AGENTIC AI FOR PHARMACEUTICAL R&D

Agentic AI that moves drug development forward.

Governed for GxP. Built to scale.

We are your trusted **AI strategy and implementation delivery partner**. SpordaTech.ai identifies, designs, governs and delivers agentic AI across Clinical Operations, Pharmacovigilance, Quality, Medical Affairs and R&D.

11	6+	9	GxP
AI and agentic use cases across the R&D lifecycle	Functions: ClinOps, PV, Quality, Medical Affairs, Business Ops, Digital	Steps from discovery to scale in one delivery lifecycle	Governance, validation and human oversight designed in

WHY AGENTIC AI

From dashboards that inform *to agents that act, with people in control.*

Most pharma AI stops at insight: a report, a dashboard, a flag. Agentic AI closes the loop. It watches the work, decides what needs attention, takes or routes the next action and learns from the outcome, so specialists spend their time on scientific, clinical and regulatory judgment instead of chasing status.

Sense
Continuously read signals across study, site, safety, quality and vendor systems.

Decide
Identify what matters, weigh dependencies and risk, and determine the next best action.

Act
Route work to the right role, draft content, trigger workflows or prepare records.

Learn
Feed intervention outcomes back in, so recommendations improve over time.

Human in the loop by design. Regulated and business-critical decisions always sit with accountable people, at defined control points, with a full audit trail.

The right tool for each step

Automation	Analytics	Predictive AI	Generative AI	Agentic AI
Rules-based, repeatable steps	Visibility and KPIs	Forecasts and risk scores	Drafting, summarizing, extracting	Coordinated action across workflows

We start with the process and choose the right tool for each step. Agentic AI is powerful, but it isn't always the answer.

Four outcomes guide every solution we build

01
Cycle time
Speed up the critical activities that set the pace of development, from study startup to contracting.

02
Productivity
Remove repetitive work so specialists can focus on scientific, clinical, medical, quality and regulatory judgment.

03
Quality
Improve consistency, completeness, traceability and compliance across regulated workflows.

04
Cost & capacity
Handle growing portfolios without growing manual effort at the same rate.

USE CASES

Explore the use cases *where we can help you.*

Agentic AI and AI capabilities across the drug-development lifecycle, drawn from our strategy and delivery work in pharmaceutical R&D. Client-identifying information and proprietary solution details are anonymized.

Clinical Operations

Study startup, monitoring, TMF, clinical data and vendor oversight

01 — AGENTIC AI

CLINICAL OPERATIONS · STUDY STARTUP

Agentic clinical study startup orchestration

Challenge. Site activation, regulatory documents, budgets, contracts, vendor onboarding, training and approvals are spread across disconnected systems and teams. Tracking dependencies, chasing actions and clearing bottlenecks all take heavy manual effort.

The solution. An agentic coordination layer brings together readiness signals, workflow status and dependencies across the startup lifecycle. It goes further than a dashboard: the workflow identifies what needs attention, determines the next action and routes it to the right role, with humans in control of regulated and business-critical decisions.

DESIGNED TO DELIVER

- ✓ Less manual coordination across startup teams
- ✓ Bottlenecks and dependencies surfaced earlier
- ✓ Better visibility into site and study readiness

02 — AGENTIC AI

CLINICAL OPERATIONS · TRIAL MONITORING

Agentic clinical monitoring & site engagement

Challenge. Monitoring teams receive signals from many study and site systems. Working out which signals matter, which sites need intervention and what should happen next takes substantial manual analysis.

The solution. An agentic intelligence layer continuously evaluates study and site signals, spots emerging risks and sends prioritized next-best actions to the right clinical role. A feedback loop lets the outcome of each intervention inform future recommendations. Monitoring moves from manual signal review to continuous oversight, with human decisions at defined control points.

