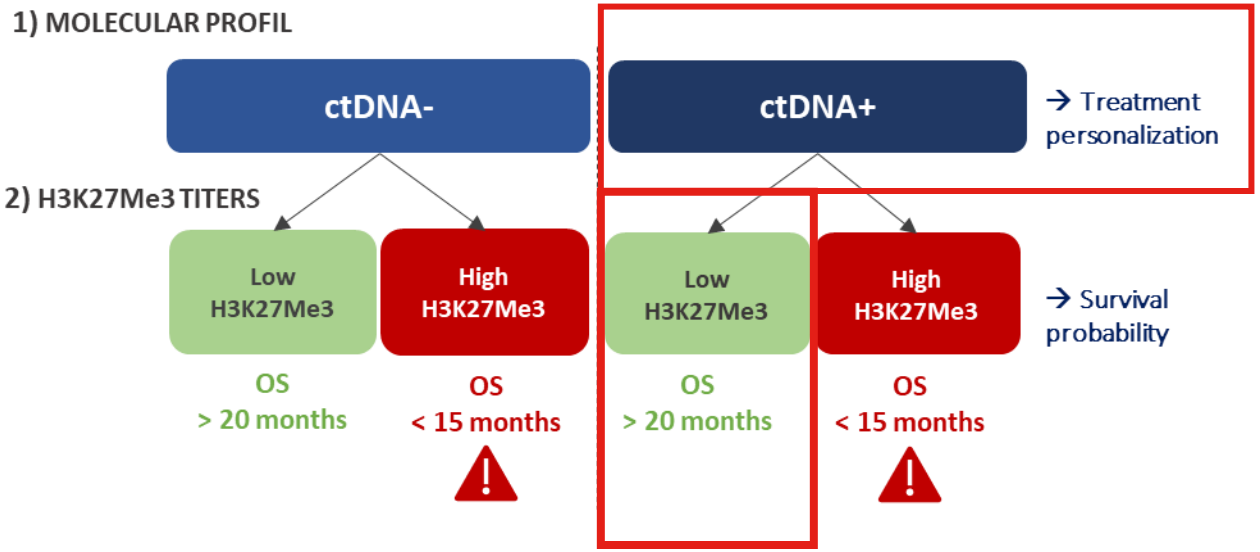

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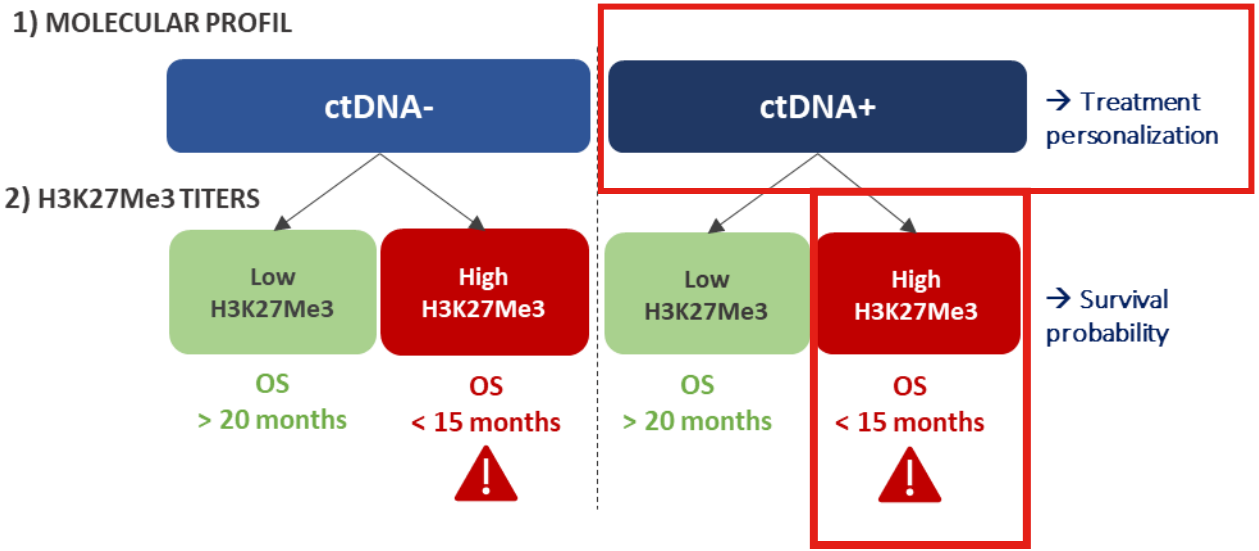
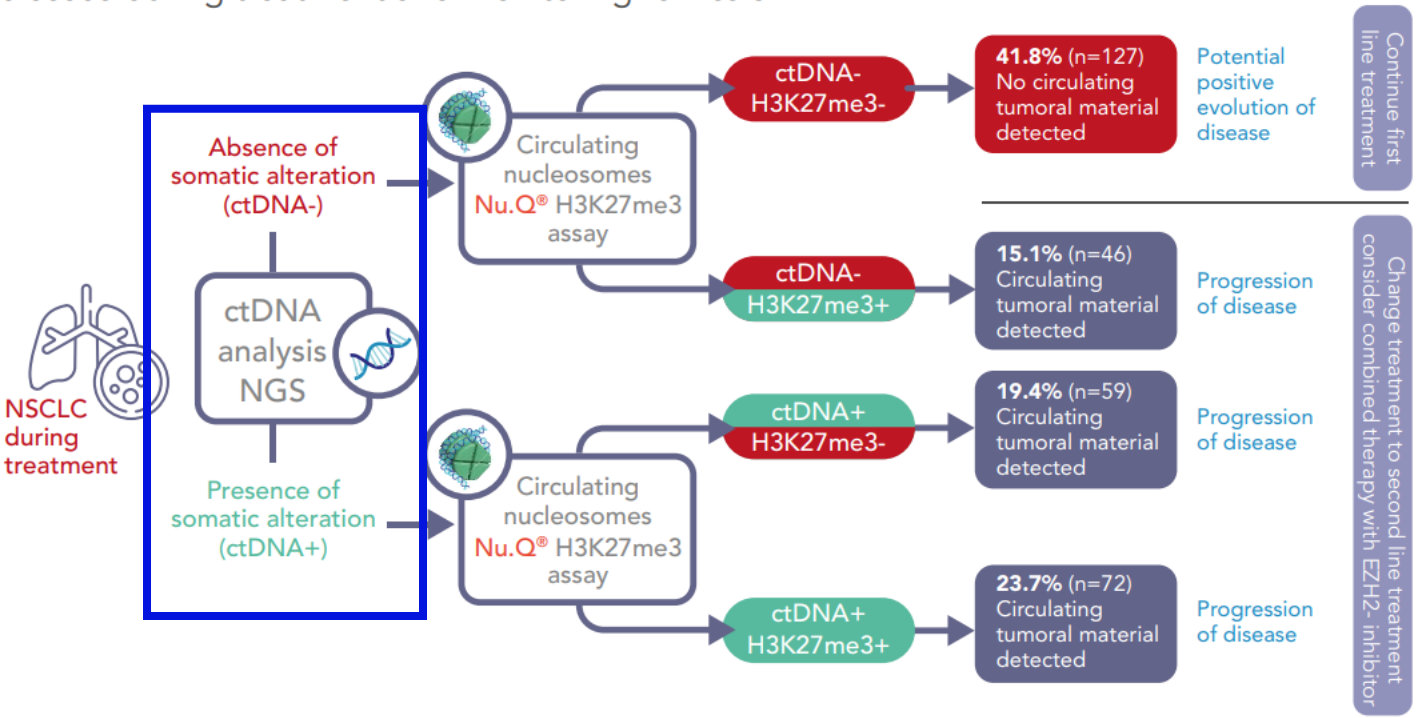


H3K27Me3-nucleosome is a strong prognostic biomarker in Non-Small Cell Lung Cancer: interim results from the analysis of up to 832 patients at baseline ELCC Poster 2025

Product #3 : Decision Tree

nu·Q cancer Lung

Improves accuracy of ctDNA molecular testing at diagnosis, detecting minimal residual disease during treatment and monitoring remission.



