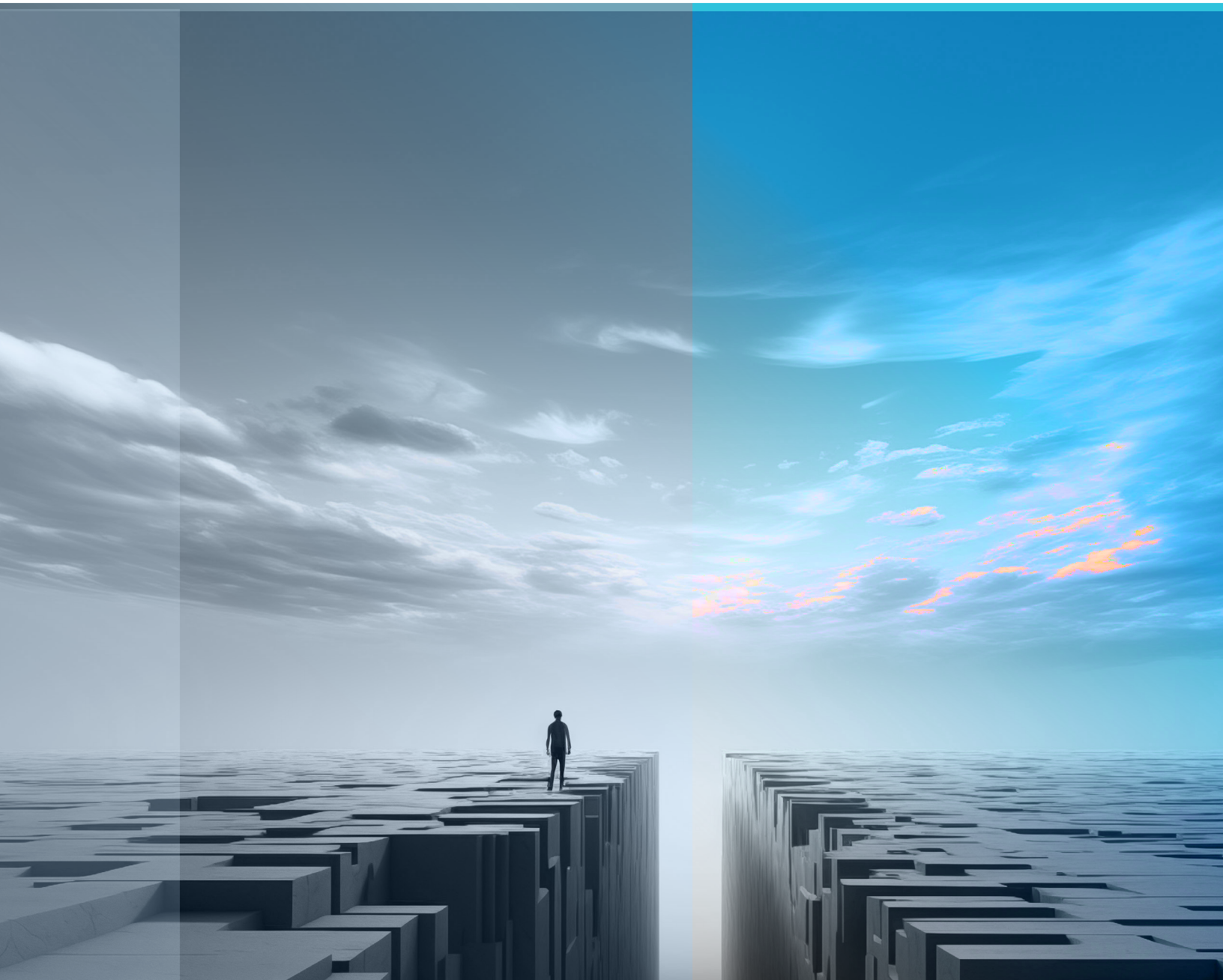
tetrascience

The Scientific AI Gap

Why biopharma companies risk falling short of AI goals

WHITE PAPER



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Executive Summary

Biopharma leaders today are poised to capitalize on the power of AI to speed delivery of new therapeutics and drive down fast-rising costs. They recognize that the large data volumes produced by their scientific instruments and applications can be used to generate key insights that help significantly enhance efficiency and improve scientific outcomes. But for many biopharma companies, there is a gap between the vision for AI and the present reality that is difficult to overcome. Dependence on legacy technology, perpetuation of an inefficient do-it-yourself approach, and a lack of data and metadata harmonization are all preventing biopharma companies from closing the gap and achieving their AI goals. Moving forward will require a revolutionary scientific data paradigm.

