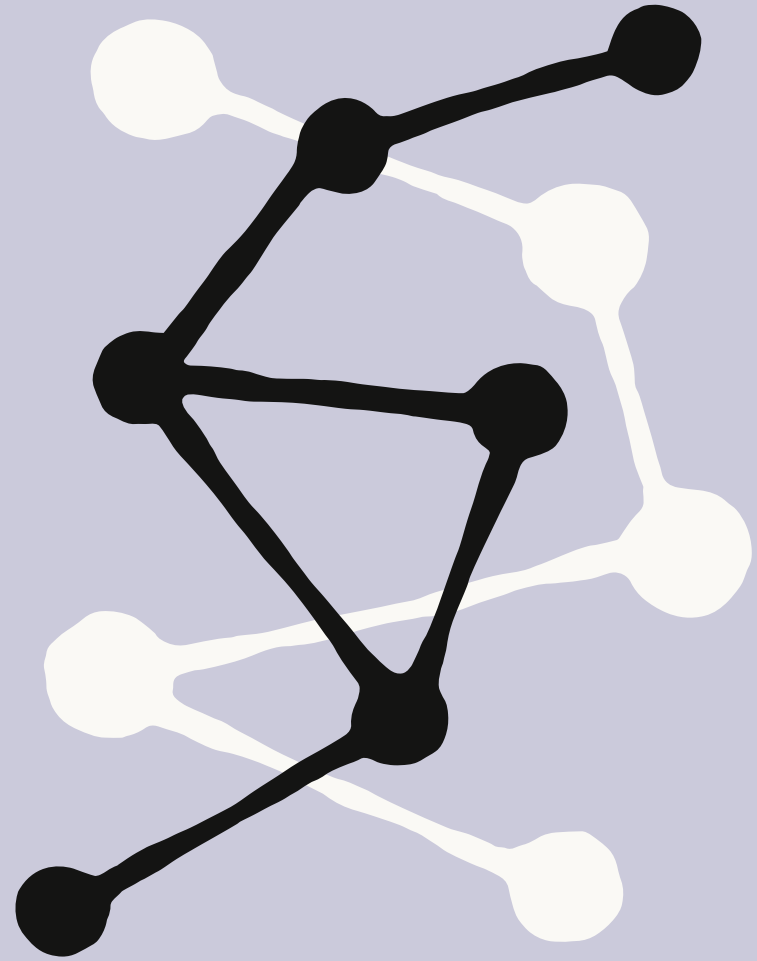


# The Enterprise AI Transformation Guide for Life Sciences

A step-by-step guide to deploying AI in  
regulated science

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# The AI imperative for life sciences

# The AI imperative for life sciences

Life sciences organizations are putting frontier AI into the hands of their scientists and regulatory teams, and the early movers are seeing real gains in how quickly they can work.

The appetite is there. [Deloitte's 2026 State of AI in the Life Sciences and Healthcare Industry](#) report found that 72 percent of healthcare and life sciences companies plan to deploy agentic AI in the next two years. But only 34 percent feel highly prepared to adopt it, and just 28 percent feel ready to handle the risk and governance that come with it.

