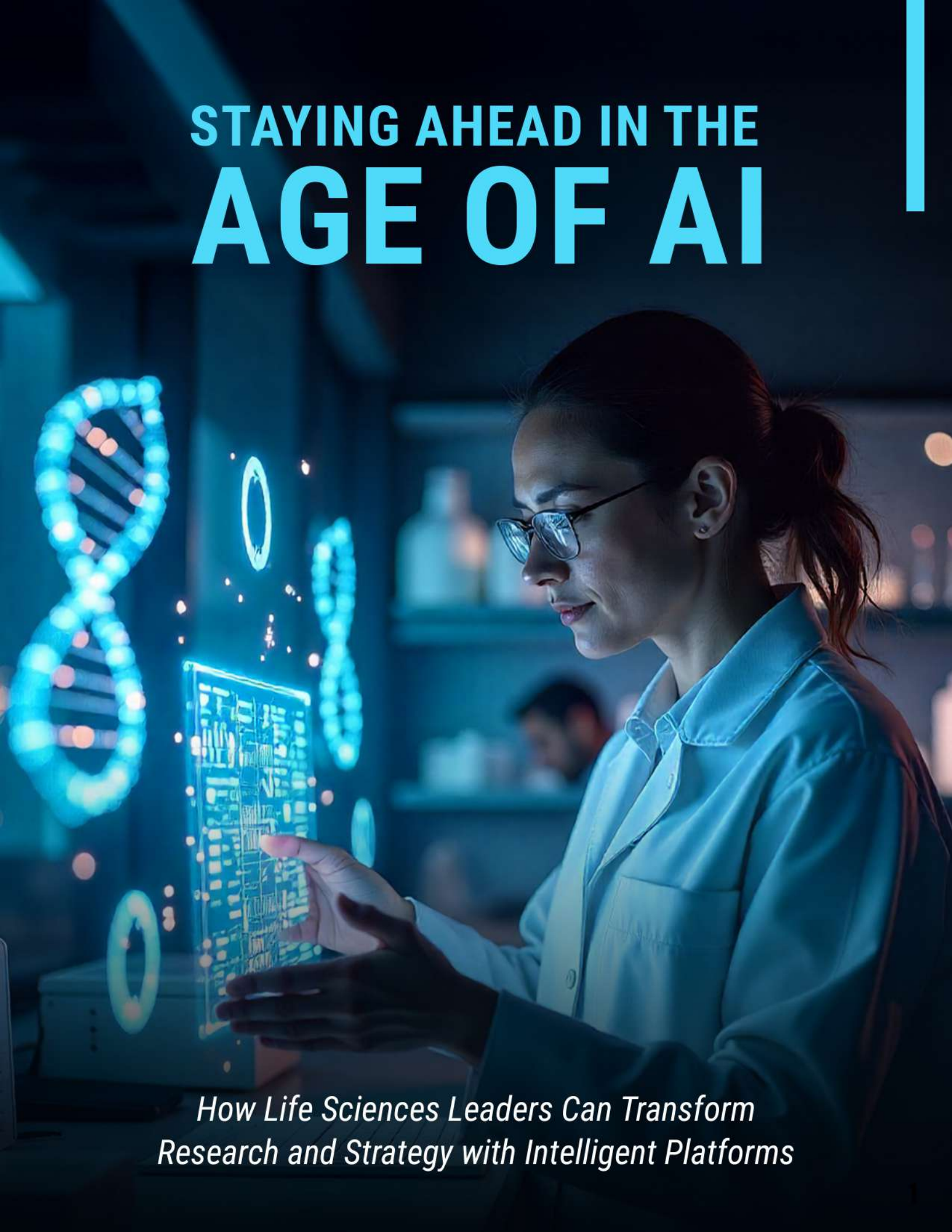
STAYING AHEAD IN THE AGE OF AI



How Life Sciences Leaders Can Transform Research and Strategy with Intelligent Platforms

Foreword

Pharma's Inflection Point

The pharmaceutical industry is standing on the edge of a strategic transformation. AI is revolutionizing how we gather insights, shape decisions, and deliver value—across clinical development, market access, medical affairs, and regulatory functions. **OpenAI reports a 5.6x increase in advanced model releases since 2022, with model execution costs down 280x.** But for life sciences leaders, this progress means nothing if the tools aren't safe, explainable, and regulatory-ready.

Generic large language models (LLMs), while promising, don't meet the precision or compliance standards required in pharma. Instead, organizations need purpose-built platforms designed for the complexities of **drug development, evidence generation, and payer negotiation.**

Knolens is such a platform—built with regulatory expectations, clinical rigor, and cross-functional workflows in mind.

