AI ADVISORY FOR PHARMACEUTICAL R&D

AI regulators can trust. *Results leaders can measure.*

SpordaTech is an independent advisory partner that takes AI from first idea to validated, inspection-ready production across Clinical Operations, Pharmacovigilance, Regulatory Affairs and Quality.

Independent

Vendor-neutral advice, driven by your business case

Regulator-ready

GxP, GAMP 5 and Part 11 designed in, aligned to FDA, EMA and PMDA

Business-first

Every engagement starts from a quantified business problem

WHY NOW

AI is reshaping drug development, *and the rules are being written now.*

Drug development is still slow, costly and uncertain. AI can change that, but only if it can be scaled, validated and defended in front of regulators.

$2.6B

Estimated cost to develop a new medicine that wins approval[1]

7.9%

Share of drug candidates entering Phase I that reach approval[2]

10

Joint FDA–EMA principles for good AI practice in drug development, published Jan 2026[3]

The regulatory clock is running

Jan 2025 — **FDA draft guidance** introduces a 7-step, risk-based credibility framework for AI used to support regulatory decisions[4]

Jan 2026 — **FDA and EMA** publish 10 shared principles for good AI practice across the medicine lifecycle[3]

2026 — **FDA Operation TrialBlazer** pilots an expedited IND pathway to speed up early-phase development[5]

Aug 2026 — **EU AI Act** transparency obligations take effect[6]

Dec 2027 — **EU AI Act** high-risk obligations (Annex III) apply, deferred by the 2026 Digital Omnibus[6]

Aug 2028 — **EU AI Act** obligations for AI embedded in regulated products (Annex I) apply[6]

THE GAP

Pilots are easy. Validated, scaled, defensible AI is hard.

Most organizations have the ambition and plenty of vendors. What they often lack is a senior partner who speaks science, compliance and technology, and can turn AI ambition into a funded, inspection-ready result.

That is SpordaTech's role.

1. Tufts Center for the Study of Drug Development (2014), capitalized cost per approved compound. 2. BIO, Informa Pharma Intelligence & QLS, *Clinical Development Success Rates 2011–2020*. 3. EMA/FDA, *Guiding principles of good AI practice in drug development*, 14 Jan 2026. 4. FDA, *Considerations for the Use of AI to Support Regulatory Decision-Making for Drug and Biological Products* (draft, Jan 2025). 5. FDA / HHS announcements, 2026. 6. EU AI Act as amended by the Digital Omnibus on AI (2026).

WHAT WE DO

Seven capabilities.
One accountable partner.

For 20 years, we have worked inside Global Development, alongside Clinical Operations, Pharmacovigilance, Regulatory Affairs and Quality. We find the AI use cases that matter, build business cases that get funded, and deliver GxP-compliant solutions that speed up drug development.

01

Strategic Business Partnership

From ambiguity to a funded, executive-backed plan.

Pre-Concept Discovery
Workshops that define the real problem before any solution is proposed

Business Case Development
Value propositions and ROI models that secure funding

Roadmap Development
Multi-year roadmaps tied to scientific and operational goals

Requirements Synthesis
BRDs, FRDs, user stories and process maps

Executive Presentations
Materials ready for steering committee decisions

Stakeholder Facilitation
Clinical, technical, quality and vendor teams aligned across regions

02

AI Strategy & Implementation

From promising pilot to validated production.

AI Use Case Identification
Prioritized AI/ML opportunities across ClinOps, Safety, Regulatory and Quality

Proof-of-Concept Design
Focused PoCs built to show measurable value

Vendor & Platform Evaluation
AI vendors assessed on business and compliance criteria

Feasibility Assessments
Data readiness, technical feasibility and compliance impact

AI Governance Frameworks
Model credibility and lifecycle management under GxP

From PoC to Production
A clear path from successful pilot to scaled, validated rollout

SIGNATURE PRACTICE

03

Pharmacovigilance AI

Faster case intake and earlier signals, with compliance intact.

Case Intake Automation
NLP that extracts adverse events from emails, literature and reports

Aggregate Report Efficiency
Automated reconciliation, authoring support and version control

Predictive Pharmacovigilance
EHR, wearable and real-world data for earlier signal detection

Signal Detection Support
AI-assisted pattern recognition and prioritization

Safety Data Integration
Clinical and post-market safety data brought together

Compliance Guardrails
Every solution meets GxP, E2B and global regulatory requirements

04

Global Regulatory Strategy

One governance model that works for FDA, EMA and PMDA.

