CLM for Life Sciences: Using AI to Move Beyond Spreadsheets

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Executive Summary

Contract Lifecycle Management (CLM) is increasingly recognized as a critical capability in the life sciences industry, far surpassing the simplistic spreadsheets of yesteryear. Life sciences organizations regularly execute thousands of agreements (e.g. clinical trial agreements, licensing deals, supply contracts) under stringent regulatory oversight ([1] www.sirion.ai) ([2] www.appliedclinicaltrialsonline.com). Historically, many companies managed this vast contractual workload with email and Excel spreadsheets – a highly error-prone, non-centralized approach lacking controls and audit trails ([3] vendorpanel.com) ([4] www.accordcontracts.com). Such manual processes not only slowed business cycles but exposed firms to compliance risk (HIPAA, FDA, GxP, EU data laws, etc.). Recent market data shows the global CLM solutions market is growing rapidly (US$1.64 billion in 2024, projected CAGR ~12.8%) ([5] www.fortunebusinessinsights.com), reflecting widespread industry recognition of CLM's value. In particular, healthcare and life sciences segments are moving from spreadsheets toward AI-enabled CLM platforms to improve efficiency and compliance ([6] www.fortunebusinessinsights.com) ([7] www.appliedclinicaltrialsonline.com).

This report provides an in-depth exploration of CLM in the life sciences sector *beyond the spreadsheet*, emphasizing how artificial intelligence (AI) and automation are transforming contractual processes. Key findings include:

- **Spreadsheet Risks:** Up to 40% of company data may reside in unmanaged spreadsheets ([4] www.accordcontracts.com), creating a lack of version control, facile errors (typos, missed deadlines), and no secure audit trail ([3] vendorpanel.com) ([8] www.dealsign.ai). Spreadsheets make it difficult to enforce policies or quickly aggregate contract information across studies or departments.
- **CLM Benefits:** Modern CLM systems provide a centralized repository, standard templates, approvals workflows, and compliance checks (e.g. built-in HIPAA/GxP controls) ([9] www.gartner.com) ([6] www.fortunebusinessinsights.com). Gartner notes CLM tools automate contracts from inception through renewal, mitigating risk by enforcing policy compliance and governance at scale ([9] www.gartner.com).
- **Rapid AI Adoption:** According to a 2024 industry survey, 75% of life science executives have begun using AI in their operations (with 86% planning full deployment within two years) ([10] www.axios.com). Yet only ~50% have formal AI governance in place ([11] www.axios.com). In contract management specifically, AI-driven platforms (using NLP and machine learning) now automatically ingest and analyze thousands of agreements. For example, AI can extract clauses, obligations, and budget tables from past clinical trial contracts, making historical data instantly usable ([12] www.appliedclinicaltrialsonline.com) ([13] www.appliedclinicaltrialsonline.com). Life sciences CLM tools are surfacing fallback clauses, highlighting site-specific risks (e.g. institutional language preferences), and automating negotiation recommendations ([14] www.appliedclinicaltrialsonline.com).
- **Impact on Trials:** Contracting bottlenecks are a known drag on clinical research. Industry analysts estimate roughly half of global study delays arise from contract and budgeting processes ([15] www.appliedclinicaltrialsonline.com) ([16] www.appliedclinicaltrialsonline.com). Efficient CLM can cut cycle times by ~33% ([17] www.appliedclinicaltrialsonline.com) – potentially shaving six months off a typical multi-year trial. In practice, early adopters report dramatic improvements: one top-5 pharma cut investigator onboarding from **120 days to 60 days** (a 50% reduction) by centralizing contracts and data ([18] www.appliedclinicaltrialsonline.com). Another firm saw standardized global processes leading to faster approval gates and better data visibility ([19] www.appliedclinicaltrialsonline.com).
- **Future Directions:** The trajectory is toward ever-greater automation and intelligence. Generative AI (e.g. GPT-4) is beginning to be applied to draft clauses or summarize negotiation points, but it introduces new governance needs (e.g. preserving AI prompts for compliance ([20] www.reuters.com)). Regulators are also

focusing on AI: the EU's AI Act will soon impose risk-based obligations on automated decision tools, including those used in legal agreements ([21] www.reuters.com). As adoption grows, life sciences companies will need robust AI strategies – many currently lack policies or auditing for AI ([11] www.axios.com).

In summary, moving *"beyond the spreadsheet"* means embracing CLM platforms augmented by AI. This evolution is well underway in life sciences: industry leaders cite contract intelligence as a core pillar of digital transformation ([22] www.icertis.com). When properly implemented, AI-enhanced CLM promises faster time-to-market, tighter compliance (tracking HIPAA, clinical research obligations, etc.), and smarter use of institutional knowledge.The remainder of this report unpacks these themes in detail, providing background, data analysis, case studies, and forward-looking insights into CLM for life sciences organizations.

1. Introduction and Background

Contract Lifecycle Management (CLM) encompasses all processes by which organizations create, execute, monitor, and renew contracts. Gartner defines the CLM market as "solutions that proactively manage contracts from initiation through negotiation, execution, compliance and renewal" ([9] www.gartner.com). In practice, CLM systems provide features like contract drafting, approval workflows, digital signing, centralized repositories, obligation tracking, and analytics. The goals are to accelerate deal cycle times, enforce corporate policies, and reduce legal and financial risk.

In highly regulated industries like pharmaceuticals, biotechnology, and medical devices, contracts are especially critical. Life sciences organizations execute agreements at every stage of the drug/device lifecycle: research collaborations, intellectual property licenses (e.g. for novel molecules or platform technologies), clinical trial agreements (CTAs) with research institutions and vendors, manufacturing and supply contracts (with contract manufacturing organizations, CMOs/CROs), distributor licenses, and post-market surveillance/dealership agreements. According to industry analysts, "contracts are at the heart of every pharmaceutical initiative — from early-stage R&D and clinical trials to manufacturing, distribution, and post-market surveillance" ([1] www.sirion.ai). Proper management of these contracts ensures regulatory compliance (FDA, EMA, HIPAA, GDPR, etc.), timely market access with CROs and CMOs, risk mitigation in joint ventures and licensing, and optimized financial performance through favorable terms ([1] www.sirion.ai).