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The Case for Purpose-Built AI in Life Sciences

AI isn't just enhancing productivity—it's redefining pharmaceutical strategy. From cost savings in SLRs to faster HTA submissions, purpose-built **AI can shrink timelines and improve scientific rigor.**

Life sciences companies embracing domain-specific AI are already realizing:

2x

faster insight cycles in Medical and Regulatory

70%

fewer errors in real-world evidence reviews

Real-time updates on competitive trials payer shifts, and approval pathways

But to capitalize on AI, companies must invest in **platforms architected for compliance, traceability, and life sciences logic**—not consumer grade tools.

The Limitations of General Purpose AI in Pharma

While generic LLMs are capable of generating fluent text, they consistently fail where pharma demands precision and accountability.

Challenges:

1. Scientific Hallucination

- **<70% accuracy** on PhD-level chemistry and biology
- Risks in **HTA, publication,** and **clinical strategy** narratives

2. No Domain Ontology

- Lacks understanding of **disease-drug-trial relationships**
- Cannot parse between endpoints, **biomarkers, or patient stratification**

3. Non-Compliance with FDA Requirements

- No source **traceability**
- Lacks lifecycle management, **audit trail, or explainability**
- Unacceptable for **regulatory or payer-facing use**

Knolens: A Platform Designed for Life Sciences

Knolens is a next-generation intelligence platform purpose-built for life sciences professionals.
It combines:

01 **Life sciences ontologies** to retain scientific relationships

02 **Dynamic, audit-ready outputs** that align with FDA and HTA requirements

03 **Cross-functional intelligence** hubs with live dashboards

04 **Searchable Scapes and Quests** for real-time reusable knowledge

With Knolens, pharma teams create evidence maps, payer simulations, regulatory scenarios, and trial benchmarks in hours not weeks.

Align – Build Cross-Functional Strategy with AI at the Core

Strategy misfires often stem from misalignment—between Medical, Regulatory, R&D, and Market Access. Knolens solves this by offering a **unified, living source of truth.**

Real-World Use Cases:

- Global Value Dossiers auto-updated from trial changes
- Regulatory-Access-HEOR alignment around HTA precedence
- Cross-functional dashboards for global launch planning

Key Actions:

- Create a cross-functional AI governance group
- Align data pipelines around payer, clinical, and RWE signals
- Use shared AI platforms for all evidence synthesis functions

Activate – Empower Scientific Teams with Domain AI

AI is most powerful when it empowers domain experts—not just data teams.

Knolens delivers user-friendly interfaces, pre-built ontologies, and automated scenario tools that work for:

- Medical Writers
- Access Strategists
- HEOR Experts
- Regulatory Professionals
- MSLs and KOL Liaisons

Activation Programs:

- AI literacy for scientific functions (not just IT)
- Live workshops using submission use cases
- Knolens Edge for mobile access to conference intelligence

Amplify – Scale Use Cases Across the Enterprise

Don’t let innovation live in a silo.

Knolens makes every asset—SLRs, value messages, protocol analyses—searchable and shareable.

Examples:

- Weekly internal newsletters auto-summarizing HTA wins
- Searchable use case libraries for new indication teams
- Insights created in France reused in LATAM launches

Scaling Playbook:

- Assign a Global AI Insights Curator
- Build a modular content hub with Scapes/Quests
- Create KPIs tied to asset reuse across affiliates

Accelerate – Drive Faster Decisions Without Losing Control

Speed matters when filing, pricing, or launching—but only if accuracy is preserved.

Knolens Enables:

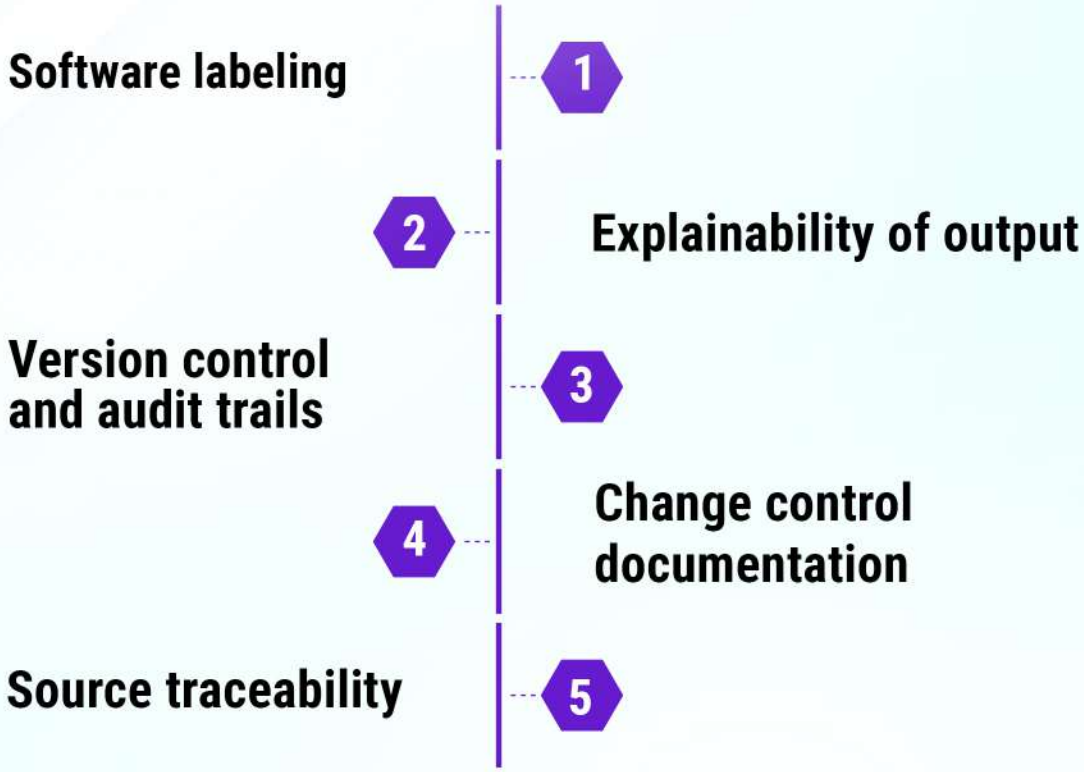
- Real-time simulation of regulatory pathways
- Auto-detection of new safety signals from competitor trials
- HTA-ready templates with full source traceability

