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Pistoia Alliance Agentic AI Standards for Pharma R&D

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Executive Summary

Agentic AI – autonomous software "agents" that link reasoning, tool use, and multi-step workflows – is poised to revolutionize pharmaceutical R&D by greatly accelerating complex tasks (e.g. target prioritization, compound optimization, literature review). For example, NVIDIA's industry survey notes that *"generative and agentic AI help medical professionals save time and costs for drug discovery, patient care and more"* (blogs.nvidia.com). Indeed, about two-thirds of respondents to an NVIDIA survey of more than 600 healthcare and life sciences professionals say their companies are actively using AI today, and 83% agree that AI will *"revolutionize healthcare and life sciences in the next 3–5 years"* (blogs.nvidia.com). However, the same emerging technology poses significant governance challenges. Without careful controls, end-to-end agents become "black boxes" whose reasoning and data provenance are opaque, threatening reproducibility and regulatory compliance (pistoiaalliance.org).

In response, the Pistoia Alliance (a global pre-competitive life-science consortium) has launched an *Agentic AI Initiative* to create standards and frameworks for safe, auditable multi-agent systems. As announced in Sept 2025, this initiative will **develop an "agent-to-agent communication protocol" and an "AI agent standard"** tailored to pharma/healthcare, and will define **shared validation frameworks and metrics** to assure robustness and transparency (pistoiaalliance.org). These deliverables will be supported by white papers, reference implementations, and best-practice guidelines co-authored by industry partners (pistoiaalliance.org). Industry experts such as Pistoia's president Dr. Becky Upton emphasize that **agentic AI will be**

transformative but requires guardrails: “Our members see agentic AI as one of the most impactful technologies… but they also recognize the risks if adoption happens without the right guardrails” (pistoiaalliance.org).

This report reviews the context and implications of the Pistoia Alliance initiative. We first define *agentic AI* and its promise in pharma, then examine the need for new standards in multi-agent coordination, including existing proposals (e.g. Google’s Agent2Agent, the Open Agent Protocol, ARSIA) that Pistoia will build upon. We analyze what features an **agent-to-agent protocol** and **agent standard** might include for drug discovery workflows. We discuss how shared validation frameworks (ranked as the top pre-competitive collaboration priority in a Pistoia Alliance webinar poll of 111 pharma professionals (pistoiaalliance.org)) can enforce reliability and bias checks across agentic pipelines. Throughout, we cite case examples (e.g. Amazon’s “Bio Discovery” lab-in-the-loop platform) and survey data to ground these concepts in real-world trends. Finally, we provide a governance “playbook” for R&D and IT leaders: outlining organizational policies, technical architectures, and regulatory considerations needed to harness agentic AI safely.

Key insights include:

- **Massive potential vs. new risks.** Agentic AI promises to compress months of lab work into hours by tightly integrating design, data analysis, and automation (pharmaphorum.com). But autonomous agents create complex entropy: participants worry about auditability and trust in AI outputs (pistoiaalliance.org) (www.biosciencetoday.co.uk).
- **Standards & protocols needed.** Pistoia’s initiative aims to define the *minimal information* that should be exchanged between collaborating agents (pistoiaalliance.org). This is analogous to Internet or IoT protocols, but specific to AI workflows (for example, the Google-led “A2A” protocol and the Open Agent Protocol already propose frameworks for agent identity, messaging and governance (www.ibm.com) (openagentprotocol.eu)). A pharma-specific protocol must encode drug-research semantics (e.g. in-vivo assay results, regulatory flags) and rigorous audit data.
- **Agent standardization.** Beyond message formats, an **agent standard** would prescribe how individual AI agents are defined, certified, and documented. For instance, Corti’s healthcare AI framework emphasizes *“fine-tuned reasoning layers optimized for healthcare language… and compliance needs”* (docs.corti.ai), illustrating how domain specificity becomes an intrinsic agent attribute. A standard might require metadata (e.g. declared objectives, domain assumptions, certification status) or common interfaces so that heterogeneous tools can truly interoperate.
- **Validation frameworks.** Life sciences demand validated evidence. The Pistoia Alliance notes that pre-competitive polls of industry experts put “shared validation frameworks and metrics” at the top of R&D leaders’ wish list (pistoiaalliance.org). This entails developing cross-company benchmarks and tests for multi-agent systems (analogous to clinical trial endpoints). Commercial vendors are also marketing validation tooling for AI systems, but such offerings are vendor claims and should be assessed independently against GxP requirements. Likewise, Mediforce’s open-source platform builds *“validation by design”* into AI pipelines with audit trails and human-in-loop checks (mediforce.ai). These examples highlight how agents must fit into existing compliance regimes (good documentation, audit trails, fail-safes) while also addressing AI-specific concerns (model bias, data lineage, continuous learning).

- **Governance frameworks for leaders.** R&D and IT executives must adapt. This includes forming cross-functional AI governance boards, training staff on AI capabilities/limits, and aligning with new international guidelines. In accord with the FDA/EMA's "Good AI Practice" principles, organizations should ensure *human-centric design*, *risk-based validation*, *adherence to standards*, and clear documentation of each agent's context of use (www.fda.gov). Pharmaceutical governance also requires merging agentic AI oversight with existing GxP policies: for example, qualifying an AI agent under 21 CFR 11 as a computerized system, or using approaches like ARSIA that cryptographically encode compliance obligations into each agent message (arsiaprotocol.org) (qualitum.ai).

Sections below that discuss the unpublished Pistoia deliverables are the author's analysis, not statements by Pistoia. The following sections unpack these points in detail, with case studies and evidence at each step.

