LIFE SCIENCES

Insights

August 2025

AI IN ACTION: REAL-WORLD INNOVATION IN LIFE SCIENCES

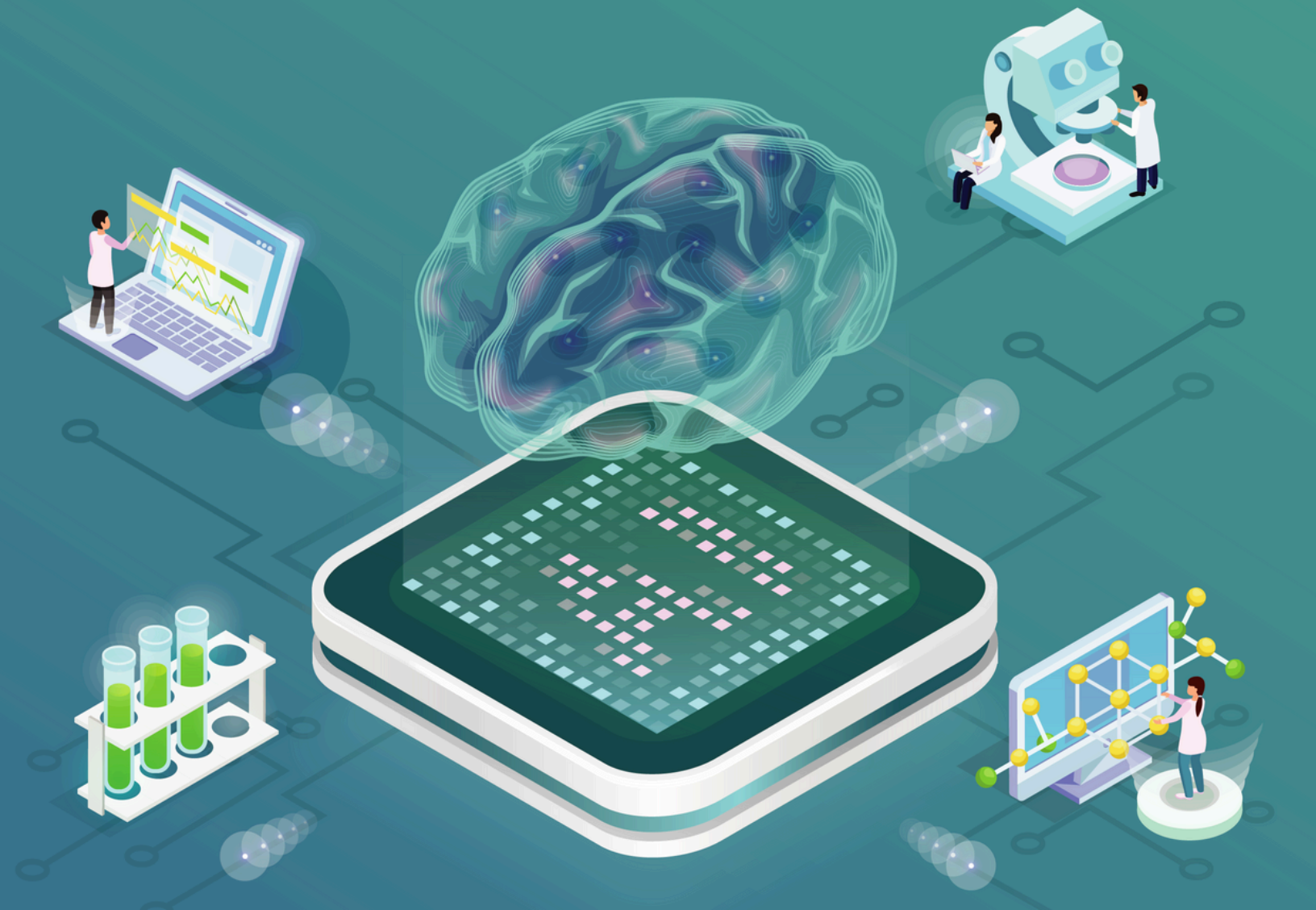

TABLE OF CONTENTS

BACK TO BASICS - DEMYSTIFYING AI

It's no secret that AI is one of the hottest topics being discussed across all industries. Within life sciences alone, AI-powered solutions hold the potential to transform everything from drug discovery and clinical trial design to patient access and commercial optimization. But before we rush to implement the latest generative AI platform or predictive algorithm, there's one important truth we can't ignore: AI is only as effective as the data, infrastructure, and people behind it.

So before your team panics about adopting the newest technology—or if you're already mid-implementation and questioning the ROI—we encourage a collective exhale. Instead of leaping toward the shiny object, let's focus on building the right foundation. Here are three critical steps to take before launching your next AI initiative:

1. DATA, DATA, DATA!

We all know the saying: "garbage in, garbage out." When it comes to AI, the quality of your data isn't just important—it's everything. Before implementing any AI solution, life sciences organizations must ensure they have strong data fundamentals in place. This includes:

- A comprehensive inventory of all data sources
- Standardization and cleansing of both structured and unstructured data
- Integrity checks and master data management across functions
- A defined data governance model to drive accountability

According to IBM Watson Health, poor data quality costs the healthcare industry $314 billion annually, largely due to inefficiencies, rework, and poor decision-making[1].

Real-world example: A global biopharma company piloting an AI platform to predict patient eligibility for rare disease trials discovered that inconsistent clinical coding and unstructured physician notes reduced model accuracy by over 40%. After investing in a data harmonization effort—standardizing terminologies, cleaning records, and enriching datasets—they improved model precision by 31%, enabling faster site screening and reducing enrollment delays[2].

With all that in mind, before you launch an AI tool, ask yourself: do you trust your data enough to let it drive business decisions?

2. CLOUD INFRASTRUCTURE & CYBERSECURITY

Cloud infrastructure is no longer optional for AI success—it's essential. AI models, especially large language models (LLMs), require scalable computing power and seamless data access that only the cloud can efficiently support. Cloud platforms also improve collaboration, version control, and real-time data availability across global teams.

However, with great flexibility comes great responsibility—89% of healthcare and life sciences organizations experienced a data breach or cyber incident in the past two years, according to the HIMSS 2024 Cybersecurity Survey[3]. Given the sensitivity of life sciences data—PHI, proprietary research, IP—cybersecurity must be a core component of every AI implementation.

Real-world example: A mid-sized biotech deploying an AI-driven clinical trial matching tool migrated legacy clinical and EHR data to the cloud. A pre-launch audit exposed weaknesses in endpoint protection and access management. After bolstering encryption protocols and implementing real-time threat detection, the company successfully avoided a ransomware attack during its go-live window[4].

Bottom line: if you're moving fast with AI, your cybersecurity strategy needs to move even faster.

3. PEOPLE & PROCESS

Here's the part most companies underestimate: technology is only as effective as the people using it. AI tools promise automation and insights, but without proper training and oversight, they can quickly become misunderstood, misused, or ignored altogether.

Employees need clear policies on how to validate and interpret AI-generated content, along with training that reinforces ethical use and human accountability.

AI is not a panacea; it won't replace the nuanced, cross-functional decision-making required in drug development, regulatory navigation, or patient engagement. But it can free teams from repetitive work, allowing them to focus on what matters most. And yet, only 28% of life sciences employees feel prepared to responsibly use AI in their daily work, according to a 2024 Deloitte Insights survey[5].

Real-world example: A commercial team at a specialty pharma company launched an AI-driven HCP segmentation tool. Early usage lagged because reps lacked context on how to use the insights in the field. After launching a targeted enablement program and reorienting KPIs around insight-driven actions—not just tool usage—adoption increased by 65%, and targeting precision improved by **30%**[6].

AI won't be held accountable for poor business decisions—your people will. That's why governance, training, and change management must be embedded in any AI rollout. All in all, the promise of AI in life sciences is real—but only if your organization is ready for it.

Before you train a model or launch a tool, ask yourself:

- Do we trust our data?
- Is our infrastructure secure and scalable?
- Are our people prepared to use this responsibly?

If not, the answer isn't to wait on AI—it's to build the foundation that will allow it to thrive. In life sciences, the organizations that get the basics right won't just adopt AI. They'll use it to lead. ■

ACCELERATING DISCOVERY

HOW AI IS BREAKNG THE GRIDLOCK IN EARLY-STAGE DRUG RESEARCH

synfini™

By Peter Madrid

The expenses involved in drug development have escalated dramatically in recent decades. The time to develop drugs is long, and the costs are high: on average, development takes 10-12 years, and the cost of creating a new drug now ranges from approximately $314 million to $4.46 billion (1). Meanwhile, pharmaceutical companies face mounting challenges to profitability due to pricing pressures.

Innovative technologies that simplify drug discovery, cut development timelines and expenses, and expedite patient access to potentially life-saving treatments are needed. However, traditional drug discovery pathways are stuck in a frustrating gridlock, hindering the rapid development of those treatments. Luckily, new applications of AI have emerged that have the potential to burst through that gridlock. While advancing drug discovery demands innovation across every stage, my discussion here centers on the preclinical phases. While clinical trials and the regulatory process themselves are also ripe for AI-enhanced transformation, the focus here is on early discovery.

THE FIRST AI LEAP

Where comprehensive datasets exist, AI's impact is immense. Over the last two decades, breakthroughs in high-throughput biological techniques have generated vast datasets. Initially hailed as revolutionary, these data volumes quickly became overwhelming, defying straightforward interpretation. Modern AI has now begun to distill this complex information into meaningful insights, identifying new drug targets at an unprecedented pace and scale. However, a new challenge has emerged: AI-identified drug targets frequently appear as lengthy sequences representing protein building blocks (strings of nucleotides and amino acids). Effective drug design requires understanding how these sequences fold into three-dimensional shapes that dictate biological function and binding characteristics.

THE SECOND AI LEAP

Traditional methods of determining protein structure, such as X-ray crystallography, remain the gold standard but come with significant time and cost burdens (commonly six months and $50,000 to $250,000+ per structure). However, years of progressively curated public databases linking amino acid sequences to known structures have provided a valuable resource. AI-driven structure prediction now routinely generates highly accurate virtual models of almost all known proteins.

With protein structures available—physically or computationally—the next hurdle is identifying chemical compounds capable of binding these targets and modulating disease processes. High-throughput screening of vast libraries—historically requiring massive automated labs and millions of compounds—has evolved significantly. DNA-encoded libraries can now screen billions of molecules in days, thanks to miniaturization and automation.

Even so, these represent only an infinitesimal fraction of the estimated 10^60 drug-like compounds believed to exist. AI-powered platforms promise to search through trillions of known or virtually designed chemicals, vastly expanding the discovery potential.

THE GRIDLOCK

It's important to note that these molecules aren't immediately drugs or drug candidates. The initial identification of binders ("hits") is just the start. These hits undergo synthesis and biological validation, followed by lengthy optimization cycles, turning early leads into viable therapeutic candidates.

Binding affinity is just one factor among several critical drug properties that must be balanced. This optimization phase typically takes many years and accounts for roughly a quarter of the entire drug development timeline.

This stage also sees the highest failure rates: nearly 70% of programs fail during early discovery due to shortcomings discovered through many Design-Make-Test-Analyze (DMTA) cycles that try to fix various compound flaws.

Unlike previous steps, these DMTA cycles remain largely manual and suffer from several challenges: limited, fragmented data due to confidentiality, inconsistency in experimental execution, high costs, and lack of reproducibility. AI struggles here due to sparse, low-quality datasets and the overwhelming chemical diversity requiring exploration without clear starting points.

THE BREAKTHROUGH

Looking ahead, overcoming this chemical optimization gridlock with AI requires coupling AI's predictive power with more rapidly generated, high-quality experimental datasets. Concepts for the lab of the future have ranged from augmented human-machine workflows to fully autonomous robotic labs with minimal human intervention.

Success relies on seamless integration of three core elements:

1. AI capable of accurate predictions using small, high-quality datasets.
2. Automated chemical synthesis platforms producing targeted compounds.
3. Biological automation systems conducting fast, reliable assays.

Neurosymbolic AI techniques, integrating expert human knowledge into AI models, are beginning to provide highly accurate molecular property predictions and enable more rapid design-test cycles. Meanwhile, automation of biological assays has matured significantly, with high-throughput platforms well established. Automated chemistry, however, has lagged due to the complexities of handling diverse chemical states (liquids, solids, gases, including corrosive or hazardous reagents).