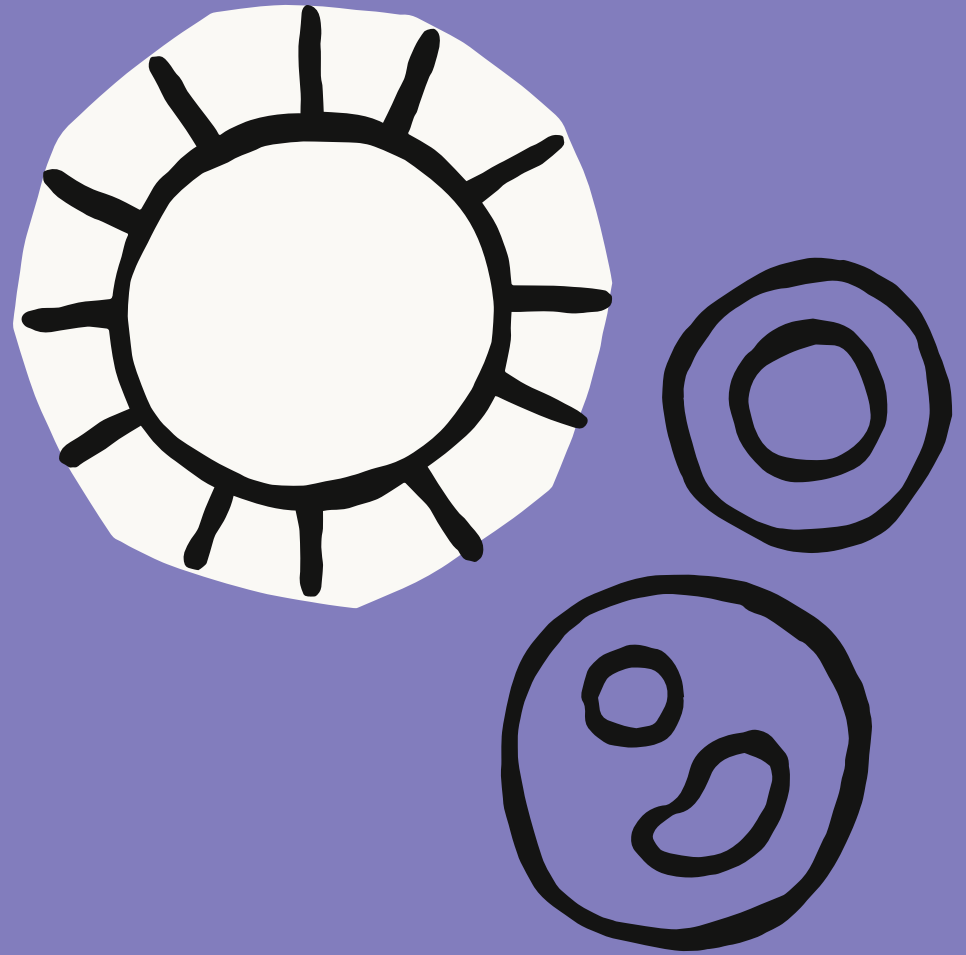
That gap is no surprise. The stakes are higher in life sciences than almost anywhere else: patient safety and scientific integrity depend on getting it right. Data is fragmented across discovery, development, and regulatory functions. Frameworks like GxP, 21 CFR Part 11, FDA guidance, and the EU AI Act demand rigorous compliance, and scientists rightly question whether AI can meet the rigor their work requires.

Working alongside our customers, Anthropic has developed a proven approach to bringing AI to life sciences organizations built for the realities of regulated science:

- **Lay the foundation.** Organizations begin by building a solid base: strategy, stakeholder alignment, and governance.
- **Launch a pilot.** Next, teams run carefully chosen pilots that show value quickly while building real expertise.
- **Scale impact.** Finally, successful pilots expand across the business through structured rollout programs and centers of excellence.

This guide covers what matters at each step. We'll start by identifying high-impact use cases across R&D, clinical development, regulatory affairs, and commercial functions. We'll then walkthrough how to build business cases that win cross-functional support while meeting compliance requirements. And we'll share how teams at [Bluenote](#), [Biomni](#), [FutureHouse](#), and [Novo Nordisk](#) put AI to work to drive better scientific and regulatory outcomes.

Let's dive in.



Step 1: Lay the foundation

# Step 1: Lay the foundation

Driving AI adoption across a life sciences organization starts with deliberate groundwork. In this section we cover how to define your strategy around life sciences use cases, build alignment among scientific, regulatory, and technical stakeholders, and establish governance that meets GxP, FDA, and EU AI Act requirements.

## Driving leadership and stakeholder alignment

Leaders need to understand both the opportunity, including **20 to 30 percent gains** in productivity and large reductions in documentation time, and the challenges, including upfront investment, regulatory complexity, data integration hurdles, and the need to keep scientific judgment at the center of every result.

### Build a coalition across stakeholders

In life sciences, stakeholder alignment means securing support from, among others:

- **Executive leadership** (CEO, CFO, COO) who control resources and set strategic priorities
- **Scientific leadership** (CSO, VP of R&D, Head of Computational Biology) who understand research realities and influence scientific teams
- **Clinical and regulatory leadership** (VP of Clinical Operations, Head of Regulatory Affairs, Head of Clinical Data Management) who own the path to submission
- **IT leadership** (CIO, CISO) who manage technical infrastructure and security
- **Compliance and quality teams** who ensure GxP and regulatory adherence
- **Bench scientists, bioinformaticians, and regulatory specialists** who will ultimately decide whether AI tools succeed or fail

Technology alone cannot drive adoption in science. People and scientific workflows have to evolve alongside it. Organizations that treat change management as an afterthought struggle with adoption, especially when scientists see AI as adding work rather than removing it.

### Assemble your AI steering committee

Successful change management starts with a steering committee that represents critical functions and holds real decision-making authority. Include a C-suite sponsor who can clear organizational obstacles, functional leaders who understand operational realities, technology executives who grasp implementation requirements, finance representatives who track ROI and budgets, and legal or compliance leaders who can set governance.