DESIGNED TO DELIVER

- ✓ Monitoring effort focused on the highest-priority issues
- ✓ Less manual signal review
- ✓ Emerging site risks detected earlier

03 — AI-ENABLED

CLINICAL OPERATIONS · TMF

AI-enabled Trial Master File automation

Challenge. Large TMF transfers during CRO transitions, acquisitions or portfolio changes mean large volumes of documents to ingest, classify and tag with metadata before they can enter controlled TMF processes.

The solution. An AI document-ingestion capability automates bulk processing and extracts metadata from incoming files. It combines document intelligence with controlled workflow automation, and keeps quality and human-review steps in place.

DESIGNED TO DELIVER

- ✓ Less manual document handling
- ✓ Faster large TMF migrations and transfers
- ✓ More consistent metadata

04 — AI-ENABLED

CLINICAL OPERATIONS · CLINICAL DATA

Intelligent EDC–CTMS clinical data integration

Challenge. Operational data captured in EDC often has to be re-keyed into CTMS and monitoring workflows. That duplicates effort and creates discrepancies between systems.

The solution. An integration connects EDC and CTMS workflows so that subject information, visit status and protocol deviations flow into operational systems and downstream monitoring. The result is a connected data foundation for enrollment planning, study management and future AI.

DESIGNED TO DELIVER

- ✓ No unnecessary duplicate data entry
- ✓ Fewer discrepancies between systems
- ✓ Up-to-date operational information

Clinical Operations (continued)

05

AI-ENABLED

CLINICAL OPERATIONS · VENDOR MANAGEMENT

AI-enabled CRO & vendor management hub

Challenge. Qualification, onboarding, performance, resourcing, deliverables, escalations and risk information for CROs and vendors is scattered across systems and studies, which makes portfolio-level oversight difficult.

The solution. A central, AI-enabled hub brings together vendor qualification, onboarding, risk assessment, performance and relationship data. AI analytics surface emerging delivery risks and show KPIs, resource use, deliverables and escalations.

DESIGNED TO DELIVER

- ✓ Stronger sponsor oversight
- ✓ Vendor risks identified earlier
- ✓ Visibility across studies and vendors

Safety & Quality

Pharmacovigilance intake and GxP quality management

06

AGENTIC AI

PHARMACOVIGILANCE · DRUG SAFETY

Agentic pharmacovigilance intake

Challenge. Post-marketing safety information arrives through many channels, including medical-information contact centers. Adverse events must be identified, triaged, structured and moved into PV processes accurately and within regulatory timelines.

The solution. AI agents review incoming information from a medical-information channel, identify potential safety cases, organize the relevant data and support its transfer into the enterprise safety workflow. Processing is controlled and traceable, with validation built in and human oversight defined up front.

DESIGNED TO DELIVER

- ✓ Less manual safety-intake effort
- ✓ Faster case triage
- ✓ More consistent intake processing

07

AGENTIC AI

GXP QUALITY · QUALITY MANAGEMENT

AI-assisted CAPA & root-cause management

Challenge. CAPA work means reviewing quality information, investigating causes, deciding on actions and documenting the rationale. It is manual and can vary in consistency from team to team.

The solution. An AI agent helps quality professionals organize evidence, explore root causes and draft CAPA content, while people remain accountable for regulated quality decisions. Intended use, human oversight, traceability, risk management, validation and controlled deployment are designed in.

DESIGNED TO DELIVER

- ✓ Faster investigation workflows
- ✓ More structured root-cause analysis
- ✓ More consistent CAPA documentation

Medical Affairs & Business Operations

Medical content and fair-market-value contracting

08

AI-ENABLED

MEDICAL AFFAIRS

AI-driven medical content planning & generation

Challenge. Medical Affairs produces large volumes of scientific content that must stay accurate, consistent and compliant while science and stakeholder needs keep changing.

The solution. Structured content management is combined with AI-assisted authoring, automated compliance support and predictive content planning. Scientific and medical review stays at the center of the operating model.