General-purpose automated synthesis platforms are finally emerging, promising substantial acceleration compared to traditional, labor-intensive methods.

High-throughput experimentation using advanced liquid handlers and inkjet printing are facilitating rapid reaction optimization on microscale volumes, while multistep automated synthesizers enable production of compounds in quantities suitable for escalating biological validation.

Combining AI with such automation presents an exciting avenue to dissolve the chemical synthesis bottleneck that has long slowed drug discovery. Parallel advances in computational chemistry also contribute, as the increasing availability of powerful computing resources enables accurate quantum-mechanics-driven simulations of drug candidates at previously unattainable speeds and costs.

Emerging large chemistry models aim to encompass vast drug discovery datasets, experimental protocols, and AI-driven automation. These platforms could enable scientists to request outcomes in natural language. The system would then design and execute the necessary synthesis and testing experiments, iteratively refining strategies based on results.

A NEW ERA FOR DRUG DISCOVERY

The integration of cutting-edge artificial intelligence with automated experimental platforms is no longer a theoretical concept; it's actively revolutionizing drug discovery. By seamlessly connecting predictive AI capabilities with the physical processes of chemical synthesis, testing, and analysis, these advanced systems are transforming the iterative DMTA cycle.

This synergistic approach allows researchers to obtain optimized drug candidates in months instead of years, significantly reducing both time and cost. Such platforms are demonstrating that AI-enhanced, automated drug discovery can finally break through long-standing bottlenecks, ushering in faster, smarter, and more cost-effective pathways to life-saving therapies. ■

HOW AI IS TRANSFORMING PHARMACEUTICAL RESEARCH WORKFLOWS

The pharmaceutical industry operates at the frontiers of science and medicine, but it faces daunting challenges as the pace of knowledge creation accelerates. With millions of scientific articles published annually and regulatory demands only growing, researchers and organizations are feeling the strain. Artificial intelligence (AI) is increasingly shaping workflows, helping companies streamline operations and enhance the pace of scientific breakthroughs.

This summary explores key challenges in pharmaceutical research, ways AI-powered solutions such as AI-driven solutions can address these issues, and the practical benefits that AI-powered tools can provide.

THE COMPLEXITY OF PHARMACEUTICAL RESEARCH WORKFLOWS

Pharmaceutical companies rely on meticulous research and evidence-based decision-making, but the complexities of working with vast and fragmented data lead to significant obstacles.

Core Challenges

- **Information Overload:** The volume of scientific literature is astonishing. In 2022, there were 3.3 million articles published globally in science and engineering, a 59% increase from a decade earlier. Staying updated on relevant studies amidst this flood of data overwhelms researchers and consumes valuable time.
- **Disjointed Systems:** Traditional literature management involves scattered workflows across multiple platforms, causing inefficiencies, poor collaboration, and frustration. Researchers often toggle between 8 to 12 separate systems just to gather, review, and cite materials.
- **Regulatory Pressure:** With patient safety a priority, pharmaceutical companies must rigorously document and comply with regulatory standards across various jurisdictions. Failures in citation accuracy or reference management can lead to missed deadlines, penalties, or credibility issues.

Smaller biopharmaceutical firms struggle to meet deadlines with fewer resources, while larger companies can find themselves navigating bureaucratic inefficiencies. In both cases, there is a clear need for more effective workflows.

HOW AI BRIDGES THE GAP

AI is becoming a critical tool for addressing these challenges. McKinsey & Company estimates AI advancements could unlock up to $1 trillion in potential value for healthcare operations. AI's ability to automate labor-intensive processes, analyze large data sets, and manage documents at scale paves the way for significant improvements in pharmaceutical research.

Key Benefits of AI in Research

- **Accelerated Literature Discovery:** AI solutions can scan and summarize vast amounts of scientific literature in moments, saving hours of manual effort. Tools using natural language processing (NLP) also help refine searches, ensuring researchers surface relevant studies they might otherwise miss.

- **Streamlined Data Management:** Centralized platforms enabled by AI consolidate data and workflows, allowing researchers to organize, annotate, and share insights without switching between numerous applications. Dashboards simplify data visualization, so teams can focus on actionable insights rather than combing through dense reports.
- **Improved Compliance and Accuracy:** AI supports regulatory compliance by automating citation generation and document tagging, helping to reduce errors and maintain information integrity. Sophisticated algorithms can also trace data provenance, ensuring the quality and ethical use of research sources.

APPROACHES TO AI-POWERED LITERATURE MANAGEMENT

AI can be integrated thoughtfully into pharmaceutical research processes to tackle many of the most common literature workflow challenges. Tools like ReadCube, for example, offer AI-powered features that support literature management and enhance the efficiency of research workflows. These approaches provide researchers with resources to manage information more efficiently.

Selected Capabilities

- **Centralized Reference Library:** Scientific literature can be brought into a single, searchable space, simplifying organization and retrieval. Integration with extensive databases helps facilitate access to a broader range of documents and insights.
- **AI-Supported Review:** AI functionalities can assist in identifying patterns, summarizing findings, and connecting information across studies. Users can interact with documents to clarify complex concepts and gain a deeper understanding of the research landscape.
- **Automated Content Alerts:** Literature monitoring and alerts help teams stay informed as new research emerges, supporting ongoing awareness in rapidly evolving fields.
- **Workflow Support:** Tools for annotating documents, managing evidence protocols, and building consistency in regulatory documentation support teams as they align their research processes.

Building Transparency and Collaboration

By supporting human oversight, AI-driven approaches can enhance researchers' decision-making while maintaining transparency in the use of AI. These systems are designed to supplement expertise, allowing users to extract greater value from their existing workflows without replacing the core knowledge brought by scientific teams.

DRIVING PROGRESS WITH AI

Across the industry, artificial intelligence is accelerating progress in drug discovery, regulatory compliance, and day-to-day research operations. AI reduces time spent on routine or repetitive tasks and helps teams focus on high-impact work. Examples such as the rapid development of the Moderna COVID-19 vaccine highlight the transformative potential of AI in pharmaceutical research. By effectively incorporating AI tools into their operations, pharmaceutical companies can improve efficiency and adapt to an ever-growing body of scientific knowledge. ■

Discover How AI Can Revolutionize Research

For a deeper exploration of how AI is shaping pharmaceutical research and practical strategies for implementation, read the full white paper, How AI Can Drive Smarter, Faster Pharmaceutical Research Workflows. Read the full white paper now.

CAUSAL GRAPHS: A BLUEPRINT DRIVING DRUG DISCOVERY FROM SINGLE-CELL OMICS

Understanding causality in a cell, mapping causal graphs from gene regulations to cell phenotype inside a patient's microenvironment is a fundamental but daunting challenge. Pinpointing true causal drivers of disease pathology and drug action is vital for drug discovery. Traditional methods focus on statistical correlations. However, as Judea Pearl noted "Correlation is not causation", underscoring the need for explicit causal models.

SINGLE CELL DATA AS THE FOUNDATION FOR CAUSAL DISCOVERY

Causality at the cellular level is difficult to establish because biological systems are highly heterogeneous; a causal link may hold in one cell state, tissue, or patient but not another, and averaging mixed populations can mask or invert true effects. Single-cell omics counters this by capturing each cell's molecular state, enabling observation of gene-activity variation across thousands of cells and supporting inference of directionality. A few 100-plus-million-cell atlases including multiple species and cell lines have been released within the past year.

DILEMMA BETWEEN INTERVENTIONAL AND OBSERVATIONAL DATA

In AI terms, we can approach causal learning in two broad ways: (1) using interventional (perturbation) data to directly induce and observe effects, and (2) relying on purely observational data across multiple conditions with appropriate assumptions. Interventions break spurious correlations and yield explicit cause–effect samples, whereas observational data retain the native patient microenvironments.

Hard (known-target) interventions: Experiments that actively perturb a known factor (eg. CRISPR knockout of a specific gene) impose a well-defined do (X=x) operation. Each perturbed cells then provides a labelled cause-effect pair. Incorporating hard interventions present the most straight forward way to directly identify causal edges since the intervention breaks dependencies implied by noncausal paths.

Soft (unknown-targets) interventions: In other settings, the exact intervention targets are unknown or indirect (e.g. small molecule, stress etc.). These "soft" interventions perturb the system's mechanisms without specifying which variables are directly targeted. Recent theory shows that soft interventions are statistically indistinguishable from multi-environment observational data under certain assumptions [1]. In other words, though still more informative than single environment observational data, soft intervention almost offers no more identifying power than observational data gathered across independent environments.

One challenge of interventional studies is transportability, which is far from default. Because direct perturbations in patients are impossible, researchers use proxy systems (cell cultures, organoids, patient-derived cells), yet causal effects learned there does not transfer to patients natively. Bareinboim and Pearl formalize this— one must encode how the environments differ to know which causal effects can transfer. If the target environment is "drastically different", then "nothing can be learned" from the source experiments without additional assumptions. Additionally, large-scale hard-perturbation datasets remain expensive: total human perturb-seq scRNA-seq datasets top out at low tens of millions of cells— minimally one order of magnitude below observational data. Further scaling will depend on broad collaboration and open data sharing. Companies such as Xaira Therapeutics, Cellarity, and others have been actively building interventional database for novel mechanism discovery and target identification.

Observational Data: Majority of biological data is intrinsically observational, meaning no variables have been actively "do"-perturbed at the time of measurement. These data collected directly in the patient context inherently avoids cross-context mismatch and for causal discovery, there is no domain shift to correct for. However, while these observational data offer clues, traditionally they often recover the adjacency skeleton and remain ambiguous on direction of causal graphs unless strong assumptions are imposed. Recent theoretical development has significantly changed this perception. Pooling purely observational data from diverse environments/domains —different laboratories, tissues, or batches—creates a set of distinct distributions and can break more symmetry and providing additional edge orientation constraints for causal discovery. Under the Markov property, pooling these environments is formally equivalent to analyzing a single domain collection of soft interventions with unknown targets [1]. Though intrinsically, the approach does not demand larger sample counts, in practice more data would be needed to obtain statistical power.

Driven by these insights, Synlico employs AI models using causal-graph representations as the backbone to pinpoint disease-driving interactions, nominate novel targets, and design mechanism-guided therapies, integrating causal discovery and inference, generative modeling, and single-cell bioinformatics. To supply the required diversity and statistical power, we aggregate large-scale primary patient scRNA-seq datasets—more than 100 million cells from over 18 000 patients—as separate observational "domains". This pooled data enables mapping of context-specific gene–gene edges, and prediction of how perturbing a driver gene reverberates through downstream pathways.

DATA VS. AI MODELS: CO-ADAPTIVE SYNERGY

Biotech and AI circles debate whether progress hinges on richer single-cell data or stronger algorithms; in practice, they co-evolve—sound data prevents mis-inference, while better models extend what can be learned. Interventional datasets have long been the gold standard for causal identification, but recent theory has also elevated observational data with natural variation. Because each causal-AI framework rests on distinct assumptions, companies match their stacks to their data type—hard & soft interventions, or purely observational data.

OUTLOOK: TOWARDS CAUSAL MODELS FOR PRECISION BIOLOGY

The field still lacks a standardized single-cell perturbation–response atlas. Such shared benchmarks create a common objective function, and power leaderboard-style iteration that tightens the loop between design and validation in the community. Integrating multi-omics—especially spatial layers—promises to resolve causal ambiguities and move to spatial model. Yet, these are not automatically "better". The experiments tend to produce sparser data for each modality with additional computational complexity for integration. As these tools mature, causal graphs will steer experiment selection within closed-loop "predict-perturb-learn" cycles, shortening the path from hypothesis to mechanism. This is especially valuable for rare diseases: it transfers causal relations learned in larger populations, clarifies which mechanisms generalize, and lowers the number of scarce patient samples needed. Precision medicine will shift to directly manipulating the molecular levers of disease, enabling smaller, smarter trials and a more rational pipeline for targeted therapies design. ■

FROM DATA TO DISCOVERY IN AI DRIVEN LIFE SCIENCES R&D

SPRINGER NATURE

By Saskia Hoving, Editor-in-Chief of The Link of Springer Nature

AI, big data, and deep scientific know-how are coming together in exciting ways, opening doors to faster drug discovery, smarter diagnostics, and more personalized treatments. But with all this potential, there are also some big questions to tackle. How do we keep up with evolving regulations? How do we make sure data is used responsibly? And how can experts from different fields work better together? In this article, we look at how AI is changing the game in life sciences R&D, with insights originally shared on Springer Nature's The Link.