### Prioritize deep listening

The most successful AI rollouts begin with listening rather than technology evangelism. Where do your scientists lose time to manual assembly work? Which workflows feel broken? What keeps regulatory teams compiling submissions late into the night?

Starting with these pain points rather than the technology builds trust and makes sure your strategy addresses real needs. When scientists see that AI targets the problems that frustrate them daily, they become advocates rather than skeptics.

### Address scientific skepticism directly

Scientists, bioinformaticians, and regulatory specialists have seen plenty of tools that promised to make their lives easier and instead added burden. That history creates legitimate skepticism, and it deserves a direct response.

- Acknowledge past technology disappointments rather than ignoring them
- Commit to measuring actual impact on scientific workflows, not just technical metrics
- Give scientists clear ways to give feedback and shape the rollout
- Commit to sunseting applications that don't deliver
- Make clear that AI enhances scientific judgment, it doesn't replace it

This honest engagement builds credibility. Scientists respect leaders who flag the hard parts early instead of overpromising.

### Develop AI implementation champions

Beyond the steering committee, identify and empower champions at every level. These are respected managers who influence their peers, technical experts who understand both legacy systems and AI, early adopters who bring energy, and thoughtful skeptics whose questions surface real risks. Give champions extra training, direct access to leadership, and recognition that makes their advocacy visible across the organization.

### Regulatory alignment

Life sciences AI governance has to address frameworks that other industries never encounter, so it's important to build compliance into your architecture from day one. Retrofitting it after deployment is costly and sometimes impossible without rebuilding. Below are the governance frameworks most likely to apply to life sciences organizations.

#### GxP and 21 CFR Part 11

Software that supports regulated development and manufacturing must meet Good Practice (GxP) expectations and, for electronic records and signatures, **21 CFR Part 11**. In practice that means validated systems, controlled changes, and complete audit trails. Build for it from the start:

- **Validation** appropriate to the system's risk, with documented evidence that it does what it's intended to do
- **Audit trails** that are tamper-evident, attributable, and readily searchable, showing who did what and when
- **Data integrity** that meets ALCOA+ principles so records stay attributable, legible, contemporaneous, original, and accurate
- **Change control** that documents and reviews modifications before they reach a regulated environment

### FDA oversight considerations

**AI that meets the definition of a medical device**, including software as a medical device (SaMD), requires FDA clearance or approval before deployment. Even if your first applications don't qualify, plan your governance with future oversight in mind. Key considerations include pre-market submission requirements, clinical validation, labeling, post-market surveillance, adverse-event reporting, and managing modifications under a predetermined change control plan.

### EU AI Act compliance

For organizations operating in Europe or serving European patients, the EU AI Act classifies certain life sciences AI systems as "**high-risk**," which triggers extensive requirements:

- **Risk management systems** with documented assessments and mitigations across the system lifecycle
- **Data governance** that keeps training and reference data relevant, representative, and free from bias
- **Technical documentation** maintained throughout the lifecycle, covering design, data characteristics, testing, change logs, and instructions for use
- **Human oversight** built into the architecture so people can interpret outputs, override them when needed, and are trained to do so
- **Robustness, accuracy, and cybersecurity** appropriate to high-risk systems, with monitoring after deployment

## Data privacy in clinical research

When AI touches patient data in clinical trials or real-world evidence, privacy frameworks may apply, including GDPR in Europe and HIPAA in the United States. Make sure you have appropriate agreements with vendors who access protected data, encryption in transit and at rest, role-based access, and breach-notification procedures. Treat patient data minimization and purpose limitation as design principles, not afterthoughts.

## Establish an AI governance framework

With compliance frameworks in place, you're ready to establish governance that puts them into practice. A good framework enables innovation while managing risk through policies that balance protection with productivity. Key components include:

- **Access controls** that determine who can use AI systems and what data they can reach, with role-based permissions aligned to responsibilities and data sensitivity
- **Usage guidelines** that clarify acceptable applications and explicitly prohibit problematic ones, such as putting confidential IP or patient data into public AI models or making consequential decisions without human review
- **Quality standards** that set review requirements and accuracy thresholds, defining when outputs need human verification and when they can proceed
- **Compliance protocols** that meet regulatory requirements across jurisdictions, from GDPR to FDA regulations and GxP standards

The earlier you prioritize governance, the more durable your AI program will be. Governance is core to how Anthropic builds. We were one of the first AI companies to earn **ISO 42001 certification** for responsible AI, and we publish the policies, evaluations, and risk reports behind our models so customers can hold us to them. Many life sciences customers have found these resources useful:

- The **Responsible Scaling Policy**, our voluntary framework for assessing and mitigating catastrophic risks as model capabilities advance — structurally similar to the biosafety levels that already govern lab work
- The **Trust Center**, where we publish certifications, sub-processors, and data-handling commitments, including the availability of HIPAA-eligible offerings to customers who execute a Business Associate Agreement
- The **Transparency Hub**, with enforcement data, legal request handling, and detail on how we approach user safety
- **Claude's Constitution**, which details the principles that guide Claude's behavior



Step 2: Launch a pilot

# Step 2: Launch a pilot

Good pilots deliver quick wins while building capability. Choose projects carefully, show cross-functional potential, and learn rigorously from every experiment.

## Choosing your pilot projects

AI adoption in life sciences starts with pilots aligned to both business objectives and scientific priorities. The goal is to find where AI delivers the most value while keeping risk to patient safety and compliance low.

Unlike industries where "move fast and break things" is acceptable, life sciences demands a measured approach. Starting with lower-risk, high-value applications builds capability and trust before tackling more complex scientific decision support. Here are three strong first projects.

### 1. Scientific documentation and regulatory report generation

Tools that turn research data, study protocols, and clinical findings into structured documentation, from regulatory submissions to research reports, are an ideal first investment. Scientific writing is low-hanging fruit because it accelerates existing workflows without altering scientific judgment, and it can start with a small team. Done well, it reduces researcher burnout, returns time to actual science, and shows quick ROI.

### 2. Research synthesis and literature review

Scientific knowledge doubles every few years, and staying current across hundreds of papers by hand is impossible. Claude synthesizes findings across large bodies of literature, drawing on PubMed, bioRxiv, and proprietary databases, and delivers cited, structured insights tied to a specific research question. The work stays assistive and fully reviewable, which keeps risk low.

### 3. Clinical trial protocol analysis

Reviewing trial protocols against regulatory guidance, eligibility criteria, and endpoint definitions can take weeks and several specialist reviewers. Claude ingests full protocols, cross-references against guidance, flags inconsistencies, and produces structured summaries with cited protocol sections for reviewer validation. Because a human validates every finding, it's a low-risk way to move faster.

## Showcase cross-functional potential

Successful pilots create momentum, but momentum alone won't scale adoption. Design pilots that reveal possibilities beyond their immediate scope. When research sees success with literature synthesis, clinical teams start imagining documentation applications. When drug safety demonstrates adverse-event pattern detection, regulatory affairs envisions faster submission preparation. This cross-pollination drives organic expansion beyond the initial plan.

To evangelize AI adoption and foster knowledge-sharing, structured opportunities for cross-functional learning, such as a monthly AI showcase where pilot teams present their work. These sessions should include live demonstrations in scientific or regulatory workflows, before-and-after comparisons of documentation time or analysis speed, and open discussion of the validation approaches and safety considerations discovered along the way.

## Aligning on clear success metrics

Before launching any pilot, set concrete success metrics that stakeholders understand and accept. They typically span five dimensions:

- **Adoption metrics** track how many people use the tools and how often, including daily active users, feature use, and session frequency across teams
- **Efficiency measures** document time saved and productivity gains, such as cutting report preparation from weeks to hours
- **Quality metrics** confirm outputs meet your standards through measures like accuracy in data extraction, error rates, and first-pass approval rates
- **Scientific and regulatory impact** tracks outcomes that matter, such as faster discovery timelines, improved trial recruitment and retention, earlier safety-signal detection, and higher-quality submissions
- **Satisfaction scores** capture the user experience through Net Promoter Scores, task difficulty ratings, and willingness to recommend the tool

Track these weekly to catch issues early, review monthly to spot trends, and adjust based on data rather than assumptions. This builds accountability and confidence in your AI program.

## **Conduct pilot post-mortems**

Once a pilot concludes, the real learning begins. Look past the headline numbers to the story behind them: the moments when users found unexpected value, the friction that emerged in practice, and the workarounds teams invented when the tool didn't quite fit their workflow. These anecdotes are often more informative than the metrics.

On the technical side, probe system reliability, integration snags, data-quality surprises, and infrastructure needs that only appeared under real conditions. Understanding adoption takes detective work: why did some teams embrace the tool while others quietly resisted, and what practical barriers got in the way?



Step 3: Scale impact

# Step 3: Scale impact

Moving from successful pilots to organization-wide adoption takes structured training that builds real capability, centers of excellence that include scientific domain experts, and governance that scales with adoption while protecting patient safety and compliance.

