Nucleai
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Artificial intelligence-powered spatial biology is transforming precision medicine

Nucleai's innovative biomarker platform analyzes and interprets pathology data in both research and clinical settings to enhance diagnostics and improve patient treatment outcomes.

While many areas of medicine and science have undergone digital and technological transformations, the field of pathology has yet to fully recognize this. The time for change is now. Using artificial intelligence (AI) and computer vision, Nucleai's spatial biology platform unlocks the data within pathology images, providing value to research and development (R&D) and clinical settings by finding better biomarkers, stratifying patients, and predicting outcomes. Applying computer vision to slides does more than just address the shortcomings of manual pathology; it also characterizes and determines the distribution of cells in a way that is impossible for humans to achieve.

Multiple organizations have recognized the power of AI-powered spatial biology. Merck KGaA and Debiopharm have formed deals to apply Nucleai's AI-powered biomarker platform to clinical-stage oncology assets, while Jefferson Health is exploring the technology as a treatment decision tool in a real-world clinical setting.

The deals point to the broad applicability of the platform, which could transform drug development and become a key diagnostic tool for hospitals. As Nucleai and its partners work to realize that potential, they will address fundamental limitations of pathology today and usher in a new era of data-driven biomarker discovery and patient stratification.

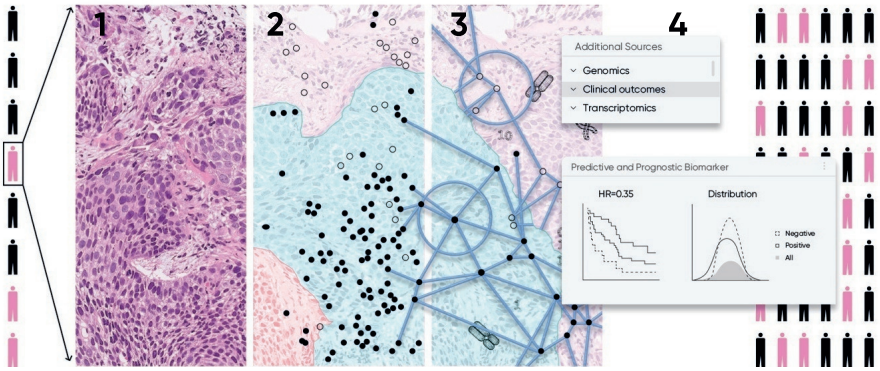

Fig. 1 | From image to insights. Nucleai's technology uses artificial intelligence-powered algorithms to analyze a standard pathology image (**1**), segment and quantify tumor areas and cell subtypes (**2**), and make advanced spatial calculations (**3**). The incorporation of multi-omics data (**4**) helps uncover novel predictive and prognostic biomarkers, maximize patient selection, and improve patient outcomes.

Realizing the power of spatial biology

Nucleai's platform is a response to multiple problems facing pathology. Image analysis is subjective, inconsistent, and highly variable—attributes that are a poor fit for R&D—because it relies on the consensus of pathologists who may interpret slides differently. There is a shortage of pathologists in many countries, emphasising the limited scalability of manual workflows and potentially slowing R&D.

Equally, the industry lacks an operating system for the next generation of spatial pathology data at scale. While biopharma companies have access to multiple tools, there is no comprehensive solution that has the data, algorithms, and models needed for quick, scalable use in research and clinical trials.

Hindered by limitations of pathology tools, the biopharma industry is yet to establish effective biomarkers for immuno-oncology (IO) and determine which patients are most likely to respond to a treatment. Incorrect or subjective analyses can lead to patients being enrolled in unsuitable studies, reducing the chances of success. The industry needs faster, more reliable ways of matching patients to clinical trials.

Nucleai is leading a spatial biology revolution that eliminates the current limitations. The company is structuring the tissue cell architecture with AI and computer vision technology to enable researchers to easily quantify cells and understand their spatial arrangement within the tumor microenvironment. Nucleai is equipped with a quantitative, reproducible way to generate biology data at scale and has built up a robust set of data partners across the healthcare ecosystem with proprietary access to pathology images and clinical data. The platform eliminates the pathologist-to-pathologist variability that slows down drug development today (Fig. 1).

The word 'pathology', as it is traditionally defined, understates the insights generated by the technology. The term 'visual next-generation sequencing (NGS)' is more representative of how the technology analyzes interactions and answers the difficult drug and biomarker development questions that the industry has been unable to resolve with genomics.

Equipped with the technology, researchers can adopt a scalable and reproducible approach to biomarker scoring, identify novel spatial signatures to improve response to therapy, and transform target discovery. The result? The identification of meaningful biomarkers, maximization of patient identification, acceleration of clinical trial timelines, and improved probability of success and patient outcomes.

Validating the technology

With Nucleai's technology poised to disrupt the way cancer research is conducted and IO therapies developed, validation on real world data sets is crucial. Nucleai has demonstrated the power and accuracy of its platform by performing response prediction on Merck's checkpoint inhibitor Keytruda (pembrolizumab) in non-small cell lung cancer (NSCLC). PDL1 expression is the only approved biomarker, but its ability to predict whether a patient will respond to Keytruda is limited.

In research presented at the 2021 American Society of Clinical Oncology (ASCO) annual meeting, Nucleai showed that the use of deep-learning models to extract details of the tumor microenvironment, specifically tumor infiltrating lymphocytes, from slide images may better predict response to therapy compared to manual pathology analysis. Nucleai correlated spatial features to clinical outcomes, and then used slides from another set of patients, at a different center, to validate the model.

Patients in the validation dataset received positive or negative scores based on their pathology slide analysis. Overall survival (OS) was significantly higher in patients with a positive score. Median OS and two-year OS were significantly higher in positive patients, suggesting the classifier can identify NSCLC patients who are more likely to have meaningful responses to Keytruda, regardless of PD-L1 score.

Nucleai's vision is that every pathology image generated in research and clinical settings will run through its platform, first to augment biomarker discovery throughout the R&D process and eventually as a fully approved companion diagnostic. Pushing the field of pathology forward with the power of AI puts Nucleai at the forefront of the spatial biology revolution.

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