Introduction

Biopharma leaders recognize that artificial intelligence (AI) will have a tremendous impact on the life science industry. AI can ultimately help improve and extend human life by accelerating and enhancing scientific R&D while streamlining manufacturing and quality assurance/quality control (QA/QC). By using AI, biopharma companies can discover and speed delivery of new, transformational therapeutics—therapeutics that are more effective, safer, and less expensive than current drugs. At the same time, AI can help substantially reduce skyrocketing costs.

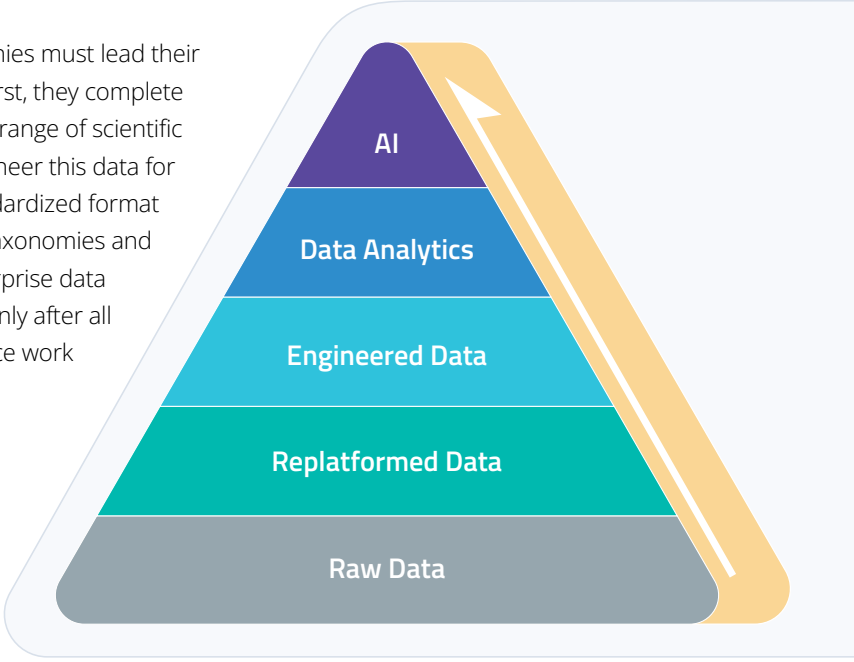
Executives across industries are ready to launch AI initiatives now. In fact, according to a recent report by Deloitte, 94 percent of business leaders surveyed agree that AI is critical to their business success in the next five years.[1] In biopharma, companies have already invested over $2.5 billion on AI initiatives and are poised to spend substantially more in the coming years.[2]

Those investments will be an increasing part of R&D, manufacturing, and QA/QC budgets. For example, Morgan Stanley estimates that AI investments will grow from 1.5 percent of R&D budgets in 2023 to 4 percent in 2030.[3]

Despite this drive to start benefiting from AI right away and the willingness to invest in AI initiatives, there is a significant gap between the vision for AI in biopharma and the present reality.

Many biopharma companies are years away from implementing AI applications and running algorithms that can fully capitalize on the wealth of scientific data they are generating. With a do-it-yourself (DIY) approach, they are struggling to do the basic data preparation of curating data and making it AI ready. Companies need to do this critical, foundational work, but too few are able to do so efficiently and to begin using AI in any meaningful way.

To advance with their AI-readiness journey, companies must lead their data through an immutable series of operations. First, they complete the integration work and assemble data from a full range of scientific instruments and applications. Then they must engineer this data for data science and AI, harmonizing it by using a standardized format and adding rich contextualization with consistent taxonomies and ontologies. At the same time, they must meet enterprise data governance and business security requirements. Only after all of these steps can they begin the actual data science work and start to capitalize on AI.