## Turn pilots into a launchpad for AI upskilling

Scaling success requires building deep AI capability across every role, from the C-suite to your bench scientists. Treat training not as compliance modules but as an investment in your people's ability to deliver better science with less administrative drag.

Don't overlook experiential learning. Hackathons bring energy and experimentation that top-down training never achieves. When teams compete to solve real problems with AI, learning happens organically and enthusiasm builds.

Consider peer learning and mentorship that pairs experienced users with colleagues just starting out, through regular check-ins, shadowing in real workflows, and problem-solving sessions. You can also create certification programs that validate competency through real-world assessments rather than multiple-choice tests.

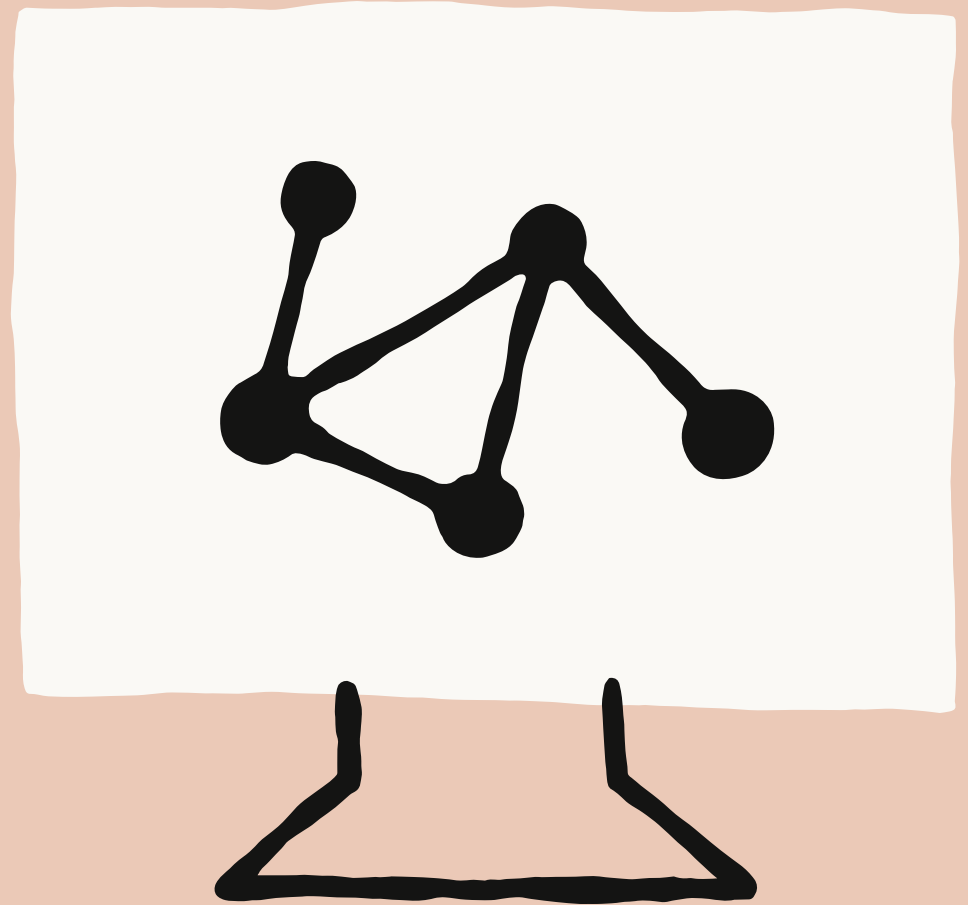
**Pro-tip:** Celebrate certified users in internal communications, give them priority support, and consider certification in promotion decisions. Nothing signals commitment like tying advancement to AI proficiency, and that mindset shift is exactly what builds capability that outlasts any single pilot.

## Establish centers of excellence

Create specialized teams, or centers of excellence, dedicated to sustaining and expanding AI capability. They develop best practices across functions, provide technical support and troubleshooting, and systematically test new use cases.

Structure them with clear accountability and cross-functional representation that prevents siloed thinking. Include technical architects who understand integration and data flows, domain experts from each major function who translate scientific needs into AI opportunities, and data scientists who tune performance and spot emerging capabilities.

**Pro-tip:** Establish rotation programs that bring functional experts into the center for three to six month stints, building their expertise while keeping the center connected to evolving scientific needs.