North America · FDA
AI credibility assessments, context-of-use documentation, engagement strategy for AI-enabled submissions, single pivotal trial strategy

Europe · EMA
EMA Reflection Paper on AI, EU AI Act readiness, GxP for AI/ML, launch sequencing under new EU pharma legislation

Asia-Pacific · PMDA & beyond
Early consultation, reliance pathways, lifecycle evaluation frameworks, multi-market submission sequencing

Cross-Regional
Harmonized governance frameworks that meet FDA, EMA and PMDA requirements at once

05

Digital Transformation & Data Strategy

The data foundation AI needs to succeed.

Transformation Roadmaps
Multi-year R&D technology strategy with prioritized investment

Data Harmonization
Fragmented sources turned into clean, AI-ready datasets

Data Lakes & Pipelines
Real-time architectures for clinical, safety and regulatory data

Data Governance
Stewardship, quality controls and compliance guardrails

Process Automation
Automation for clinical ops, safety reporting and submissions

IoT & Wearable Data
Patient device data in compliant, real-time analytics

06

GxP Compliance & Validation

Innovation that stands up to inspection.

GAMP 5 Validation
Risk-based validation planning and execution

21 CFR Part 11
Compliant electronic records and signatures

Data Integrity (ALCOA+)
Assessment, remediation and ongoing governance

Audit Readiness
Inspection preparation and audit trail design

CAPA Management
Corrective and preventive action for quality events

AI Compliance
Model credibility and regulatory defensibility

07

RFI/RFP Management & Vendor Selection

The right vendor, chosen on evidence rather than demos.

RFI/RFP Development
Structured to your business and compliance needs

Weighted Scorecards
Criteria based on business value, not vendor marketing

Vendor Evaluation
Demos, workshops and PoCs with the shortlisted vendors

Decision-Ready Briefings
Clear recommendations for leadership

Contract Negotiation Support
SLAs, RFQs and onboarding with procurement and legal

Consultant Orchestration
External consultants kept aligned to your objectives

CASE STUDIES

Real AI. Real results.
Details kept confidential.

Selected work led by our team inside top-5 pharmaceutical companies, global pharma and biotech, from building the data foundation to governed AI in production. Client names are anonymized to respect confidentiality. The challenges, approaches and outcomes are real.

01 AI in action

Case 01 — GLOBAL PHARMA

PHARMACOVIGILANCE · GLOBAL PATIENT SAFETY

AI-powered signal detection in pharmacovigilance

40% faster signal detection in the PoC, with no loss in sensitivity

Challenge. ICSR volume was overwhelming the safety team, and signals surfaced weeks or months late through manual periodic review.

What we did. Prioritized AI use cases, defined NLP and ML requirements with explainability, set up GxP AI governance with QA, and ran a vendor PoC.

Outcome. PoC detected signals 40% faster with no loss in sensitivity, earned high user confidence and produced a path to production.

AI angle. AI applied directly to patient safety, with explainability, human oversight and regulatory defensibility built in.

Case 02 — MID-SIZE BIOTECH

REGULATORY AFFAIRS

AI-assisted regulatory submission assembly

30% projected reduction in submission assembly time

Challenge. Manual assembly took up more than 50% of each submission cycle, and HAQ responses needed fast precedent research from a small, stretched team.

What we did. Mapped the workflow, identified NLP assembly and ML precedent-search use cases, defined compliant requirements with human approval, and led the RFI.

Outcome. Recommended solution and roadmap, a projected 30% faster assembly, and a regulatory AI governance framework.

AI angle. Generative and NLP-based AI for regulatory operations, with humans approving every output.

Case 03 — TOP-5 GLOBAL PHARMA

R&D TECHNOLOGY STRATEGY · AI AT SCALE

Enterprise AI orchestration for R&D

6 functions united under one enterprise AI governance council

Challenge. Siloed AI pilots, inconsistent governance and stalled projects left leadership with little ROI from AI.

What we did. Inventoried the AI portfolio, designed the orchestration architecture, set up a 6-function AI council and built the enterprise business case.

Outcome. AI strategy approved and funded, with a roadmap from quick wins to agentic AI and a clear path to production.

AI angle. Moving from scattered pilots to governed, enterprise-scale AI, including a path to agentic AI.

02 Building the foundation for AI

Every successful AI program starts with data, process and strategy. These projects built that foundation.

Case 04 — TOP-5 GLOBAL PHARMA

CLINICAL DEVELOPMENT · AI-READY DATA

IoT wearable data platform and AI proofs of concept

60% less time spent pre-processing data by clinicians

Challenge. Wearable data from hundreds of sites arrived in inconsistent formats. Clinicians spent up to 70% of their time reconciling it, and no data foundation existed for AI.

What we did. Designed a GxP data lake with ML-assisted harmonization, then ran two AI PoCs on it: enrollment prediction and clinical data review.