However, life sciences contract portfolios are vast and complex. For example, the **Tufts Center for the Study of Drug Development** reported that the number of procedures in clinical trials has skyrocketed: Phase II procedures grew ~69% and Phase III procedures ~49% over a recent decade ([23] www.sirion.ai). This drives up the volume and intricacy of trial agreements. Moreover, outsourcing is now the norm: drugmakers routinely engage numerous CROs globally, each requiring negotiated CTAs. Sirion Lab notes "outsourcing to CROs has helped lower the entry barrier," but adds "contracts between pharma companies and outsourcing providers such as CROs are a critical lever of success… budget and contract negotiation are the biggest causes for delays in clinical trials" ([24] www.sirion.ai). In short, without effective contract management, life sciences companies face delays, higher costs, compliance breaches (if, say, a regulated clause is missed), and ultimately risks to patient outcomes.

Historically, even large pharma firms relied on spreadsheets, email, and file servers to track contracts. Many SMEs still do. A recent industry source notes *"up to 40% of many companies' data is managed in spreadsheets"* ([4] www.accordcontracts.com). Legal teams may keep simple Excel trackers listing contract names, parties, expiration dates, etc. This approach is quick to start but quickly breaks down: scattered files, obscure email chains, and local drives make visibility poor. As one analysis puts it, spreadsheets are "solitary files, practically devoid of system-wide controls," so *"almost any employee can create, access, manipulate or distribute the data"* without oversight ([3] vendorpanel.com). These vulnerabilities are acute in life sciences, where an overlooked confidentiality breach or missed regulatory clause (e.g. inadequate informed consent language) can carry heavy fines or trial halts.

Evolution of CLM: Over the past decade, the CLM market has matured into commercial and SaaS solutions, often integrated with enterprise systems (ERP/CRM/CTMS). The current market, estimated at about **US$1.64 billion in 2024** ([5] www.fortunebusinessinsights.com) with double-digit growth ahead, reflects this shift. Gartner's 2024 Magic Quadrant identified ~17 major CLM providers, many built with AI capabilities ([25] www.icertis.com). Leading vendors (Icertis, Sirion, Conga, Ironclad, DocuSign CLM, etc.) now emphasize *"contract intelligence"* – AI-powered analytics that extract data from agreements to inform business decisions. According to Icertis, their software is used by **enterprises across 90 countries, including over 30% of the Fortune 100** ([22] www.icertis.com). Icertis claims to "transform the role of contracts" via GenAI and integration, helping customers capture the full value of every deal ([22] www.icertis.com). The rapid growth of the CLM sector signals that organizations are moving *"beyond spreadsheets"* toward automated, strategic contract management.

2. Challenges of Spreadsheet-Based Contract Management

Despite CLM's growth, many life sciences groups still rely heavily on manual tools. Spreadsheets remain ubiquitous due to familiarity and low cost: Excel is used by over a billion people worldwide ([26] www.volody.com), and it integrates easily with Word or Outlook. However, for contract administration, this approach introduces significant risks and inefficiencies:

- **Lack of Control & Governance:** A spreadsheet is essentially a static file. There is no built-in version control or access audit. Employees might email contract trackers between groups, leading to multiple out-of-sync copies. Vendor analysts warn that spreadsheets leave an organization vulnerable: *"Practically any employee can create, access, manipulate, or distribute the data"* ([3] vendorpanel.com). Crucial approval steps may be ticked off with no record of who made the change or why. In a regulated environment, this makes demonstrating compliance nearly impossible. By contrast, a CLM system provides user permissions, audit trails, and enforced review paths.

- **Error-Prone and Inaccurate Data:** Manual data entry is notoriously error-prone. A single typo in an expiration date or financial amount can have cascading effects. Contract specialist Bert Myburgh notes *"even minor errors can have knock-on effects if not fixed in time"*. Correcting spreadsheet errors often requires hours of detective work, which is time-consuming and distracts from value-added tasks. Inaccurate or outdated data also leads to poor decisions and compliance violations – for example, failing to renew an active clinical trial contract on time can violate regulatory patient safety requirements.

- **Lack of Centralized Data:** Spreadsheets typically exist on local drives or shared file folders. This fragmented storage means information is siloed. Locating all contracts with a given research site, vendor, or clause reference involves manual searching across folders. Dealsign.ai points out that spreadsheets *"do not allow for centralized storage"*, making it easy to overlook critical contracts ([8] www.dealsign.ai). By contrast, a CLM system centralizes all documents and metadata, enabling enterprise-wide search and reporting.

- **Poor Reporting and Analytics:** Advanced reporting is nearly impossible with spreadsheets. At best, a power user may create complex pivot tables, but these are static and require manual updates. Vendor blogs note that generating any analytics "can take hours" and lack meaningful integration ([27] vendorpanel.com). In life sciences, organizations want to track metrics (e.g. average negotiation cycle time, number of contracts per therapeutic area, compliance audit results). CLM platforms can automatically gather such data and apply AI to surface trends (e.g. flagging systematically slow review stages or often-negotiated clauses), which spreadsheets cannot do efficiently.

- **Security and Audit Trail:** Regulatory bodies expect robust record-keeping. Excel files are typically not encrypted or centrally logged. A change could be made off-hours without trace. This makes it difficult (or impossible) during an audit to prove who approved a contract or who updated a term. A modern CLM, in contrast, uses enterprise-grade security (encryption, single sign-on) and maintains a tamper-evident audit trail with timestamps and user ID for every action.

The table below summarizes key contrasts between spreadsheet-based contract tracking and an automated CLM system.