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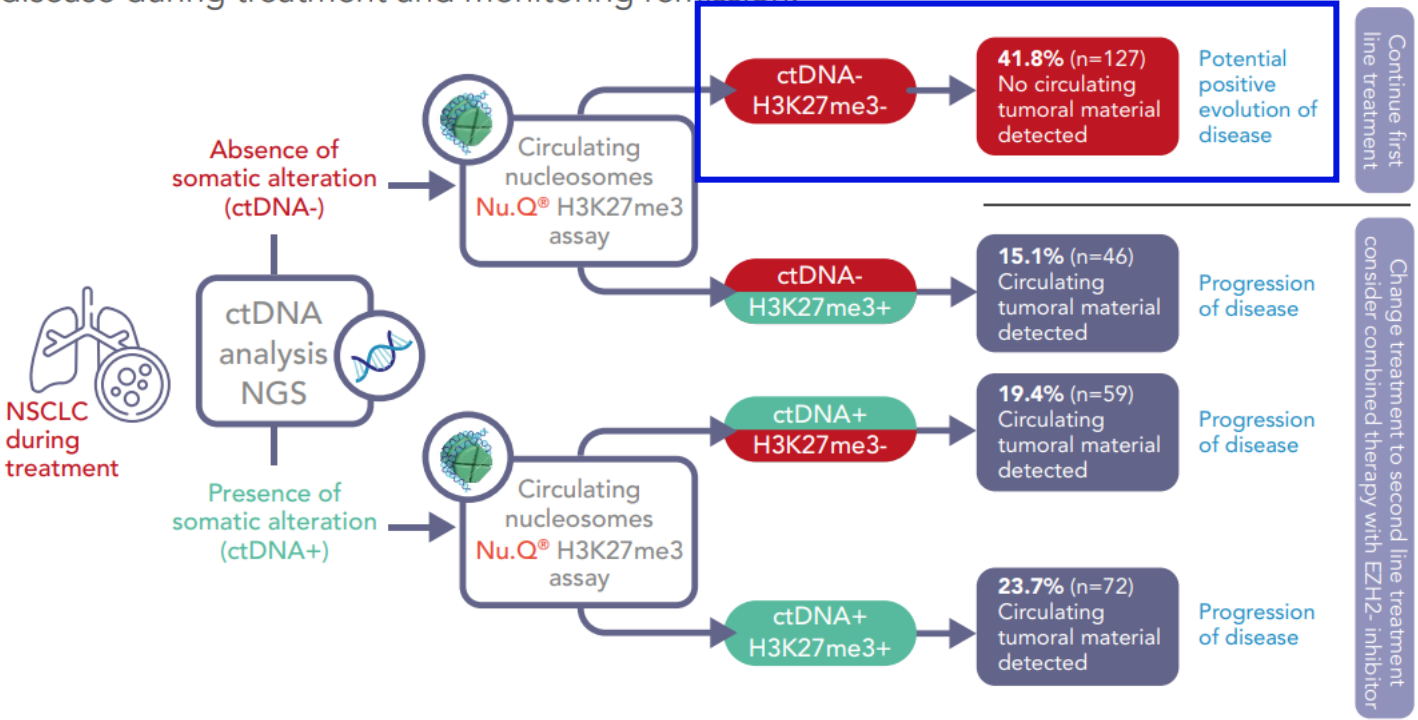

Grol... et al, Biomolecules, Aug 2020, https://doi.org/10.3390/biom10081208

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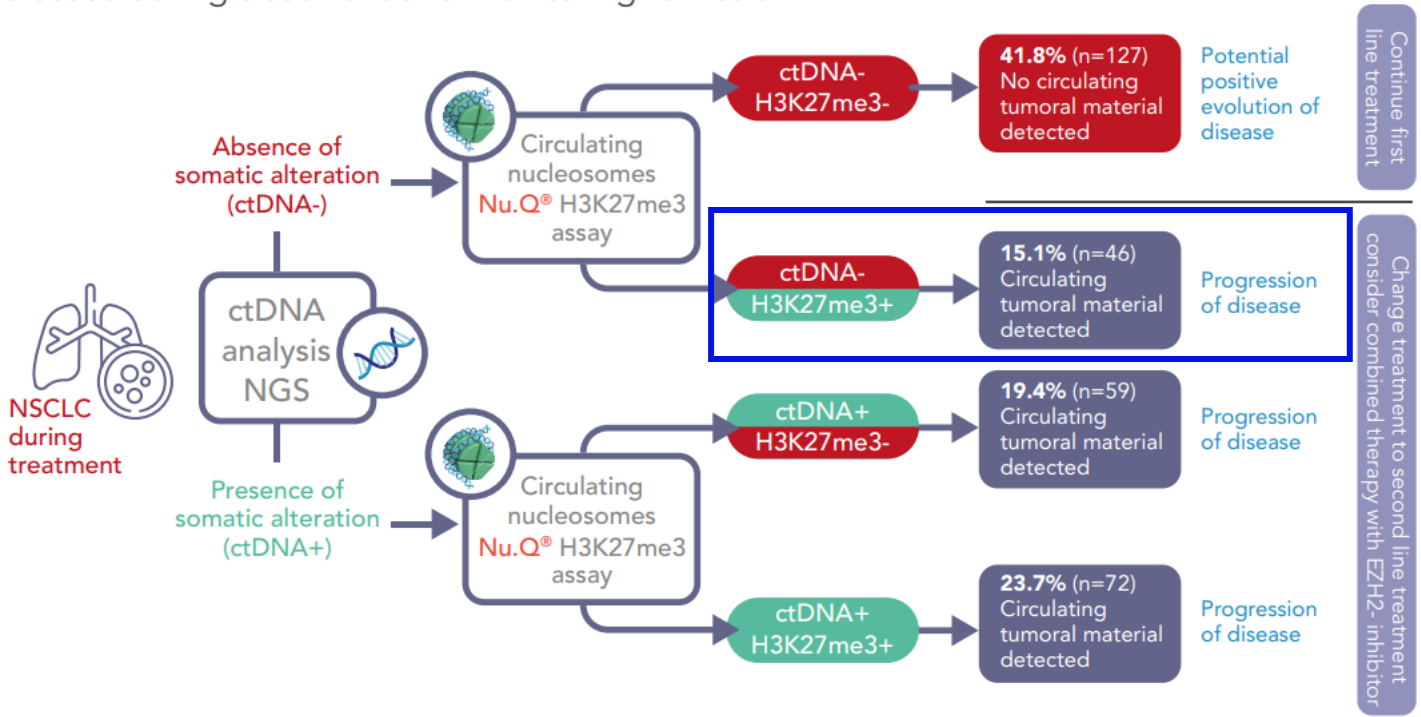