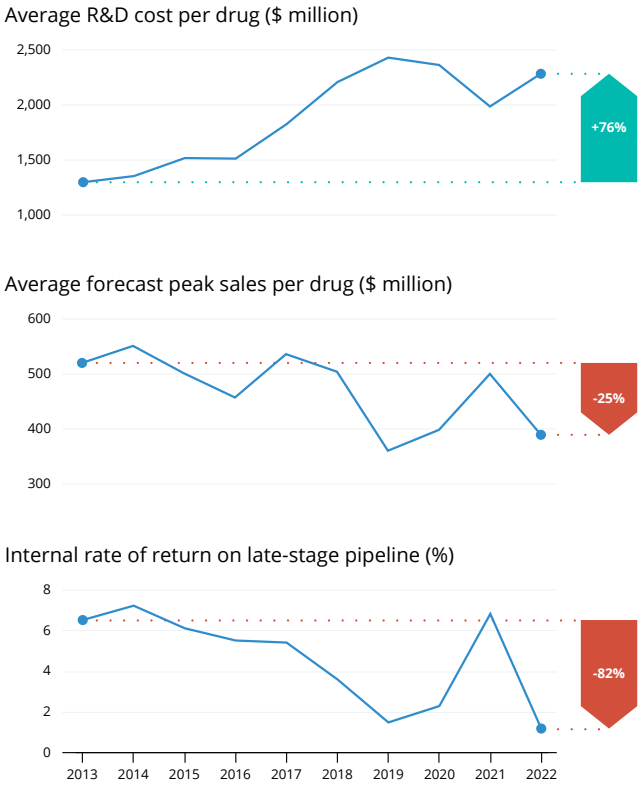


Why is there such a huge gap between the vision for AI and the present state, in which companies are bogged down in data preparation? What challenges do companies need to address before they can close that gap and ascend the data maturity pyramid?

The promise of Scientific AI in biopharma

Biopharma organizations are looking to AI to revolutionize the entire value chain for therapeutics. That revolution will be critical for addressing key challenges. In particular, biopharmas are spending more than ever on R&D, but the returns are diminishing. Last year it cost an average of $2.3 billion to bring a drug to market—76 percent more than a decade ago.[4] During the same period, sales have slumped 25 percent on a per-drug basis. Both trends have contributed to a five-fold reduction in R&D productivity.

R&D productivity is declining



Source: Deloitte, 2023.

Drug development is not only costly but also long and risky. Clinical development lasts over 10 years on average with a measly 8 percent of drug candidates earning regulatory approval.[5]

The industry needs a paradigm shift—and AI could enable the required transformation.

Morgan Stanley estimates that using AI in early-stage drug development over the next decade could bring an additional 50 therapies to market worth over $50 billion in sales.[6] A McKinsey analysis predicts that generative AI could unlock the equivalent of 2.6 to 4.5 percent of annual revenue ($60 billion to $110 billion) for the industry.[7]

Executives in biopharma are becoming increasingly optimistic about the impact of AI on their business. Nearly half of the top 50 biopharma companies have mentioned AI on earnings calls over the past five years.[8] Sanofi recently announced its ambition "to become the first pharma company powered by artificial intelligence at scale."[9]

Recognizing the potential of AI

AI can "improve the biggest challenge of the [pharmaceutical] sector, which is the productivity of R&D."[10]

—Emma Walmsley, CEO of GSK

"AI will reduce the cost of R&D [per] molecule. It has to."[11]

—Christophe Weber, CEO of Takeda

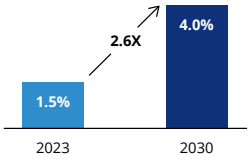
SURGING INVESTMENT IN AI

To bring AI ambitions to fruition, biopharma companies are ready to spend billions. According to one report, spending will climb from $1.64 billion in 2023 to $4.61 billion in 2027.[12] Within R&D specifically, AI investments will grow from 1.5 percent of R&D budgets in 2023 to 4 percent in 2030, according to Morgan Stanley.[13]

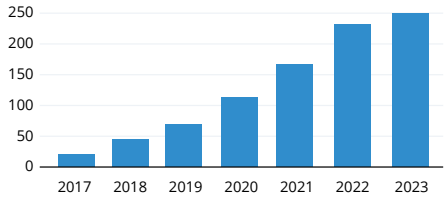
Top biopharma companies are building dedicated AI teams, with clear mandates from leadership.[14] In late 2022, AI-related jobs accounted for 7 percent of new job postings by biopharma companies, more than double the average across all sectors.[15] Most of these roles are likely to devote a significant portion of their time to data preparation. Low-quality and poorly curated datasets are seen as the largest barrier to implementing AI, according to a recent industry survey.[16]