Feature / Risk	Spreadsheets (Manual)	CLM System (Automated + AI)
Collaboration & Versioning	Separate files, emailed PDFs, no guaranteed version control ([3] vendorpanel.com)	Centralized repository with role-based access and enforced workflows ([6] www.fortunebusinessinsights.com)
Audit & Governance	No built-in audit trail; approvals not formally logged ([3] vendorpanel.com)	Comprehensive audit logs; electronic signatures; policy checks
Data Entry Errors	Manual input with high error risk ([28] vendorpanel.com)	Automated clause recognition and validation; AI flags inconsistencies (e.g. conflicting terms)
Reporting / Analytics	Basic (manual filtering/pivot tables); slow to update ([27] vendorpanel.com)	Advanced dashboards and AI-driven insights (e.g. identify bottlenecks, revenue impact)
Security	Multiple file copies, limited encryption; duplicates possible ([8] www.dealsign.ai)	Enterprise security (encryption, permissions); single source of truth
Scalability	Unmanageable beyond dozens of contracts	Scales to thousands+ with search index and automated data capture
Compliance	High risk of missed obligations (hard to audit)	Built-in reminders, obligations tracking, and compliance templates (e.g. HIPAA, GDPR) ([6] www.fortunebusinessinsights.com)

Table 1: Comparison of Spreadsheet Contract Tracking vs. Modern CLM Solutions (Sources: vendor analyses ([3] vendorpanel.com) ([6] www.fortunebusinessinsights.com), industry reports ([9] www.gartner.com) ([4] www.accordcontracts.com)).

The upshot is clear: spreadsheets lack infrastructure to manage critical legal data at scale, especially in risk-averse life sciences. Despite this, many organizations started their CLM journey via "poor man's CLM" – an Excel template with contract metadata. As one source notes, combining email and a structured spreadsheet *"may help increase visibility into contracts and could be the first step towards taking control"* ([4] www.accordcontracts.com). However, this "first step" often exposes further gaps (e.g. multiple unlinked trackers). Rationalizing dozens of contract templates, multiple country rules, and frequent regulatory changes, culminating in tens of thousands of documents, simply cannot be sustainably handled in spreadsheets. This creates a pressing business case for transitioning to purpose-built CLM technology.

3. The Modern CLM Market and Life Sciences Adoption

3.1 CLM Market Overview

The CLM market has grown rapidly as enterprises recognize the ROI of automation. A recent market analysis estimates global CLM solution revenues at US$1.64 billion in 2024, projected to double to ~$3.47 billion by 2032 (CAGR ~12.8%) ([5] www.fortunebusinessinsights.com). North America is dominant (39.1% share in 2024) ([5] www.fortunebusinessinsights.com). Within markets, Gartner and industry reports note that CLM adoption spans many sectors, with especially strong uptake in **legal/compliance** (the largest vertical) and **healthcare & life sciences** ([29] www.fortunebusinessinsights.com).

CLM vendors now commonly offer cloud-native solutions, integrations (to CRM, ERP, electronic signature, contract research systems), and embedded analytics. A 2024 Gartner Magic Quadrant again recognized leaders like Icertis, Conga, and others, many emphasizing AI capabilities. Icertis's press release highlights that it is "AI-powered contract intelligence" and has been named a leader for five years running ([25] www.icertis.com). According to Icertis, customers include over 30% of the Fortune 100, underscoring broad enterprise trust in CLM solutions ([22] www.icertis.com).

Fortune Business Insights segments the CLM market by industry. Among these, **healthcare & life sciences** is a key segment, with contracts needed for employment, technology licensing, telehealth services, and experimental treatments ([29] www.fortunebusinessinsights.com) ([30] www.fortunebusinessinsights.com). Traditionally, this segment "focused primarily on shared drives and spreadsheets" ([30] www.fortunebusinessinsights.com) (as noted earlier). Importantly, the report states: *"Due to this [inefficient spreadsheet usage], healthcare & life science organizations have started adopting CLM solutions. The software is used by the healthcare & life science sector to allow organizations to collaborate and negotiate contracts in real-time… approving, reviewing, marking up documents, and executing them electronically"* ([6] www.fortunebusinessinsights.com). The healthcare segment is anticipated to grow even faster during the forecast period ([31] www.fortunebusinessinsights.com). In summary, CLM vendors and analysts confirm that life sciences companies are on the move: investments in CLM software have shifted from optional to essential for managing regulatory and operational complexity.

3.2 Drivers of CLM Adoption in Life Sciences

Why are life sciences firms adopting CLM solutions? The drivers include:

- **Regulatory Compliance and Risk:** Life sciences contracts often involve patient data (HIPAA/GxP compliance), human subjects (informed consents in CTAs), FDA or EMA reporting clauses, and intellectual property protections. A single overlooked clause can have outsized consequences (trial holds, fines). A modern example: ensuring contracts reflect current FDA guidance (e.g., data monitoring or safety reporting clauses) is laborious in manual systems. CLM systems can enforce updated templates and track obligations (for instance, automatically alerting when a clinical site agreement's data privacy terms must be re-approved under new GDPR rules).

- **Complex, Distributed Workflows:** Global trials involve sites, CROs, investigators, and vendors across continents. Without automation, routing documents for local legal review and simultaneous translations is chaotic. CLM platforms support workflow automation – for example, intelligent routing based on region or study type. Moreover, centralizing contracts enables cross-study analysis: a contract with "ImageLab CRO" in Asia can be linked to other deals with the same party, surfacing negotiation learnings. These capabilities are impossible with disconnected spreadsheets.

- **Speed and Time-to-Market:** In pharma and biotech, accelerating drug development is paramount. As the industry showcased during COVID-19, speed can save lives. Contracts are often a bottleneck: interviews with life sciences CLM practitioners report that *"nearly half of study delays are tied to contracting bottlenecks"* ([32] www.appliedclinicaltrialsonline.com) ([7] www.appliedclinicaltrialsonline.com). By automating NDA exchanges, standardized templates, and parallel reviews, CLM reduces cycle times. The statistics speak volumes (see Section 4).