Introduction

Artificial intelligence has increasingly permeated pharmaceutical research. From predictive models in target identification to robotic lab automation, AI/ML tools are speeding up fragments of the R&D cycle (e.g. high-throughput screening, image analysis, even automating standard lab protocols). According to a survey of 408 researchers, 87% use AI for work-related research tasks, up from 75% in 2023 (www.prnewswire.com), reflecting "surging adoption" despite concerns over trust and data quality (www.prnewswire.com) (www.biosciencetoday.co.uk). By early 2026, a broad consensus emerged that **the next frontier is "agentic" AI** – autonomous, multi-step AI systems that can plan, execute, and iterate across tasks without human intervention. In practical terms, this means AI agents capable of linking together multiple sub-tasks (e.g. designing a molecule, running a simulation, analyzing results, and planning follow-up experiments) in a single automated workflow.

The Pistoia Alliance, a global not-for-profit of pharmaceutical, biotech, tech and academic organizations, has identified agentic AI as *"one of the most disruptive emerging technologies"* on the 2–3 year horizon (www.biopharminternational.com). At its European conference in early 2025, life science professionals repeatedly flagged the need for new standards and collaboration to manage such advanced AI use (www.biopharminternational.com) (pistoiaalliance.org). Indeed, Pistoia's own event descriptions define **Agentic AI** as *"systems capable of autonomous planning, tool use, and multi-step reasoning,"* with implications spanning *"automated literature review and hypothesis generation to end-to-end orchestration of research workflows"* (pistoiaalliance.org). The urgency is underscored by polls: for example, a Pistoia Alliance webinar poll of 111 pharma professionals showed that the top priority for pre-competitive collaboration is creating shared validation frameworks and metrics for model robustness and bias (pistoiaalliance.org). A separate Pistoia conference poll, discussed later in this report, reported that many respondents do not know what scientific content their AI tools use. This "scientific content crisis" signals a glaring governance gap – without standards, AI agents may deliver outputs that cannot be traced or validated against real evidence.

As traditional AI tools (like chatbots or predictive ML models) have matured, industry and regulators have stressed the importance of *good practice*. The FDA and EMA jointly released 10 *Good AI Practice* principles for drug development (Jan 2026), emphasizing human-centric design, risk-based validation, data governance, and - critically - *"adherence to standards"* (www.fda.gov). In shorter form, life science overseers expect AI systems

(even agents) to have clear scope, documented data sources, multidisciplinary oversight, and ongoing performance monitoring. Yet these guidelines are general; agentic AI raises new questions (e.g. how to audit an autonomous experiment planner).

Recognizing this need, Pistoia Alliance announced in September 2025 a dedicated agentic AI initiative for life sciences . Seed funded by Genentech, the initiative's mission is to collaboratively define *how* AI agents should communicate, be structured, and be validated in pharma and healthcare contexts (pistoiaalliance.org). As Pistoia President Dr. Becky Upton notes, the Alliance brings *"more than eight years' experience in pre-competitive collaboration around AI"*, from benchmarking LLMs to pharmacovigilance forums, and is now extending that expertise to autonomous agents (pistoiaalliance.org).

This report dissects the Pistoia Alliance's agentic AI initiative. We first clarify **what agentic AI is and why pharma cares**, then delve into each main pillar of the initiative: agent-to-agent communication protocols, an AI agent standard, and shared validation frameworks. We compare emerging technical proposals (e.g. from IBM, Google, open-source groups) and highlight pharma-specific requirements. Case studies (e.g. AWS's new *Bio Discovery* agentic platform (www.investing.com), healthcare agent frameworks by companies like Corti (docs.corti.ai)) illustrate how these ideas play out. We also examine key survey data and expert opinions on the challenges (trust, integration, regulatory risk). Finally, we offer recommendations for R&D and IT leaders: how to govern agentic AI deployments in practice, including organizational structures, technology guardrails, and alignment with regulatory guidelines.

Throughout, each claim and insight is grounded in citations from industry reports, academic research, and expert sources. The evidence demonstrates that while agentic AI holds great promise for pharmaceutical innovation, **new interoperable standards and rigorous validation regimes will be essential** to realize that promise safely and responsibly.

Agentic AI in Pharma: Definition and Potential

Agentic AI advances beyond traditional AI assistants or predictive models by exercising a degree of autonomy. In practice, an **AI agent** is a system that can *plan*, *take actions*, and use tools or external data to achieve complex goals, often involving multiple steps and loops. For example, an agent could take a high-level goal ("optimize a lead compound against off-targets and ADME"); then *reason* (select computational models to use), *act* (run a docking simulation), *observe* (analyze results), and *plan* further steps (synthesize and test analogues). Such agents effectively become digital research assistants or "AI scientists," orchestrating workflows that previously required interplay of humans, instruments, and data.

Industry analysts emphasize this leap: **"Agentic AI represents one of the most transformative and potentially disruptive shifts in the AI landscape,"** especially in life sciences (pistoiaalliance.org). Analogous to how autonomous vehicles transformed transportation, agentic AI could transform R&D by linking fragmented processes. NVIDIA's survey of more than 600 professionals across digital healthcare, medical technology, pharma and biotech, payers and practitioners (a broad healthcare and life sciences sample, not pharma R&D specifically) underscores this optimism: about two-thirds of respondents said their companies are actively

using AI, 81% of respondents said AI has helped increase revenue, and 73% said AI is helping to reduce operational costs (blogs.nvidia.com). These gains come partly from better data mining and model accuracy, but agentic systems promise even greater efficiency: full "lab-in-the-loop" automation where design, data analysis, and experimentation form one continuous feedback cycle, compressing work that took months into weeks or days (pharmaphorum.com).

Case Example – Amazon Bio Discovery: In 2026, AWS launched *Amazon Bio Discovery*, an "agentic AI application" for drug discovery (www.investing.com). It integrates dozens of specialized molecular-design AIs with a user-facing *AI agent* that helps guide researchers. AWS describes the application as giving scientists access to *a broad catalog of specialized AI models called biological foundation models*, along with an AI agent that helps design experiments (aboutamazon.com). Crucially, this system forms a closed *design loop*: as one lead is evaluated (in silico or by wet lab), the agent adaptively proposes refinements. According to AWS, in work with Memorial Sloan Kettering Cancer Center the platform's agent orchestrated multiple models to design nearly 300,000 novel antibody molecules, and the 100,000 top candidates were then sent to Twist Bioscience for testing, shortening antibody design from months to weeks. AWS describes this as a lab-in-the-loop experimentation cycle in which lab results return to the application to inform the next round (aboutamazon.com). Such examples demonstrate agentic AI's potential to accelerate early-stage discovery by orders of magnitude.