Outcome. 60% less pre-processing, an AI-ready foundation and two AI PoCs delivered.

AI angle. AI starts with data. We built the foundation and then delivered AI proofs of concept on top of it.

Case 05 — GLOBAL PHARMA

R&D DATA STRATEGY · AI FOUNDATION

Enterprise data harmonization for R&D

40% fewer redundant data pipelines in phase one

Challenge. More than 15 redundant channels carried the same core data, teams worked from different versions of the truth, and there was no AI-ready data.

What we did. Defined a single source of truth using publish-and-subscribe, built the ROI case and planned phased adoption.

Outcome. Multi-year program funded, with 40% fewer redundant pipelines and a clean, AI-ready data foundation.

AI angle. Harmonized data is a prerequisite for AI. Without it, AI projects fail.

Case 06 — GLOBAL PHARMA

GLOBAL PATIENT SAFETY · PHARMACOVIGILANCE

Safety aggregate report automation

~40 hrs of manual work per report identified and targeted

Challenge. Aggregate reports were manual, reviewed over email by up to 15 people, generated repeated audit findings, and had no AI foundation.

What we did. Quantified about 40 wasted hours per report, led an RFI that included AI-readiness criteria, and built a business case targeting about 30% faster cycles.

Outcome. Phased implementation funded, with a foundation for AI-assisted signal detection.

AI angle. You can't apply AI to signal detection when safety data and processes are chaotic. This project built that foundation.

Case 07 — MID-SIZE BIOTECH

GLOBAL REGULATORY AFFAIRS · REGULATORY INTELLIGENCE

Global regulatory submission sequencing

4 regulatory regions sequenced into one prioritized roadmap

Challenge. A global launch across 4 regions with limited resources, no reliance strategy and heavy manual regulatory-intelligence work.

What we did. Scored markets, built a reliance-based submission roadmap and recommended an AI regulatory-intelligence approach.

Outcome. A prioritized roadmap, less duplicate effort and faster time to market in priority regions.

AI angle. Recommended AI-powered regulatory intelligence to monitor changing requirements and assess their impact.

Case 08 — GLOBAL PHARMA

R&D TECHNOLOGY STRATEGY · AI-FIRST TRANSFORMATION

AI-first digital transformation roadmap for R&D

36-mo AI-first roadmap approved by executives

Challenge. Legacy systems, a fragmented landscape and ad hoc, siloed AI with no enterprise strategy.

What we did. Defined an AI-first target state and a phased roadmap from AI quick wins to agentic AI, with executive buy-in.

Outcome. A multi-year AI-first roadmap approved, with investment aligned.

AI angle. AI embedded in the transformation strategy from the start, not added later.

OUR METHOD

Chaos to Actionable
From problem to funded roadmap.

Good technology decisions start with the business problem, not a vendor pitch or a demo. Our framework moves every engagement from uncertainty to a decision in four disciplined phases. Each phase ends with a concrete deliverable.

1
Discovery & Problem Framing

We resist the urge to jump to a solution. We map the current state, quantify the pain and state the problem in your terms.

- Stakeholder interviews and workshops
- Current-state process mapping
- Pain point quantification
- Root cause analysis

DELIVERABLE
Clear problem statement and baseline metrics

2
Structuring & Requirements

We define the future state, success metrics and constraints, turning broad goals into measurable success criteria.

- Future-state visioning
- Requirements: BRD, FRD, user stories
- Success metric definition
- Compliance, budget and timeline constraints

DELIVERABLE
Prioritized requirements and success criteria

3
Options & Feasibility

We weigh solution options against your business criteria and set vendor hype aside.

- Market and vendor scanning
- RFI/RFP management
- Weighted scorecard evaluation
- Feasibility assessment
- Business case development

DELIVERABLE
Side-by-side comparison and a recommendation

4
Roadmap & Business Case

A decision-ready package: the recommended solution, a phased roadmap, a business case with ROI and clear next steps.

- Implementation roadmap
- Phased delivery plan
- Business case and ROI model
- Executive presentation
- Governance and change management

DELIVERABLE
Funded roadmap with clear next steps

Clarity. Confidence. *Action.*

With the business leading the way at every step.

TOPICS WE ADVISE ON

- AI in pharmacovigilance & predictive safety
- Model credibility & regulatory defensibility
- AI orchestration across clinical, safety & regulatory
- GxP-compliant AI governance & validation
- Agentic AI for discovery & development
- Real-world data & digital biomarkers
- Single pivotal trial strategy
- EU pharma legislation & launch sequencing
- APAC reliance & expedited pathways
- Scaling AI from PoC to production

TRUST BY DESIGN

Trust is engineered, *not claimed.*

Every AI solution we shape is built to answer an inspector's questions. Our approach follows the FDA's risk-based credibility framework and the joint FDA–EMA principles for good AI practice.

