

**AI IN EARLY DISCOVERY:**

# Hype vs. Reality for GxP Teams

Why governance, validation, and platforms matter more than algorithms.

# Introduction

**If we're going to experiment with AI anywhere, early discovery is the safest place to do it.**

That assumption drives many early AI initiatives. Discovery work is exploratory, data is still evolving, and the perceived stakes feel lower than in later phases. On the surface, it appears to be a contained environment where moving quickly carries no consequences.

The challenge is that early discovery decisions rarely stay isolated. Data generated here often informs regulated decisions later. Tools introduced as pilots tend to persist. When AI workflows are created outside validated systems or without clear ownership, teams inherit complexity that becomes harder to unwind as programs advance.

**This is where the promise of AI begins to collide with GxP reality. What appears to be a low-risk experiment can introduce traceability gaps, validation challenges, and accountability questions that surface long after the initial value is realized.**

In this article, R&D, IT, and operations leaders will learn how to evaluate AI use in early discovery through a compliance-first lens, identify assumptions that create downstream risk, and understand what foundations are required to adopt AI responsibly without eroding trust.



# Where AI Assumptions Start to Clash with GxP Reality

**Early discovery often feels like the safest place to introduce AI. Timelines are flexible, outputs are not immediately tied to submissions, and experimentation feels contained.**

A familiar pattern emerges. A discovery team deploys an AI model to accelerate data analysis. The pilot performs well. Results look promising. Outputs begin to circulate across projects because they save time and improve consistency.

Months later, those same outputs appear in downstream discussions. Teams are asked where the data came from, how the model was trained, whether the workflow was validated, and who owns the process. What began as a lightweight experiment is now supporting decisions that require defensibility.

This pattern is familiar. Gartner research shows that many AI initiatives stall at the pilot stage, most often due to gaps in data quality, governance, and operational readiness rather than limitations of the technology itself. In GxP contexts, these gaps become apparent when AI outputs need to be reused, scaled, or inspected.

**What ultimately matters is whether AI introduced in early discovery can be sustained as expectations increase. Decisions made here shape future risk, scrutiny, and corrective efforts, determining whether AI can scale or become a regulatory issue.**



# The Hype vs. the Reality

## HYPE 1:

### AI will replace scientific and operational roles

AI is often framed as a substitute for human effort. By automating analysis and surfacing patterns at scale, it is assumed to reduce reliance on scientific judgment and operational oversight.



## THE REALITY:

AI does not remove accountability. Scientific interpretation, data stewardship, and operational ownership remain essential, regardless of model sophistication. Outputs must be understood, contextualized, and owned by people who can stand behind their use.

**“AI is not there to replace roles. Especially in GxP systems, accountability doesn’t go away. Someone still has to own the decision, understand the output, and stand behind it”.**

– Sandy Tammisetty, VP, Veeva Services Practice Group, at Conexus Solutions, Inc.

In practice, AI shifts where expertise is applied. Scientists spend less time on manual processing and more time evaluating results. Operational teams take on greater responsibility for governance and integration. When those responsibilities are unclear, AI introduces ambiguity instead of efficiency.

## HYPE 2:

### If it works elsewhere, it will work in pharma

Success stories from other industries are often treated as transferable. If similar models improve speed and decision-making in tech or finance, the assumption is that they can be applied to discovery with minimal adaptation.

## THE REALITY:

Pharma operates under constraints that fundamentally change how AI can be used. Data lineage, validation, and auditability are not optional. Many tools designed for unregulated settings do not account for these requirements.

**Success depends less on the model itself and more on whether it can operate within governed systems and established processes. AI that works elsewhere can create friction if it cannot meet these expectations.**

**HYPE 3:**

**Moving faster with AI is always better**

AI is synonymous with speed: faster analysis, faster insights, faster decisions.



**THE REALITY:**

Speed creates value only when outputs can be trusted, reused, and defended. Accelerating work outside governed workflows often shifts effort downstream rather than eliminating it.

**Short-term momentum can turn into revalidation, rework, or corrective action later. Sustainable progress comes from controlled execution, not unchecked acceleration.**

**HYPE 4:**

**AI value is obvious once deployed**

AI is expected to prove itself quickly. Once deployed, insights should surface, and returns should be clear.



**THE REALITY:**

Value is not defined by output alone. AI-driven results must be explainable, traceable, and appropriate for their intended use.