However, these gains come with novel challenges. Autonomous agents are by definition "black boxes" in part: their internal reasoning (chain-of-thought, decision logic, use of tools) is usually not exposed in human-readable form. The Pistoia Alliance aptly warns that *"full autonomy creates a 'black box' around AI that undermines trust, reproducibility and regulatory compliance"* (pistoiaalliance.org). In pharma, where "evidence must be validated," an unlogged decision path is unacceptable. For instance, if an agent recommends a new experiment, regulators will want an audit trail of *why* that experiment was chosen over others, and what data it relied on. Similarly, if multiple companies collaborate (as in pre-competitive research), each will require assurance about data integrity and model performance – things that opaque multi-step AI threatens to obscure.

Survey data reflect these tensions. In a Pistoia Alliance poll at its US conference in Boston, 27% of life-science professionals said they do not know what scientific content their organization's AI/LLM systems use, or that those systems rely only on titles and abstracts, and only about 36% said they are plugging internal documents into models (pistoiaalliance.org). This "scientific content crisis" underscores the need for provenance standards: if one in four professionals can't say what scientific content feeds an AI system, auditing the inputs to an AI recommendation is hard, the industry cannot trust agentic automation. In summary, while agentic AI can *entwine many tools into seamless automated R&D workflows*, doing so safely will require explicit interoperability and validation mechanisms.

Figure 1 (below) summarizes the potential and pitfalls of agentic AI in pharma:

Benefit	Challenge
Speeds up multi-step workflows (e.g. target ID → molecule design → assay) (pistoiaalliance.org)	Creates complex "black box" decisions that are hard to audit (pistoiaalliance.org)

Benefit	Challenge
Integrates disparate tools and data (e.g. LLMs, bio models, robotics)	Agents from different suppliers may not “speak the same language” (silos integration issue) (www.ibm.com)
Enables continuous optimization (closed-loop learning) (pharmaphorum.com)	Risks bias or unsafe actions if not properly validated; regulatory non-compliance
Provides 24/7 autonomous operation	New security risks (e.g. if an agent is hijacked or goes off-policy)

Figure 1. Agentic AI in Pharma: Potential benefits (left) vs. governance risks (right), with examples.

In response to these and related issues, the Pistoia Alliance and other stakeholders stress the need for **pre-competitive collaboration** on standards. As one expert put it, *“AI agent protocols establish standards of communication among artificial intelligence agents and between AI agents and other systems. These protocols specify the syntax, structure and sequence of messages, along with communication conventions…”* (www.ibm.com). This is analogous to how the Internet uses TCP/IP or how industrial IoT uses OPC UA. Just as standard networking lets diverse computers interoperate, an AI-agent protocol would let heterogeneous agents coordinate. The following sections examine how such standards can be built, and what else is needed for robust, trustworthy agentic systems in pharma.

Pistoia Alliance’s Agentic AI Standards Initiative

On **4 September 2025**, Pistoia Alliance (London) announced a new, industry-wide Agentic AI initiative, shaped by funding from Genentech with sponsorship sought from other pharma, biotech and tech companies . The initiative’s **mission** is to “shap [e] standards and protocols for AI agents” in life sciences, under Pistoia’s strategic priority to *Harness AI to Expedite R&D* (pistoiaalliance.org). In practical terms, the project is led by Program Manager Robert Gill and centers on two **key deliverables**: (1) a **Life-Sciences-Specific Agent-Agent Communication Protocol**, and (2) an **AI Agent Standard** (specifications) (pistoiaalliance.org). These outputs will be published as whitepapers, guidelines and reference implementations for community use, along with scientific articles to drive adoption (pistoiaalliance.org). Early sponsors will be able to shape the direction and co-author the outputs, ensuring industry buy-in.

The press release makes clear why these deliverables are urgent. On one hand, agentic AI *“can accelerate multi-step processes such as target prioritization and compound optimization by chaining reasoning, tool use and execution”* (pistoiaalliance.org). On the other hand, *“full autonomy creates a ‘black box’… undermining trust, reproducibility and regulatory compliance”* (pistoiaalliance.org). To bridge this gap, Pistoia proposes building “auditable agent workflows shaped by subject matter experts and approved data sources” (pistoiaalliance.org). This concept of “human-in/over-the-loop” design echoes industry principles: for example, the FDA’s Good AI Practice guidelines emphasize human-centric design and clear context of use (www.fda.gov). By involving domain experts in agent processes (e.g. vetting the data an agent uses), Pistoia aims to preserve scientific rigor even in autonomous workflows (pistoiaalliance.org).

The initiative also leverages Pistoia's track record in AI collaboration. Pistoia President Dr. Becky Upton highlights that the alliance has *"eight years' experience in pre-competitive collaboration around AI, from benchmarking frameworks for large language models to a pharmacovigilance community focused on responsible AI deployment"* (pistoiaalliance.org). In her words, *"more expert minds focused on the same topic will advance the safe and successful use of AI technologies"* (pistoiaalliance.org). Pharmaceutical R&D is inherently high-stakes and expensive, so pooling knowledge on safety and interoperability is seen as far more efficient than isolated company efforts. Indeed, the press quotes a new internal poll where life sciences experts ranked *"shared validation frameworks and metrics for model robustness and bias"* as the #1 cross-industry priority (pistoiaalliance.org). Thus, the Agentic AI initiative is not lone company work but a true consortium approach.

Deliverables: Agent Communication & Agent Standard

Agent-to-Agent Communication Protocol: The first deliverable is a standard protocol defining *"what minimal set of information"* any two collaborating agents should exchange so that they can "work together on the same project" (pistoiaalliance.org). In other words, this is an **interoperability specification** at the message-passing level. The goal is akin to defining a common "language" for AI workflows. For instance, an agent A might need to tell agent B: *"I have this hypothesis and these intermediate results, and I want you to perform analysis using tool X."* The protocol would specify how such messages are formatted, secured, and semantically annotated.