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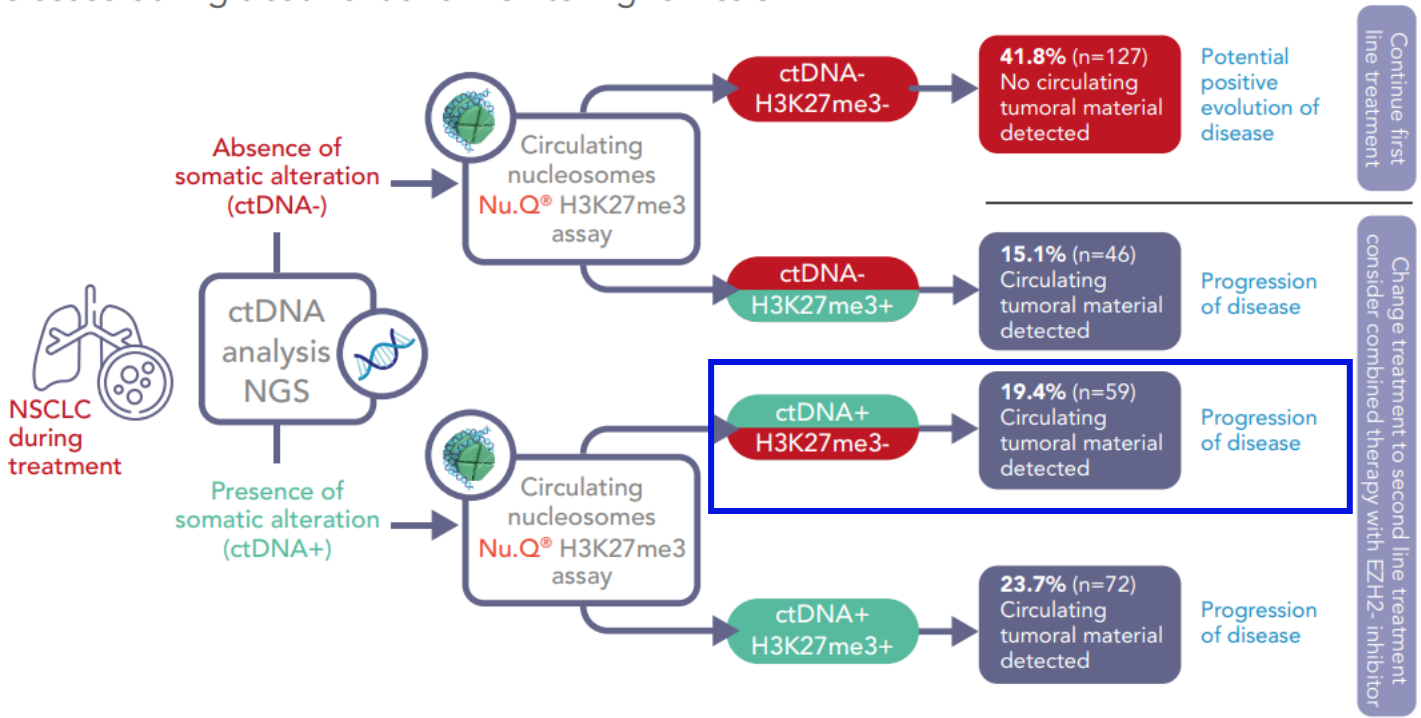
Improves accuracy of ctDNA molecular testing at diagnosis, detecting minimal residual disease during treatment and monitoring remission.