AI investment is surging

Biopharma spending on AI (% R&D spend)



Partnerships between top 20 biopharmas and AI companies



Source: Morgan Stanley, 2022; Deep Pharma Intelligence, 2023

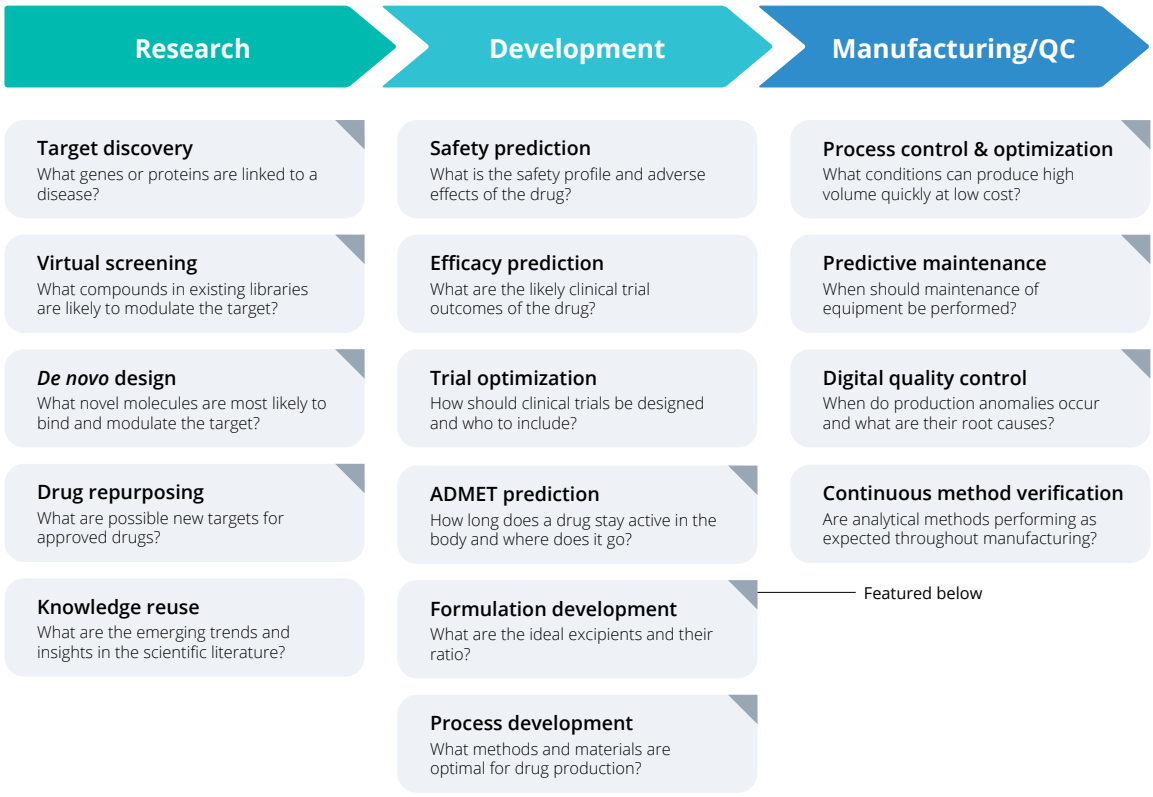
Biopharma companies are also looking to collaborate with partners to gain the necessary technology and know-how to carry out their AI initiatives. About 800 companies are currently applying AI to drug discovery and development.[17] Many are startups providing software as a service (SaaS) offerings, custom data sciences services, drug discovery (drug candidate as a service), and clinical trial support.[18]

R&D partnerships between leading biopharma organizations and AI companies have grown over the last six years[19]—half of the 50 largest biopharma companies have entered into partnerships or licensing agreements with AI companies. This group has also ramped up direct investment in AI companies.[20]

THE SCIENTIFIC USE CASES FOR AI

How can life science companies use AI?

Virtually every stage in the pharmaceutical value chain has the potential to be transformed by AI.



Research

Target discovery: AI algorithms can mine diverse datasets—including scientific literature, multi-omics, clinical records, and public databases—to find proteins, genes, or pathways correlated with specific diseases or conditions. The result could be a ranked list of promising targets for further investigation as well as the corresponding genetic profiles of patients expected to benefit from treatment.