There are promising precedents outside pharma. In April 2025, Google announced the **Agent2Agent (A2A) Protocol**, a vendor-neutral spec for agent messaging (developers.googleblog.com). A2A proponents herald it as *"a new era of agent interoperability"*, designed to let organizations orchestrate diverse AI agents much like microservices (developers.googleblog.com). Similarly, the **Open Agent Protocol (OAP)** is an open standard (with dozens of RFCs) for agent communication and identity (openagentprotocol.eu). OAP promises *"verifiable identity, discovery, invocation, governance, and accountability"* in agent interactions (openagentprotocol.eu). Architecturally, these protocols layer on cryptographic identities, certificates, and structured metadata so that agents can authenticate messages and discover each other (e.g. via a registry).

Pistoia's protocol will build on such general frameworks but tailor them to life-science needs. Agents in R&D must exchange domain-specific content (e.g. chemical structures, assay data, controlled vocabulary terms) as well as generic signals (e.g. confidence scores, error states). The protocol must handle streaming large scientific datasets (e.g. molecular libraries) and integrate with laboratory information systems (LIMS) and electronic data capture. Crucially, it should carry compliance-related metadata: as ARSIA's compliance envelope idea illustrates, each message might *"carry its own trust"* via audit tags, version history, and cryptographic hashes (arsiaprotocol.org). For example, an agent recommending a new assay could include a signed reference to the validated version of the model it used, or a timestamped pointer to the provenance of input data. These features are rarely present in ad-hoc AI tool integrations, but Pistoia aims to make them standard.

AI Agent Standard (Specs): In parallel, Pistoia will define what constitutes an **"AI agent"** in pharmacy/healthcare – essentially, a standard or schema for agent characteristics. This may cover *agent identity*, *capabilities*, *interfaces*, and *operational policies*. For instance, the standard might require every agent

to declare its domain (e.g. *“Medicinal Chemistry Assistant Agent”*), the tasks it can perform, the confidence or reliability bounds of its reasoning, and how it should be invoked by others. It could mandate structured *agent profile documents* (similar to OWL ontologies or FIPA agent descriptions) that other systems can parse.

To illustrate, some vendor frameworks already hint at this. Corti (an AI healthcare startup) describes its *Agentic Framework* as a *“modular AI system”* for healthcare tasks (docs.corti.ai). Corti’s documentation highlights *“fine-tuned reasoning layers optimized for healthcare language, workflows, and compliance needs”* (docs.corti.ai). In other words, Corti builds specialized knowledge (medical terminology, regulatory guidelines) into the agent’s core. This kind of domain adaptation could form part of an agent standard. A standardized agent profile might include fields like “Applicable Regulations” or “Data Privacy Level”.

Additionally, IEEE and other bodies are developing high-level standards on ethical AI and agent design. Pistoia’s agent standard would complement those by focusing on operational detail in drug R&D. The press release suggests outputs will include not just concepts but *requirements documents* (specs), presumably outlining how to build or certify an agent. By unifying these definitions, sponsors of the initiative can achieve interoperability: a drug-safety agent built by Vendor A and a lab scheduling agent by Vendor B could automatically connect if both comply with the agent standard.

Shared Validation Frameworks

A crucial insight from Pistoia’s research is that **validation is a top priority**. In a poll of 111 industry professionals, the largest share identified *“creating shared validation frameworks and metrics for model robustness and bias”* as the highest-value area for cross-company collaboration (pistoiaalliance.org). This reflects a common realization: traditional model validation (e.g. train/test splits) is insufficient for agentic pipelines. We need end-to-end validation of sequences of decisions, stress-testing agent workflows under diverse conditions, and agreed metrics for success.

In practice, a *shared validation framework* might include:

- **Standardized Test Scenarios:** Curated, open test cases that drive agents through realistic workflows. For example, a synthetic drug target dataset could be used to benchmark any agent’s target prioritization process, or a mock data freeze simulation to test reporting agents. The goal is reproducibility: any company can run these scenarios against their agent system and compare results.
- **Audit Logging & Metrics:** Agents should produce detailed logs at each step (timestamped decisions, intermediate values). Shared specifications will define key metrics to extract from logs (e.g. time-per-iteration, distribution of outcomes, reproducibility rate). Pistoia’s initiative may recommend logging standards much like Good Laboratory Practice standards do for experiments. Indeed, Pistoia explicitly calls for “auditable agent workflows” with traceable inputs (pistoiaalliance.org).
- **Bias and Robustness Checks:** Because agents may incorporate ML models, the framework should embed fairness and robustness tests. For instance, synthetic perturbations of input data can reveal if an agent’s decisions change unexpectedly. Shared guidelines could define minimal performance thresholds (e.g. allowed error rates) for critical decisions (e.g. predicting toxicity).

- **Continuous Validation:** Unlike a one-off model, agents may keep learning or be updated. Frameworks should mandate re-validation after updates. As Pistoia notes (and as implementing a formal computer system validation would require), each version might need qualification under GxP rules. Validation workflows for agents should align with existing compliance expectations (Good Automated Manufacturing Practice, electronic records regulations, etc.).

Case in point is **Mediforce's open-source toolkit**: it is explicitly designed for regulated clinical processes, with *"validation, security and governance by design"* (mediforce.ai). Mediforce automatically captures audit trails and enforces human approval gating. Pistoia can leverage such work: the goal is to make "regulatory-grade" AI as routine as validated laboratory equipment.

Overall, the shared frameworks will serve as governance criteria: any agent deployed in R&D should pass these common tests before its use. By developing them pre-competitively, the industry avoids duplicated effort. As Pistoia confirmed, project **sponsors will get early access to all draft frameworks** and can co-develop evaluation criteria (pistoiaalliance.org).