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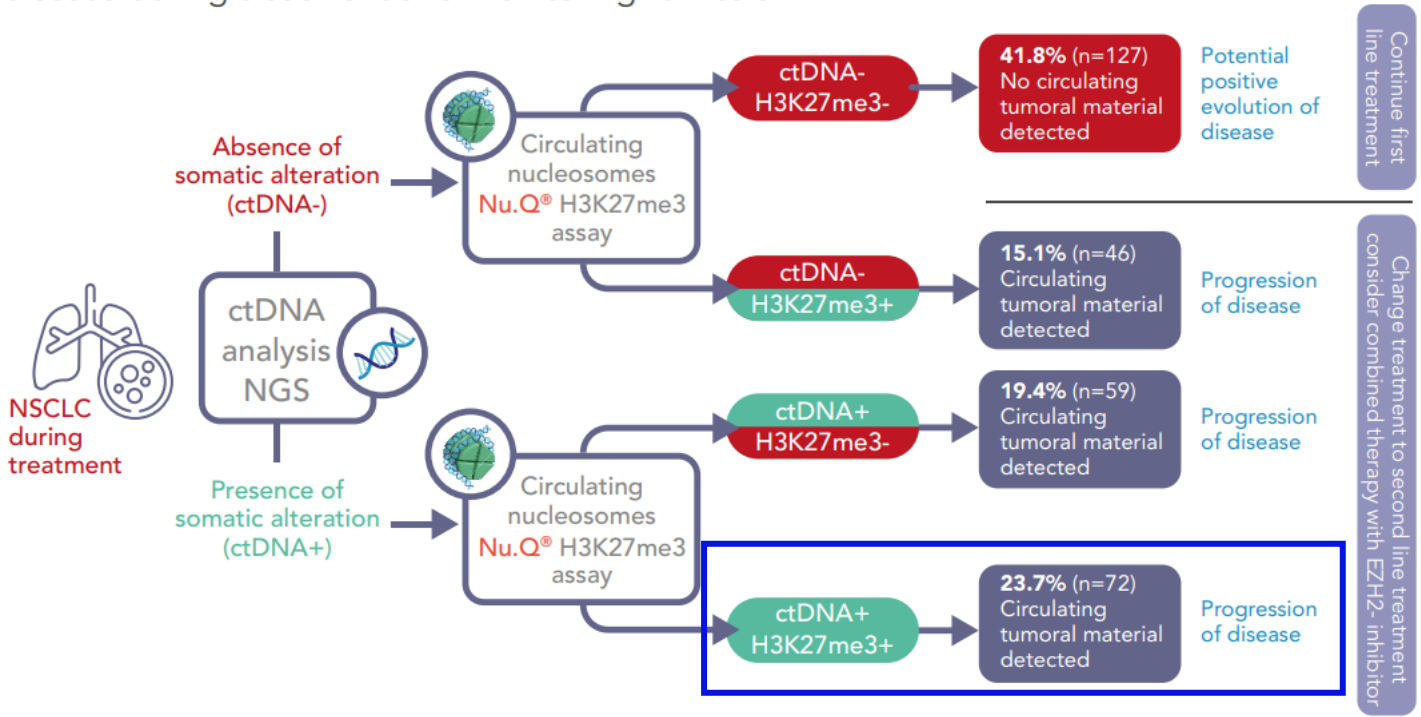

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Lung Cancer Package Summary

- In combination with LDCT

- In combination with NGS on tissue
- Prognostic Value at diagnostic

- Aid for treatment decision

- In combination with NGS liquid biopsy
- Treatment response monitoring
- Minimal Residual Disease

