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# A new era of precision medicine

The unprecedented impact of generative AI

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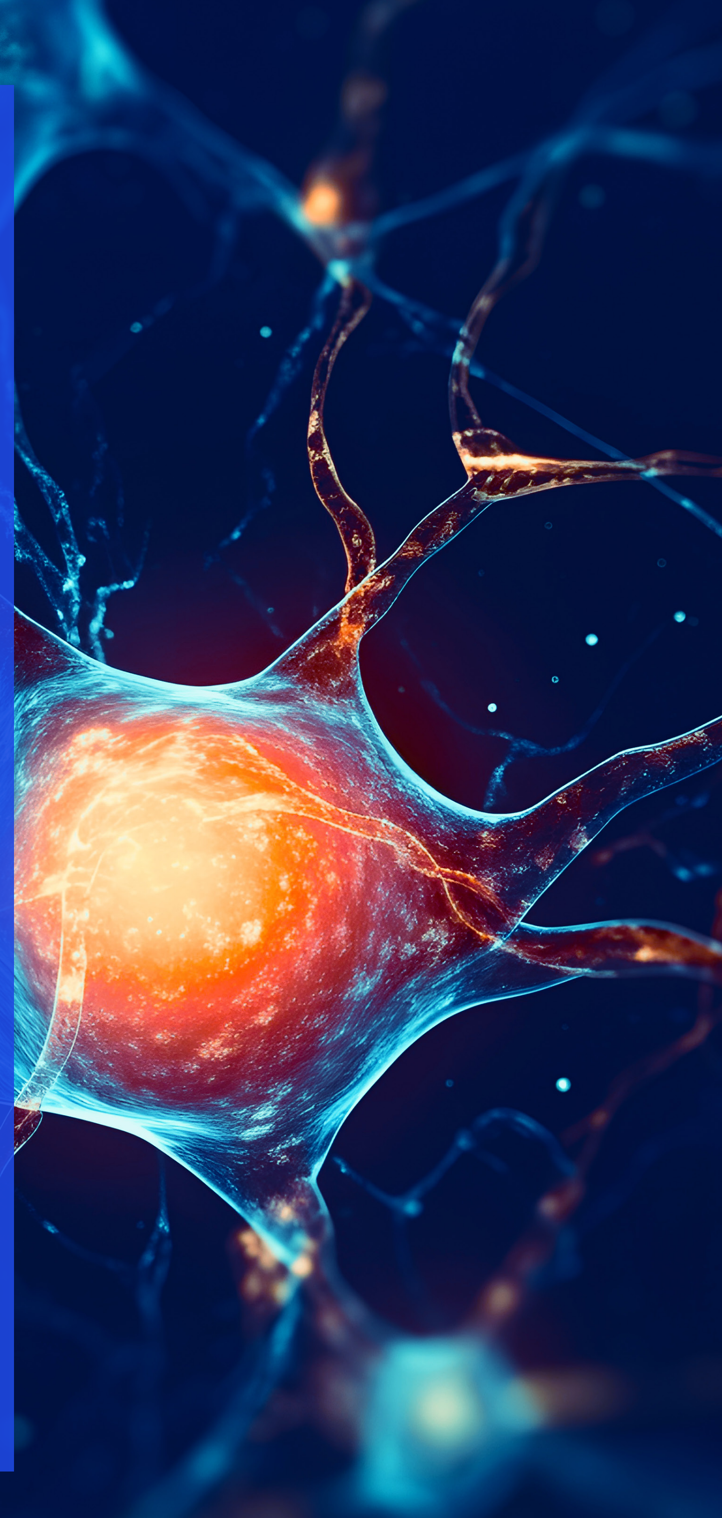
# Introduction

Precision medicine (PM), a paradigm-shifting model in healthcare and life sciences, is focused on delivering tailored treatments and prevention strategies to individual patients. As this important clinical discipline continues to evolve, artificial intelligence (AI), and more specifically generative AI, will likely serve as the cornerstone of innovation and accelerator of progress.

The use of AI in patient risk assessments, screening, and diagnosis are showing the most progress to date. However, AI-driven treatment decisions are where we see the most opportunity. Healthcare providers and ancillary technical experts (e.g., data scientists, machine learning engineers, etc.) can use AI to analyze complex data patterns, determine optimal patient treatment paradigms, anticipate treatment responses, and deliver personalized healthcare experiences.

On the operational front, AI's potential to enhance research-based and clinically based healthcare operations is significant. However, there are challenges that need to be addressed, including ensuring data privacy, managing ethical implications, obtaining regulatory approvals, and securing infrastructure investments. Further, there is a need to foster trust among healthcare professionals and patients regarding AI's reliability and transparency, which will require robust validation studies.