Technical Foundations: Protocols and Standards

To achieve interoperability, Pistoia's initiative must align with broader technical efforts in AI agent design. Below are key perspectives and existing efforts that inform the Agentic AI standards project.

AI Agent Communication Protocols

Definition and need: As noted by IBM researchers, *"AI agent protocols establish standards of communication among artificial intelligence agents… specifying the syntax, structure and sequence of messages"* (www.ibm.com). Without such a standard, agents built on different platforms or by different teams end up in silos, with bespoke connectors needed for every pair. IBM warns that *"agent-based AI systems often run in silos… built by different providers using diverse frameworks and distinct architectures"*, making real-world integration difficult (www.ibm.com). A standard protocol solves this by giving every agent common conventions.

Examples of protocols: Several open efforts are emerging:

- **Agent2Agent (A2A):** Google announced this in April 2025 as an open-spec protocol for AI-agent messaging (developers.googleblog.com). A2A is built on existing web standards, including HTTP, SSE and JSON-RPC. It is explicitly touted as a *"critical open standard"* that will let enterprises confidently orchestrate diverse agents (developers.googleblog.com). Pistoia could evaluate building on A2A and extending it for pharmaceutical data.
- **Open Agent Protocol (OAP):** An independent open-standard initiative offers a similar stack. The OAP spec (public v1.0) focuses on secure identity, event publishing, and compliance layers. Its charter describes OAP as *"a vendor-neutral specification for verifiable identity, discovery, invocation, governance, and accountability between autonomous AI agents"* (openagentprotocol.eu). For example,

OAP uses decentralized identifiers (DIDs) so each agent has a cryptographic identity. Such features could be crucial for traceability in R&D, as they allow any recorded message to be verified as coming from a specific certified agent.

- **ARSIA (AI eRASIA Protocol):** Rather than defining workflows, ARSIA embeds compliance into every message. Its whitepaper states *"every AI agent message should carry its own trust… [an] open, transport-agnostic envelope protocol that embeds compliance, cryptographic identity, audit, and human oversight"* (arsiaprotocol.org). In practice, ARSIA wrappers add metadata fields (e.g. timestamps, signer ID, audit record links) to messages. Pistoia's discussions of agent communication will likely examine how such audit envelopes could be integrated into the pharma protocol.
- **FIPA ACL (historical note):** The IEEE's Foundation for Intelligent Physical Agents (FIPA) defined an Agent Communication Language decades ago. While FIPA itself is somewhat dated and not widely used in industry, it did introduce concepts like message "performative" and supply/demand semantics. Pistoia might draw on FIPA's lessons (or on OASIS's more modern efforts) to ensure new standards are compatible with existing research in agent systems.

Pharma-specific requirements: Any chosen protocol must handle life-science data models. For instance, if two agents collaborate on a molecular design project, the protocol may need to exchange chemical structure files (e.g. in CML or SMILES format), biological assay results (possibly in CDISC or other clinical formats), and ontology terms (e.g. MeSH, ChEBI identifiers). One approach is to incorporate existing healthcare interoperability standards (like HL7 FHIR for clinical data or CDISC for trials) into the agent messages' payload format. For laboratory data, the protocol could specify adherence to standards like AnIML (Analytical Information Markup Language).

From a security standpoint, the protocol should enforce encryption (e.g. TLS for transport, or message-level signatures as in ARSIA) to protect proprietary IP in messages. Identity management is critical: Pistoia is likely to require that agents use digital certificates, so that any action (like changing a reagent on a robot) can be traced to an authorized source. This mirrors how industries using industrial control systems rely on identity-based protocols (e.g. OPC UA has application-level certificates for process controllers).

Finally, orchestration aspects matter. The Pistoia press highlighted the goal of "link [ing] standalone AI applications into a dynamic network" (pistoiaalliance.org). This implies not only point-to-point channels but also *brokered coordination*. The protocol might include a registry or directory service where agents announce services (e.g. "analysis agent available for toxicity prediction"). It could support pub/sub messaging for events (an agent broadcasting a result) and workflow choreography (agents consulting a "workflow manager" agent). In other words, Pistoia's protocol design will need to specify both the low-level message formats and the higher-level software architecture patterns.

AI Agent Standards

Beyond message exchange, defining **what an AI agent is and should do** is also critical. The initiative's second deliverable – an *AI Agent Standard* – addresses this. While a communications protocol treats agents as abstract endpoints, an agent standard would detail each agent's structure, capabilities, and validation requirements.

Key elements of an AI Agent Standard might include:

- **Agent Description Schema:** A standardized template listing an agent's declared functions, inputs/outputs, trust boundaries, and domain context. For example, an agent might have metadata fields for *"Allowed Data Sources"*, *"Applicable Assays"*, or *"Regulatory Classification (GxP level)"*. These fields could be encoded in a machine-readable manifest (e.g. JSON or XML) attached to the agent binary. By requiring a common schema, any system can introspect an agent to understand its scope.
- **Certification and Versioning:** Agents used in pharma will often need formal approval (analogous to software validation). The standard could prescribe version formats and change logs. Whenever an agent's code or knowledge base is updated, it would increment a version and attach a tamper-proof record (e.g. a hash accession). This would allow traceability of exactly which codebase generated a result. (Vendor tooling such as Qualitum's, which lists URS and IQ/OQ/PQ protocol use cases on its own site, shows commercial interest in validation workflows; this is an unverified marketing claim (qualitum.ai).)
- **Development Practices:** The standard may borrow from Software Development Life Cycle (SDLC) best practices. For example, it could mandate testing benchmarks (unit tests for modules, integration tests for workflows) and documentation of training data. This aligns with evolving norms (e.g. the FDA/EMA "human-in-the-loop" principle and "risk-based approach" in their AI guidelines (www.fda.gov)). By baking such practices into the agent spec, the industry moves towards *"validation by design"* (mediforce.ai).
- **Operational Constraints:** The standard might specify runtime policies: how often an agent can self-update, maximum autonomy levels (what class of decisions require manual override), and encryption requirements. For example, an agent could be required to consult a human if its confidence in a decision falls below a threshold (implementing the "human-on-the-loop" concept). These constraints can be part of the agent's profile, so that a deployment system can enforce them globally (e.g. "no decision can proceed without human review if a critical label is changed").