TURNING INFORMATION OVERLOAD INTO INSIGHT

One of the most powerful applications of AI in life sciences is text and data mining (TDM). Researchers today face an overwhelming volume of scientific literature, patents, clinical trial data, and regulatory documents. TDM tools, powered by natural language processing (NLP), allow scientists to extract meaningful insights from this vast information landscape.

For example, TDM can identify previously unknown relationships between genes, diseases, and compounds by analyzing thousands of publications in minutes. This capability not only accelerates hypothesis generation but also supports evidence-based decision-making throughout the R&D process. These tools are becoming indispensable for information professionals and researchers alike. They enable a shift from reactive to proactive research strategies, where insights are surfaced before questions are even asked.

RETHINKING SCIENTIFIC WORKFLOWS WITH GENAI

Generative AI is quickly becoming a creative partner in scientific research. From drafting literature reviews and summarizing complex datasets to suggesting experimental designs, these tools help researchers save time and spark new ideas, especially in the early stages of discovery were speed and innovation matter most. But as these technologies become more integrated into research workflows, they also bring important questions to the forefront. How do we ensure the accuracy and reproducibility of AI-generated content? What are the implications for peer-reviewed publications, regulatory submissions, and even intellectual property? These aren't just technical concerns, they touch on ethics, policy, and the evolving role of information professionals. As a result, many organizations are beginning to craft internal guidelines to ensure these tools are used responsibly and effectively.

ACCELERATING DRUG DISCOVERY AND BIOLOGICS DEVELOPMENT

AI is making a major impact in drug discovery, especially in the fast-evolving world of biologics. Traditionally, bringing a new therapy to market could take over a decade and cost billions. Now, AI is helping to speed things up, predicting molecular interactions, identifying biomarkers, and optimizing compound selection with impressive efficiency. It's not just about faster results; it's about smarter, more targeted innovation. What really makes this work is collaboration. AI thrives on data, and the best outcomes happen when academic institutions, biotech firms, and pharma companies break down silos and share insights. By aligning data standards and working together, they're creating a more connected, data-driven approach to drug development, one that's not only faster but also more precise and scalable.

APIS AND THE INFRASTRUCTURE OF INNOVATION

To make the most of AI, organizations need the right digital infrastructure. APIs (Application Programming Interfaces), for example, are becoming essential tools for integrating AI into research workflows. They allow systems to communicate with each other, automate repetitive tasks, and provide real-time access to data.

This kind of infrastructure not only improves efficiency but also supports transparency and reproducibility, two key priorities in scientific research. As more organizations adopt these tools, we're seeing a shift toward more agile, collaborative ways of working.

CROSS-DISCIPLINARY THINKING DRIVES INNOVATION

One of the most powerful aspects of AI is its ability to transfer ideas across disciplines. Techniques developed in one area often lead to unexpected breakthroughs in another.In life sciences, staying ahead means not only having deep domain knowledge but also being open to insights from other fields. In materials science, AI helpsdesign new compounds. In finance, it's used to detect fraud and model risk. These examples offer valuable lessons for life sciences, particularly in areas like data integration, model validation, and ethical oversight.

Adopting best practices from adjacent industries can help accelerate innovation, avoid common pitfalls, and maintain trust and accountability. This kind of cross-disciplinary thinking is becoming a key driver of progress.

TOWARD RESPONSIBLE INNOVATION IN LIFE SCIENCES

As AI becomes more integral to life sciences, it brings not only powerful capabilities but also complex responsibilities. Issues like data privacy, algorithmic bias, and intellectual property are no longer theoretical, they're shaping how AI is built, trusted, and applied. Addressing these challenges requires more than technical solutions; it calls for cross- sector collaboration to develop ethical frameworks, regulatory standards, and best practices that ensure transparency, accountability, and fairness.

Springer Nature partners with research and development teams to support this journey. Through trusted tools, expert insights, and collaborative partnerships, we help organizations accelerate innovation and achieve impactful outcomes. For a closer look at how AI is reshaping early-stage drug discovery, don't miss our blog with insights from FRONTEO's Dr. Hiroyoshi Toyoshiba. ■

AI DRUG DISCOVERY & DEVELOPMENT FOR DNA DAMAGE RESPONSE (DDR) ONCOLOGY THERAPEUTICS

Irrespective of where one lies in the spectrum of Artificial Intelligence (AI) being real or too hyped, it is undeniable that massive growth in computing power and availability of massive amounts of data, has forever changed the AI field that now serves as an umbrella of a few sub-fields: data science/data analytics, machine learning/deep learning/neural networks and large language models. These results have deeply penetrated everyday lives, from casual online activities like shopping and movie recommendations to personal items like searching photo albums to offline activities like autonomous vehicles. Like technology companies, life sciences, drug discovery, drug development, medical science and healthcare companies have also joined the AI bandwagon.

In drug discovery and development, thanks to many years of development of public databases around biology, for example, genes and genomics; proteins and proteomics; target biology; and clinical trials; AI methods are being explored and applied for all components, including target discovery and validation, hit discovery, lead generation, preclinical studies, and clinical and regulatory studies. Our AI Drug Discovery/Design/Development (AIDD broadly) platform at Accelero Biostructures (Accelero) is founded on the use of protein-ligand interaction data from structural biology/co-crystallography on various drug targets, generated through our other platforms, in combination with other bioassay data on those targets. Much of the current AI on protein-ligand data involves the use of data from public databases, leading to AI models that lack diversity, uniqueness and negative data, all important components for training AI models. Our platforms generate high impact, target-specific, proprietary, positive and negative experimental data with good feedback loops that are critical for AI model training and optimization.

A decade (2015-2025) of California-based biopharma-directed high-throughput protein crystallography-based drug discovery at Accelero (1) is founded on 15 years (2000-2015) of experience in structural genomics (2), a field that was born following the human genome project and other genome sequencing projects (3), and which we performed at California-based Berkeley Structural Genomics Center (BSGC) (4) and the Joint Center for Structural Genomics (JCSG) (5). Massive structural genomics efforts to experimentally determine novel protein crystal structures to populate the Protein Data Bank (PDB) ultimately led to the success of AlphaFold (6).

Accelero's AIDD focus is on early drug discovery and development to rapidly accelerate hit-to-lead generation and for maximizing clinical success. A critical part of this is to generate novel positive and negative experimental data that can be used for training and refinement of AI models to then use them for predictive optimization of chemical entities that can be quicker and more successful as they go through discovery and development. Our generation of novel data starts with proprietary experimental data on protein-ligand interactions from protein X-ray crystallography-based screening and co-crystallography of compounds bound to drug targets, which then feeds into partner drug discovery programs, for example, at XPose Therapeutics (7), and Legend Innovation Life Science Fund (8), that generate other streams of proprietary experimental data.

Specifically, as in the title of this article, this feeds into the AIDD program of one of our partners, XPose Therapeutics (XPose), focused on the discovery and development of novel inhibitors targeting DNA Damage Response (DDR) for oncology therapeutics. Cancer cells respond to increases in DNA damage, from elevated metabolism or exposure to therapeutic genotoxins, by upregulating their DDR. Several DDR pathways, each with multiple proteins, repair DNA damage in cancer cells, thereby prolonging cancer. Targeting DDR is a viable strategy in the treatment of cancer in both combinatorial therapies and monotherapies involving cancer-selective synthetic lethality. Despite immense potential of targeting DDRs, only a few targets are currently clinically

(PARP1) or near-clinically targeted (for example ATM, ATR, WRN), highlighting challenges in targeting DNA-binding DDR proteins (larger binding surfaces, charged), including nucleases, helicases, polymerases and transcription factors, proteins often refractory to drug discovery or “undruggable”. Our AIDD, coupled with other new and conventional drug discovery approaches, has the potential to propel DDR drug discovery to advance additional targets. XPose generates novel experimental data including new compounds; in vitro biochemical, biophysics, cell biology and ADME/PK assays; and in vivo data. Our data on diverse DDR targets, differentiated due to data novelty including protein-ligand structural data, will ultimately narrow the development path responding best to DDR inhibitors. We already see promising results with target APE1 in high-grade serous ovarian cancer. ■

TRANSFORMING NEUROTHERAPEUTIC DISCOVERY WITH AI AND HUMAN BRAIN ORGANOIDS

Brain diseases are the leading cause of disability and second-leading cause of death worldwide, a burden expected to double within 20 years. Yet despite decades of research, disease-modifying therapies remain out of reach for most neurological disorders due to the inability of traditional disease models to predict clinical success. At BrainStorm Therapeutics, we are leveraging artificial intelligence (AI) to tackle this challenge head-on. By combining advanced AI with human mini-brain models, we are accelerating the discovery of precision therapeutics for disorders such as Parkinson's disease, Alzheimer's disease, and epilepsy.

AI MEETS HUMAN BIOLOGY

Our platform takes a biology-first approach. We generate brain organoids: 3D "mini-brains" derived from patient stem cells. These organoids faithfully replicate disease-relevant cell types and neural circuits, offering an unprecedented window into human brain biology.

We use our brain organoids to generate single-cell RNA sequencing, high-content imaging, and functional network activity datasets. These rich biological datasets allow us to train multimodal AI models to map gene expression, track disease-related pathways, and uncover new therapeutic targets, many of which would be missed by conventional drug discovery approaches.

In our recent collaboration with NVIDIA, we adapted cutting-edge AI foundation models like scGPT and Geneformer to create high-resolution gene co-expression networks. This approach allows us to predict disease progression and identify dysregulated pathways associated with neurological disease. As highlighted in a recent NVIDIA blog, this AI-biological feedback loop enables faster, more precise experimental design and target discovery for validation in brain organoids.

PARKINSON'S DISEASE AS A PROOF-OF-CONCEPT

We've applied our AI-powered platform to Parkinson's disease (PD), the second most common neurodegenerative disorder. People with PD still rely on symptomatic treatments that haven't changed in decades and offer only mild, temporary benefits that wane over time. Research progress has long been hindered by the inability of animal models to capture the disease's human-specific complexity.

To overcome this, we developed midbrain organoids derived from patients with pathogenic GBA1 mutations, the most common genetic risk factor for PD. These organoids exhibit hallmark PD features, including dopaminergic neuron loss and impaired dopamine secretion. Analysis using our AI foundation model approach revealed dysregulated gene networks related to cell cycle, neurogenesis, and synaptic signaling, mirroring results from post-mortem brain tissue of idiopathic PD patients. The organoids also showed detects in lipid metabolism, demonstrating the ability of this model system to capture both generalizable and mutation-specific disease mechanisms. Our approach revealed potential therapeutic targets for PD, including several known GWAS hits as well as novel candidates.

Our drug discovery engine functions as a "clinical trial in a dish," providing actionable insights into PD mechanisms and enabling in silico simulations of drug response. By integrating patient-specific biology with predictive AI, we aim to develop precision therapeutics that can prevent, halt, or reverse PD.

A PLATFORM FOR PRECISION NEUROSCIENCE

Our platform enables us to:

- Map disease-relevant gene networks and prioritize therapeutic targets
- Perform virtual screening of candidate therapeutic targets
- Identify shared and divergent mechanisms across brain diseases
- Stratify patients by molecular subtype for more targeted clinical trials

Through an ongoing collaboration with the CURE5 Foundation, we're currently applying this platform to discover new therapeutics for CDKL5 Deficiency Disorder, a rare genetic form of epilepsy. Our long-term goal is to build a multi-modal AI platform that bridges the gap between organoid biology and patient phenotypes.

ALIGNING WITH INDUSTRY TRENDS

The biopharma industry is undergoing a notable shift: biopharma M&A and licensing deals are increasingly focused on preclinical early-stage startups and assets. Recent transactions—such as Mitokinin/AbbVie, Caraway/Merck, and Aliada/AbbVie—reflect a growing appetite for preclinical-stage assets.

This trend is driven by both scientific opportunity and market necessity. With patent cliffs approaching and R&D productivity under pressure, pharmaceutical companies are increasingly turning to early, de-risked innovation to sustain their pipelines.