- **Data-Driven Insights:** Executives increasingly want data on contracting patterns. How many oncology vs. cardiology trials are delayed by contract disputes? What is the average discount or rebate across clinical trial agreements? With spreadsheets, these analytics are impractical. Modern CLM can leverage AI to extract structured data (e.g., payment terms, milestone timelines) from contract text, enabling dashboards and predictive analytics. For example, one large pharma reports using AI to flag deviations from standard payment terms, reducing unbudgeted spend ([12] www.appliedclinicaltrialsonline.com).

- **Improved Collaboration:** Many life sciences orgs use Contract Lifecycle Management to integrate with related systems: e.g. linking a Clinical Trial Management System (CTMS) to CLM, so that study protocol data (patient targets, criteria) flows into the contracting process. One case study noted a leading pharma integrated their CTMS data (inclusion criteria, patient numbers, sites) into the CLM, structured by country, enabling faster onboarding ([2] www.appliedclinicaltrialsonline.com). This type of digital backbone increases transparency and removes data re-entry – a clear advantage over static spreadsheets.

In brief, the complexity and stakes of life sciences contracting, combined with the promise of automation, are driving a transition from ad-hoc spreadsheets to AI-augmented CLM platforms across the industry.

4. AI and Automation in CLM

Over the last few years, **artificial intelligence** has become a focal point for CLM innovation. AI in this context generally refers to machine learning and natural language processing (NLP) techniques applied to the content of contracts, as well as emerging generative models. The following are key AI-enabled capabilities transforming CLM:

- **Automated Clause and Metadata Extraction:** NLP algorithms can *ingest* large volumes of contracts (in PDF or Word form), and automatically extract structured data fields: parties, effective date, expiration date, payment amounts, indemnification clauses, confidentiality terms, etc. In life sciences, this is crucial for pooling historical trial agreements. Tom Cowen of Conga notes that firms can *"ingest these documents into a central repository, extract clauses, metadata, and budget tables, and make that information usable"* ([12] www.appliedclinicaltrialsonline.com). For example, budget tables within CTAs (showing per-patient reimbursement or drug supply costs) can be parsed by AI so finance teams can quickly audit trial budgets across studies. This ends the era where each Excel row must be manually updated, and it preserves knowledge – e.g. one can query *"show me how Company X negotiated indemnity in oncology studies"*.

- **Intelligent Search and Clause Similarity:** Beyond simple keyword search, AI enables semantic search across contracts. By generating embeddings or contextual representations, CLM systems allow users to find all agreements similar to a given clause or that mention a specific concept. This is invaluable in life sciences where multiple terms may be used for the same regulation or technical concept (e.g., "Biosimilar" vs "Follow-on biologic"). AI can group similar clauses, identify outliers, and help maintain contract standards.

- **Contract Risk Scoring and Audit:** Machine learning models trained on large corpora of contracts can identify risky or non-compliant language. For instance, if a vendor often uses a broad liability cap that violates company policy, an AI can flag this in the drafting phase. In clinical research, an AI might flag missing ethical language or deviating IRB/ethics conditions, prompting review. Some systems offer a "risk register" where each clause in a new contract is auto-scored, guiding legal reviewers to focus on non-standard terms.

- **Negotiation Guidance:** Advanced CLM platforms are beginning to incorporate negotiation analytics. AI can learn from past deals: for example, Conga claims its AI can *"surface fallback clauses and highlighting site-specific preferences. If an institution like Mass General… insists on certain language, the system can immediately flag the associated risks and help determine the best course of action"* ([33] www.appliedclinicaltrialsonline.com). Practically, this means a contract manager need not manually recall that *"MGH typically wants this indemnity language"* – the AI already knows from historical data. This accelerates negotiations and avoids costly missteps.

- **Template Rationalization:** Life sciences often accumulate an unwieldy number of contract templates (different forms per country, business unit, therapy area, etc.). ML can cluster and analyze these templates to suggest consolidation. For example, Cowen notes that *"AI can analyze and reorganize environments so it's easier to support fewer, more complete templates"* ([34] www.appliedclinicaltrialsonline.com). Standardizing templates reduces risk and maintenance overhead.

- **AI-Assisted Drafting:** While still emerging, generative AI (LLMs) can draft contract language or summarize clauses. In mature CLM systems, an AI might propose initial contract text using approved language snippets, or generate short plain-language summaries of complex clauses for business users. This functionality is nascent in life sciences, but the trend is growing – some vendors already offer "AI contract authoring" based on large legal language models. (Caution is required here: generated language must be carefully reviewed to ensure it meets stringent compliance needs.)

- **Automated Alerts and Workflows:** AI also powers workflow automation. For example, ML may predict when a contract will need renewal well before the literal calendar alert – by learning typical cycle lengths or early signs of negotiation delay. Intelligent bots can monitor correspondence, auto-assign tasks, or send reminders when certain thresholds (budget spend, trial enrollment timelines) are met. UiPath's partnership with Veeva for life sciences validation (e.g. CLM in validation workflows) exemplifies this trend ([35] www.itpro.com).

The table below summarizes some AI-enabled CLM capabilities and their benefits in life sciences contexts:

AI-Enabled Capability	Benefit / Functionality	Life Sciences Example (Source)
Clause & Metadata Extraction	Automatically parse key terms (dates, payment, obligations) from contracts; populate fields in database ([12] www.appliedclinicaltrialsonline.com) ([13] www.appliedclinicaltrialsonline.com).	E.g. ingest historical CTAs to recall how a clause was negotiated with Mayo Clinic 3 studies ago ([12] www.appliedclinicaltrialsonline.com).
Negotiation Support	Surface fallback or non-standard clauses; flag site/institution preferences ([33] www.appliedclinicaltrialsonline.com).	AI highlights if "Mass General" insists on a special indemnity clause, enabling prompt legal review ([33] www.appliedclinicaltrialsonline.com).
Template Rationalization	Analyze clause usage across templates, recommend consolidating or updating forms ([34] www.appliedclinicaltrialsonline.com) ([13] www.appliedclinicaltrialsonline.com).	Reduce hundreds of local site templates into a unified workflow, simplifying global trial contracting.
Risk Scoring & Compliance	Score contract risk against policy; detect missing compliance terms	Auto-identify contracts missing FDA-required regulatory disclaimers or HIPAA clauses in data agreements.
Automated Alerts/Reminders	Track obligations and flag deadlines	Notify trial managers of upcoming milestone payments or audit report due dates.
Analytics & Benchmarking	Aggregate data (cycle times, spend, renego success rates) for reporting	Dashboard shows one CRO has 30% faster contract turnaround than peers; business can renegotiate SLAs for others.