Real-world agentic frameworks already use similar ideas. Corti's Agentic Framework (in beta) highlights *"domain-specific reasoning"*: its agents are pre-trained with healthcare knowledge and compliance rules (docs.corti.ai). If Corti's approach were open, we could adopt analogous requirements: any *healthcare agent* must include a knowledge base of medical terms and be validated on standard clinical data. Pistoia may also look at other emerging approaches to agent assurance as its work develops.

Ultimately, the AI Agent Standard will ensure that "agentic" systems are not wildcards: they'll have the same rigorous identity and quality requirements as equipment and software in regulated R&D. Table 1 (below) summarizes some key initiatives and how they relate to Pistoia's goals.

Initiative / Framework	Domain	Focus / Key Output	Relation to Pistoia Scope
Pistoia Alliance Agentic AI Initiative	Life Sciences / Pharma R&D	Defining pharma-specific *agent-to-agent protocol* and *AI agent standard*; producing whitepapers/guidelines for safe agentic AI in R&D (pistoiaalliance.org)	Core subject of this report (cross-industry collaboration on standards)
Agent2Agent (A2A) (developers.googleblog.com)	General AI Industry	Open protocol (announced by Google in April 2025) for interoperable agent messaging; built on HTTP, SSE and JSON-RPC	Potential base protocol; Pistoia may adapt for healthcare context (with extra semantics)
Open Agent Protocol (OAP) (openagentprotocol.eu)	General AI / Computing	Vendor-neutral spec for identity, discovery, invocation, and accountability in agent networks	Can inform Pistoia's identity/authentication approach and governance layers in communication protocol
ARSIA Protocol (arsiaprotocol.org)	AI Governance / Security	Envelope protocol embedding compliance, cryptographic identity, and audit data into each agent message	Illustrates embedding trust data (human oversight, policy) directly in communications, aligning with need for auditability
Qualitum – Agentic Validation (qualitum.ai)	Pharma (Computer System Validation)	Commercial vendor offering described on its own site as an "agentic validation platform" (vendor marketing claim; not independently verified)	Illustrates vendor interest in validation tooling for AI agents; no affiliation with or endorsement by Pistoia is implied
Mediforce – AI Workflow Governance (mediforce.ai)	Healthcare (Clinical Processes)	Open-source AI orchestration with built-in validation/audit and human-in-the-loop controls	Proof-of-concept that "validation and governance by design" can be built into AI workflows in regulated settings
Corti Agentic Framework (docs.corti.ai)	Healthcare AI Applications	Modular AI agents for clinical and operational tasks; domain-tuned reasoning layers for health compliance	Illustrates agent design principles (specialized reasoning, compliance layers) relevant to defining pharma agent standard
FDA/EMA Good AI Practice (www.fda.gov)	Regulatory Guidelines	10 Guiding Principles (human-centric, risk-based, standards adherence, etc.) for AI in drug R&D	Philosophical framework underpinning the need for standards; Pistoia's planned standards could be considered alongside Principle #3 "Adherence to standards" and #6 "Data governance and documentation"; the principles are non-binding and Pistoia's work is not an endorsed means of meeting them
IEEE/Standards Bodies	Technology Standards	Various ongoing AI and agent standards efforts (e.g. open multi-agent specs)	Broader context. The Pistoia initiative can align with these (e.g. incorporating transparency and ethics requirements already in draft standards)

Table 1. Selected initiatives and frameworks related to agentic AI interoperability and governance. Pistoia's project will need to harmonize and specialize these efforts for life-science R&D.

Validation and Trust Frameworks

Since life sciences is one of the most regulated industries, any new AI paradigm must fit into existing Quality and Compliance frameworks. Pistoia's emphasis on **shared validation frameworks** reflects this reality. We discuss how agents can be certified and monitored so that their outputs are scientifically reliable and regulatorily defensible.

Lifecycle and Compliance Integration

In pharmaceuticals, computer systems undergo strict validation (following GxP guidelines). Agents must be treated no differently. For example, the EU's GMP Annex 11 and the US FDA's 21 CFR 11 require that computerized processes are qualified (verified to operate correctly). One vendor, Qualitum, markets agentic computer system validation tooling and references GAMP 5 and ALCOA+ on its own site (an unverified vendor marketing claim, not evidence of Annex 11 or Part 11 compliance) (qualitum.ai). In practice, deploying an agent would involve writing Specifications (URS), designing Controls, Installation and Operational Qualifications, and documenting all steps – just as with a laboratory instrument or an LIMS.

Pistoia's guidelines will likely recommend exactly that: treat AI agents as *value-impacting computerized systems*. That means starting with a requirement spec (what the agent is intended to do) and following through with thorough documentation. The difference with AI is incremental updating; if an agent retrains on new data, the standard would require re-validation of the changed module. Essentially, validation becomes continuous. This meshes with FDA/EMA guidance on lifecycle management of AI (their Good AI Practice principle #9 is "Life cycle management" (www.fda.gov)).

Auditability and Metrics

A cornerstone of trust is **auditability**. Every decision an agent makes in R&D should be traceable. Shared validation frameworks must specify what logs to keep. For instance, every time an agent changes a reagent or marks a lead compound for synthesis, it should record: which sub-model it used, what inputs it saw, and why it made that decision. Techniques from explainable AI can help annotate agent decisions, but the industry standard will demand recording even the low-level "chain of thought" or feature importance data.

Alongside raw logging, we need **metrics** to summarize performance. Pistoia's survey highlights "robustness and bias" as top concerns (pistoiaalliance.org). Thus, frameworks will likely define test metrics like prediction accuracy under distribution shifts, fairness indices (e.g. does the agent perform equally on subsets of data?), and run-time safety margins. These metrics can be standard benchmarks run offline, or real-time dashboards. For example, if an AI agent designs a molecule predicted to be toxic, the system should flag how certain it was and what alternative options it considered – enabling risk assessment.