In this shifting landscape, platforms like ours that are rooted in human biology and AI are becoming increasingly important to how new drugs are discovered and developed.

REDUCING RISK, COST, AND TIME

Brain diseases remain one of the highest-risk areas in drug discovery, with clinical trial failure rates exceeding 90%. There are no disease-modifying therapies currently approved for PD or other common neurodegenerative diseases.

By introducing human relevance at the earliest stages of discovery and applying AI to de-risk target selection, we are reducing both the timeline and cost associated with early R&D, while increasing the odds of success in the clinic.

LOOKING AHEAD

At BrainStorm Therapeutics, we believe the future of neurotherapeutics lies at the intersection of AI and human biology. By uniting these technologies, we're creating a new blueprint for understanding and ultimately treating some of the most challenging diseases of our time. ■

POWERHOUSES AND FOODSTUFF

There are few things that solidify a reputation better than a sticky nickname. In 1957, Philip Siekevitz observed that the mitochondrion is "a small body which appears to play a central role in the oxidation of foodstuff," and as such, he dubbed the mitochondrion the powerhouse of the cell. In the 68 years since that report, we have learned that these small bodies are more than just foodstuff oxidizers. They are also highly dynamic organelles that dictate cellular fates downstream of a wide array of nutrient, energy, or stress signals. Mitochondria are essential, but mitochondrial efficiency and regulation are especially critical in tissues with high metabolic demands such as muscle, heart, and brain. As we age, those energy-demanding tissues accumulate decades of small, unresolved stresses that can tip our mitochondria towards dysfunction. While we can't go back in time, we believe we can use AI to mitigate the effects of aging and age-related pathologies by directly targeting mitochondrial dysfunction.

Mitochondria continuously react to their environments by rapidly modifying how they look, where they go, when they get there, and how much energy they need to get the job done (sidenote: this feels like an analogy to parenthood). With all of these critical functions, it isn't surprising that a little dysregulation or lapse in maintenance can devolve into pathological conditions, especially when amplified over time. It is also easy to imagine the scale of dynamic cellular responses that correlate with these changes, and in that realization, we have to acknowledge that the dimensionality of traditional cell biological assays is insufficient to resolve the mitochondrial behaviors that drive age-related diseases.

For example, single endpoint assays, such as those that measure viability or cell death, are designed to assess acute, non-sustainable cellular states. To assess biological phenomena such as prolonged mitochondrial dysfunction, we instead need assays with high-dimensional readouts that are representative of persistent states of cellular health. We have therefore built our mito-centric platform around a live fluorescence imaging assay that captures cellular compartments and features, and coupled that to temporally linked omics data. Importantly, these datatypes are target-agnostic, so we can use machine learning to train multi-modal fingerprints of mitochondrial behavior without biases towards specific pathways or functions.

Much like the crime drama CSI (only without the drama), we will match these AI-generated mitochondrial fingerprints to generalized profiles from a large cohort of patient sample data. This will allow us to identify in vitro cellular states associated with mitochondrial dysfunction that closely resemble human diseases. Using the experimental conditions that are most representative of real world human health conditions, we will then test a series of in vitro treatments that mimic real world human drug responses.

In CSI, this looks something like feeding data into a computer, saying "enhance" a few times, and getting our answers. In reality, however, training AI models that generate accurate outputs (and not word salad) hinges on our ability to (1) generate data that are optimized for AI model training and representative of human physiology, and (2) analyze those data using AI while adhering to the scientific method.

In classical cell-based assays, we can designate positive and negative controls at either end of a spectrum and plot test conditions along that spectrum to look for drug-dependent shifts. This becomes more complicated as we add layers (or dimensions) of data, and so to generate AI-ready data, we must be thoughtful in how we design our experiments and analytical workflows. To this effort, there should be control conditions and quality metrics implemented that can be used to identify batch effects, experimental variability, or potential confounding factors.

These are critical for understanding whether downstream model performance is driven by biologically relevant effects rather than plate, date, or donor dependent ones. And while we need to minimize experimental variability, we should simultaneously maximize human variability and generate a sufficient amount of high quality data to encourage models to differentiate conditions by generalizable and biologically relevant features. Thus, biological controls that allow us to implement normalization strategies across experiments, plates, and donors should be included in experiments so that trained models more accurately represent the underlying biology.

Bearing the above in mind, it is important to remember that not all data are suited for model training, and not all of their subsequent outputs tell us what we think they do. For example, models trained to identify healthy or diseased states can get confused when encountering cells that are very different from everything in the training data. In biology, this can happen frequently with compound treatments or cell perturbations that shift cells to unknown states. If we don't have a means, such as anomaly detection or off-basis measurements, to remove such data, then we should expect model outputs to be populated with a mixture of accurate predictions and total misses.

Ultimately, AI can be an incredibly powerful tool to build profiles of complex biological states in an automated and unbiased way, but only if we can generate data that are optimized for AI analysis. AI (at least in its current form) is incapable of hypothesis generation and testing, so to maintain scientific rigor and progress, AI outputs need to be interrogated and held to the same standards as all scientific analyses. We therefore must encourage close collaborations between scientists and engineers for experimental design, analytical workflows, and model validation.

Mitochondrial dysfunction has been causally linked to aging and age-related diseases, yet it has historically been difficult to establish preclinical human-relevant systems that accurately capture sustained, pathological mitochondrial behavior. Recent progress in AI now enables us to generate profiles of functional cellular states from high-dimensional datasets that are representative of human health. By following the guidelines outlined above, we can apply these AI advances to develop effective mitochondrial therapeutics that unlock the power of our little powerhouses and maximize our health as we age. ■

HOW AI AND HIGH-THROUGHPUT LIBRARY GENERATION ARE ACCELERATING ANTIBODY DISCOVERY

By Emily Leproust

Therapeutic antibodies have a powerful impact on human health. These medicines are revolutionizing how we treat cancer, autoimmune diseases and many other conditions. Because antibodies can have such high affinity for their therapeutic targets, they offer tremendous promise to improve care.

Still, antibody drug development is a hard road. There are a massive number of potential molecules to choose from. The human body can create as many as 10^{20} distinct antibodies. To put that in context, there are roughly 10^{23} stars in the universe.

This impressive diversity underscores why antibodies play such critical roles in human immunity, but it also makes identifying suitable molecules incredibly challenging. Finding a needle in a haystack would be far easier.

Fortunately, AI is evolving into a powerful tool to accelerate and de-risk antibody drug development. Biopharma companies are actively developing AI tools that can help them narrow their choices, making it easier to identify potential therapeutics.

This is where Twist comes in: to translate digital to physical. Turning a sequence design into validated data at scale enables the ability to cull this massive universe of molecules to find the handful that are readily developable and possess therapeutic value. Conducting these studies in silico, rather than in the lab, dramatically accelerates our ability, as a global industry, to create valuable therapies for patients in need.

IDENTIFYING THERAPEUTIC ANTIBODIES

At Twist, we provide the enabling materials, including DNA, proteins, antibodies and data that help therapeutic development companies take potential treatments to the clinic. Now, increasingly critical in this evolving ecosystem, is our ability to generate high quality characterization data in very high-throughput.

Going back to the 10^{20} problem, one of the most powerful things we can do is help companies narrow that funnel. Because Twist can write DNA at scale, we can build incredibly large libraries that routinely exceed one trillion distinct sequences. As our customers use AI to generate antibody sequences, we can build libraries with the specific sequences that they need and generate both positive and negative training data for refinement of their AI tools. Furthermore, Twist can produce and generate data for thousands of distinct sequences arising from de novo designs, library screening, or any other output, including but not limited to in-depth binding and developability (Tm, Tagg, polyreactivity, etc.) characterization. Screening and drug selection at this scale was previously only possible for small molecules, but Twist enables this for large molecules (proteins and antibodies).

AI is not a magic wand that can solve all of biopharma's antibody challenges. And cannot predict whether a specific antibody will become a successful drug. It also cannot provide straight yes or no answers about a molecule's developability, but rather, can provide probabilities. Human judgment will always play a crucial role in these decisions. However, AI increases the number of high-quality shots on goal and becomes increasingly important to de-risk the decision making around whether an antibody has the necessary qualities to warrant further development.

Streamlining this workflow is having a profound impact on cost and throughput of the early stages of antibody discovery. We believe this process will ultimately shorten the time and increase the probability of success for taking a program from a concept to an approved medicine.

PROVIDING THE DATA THAT TEACHES BIOPHARMA MODELS

To be clear, we do not currently build the computational models biotech and pharma companies use to delineate the best possible antibodies – we provide the data that informs those models.

We bring value in combining high-throughput protein and antibody expression, purification and analytics under a seamless process and business model. Because we can create and characterize tens of thousands of antibodies and have plans to expand this, we are poised with the ability to give the industry the tools to build their high-quality models.

In other words, we create the data that creates the model that creates the drug that addresses the disease that positively affects our goal of expanded global health. ■

BEYOND EXPECTATIONS: TRANSFORMING LIFE SCIENCES WITH AI-POWERED MULTI-OMICS INTEGRATION

By Suyash Bagad, Consulting Associate

AI MEETS MULTI-OMICS: UNLOCKING THE FUTURE OF MEDICINE

Artificial intelligence (AI) is fast becoming the engine of innovation in life sciences. What was once a futuristic promise is now a practical necessity, streamlining drug discovery, expediting clinical trials, and enabling highly targeted therapies. But the real frontier? The fusion of AI with multi-omics—genomics, proteomics, metabolomics, and transcriptomics—to unlock predictive, precision medicine at scale. Multi-omics data provides a systems-level understanding of disease biology. When layered with AI, these datasets are no longer just descriptive—they become diagnostic, prognostic, and therapeutic tools. Companies like SOPHiA GENETICS, Foundation Medicine, and Tempus are leading this transformation, integrating disparate omics streams into unified insights that help decipher disease progression and optimize intervention points.

PRECISION MEDICINE IN ACTION

Precision medicine aims to tailor treatments to an individual's unique biology, and multi-omics makes this possible. By analyzing multiple data layers, clinicians can now identify molecular signatures that predict disease onset or therapeutic response with a degree of specificity previously unattainable. Consider Avenda Health's Unfold AI—an advanced tool that maps prostate cancer spread to avoid unnecessary gland removal. Or Deep6 AI, now part of Tempus, which has revolutionized patient recruitment, cutting timelines by up to 75% by matching patients to trials using AI-based clinical records mining. These technologies do more than optimize processes—they directly impact lives.

THREE LEVERS TO SCALE IMPACT

For stakeholders across life sciences, realizing the full potential of AI-driven multi-omics requires action on three strategic fronts:

1. Unified, Modular AI Platforms. Design end-to-end systems that ingest, clean, integrate, and analyze omics data at scale. These platforms must support real-time feedback loops to refine predictions as new data flows in. The goal: make insights actionable, not just academic.

2. Build Data Ecosystems That Collaborate, Not Compete. Data remains fragmented. Solving this requires consortium-style collaboration between hospitals, academia, industry, and payers.

Prioritize:

- Longitudinal and diverse patient data
- Standardized data entry and labeling
- Shared governance models

Done right, these ecosystems can power everything from predictive diagnostics to evidence-backed reimbursement models.

3. AI-Augmented Clinical Decision Support (CDS)
Embedding AI into clinical workflows is key. Real-time analytics can flag risk earlier, guide personalized care, and enable precision dosing. Agentic AI—systems that independently pull, clean, and analyze data—are already being utilized to accelerate HEOR, market access, and commercialization workflows on a pilot basis, demonstrating the potential for these AI systems to enhance productivity across the healthcare value chain.

THE REGULATORY AND ETHICAL BALANCING ACT

Rapid innovation has outpaced regulation. AI doesn't fit neatly into traditional clinical validation frameworks, especially when models are updated continuously. This regulatory lag breeds uncertainty, and frequent shifts in health policy risk scaring off investors—even from high-value ventures.

Meanwhile, AI systems are only as unbiased as the data they're trained on. Underrepresentation of diverse populations can skew insights, compromising equity in care. Addressing this is not optional—it's foundational.

Key steps forward:
- Engage regulators early to co-create adaptive policies
- Create in-house ethics boards to monitor bias
- Support global standards through public-private partnerships

Embedding transparency and fairness from the outset will separate the market leaders from the laggards.