DESIGNED TO DELIVER

- ✓ Faster medical-content development
- ✓ More reuse of approved content
- ✓ More consistency across materials

09

AGENTIC AI

CLINICAL BUSINESS OPS · CONTRACTING

AI-assisted fair market value & contracting

Challenge. FMV assessments and contracting involve many handoffs: credential evaluation, compensation analysis, compliance review, contract preparation and approval. That lengthens cycle times and adds administrative burden.

The solution. An intelligent capability combines predictive FMV modeling with automated credential evaluation, compliance monitoring, contract generation and approval orchestration. Every input, decision and approval stays traceable for oversight and audit.

DESIGNED TO DELIVER

- ✓ Shorter contracting cycle times
- ✓ Automated repetitive evaluations
- ✓ More consistent FMV assessments

Enterprise Strategy & Adoption

From hundreds of ideas to a roadmap, and from rollout to real adoption

10 AGENTIC AI

R&D DIGITAL STRATEGY

Enterprise agentic AI opportunity assessment & roadmap

Challenge. Organizations often identify hundreds of generative and agentic AI ideas but have no consistent way to choose which to pursue first. Technical feasibility is not enough on its own.

The solution. An enterprise assessment of AI and agentic-automation opportunities across R&D processes. Each opportunity was evaluated on business value, process maturity, data readiness, regulatory impact, risk, adoption and complexity, and the results became a prioritized portfolio, roadmap and business cases.

DESIGNED TO DELIVER

- ✓ A shift from disconnected experiments to an enterprise strategy
- ✓ Use cases prioritized on consistent criteria
- ✓ Investment tied to measurable outcomes

11 AI-ENABLED

CROSS-FUNCTIONAL R&D · DIGITAL ENABLEMENT

Digital adoption for complex R&D platforms

Challenge. R&D staff work across increasingly complex platforms, and classroom training rarely helps with infrequent or complicated workflows.

The solution. Contextual guidance inside the application walks users through workflows step by step. It addresses an often-overlooked part of AI transformation: making sure people can actually adopt new ways of working.

DESIGNED TO DELIVER

- ✓ Shorter learning curve for enterprise apps
- ✓ Help at the moment of need
- ✓ Less reliance on traditional training

AT A GLANCE

01	Agentic clinical study startup orchestration — AGENTIC AI	02	Agentic clinical monitoring & site engagement — AGENTIC AI
03	AI-enabled Trial Master File automation — AI-ENABLED	04	Intelligent EDC–CTMS clinical data integration — AI-ENABLED
05	AI-enabled CRO & vendor management hub — AI-ENABLED	06	Agentic pharmacovigilance intake — AGENTIC AI
07	AI-assisted CAPA & root-cause management — AGENTIC AI	08	AI-driven medical content planning & generation — AI-ENABLED
09	AI-assisted fair market value & contracting — AGENTIC AI	10	Enterprise agentic AI opportunity assessment & roadmap — AGENTIC AI
11	Digital adoption for complex R&D platforms — AI-ENABLED		

Benefits describe what each capability is designed to deliver. Specific results are shared one-to-one where confidentiality allows.

OUR APPROACH

Process first. Technology second.
From idea to scaled capability.

We don't start with a technology and look for somewhere to deploy it. We start with the drug-development process, the decisions that matter, the work scientists and clinical professionals actually do, and the regulations that govern it. Then we deliver across the full lifecycle, so AI moves beyond isolated proofs of concept.

STRATEGY

1 Discover

2 Prioritize

Find and rank opportunities on value, data readiness, regulatory impact and risk.

DESIGN & BUILD

3 Redesign

4 Architect

5 Build

Redesign the process, architect the agents and integrations, and build.

ASSURE & RELEASE

6 Govern & Validate

7 Deploy

Establish intended use, oversight and validation, then deploy under control.

EMBED

8 Adopt

9 Scale

Drive real adoption, then extend proven patterns across the portfolio.

Multidisciplinary teams, not a lone AI specialist

Each engagement brings together the mix of expertise the use case needs, so strategy, build, compliance and adoption move forward together.

