U.S. Pharma Consulting

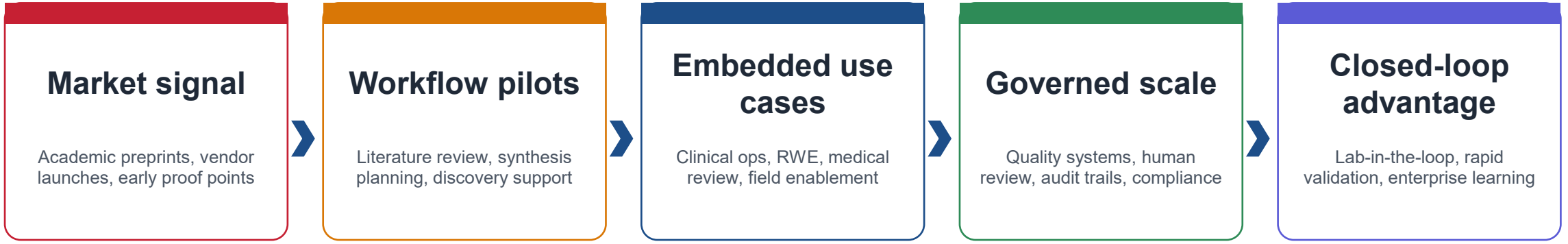
A direct link to the Pharma and MedTech Industry

A strategic briefing that maps where AI-enabled biopharma workflows are gaining traction, where value is showing up first, what is still breaking, and how to build a governed operating model.

Positioning USPC for an unparalleled U.S. market assessment, AI partner strategy, regulatory & commercialization support

Biopharma Agentic Maturity Curve

Biopharma Agentic Workflows



This is where the market is deploying, what is working, and how to build a governed operating model

USPC Lens

Near-term value is in workflow compression, orchestration, and governed decision support. Durable advantage emerges when agentic workflows are linked to proprietary data, validated process controls, and real-world execution.

Executive Summary

Consultant view: value is real, but sustainable scale requires governance and validation

What is happening now

Selective production deployments are expanding across discovery support, clinical operations, and commercial workflows.
Compute and platform investments are accelerating (large pharma + major vendors).
Regulators are publishing shared expectations for good AI practice across drug development.

Where leaders win

Use orchestration to compress analysis + coordination, not to replace accountability.
Tie outputs to expert review and real-world validation loops.
Design for audit trail, data rights, security, lifecycle monitoring from day one.

USPC principle: compress cycle time and improve evidence packaging — keep scientific judgment, regulatory accountability, and capital allocation visibly human-owned.

2026 Market Signals

Publicly disclosed partnership values and governance signals tied to biopharma agentic workflows.

Signal	Partner(s)	Deal value / scale (public)	What it indicates
Lilly + Insilico (Mar 2026)	Eli Lilly Insilico Medicine	**$115M upfront** **Up to ~$2.75B total**	Capital is moving from AI enablement toward AI-originated assets and licensed preclinical programs.
Lilly + NVIDIA (Jan 2026)	Eli Lilly NVIDIA	**Up to $1B** **over 5 years**	Enterprise AI infrastructure is being funded at strategic scale across discovery, development, and manufacturing.
Roche + NVIDIA (Mar 2026)	Roche NVIDIA	**Not publicly disclosed** **2,176 GPUs added; >3,500 total – talks are over 2.5 billion**	Roche publicly disclosed compute scale and infrastructure expansion, but not a partnership dollar amount.
FDA + EMA (Jan 2026)	FDA European Medicines Agency	**Guidelines published** **(10 principles)**	Regulators are aligning on expectations for AI practice, documentation, and lifecycle control.
Axiom (Apr 2026)	**Menlo Ventures** **(Series A lead)**	**$200M Series A** **$1.6B valuation**	Investor capital is also flowing to AI verification infrastructure, reinforcing the governance and trust layer needed for regulated workflows.

Where Value Is Showing Up First

Practical deployments cluster around evidence-heavy, review-sensitive workflows

Discovery support

- Target landscaping
- Design + synthesis planning support
- Evidence packaging for decisions

Clinical operations

- Data review + query resolution
- Protocol and CSR drafting assistance
- Operational triage and routing

Real-world evidence

- Cohort definition support
- Signal detection + monitoring
- Faster analytic readouts

Commercial & medical

- Market landscaping
- Field enablement drafts
- Scientific response preparation

Common trait: these workflows already exist — orchestration reduces coordination overhead & standardizes evidence packaging

What Is Still Breaking

Reliability, tool fragility, and error compounding limit long chains

Reliability does not scale automatically

A 2026 reliability evaluation of agentic models reports only modest improvements despite rapid capability gains.
Operational reliability needs metrics beyond pass/fail accuracy (consistency, robustness, predictability, bounded severity).