Data Management and Provenance

Data is king in life-science R&D. Shared frameworks will insist on stringent **data governance** for agents. This includes tracking the provenance of every piece of input data an agent uses (meeting *Principle 6: Data governance and documentation* of FDA/EMA (www.fda.gov)). In practice, agents should reference data by immutable IDs or timestamps. The Pistoia press release explicitly calls for agents to use *"approved data sources"* in their workflows (pistoiaalliance.org). For example, if an agent queries a compound database, it should log which version of the database (and its content hashes) it saw. If new literature is ingested, the agent must log the DOI or archive ID of each source.

Recent polls show this is sorely needed: more than one in four life-science professionals polled at a Pistoia conference said they do not know what scientific content their organization's AI or LLM systems use, or rely only on titles and abstracts (pistoiaalliance.org). By contrast, good practice would enforce that all models feeding an agent are trained on traceable datasets. The upcoming IEEE and ISO AI standards (e.g. ISO/IEC 42001 "Management System for Trustworthy AI") stress data quality and documentation, which Pistoia's outputs can concretely implement in the context of agentic workflows.

Human-in/On-the-Loop and Expert Oversight

No matter how autonomous, agents in pharma should operate under defined human oversight. Pistoia's wording *"shaped by subject matter experts and approved data sources"* (pistoiaalliance.org) implies a governance model: expert scientists curate the system and receive its outputs. The validation frameworks will likely require *"in the loop"* checkpoints. For example, agents could be constrained to propose hypotheses but require human approval before executing any real experiment or submitting to regulators. This is consistent with FDA's "human-centric design" (Principle 1) and prioritizing humans as ultimate decision makers.

Additionally, agents themselves could be subjected to **external auditing**. One approach is "red teaming" : having an independent team probe the agent with adversarial scenarios to test failure modes. A practical example: before an AI-driven dose-selection agent is deployed, an internal audit runs it on past clinical trial data to see if it would have made the same recommendations as the original researchers – a form of back-testing for correctness. Any deviations would be counted in the validation report.

Such human oversight also extends to security. IT teams must certify that agent communication channels are secure (using protocols from the previous section) and that agents cannot be hijacked by malicious code. The validation framework will include penetration tests and code reviews as part of the approval process. Over time, compliance auditors will likely treat agentic AI the way they treat any computerized system in GMP: with regular inspections and certification checks.

Case Study: Amazon's Bio Discovery (Lab-in-the-Loop AI)

To illustrate these ideas, consider the emergence of **lab-in-the-loop AI** platforms, which exemplify agentic workflows. Amazon Bio Discovery (2026) integrates computational design with actual lab experiments through an AI agent interface. As Reuters reported, it provides *"a library of specialized biological foundation models… along with an AI agent that helps users select models, set parameters and interpret results"* (www.investing.com). Importantly, this platform is described as augmenting scientists, not replacing them. Amazon emphasizes that Bio Discovery compresses multi-month cycles into weeks by closing the loop (an experiment's data immediately refines the next iteration).

From a governance perspective, such a system would need to implement many Pistoia concepts:

- A **communication protocol** underlies its operation (between design agent, lab scheduling agent, analysis agent, etc.), ensuring each component receives consistent data.
- Each **agent's profile** (e.g. the molecular optimization agent vs. the lab automation agent) is likely standardized so the system knows how to invoke and trust them.
- A **validation framework** must be applied: AWS implicitly vetted Bio Discovery internally (and possibly by partners) to ensure that predictions correlate with experimental outcomes. Ongoing monitors measure success rates (since AWS boasts speed to "top results") – a form of metric for agent robustness.

This real-world example shows that the Pistoia initiative is addressing imminent needs: as more organizations build similar AI-driven discovery tools (from major pharma companies to startups), they will face exactly the interoperability and validation questions Pistoia is tackling.

Governance Playbook for R&D and IT Leaders

Based on the above, we outline key governance actions for organizations adopting agentic AI. These are meant to complement existing pharma policies (GxP, data safety/security, etc.), and should be updated as the standards initiative releases outputs.

- **Establish an AI Governance Committee:** Form a cross-disciplinary team (R&D scientists, IT architects, legal/compliance, QA) to oversee agentic AI initiatives. This committee should review emerging frameworks (e.g. Pistoia's protocols) and adapt them into corporate policy. It will ensure that any agent development project is evaluated for risk and compliance from the outset.
- **Adopt Standard Protocols and Tools:** Wherever possible, use open agent protocols rather than ad-hoc integrations. For example, mandate that any AI workflow use message formats aligned with A2A/OAP principles. Select AI orchestration platforms (like Mediforce or commercial equivalents) that

support validation by default (mediforce.ai). Continuously monitor industry updates: Pistoia's deliverables may include reference implementations. **Table 2** (below) summarizes recommended considerations and example solutions in key governance domains.