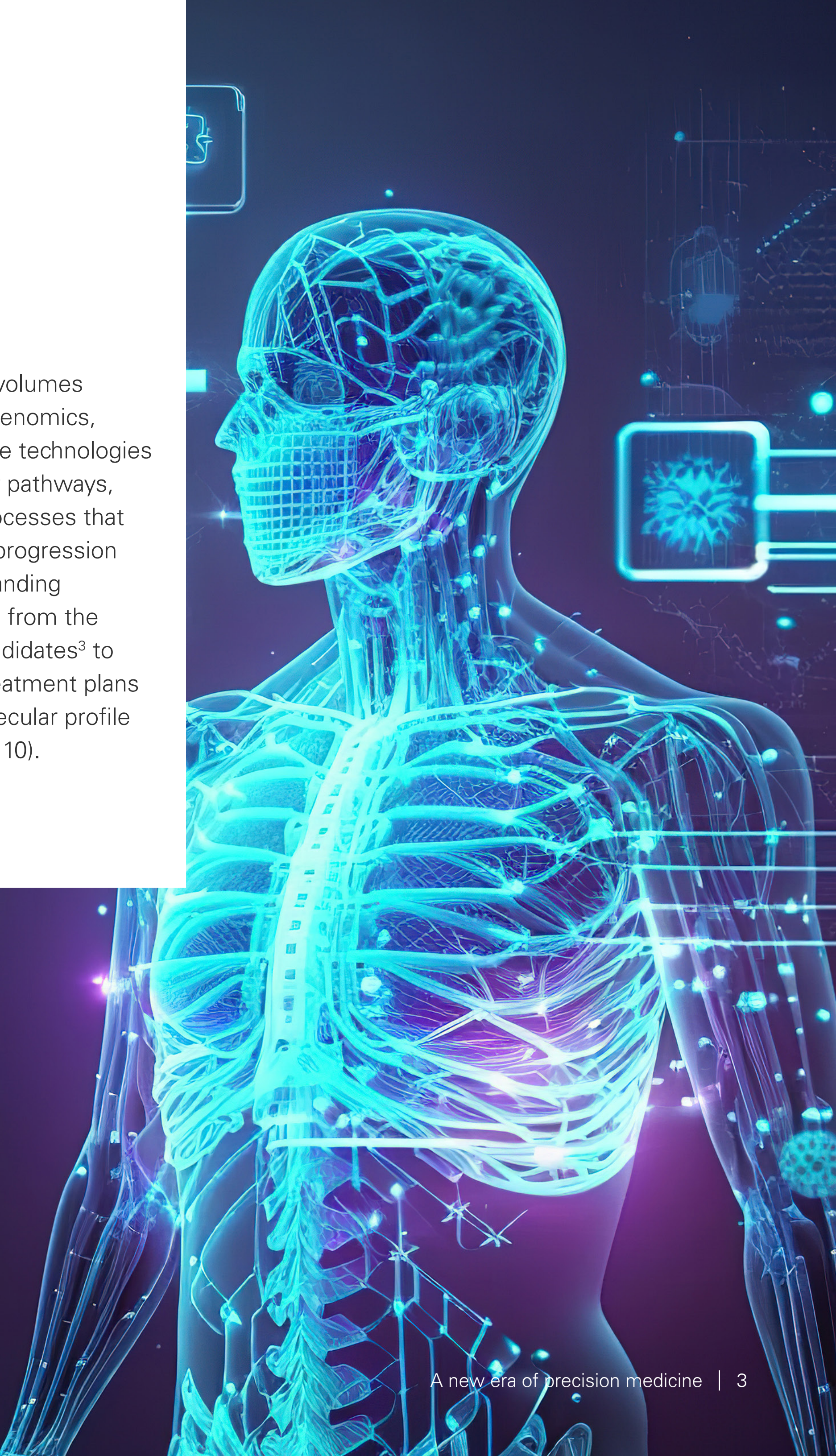
This paper delves into AI's current role across the PM landscape. We address the challenges impeding broader adoption and provide insights into potential AI-driven solutions based on emerging learning models through illustrative case studies. Federated learning, in particular, will play a pivotal role in constructing a robust, scalable, and privacy-preserving PM ecosystem.



# Current state of AI across the PM continuum

The identification and understanding of biomarkers are vital to PM, as they serve as measurable indicators of biological processes, disease states, and responses to therapeutic interventions. Their importance can be seen across the PM continuum when it comes to influencing decisions surrounding disease diagnoses, prognoses, patient stratification, treatment selection, drug development, therapy monitoring, and disease prevention.

AI (encompassing machine learning (ML) and deep learning (DL)/neural networks (NN))[1] has significantly improved the biopharma industry's ability to process and analyze large volumes of complex multi-omics data (e.g., genomics, proteomics, and metabolomics).[2] The technologies help illuminate underlying molecular pathways, genetic variations, and biological processes that contribute to the development and progression of diseases. This increased understanding has informed various aspects of PM from the identification of novel biomarker candidates[3] to the development of personalized treatment plans based on an individual's unique molecular profile (see discussion of ArteraAI on page 10).



[1] Source: Stefano A. Bini MD, "Artificial Intelligence, Machine Learning, Deep Learning, and Cognitive Computing: What Do These Terms Mean and How Will They Impact Health Care?" Volume 33, Issue 8, The Journal of Arthroplasty, AAHKS Symposium, ScienceDirect, July 19, 2018

[2] Source: Matthias Mann, Chanchal Kumar, Wen-Feng Zeng, and Maximilian T. Strauss, "Artificial intelligence for proteomics and biomarker discovery," Volume 12, Issue 8, Perspective, Cell Systems, ScienceDirect, August 18, 2021

[3] Ibid.

# Deeper dive into different types of AI models

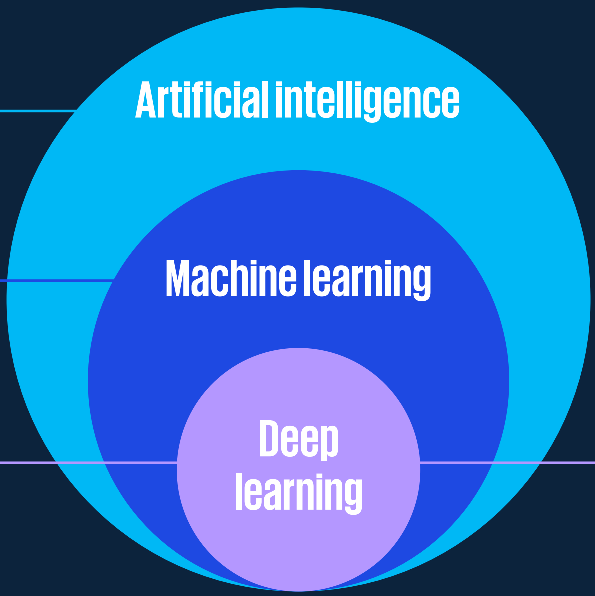
There has been a steady progression of AI advancements and models being applied to the challenges across the PM landscape. These include the more common ML models based on supervised learning (where each data point has an associated label),[4] as well as more recent generative models like generative adversarial networks (GANs) and variational auto-encoders (VAEs)[5] (Exhibit 1). These advancements have the unique capability of being able to operate with missing data and disentangle complex data to advance applications in areas such as bio-marker discovery, patient stratification, and drug re-purposing.