Defined context of use

Every model has a documented question, scope and decision it supports.

Risk-based credibility

The level of validation matches model influence and decision consequence, following GAMP 5.

Data integrity by design

ALCOA+ principles and 21 CFR Part 11 controls are built in from the first requirement.

Human oversight

Clear roles for human review where decisions affect patients or submissions.

Traceability & audit readiness

Every step from data to decision can be traced and shown to inspectors.

Lifecycle monitoring

Performance and drift monitoring under change control once the model is live.

Global regulatory fluency

FDA

North America

- AI credibility assessments and context-of-use documentation
- Engagement strategy for AI-enabled submissions
- Single pivotal trial and evidence narrative
- FDA PreCheck and Operation TrialBlazer readiness

EMA

Europe

- EMA Reflection Paper on AI across the product lifecycle
- EU AI Act obligations for life sciences
- GxP compliance for AI/ML systems
- Launch sequencing under new EU pharma legislation

PMDA+

Asia-Pacific

- Early consultation for AI-enabled products
- Reliance pathway strategy across APAC
- Lifecycle evaluation and traceability documentation
- Multi-market submission sequencing

GLOBAL

Cross-Regional

- Harmonized FDA, EMA and PMDA governance
- Global AI policy monitoring and impact assessment
- Regulatory intelligence on emerging AI guidance

FRAMEWORKS WE WORK TO

GxP (GCP · GLP · GMP) | GAMP 5 | 21 CFR Part 11 | ALCOA+ | HIPAA | ICH E2B | EU AI Act | Inspection Readiness

WHY SPORDATECH

Senior expertise. Independent advice. *Accountable for the outcome.*

	SpordaTech	Large consultancies	Technology vendors
Senior practitioner leads every engagement	✓ Always	Varies by team	Sales-led
Vendor-neutral recommendations	✓ By design	Usually	Own platform first
Deep ClinOps, PV, Regulatory & Quality expertise	✓ Two decades	Specialist teams	Product-specific
Business case before technology	✓ Always	Often	Rarely
GxP, GAMP 5 and Part 11 from day one	✓ Built in	Often a separate workstream	Varies
Right-sized for lean teams	✓ Fractional to full	Rarely	License-driven

WAYS TO ENGAGE

FIXED SCOPE

Discovery Assessment

Define the problem, assess feasibility and recommend next steps.

YOU RECEIVE
Problem statement, feasibility view and a recommendation

BEST FOR
Organizations exploring AI or new technology

FRACTIONAL OR INTERIM

Embedded BSP/BRM

A senior Business Solution Partner working inside your team.

YOU RECEIVE
Strategic partnership without adding permanent headcount

BEST FOR
Lean teams that need strategic support

DEFINED SCOPE & TIMELINE

Project-Based

Specific deliverables with a defined scope and timeline.

YOU RECEIVE
A business case, RFI/RFP or roadmap, delivered

BEST FOR
Initiatives with clear objectives

ONGOING

Advisory Retainer

Ongoing strategic advisory and support.

YOU RECEIVE
A trusted advisor and regulatory intelligence on call

BEST FOR
Organizations that want an ongoing partnership

LET'S TALK

Bring us your hardest *AI question.*

Exploring AI, choosing a new system, planning a digital transformation or working through global regulatory complexity? Start with a conversation.

BOOK A 30-MINUTE DISCOVERY CALL
spordatech.ai

EMAIL
contact@spordatech.ai

What to expect on the call

- **30 minutes**, with no obligation
- We listen to your challenges and goals
- You leave with at least one idea you can act on
- If we're a good fit, we propose next steps

ABOUT SPORDATECH

Insiders by experience. *Advisors by choice.*

SpordaTech's experience was built inside Global Development at top-5 pharmaceutical companies, leading biotechs and healthcare technology firms. We have worked as Business Solution Partners and Business Relationship Managers alongside Clinical Operations, Pharmacovigilance, Regulatory Affairs and Quality.

You work directly with a senior practitioner. Your engagement is never handed off to a junior team.

Discretion is part of the service. We don't publish client names or engagement details. Detailed credentials are shared one-to-one during your Discovery Call.

INDUSTRIES WE SERVE

- Pharmaceutical R&D
- Biotechnology
- CROs
- Healthcare Technology
- Medical Devices
- Life Sciences

FUNCTIONS WE PARTNER WITH

Clinical Operations · Pharmacovigilance · Regulatory Affairs · Quality