- HCL and APHP
- Project to start in 2025

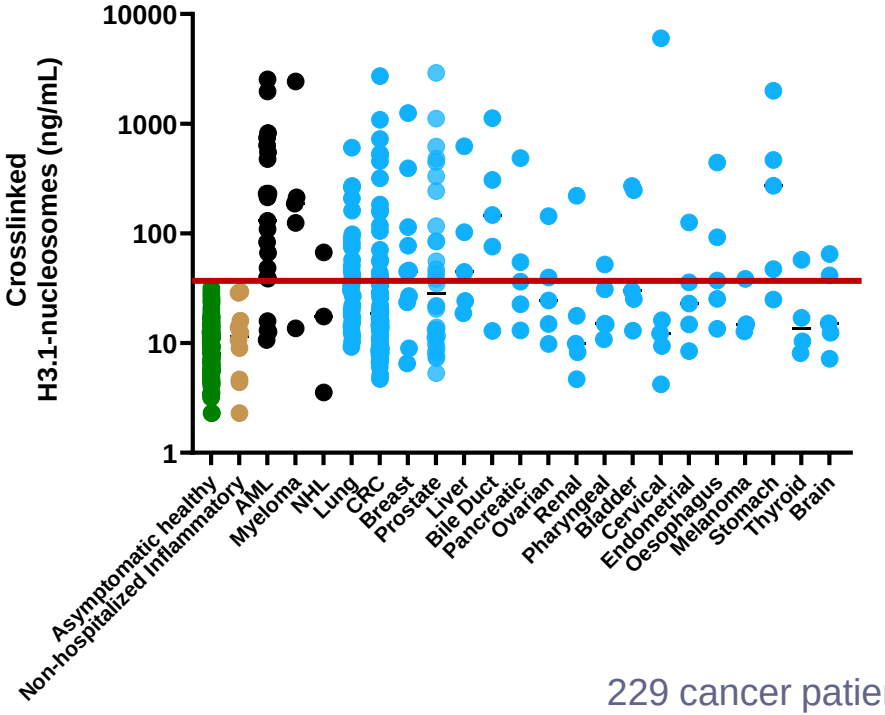
Study	Country	Cohort Size	Key Results	Status
NTU Lung	Taiwan	806 patients	• improve specificity of LDCT • avoid up to 50% of unnecessary biopsies	Published
NTU V	Taiwan	500 patients	• prospective study "Epigenetic Nucleosomes in Plasma for Pulmonary Nodule Differentiation"	Ongoing. Due Q4 25
OncoProLung	Lyon, France	64 patients	• identify a subset of patients who may benefit from immunotherapy • identify a subset of patients who can be cured instead of palliative care • predictive of Overall Survival and Progression Free Survival	**Completed**. Target Sub Q2 25
CircanBis	Lyon, France	1050 patients	• detecting tumor burden to complement the current ctDNA gold standard at diagnosis • when combined with ctDNA, H3K27Me3 levels improve the prognostic value for overall survival and could help inform treatment decisions.	**Completed**. Target submission Q2 2025
ULYSEE Map	Lyon, France	100 patients	• prospective study for Prognostication and MRD detection	Ongoing. Due Q4 25
NucleoCircan	Lyon, France	628 subjects 319 LC 309 Healthy	• identify additional 23% of patients that have MRD over ctDNA alone • Supports clinical decision to continue first line treatment (-ve MRD) or change treatment (+ve MRD)	Published
REVEAL	Paris, France	800 subjects	• retrospective study for treatment selection and MRD detection	Analysis Q2 25
REVEAL	Paris, France	2000 subjects	• prospective study for treatment selection and MRD detection	Ongoing to 2026

Continuous new technology development

Early-stage cancer detection with a simple, rapid, low-cost Nu.Q® immunoassay test

Dr. Jake Micallef

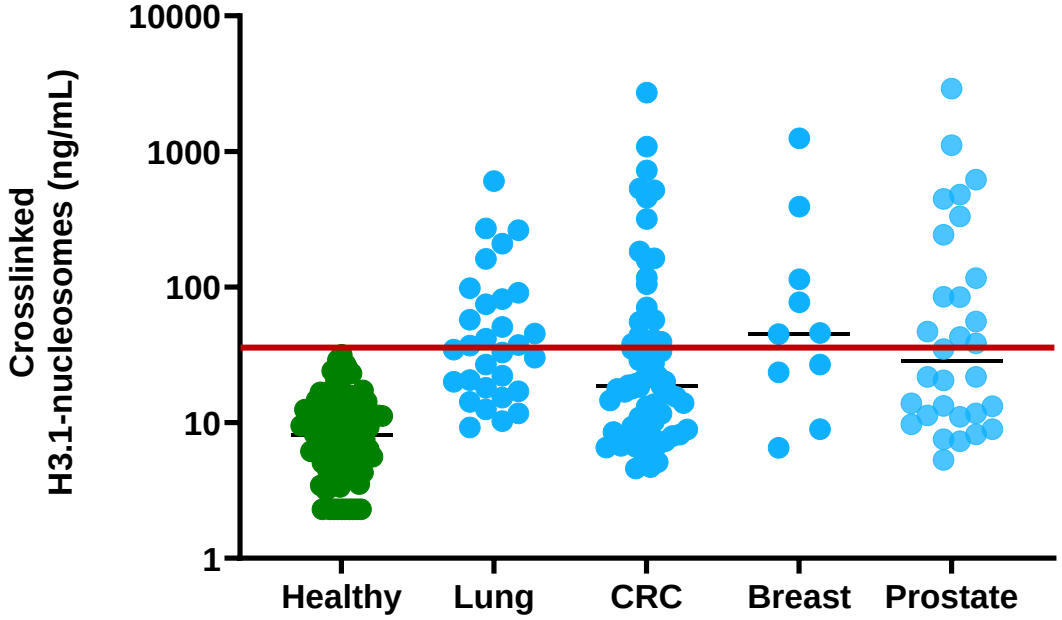
Nu.Q® assay for cross-linked plasma cf-nucleosomes