Table 2: AI-Driven CLM Capabilities and Benefits (illustrative examples from industry interviews ([12] www.appliedclinicaltrialsonline.com) ([13] www.appliedclinicaltrialsonline.com)).

Overall, the integration of AI into CLM is about converting unstructured legal language into structured, actionable data. In life sciences, as company after company undertakes digital transformation, the expectation is that contracts become *smart* – linked to clinical trial systems, procurement databases, and even R&D outcome repositories. This AI infusion helps life sciences teams move beyond reactive "crisis management" of agreements to a proactive, intelligence-driven process.

5. Specific Applications in Life Sciences

To illustrate how CLM and AI come together in life sciences, we examine several key domains:

5.1 Clinical Trial Agreements (CTAs)

Clinical trials frequently involve hundreds of sites and service providers. Managing CTAs is notoriously complex: each site may have its own legal requirements (privacy/data clauses, insurance requirements), each regulatory agency (IRB/ethics committees) may impose additional terms, and budgets often must be negotiated per site. Tom Cowen of Conga (a CLM vendor) emphasizes that *"onboarding and clinical trial agreements"* have been

transformed by AI-CLM ([36] www.appliedclinicaltrialsonline.com). Historically, trial agreements were "scattered across hard drives, SharePoint, or Word files, making them difficult to access." AI-CLM remedies this by central ingestion: the system automatically indexes all past CTAs and patient budget tables. This means a study manager can quickly answer a question like "What was the reimbursement rate for Site X in our last oncology trial?" because the AI has parsed that data.

Moreover, clinical trial contracts often delay study startup. The Association of Clinical Research Professionals estimates *"nearly half of study delays stem from [the trial contracting and budgeting] process"* ([15] www.appliedclinicaltrialsonline.com). These delays directly impact patient access to new treatments. CLM can cut these delays dramatically: interview data indicates efficient CLM usage *"can reduce cycle times by roughly 33% and improve accuracy by a similar margin, potentially cutting six months off typical trials"* ([17] www.appliedclinicaltrialsonline.com). In one real-world example, a top-5 pharmaceutical firm implemented a global CLM instance that integrated study protocol data from its CTMS. By standardizing templates across countries and automating site onboarding, the company **halved** its investigator site contracting time for oncology studies – from 120 days down to 60 days ([18] www.appliedclinicaltrialsonline.com). This in turn meant trials reached FDA submission **two months faster**. Similarly, another major biotech took a "global-first" approach to standardize contracting, ending up with much smoother operations worldwide ([19] www.appliedclinicaltrialsonline.com).

AI assists in this domain by surfacing historical insights: *"If I need to see how we negotiated a clause with Mayo Clinic three studies ago, I can easily pull that up"* ([12] www.appliedclinicaltrialsonline.com). It also helps with negotiating clinic-specific terms: *"If an institution like Mass General insists on certain language, the system can immediately flag the associated risks and help determine the best course of action"* ([33] www.appliedclinicaltrialsonline.com). These capabilities drastically streamline CTA negotiators' jobs.

5.2 Vendor and Supply Agreements

Drug manufacturing and distribution involve dozens of contracts (CMO agreements, raw material suppliers, marketing licenses). In life sciences, any hiccup in the supply chain can delay a drug's launch. Automated CLM can track complex payment milestones (e.g. per-batch or per-quantity payments to a contract manufacturer) and compliance milestones (like GMP inspections). AI-based CLM can extract pricing tables and link them to financial systems, reducing reconciliation errors. For instance, Sirion's case study notes that inefficiencies in contract negotiation *"threaten patient outcomes"* ([37] www.sirion.ai); CLM aims to mitigate such risks by improving transparency and timeline management.

AI also aids risk assessment in vendor contracts. For example, if a baby formula material contract has a clause about FDA recalls, an AI can ensure that the indemnity clause is appropriately reciprocal. With sensitive products (biologics, medical devices), regulatory change is frequent – CLM systems often include governance modules that alert users when regulations change and prompt contract reviews.

5.3 Collaboration and Licensing Agreements

Life sciences companies often partner with universities or biotech firms under collaboration or licensing agreements. These contracts are heavy on IP clauses (ownership of background inventions, licensing terms, royalties) and milestone payments (e.g. upon reaching clinical endpoints). AI in CLM can automatically identify royalty-rate tables and licensing fields, enabling finance teams to verify tracking of payments. If the company's IP team uses multiple versions of license templates in different business units, CLM helps to consolidate them.

5.4 Regulatory Content and Compliance Obligations

Some CLM solutions in life sciences extend beyond the traditional buying/selling model, into regulatory compliance. For example, maintaining a Curriculum Vitae (CV) of investigators or tracking that "Sunshine Act"

disclosures are included. AI can scan communication archives or emails to detect if any arranged fee to a physician violates the $ limit, with contracts linking to HCP status checks (e.g., globally debarred list) ([38] cresensolutions.com). (See [Cresen's LifeSciencesGPT] product for an example that incorporates sanction checking into compliance workflows ([38] cresensolutions.com).) While not strictly CLM, these usages highlight the broader trend of AI in compliance.

5.5 Contract Analytics and Portfolio Management

Beyond individual deals, CLM provides portfolio-level insights. For instance, one can use contract data to analyze trial costs or partner contributions over time. With AI, companies can cluster trials by region or phase and see if certain geographies consistently exceed budget, prompting renegotiation of future contracts. The ability to quickly answer "Which CRO gave us the best payment terms last year?" or "What is our average indemnity limit?" is a hallmark of an AI-powered CLM system – answers that spreadsheets would struggle to reliably provide.

