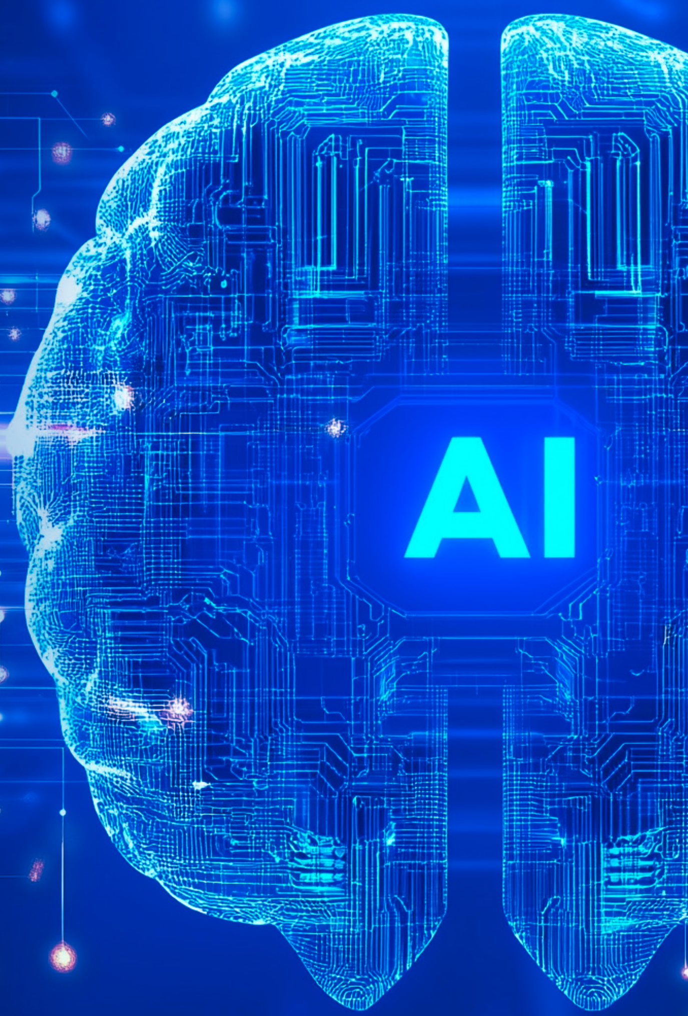
INFORMATICS

WHITE PAPER

AI-Enabled Digital Pathology

Using AI in precision oncology to enhance screening and streamline workflows.



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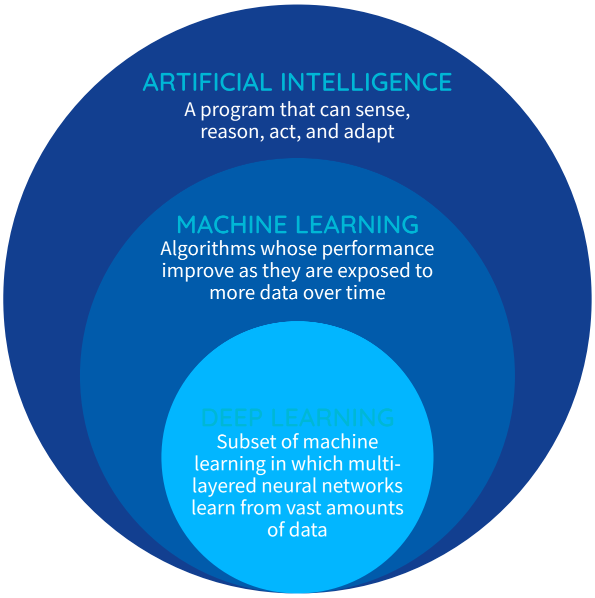
As we move deeper into the 21st century, the applications of Artificial Intelligence (AI) are becoming more practical and more widespread as technology evolves and investments increase. For many, 'Artificial Intelligence' evokes images of futuristic sci-fi films with robots and gadgets designed to replicate human functionality. However, millions of people now have AI at their fingertips with technologies like Siri,® Amazon Alexa, ChatGPT, and on-demand music streaming services. Applications such as these have become such an integrated part of everyday life, that many people don't even recognize that they are using AI.

What is AI?

Simply put, Artificial Intelligence (AI) uses computer systems and algorithms to mimic human behavior. Within this large umbrella term, Machine Learning is the most common type of AI that allows computers to use prior data to learn and improve performance over time. Deep Learning is a subset of Machine Learning that structures algorithms in layers to create an "artificial neural network" that can learn and make intelligent decisions on its own.

While AI largely made its foray into the consumer market over the last several years, applications to support business professionals are also growing. Companies like Microsoft, AWS, and Google are using AI platforms for features like intelligent search, smart response, and image recognition while other businesses are using AI solutions for productivity insights, personalized recommendations, and workflow automation.