229 cancer patients at diagnosis (treatment naïve)
150 healthy volunteers
10 inflammatory patients (not hospitalized)

https://www.medrxiv.org/content/10.1101/2025.03.14.25323908v1

Nu.Q® assay for cross-linked plasma cf-nucleosomes



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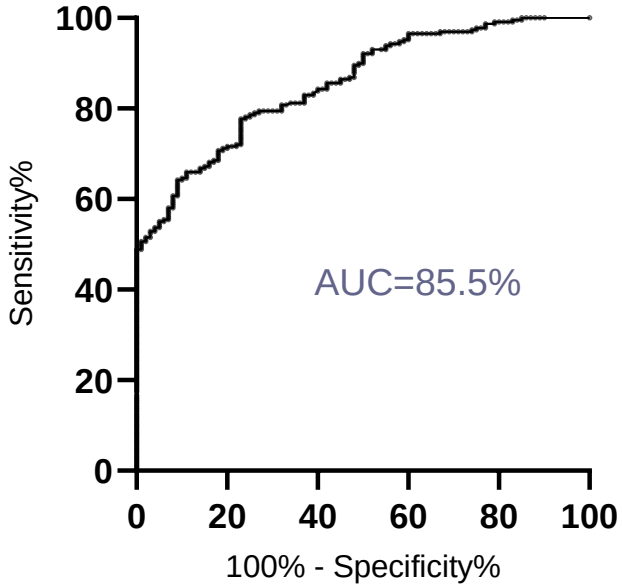

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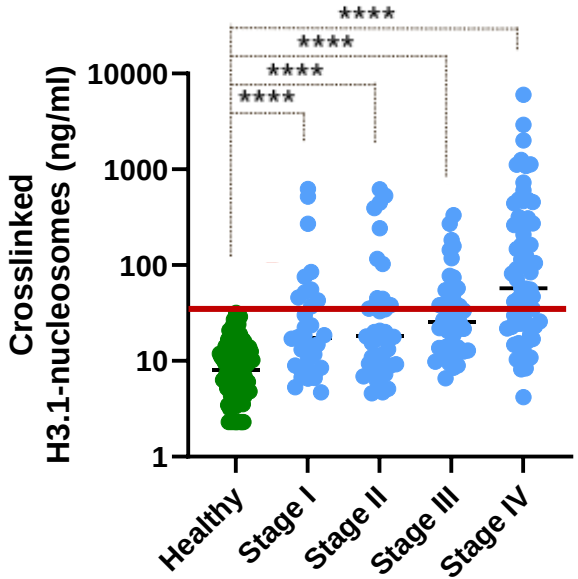
Early-stage detection



Stage	Lung	Liver and bile duct	Breast	Prostate	CRC	All solid cancers (n = 177)
I	29% (2/7)	100% (2/2)	33% (1/3)	50% (3/6)	10% (1/10)	34% (11/32)
II	38% (3/8)	100% (2/2)	50% (1/2)	63% (5/8)	12% (2/17)	39% (15/38)
III	67% (4/6)	0% (0/2)	50% (1/2)	29% (2/7)	38% (6/16)	42% (18/43)
IV	89% (8/9)	75% (3/4)	100% (3/3)	56% (5/9)	71% (12/17)	67% (43/64)