**Exhibit 1. Generative model benefits**

The ability of machines to perform "intelligent" tasks, including algorithm development, computer programming, and ML models

Machines learn automatically and improve from experience without explicit programming

Involves the use of artificial neural networks that make predictions and decisions from complex data




### Benefits of generative AI models

**Data augmentation:** Synthetic data can be created to increase training dataset sizes, expediting model training times, and improving model quality

**Medical research:** Simulation of biological processes can assist medical professionals in understanding disease mechanisms, paving the way for advances in treatment

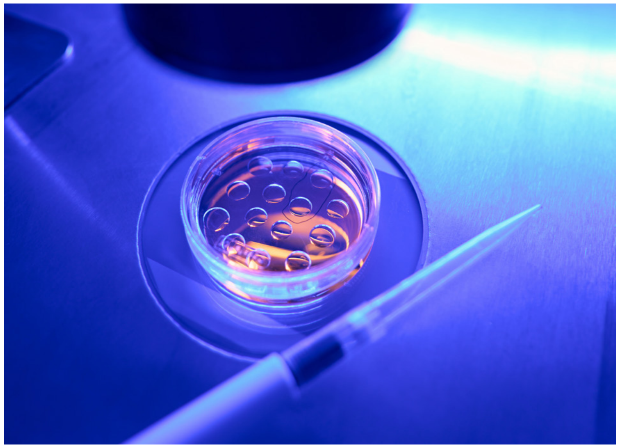
**Video and image processing:** Video and image enhancement and processing can assist doctors in medical image-based disease detection

**Data anonymization:** Generation of synthetic data can maintain data privacy in some cases where confidentiality is necessary

[4] Source: Stefano A. Bini MD, "Artificial Intelligence, Machine Learning, Deep Learning, and Cognitive Computing: What Do These Terms Mean and How Will They Impact Health Care?" Volume 33, Issue 8, The Journal of Arthroplasty, AAHKS Symposium, ScienceDirect, July 19, 2018

[5] Source: Bilal Ahmad, Jun Sun, Qi You, Vasile Palade, and Zhongjie Mao, "Brain Tumor Classification Using a Combination of Variational Autoencoders and Generative Adversarial Networks," Volume 12, Issue 8, Biomedicines, MDPI, January 21, 2022

# The PM patient continuum



The acceleration of AI technology has enhanced efficiency across the PM continuum, providing medical professionals with broader access to advanced predictive modeling and decision support tools to supplement personalized treatment strategies. PM can be broken down into a series of steps that correspond to the key milestones along the patient journey, each of which has potential to be enhanced by AI (Exhibit 2).

**Exhibit 2. Each stage of the PM patient journey has AI-driven transformation potential[6]**

| | Risk assessment | Screening | Diagnosis | Staging and prognosis | Therapy selection | Monitoring |
|---|---|---|---|---|---|---|
| Stage description | Assessing patient risks based on individual genetic and other biomarker data, clinical findings, and environmental factors | Testing at a predetermined cadence for early disease identification | Enhancing the accuracy of disease confirmation via individual biomarker and other unique data | Assessing disease progression, severity, outlook, and risk of recurrence via individual prognostic biomarkers | Tailoring treatments using multi-omics data, as well as medical history, social factors, and environmental dynamics | Monitoring treatment safety, side effects and response via individual biomarker data |
| Examples of AI's impact | Predicting phenotype expression via genotype data and assessing disease risk via image analysis | Tailoring recommendations for screening protocols and frequency via neural network modeling based on image analysis and clinical data | Expediting gene variant analysis and identification of disease-causing variants in newborns via rapid whole genome sequencing and natural language processing phenotyping | More rapidly and accurately predicting COVID-19 prognoses and severity via blood work, imaging, and electronic health record data analysis | Better predicting therapy responses using multimodal analyses of biopsy imagery, biomarker tests, and clinical data | Predicting chemotherapy toxicity risks using multi-variable, single nucleotide polymorphism-based models |

Examples of impact not comprehensive.

[6] Source: Internal KPMG Analysis

## Stage 1 Risk assessment

Traditionally, risk assessment in PM focuses on utilizing predisposition biomarker tests, genomic data, internal scans, and other data to complement traditional clinical and risk factor assessments. The development of robust risk assessment protocols has been challenging due to the complexity of biological data and genotype-phenotype relationships.

AI helps address this challenge by efficiently interpreting vast amounts of genetic information and predicting gene expression. This improved understanding of genomic variation and its connection to disease presentation, therapeutic success, and prognosis enhances the ability to assess patient risk. Consider the first use case on the right.

AI has also been used to enhance risk assessment beyond interpreting genomics or other biomarkers. Consider the second use case on the right case on how image data is being used to train models to evaluate risk.

## Risk assessment use cases:

### Statistical genomics and ML predict breast and ovarian cancer risk

A collaboration between the Institute for Research in Biomedicine and the Centre for Genomic Regulation identified 42 hereditary genes that predispose individuals to a higher number of mutations. These mutations correlate with a greater probability of developing cancers, specifically breast and ovarian cancer. The researchers used statistical genomics and a ML model known as the "autoencoder" neural network to find patterns in complex data (specifically, 11,000 genome sequences from cancer patients of European ancestry) to link certain genes to specific somatic mutations that indicate an increased risk of cancer.

Source: Dr. Fran Supek and Nahia Barberia, "Hereditary factors that increase the likelihood of cancer mutations detailed in new study," Scientific, News, Institute for Research in Biomedicine (IRB), Barcelona, July 5, 2022

### AI and imaging predict lung cancer risk

Harvard Medical School investigators and MIT researchers collaborating at Massachusetts General Hospital hypothesized that they could build a deep learning model to assess lung scan imaging and predict individual risk without additional demographic or clinical data. The Harvard/MIT team trained a 3D convolutional neural network architecture using three data sets of low-dose computed tomography scans (LDCT scans), a set of 6,282 LDCTs from NLST participants, 8,821 LDCTs from Massachusetts General Hospital, and 12,280 LDCTs from Chang Gung Memorial Hospital, which included people with a range of smoking history (including nonsmokers). Funded by several large healthcare companies and investors, their model, named Sybil, has been shown to accurately predict future lung cancer risk for both smokers and non-smokers from a single low-dose computed tomography (LDCT) scan.

Source: Peter G. Mikhael, Jeremy Wohlwend, Adam Yala, Ludvig Karstens, Justin Xiang, Angelo K. Takigami, Patrick P. Bourgouin, PuiYee Chan, Sofiane Mrah, Wael Amayri, Yu-Hsiang Juan, Cheng-Ta Yang, Yung-Liang Wan, Gigin Lin, Lecia V. Sequist, Florian J. Fintelmann, and Regina Barzilay, "Sybil: A Validated Deep Learning Model to Predict Future Lung Cancer Risk From a Single Low-Dose Chest Computed Tomography," Volume 41, Issue 12, List of Issues, Journal of Clinical Oncology, January 12, 2023

### Spotlight on cancer diagnoses

Supervised ML and DL algorithms can help assess hereditary cancer risk by:

- Analyzing large volumes of genetic data identifying high-risk genes
- Stratifying patients based on genetic profiles
- Aiding clinical decision-making through AI-powered decision support tools

# Stage 2 Screening

Traditionally, PM screening involves testing high-risk patients at predetermined intervals for early disease identification.