Within the healthcare space, we have also seen tremendous interest in AI-enabled technologies, as evidenced by six-and-seven figure investments.

Some examples of this include:

1. Analyzing X-Rays and MRIs to speed diagnosis/turnaround time as well as identify abnormalities that may have been overlooked by physicians.
2. Sharing real-time data with providers via wearable technology that sends alerts and statistics directly from the patient to his/her care provider.
3. Supporting patients, answering questions, and scheduling appointments through use of virtual health assistants.

AI applications can empower healthcare professionals with tools that aim to transform how they interact with and leverage technology. Ultimately, the goal is to reduce subjectivity, improve efficiency and overall lead to better patient care and outcomes.

AI-enabled Precision Oncology

As cancer represents one of the leading causes of death across the globe and comes with a complex patient journey, it has become a prime target for AI-enabled solutions. There is no question that cancer testing today contains gaps and limitations. Diagnosis is dependent upon subjective review of tissue biopsies by a pathologist. Additionally, every test ordered requires the use of tissue and, as such, when minimal tissue is collected and sent for testing, the testing ordered may need to be limited or prioritized. A review of NeoGenomics data has shown that up to 20% of comprehensive solid tumor next-generation sequencing (NGS) could not be performed in 2023 due to specimen quantity or quality limitations. Furthermore, comprehensive testing is costly and can take weeks to obtain complete results. These factors often lead providers to make clinical decisions, or even initiate treatment, based on limited information.

Use Cases for AI in Oncology:

1. Automating and optimizing the pathologist workflow, with tools like automated cell counting, annotation, and scoring for specific biomarkers including ER, PR, and Ki67 in breast tumors.
2. Screening and prediction, with tools that can predict biomarker status, response to treatment, and overall outcomes.

AI companies have begun using deep learning algorithms to speed the identification of biomarkers in cancer testing. These algorithms use an image of a biopsy to determine biomarker status and presence of certain mutations associated with cancer. Understanding the status of these biomarkers can help aid physicians in diagnosis as well as predict whethera patient might respond to certain treatments.

Algorithms can often detect patterns in the biopsy image that cannot be seen by the human eye, or which can easily be overlooked. These patterns can help providers prioritize the use of biopsy tissue. This allows for more timely screening of broader patient populations, as well as triaging of cases that require confirmatory testing. Additionally, because these techniques use a biopsy image to perform screening, the tissue may be preserved and saved for other vital testing.

In addition to biomarker prediction, AI has the ability to support pathologists on cases with very subtle features that could potentially be a critical part of a diagnosis, or lead to a confident diagnosis. Consider a pathologist in a remote or rural area, or a smaller community hospital where they might not be able to share or review cases to confirm a borderline or difficult case. Given how subjective Pathology can be, and the challenges that complex cases present, many cases are reported as inconclusive and/or indeterminant. AI can help support a theory or hypothesis, or importantly, highlight features that may have been missed or overlooked. AI can also be incredibly helpful in providing advanced insights to help a pathologist make a call on rare cancers or identify tumors of unknown origin.

As the capabilities of AI become more robust, both digital pathology and Pharmaceutical companies are driving the development of algorithms with use cases centered around more accurate and timely decision making.

Some examples of this include:

1. Screening of samples to in order to support additional testing not initially ordered.
2. Screening of all QNS/TNP (Quantity Not Sufficient or Test Not Performed) cases to provide additional information for physicians or support ordering of a liquid biopsy test.
3. Screening of samples to provide a preview of targeted biomarker results on day 1 so that providers can make informed treatment decisions.
4. Screening for clinical trials in order to reduce costs of wet lab testing, thus increasing patient identification and expediting enrollment.