Virtual screening: Researchers need to find molecules that can bind to and modulate a target. Virtual screening moves the initial rounds of assays *in silico*, simulating drug-target binding. AI can improve the speed and accuracy of virtual screening while reducing costs by replacing costly wet lab experiments. Organizations could analyze millions of compounds this way, then validate the most promising ones in the lab.

***De novo* design:** The millions of compounds amassed by biopharma company libraries are only a tiny sliver of the molecular species possible. AI algorithms can explore the entire chemical space to find molecules with favorable pharmacological properties. *De novo* design can greatly accelerate drug discovery while yielding superior drugs, since this approach is not limited by what can be found in the natural world.

Drug repurposing: AI can uncover new targets for known drugs. Scientists can model interactions between an existing, already-approved drug and a collection of protein structures to predict new therapeutic applications. This approach streamlines discovery and reduces costs while minimizing risks, since the drug's safety and manufacturing processes are well established.

Development

ADMET prediction: Accurately forecasting how a drug will behave within human subjects is a major challenge. AI can leverage existing and future datasets, including positive and negative results from clinical studies, to accurately model absorption, distribution, metabolism, excretion, and toxicity (ADMET) properties in patients. This approach eliminates unfavorable candidates much earlier in development. Failing faster will avoid significant downstream efforts and costs.

Formulation development: Effective therapies combine active pharmaceutical ingredients with other excipients to facilitate delivery, enhance efficacy, reduce side effects, and improve shelf life. AI tools can rapidly probe a large parameter space and recommend optimal formulations to test, greatly increasing the speed and efficiency of this process.

Process development: AI can expedite process development and technology transfer by optimizing drug production for scale-up, reproducibility, and cost. Leveraging historical and newly generated datasets, machine learning models can rapidly identify critical process parameters and forecast the best conditions for drug synthesis.

Manufacturing and QC

Process control and optimization: AI-driven systems can continuously monitor and analyze vast amounts of real-time data from sensors, instruments, and production lines. Predictive analytics and ML algorithms can anticipate process deviations, enabling proactive adjustments to maintain proper conditions. AI can also optimize complex bioprocess parameters to reduce the risk of product variability, increase yields, improve product quality, and ensure compliance.

Predictive maintenance: With AI, biopharma companies can shift from reactive to proactive maintenance strategies. Through continuous data collection and analysis, AI applications can identify subtle anomalies and wear patterns that might signal impending machinery faults or maintenance needs. This use of AI could make failures of manufacturing and laboratory equipment a thing of the past.

Digital QC: Consistent and safe production of pharmaceuticals requires rigorous QC. Using AI, labs can automate the analysis of complex datasets, helping scientists identify patterns, trends, and anomalies more quickly. Predictive algorithms can preemptively flag potential out-of-spec results, enabling a "review by exception" approach that speeds up the release of products. Timely interventions can prevent production disruptions and compliance issues, potentially saving millions of dollars.[21] If deviations occur, AI can unearth root causes fast.

THE BENEFITS OF AI

By unlocking the full value of their scientific data troves, biopharma companies can expand their portfolios with drugs that deliver markedly higher ROI. What are the high-level benefits of AI?

- **Faster time to market:** It usually takes over a decade to bring a drug to market. Much of this time is spent gathering and analyzing scientific data to determine if a potential drug can advance to the next stage. AI can boost the efficiency of many of these steps by orders of magnitude, slashing development time.
- **Reduced costs:** AI can help increase staff productivity and optimize the utilization of resources in labs and manufacturing plants, cutting costs. Moreover, by improving the quality of drug candidates in the pipeline, AI can minimize expensive late-stage failures or low-quality batches.
- **Reduced risks:** Organizations can use AI to minimize errors and deviations; address data integrity issues that threaten drug safety, efficacy, and quality; and streamline compliance.
- **Better scientific outcomes:** AI can help open new avenues of scientific inquiry and drive a wave of breakthroughs: new therapeutic targets and chemical/biological compound structures, novel mechanisms of action and delivery, innovative manufacturing processes, and so on.

Impediments to Scientific AI

Given AI's potential for delivering significant benefits and the commitment to AI among biopharma leaders, why are biopharma companies slow to launch AI initiatives? And why are they struggling to harness the value of the AI applications they have already implemented?