THE NEXT WAVE: WHAT'S COMING

We're just scratching the surface. Emerging tools like HEOR-focused large language models (LLMs) will soon synthesize outcomes and potential pricing data to support real-time payer negotiations. Personalized digital twins—AI-generated replicas of patients based on multi-omics and clinical data—could simulate treatment outcomes before any drug is administered.

And interoperability is on the horizon. Future platforms will span the full healthcare value chain—from research to bedside to billing—breaking down silos and enabling more adaptive, responsive systems.

Organizations that prioritize AI literacy, invest in scalable infrastructure, and create agile governance frameworks will find themselves at the forefront of this revolution. In the near term, the optimal use of AI will not come from replacing human expertise but from augmenting it. Given the current limitations of AI—such as hallucinations and lack of context-specific judgment—embedding human oversight is not only prudent but necessary. Strategic integration, rather than unchecked automation, is what will ensure safe, effective, and trustworthy deployment of AI in life sciences.

CONCLUSION

The fusion of AI and multi-omics is not a distant future—it's unfolding right now. What's needed is vision, cross-sector collaboration, and a relentless focus on ethics and equity. If we get it right, the future of healthcare won't just be personalized. It will be predictive, precise, and profoundly transformative. ■

FROM PAPER TO PREDICTIVE: 3 WAYS AI IS POWERING SMART MANUFACTURING IN BIOPHARMA

KATALYZE AI

By Reza Farahani, CEO at KatalyzeAI

Smart manufacturing is the promise everyone is pursuing, but few have operationalized at scale. The term shows up at every life sciences conference, often paired with buzzwords like Industry 4.0, digital twins, or automated orchestration. But step inside a real biopharma plant and you'll likely see something different. Batch records on paper. Deviations logged in Word docs. Raw material specs emailed as scanned PDFs. This is not smart, but rather slow and reactive. It reflects a fundamental disconnect between R&D innovation and how drugs actually get made. So let's ask the real question: What does smart manufacturing actually mean for biopharma?

According to ISPE (International Society for Pharmaceutical Engineering), smart manufacturing is "the integration of digitalization and automation across all stages of the pharmaceutical product lifecycle, connecting processes, people, and data to enable faster decision-making, real-time control, and improved production processes." It emphasizes regulatory compliance, operational transparency, and adaptability, cornerstones for accelerating therapeutic innovation and improving patient outcomes.

STEP ONE: START WITH VISIBILITY

Every intelligent system begins with visibility. Yet in biologics manufacturing, much of the information needed to operate effectively is missing in action. Not because it was never recorded, but because it was trapped in documents no one can use.

Consider where critical knowledge actually lives:

- 80-page PDF batch records
- Scanned deviation investigations
- Paper-based QC logs
- Supplier COAs sent as attachments

These are not searchable. They are not connected. And they certainly are not feeding your models in real-time. This is where AI becomes essential. At Katalyze AI, we built Digityze AI to transform these unstructured documents into structured, GMP-grade data, not just for archiving but for real operational decisions. What was previously buried in PDFs is now accessible, traceable, and usable across the entire plant floor.

STEP TWO: UNDERSTAND WHAT MATTERS BEFORE IT BREAKS

Smart manufacturing is not just about sensors or predictive maintenance. It is about understanding cause and effect before deviations occur. The goal is to stop treating symptoms and start recognizing root causes early.

AI makes this possible by revealing patterns that were previously invisible:

- A three-degree temperature rise during fermentation correlates with a specific raw material lot from a single supplier
- A deviation on Line 4 matches trends buried across seven months of production history
- A yield drop at Site A mirrors an issue flagged at Site B the previous quarter

When these connections surface in real time, operations become proactive instead of reactive. Teams are no longer chasing problems. They are preventing them.

STEP THREE: SCALE INTELLIGENCE WITHOUT REBUILDING YOUR FACTORY

Traditional upgrades often assume you have the time and capital to redesign your manufacturing site from the ground up. But most biopharma companies are operating within legacy infrastructure, limited bandwidth, and tight compliance constraints. Smart manufacturing should not require a new plant. It should make your current plant smarter.

This is why Katalyze AI was designed to integrate with existing systems. It integrates with current MES, LIMS, and SCADA systems. It extracts insights from years of historical documentation without requiring a complete data lake or custom configuration. It equips engineers with practical guidance, not more dashboards. As one of our customers said, “Before, we had data. Now we have answers.”

THE HUMAN MULTIPLIER

Smart manufacturing helps people free their time to focus on what matters most. Instead of spending hours digging through paperwork or investigating past failures, engineers can spend time optimizing future batches.

Imagine a world where:

- Engineers focus on innovation rather than troubleshooting
- New hires can access decades of process knowledge on day one
- Investigations take hours instead of weeks

This is what happens when domain expertise is paired with AI-driven insights. Tribal knowledge becomes institutional knowledge. Process optimization becomes continuous. The factory starts learning.

WHY NOW

Biopharma is not just producing drugs. It is delivering cell therapies, gene therapies, and personalized biologics. These are complex to make, expensive to scale, and highly sensitive to variability. The margin for error is shrinking. The cost of inefficiency is growing.

Smart manufacturing is no longer a nice-to-have. It is how we keep up with scientific progress.

And here is the truth: you do not become a smart manufacturer by adding more sensors or buying new equipment. You get there by finally understanding the data you already have but cannot see. AI gives you the eyes to find it, the structure to use it, and the insight to act on it.

This is what smart actually looks like. ■

About the Author

Reza Farahani is the CEO and founder of Katalyze AI, a CLS member company pioneering AI-powered solutions for biomanufacturing. With a background in engineering and machine learning, Reza focuses on transforming slow, manual production systems into intelligent, adaptive operations using existing infrastructure and data.

MAXIMIZING CLINICAL TRIAL ACCESS WITH AI

By Jack Owens

Clinical trials make a salient barrier to the drug approval process for pharma and biotech companies. Upwards of 70% of investor funding at pharma and biotech startups is allocated toward the clinical approval process, and it takes an average of 10-15 years and $1-2B to bring a drug to market. Within the clinical pipeline, a significant bottleneck is patient recruitment and retention. Despite the fact that suitable trials exist for 85% of patients whose most viable treatment option would be a clinical study, nine in ten trials still fail to meet their enrollment timelines, and more than a quarter of research sites fail to enroll even a single participant. Meanwhile, patients are faced with an arduous process to find a clinical trial that both targets their specific condition and has eligibility requirements that they satisfy, all the while faced with an impending deterioration in their health.

The primary database patients have to search for clinical trials, ClinicalTrials.gov, does not offer an easy way for patients to locate trials based on their specific background. Searches on ClinicalTrials.gov are often based on keywords that are arbitrarily chosen by researchers who enter trial information into the website, making it easy to overlook relevant studies. Search results are not organized based on any apparent relevance, making it difficult to decide on a trial without further investigation. Furthermore, the search feature provides minimal means to rule out trials for which the patient would be ineligible. Sex and age are the only inclusion and exclusion criteria a user can easily tailor searches to, and other eligibility criteria, much like with keywords, are not standardized across studies. Ultimately, users have to carefully review eligibility criteria line by line in order to determine whether a study is relevant or not. Patients who consult with doctors to search ClinicalTrials.gov for them rarely receive consistent recommendations, often getting completely different sets of trials from each.

When patients instead seek direct referrals to clinical studies, most doctors do not have specific trials to recommend, and tend to refer patients to large institutions with strong reputations that aren't necessarily running the most suitable trials. The only truly effective option to find a trial is by hiring an expert to spend hours searching for and reviewing studies by evaluating the results of preclinical and previous study phases, perusing drug companies' financial information that may suggest positive unpublished findings, identifying each study's specificity to the patient's particular ailment, and comparing trials to successful past research — a very costly process that still is not guaranteed to identify the most optimal studies.

Icarus Therapeutics is a TechBio startup developing an end-to-end platform for both the provider and site facing sides of clinical recruitment that leverages large language models(LLMs) to rapidly digitize patient records and clinical documentation with a core matching engine that uses said data to automatically pair patients with trials and also provide detailed reasoning behind each referral, allowing for a user-friendly review and final decision on every match. Through the use of natural language processing (NLP), what had previously required days to weeks of careful review by multiple research site employees can be done in a fraction of the time without any direct human involvement. 80% of patient data is found in doctor's notes, which have minimal structure and consistency across a patient's journey. The unstructured and text-heavy nature of this data makes it ripe for analysis with NLP. In addition to patient data, LLMs can also expedite the analysis of trial documentation. Clinical trial protocols outline all aspects of a study and come in the form of large text documents. These protocols can be up to hundreds of pages long, which makes evaluating trials by humans a grueling process on both sides of recruitment. LLMs also come into play within the matching engine, used for cross checking trials' extensive eligibility criteria against thousands of patients quickly and for translating the internal logic behind each match into a human-readable format, helping to get around AI's black-box problem.

A common issue facing artificial intelligence and machine learning is that when a model is trained to recognize patterns in data, the internal rules it produces to accurately analyze inputs are often difficult to identify or explain. This lack of transparency raises many practical and ethical concerns, especially within a field as serious as healthcare. To address this problem, the Icarus Therapeutics' software provides a detailed synopsis behind every match it makes such that a human reviewer at a research site can always verify whether a particular patient is well-suited to their study, and a patient will have better access to information when consulting with their doctor to choose whether a particular trial is right for them.

While not a complete replacement for human decision making in selecting patients or trials, Icarus is a powerful tool that provides users with better information that will allow them to make more informed decisions within a shortened time frame. On the provider side, users can obtain a brief list of studies organized by relevance, each with a concise explanation as to why it's applicable, sparing them the taxing effort of sifting through thousands of clinical protocols and their supplementary information. On the site side, users can receive a highlighted description of every prospective patient's history as it relates to each trial, avoiding hours of meticulous review of patient medical records. With future prospects to incorporate more complex patient information such as genetic signatures and genealogy records and to provide insights beyond recruitment to allow real-time optimization of studies at sites, the working Icarus Therapeutics platform demonstrates AI's profound capacity to accelerate the drug discovery process through a highly user-friendly, end-to-end matchmaking tool.

TRAINING AI TO ACCURATELY IDENTIFY BIOMARKERS IN TUMOR BIOSPECIMENS

By Courtney Noah, PhD, and Daryl Waggott, MSc

Digital pathology is a rapidly growing field. Key to this growth has been the development of Whole Slide Imaging (WSI), the ability to scan traditional pathology biospecimens on glass slides and create high quality digital images which are easier to store, share with other medical professionals, and analyze using AI.

WSI paired with AI and machine learning models have opened new doors for image analysis leading to innovations in biomarker identification and diagnostic development. WSIs are essential for developing AI solutions in computational pathology as they provide a digital, comprehensive representation of tissue architecture. These enable AI models to determine genetic mutations from structural changes present in the tissue, leveraging the fundamental principle that genetic alterations drive corresponding morphological transformations. That is particularly important when training AI algorithms to analyze tissue biospecimens and increase their diagnostic accuracy.

Developing AI models for digital pathology requires meticulously collected biospecimens and curated, standardized data. They need high quality biospecimens that were processed, stored, and sectioned following the same clinical protocol. The biospecimens must also be supplied with the appropriate patient demographic and clinical data, and molecular data to identify the mutations and biomarkers present.

BIOLOGICAL DIVERSITY

With oncology cases, WSI provides a complete view across the tumor, adjacent normal tissue, and the edges and artifacts, revealing true tissue diversity and variability. It is important to address heterogeneity, not only within the WSI scan, but also across the entire tissue block. One side of the tumor can be quite different from the other. These data provide AI with the requisite edge cases and context to broaden its knowledge.

TECHNICAL DIVERSITY

AI models also need diversity in terms of the quality of the samples on which they are trained. It's critical that there is proper representation of the real-world scenario which may include samples with artifacts, low tumor cellularity and/or edge cases. As the AI is learning, it needs to recognize that not every sample will look perfect, but it still needs to show robustness in delivering the right result. Researchers do not only want 40X images in the training set, but also 20X and 10X images as well. Capturing both biological and technical diversity is important.