**When teams cannot articulate how outputs are governed and validated, perceived value remains subjective. AI delivers value when it is embedded into accountable workflows, not when it operates in isolation.**

**HYPE 5:**

**AI automatically simplifies compliance**

AI is sometimes viewed as a way to reduce compliance effort by automating documentation and oversight.



**THE REALITY:**

AI does not simplify compliance by default. It introduces new requirements around validation, explainability, change control, and ongoing oversight.

**Compliance improves only when AI operates within governed systems that support traceability, accountability, and inspection readiness.**

After separating the hype from reality, a clearer picture emerges. AI is neither a silver bullet nor something to dismiss. Its value today is limited to specific, bounded applications, primarily when it supports existing discovery workflows rather than replacing them.



## Where AI Actually Adds Value Today in Early Discovery



### Focused support, not replacement

AI is most effective when applied in low-risk ways that reduce friction in well-understood areas, not when it attempts to replace scientific judgment.



### Efficiency and augmentation

Practical use cases center on pattern detection, classification, prioritization, and accelerating repetitive tasks. These gains compound without introducing unnecessary risk when applied thoughtfully.

**“If AI helps you move faster outside controlled workflows, you’re not eliminating work. You’re just pushing it downstream.”**

– Sandy Tammisetty



### Human accountability remains central

Decisions that influence scientific direction or downstream development cannot be delegated to automated systems. AI may assist with analysis, but responsibility remains with the people who interpret results and stand behind the outcomes.



### Why early discovery works as an entry point

Discovery benefits from analytical support while still allowing clear boundaries, validation, and oversight. Within those constraints, AI can add value without undermining trust or inspection readiness.

## What Breaks When AI Moves Beyond Experimentation

Many teams introduce AI using standalone tools or low-risk pilot workflows.

### Problems emerge when outputs are reused.

Models trained outside governed systems lack clear ownership, traceability, and validation. When questions arise later, teams struggle to explain how results were generated or whether they can be trusted.

**Shadow tools and unmanaged data often create more work downstream.** What

saves time early can trigger revalidation, rework, or corrective action as programs advance.

**The risk is rarely the AI itself. It is the lack of readiness to support it responsibly.**

## Why Foundations Matter More Than Models

**AI never operates in isolation. Its usefulness depends on where it runs, how outputs are governed, and whether results can be traced back to source data and decisions.**

Infrastructure matters more than algorithms. Introducing AI into external systems of record creates gaps in ownership and auditability that become harder to resolve over time.

Platforms like Veeva Vault provide the conditions under which AI can be used

responsibly. Standardized data structures, controlled workflows, audit trails, and validation processes allow AI to be embedded into day-to-day work rather than layered on top of it.

**Early discovery feeds broader GxP operations. Platforms determine whether AI insights remain usable as programs evolve or become liabilities.**

## What IT, Ops, and R&D Leaders Should Focus on Now

**AI adoption is accelerating, but outcomes depend far more on foundations than tools.**

Teams that move forward with clarity focus first on readiness, ensuring data quality, ownership, and validation practices can support reuse and scale.

Platforms shape whether AI insights can be explained, governed, and sustained. When AI operates outside systems of record, value is often short-lived. When embedded within governed environments, it has a more straightforward path into everyday operations.

Early discovery offers room to learn, but decisions made here shape downstream effort and risk. The work done now influences how easily AI can mature alongside programs, expectations, and change.

**The path forward is not about moving faster. It is about creating conditions that allow AI to be adopted deliberately and with confidence as capabilities continue to evolve.**

### Where Conexus Helps:

Conexus supports life sciences teams in building the conditions that allow AI in early discovery to create durable value, not downstream rework, by focusing on:

- **Clear ownership and validation models** that stand up to audit and inspection
- **Platform-based foundations** that keep AI outputs usable as programs advance
- **AI integration approaches** that align discovery speed with long-term compliance requirements

**Our goal is to help teams ensure that early AI decisions remain defensible, reusable, and trusted as programs progress.**

# About **Conexus Solutions, Inc.**

We combine deep industry knowledge with specialized talent to support progress for pharma and life sciences companies. Our team brings practical experience in commercial operations and technology, helping organizations strengthen capabilities, navigate change, and deliver results efficiently. By aligning strategy with the right tools, we help clients reduce risk, respond to evolving market demands, and build long-term value.

Schedule a consultation at [cnxsi.com](https://cnxsi.com).

#### Sources

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