> *"The first thing we've learned is the importance of having outstanding data to actually base your ML on. In our own shop, we've been working on a few big projects, and we've had to spend most of the time just cleaning the datasets before you can even run the algorithm. It's taken us years just to clean the datasets."*
>
> —Vas Narasimhan, M.D.
> CEO, Novartis

The answer centers on data. The vast volumes of data that biopharma companies generate and collect are not ready to be used by advanced analytics, AI, or machine learning (ML) applications.

For many organizations, data is stuck in siloed environments and proprietary formats, unable to be moved or assembled into the large-scale datasets needed for AI.

- **Siloed:** Data is often trapped in isolated storage environments—from external drives and workstations to file shares and tape archives. Companies need to liberate their data from these decades-old silos, centralizing data and making it easily accessible by AI applications.
- **Proprietary:** Many scientific instruments produce data in vendor-proprietary formats, locking teams into small vendor ecosystems with limited applications. To compare, visualize, analyze, or use data for AI, teams need to break free of these walled gardens. They must transform proprietary and often unstructured data into a single, standardized format. That format must have harmonized metadata taxonomies (definitions of data elements and structures) and ontologies (descriptions of relationships among data elements).
- **Static:** Siloed data in proprietary formats is illiquid—it cannot easily be moved and shared. To streamline workflows, share data and information, facilitate collaboration, and capitalize on data for AI applications, biopharma companies need data to flow seamlessly across instruments, applications, departments, and even among organizations.
- **Subscale:** AI algorithms and ML models require high-quality, large-scale datasets. But when data is stuck in siloed environments, in proprietary formats, companies cannot assemble high-quality, large-scale datasets.

What is keeping organizations from producing the AI-native data they need? There are three primary obstacles: legacy architectures, an entrenched DIY approach to scientific IT, and a lack of data standards.

Obstacle #1: Legacy data architecture

Biopharma organizations often attempt to progress with AI initiatives using a data architecture that isn't built for AI. In particular, many are using legacy scientific data management system (SDMS) solutions originally designed to store and archive data for compliance.

An SDMS has three primary functions:

- **Collecting data:** An SDMS collects data and PDF files from instruments and applications.
- **Cataloging data:** An SDMS can provide some contextualization for data and files by adding metadata. That contextualization is critical for finding and using data after it is collected.
- **Archiving data:** Organizations can use an SDMS to archive data in a compliant manner. When necessary, teams can restore data from the archive to another location and then work with that data using the original software.

Despite the utility of an SDMS for these functions, most traditional SDMSs present essential limitations for closing the AI gap.

Inflexible data flow

Traditional SDMSs have few options for data flow and processing. An SDMS often becomes an archival dumping ground because it cannot accommodate the sophisticated, dynamic data liquidity required by biopharma teams. For example, R&D teams should be able to send data to multiple destinations—including informatics systems, data warehouses, analytics applications, visualization tools, and AI applications. But the simple archiving offered by many SDMSs cannot provide that flexibility.

Little data engineering

SDMSs are designed to store data but not transform it. Traditional SDMSs do not engineer data for scientific use cases. They do not convert data from proprietary formats into a standardized, harmonized, future-proofed format that is engineered specifically for data science, analytics, or AI. To analyze data, teams would need to undertake significant curation and transformation work.

Poor discoverability

Some SDMSs add metadata to files. But because SDMSs typically do not harmonize metadata taxonomies and ontologies, scientists can have difficulty discovering new or historical datasets. Data is searchable and consumable only if someone knows precisely what terms or labels to query. In many cases, lab scientists end up re-running an assay or an experiment because that's easier than finding historical data. As a result, SDMSs often become a black hole for experimental data: Data is sent to the SDMS but then forgotten.

Inflexible accessibility

SDMSs are closed, siloed data repositories. Many organizations want to access data from the apps they use daily, such as electronic lab notebooks (ELNs). Others want to consume data in analytics or AI applications. But a traditional SDMS typically requires organizations to access data exclusively through the SDMS interface, making ELN, analytics, and AI use impossible. Exporting data to other environments to support these applications is cumbersome.

Lack of scalability

Traditional SDMSs are largely implemented on premises and cannot be scaled easily. Every upgrade requires changes for every component—including the database, servers, and file storage. If these solutions use cloud services at all, they use the cloud as simply another data center: The cloud might add resources but at the expense of adding management complexity. Consequently, SDMSs are not the best environment for assembling the large-scale datasets required for AI.