BREAST CANCER CASE STUDY

Molecular profiling of the estrogen receptor (ER), progesterone receptor (PR) and human epidermal growth factor receptor 2 (HER2) in malignant breast tumors is used to determine how the cancer is developing and to choose the best therapy for the patient. The status of those molecular biomarkers is typically analyzed using immunohistochemistry (IHC) and in-situ hybridization, tests that are both expensive and time-consuming to perform in a laboratory and for a pathologist to interpret.[2]

Panakeia, a pioneer in AI-driven multi-omic biomarker profiling, has developed an AI-driven software platform which can provide comprehensive multi-omic information (DNA, RNA, protein, metabolites) from routinely used images of tissue samples.[3] Their PANProfiler Breast solution uses AI to assess the ER, PR, and HER2 status of breast adenocarcinoma by analyzing digital images of hematoxylin and eosin (H&E) stained biopsy or resection slides.

Panakeia partnered with BioIVT to obtain a proprietary dataset that it could use to train its AI models on biomarker identification. Combined with other public and proprietary datasets, the company developed and validated AI models for detecting molecular biomarkers in breast cancer.[2]

BioIVT's dataset consisted of more than 1,000 scanned slides from formalin-fixed, paraffin-embedded, core breast biopsy and resection sections. All the slide images were well-characterized and reviewed by a BioIVT pathologist to confirm that they portrayed the clinical diagnosis. The images were delivered together with the patient's ER, PR, and HER2 status, their demographic and clinical information, and any follow-up data.

Since its initial development and validation using BioIVT data, subsequent iterations of PANProfiler Breast (ER, PR, HER2) have achieved superior performance following multi-site validation. More specifically, PANProfiler Breast displays ER sensitivity 98.2%/specificity 62.0%, PR sensitivity 97.9%/specificity 45.7%, and HER2 sensitivity 90.6%/specificity 100.0%.[4] These advancements enabled the company to secure UKCA and CE (IVDD) marks for their in-vitro medical devices that can provide pathologists with quick, accurate, reproducible patient biomarker profiles. This case study clearly demonstrates how WSI, with associated clinical and genomic data, can be leveraged to develop digital pathology AI algorithms.

DYNAMIC DATASET

BioIVT has an extensive donor network (11 donor centers and 425 clinical sites globally), which allows it to continually acquire new biospecimens. This growing biospecimen inventory will allow it to adapt to address new and emerging scientific challenges and opportunities that AI will uncover. Many AI products and projects fail because they have a static dataset that cannot accommodate requisite changes when the researchers realize they need to head in a different direction or pivot slightly.

BENEFITS OF AI

Incorporating AI algorithms into pathology workflows is enabling the detection of tumors and tumor subtypes, identification of novel morphological structures, and analysis of quantitative biomarkers, thus supporting precision medicine. While AI-assisted insights are valuable, they are used to support and not replace pathologists' insights. Pathologists remain the ultimate diagnostic decision-makers. ■

Author Biographies

Dr. Courtney Noah is BioIVT's Vice President of Scientific Affairs. She leads a team that provides solutions for BioIVT's clients and business partners. Dr. Noah received her PhD in Molecular and Cellular Biology from Stony Brook University, and her BS in Food Science from Cornell University.

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THE POWER OF AI IN LIFE SCIENCES: RETHINKING BUSINESS PROCESSES

MOSSADAMS × bakertilly

The integration of artificial intelligence (AI) in life sciences is rapidly becoming a fundamental driver of competitive advantage and discovery. While the pharmaceutical and biotechnology segments command attention, AI applications are creating transformative opportunities across the entire life sciences spectrum—including operations.

Forward-thinking organizations are leveraging AI capabilities to accelerate mundane or complex business processes that have traditionally consumed significant time and resources. The implications are vast, revolutionizing how companies approach all aspects of their business, including knowledge search, policy evaluations, and regulatory compliance.

TOP THREE AI APPLICATIONS TRANSFORMING LIFE SCIENCES

Strategically implementing AI capabilities into your organization now can accelerate research timelines while maintaining the rigorous standards that define excellence in life sciences. Here are three applications to start with.

1. AUTOMATED LITERATURE REVIEW

Your research teams face an ever-expanding universe of scientific publications, clinical data, and regulatory information. AI-powered literature review tools can systematically analyze thousands of documents in a fraction of the time required for manual review, identifying relevant insights and connections that might otherwise remain undiscovered. Researchers can rapidly synthesize findings across disparate areas, identify emerging patterns and opportunities, maintain comprehensive awareness of competitor activities, and ensure research direction aligns with the latest scientific consensus. Leveraging these advanced analytical capabilities can dramatically accelerate literature review processes while simultaneously improving the depth and breadth of analysis, driving more informed research strategies and decision-making.

2. DOCUMENTATION GENERATION

Your company operates in a highly regulated environment where documentation quality directly impacts compliance, approval timelines, and ultimately, market success. AI-assisted documentation tools are revolutionizing this critical function by generating standardized regulatory submissions with greater consistency and creating comprehensive technical documentation that meets regulatory requirements. These advanced tools significantly reduce human error incompliance documentation while accelerating the preparation of reports, protocols, and standard operating procedures. The implementation of AI in documentation processes not only streamlines regulatory submissions but also enhances quality control measures, allowing your company to navigate complex compliance landscapes more

efficiently and with greater confidence. This transformation in documentation management represents a competitive advantage in an industry where speed to market must be balanced with unwavering quality standards and regulatory adherence.

3. ADVANCED DATA MINING

The volume of data generated across the life sciences industry is expanding exponentially. AI-powered data mining capabilities enable your organization to extract actionable insights from vast data repositories, helping to identify previously unrecognized patterns across both business and research data and accelerate discovery and validation.

By deploying advanced data mining solutions, you can navigate the increasingly complex research landscape with greater precision, unlocking hidden insights that may lead to breakthrough discoveries and accelerating the pathway from initial research to clinical application. The strategic implementation of AI-driven data mining can provide a competitive advantage in an industry where the ability to rapidly extract meaningful insights from expanding data sets directly impacts research productivity and market leadership. ■

VENDOR CONSIDERATIONS IN AI-DRIVEN PHARMACEUTICAL ECOSYSTEM

Hogan Lovells

By Jason Conaty and Ashley Grey

The pharmaceutical industry is undergoing a profound transformation driven by advances in AI that are reshaping every stage of the product lifecycle — from drug discovery and clinical trials to manufacturing, marketing, and real-world evidence (RWE) generation. AI's use in the development process, including in the rapid development of COVID-19 vaccines, has shown that AI-driven innovation can drastically shorten the drug development timeline. AI's success in accelerating the development timelines of FDA-approved drugs has ushered in an era marked by the growing embeddedness of AI within core functions at life sciences companies, and increasing prominence and importance of AI governance. As AI becomes more broadly implemented for regulated products and functions, aligning AI governance with traditional regulatory frameworks is essential. Given the robust regulations pharmaceutical and biotechnology companies face, evolving state laws, and regulatory uncertainty caused by the absence of comprehensive federal AI legislation, companies will need to exercise critical judgment in applying best practices to AI hygiene. FDA's recent draft guidance on AI in regulatory decision-making introduces a comprehensive risk-based AI credibility framework for drugs and biologics and may prompt biopharmaceutical companies to flow down key responsibilities to AI technology vendors to help maintain regulatory compliance.

THE REGULATORY FRAMEWORK FOR AI USED IN DRUG DEVELOPMENT

FDA's recent draft guidance on AI in regulatory decision-making makes clear that the agency intends to regulate AI used in drug development using its traditional regulatory tools. Limiting its regulatory authority to nonclinical, clinical, post-marketing, and manufacturing phases of the drug and biologic lifecycle, FDA does not intend to regulate AI use for drug discovery and operational efficiencies that do not impact patient safety, drug quality, or the reliability of results from a nonclinical or clinical study.

Key regulatory expectations set out in the draft guidance include:

- A **7-step risk-based framework**, which FDA expects sponsors to use to assess AI model credibility.
- **Credibility assessment plan**, which would be submitted to FDA and comprehensively outline the model's design, data strategy, training methodologies, performance metrics and evaluation methodologies.
- **Credibility assessment report**, compiled from the execution of the credibility assessment plan. The report should include a comprehensive description of the outcomes of the plan, confirm the AI model's credibility for its intended context of use (COU), outline any deviations from the plan, and be submitted to FDA early in the process, either within a regulatory submission or upon request during an inspection.
- **Lifecycle maintenance plan** to ensure continuous monitoring and maintenance of AI model performance throughout its lifecycle, considering ongoing updates and new data.
- **Early engagement with FDA** to navigate evolving regulatory expectations.

In addition, life sciences companies will need to comply with state laws regulating AI (such as Colorado, California, and Utah) and consumer protection, which often impose obligations, like notification, on high-risk uses of AI (e.g., AI-enabled digital health technologies (DHTs) which are used by patients in clinical trials or AI-generated fake testimonials in advertising).

To help life sciences companies comply with both FDA guidance and emerging state-level AI regulations, the following section outlines key considerations when entering into vendor agreements with AI developers.

KEY CONSIDERATIONS FOR AI TOOLS AND VENDOR AGREEMENTS

Pharmaceutical and biotechnology companies must first assess whether an AI tool meets the FDA's definition of AI. This distinction is critical because regulatory obligations hinge on whether the tool is considered AI based on FDA or the relevant state regulator's definition of AI. For purposes of FDA regulation, AI is any machine-based system that, given human-defined objectives, generates predictions, recommendations, or decisions affecting real or virtual environments. Early FDA engagement is essential when using generative AI in these contexts.

Next, companies must clearly define the AI tool's intended use, including:

- How it will be applied (e.g., clinical trial design, manufacturing control, pharmacovigilance, marketing analytics).
- Whether the use falls under FDA or state regulatory scope.
- Potential for expansion into regulated areas triggering additional obligations.

It is critical to confirm the AI tool is fit for purpose within its defined context of use and meets FDA expectations for AI credibility set out in its guidance.

When entering into agreements with AI vendors, pharmaceutical companies must ensure contracts reflect regulatory requirements and enable effective risk management under FDA's evolving AI framework.

Pharmaceutical companies should ensure agreements require vendors to:

- Comply with all applicable regulations, including FDA Quality System Regulations, Part 11 electronic records requirements, and relevant state laws governing AI use and data privacy. This includes obligations around data integrity, cybersecurity, and timely reporting of cybersecurity attacks, access to personally identifiable information (especially health information), or system malfunctions.
- Provide full transparency, access to data and model information, and clear delineation of data ownership and confidentiality, including raw data, training sets, audit trails, and performance metrics, enabling the sponsor to conduct thorough audits, and to support regulatory submissions.
- Participate actively in AI risk assessments and lifecycle management by supporting continuous monitoring, model retraining, and prompt notification of any changes that could impact product safety, efficacy, or regulatory compliance.
- Adhere to ethical AI practices and align with corporate AI governance or technology policies such as transparency, data privacy, and responsible AI use.
- Maintain clear communication channels to report any issues affecting system performance, compliance, or data integrity immediately, ensuring that the sponsor can meet its regulatory reporting and oversight obligations.

Embedding these responsibilities into vendor contracts helps pharmaceutical companies manage risk, ensure compliance with evolving FDA guidance, and maintain control over critical AI tools across drug development, manufacturing, and application submission. Of course, companies should also incorporate consumer protection, environmental, social, and governance (ESG) principles; ethics; and sustainability considerations into AI vendor agreements to support responsible innovation, long-term corporate accountability, and existing company policies and goals. But most critically, data is the beating heart not only of AI, but also successful drug and biologic development. Ownership and control of data, before, during, and after an application is submitted to FDA is critical to protecting innovation and return on investment. It should be uppermost in mind in navigating life sciences AI transactions.

AI regulation remains a rapidly evolving landscape. At Hogan Lovells, we advised both emerging companies and global multinationals across the life sciences sector, helping them navigate regulatory uncertainty and seize opportunities in the next era of health care transformation. Our California-based team is particularly well positioned at the intersection of technology, life sciences, and policy, allowing us to support clients at the forefront of innovation and compliance. ■

Related Publications

- *FDA unveils long-awaited guidance on AI use to support drug and biologic development*
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- *FDA lists top 10 artificial intelligence regulatory concerns*
- *AI Health Law & Policy: FDA's rapidly evolving regulatory paradigms*
- *JPM2025: Regulation of artificial intelligence: Navigating a new frontier in health care*
- *FDA's first Digital Health AdComm meeting mulls promises & perils of Generative AI*

BOOST COMPLIANCE, CUT COSTS: AI INVOICE SOLUTIONS FOR THE LIFE SCIENCES INDUSTRY

consolut

By Bandita Maini, Executive Vice President at consolut

The strict regulatory requirements of the life sciences industry also impact the processing of incoming invoices. With new AI-powered solutions, companies can now ensure that their workflows meet compliance standards while operating efficiently and saving time.