Governance Domain	Key Considerations / Actions	Examples / References
Standards & Protocols	Use open agent communication standards (e.g. A2A, OAP) to ensure interoperability (www.ibm.com) (developers.googleblog.com). Define minimal message schema and enforce it in development.	Google A2A Protocol (developers.googleblog.com), OAP spec (openagentprotocol.eu)
Agent Certification	Require formal profiling of agents. Maintain an "agent directory" with metadata (capabilities, version, certification status). Ensure agents meet defined criteria before use.	Corti Agentic spec (docs.corti.ai)
Validation & Audit	Integrate agent testing into SDLC. Use shared test suites and re-validate after updates. Log every decision with audit trails; use ARSIA-like envelopes (arsiaprotocol.org).	Pistoia's shared validation frameworks (pistoiaalliance.org); vendor-marketed agentic CSV tooling (e.g. Qualitum; unverified marketing claim) (qualitum.ai)
Data Governance	Enforce traceability of all data used by agents. Implement metadata tagging (source, timestamp) at each step. Consider the FDA/EMA "data governance and documentation" principle (www.fda.gov).	FDA/EMA Good AI Practice Guideline (www.fda.gov)
Human Oversight	Define clear human-in/on-loop rules. E.g. require human review for high-risk decisions. Document SME approvals of workflows (as Pistoia advises) (pistoiaalliance.org).	Expert review gates; "human-centric" AI principle (www.fda.gov)
Regulatory Compliance	Treat agents as regulated systems under 21 CFR 11/EU Annex 11. Ensure ALCOA+ data integrity and GxP documentation. Consider cryptographic audit techniques (e.g. blockchain logs).	GxP validation practices; ALCOA+ (referenced in Qualitum's vendor marketing) (qualitum.ai)
Organizational Readiness	Train scientists and IT on agentic concepts: capabilities, limits, and governance. Update SOPs and quality manuals. Foster an "AI culture" where issues are reported and shared.	Change management (align with Pistoia's AI/ML community input)

Table 2. Governance considerations and example actions for R&D and IT leaders in implementing agentic AI systems. Bracketed references illustrate sources or analogous efforts.

Implementing these requires collaboration between R&D and IT departments. For instance, IT should provision specialized infrastructure (e.g. private cloud or on-prem clusters) that can host agents securely and meet data-security requirements. The IT team must also enforce network policies for agent communication (e.g. restricting certain agents to internal networks only) and manage keys/certificates for agent identities. R&D leaders, meanwhile, should ensure that any proposed agent application has clear scientific rationale, defined endpoints, and a plan for continuous monitoring. Together, they should contribute to the pre-competitive dialogue: by sharing learnings with Pistoia and other consortia, they can influence emerging standards before committing large resources.

Finally, leaders must engage with regulators. Neutral regulatory guidance on agentic AI is still maturing, but the FDA/EMA “Good AI Practice” guiding principles (January 2026) for AI in drug development offer a useful reference point, although they are principles rather than formal guidance. Pistoia members should participate in workshops and consultations (as indeed it is doing) to convey how agentic AI operates. Aligning company policies with Pistoia’s frameworks may support internal governance, but it does not establish regulatory compliance. Separately, sponsors of the initiative will be featured as industry co-authors and get early access to the standards under development (pistoiaalliance.org).

Implications and Future Directions

The Agentic AI initiative is forward-looking, but its outcomes will ripple across the industry. By setting standards now, Pistoia and its sponsors aim to avoid the fragmentation seen in past technologies (e.g. each company building incompatible AI pipelines). In the near term, we expect to see:

- **Reference Architectures:** Pistoia or other bodies may publish exemplar architectures for agentic pipelines in drug R&D. For example, a “Standard Pharma AI Agent Stack” might include an identity/auth broker, a message bus compatible with A2A/OAP, agent registries (with specifications from the Agent Standard), and monitoring dashboards. Vendors and integrators will likely start offering “plug-and-play” agentic modules that conform to these architectures.
- **Regulatory Alignment:** The FDA/EMA Good AI Practice principles are non-binding, and Pistoia’s standards have not yet been published. No regulatory benefit, such as faster reviews or easier compliance with the EU AI Act, can be assumed from adopting them; companies should check their own obligations directly with the relevant regulators.
- **New Tools and Platforms:** We may see new software platforms that embody the standards from the outset. For instance, a drug company might adopt a platform like Mediforce or others that already include AI orchestration, so they only need to plug in domain-specific models. Over time, *”agent factories”* could emerge: standardized toolchains for building, testing and deploying agents that meet the Agent Standard. Some of these might be community-supported (open source) or vendor-funded.
- **Expanded Use Cases:** Initially, agentic AI may focus on discovery (molecule design) and non-critical operations (lab scheduling, literature curation). As trust builds, it could expand into clinical trial management (adaptive trial design), supply chain optimization (autonomous procurement), and personalized medicine (automated treatment planning). Each new domain will raise fresh validation questions (e.g. veterinary vs. human data splits in translational research). Future updates to the standards initiative will need to keep pace with such extensions.
- **Global Collaboration:** While Pistoia is one consortium, other regions may form their own collaboratives or collaborate with Pistoia. The eventual goal is harmonization – akin to how ICH harmonizes drug regulations globally – so that an agentic solution developed in one country can be understood and accepted in another. Given the pre-competitive nature of much basic R&D, we anticipate increasing international alignment on these AI standards.

Conclusion

Agentic AI stands at the frontier of pharmaceutical innovation: it offers to break down silos and automate entire R&D pipelines, but it also demands a new level of governance. The Pistoia Alliance's initiative is a critical step toward making these systems *safe, trustworthy, and interoperable*. By uniting industry leaders around an agent-to-agent communication protocol, a formal agent specification, and shared validation frameworks, Pistoia is laying the groundwork for "lab-of-the-future" scenarios where multiple digital agents collaborate as seamlessly as lab technicians do today.

For R&D and IT leaders, the message is clear: start planning now. Engage with these standards, adapt your policies, and contribute your experiences. In a domain where reproducibility is paramount, **no company can afford to deploy autonomous AI systems in isolation or ignorance**. Those who follow the emerging Pistoia guidelines and related frameworks will position themselves as pioneers – shaping the rules, rather than scrambling to play catch-up.

Factual statements above are drawn from the cited industry sources and reports; the projections, the likely content of the unpublished Pistoia standards and the recommendations are the author's own analysis (pistoiaalliance.org) (blogs.nvidia.com) (www.biosciencetoday.co.uk) (www.fda.gov). By heeding this body of work and collaborating on the solutions outlined, pharma organizations can harness the power of agentic AI while upholding the scientific rigor and compliance their stakeholders demand.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://blogs.nvidia.com/blog/ai-healthcare-life-sciences-survey-2025
2. https://pistoiaalliance.org/ai/pistoia-alliance-unveils-agentic-ai-initiative-and-seeks-industry-funding-to-drive-safe-adoption
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