AI is being leveraged to support screening in various ways, particularly by enhancing the accuracy and efficiency of medical imaging. AI algorithms, especially DL techniques like convolutional neural networks (CNNs), have shown great promise for analyzing medical images, such as mammograms, computed tomography (CT) scans, and magnetic resonance imaging (MRI) scans, helping detect early signs of cancer (e.g., tumors, abnormal tissue growth, etc.).

For example, MIT and Mass General Hospital developed a DL model called Mirai, which can predict a patient's likelihood of developing breast cancer up to five years in advance using mammogram data. Mirai was trained on more than 200,000 exams from MGH and validated on test sets from MGH, the Karolinska Institute, and Chang Gung Memorial Hospital. The model outperforms traditional methods[7] in predicting cancer risk,[8] identifying high-risk groups, and stratifying patients for increased screening. In comparison to the Tyrer-Cuzick model.[9] Mirai identified nearly twice as many future cancer diagnoses among high-risk cohorts.[10] Notably, the model demonstrated consistent accuracy across different age groups, breast density categories, cancer subtypes, and races, etc. Given the higher breast cancer rates among women of color (see box below), Mirai is an effective illustration of AI's ability to overcome some of the biases inherent in traditional screening models.

## Addressing bias in PM

**Black women have a 40 percent higher mortality rate from breast cancer compared to white women.[11]** Use cases such as the Mirai DL model address the important issues of health equity and model bias in AI-based PM and medicine in general. The work demonstrates a commitment to inclusivity and shows equal accuracy for both white and Black women.

[7] Source: Traditional cancer screening methods include the Gail Model, the Breast Cancer Risk Prediction Tool [BCRAT], the Tyrer-Cuzick Risk Assessment Calculator, and others.

[8] Source: Dr. Fran Supek, and Nahia Barberia, "Hereditary factors that increase the likelihood of cancer mutations detailed in new study," Scientific, News, Institute for Research in Biomedicine (IRB), Barcelona, July 5, 2022.

[9] Source: The Tyrer-Cuzick Model is a risk assessment model uses questions about personal and family history to determine the possibility of developing breast cancer. The results will display as a 10-year risk score and a lifetime risk score; Tyrer-Cuzick Risk Assessment Calculator, magview.com, MagView

[10] Source: Rachel Gordon, "Robust artificial intelligence tools to predict future cancer," MIT Computer Science and Artificial Intelligence Laboratory (MIT CSAIL), MIT News, Massachusetts Institute of Technology, January 28, 2021

[11] Source: "Breast Cancer Death Rates Are Highest for Black Women—Again," American Cancer Society, October 3, 2022.

# Stage 3 Diagnosis

Diagnostic tests are used for definitive diagnoses of diseases and inform the next steps in the PM patient journey, which is disease management.

AI is being leveraged to support diagnostics in various ways, particularly by enhancing the accuracy, efficiency, and objectivity of diagnostic tests. For example, AI's ability to extract relevant information and identifying patterns in EHR data, clinical notes, laboratory results, and imaging data can help clinicians make more accurate and timely diagnoses.[12] Further, integration of diverse sources (as described in the screening section) provides a more thorough view of a patient's condition.[13] In addition to facilitating more accurate diagnoses, this integrated approach can inform personalized treatment strategies.[14]

It is important to note that the clinical understanding of genetic variations with respect to an individual's phenotype is becoming the largest contributor to cost and time expenditures for genome-based diagnosis of rare genetic diseases.[15] AI has the power to significantly expedite and streamline genome interpretations by integrating predictive methods and enabling better understanding of genetic diseases and their causes.

Further, AI-driven diagnostics are of particular value in newborn care. More than 8 million infants are born with life-threatening genetic disorders globally each year,[16] and early diagnosis is crucial for survival. By employing natural language processing (NLP) for automated phenotyping and using whole genome sequencing (WGS), AI can rapidly provide crucial diagnoses in emergency neonatal care situations. Consider the use case below.

Finally, automated EHR extraction by NLP programs use patients' historical medical documents to match phenotypes to their potential causes. NLP in ensembles has shown to be effective even in cases where there is insufficient training data for one specific program to effectively reduce errors (i.e., an ensemble of NLPs determines outputs via majority rule).

## Diagnosis use case:

### More rapid diagnoses—and interventions—for infant genetic disorders

To expedite genome interpretation, University of Utah Health, Fabric Genomics, and Rady Children's Hospital developed Fabric GEM, an AI-based algorithm for diagnosing genetic disorders in newborns. GEM demonstrates a new level of accuracy, ranking causative variants first or second more than 90 percent of the time, which is a significant improvement over existing tools. By reducing the burden of gene variant analysis, this tool is improving both the speed and accuracy of infant diagnoses.

Source: Rapid SV identification | Speeding up disease diagnosis with AI (fabricgenomics.com); AI quickly identifies genetic causes of disease in newborns – @theU (utah.edu).

[12] Source: "Applications of Artificial Intelligence to Electronic Health Record Data in Ophthalmology," Translational Vision Science & Technology, 27 Feb. 2020.

[13] Source: "Limiting Bias in Artificial Intelligence Tools, Personalized Medicine." HealthITAnalytics, 9 Dec. 2021.

[14] Source: "Precision Medicine, AI, and the Future of Personalized Health Care," Clinical and Translational Science, January 2021.

[15] Source: Francisco M De La Vega, Shimul Chowdhury, Barry Moore, Erwin Frise, Jeanette McCarthy, Edgar Javier Hernandez, Terence Wong, Kiely James, Lucia Guidugli, Pankaj B Agrawal, Casie A Genetti, Catherine A Brownstein, Alan H Beggs, Britt-Sabina Löscher, Andre Franke, Braden Boone, Shawn E Levy, Katrin Õunap, Sander Pajusalu, Matt Huentelman, Keri Ramsey, Marcus Naymik, Vinodh Narayanan, Narayanan Veeraraghavan, Paul Billings, Martin G Reese, Mark Yandell, and Stephen F Kingsmore, "Artificial intelligence enables comprehensive genome interpretation and nomination of candidate diagnoses for rare genetic diseases," PMCID: PMC8515723, PubMed Central, National Institutes of Health (NIH), National Library of Medicine (NLM), October 14, 2021

[16] Source: "World Birth Defects Day 2023: Global Efforts to Raise Awareness and Support Families," cdc.gov, February 27, 2023.