Life sciences companies face a dual challenge: on one hand, they must process every incoming invoice with great care and in compliance with numerous regulations—such as audit-proof documentation, batch tracking, or export certificates. On the other hand, they are confronted with a high volume of invoices that is difficult to manage manually. The result: errors, delays, and unnecessary costs. That's why intelligent AI solutions are in demand—solutions that automate workflows, ensure data quality, and reliably meet regulatory standards.

A real-world example shows how life sciences companies can benefit from automating their invoice intake process: New England Biolabs® (NEB®) processes up to 2,000 incoming invoices per month at its Ipswich location. The company wanted to handle invoices more efficiently and with fewer errors—without relying on external service providers.

To achieve this, NEB® automated its invoice intake workflow directly within its own ERP system, an SAP S/4HANA system. For example, incoming invoices are checked to ensure that the data is complete, that master data exists in the ERP system, and that the quality of the extracted data is sufficient to post the invoice. The result of the automation: a fully integrated solution that significantly improves data capture quality, greatly reduces manual effort, and ensures compliance. It also paved the way for the company's move to the cloud—laying the foundation for further digital innovation.

Life sciences companies benefit from AI-powered invoice automation in several ways:

- **Time savings:** Over 90% of incoming invoices are processed automatically, freeing up time for other important tasks.
- **Transparency and control:** All steps are audit-proof and documented, making it easier to comply with regulatory requirements.
- **Compliance by design:** Humans remain a central part of the process. Every AI decision is traceable and can be overridden with a single click—no black box.
- **Increased efficiency:** Automated data capture from PDFs, emails, or XMLs can reduce costs by up to 30% —while improving data quality.

The combination of regulatory security, operational efficiency, and technological future-readiness makes AI-powered invoice processing an ideal solution for the life sciences sector. Companies that invest in intelligent automation today not only gain a competitive edge—they also lay the groundwork for sustainable growth in a highly regulated environment.

consolut—an SAP consultancy specializing in AI and cloud solutions—advised NEB® and supported the implementation of the automation solution. The solution runs on the SAP Business Technology Platform (SAP BTP) and integrates seamlessly into existing SAP systems—a key advantage for companies already using SAP S/4HANA. ■

BEYOND THE LAB: WHY AI'S NEXT FRONTIER IN LIFE SCIENCES IS ON THE PRODUCTION FACILITY FLOOR

By Robin Coward, Director of Life Sciences at QAD

Looking at the life sciences industry today, it's clear to see that artificial intelligence (AI) is everywhere. From discovering new drugs to designing smarter clinical trials, AI is reshaping how we tackle some of the toughest challenges in science and medicine – and the money flowing into AI backs this up. In just the first quarter of 2025, AI startups attracted over $3 billion, making up 60% of all digital health investment, according to the American Hospital Association's Center for Health Innovation.

Other reports show how fast things are moving. Tecknoworks, for instance, notes that AI in pharma was valued at $1.8 billion in 2023 and is expected to soar to more than $13 billion by 2034. However, the same survey found that adoption varies. While 75% of "AI-first" biotech firms have deeply integrated AI into drug discovery, traditional pharmaceutical companies are still catching up. In fact, the pharmaceutical industry is the one industry that has adopted the use of AI in actual workflows more than any other industry. Med Tech is catching on.Even though the pharmaceutical research and development side of life sciences is moving full-speed ahead, there's another part of the story that doesn't get nearly enough attention: manufacturing.

BRIDGING THE GAP BETWEEN DISCOVERY AND DELIVERY

Life science organizations run on brilliant ideas but, as anyone who's worked in our industry knows, ideas alone don't save lives. Patients depend on the complex systems that manufacture, package and deliver therapies safely, reliably, and on time. Right now, those systems are feeling the strain. Manufacturers are under daily pressure to balance quality, regulatory compliance and costs – all in an environment where even a small mistake can have huge consequences.

Despite the promise AI holds, many manufacturers remain cautious. McKinsey & Co. recently reported that although nearly all life sciences companies are experimenting with AI, only about 5% have actually turned it into a real competitive advantage. There is great opportunity to expand the use of AI in life sciences manufacturing

EARLY SIGNS OF PROGRESS

Even though AI adoption in life sciences manufacturing has lagged behind other areas, some companies are finding ways to bring the technology into their operations.

In Pfizer's 2023 Annual Report, they shared how they're using a proprietary generative AI system to find the optimal process parameters for manufacturing a given product – a "Golden Batch," as they call it. The system keeps an eye on production in real time, identifies any issues and recommends actions for improvement. Pfizer estimates the approach could boost product yields by 10% and cut cycle times by 25%, driving as much as $1 billion in near-term value.

Meanwhile, AstraZeneca is also thinking beyond the lab. It has publicly shared about using AI to tackle the massive amounts of data from its clinical trials. By automating statistical analyses and speeding up regulatory submissions, the company hopes to get new medicines to patients faster while also keeping IT costs under control.

WHY AI ADOPTION IN MANUFACTURING LAGS BEHIND

So why hasn't AI taken hold in manufacturing as quickly as it has in drug discovery or clinical development?

Even though billions of dollars are pouring into the sector, more investment is needed. There are also other factors to consider, such as regulation:

- Changing a validated manufacturing process requires meticulous documentation. Testing, and even slight AI-driven changes can trigger a wave of compliance work that adds cost and complexity.
- Data fragmentation is another challenge for some companies. Many facilities rely on disconnected systems, spreadsheets and manual processes that leave critical information trapped in silos.
- The human factor. Shifting from manual oversight to machine-generated insights is a major change. It takes time, trust and new skills to embed AI into decision-making.

Despite these challenges, our complex, high-stakes industry is exactly where AI can have the greatest impact. In manufacturing, even small improvements can have a ripple effect, resulting in significant improvements in quality, cost savings and, ultimately, patient outcomes.

ENCOURAGING SIGNS: USE OF AI BEYOND DRUG DISCOVERY AND DEVELOPMENT

American Pharmaceutical company* is a great example of use of AI beyond drug discovery and development. American Pharma's procurement team wanted to maintain high standards with payments to their suppliers even through times of supply chain difficulty. They needed to visualize errors and delays throughout the entire procure-to-pay process. While every company experiences procure-to-pay process inconsistencies at times, American Pharmaceuticals' process had eroded over time and complications caused suppliers to be paid late with greater frequency. Global disruptions added even more stress and the P2P process slowed considerably, due to request blockers, erroneous data entries and supplier changes.

American Pharmaceutical company applied Process Intelligence, an AI tool that monitors processes in real-time and detects variances and anomalies. The application conducted3 axes of analysis:

1. Process analysis with the identification of nonconforming steps (invoices without purchase orders, loops, bottlenecks, etc.)
2. Temporal analysis: slow approvals, late receipts, missed discounts
3. Dimensional analysis: benchmark by supplier, deviation by country, type of invoice, etc.

The outcome? American Pharmaceutical company realized $300K in cost savings within 6 months, as well as:

- A 12% increase in the rate of invoices paid on time
- Double payment rate down 5 points
- Contactless payment rate up significantly
- Identification of areas to be automated

THE ROAD AHEAD: AGENTIC AI

When you think of AI, you probably think about a conversational large language model that analyzes huge quantities of data at light speed. It might send alerts if something looks wrong, but it doesn't take action.

There's where agentic AI is different. Think of it like having a team of specialized agents who not only identify problems in real time, but actually step in and fix them. The technology can adjust machine settings, shift production schedules and even run routine maintenance – and it keeps incredible records so nothing slips through the cracks from a regulatory perspective.

It is understandable why people may be uncomfortable giving that kind of power to software, but life sciences is well-suited for such a shift. We're used to stringent controls and careful checks. We already follow clearly defined rules and document everything. With the right safeguards in place, agentic AI can help us maximize quality, reduce costs and increase efficiency. Plus, the life sciences industry - an pharmaceutical firms in particular, have shown responsible and proactive “real-world” use of AI already.

Imagine a production facility where skilled individuals are empowered to focus on the work that really matters instead of repetitive, manual tasks. That means more time for solving complex problems and delivering the best patient outcomes possible, letting agents handle the mundane.

DON’T MINIMIZE AI USE AT THE PRODUCTION FACILITY - OR OTHER BUSINESS PROCESSES

The future of life sciences doesn’t hinge only on what we invent. There are so many great ideas and innovations in development – it hinges on how well we produce and deliver them.. For many companies, adopting AI doesn’t have to mean a billion-dollar moonshot. It can start small: improving one process, learning from the results and growing thoughtfully from there.

The technology exists today. What we need now is the vision, and the courage, to bring AI beyond the lab and onto the factory floor, with the same care and patient focus that define the best of our industry. ■

**Name of actual pharmaceutical company withheld at the company’s request. The story can be verified as factual.*

SMARTER CONTAINMENT: HOW AI IS RESHAPING ASEPTIC ENVIRONMENTS

By Chelsea Lauridsen

Cleanroom isolators are built to protect product integrity and ensure aseptic control—but even the most advanced systems today still rely on fixed routines and operator input. What happens inside the isolator often follows a rigid path: programmed cycles, manual interventions, and pre-set timelines. But what if isolators could adapt in real time, making decisions based on what's actually happening inside the chamber?

Artificial intelligence opens the door to more dynamic, responsive isolator environments. Rather than operating on static logic, isolators could learn from patterns, respond to sensor data, and optimize internal workflows—minimizing contamination risks and reducing downtime.

Imagine an isolator where internal movements—whether robotic, operator-assisted, or semi-automated—are optimized in real time by AI. This goes beyond basic programming. Intelligent path planning could adapt to shifting conditions inside the chamber: avoiding areas recently exposed to higher particulate levels, dynamically adjusting movements to prevent cross-contamination, and predicting the most efficient task flow based on the current process stage.

AI could also support closed-loop decontamination strategies by analyzing activity patterns inside the isolator and initiating targeted cleaning cycles only when—and where—they're needed. This approach could reduce downtime, preserve resources, and extend the operational readiness of the system.

At Germfree, we design and manufacture custom isolators for pharmaceutical, healthcare, and biocontainment applications. While our isolators do not currently include AI systems, we've worked alongside organizations that are taking meaningful steps toward this future—integrating robotics and automation into aseptic environments in ways that align with AI's potential.

The integration of AI into isolator design is still emerging, but the groundwork is here. With intelligent motion planning, behavior modeling, and predictive system control, isolators may soon become more than static containment systems—they could become collaborative tools that anticipate and respond to the needs of modern aseptic workflows. ■

THE POWER OF TIGAR™ IN DIABETES OUTCOMES

TIGAR Health™

The objective of this article is to cover a novel AI expert system solution for the main issues in current type II diabetes care. We will briefly summarize the major problems from the perspective of the primary participants in diabetes care, the nature of a solution, and close with a high level view of the way the solution, called TIGAR [Treatment Integration and Guidance Analytical Reporting], works.

Multiple problems in type II diabetes prevention and care are well known.

The clinicians who are responsible for type II routine care are almost always front line practitioners, not diabetologists or endocrinologists. They are typically constrained by management and payers to 10 - 12 minute visit times, thus limiting all facets of care. These facets span the complexity of drug regimens and standards of care that include managing many complications of diabetes plus the goal of influencing patient diets and exercise. Non-compliance by the patient with desired lifestyle is often cited by providers as the main patient management issue, but it isn't under clinician control. Further, lifestyle is often what got the patient where they are. Another direction is needed.

Payers face a disease with increasing numbers of patients, rising costs and further escalation due to increasing complications. They need an off-ramp that achieves savings because it simultaneously improves patient outcomes.

Patients face difficult circumstances now. They realize that they will be living with a lifetime disease. It will be controlled enough to slow it down, not cured, and usually will worsen over time. Overall health declines, significant complications are likely in the later stages, and more personal time and money go into healthcare. A broad range of negative emotions is the usual result –anger, shame, frustration, despair, resignation – with little hope of a sustained turnaround. Lifestyle changes are a large part of the "solution" of slowing progression of disease. Continuing compliance with such changes, particularly over many years, is very difficult.