SDMSs simply aren't designed to prepare data for AI. Some vendors might tack on capabilities to address some of the limitations of their solutions. But at their core, most SDMSs cannot provide sufficient data liquidity, allow adequate discoverability, enable data accessibility, or efficiently scale up to support the massive data volumes needed for AI algorithms.

Obstacle #2: The DIY model

The problems with legacy architectures are compounded by legacy mindsets. Too many scientific organizations maintain a DIY approach to data integration and management. With that DIY approach, internal IT teams or third-party consultants build rigid point-to-point data integrations for specific instruments and applications. These teams might enable some degree of contextualization or data harmonization, but they typically remain focused on specific integrations and their related data. They are not future-proofing data or implementing end-to-end scientific workflows that will enable the AI journey.

There are multiple, interrelated problems with the DIY approach.

Time-consuming and costly

Creating, validating, and thoroughly documenting point-to-point integrations is extremely labor intensive. As teams work to fulfill current needs, they must also maintain and continuously update integrations, ensuring support for the latest versions of software. Once integrations are established, moving data within and between research, development, manufacturing, and QA/QC workflows might still require error-prone manual data transcription tasks using rigid, fragile, and costly point-to-point integrations. All of this work requires a unique combination of scientific and technical expertise that not all organizations possess.

Inflexible

IT project-based point-to-point integrations yield static, complex, and inflexible data architectures that produce subscale and fragmented raw datasets. Those datasets cannot be accessed or shared across the enterprise, and they cannot be used for AI.

Limited application options
The DIY approach often leaves files trapped in proprietary formats. As a result, organizations cannot use their preferred third-party, best-of-breed analytics or AI applications with that data. Without access to these applications, and without the ability to achieve economies of scale, companies struggle to produce the insights needed to innovate.

Poor scalability
The DIY model often creates an "n-of-1" internal customer business model: In other words, IT creates individual data integrations for each workflow or team. Without the ability to reuse software components or data integrations, a company cannot achieve any economies of scale. It certainly cannot create the kind of Scientific AI factory needed to produce large-scale datasets for AI applications.

Not designed for an end-to-end scientific workflow
DIY efforts are often led by IT teams, not scientists. They typically do not have end-to-end scientific workflows in mind as they design and build the solution. As a result, scientists may be left with a piecemeal solution that addresses distinct integration needs without enabling the seamless flow of data across an entire scientific process.

Unable to produce AI-native data
Frequently data engineered through the DIY approach is still not ready for AI applications. Data must be well engineered, drawing on a deep understanding of the scientific data workflow. It should be allowed to flow across applications and teams, and to be assembled into the large-scale datasets required for AI. DIY teams are generally solving short-term, low-level, point-to-point data integration problems, not seeing the big picture of how all scientific data must be prepared for enabling AI across the enterprise.

Given all the problems with the DIY paradigm, it might seem clear that this approach to data integration and management is on a terminal path. But many organizations hold onto this paradigm. Some believe they can develop better, more customized solutions than those that are commercially available. Yet this bespoke approach means they cannot leverage industry best practices and build a future-proof solution.

Many maintain the DIY paradigm simply because of inertia. The DIY approach is too well entrenched. Still, organizations need to recognize that DIY is keeping them from reaching their AI goals, and they need to see a viable alternative before making a change.

Obstacle #3: A lack of harmonization

A lack of harmonization among data formats and metadata presents a third key obstacle to moving forward with AI initiatives. Scientific instruments and applications typically produce files in vendor-specific proprietary formats, with unique metadata taxonomies and ontologies, that have limited accessibility outside vendors' walled gardens. Without harmonization of data formats and metadata, organizations are unable to use best-of-breed applications to analyze data. And they are unable to assemble the data from all of their instruments and applications into the high-quality, large-scale datasets needed for AI.

DATA FORMATS

There have been several efforts to create data format standards in the life science industry. But none has been widely adopted.

- The **Allotrope Foundation** developed a somewhat complex Allotrope Data Format (ADF) and then subsequently created the Allotrope Simple Model (ASM) to standardize the structure of instrument data.
- **Analytical Information Markup Language** (AnIML) is a standard for storing and sharing any analytical chemistry and biological data.
- The **Standardization in Lab Automation** (SiLA) consortium is working to standardize software interfaces specifically for working with robotic automation. But the consortium isn't providing a true solution for harmonizing the actual data for other data usages.
- The **Pistoia Alliance** created the Unified Data Model (UDM) project to produce an open data format for storing and exchanging experimental information about compound synthesis and testing.
- Individual vendors have attempted to establish their own formats as "standards."