# Building an AI-first enterprise: real-world examples

# Building an AI-first enterprise: real-world examples

Moving from isolated pilots to AI-native operations means rethinking entire workflows around AI rather than bolting on point solutions. The most successful programs share a pattern: a breakthrough in one function becomes the catalyst for adoption across the enterprise. From day one, Anthropic has been committed to working with life sciences organizations to help them realize the potential of AI across their organization. In fact, earlier this year, we announced our partnership with Bristol Myers Squibb to deploy Claude across the company's research, clinical development, manufacturing, commercial, and corporate functions.

The examples below show how organizations use Claude across the value chain, and how early wins create momentum for broader change.

## Research and discovery: from literature to lab

Life sciences organizations see their biggest gains when they connect related workflows across discovery and development.

### Bioinformatics

**Biomni** set out to remove the bottleneck that locks most scientists out of genomic insight: the deep programming expertise that bioinformatics pipelines usually require.

#### **The challenge: specialist dependencies slowing science**

A bench scientist with a hypothesis often can't run a genomic analysis without a bioinformatician, so the scientists who could be designing the next experiment end up waiting for someone else to run the last one.

#### **The solution: Claude as a bioinformatics agent**

Biomni built on Claude to run validated bioinformatics pipelines and deliver annotated, reproducible reports, with built-in biosafety controls and full methodology documentation.

- 800 times faster bioinformatics analysis, 35 minutes instead of three weeks
- Cloning experiment designs validated as equivalent to a 5+ year expert in blind testing
- Claude connected to 150 tools, 59 databases, and 106 software packages

### Literature synthesis

**FutureHouse** built specialized research agents on Claude to help scientists stay current across a literature base that doubles every few years.

#### **The challenge: science outpacing scientists**

Biomedical literature is growing faster than any researcher can track. Staying current across relevant studies, synthesizing findings, and identifying novel directions can take months — time that isn't being spent on the research itself.

#### **The solution: specialized agents for scientific discovery**

FutureHouse built four Claude-powered agents spanning literature search, analysis, novelty assessment, and drug discovery. Rather than replacing researchers, the agents compress the front end of the scientific process — surfacing what's known, flagging what's new, and freeing scientists to focus on what's next.

- Literature reviews completed in days instead of months
- Four specialized agents covering the full research workflow, from literature search to drug discovery

## Regulatory and clinical development: from data to submission

While discovery teams accelerate the front of the pipeline, regulatory and clinical development teams use Claude to clear the documentation work that stands between a finished trial and patient access.

### Regulatory documentation: Novo Nordisk

Novo Nordisk tackled the documentation bottleneck that delays treatments from reaching patients.

#### The challenge: documentation delays blocking patient access

Each new treatment requires mountains of documentation: clinical study reports running hundreds of pages, technical device verification protocols, and patient guides written in plain language. Producing a single clinical study report was a multi-month effort, with staff writers averaging only 2.3 reports a year. Each day of delay in bringing a medicine to market can cost up to 15 million dollars in potential revenue, and patients keep waiting.

#### The solution: the NovoScribe documentation platform

Novo Nordisk built NovoScribe, a generative AI platform on Amazon Bedrock and MongoDB Atlas with Claude as the frontier intelligence, developed using Claude Code. It combines retrieval-augmented generation with expert-approved text and case-specific variables to produce accurate, compliant documentation, starting with clinical study reports and expanding to device protocols and patient materials.

- 10+ weeks to 10 minutes for clinical study documentation
- 95 percent reduction in resources for device verification protocols, from entire departments to single users
- 50 percent fewer review cycles through improved clinical accuracy
- Complete study booklets produced in under one minute
- An 11-person team that stays agile while expanding capabilities

## Clinical workflows: Bluenote

Bluenote built AI agents that let life sciences researchers spend their time on science, not paperwork.