Toolchain fragility

Model upgrades can shift behavior.
Supervisor/sub-agent drift and refusals remain common in multi-agent setups.
Recovery from unexpected tool responses is often ad hoc.

Error compounding

High per-step accuracy can still fail across long multi-step chains.
The more tools + datasets involved, the more brittle the workflow becomes.
Governed review gates reduce downstream risk.

90-Day Build Sequence

Practical path from pilot to governed operating capability

Phase 1
Days 0-30

- Define context of use
- Select one high-friction workflow
- Map data sources and owners
- Establish success metrics

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Phase 2
Days 31-60

- Stand up orchestrator and specialist roles
- Create human review gates
- Pilot with bounded datasets
- Document failure modes

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Phase 3
Days 61-90

- Operationalize audit trail
- Expand to validation workflows
- Train users and governance team
- Approve scale decision

Success metric:

One workflow that is measurably faster, more traceable, and easier to review than the current-state process (before expanding scope)

Avoid enterprise sprawl

Governance Checklist (FDA/EMA-aligned)

Build credibility by designing for reviewability and control from day one

- Human-centric by design (clear accountability and sign-off)
- Risk-based approach (impact, likelihood, controls)
- Standards + documentation (traceability, versioning, records)
- Clear context of use (what it is / is not authorized to do)
- Multidisciplinary expertise (clinical, regulatory, quality, security)
- Data governance (source systems, rights, retention, lineage)
- Model development practices (validation plan, monitoring, change control)
- Risk-based performance assessment (beyond accuracy)
- Lifecycle management (drift, retraining, decommissioning)
- Clear essential information (what reviewers must see to trust outputs)

Leadership Decisions (What to Decide Early)

Avoid enterprise sprawl; decide operating model and controls before scale

Decisions

1. Which workflow first (highest friction + review sensitivity)
2. Who owns sign-off (scientific, clinical, regulatory, quality)
3. Which data sources are authorized and why
4. What “good” looks like (time, quality, traceability)
5. When to scale (clear go/no-go criteria)

Recommended posture

1. Treat as an operating-model program, not a tool purchase.
2. Build traceability + governance in the first workflow.
3. Tie outputs to validation loops (lab / clinical / operations).
4. Keep accountability human-owned and visible.
5. Scale only after stability is demonstrated.

USPC recommendation:
Prove one governed workflow end-to-end, then expand by pattern — not by enthusiasm.

Illustrative Solution Pathway: Miracural AI / DeepDrug®

An example of how governed, workflow-aligned AI can support earlier development and portfolio decisions.

Why it fits this deck

Miracural AI's DeepDrug® platform is an example of the type of validated, mechanism-informed decision support this deck is describing.

Rather than functioning as a standalone AI point solution, DeepDrug® is positioned to strengthen decision-making across candidate selection, toxicity triage, drug-drug interaction assessment, polypharmacy analysis, and broader portfolio prioritization.

Its relevance is not simply that it produces analytical outputs. Its value is in helping teams' surface earlier risk signals, improve evidence packaging, and support more disciplined development decisions before downstream cost and complexity compound.

Decision-support focus

- Mechanism-informed AI
- Upstream toxicity and DDI risk modeling
- Polypharmacy and combination-risk assessment

Operating-model relevance

- Workflow-aligned deployment
- Bounded by human review
- Designed to support governed execution

USPC lens: DeepDrug® reflects the type of platform that may help compress workflow friction while preserving scientific judgment, regulatory accountability, and capital allocation discipline.

Where Miracural AI / DeepDrug® Fits

A practical example of decision-support deployment in biopharma.

What it is

1. Designed to model toxicity and drug-drug interaction risk upstream
2. Aligned with polypharmacy and real-world development complexity
3. Intended to support decisions, not replace expert review

Why it matters

1. Strengthens candidate and portfolio prioritization
2. Helps surface earlier safety and interaction risk
3. Supports governed workflow integration across R&D and lifecycle decisions
4. Better aligns AI deployment with validation, oversight, and measurable ROI

For USPC, solutions like DeepDrug® are most compelling when they are implemented as part of a governed operating model, not as a standalone technology purchase.

Selected References

Primary sources used for factual grounding

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2. AstraZeneca ChatInvent case study (Drug Discovery Today, 2026)
3. IQVIA.ai launch (IQVIA press release, Mar 16, 2026)
4. LillyPod positioning (Lilly story, 2026)
5. Roche AI factory announcement (Roche media release, Mar 16, 2026)
6. FDA/EMA Good AI Practice principles (Jan 14, 2026)
7. Agent reliability metrics (arXiv 2602.16666, Feb 2026)
8. FDA internal agentic AI deployment (Dec 1, 2025)