In parallel with efforts at creating data format standards, an international consortium of scientists and organizations introduced FAIR data principles with the aim of optimizing the reuse of data. FAIR data is findable, accessible, interoperable, and reusable. These principles are a good start, but they are still only principles—they are insufficient to overcome the obstacles to standardization.

Why have there been relatively few attempts at standardization? And why have proposed standards failed to gain traction? There are few incentives for life science technology companies to establish or adopt standards.

The quest for competitive advantage

Where there is competition for market share, instrument vendors try to outperform one another, producing equipment with increasingly impressive specifications. They develop proprietary data formats adapted and optimized for their specific methods.

Legacy designs

Meanwhile, much of the instrument control and data acquisition software available today was initially built on legacy technology and meant to be installed on PCs in a laboratory. Each application was designed to give scientists all the essential functionality to complete their work without leaving that application. Vendors have had no motivation to develop an open data format or push for standards.

Customer retention

Maintaining proprietary data formats also helps vendors retain existing customers. Using proprietary data formats, instrument and application vendors bind scientists to their particular ecosystem.

Standardization challenges

Different instruments and modalities produce different bits of information—it is difficult to find one size to fit all. Moreover, the efforts of consortia to create standards have shown how challenging it is to achieve compromise among multiple parties.

Without standards for data formats, biopharma companies are often left with multiple data silos across the enterprise. Data is trapped in vendor-specific data formats within on-premises environments. Preparing data for AI requires organizations to invest time and money for harmonization.

METADATA

Harmonization efforts must include not only data formats but also the taxonomies and ontologies of the metadata. Metadata often differs from instrument to instrument and from user to user.

Instruments, applications, and users add context in a variety of formats. As organizations collect data from a variety of instruments and applications, they are left with a variety of terms to describe the same data—which becomes clear when comparing metadata between departments, sites, regions, and geographies.

The taxonomies and ontologies in this metadata must be harmonized. The vocabulary of terms that captures information about uses, samples, materials, equipment, processes, results, and more is vital for finding, interpreting, analyzing, and assembling data. Without harmonization, organizations will struggle to find, compare, and reuse data from all of their different sources—and they will be unable to assemble that data into the large-scale datasets needed for advanced analytics and AI.

Harmonization will likely be an ongoing effort because taxonomies and ontologies can evolve. For example, the Allotrope Taxonomies and Ontologies included with the Allotrope Data Format were initially based on existing vocabularies but then grew to several thousand terms and properties as more companies began using the data format. That flexibility is helpful as organizations refine their workflows and use cases over time—but the evolving taxonomies and ontologies must be maintained.

The vocabulary of metadata

Taxonomy: Defines elements and their organization
Ontology: Describes relationships among elements

Closing the gap

Biopharma leaders today are driven to launch new AI initiatives to advance science. They see the promise of using AI in a wide range of R&D, manufacturing, and QA/QC use cases. By applying AI to their vast collections of data, they can accelerate time to market for new therapeutics, reduce costs, minimize risks, and ultimately deliver better scientific outcomes.

But many companies face a wide gap between the vision of their leadership and the reality of their ability to execute on it. They are unable to move past the integration of instruments and applications—an essential but early step in the immutable progression of operations required to produce AI-native data. They are hampered by legacy data architectures and limited by entrenched DIY mindsets. And without standard data formats, or harmonized taxonomies and ontologies, they struggle to free their data for reuse.

It is possible to close the AI gap. But organizations will need to shift their thinking and revolutionize their scientific data strategies. They must commit to efficiently and fully preparing data for AI. Raw, scientific data must be transformed into liquid, harmonized, large-scale, and compliant data that is designed for AI. To succeed with that transformation, organizations will need a new data architecture—one that is open, purpose built for science, collaborative, and designed specifically for supporting AI journeys.

Learn how TetraScience can help you close the AI gap. Contact us to arrange a demo of the Tetra Scientific Data and AI Cloud™.

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Corporate Headquarters | 177 Huntington Avenue, Suite 1703, Boston, MA 02115