# Stage 4 Staging and prognosis

In PM, staging and prognosis involve the use of individual prognostic biomarkers to better assess disease progression, severity, outlook, and risk of recurrence.

Currently, ML and DL enhance these processes by analyzing prognostic biomarkers, disease imaging, and other disease data. For example, ML/DL algorithms are adept at analyzing gene expression, protein levels, and other molecular data to identify patterns associated with disease outcomes.

In a pathological context, slide images are converted into numerical data, which turn into convolution layers that convolutional neural networks (CNNs) can "pool" to filter down to the most relevant layers. These layers then turn into a "flattened" dataset that is used via traditional artificial neural network processes to evaluate disease characteristics on a personalized level (Exhibit 3).

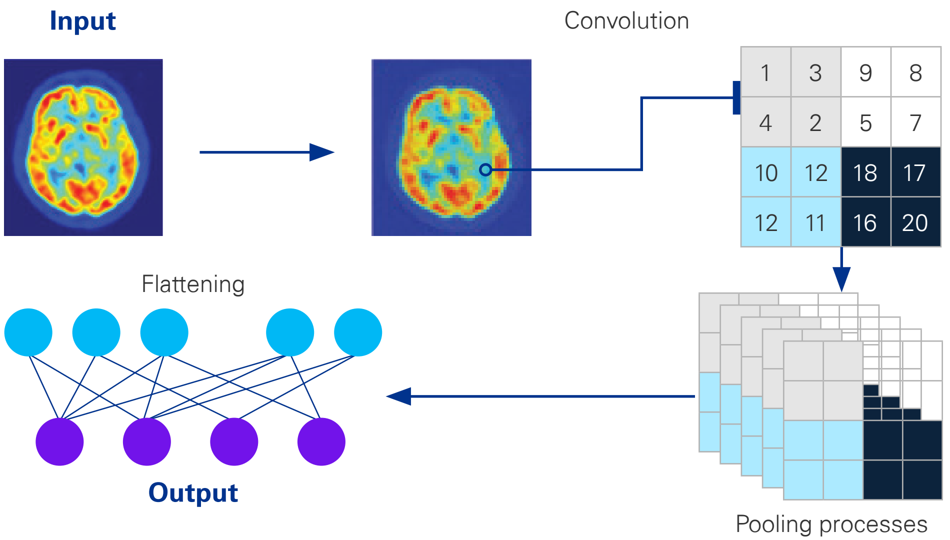
## Staging and prognosis use case:

### First-in-class AI-enabled prognostic testing platform for diabetic kidney disease

Renalytix, a global leader in the new field of bioprognosis™ for kidney health, has received De Novo marketing authorization from the FDA for its AI-enabled prognostic testing platform KidneyIntelX™. The platform is based on technology developed at the Icahn School of Medicine at Mount Sinai and licensed to Renalytix. KidneyIntelX gives doctors a detailed view into the rate at which patients with chronic early-stage diabetic kidney disease may continue to lose kidney function over five years. Patients are stratified into three risk levels – low, moderate, and high. Results are gleaned from a combination of blood-based biomarkers and clinical variables using an AI algorithm, which provides reliable and actionable information to guide care in large, at-risk patient populations. Since its introduction, the tool has been used on approximately 10,000 patients in the U.S. The potential for further expansion is significant given the fact that more than 30 million Americans have Type 2 diabetes[17] and kidney disease impacts more than 850 people worldwide.[18]

Source: "FDA Grants De Novo Marketing Authorization for KidneyIntelX.dkd to Assess Risk of Progressive Kidney Function Decline in Adults with Diabetes and Early-Stage Kidney Disease," Press release, Renalytix, June 29, 2023

**Exhibit 3. CNNs filter data into layers to evaluate disease characteristics**




Source: Milecia McGregor, "What Is a Convolutional Neural Network? A Beginner's Tutorial for Machine Learning and Deep Learning," #Machine Learning, freeCodeCamp.org, February 4, 2021

[17] "Type 2 Diabetes," Centers for Disease Control and Prevention, www.cdc.gov

[18] "The hidden epidemic: Worldwide, over 850 million people suffer from kidney diseases," American Society of Nephrology, Leading European Nephrology, and International Society of Nephrology, June 27, 2018

## Stage 5 Therapy selection

Personalized therapy selection is traditionally based on multi-omics data combined with medical history, social factors, and environmental dynamics.

AI comprising ML, DL, and NN techniques, is helping enhance therapy selection across various avenues, including predicting patient response to specific treatments, identifying potential drug targets, and optimizing treatment regimens. However, key considerations for adoption include the quality and availability of data, as well as ethical and regulatory considerations around privacy and security.

For example, the ArteraAI Prostate Test is a groundbreaking AI-driven test designed to identify patients with localized prostate cancer who will likely benefit from therapy intensification. Developed by a consortium of prominent pharmaceutical companies and healthcare investors, including Coatue, Johnson & Johnson Innovation, Koch Disruptive Technologies, Walden Catalyst Ventures, TIME Ventures, and Breyer Capital, the test employs a multimodal artificial intelligence (MMAI) architecture that combines clinical and histopathology image data.[19]

This innovative approach, validated in multiple large phase III clinical trials, demonstrates superior performance compared to such traditional risk models as the NCCN model when it comes to predicting outcomes like biochemical recurrence, distant metastasis, prostate cancer-specific survival, and overall survival.[20]

## Stage 6 Monitoring

Individual biomarker data is used in PM to monitor treatment safety, side effect development, and disease progression.