Pharmaceutical R&D · AI strategy · Agentic AI · Process transformation · Product management · Data & technology architecture · GxP & validation · AI governance · Change management · Implementation

FUNCTIONS WE WORK WITH

- ✓ Clinical Development & Operations
- ✓ Pharmacovigilance
- ✓ Quality
- ✓ Medical Affairs
- ✓ Clinical Business Operations
- ✓ Data & Technology

AI WE DESIGN & DELIVER

- ✓ AI agents and orchestration
- ✓ Next-best-action intelligence
- ✓ Generative AI and content intelligence
- ✓ Intelligent document processing
- ✓ Predictive analytics
- ✓ Systems and data integration

HOW WE ENGAGE

- ✓ Opportunity assessment and roadmap
- ✓ Use-case design and business case
- ✓ Build, validate and deploy
- ✓ Governance and GxP assurance
- ✓ Adoption and scale-out

GOVERNANCE FOR AGENTIC AI

Autonomy with accountability. *Built for GxP from day one.*

Agents that act inside regulated workflows need stronger controls, not fewer. Every capability we deliver is designed around these safeguards.

Defined intended use
A clear scope for what each agent may and may not do, and the decisions it supports.

Human oversight at control points
Accountable people approve regulated and business-critical actions.

End-to-end traceability
Inputs, decisions, approvals and actions can be reconstructed for oversight and audit.

Risk-based validation
Validation effort matches the risk and influence of each AI component.

Controlled deployment
Staged release under change control, with quality and review mechanisms in place.

Lifecycle monitoring
Ongoing performance monitoring and feedback, so agents stay reliable after go-live.

The regulatory context

JAN 2025
FDA draft guidance on AI
A risk-based credibility framework for AI used in regulatory decision-making.[1]

JAN 2026
FDA–EMA good AI practice
Ten shared principles for AI across the medicine lifecycle.[2]

2026–2028
EU AI Act
Transparency and high-risk obligations phasing in for AI in the EU.[3]

FRAMEWORKS WE WORK TO

GxP · GAMP 5 · 21 CFR Part 11 · ALCOA+ · ICH E2B · FDA AI credibility framework · EU AI Act

1. FDA, *Considerations for the Use of AI to Support Regulatory Decision-Making for Drug and Biological Products* (draft, Jan 2025). 2. EMA/FDA, *Guiding principles of good AI practice in drug development*, 14 Jan 2026. 3. EU AI Act as amended by the Digital Omnibus on AI (2026).

WAYS TO START

Wherever you are on the journey, *we can start there.*

STRATEGY

Agentic AI opportunity assessment

Map your R&D processes, score opportunities on consistent criteria and build a sequenced roadmap.

YOU RECEIVE
A prioritized portfolio, roadmap and business cases

DESIGN & DELIVERY

Use-case design and implementation

Take a priority use case from process redesign through architecture, build and deployment.

YOU RECEIVE
A working, governed AI capability

ASSURANCE

Agentic AI governance and GxP validation

Set up intended use, oversight, traceability and risk-based validation for AI in regulated work.

YOU RECEIVE
A governance framework you can defend to regulators

EMBED

Adoption and scale

Change management, in-app guidance and operating models that turn pilots into everyday practice.

YOU RECEIVE
Capabilities your teams actually use

LET'S TALK

Ready to put agentic AI *to work in your R&D?*

Whether you have a hundred AI ideas and no roadmap, or one use case ready to build, start with a 30-minute conversation.

BOOK A 30-MINUTE DISCOVERY CALL
cal.com/spordatech-ai/discovery-call

EMAIL
contact@spordatech.ai

What to expect on the call

- **30 minutes**, with no obligation
- We listen to your AI goals and constraints
- We share relevant agentic AI patterns from pharma R&D
- You leave with at least one idea you can act on

Discretion is part of the service. Pharma work is confidential, so we don't publish client names or proprietary solution details. We share relevant experience and results one-to-one during your Discovery Call, under NDA where needed.

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