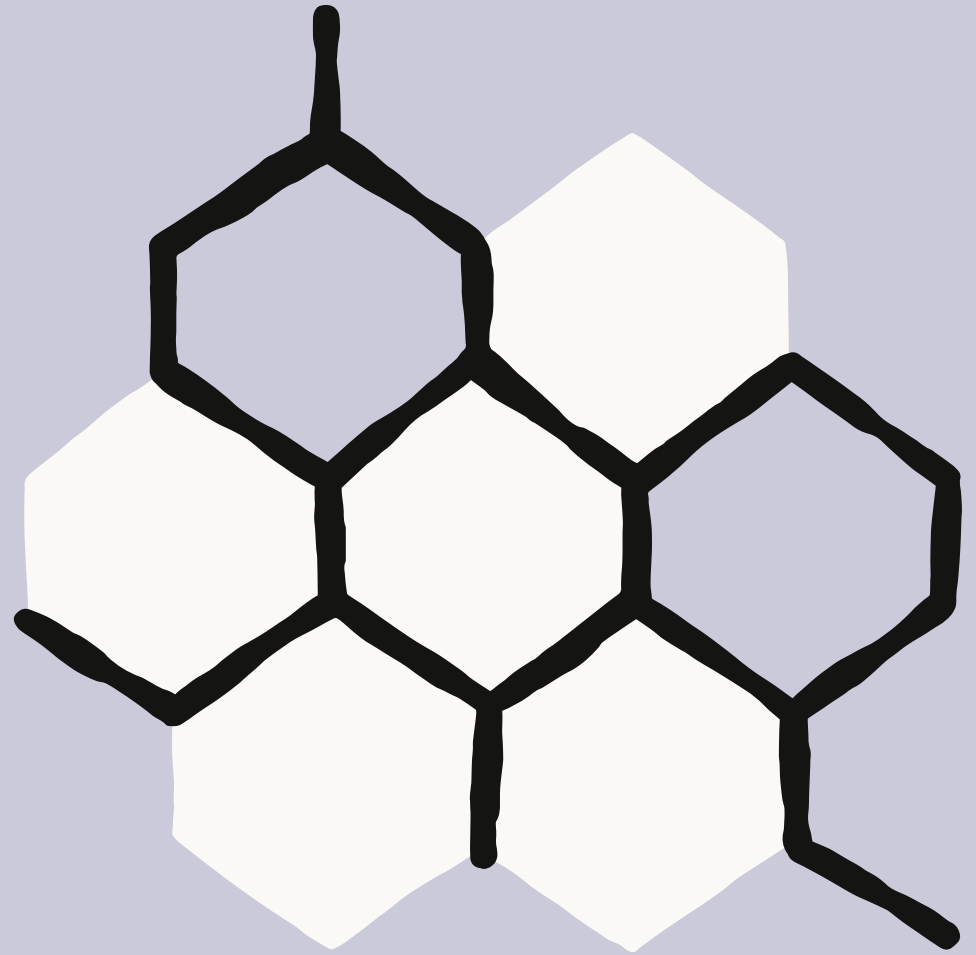
#### The challenge: documentation that consumes researchers

Bringing a new treatment to market demands as much paperwork as it does research. Regulatory submissions, clinical trial reports, and quality validations are essential — but they consume days or weeks of a researcher's time.

#### The solution: Claude-powered agents for clinical and regulatory workflows

Bluenote builds AI agents that automate the documentation work woven throughout clinical operations—regulatory submissions, study reports, validation protocols, compliance forms. Their agents process regulatory documents, generate technical reports with proper citations, and handle complex multi-step workflows, all with robust guardrails, data traceability, and highlighted calls to action for human experts to contribute additional context and review. Claude serves as the default model for scientific and technical documentation, chosen for its citation capabilities and accuracy in a domain where every claim must trace back to a source.

- 50–75% faster regulatory document production
- 10x faster protocol analysis for scientists
- Multi-hundred-page scientific documents with tables, figures, and citations generated in minutes
- Compliance gaps flagged automatically against the latest regulatory guidelines



Your AI transformation  
starts today

# Your AI transformation starts today

Successful adoption begins with an honest assessment of where you stand and a clear view of the path forward.

## Life Sciences AI Adoption Index

Before your first pilots, evaluate your organization across the dimensions below to find your starting point.

Dimension	Building foundation (1-2)	Growing capability (3-4)	Transformation ready (5-6)	Your score
<b>Executive commitment</b>	AI viewed as an IT or informatics project	C-suite interested, competing R&D priorities	CEO championing AI across drug development, multi-year commitment	
<b>Data infrastructure</b>	Siloed lab, clinical, and manufacturing systems; manual data entry	Centralized data warehouse, basic governance and lineage tracking	Modern platform, automated pipelines from bench to submission	
<b>Technical capabilities</b>	Legacy LIMS and ERP, limited cloud adoption	Hybrid cloud, basic DevOps, some API integrations	Cloud-native, strong engineering team, real-time data access	
<b>Regulatory and compliance readiness</b>	Reactive, manual controls; AI outputs not audit-ready	Established validation program, regular audits, basic 21 CFR Part 11 compliance	Proactive controls, automated audit trails, AI outputs validated for submission	
<b>Change management</b>	Initiatives stall due to scientific skepticism or IT friction	Mixed adoption; scientists using AI tools inconsistently	Proven change management, high trust among researchers and compliance teams	
<b>Cross-functional collaboration</b>	R&D, regulatory, and manufacturing operate in silos	Regular cross-functional meetings, shared goals emerging	Integrated teams across discovery, clinical, CMC, and regulatory affairs	
<b>AI and ML maturity</b>	No AI experience beyond exploratory tools	Initial models in production (e.g., predictive analytics, image analysis)	Multiple AI applications deployed across the development lifecycle	
<b>Validated data and IP governance</b>	No formal data governance for AI inputs	Data classification in progress, basic access controls	Validated data sources, clear IP ownership, audit-ready provenance	
<b>Budget and resources</b>	Project-based funding tied to individual studies	Annual AI budget established, dedicated informatics team	Multi-year investment secured, AI embedded in portfolio planning	