AI can enhance physicians' ability to monitor treatment efficacy and safety, make educated predictions about disease advancement, and anticipate side effect development. Regarding the latter, there are certain diseases—like acute lymphoblastic leukemia (ALL)—where the incidence of treatment complications increases the likelihood of post-disease chronic health conditions and even early death. In these cases, there is great value in being able to predict which patients will have negative treatment responses and ongoing side effects, as care teams can then ensure these patients are monitored closely.[21]

As an illustration, researchers from the University of Florida (UF) recently developed an AI-based tool capable of predicting ALL patients' risk of developing chemotherapy drug toxicity.[22] Researchers used an AI model, trained on UF patient data, to predict which combinations of SNPs and other genetic variants were likely to lead to toxicity, ultimately yielding "toxicity scores" for individual patients.[23] The AI-fueled multivariable analysis was used to synthesize a large set of potential SNP-genetic variant combinations in an efficient manner to help determine which combinations were likely to increase patient vulnerability to chemotherapy, the results of which were validated in subsequent treatment findings.[24]

[19] Source: "Artera Launches with $90 Million in Funding to Personalize Cancer Therapy with Multimodal AI," News - Artera, Business Wire, March 21, 2023

[20] Source: "AI-Powered Biomarker Predicts Outcomes Better than NCCN Risk Groups For Men with High-Risk Prostate Cancer," ASCO Daily News, February 16, 2023.

[21] Source: "Late Effects of Therapy in Childhood Acute Lymphoblastic Leukemia Survivors," Turkish Journal of Haematology : Official Journal of Turkish Society of Haematology, February 7, 2019.

[22] Source: Leah Buletti, "UF researchers create method to predict leukemia drug complications," College of Pharmacy, University of Florida, March 24, 2023

[23] Source: Trisha Larkin, MD, Reema Kashif, MD, Abdelrahman H. Elsayed, PhD, Beate Greer, BA, Karna Mangrola, MD, Roya Raffiee, PhD, Nam Nguyen, PharmD, Vivek Shastri, PhD, Biljana Horn, MD, and Jatinder K. Lamba, PhD, "Polygenic Pharmacogenomic Markers as Predictors of Toxicity Phenotypes in the Treatment of Acute Lymphoblastic Leukemia: A Single-Center Study," Volume 7, JCO® Precision List of Issues, JCO® Precision Oncology, March 23, 2023

[24] Source: Sophia C. Kamran, and Kent W. Mouw, "Applying Precision Oncology Principles in Radiation Oncology," Volume 2, List of Issues, JCO® Precision Oncology, May 14, 2018

# Critical considerations for leveraging AI in PM

As the use of AI in PM evolves, there are several imperatives companies should consider across self-learning AI, generative AI, and, perhaps most critically, federated learning. Guidelines follow in the next three subsections.

## 01 Self-learning AI considerations

**Collaborative development tools:** The infrastructure needed for collaborative development of AI models—including shared coding platforms—are necessary for operationalizing in-house AI models that may work in tandem with ML frameworks.[25]

**Partnerships and collaboration:** Companies within the PM ecosystem should be ready to form partnerships with various stakeholders, including hospitals, researchers, and biopharma firms, to access necessary data, enhance scale, and supplement clinical implementations.[26]

**Ethical considerations and efforts to minimize bias:** Critical consideration must be given to the ethical use of AI in PM. This includes maintaining patient privacy and informed consent, as well as efforts to ensure training data sets don't reinforce biases. It is also essential to establish transparent data handling and analysis protocols that respect individual autonomy and confidentiality while also ensuring the equitable use and accessibility of AI-driven medical interventions. Additionally, it is imperative that the data be used for its intended purpose and not reach the hands of parties who could use the information for their own benefit.

**Evolving regulations:** Biopharma companies should stay ahead of potential compliance, legal, and regulatory requirements related to patient data sharing and data privacy. Just as CMS-regulated payers are required to use secure, standards-based Application Programming Interfaces to allow patients to access their claims and encounter data, providers will soon have to follow the same guidelines.[27] Further, public reporting of non-compliant providers is becoming the norm as PM becomes more prevalent and related data becomes more complex.[28]

**Robust data sharing protocols amid ecosystem connectivity:** AI in PM must adhere to secure, privacy-compliant practices for handling diverse data types, including genetic, phenotypic, and lifestyle data. Further, policies that enable secure and compliant data sharing across institutions are becoming increasing essential.

[25] Source: TensorFlow, for example, utilizes Keras API to build neural networks, efforts for which are typically driven by ML engineers and data scientists. However, the interface peels away more granular neural network details, making flow and model understanding comprehensible to working team members without advanced data science backgrounds

[26] Source: Onconova Therapeutics has a research partnership with oncology-focused machine learning company Pangea Therapeutics. Onconova will use Pangea's proprietary ENLIGHT AI platform to identify biomarkers of response to rigosertib, one of Onconova's small molecule drugs to treat various solid cancers. This partnership will help expedite trials, develop appropriate companion diagnostic(s), and ultimately drive greater commercial success across a broad range of patient populations.

[27] Source: "Latest FHIR Standard R5 Elevates Data Exchange, Interoperability," ehrintelligence.com, April 18, 2023.

[28] Source: "The impact of Public Reporting on clinical outcomes: a systematic review and meta-analysis," BMC Health Services Research, July 22, 2016.

## 02 Generative AI-specific considerations

**Infrastructure and Computational Power:** AI—and generative AI in particular—requires considerable computing power. Biopharma companies may need to invest in such capabilities as high-performance computing, as well as data storage and development tools. High-performance computing is specifically designed to take on large-scale data processes and modeling, requiring significant hardware investments in line with the model development timeframe.

**Greatly increased data storage:** Storage systems such as Network Attached Storage (NAS) and Storage Area Networks (SANs) are often used for small- to medium-scale storage needs. By contrast, cloud-based infrastructures offer the larger scale needed for generative AI solutions.

**Model validation:** Validating and verifying generative AI models in a clinical context is critical since, to democratize these technologies, researchers need to use synthetic data. For example, using generative AI to expand clinical trial control groups and conduct virtual trials will require enhanced quality assurance of the data used.

**Workforce considerations:** The design and deployment of unique generative AI systems in PM necessitate a team of data scientists, ML engineers, software developers, UX designers, and specialized project managers. In the face of the existing talent gap in the technology industry, biopharmaceutical firms should be proactive and initiate their recruitment drives early. They must also adapt to contemporary employment models, considering virtual workforce structures where applicable, to secure the best talent in the field.

## 03 Spotlight on Federated learning: A critical consideration for ensuring data privacy [29, 30, 31, 32, 33]

Given the critical factors for successfully implementing a PM ecosystem, such as data privacy, interoperability, and effective utilization of diverse datasets, federated learning can be a fitting approach. Federated learning is a ML methodology where a global model is trained across multiple decentralized nodes, each housing their own local data (Exhibit 4).