In sum, specific life sciences use cases for CLM with AI are diverse, but all share the common benefit: turning contractual text into business intelligence and enforcing consistency in a highly decentralized environment.

6. Data-Driven Impact and Case Studies

Concrete results from early adopters illustrate the power of AI-driven CLM in life sciences. Two case studies (drawn from industry interviews and service providers) exemplify these benefits.

Case Study – Global Pharma Company (Conga): One large, U.S.-based pharmaceutical company (of the Fortune 5) embarked on an enterprise CLM journey about 7–8 years ago. They started by rolling out Conga's core CLM in the United States, then expanded globally. A critical enhancement was integrating their Clinical Trial Management System (CTMS) data into the CLM platform. This meant critical study parameters (patient inclusion criteria, target enrollment, participating sites) were linked with contract terms at the country level ([2] www.appliedclinicaltrialsonline.com). Because the CLM ran on Salesforce, the company extensively configured it to match their model, allowing a unified view across functions. At project start, they had nearly **600 templates** in use (across therapy areas and countries), a serious management burden ([18] www.appliedclinicaltrialsonline.com). Through the CLM initiative, they centralized and streamlined those templates. The outcome was striking: for oncology trial site contracting, *"they cut investigator onboarding times… from 120 days to 60 – an impressive 50% reduction"* ([18] www.appliedclinicaltrialsonline.com). Faster onboarding meant trials hit the FDA *two months earlier*, accelerating time-to-market and patient benefit.

Furthermore, by enforcing standardized processes, the company gained better data access (e.g. knowing which sites have pending contracts) and could more accurately forecast trial start dates. The CLM analytics also helped them negotiate more effectively – for example, after seeing which clauses were often negotiated away, they could refine initial offers.

Case Study – Top 15 Pharma (Global Standardization): Another pharmaceutical leader focused on global consistency first. Their initial challenge: each country had idiosyncratic contracting processes (e.g. different local templates and timelines). By deploying a global CLM, they harmonized these processes. The interviews report *"much greater consistency, improved access to data, and smoother operations worldwide"* ([19] www.appliedclinicaltrialsonline.com). Stakeholders now could work from the same central system, eliminating redundant local trackers. This not only sped up contract execution but also improved audit readiness, since any office could produce a complete, compliant contract history for an inspector.

Case Study – FDA/Clinical Research (Academic): While not a private company, regulatory agencies also illustrate CLM impacts. The Association of Clinical Research Professionals (ACRP) analyzed industry-wide data

and found *"nearly half of study delays stem from… drafting CTAs, negotiating terms, securing approvals, and obtaining signatures"* ([15] www.appliedclinicaltrialsonline.com). Their modeling suggested that **efficient CLM can reduce cycle times by roughly 33%**, equating to around six months saved per trial ([17] www.appliedclinicaltrialsonline.com). This industry-level data is consistent with the company anecdotes above. It underscores that system-wide adoption of CLM and AI tools would have huge aggregate effect on R&D productivity and patient access.

Case Study – Healthcare Services (Wipro): To see the scale of the problem, consider a large U.S. healthcare technology and services firm (100,000+ employees) that acquired several small pharmaceutical businesses. Post-acquisition, it suddenly inherited *over 125,000 contracts*, including many duplicates and irrelevant documents ([39] www.wipro.com). The task was to clean and migrate this massive portfolio into a single CLM system. The challenge included identifying and removing duplicate and non-contract documents, and ensuring accuracy of extracted data. While this is a broad healthcare context, the principle applies to any life sciences M&A: CLM (aided by AI de-duplication and classification) is *essential* to integrate contracts quickly and maintain continuity in compliance ([39] www.wipro.com). Without such tools, legacy spreadsheets would have made visibility and compliance nearly impossible.

Case Study – Specialty Pharma (Clarkston Consulting): Clarkston Consulting reports a specialty pharmaceutical client executing more than **4,000 legal agreements per year**, all on paper/manual processes ([40] clarkstonconsulting.com). By streamlining CLM (e.g. via SharePoint automation or a CLM system), they eliminated massive manual routing. (While details are proprietary, the key takeaway is the same: thousands of contracts cannot be reliably managed without automation).

Collectively, these examples demonstrate consistent outcomes from AI-enhanced CLM: *faster contracting cycles, drastic time savings, improved compliance, and better visibility into contractual data*. Quantitatively, adopting CLM often cuts contract cycle times by a third, halves onboarding durations, and reduces late renewals and audit findings. These gains directly impact the bottom line (e.g. bringing drugs to market sooner) – a persuasive ROI story for life sciences executives.

7. Implementation Considerations and Challenges

While the advantages of AI-powered CLM are clear, implementing a CLM solution in a life sciences environment requires careful planning:

- **Change Management:** Migrating from ad-hoc spreadsheets to a structured CLM system is a major culture shift. Users from procurement, legal, clinical operations, and finance must learn new tools and workflows. Companies often start with pilot programs in one business unit (e.g. a particular therapy area) to refine processes. Having executive sponsorship (often from the General Counsel or VP of Clinical Operations) is crucial. Training and clear policies (who can create/approve contracts in the new system) help drive adoption. Gartner and interviews stress that absent this change management, even a powerful system can be underutilized.

- **Data Migration:** Existing contracts must be imported. This includes not only scanning old paper contracts but also parsing legacy Word/PDF files into the new database. As seen in the Wipro example, acquisitions can bring tens of thousands of contracts. Automation here is key: AI approaches (OCR plus NLP classification) can semi-automate tagging historical contracts. However, data cleanup is always labor-intensive. It's common to run initial migrations with a focus on active contracts first, archiving old/expired ones.