How can so many issues be addressed effectively? The answer is simple. Get each patient on the right medicine, which means medicine that best targets the root causes and drivers of their individual disease. Improvement at the level of underlying metabolic regulation then drives improvements in patient physical and mental condition as well as lowering total cost per covered life in the first year, which is sustained.

Personalized medicine has addressed issues like these problems in other fields of medicine. To date the main application has been in the field of oncology. A whole spectrum of tests and tools, covering oncogenes to tumor suppressors to hormones and so on, is used to very precisely define the characteristics of a patient's tumor and pathophysiology. Treatment is selected accordingly. To a lesser extent, cardiology (with blood tests, imaging etc.) and sepsis (when culture succeeds, doing ID to AST to MIC) have adopted a similar approach.

Practitioners in these fields wouldn't dream of treating a patient without specifically targeting individual disease drivers and characteristics. Why not in diabetes?TIGAR delivers this capability, with compelling pilot market results in true routine practice.

TIGAR is positioned at the convergence of Clinical Decision Support (CDS) and precision medicine, using AI in an expert system analytical reporting platform to assist the clinician in delivering standard of care and true personalization of type II diabetes treatment.

How does TIGAR work? First an individual patient profile is determined using precision medicine with panels of 7 - 14 tests and demographic information. The blood tests are well known chemistries and proteins. These profiles have over 4 million permutations, giving sufficient granularity to have true personalization. That profile maps to the AI expert rules set, which in turn maps to a rank ordering of anti-diabetic drug class regimens with explanatory rationales. The three database identifier thus created by the linkage pulls report content from a fourth database to populate the report.All four databases are proprietary.

The AI expert rule set is the centerpiece - the key to the utility of the platform.Subsets of the profile data are used to classify dimensions of patient condition (e. g., liver condition, insulin resistance, etc.) into categories of severity of dysregulation (e. g., good function, mildly dysregulated, moderately dysregulated, etc.). Each of these dimensions' classifications goes into the summary profile of condition.The summary was assessed by prominent endocrinologists to determine a rank ordering of drug classes by effectiveness. Typically classes are sorted into lists of 'Recommended', 'Possible', and 'Not recommended'. Frequently multi-drug regimens are indicated. There are thousands of rules that link the overall assessment data of each patient profile to a specific drug class recommendation hierarchy.

The TIGAR AI expert system incorporates both top doctor judgment and transparency. It is a living system kept at state of the art, and derivation of information is easy to understand. In these ways it meets the # 1 issue in clinical decision support for a prescription decision, which is doctor trust.

The scope of problems in type II diabetes requires a solution like TIGAR. It is eminently suitable for implementation in the current medical system. Doctors can easily write a prescription. Payers know their drug expenses are targeted correctly and get rapid net cost savings. Patients can take a more effective pill or injection much more easily than changing their lifestyle. The excellent results of our true routine practice pilot market validate these conclusions.

Contact Robert Maurer at rmaurer@tigarhealth.com for more information.

THE FUTURE OF AI IN LIFE SCIENCES: A GUIDE FOR COMPANIES JUST STARTING THEIR AI JOURNEY

KAMI Think Tank

For life sciences companies just starting their AI journey, the temptation to "do something with AI" is strong, but the reality is more nuanced. Over the past few years, companies that have gotten it right haven't rushed in. Many of them began envisioning how AI would play a role at their company years ago (before the introduction of genAI) and invested in their data, worked with the right partners, integrated people thoughtfully, and pursued measurable wins.

START WITH A BUSINESS PROBLEM, NOT A BUZZWORD

The most common mistake new adopters make is starting with a tool and looking for a use. Companies that succeed start with a pain point they understand deeply. In 2024, Eli Lilly partnered with Genetic Leap, a startup applying AI to RNA-targeted drug design. Lilly didn't just want to "use AI"; it needed help designing oligonucleotide therapies (an emerging but technically complex modality). Genetic Leap's AI platform helped generate novel sequences tuned to therapeutic and safety profiles, specific to the needs of Eli Lilly. (Reuters, 2024) To begin AI augmentation, identify where your current process is slow, expensive, or error-prone and let that guide your efforts.

BUILD YOUR DATA FOUNDATION

AI doesn't magically overcome bad data - it amplifies it. Yet companies often overlook the importance of building data foundations and knowledge graphs. In 2025, Pfizer deepened its collaboration with XtalPi, combining AI and quantum physics to predict small-molecule crystal structures. It was able to do so by investing years in collecting, labeling, and integrating structural data. Pfizer's ability to supply clean, organized data meant XtalPi's models could deliver accurate predictions. This resulted in reducing crystal-structure determination time from months to days. (XtalPi, 2025)

For a company starting its journey, this means prioritizing data readiness before investing heavily in AI. Assess whether your trial protocols, manufacturing records, or discovery results are standardized, accessible, and trustworthy. If not, begin there.

DON'T GO AT IT ALONE

Hiring a few data scientists and hoping they can reinvent what others have spent a decade building is unrealistic and unnecessary. The most successful companies are those who find and collaborate with the right external expertise.

In 2023, Recursion Pharmaceuticals acquired Cyclica and Valence, two companies with specialized AI platforms for generative chemistry and predictive toxicology. Instead of building these capabilities internally, Recursion integrated them directly, strengthening its drug-discovery pipeline and accelerating early-stage programs. (Recursion, 2023)

f you're just starting out, look for established AI partners, whether startups, or academic groups, who already know the landscape and can get you moving faster.

EMBRACE THE HUMAN ELEMENT

Even the smartest AI fails if people don't trust it. In 2023, a European CRO rolled out a generative AI tool to draft clinical trial protocols. Initially, uptake was slow; staff doubted the accuracy and worried about accountability. The company eventually paired AI outputs with human reviews and trained employees to recognize when to trust the tool and when to override it. Adoption improved dramatically. Similarly, in pathology, initiatives like EMPAIA have shown that integrating AI alongside human pathologists improves both speed and accuracy while maintaining trust. For beginners, this means preparing your workforce; involve them early, train them well, and frame AI as an assistant, not a threat.

LOOK FOR MEASURABLE EARLY WINS

The biggest successes of the last few years have come from modest, well-chosen projects that delivered measurable value quickly. For instance:

- In early 2024, Insilico Medicine advanced an AI-designed fibrosis drug into Phase II trials. This was a major milestone for a generative pipeline, proving its approach could deliver a viable candidate. In order to design the drug, Insilico used the Biology AI module of the Pharma.AI platform, which integrated large repositories of published data such as "omics" data sets, patents, grants, publication texts, to identify genes likely to be responsible for IPF pathology and disease resolution. (Insilico, 2024)
- In 2024, Takeda scaled its use of natural language processing and LLMs to process global adverse event reports faster and more reliably, meeting compliance obligations more efficiently. (Takeda, 2024)
- Sanofi and Exscientia pushed their AI-designed immunology drug into Phase I trials in late 2023, a product of four years of focused collaboration. They began this collaboration by looking to develop up to 15 novel small molecule candidates, leveraging Exscientia's AI platform utilizing actual patient samples.(Sanofi, 2023)

Companies can and should start with contained, data-rich, and impactful problems where outcomes are easy to measure, rather than looking to integrate new AI tools to fit their company's needs.

THE ROAD AHEAD

The most effective AI adopters within life sciences have followed a similar path, over the past few years:

- They picked specific, meaningful problems to solve
- They invested early in making their data usable
- They partnered with organizations who already had expertise in solving the meaningful problems
- They upskilled their workforce to use the tools effectively
- And they focused first on clear, measurable wins before scaling

For those just beginning, success with AI will depend not on how advanced the tools are, but on how deliberately they're applied.

KAMI Think Tank is an organization which translates the latest AI research into long-term meaningful impacts for life science companies and their patients. Co-founders Kamayani Gupta and Michelle Yi blend together their combined 20+ years of experience in the AI and life sciences worlds to provide education and best practices to life sciences practitioners. KAMI Think Tank will be launching a membership platform in September, to ensure practitioners can get up to speed on AI in Life Sciences - if you would like to be a beta tester, please reach out to info@kamithinktank.com

HOW THE HILTON LAB IS REVOLUTIONIZING SCIENCE EDUCATION WITH IMMERSIVE DIGITAL INNOVATION

The scientific breakthroughs of tomorrow begin with the curiosity and passion of today's students. Dr. Stephen Hilton, associate professor at UCL School of Pharmacy, is reimagining science education—moving beyond traditional lectures to create immersive, inclusive, and deeply engaging student experiences. "I want students to feel like scientists, not just study science."

Dr. Hilton elaborated, "Pharmacy is a uniquely powerful discipline that bridges so many fields—including chemistry, biology, engineering, data science, and healthcare—making it the ideal platform to apply emerging technologies in ways that truly matter. Whether it's developing new digital tools for training, or applying virtual reality (VR) and artificial intelligence (AI) to lab environments, pharmacy allows me to connect different disciplines and work across boundaries."

The Hilton Lab is a truly interdisciplinary team. "What makes the team special is that everyone—regardless of their primary discipline—integrates VR, 3D printing, or both into their research projects. It's not an add-on; it's core to how we innovate," said Dr. Hilton. The team's educational research focuses on how immersive, interactive tools can improve learning outcomes for students across diverse backgrounds, contributing to more accessible and future-ready science education models.

Tools like VR, multilingual AI mentors, and digital twin labs remove geographical and financial barriers. This gives students access to environments and instruments they may otherwise never experience—an especially powerful opportunity for apprentices and distance learners, who often lack access to hands-on training. The lab's multi-award-winning 3DI Virtual Reality Institute brings these technologies together, training students globally on real-world instruments, including Agilent HPLC systems. Dr. Hilton emphasized, "This isn't just VR for demonstration—it's interactive, skills-focused, and available 24/7."

An AI conversational assistant, inspired by "Jarvis" from Iron Man, provides personalized, on-demand mentorship within the VR labs. "It acts as a virtual guide—responding to voice commands, offering real-time support, explaining protocols, and even assisting with instrument use," Dr. Hilton explained.

Furthermore, students can access a fully interactive virtual replica of a real-world lab environment—LAB427 at the UCL School of Pharmacy. Dr. Hilton detailed, "Our digital twins go beyond static simulations. They're dynamic, data-rich environments, where students can run virtual experiments, operate real equipment, and receive live feedback." The team builds digital twin labs using actual lab blueprints, instrument manuals, and technical specs. "Everything from sample preparation to method setup to data analysis is built into the VR flow."

Agilent Infinity III LC Series blueprints are being used to expand VR training, integrating detailed structural and functional data to build more precise and immersive digital twins. "These blueprints allow us to accurately replicate not just the interface, but the physical layout, flow paths, modular components, and real-world workflows of the Infinity III systems," stated Dr. Hilton. "In parallel, we're also developing AI-guided walkthroughs of Infinity III operation—from setup to troubleshooting—which will further enhance the usability and learning experience."

Dr. Hilton noted, "For students, our VR labs aren't just training tools—they're pure information environments where learning happens through direct interaction with scientific systems. They're not watching or reading about a process—they're inside it, engaging with it in a structured, hands-on way."

He also highlighted the flexibility and inclusiveness of the VR and digital twin lab environments, which cater to a range of learning styles and backgrounds. “Visual learners benefit from being able to see complex processes in 3D, such as chromatographic separations or flow reactions. Kinesthetic learners can actively manipulate equipment, prepare samples, and run methods. Auditory learners can receive spoken guidance form the AI mentor, while self-directed learners can move through the experience at their own pace.” As a result, students arrive at real labs with far more confidence and familiarity.

Over 75% of students in a recent evaluation reported feeling more confident operating Agilent HPLC systems after completing VR training using Agilent digital twins. “By the time they use a physical HPLC system, they are already fluent in its operation and logic,” said Dr. Hilton. “From our side as educators, Agilent HPLC systems have been ideal for building structured, stepwise learning modules.”

In their quest to revolutionize science education, Dr. Hilton and his team are embracing innovative technologies. “AI, VR, and emerging lab technologies are fundamentally reshaping analytical chemistry—from how we train the next generation to how we run, monitor, and optimize experiments. They’re transforming the entire philosophy of laboratory science.”

See full customer story video here >> https://www.agilent.com/sites/agilent/en/video/stephen-hilton-ucl

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