In the realm of generative AI, federated learning facilitates the local generation and refinement of model updates, thereby ensuring data privacy and minimizing data transfer requirements. This process enriches the global model, bolstering its capacity to generate innovative and diverse outputs grounded in an extensive array of data sources. Despite federated learning's potential in the context of PM, it is important to address implementation challenges, including system architecture variability and the need for standardization of acquisition protocols and labelling methodologies.

[29] Source: Mohammed Aledhari, Rehma Razzak, Reza M. Parizi, and Fahad Saeed, "Federated Learning: A Survey on Enabling Technologies, Protocols, and Applications," PMCID: PMC7523633, HHS Author Manuscripts, Journal List, PubMed Central, National Library of Medicine (NLM), September 29, 2020

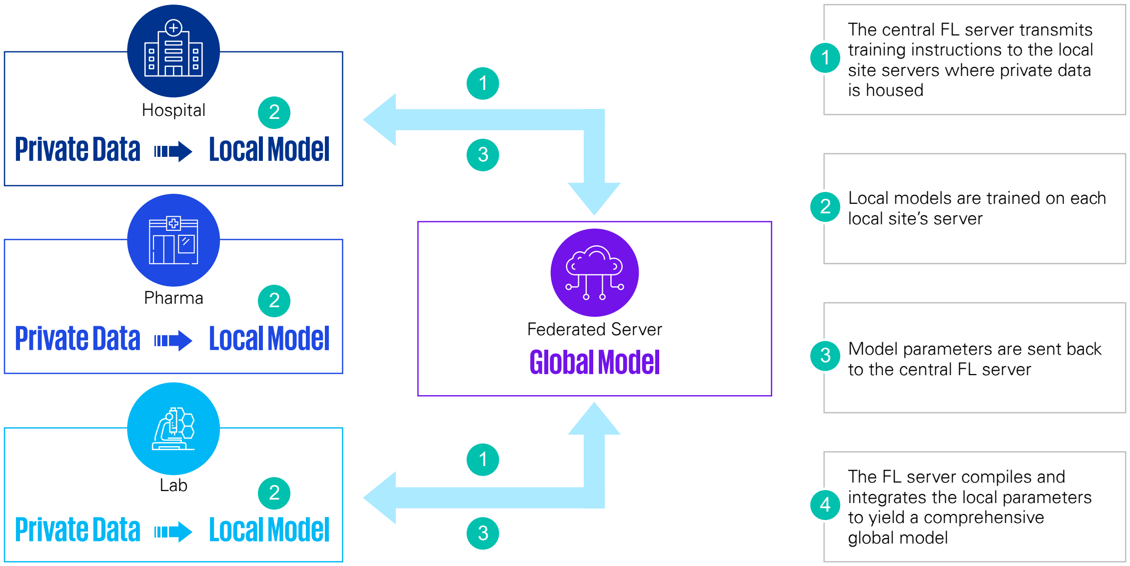
[30] Source: "Unlocking Distributed Health Data for Machine Learning," Whitepaper, integrate.ai

[31] Source: Srinivasa Rao Chalamala, Naveen Kumar Kummari, Ajeet Kumar Singh, Aditya Saibewar, and Krishna Mohan Chalavadi, "Federated learning to comply with data protection regulations," Article, CSI Transactions on ICT, March 15, 2020

[32] Source: Jie Ding, Eric Tramel, Anit Kumar Sahu, Shuang Wu, Salman Avestimehr, and Tao Zhang, "Federated Learning Challenges And Opportunities: An Outlook," arXiv:2202.00807v1 [cs.LG], arXiv, Cornell University, February 1st, 2020

[33] Source: Tian Li, Anit Kumar Sahu, Ameet Talwalkar, and Virginia Smith, "Federated Learning: Challenges, Methods, and Future Directions," arXiv:1908.07873v1 [cs.LG], arXiv, Cornell University, August 21, 2019

## Exhibit 4. The Federated Learning Model in action




Source: "Unlocking Distributed Health Data for Machine Learning," Whitepaper, integrate.ai.

### Federated learning use cases

**HealthChain project:** HealthChain aims to develop and deploy a federated learning framework across four hospitals in France to predict treatment response for breast cancer and melanoma patients. This work will help oncologists determine the most effective treatment for each patient based on their histology slides or dermoscopy images.[34]

**Project ATHENA (Augmenting Therapeutic Effectiveness through Novel Analytics):** ATHENA is a collaborative network that brings together a multidisciplinary partnership of academics, hospitals, and industry leaders who use machine learning to conduct predictive analytics in oncology.[35]

**MELLODDY (Machine Learning Ledger Orchestration for Drug Discovery):** Project MELLODDY involves 10 major pharmaceutical companies that inked an agreement to build the shared platform in partnership with Nvidia, Owkin, and others. The participants plan to use federated learning to collectively train AI on datasets without having to share proprietary data.[36]

[34] Source: Nicola Rieke, Jonny Hancox, Wenqi Li, Fausto Milletarì, Holger R. Roth, Shadi Albarqouni, Spyridon Bakas, Mathieu N. Galtier, Bennett A. Landman, Klaus Maier-Hein, Sébastien Ourselin, Micah Sheller, Ronald M. Summers, Andrew Trask, Daguang Xu, Maximilian Baust, and M. Jorge Cardoso, "The future of digital health with federated learning," PMCID: PMC7490367, v.3; 2020, NPJ Digit Med, Journal List, PubMed Central, National Library of Medicine (NLM), September 14, 2020

[35] Source: "Augmenting Therapeutic Effectiveness through Novel Analytics," Project ATHENA (Augmenting Therapeutic Effectiveness through Novel Analytics), ATHENA consortium, portal.athenafederation.org

[36] Source: "MachinE Learning Ledger Orchestration for Drug DiscoverY," MELLODDY Grant agreement ID: 831472, Horizon 2020, CORDIS