### Scoring guide:

- **30 to 48 points (high readiness):** Launch a comprehensive program with multiple pilots across functions.
- **16 to 29 points (moderate readiness):** Begin with three to five strategic pilots while addressing foundational gaps.
- **8 to 15 points (building readiness):** Secure executive sponsorship and establish governance before launching one or two narrow pilots.

## Your first 90 days: a pilot roadmap

The three steps in this guide fit inside a single quarter. Ninety days gives you enough time to lay the foundation, prove value with real users, and earn the mandate to scale, without compromising the rigor regulated science demands.

### Days 1–30: Start and scaffold

Spend the first month on groundwork. None of it produces output yet, but all of it determines whether the next sixty days hold up.

- **Convene your steering committee.** Confirm the executive sponsor, agree on decision rights, and set a meeting cadence that keeps pace with your speed of execution.
- **Pick one or two pilots.** Start with the lower-risk, high-value use cases from Step 2, such as scientific documentation or literature review, and define exactly which workflow each pilot lives in.
- **Set success metrics before launch.** Agree on the adoption, efficiency, quality, and satisfaction measures you'll track weekly, and capture a baseline so improvement is measurable.
- **Put guardrails in writing.** Document access controls, review requirements, and escalation paths so compliance and quality teams can sign off before the first user logs in.
- **Recruit your first users and champions.** Choose respected scientists and regulatory specialists, including a few thoughtful skeptics, and give them a direct line to the project team.

### Days 31–60: Prove

With scaffolding in place, move the pilot into real work and let the evidence accumulate.

- **Go live in real workflows.** Run the pilot inside actual studies and submissions rather than sandboxes, with human review on every output.
- **Track metrics weekly.** Review adoption, efficiency, and quality numbers as they come in so you catch friction while there's still time to fix it.
- **Hold structured feedback sessions.** Capture what users route around, what surprises them, and what they'd protect if the tool disappeared tomorrow.
- **Build the validation record as you go.** Collect audit trails, review evidence, and change documentation now rather than reconstructing it later.

### Days 61–90: Scale

The final month converts pilot results into an expansion mandate.

- **Run the post-mortem.** Look past the headline numbers to the workarounds, surprises, and adoption patterns described in Step 2.
- **Take results to the steering committee.** Present metrics against the baselines you set in month one, and secure budget and sponsorship for the next wave.
- **Stand up your center of excellence.** Seed it with pilot champions and the validation practices you've already proven, so the second wave starts faster than the first.
- **Choose the next use cases.** Let cross-functional demand from your showcases guide the queue, and sunset anything that didn't earn its place.



The vision: *AI-first enterprises*  
that reshape life sciences

# The vision: AI-first enterprises that reshape life sciences

Six months from now, your organization could look different. Research teams compress discovery timelines by months as AI agents synthesize decades of literature and surface novel targets. Regulatory teams prepare submissions in weeks instead of quarters, with assistants that understand CFR, ICH guidelines, and global requirements. Clinical operations resolve protocol questions and safety signals in near real time.

The deeper change goes beyond efficiency. AI-first life sciences organizations bring therapies to patients faster, catch safety signals earlier, and draw out insight buried in decades of clinical and real-world data. They free every scientist to focus on discovery and every regulatory team to build stronger submissions.

The question isn't whether AI will reshape life sciences. It's whether your organization will lead that change or follow competitors who moved first.

## Ready to begin your AI transformation?

Join organizations already putting Claude to work.

- **Contact Anthropic's Sales team** to discuss your use cases and implementation strategy
- Learn about **Claude for Life Sciences**, trusted by organizations like Eli Lilly, AbbVie, and Sanofi to accelerate scientific discovery
- Access Claude through the **Claude for Microsoft 365**, **Claude Cowork**, and **Claude Code**
- Review our enterprise documentation and safety guidelines at **docs.anthropic.com** and the **Trust Center**
- Explore **Claude Code** to accelerate scientific and regulatory engineering workflows