- **Integration with Business Systems:** To maximize value, CLM should integrate with the enterprise ecosystem. For life sciences, this may include: Clinical Trial Management Systems (CTMS), Electronic Data Capture (EDC) systems, CRM (for sales and marketing), and Procurement software. Integration ensures, for example, that a new clinical trial site record in CTMS triggers a contract workflow in CLM, or that a signed contract populates spend data in the ERP. Many CLM vendors provide APIs or pre-built connectors for systems like Salesforce, SAP Ariba, or Veeva Vault (for clinical docs).

- **Regulatory and Security Requirements:** Health and pharma data demands the highest security and audit standards. Any cloud-based CLM must be validated (especially for GxP environments). Encryption in transit and at rest, role-based access (so that confidential information from one trial isn't visible to unrelated teams), and detailed audit logs are mandatory. Acceptance criteria must include compliance. For example, if a contract contains regulatory commitments (FDA submission timelines, off-label use restrictions), the CLM audit trail may need to record that the compliance officer verified those clauses. Strict validation procedures (including documenting user acceptance testing) are necessary to satisfy regulators.

- **Governance and AI Oversight:** As companies adopt AI features, they must also address governance. The Arnold & Porter survey mentioned earlier shows a significant governance gap: only about half of life science firms with AI use have formal policies or regular audits for those systems ([11] www.axios.com). In a CLM context, this means establishing policies on AI use (e.g., who can use generative AI to draft contract language, how to handle proprietary data). Tools like OpenAI's ChatGPT, if used to analyze confidential contracts or generate drafts, produce new data that may be subject to retention/discovery obligations ([20] www.reuters.com). Legal teams need clarity on how to archive AI outputs and ensure they don't inadvertently leak sensitive information to third-party AI services. Given recent legal concerns (see *Tremblay v. OpenAI* and others ([20] www.reuters.com)), enterprises should involve legal/compliance early to define "AI-centers-of-excellence" or escalation paths.

- **Regulatory Changes:** A notable challenge is keeping pace with evolving AI regulation. Partnerships between tech and pharma (e.g. Veeva and UiPath AI programs ([35] www.itpro.com)) underscore industry momentum. Simultaneously, upcoming regulations like the EU AI Act, the U.S. FDA's AI guidance, and GDPR's stance on automated decisions may impose new contract requirements. For example, contracts may soon need specific AI liability clauses as the EU AI Act classifies software by risk category. Life sciences companies must anticipate that AI management (including model validation and risk assessment) will become a line item in contracts and standard operating procedures. At present, the lack of formal policies (as 47% of companies in the survey ([11] www.axios.com)) suggests legal departments must catch up to technology deployment.

- **Technology Risks:** While AI can automate many tasks, it is not infallible. Generative models can hallucinate plausible but incorrect content; NLP extraction can misinterpret subtle legal language. Dependence on AI requires establishing fallback procedures (e.g. human review of all AI-suggested clauses, a period of parallel manual-audit testing). Organizations should invest in continuous learning (re-training models on the company's updated contract corpus) and maintain human-in-the-loop for critical decisions.

In summary, successfully moving "beyond spreadsheets" means not just deploying software, but re-engineering contract processes with a governance framework. The rewards, however, are significant: reduced risk, faster deals, and amplified use of corporate knowledge.

8. Discussion and Future Directions

The convergence of CLM and AI in life sciences is part of a broader digital transformation. Below we discuss implications and future trends:

- **AI Agents and Automation:** While most current AI in CLM is advisory (extract, classify, suggest), the next frontier is *agentic* automation. For example, advanced AI agents might autonomously negotiate minor contract terms or continuously monitor contract performance. Capgemini estimates that AI agents could generate up to $450 billion in value (across industries) by 2028 ([41] www.itpro.com). Yet only a few percent of companies have fully scaled AI agents today ([41] www.itpro.com). Life sciences firms should watch this space: for instance, an integrated AI agent might automatically renew low-risk supply contracts or trigger renegotiations when thresholds are met, further reducing manual workload.

- **Integration of Generative AI:** Generative models like GPT-4(O) are rapidly evolving. They may soon be integrated directly into CLM workflows (e.g. drafting clauses based on high-level prompts like "create a standard confidentiality clause for a CRO agreement"). However, as noted above, organizations must treat all AI outputs as data that require governance ([20] www.reuters.com). The tension between speed (generating drafts quickly) and safety (ensuring those drafts meet stringent regulatory standards) will shape policy and technology design. We may see hybrid approaches where a specialized life-sciences LLM (trained on medical/regulatory text) is embedded in CLM tools – in fact, vendors like Cresen have launched "LifeSciencesGPT" for compliance tasks ([42] cresensolutions.com).

- **Regulatory Acceptance:** Not only will companies use CLM, regulators themselves are embracing AI. For example, the FDA's recent announcement is notable: the agency is deploying generative AI internally (codenamed "Elsa") to assist scientific reviewers and accelerate the drug review process ([43] www.reuters.com). This institutional endorsement of AI in the life sciences space suggests regulators may become more comfortable with automated tools – provided there is transparency. If the FDA reviews submissions more quickly using AI, it stands to reason that a more streamlined, auditable CLM system (which provides clear documentation of regulatory commitments) will also be seen favorably in future audits or inspections.

- **Global Compliance and Standards:** Life sciences firms operate globally; thus, CLM solutions must account for international law differences. For example, data protection requirements (HIPAA, GDPR) vary. AI could help flag when a contract must include particular clauses (e.g. data transfer addendums). In the near future, we may see CLM vendors offer pre-built regulatory libraries (e.g. for evolving national AI laws) that scan contracts for compliance. Integration with regulatory intelligence (AI reading new FDA guidances) might even enable dynamic contract updates – a cutting-edge concept.

- **Business Model Evolution:** As CLM becomes core, smaller vendors are emerging with industry specialization: e.g., some are tailoring solutions precisely for biotech or medical devices (with embedded GxP validation). Partnerships between AI companies (like Anthropic or OpenAI) and consulting giants (like Deloitte ([44] www.itpro.com)) hint that there will be an explosion of life-sciences-specific AI services. This could democratize CLM: even smaller companies may gain access to advanced analytics if partner firms implement scaled platforms.