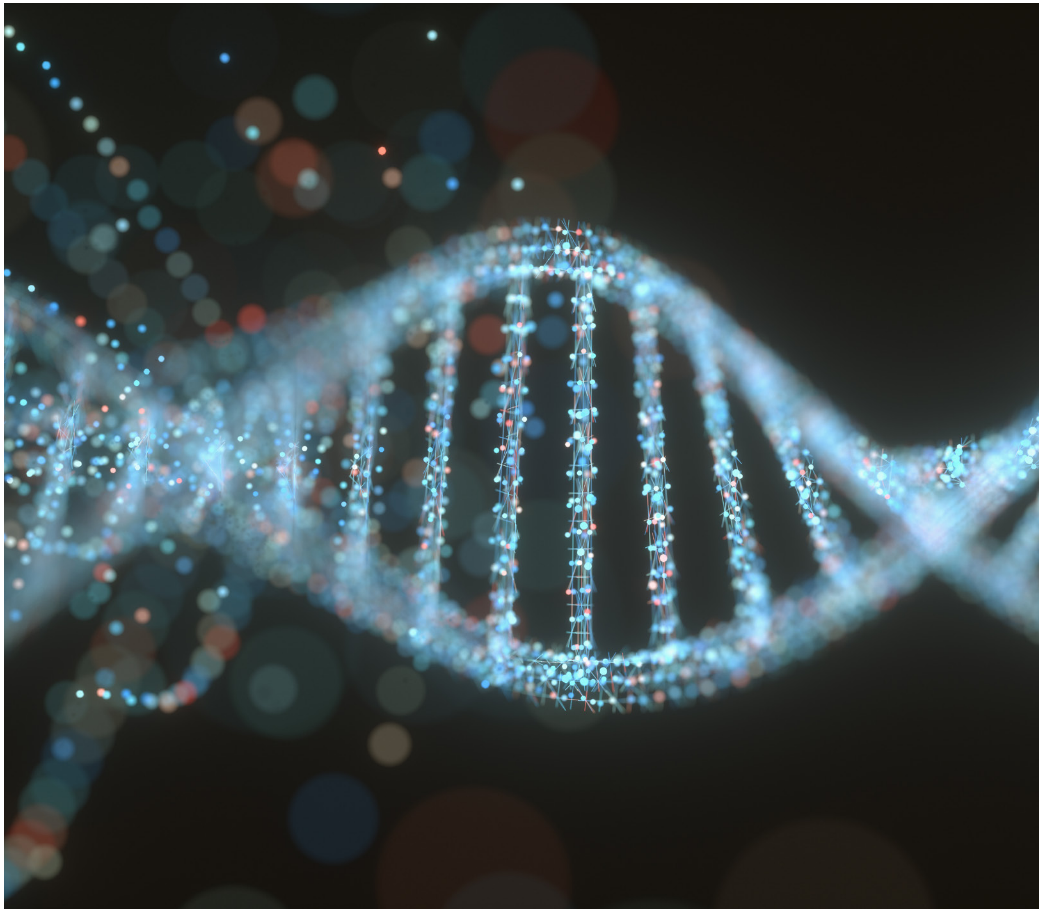
# Conclusion

As we continue to journey through the age of personalized healthcare, the interplay of AI and PM is becoming more critical. This model allows for potentially life-changing tailored treatments and disease prevention strategies. In this paper, we have explored AI's potential to impact risk assessment, screening, diagnosis, prognosis, treatment selection, and monitoring, reflecting its transformative potential across the healthcare continuum. Still, the industry must address several hurdles to drive AI's broader adoption, including mitigating issues surrounding data privacy, ethical implications, regulatory approvals, and infrastructure investments. By addressing these challenges, fostering trust in AI, and nurturing talent in the field, we can pave the way for a future where AI and PM converge to deliver more rapid, patient-centric, and personalized healthcare interventions.

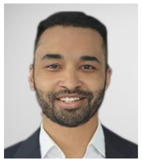
# How KPMG can help

Our firm is uniquely positioned to assist companies across the biopharma landscape, leveraging our strategic partnerships and insights into how generative AI is poised to revolutionize precision medicine. Through the various services summarized below, we have helped guide clients in navigating the complex realm of precision medicine and other drug development, identifying trends, assessing potential impacts, and developing strategies to capitalize on opportunities and threats driven by the emergence of generative AI.

- **Strategic Advisory** helps clients develop their overall generative AI in precision medicine strategies by identifying trends, assessing how these trends could impact a client's business, and helping the client develop strategies to capitalize on these trends.
- **Deal Sourcing and Evaluation** to identify potential acquisition or partnership opportunities specifically within the intersection of precision medicine and generative AI. Factors taken into account include market positioning, portfolio synergies, alignment with advanced precision medicine initiatives, and anticipated return on investment.
- **Commercial Due Diligence** including the evaluation of a target company's market position, business model, customer relationships, and growth prospects
- **Market and Competitive Intelligence** involves continuous monitoring of advancements in generative AI, including implications on the precision medicine landscape. Provides clients with insights on evolving market trends, competitor adaptations to generative AI in precision medicine, regulatory shifts influenced by generative AI advancements, and other pivotal dynamics shaping their business environment.
- **Integration Planning and Post-Merger Integration** happen after a deal is completed and involve helping a client integrate the acquired company or assets emphasizing the seamless integration of technologies, including generative AI. This could involve identifying potential synergies, developing an integration plan, or helping manage the integration process.



# Authors

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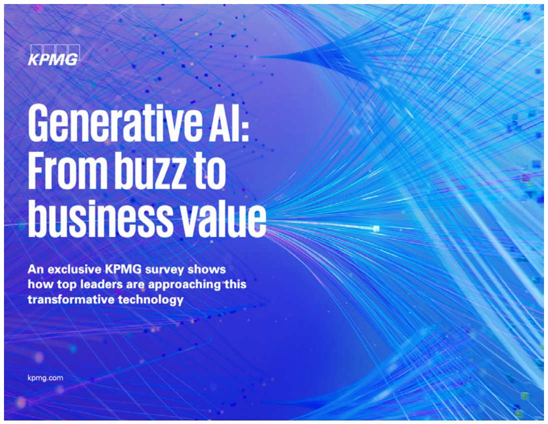
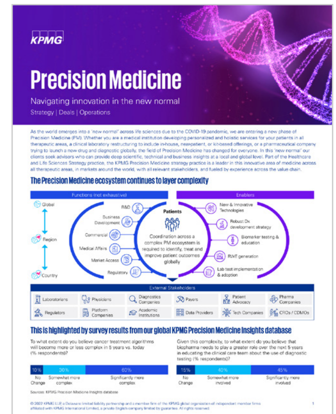
# Related thought leadership:







Learn how KPMG can help make your generative AI implementation successful, and explore how we can help you adopt AI in a safe, trustworthy, and ethical manner.

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