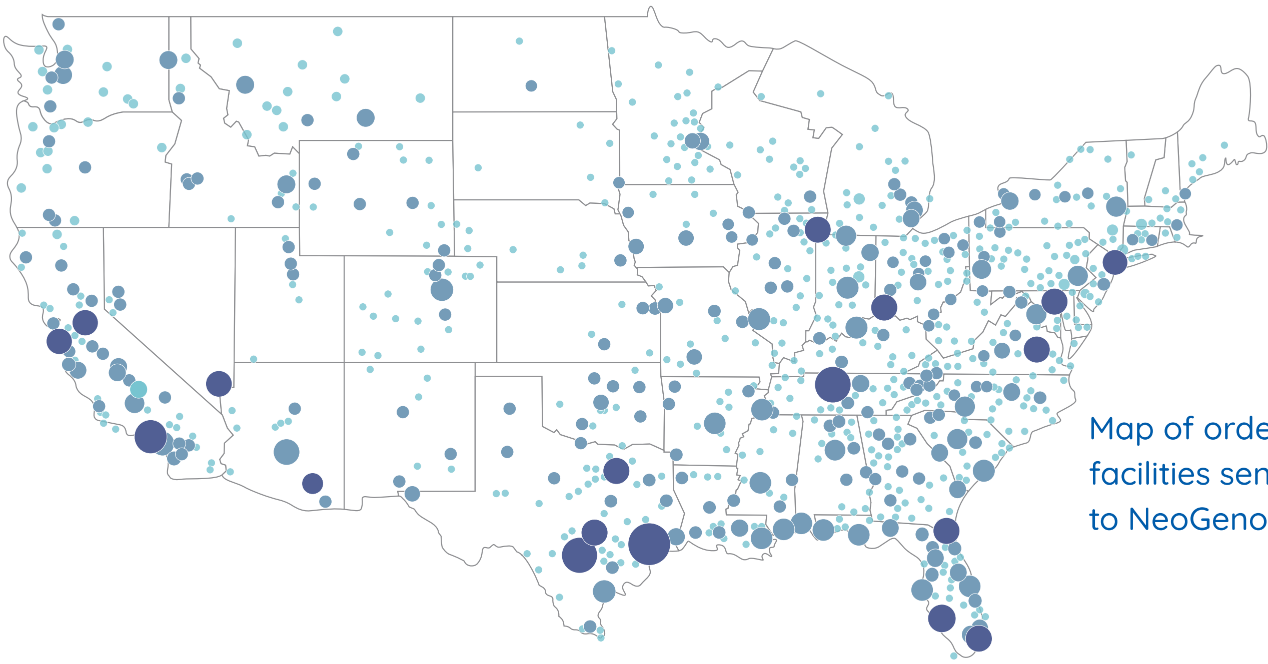
Bringing an AI Algorithm to Life

Whether for biomarker prediction or optimization of Pathology workflow, the AI algorithm development process involves initial training of the model on a broad and diverse dataset, followed by a period of refining and optimization to improve accuracy, sensitivity, and specificity. Once refined, the algorithm is validated using clinical data to verify accuracy in real-world settings. After validation is complete, the algorithm can be launched for use in the clinical setting.

NeoGenomics is helping to drive algorithm development through our comprehensive digital image library – currently consisting of over 2 million H&E and IHC images and metadata. In addition to the digitized images, NeoGenomics provides granular de-identified metadata details to accompany each image, including specimen and result details, as well as information on scanner type and magnification. This information is entered into structured fields when an order for testing is placed, and therefore may be queried directly using the LIS system

Along with structured data elements, NeoGenomics often receives printed Pathology reports and other medical notes that accompany test orders. Through data curation tools and manual abstraction, additional de-identified clinical information can be extracted and stored in the lab's database for future querying. These elements provide comprehensive histology, staging, and diagnosis information, as well as details surrounding prior therapy, race/ethnicity, and constitutional factors.

Not only is the breadth and depth of data elements within the NeoGenomics database paramount, but the patient population represented within the data is also critical to algorithm development and validation. NeoGenomics serves all 50 states within the US and over 85% of the lab's testing comes from the community setting. As such, NeoGenomics data provides an accurate and comprehensive representation of the diverse US population – a key factor in preventing bias in algorithm development.



Map of ordering facilities sending testing to NeoGenomics

TECHNOLOGY	UNIQUE IMAGES
Total Unique Images	~2,000,000
IHC Images	70%
H&E Images	30%
H&E with IHC Test Results	*30%*
H&E with FISH Test Results	*11%*
H&E with MOL Test Results	*8%*

Commercializing AI-Enabled Precision Oncology

AI companies have made great strides in solving for the challenges that many laboratories and healthcare providers face with oncology testing today. Providing testing opportunities to broader populations at decreased cost, TAT, and specimen requirements further enables accurate and timely diagnosis and treatment for cancer patients. With its vast library of digital images, comprehensive metadata capabilities, and extensive reach within the community setting, NeoGenomics is a valued partner to support development and refinement of these AI solutions and overall outcomes.

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1. NeoGenomics data
2. https://www.edureka.co/blog/ai-vs-machine-learning-vs-deep-learning/
3. https://www.nature.com/articles/s41379-022-01141-4

NeoGenomics, Inc. is a premier cancer diagnostics company, specializing in cancer genetics testing and information services. We offer one of the most comprehensive oncology-focused testing menus across the cancer continuum, serving oncologists, pathologists, hospital systems, academic centers, and pharmaceutical firms with innovative diagnostic and predictive testing to help them diagnose and treat cancer. Headquartered in Fort Myers, FL, NeoGenomics operates a network of CAP accredited and CLIA certified laboratories for full-service sample processing and analysis services throughout the US; and a CAP accredited full-service, sample-processing laboratory in Cambridge, United Kingdom. ©2024 NeoGenomics Laboratories, Inc. All rights reserved.

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