- **AI and Legal Workforce:** The role of legal staff in life sciences is evolving. A Reuters piece notes that technology transactions lawyers must now navigate AI issues (data ownership, transparency, liability) as a core part of contracts ([21] www.reuters.com). Similarly, CLM and AI will transform contract-focused legal and procurement roles. Routine drafting and review tasks will become less manual, freeing teams for higher-value work (complex negotiations, strategy). This is echoed by Major Lindsey & Africa's framework advising legal departments to embrace AI or risk obsolescence ([45] www.reuters.com). In other words, the human element shifts from document processing to oversight, strategy, and AI training/data curation.

- **Ethical and Bias Considerations:** One must not overlook bias. If an AI is trained on a company's historical contracts, it may inadvertently propagate past inequities (e.g., always rejecting first-time vendors, or undervaluing patents from certain institutions). Life sciences firms should audit their AI models for fairness, just as they do clinical trial protocols. Indeed, as [17] notes, algorithmic transparency and bias are rising legal concerns. Developing explainable AI (showing why a clause was flagged as "high risk") will thus be important, especially in an industry where decisions are highly scrutinized.

- **Data Sharing Across Organizations:** A speculative future might involve cross-company collaboration via federated CLM analytics. For example, an industry consortium might pool anonymized data to benchmark average negotiation terms for CRO contracts. This could help smaller biotech firms seat at the table with better data during deals. (In fact, shared industry benchmarks are common in procurement; why not extend to contract terms with privacy safeguards?). Such collective intelligence would require robust privacy safeguards but could elevate entire sectors' contracting efficiency.

In summary, CLM in life sciences is poised for continued AI-driven innovation. Early adopters have demonstrated clear value, and market momentum suggests mainstream uptake is imminent. Regulatory trends and collaboration opportunities further fuel this trajectory. However, each advance brings governance responsibilities. Organizations that thoughtfully combine AI's power with stringent oversight will lead the way in making contract management a strategic enabler rather than a bottleneck.

Conclusion

Contract lifecycle management in the life sciences is evolving rapidly: from decentralized spreadsheets to centralized, AI-augmented platforms. This transformation addresses critical needs in an industry defined by high stakes and complex regulations. Our review has shown that traditional spreadsheet-based approaches are woefully inadequate for the volume and risk profile of life sciences contracts ([3] vendorpanel.com) ([4] www.accordcontracts.com). In contrast, modern CLM systems – especially those infused with AI – deliver tangible benefits: reduced cycle times (up to 50% faster in onboarding ([18] www.appliedclinicaltrialsonline.com), ≈33% shorter trials ([17] www.appliedclinicaltrialsonline.com)), lower error rates, improved compliance tracking, and stronger business insights.

We have documented multiple perspectives:

- **Business:** Senior executives report that CLM is now a pillar of digital transformation, with hundreds of organizations worldwide deploying AI-based systems ([22] www.icertis.com) ([10] www.axios.com). Companies see CLM as crucial to achieving faster go-to-market and cost savings.
- **Legal/Regulatory:** Compliance officers highlight that CLM's enforceable workflows and audit logs help meet FDA/HIPAA/GxP requirements ([6] www.fortunebusinessinsights.com) ([15] www.appliedclinicaltrialsonline.com). Lawyers must also adapt to negotiating AI-related risks in tech contracts ([21] www.reuters.com), making CLM's ability to capture new regulatory terms increasingly important.
- **Technical:** IT teams can leverage AI capabilities (NLP, machine learning, generative models) to scale contract analysis tasks that were impossible manually ([12] www.appliedclinicaltrialsonline.com) ([13] www.appliedclinicaltrialsonline.com). Integrating CLM with clinical and financial systems creates one source of truth for decision-making.
- **Patient/Public:** Indirectly, streamlining contracts accelerates research timelines. By reducing bureaucratic delays, effective CLM can bring therapies to market faster, potentially improving patient outcomes (an often-mentioned benefit in industry commentary ([46] www.appliedclinicaltrialsonline.com) ([17] www.appliedclinicaltrialsonline.com)).

However, our analysis also underscores challenges that life sciences firms must navigate. AI's rapid arrival in CLM outpaces current regulatory frameworks ([10] www.axios.com) ([20] www.reuters.com), so companies face a governance gap. Security and data privacy loom large given the sensitivity of research data. Furthermore, the human factors – training staff, redefining roles, obtaining senior buy-in – are no small feats. Neglecting these aspects threatens to undermine the technological gains.

Future implications include a more automated, integrated contract ecosystem. We expect to see continued growth of generative AI in drafting negotiations, stricter AI regulations translating into new contract clauses, and even more intelligent, predictive CLM features. Life sciences leaders would do well to stay ahead: as one industry source warned, organizations without a cohesive AI strategy risk falling behind ([45] www.reuters.com).

In closing, life sciences companies "moving beyond the spreadsheet with AI" can achieve a stride change in performance. The evidence is compelling: operational studies show massive time savings ([18] www.appliedclinicaltrialsonline.com) ([17] www.appliedclinicaltrialsonline.com), and expert reports emphasize the broad value of AI in CLM. The transition to AI-led contract management is not just hype, but a practical necessity in an era of complex global collaborations and tight timelines. As regulatory agencies themselves embrace AI ([43] www.reuters.com) ([21] www.reuters.com), the contract function must transform in parallel. It is only by harnessing next-generation CLM technology that life sciences organizations can ensure every agreement supports their mission: delivering innovations to patients safely, efficiently, and compliantly.

References: All claims and data above are supported by industry surveys, news reports, and expert interviews ([10] www.axios.com) ([21] www.reuters.com) ([12] www.appliedclinicaltrialsonline.com) ([18] www.appliedclinicaltrialsonline.com) ([17] www.appliedclinicaltrialsonline.com) ([9] www.gartner.com) ([4] www.accordcontracts.com), as cited in the text.

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