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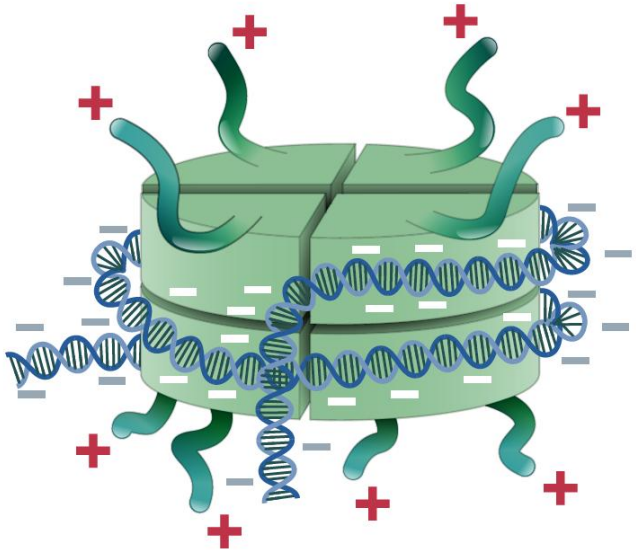

167 bp nucleosome

- Histone core charge **+58**
- Histone tail charge **+98**
- DNA charge **-334**

Net charge -178

Cell-free nucleosomes are unique plasma immunoassay analytes
It is common practice to cross-link nucleosomes for ChIP in cell extracts
Nucleosome immunoassay is essentially ChIP in plasma

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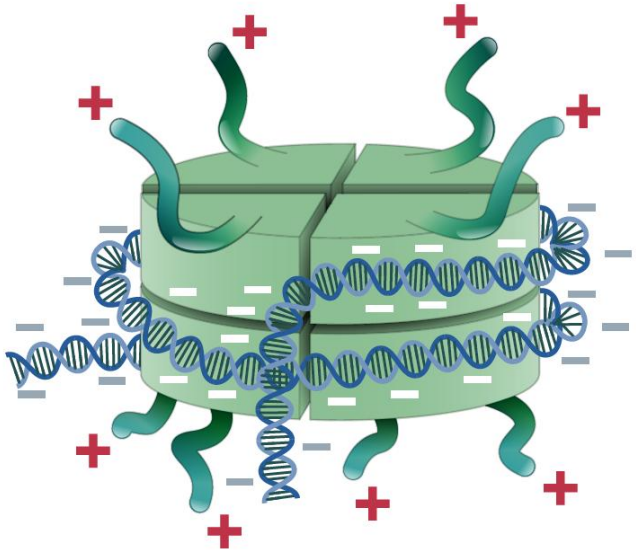

Damaged nucleosomes in samples from cancer patients are unstable and lost to assay – but stabilized by cross-linking.

Preservation of damaged nucleosomes leads to sensitive early stage I cancer detection.

New development distinguishes cancer and inflammatory derived nucleosomes

https://www.medrxiv.org/content/10.1101/2025.03.14.25323908v1

Patient centered diagnostics

EDTA plasma samples require rapid processing

Streck plasma samples can be taken in a screening truck, sent to lab for later processing by our rapid, low-cost test.

Nu.Q® assay for cross-linked plasma cf-nucleosomes

Automated ~45-minute test (same as PSA or CEA)

Available now as RUO assay (not FDA approved)

Some potential applications

- Low cost MCED worldwide
- Aid to diagnosis in conjunction with scanning
- Monitoring / Minimal Residual Disease

https://www.medrxiv.org/content/10.1101/2025.03.14.25323908v1

Also…

Summary

Licensing Portfolio: Platform stable, reproducible

Application	Proof of Concept	Viability study	Final Validation study	Licensed
Animal				
Canine Cancer Screening	→	→	→	✓ Launched
Canine Cancer Monitoring	→	→		✓
Feline Cancer	→			✓
Automated test	→	→		✓
Human			Regulatory/Adoption study	
Sepsis	→	→		Data room active
Cancer				Data room active
Lung Cancer Screening	→	→	→	
Minimal Residual Disease & Disease Management	→	→	→	
Multi-Cancer Early Detection	→	→		
Capture-PCR™/ Seq™	→			

Investment Summary: NYSE:VNRX

- Listed NYSE, commercial stage diagnostics company — developing **low-cost, early detection and treatment monitoring diagnostics** in human and animal health
  - Disease areas – global killers: Cancer, Sepsis; significant market opportunities, >$10's Billion
  - $23 million in vet milestone payments banked
  - Early 2025 revenue targeting:
- **Nu.Q® Vet (8 licensing deals already selling)**
- **Nu.Q® Discover**
- **Nu.Q® NETs / Nu.Q® Cancer direct/indirect sales of CE-Marked human clinical product(s) in Europe**

2025 Focus: closing large human licencing deals, in cancer and sepsis

Question & Answer Session

Lou Batchelor