Results:

- HTA submission prep: from 3 weeks to 3 days
- Pricing models updated with new trial outcomes in hours
- Portfolio-wide strategy simulation by indication, region, and timeline

Govern – Ensure Traceability Compliance & Scientific Integrity

FDA's guidance on AI-enabled medical functions outlines expectations around:



Knolens bakes all of these into the platform—ensuring trust, auditability, and lifecycle control.

Governance Features:

- Output versioning with timestamps
- Source links to original literature, HTA records, or trial data
- Role-based workflows for MLR review
- CFR Part 11-aligned access and signature control

The Competitive Advantage of Compliant AI

Pharma leaders using compliant AI platforms report:

- 80% faster clinical design strategy
- 3x increase in trial feasibility insight
- 70% fewer errors in submission-ready documentation
- Faster affiliate onboarding and strategy alignment
- Lower total cost of insight generation

Preparing Your Organization to Lead in the AI Era

Organizational readiness is key.

Must-Haves:

- AI vision from C-level sponsors
- AI included in Access, Regulatory, and Medical OKRs
- Training plans for functional teams
- Budget lines for platform governance and change management

Knolens Use Cases for Pharma Leaders

Function	Use Case	Value
Market Access	HTA feedback explorer	Tailor pricing & access strategy
Medical Affairs	Publication strategy builder	Respond to new competitor data
Regulatory	Global submission simulator	Generate region-specific content
R&D	Protocol benchmarker	Optimize trial design
BD & Strategy	Pipeline tracker	Monitor licensing targets
HEOR	Dynamic cost effectiveness modeling	Align with payer evidence frameworks

Regulatory & Compliance Alignment with FDA AI Guidance

Knolens aligns with:

- 21 CFR Part 11
- Good Machine Learning Practices (GMLP)
- AI Software Labeling Requirements
- Risk-based review frameworks

Key Regulatory Features:

- Traceable source attribution
- Explainable, auditable outputs
- Change logs for version control
- Submission-ready document formats

Change Management The Role of Medical Access & Legal

Medical:

- Validate scientific accuracy
- Guide evidence narrative generation

Market Access:

- Operationalize HTA and pricing strategies
- Drive payer insight reuse

Legal/Regulatory:

- Review audit trail requirements
- Set rules for traceability and model change logs

Building a Pharma AI Center of Excellence

What it does:

- Prioritizes AI use cases
- Standardizes platforms and playbooks
- Ensures regulatory compliance
- Measures ROI and value creation

Team Structure:

- C-level sponsor (CMO, Head of Regulatory, etc.)
- Cross-functional leads (Medical, Access, IT)
- Training & enablement leader
- Knowledge manager

Conclusion: Leading the Future of Intelligent Pharma Strategy

AI in life sciences isn't optional—it's transformational.

But without platforms designed for the scientific, regulatory, and strategic realities of pharma, AI becomes a liability, not an advantage.

Knolens empowers pharma to:

- Align cross-functional teams
- Activate insight generation
- Amplify successful strategies
- Accelerate regulatory and commercial timelines
- Govern intelligence with traceability and confidence

The future of pharma will be built by leaders who treat AI as infrastructure, not just innovation.

Want to learn how Knolens can future-proof your pharmaceutical strategy? Contact us today to schedule a customized demo or workshop for your leadership team.

Let me know if you'd like this content split into sections for slides formatted into a whitepaper, or uploaded to your CMS.