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Pharma AI Readiness: A 90-Day Diagnostic Framework

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Executive Summary

Artificial Intelligence (AI) is rapidly reshaping the pharmaceutical industry, promising to accelerate drug discovery, improve patient outcomes, and streamline operations. Leading studies estimate that fully industrializing AI across pharma could double industry profits and unlock on the order of **$250–$254 billion** in value annually by 2030 (www.strategyand.pwc.com) (scw.ai). Recognizing these stakes, most large pharma companies now treat AI as a top strategic priority: one recent survey found *70% of pharma executives* view AI as an “immediate priority” (85% among top-20 firms), and **80%** are boosting their AI budgets (www.fiercepharma.com). At the same time, analysts and regulators emphasize that in this highly regulated sector—where patient safety and scientific integrity are paramount—AI must be adopted *responsibly and*

systematically. Pharma leaders therefore need structured frameworks to assess their “AI Readiness”: that is, their organizational capacity in data, technology, skills, governance and culture to adopt AI safely and effectively.

This report proposes a **90-day diagnostics framework** for evaluating AI readiness in pharmaceutical organizations. It draws on academic and industry research, case studies, and expert guidance to define the dimensions of readiness (regulatory compliance, data integrity, talent and culture, infrastructure, use-case strategy, etc.) and outline a phased program for assessment, gap analysis, and roadmapping. We begin with background on AI in pharma and the critical need for readiness. We then examine the current AI landscape, summarizing surveys of adoption, investment trends, and early successes and failures in the industry. Subsequent sections develop a maturity model for AI readiness in pharma along multiple perspectives: **Regulatory & Compliance**, **Data & Technology Infrastructure**, **Organizational Capability & Culture**, **Scientific & Clinical Integrity**, and **Commercial/Operational Applications**. Across these sections we integrate statistics (e.g. survey data on AI adoption, impact estimates), diverse viewpoints (pharma executives, consultants, regulators), and concrete examples (programs at Pfizer, Lilly, Roche, etc.).

We also include comparative tables: for instance, a breakdown of AI’s potential impact by business function, and an illustrative timeline of activities for a 90-day assessment. Case studies illustrate how pharma companies have applied AI – notably Pfizer’s Watson partnership and Lilly’s Insilico collaboration – highlighting both achievements and challenges. We analyze how industry frameworks (e.g. PwC’s AI value study, FDA’s guidance on AI/ML as medical devices, and the EU AI Act) shape readiness requirements. Throughout, we emphasize an evidence-based approach: all assertions are backed by citations from reputable sources. The goal is a **thorough, actionable report** that prescribes how a pharma organization can systematically gauge where it stands on AI and what steps are needed to govern AI responsibly and drive real results.

Key findings include:

- **AI is a high priority, but readiness lags:** Surveys indicate rapid AI adoption plans (75–86% of life-sciences firms implementing AI soon (www.axios.com)) and increased spending (www.fiercepharma.com). However, many lack formal policies or governance (under 60% have AI-specific SOPs and audits (www.axios.com)), and widespread skepticism still exists about AI’s capabilities (www.fiercepharma.com).
- **Regulation and trust are critical in pharma:** AI projects must be designed with compliance and patient safety baked in. The FDA describes GMLP as guiding principles for AI/ML medical-device development (FDA). Assess each project’s applicable obligations under the EU AI Act. As an internal readiness recommendation, scope quality-system controls to the regulated process and intended use.
- **Data quality and governance underpin success:** Consistent with studies of digital maturity, data integrity, lineage, and interoperability are major bottlenecks in pharma AI. Organizations need robust data pipelines and metadata tracking (e.g. GxP compliance on data handling (solutionsreview.com)) before any AI models can be trusted.
- **Talent and culture are as important as tech:** Even with the best algorithms, lack of trained personnel or siloed incentives can derail AI. Integrating AI requires cross-functional teams (data scientists paired with biologists, for example) and a culture of experimentation with governance. Industry commentators

stress “foundations in people, processes, and platforms” and targeted initiatives to build digital maturity (www.intellishore.dk).

- **Practical phased approach:** A 90-day assessment can be organized into phases (initial audit of data and capabilities, pilot project scoping, governance setup, etc.) as shown in our detailed framework and supporting table. Quick “wins” on low-risk use cases (e.g. administrative automation) build momentum, while core readiness gaps (infrastructure, compliance, training) are systematically addressed.

This report concludes with forward-looking discussion: as regulatory guidance evolves and new AI technologies (e.g. generative models, digital twins) emerge, pharma companies must continuously iterate on readiness. They should monitor metrics (e.g. ROI of AI projects, audit findings) and refine governance in an environment where “AI thrives on scale” of data (www.pharmtech.com). The 90-day diagnostic is just the beginning of a long transformation. In summary, this report assembles a comprehensive, evidence-based blueprint for pharma leaders to diagnose and accelerate their AI readiness in the near term – and beyond.

Introduction and Background

The Promise and Complexity of AI in Pharma

Artificial Intelligence (AI) – encompassing machine learning, deep learning, and emerging generative models – holds transformative potential for pharmaceutical research, development, manufacturing, and commercial operations. Studies indicate that strategic AI adoption could nearly **double pharma’s operating profits** by 2030 (www.strategyand.pwc.com). For example, PwC’s Strategy& analysis estimates an additional ~$254 billion per year in profits (global) through AI efficiency gains and new revenue streams (www.strategyand.pwc.com). Leading AI applications range from **drug discovery** (predicting molecular targets, simulating protein folding, mining literature) to **clinical development** (optimizing trial design and patient matching) to **manufacturing** (smart scheduling, predictive maintenance) and **commercial activities** (personalized marketing, sales forecasting). In aggregate, PwC projects that AI could uplift pharma’s operating margins from ~20% to 40% (scw.ai) (www.strategyand.pwc.com).

However, realizing this upside is far from automatic. The pharmaceutical industry is characterized by **high risk**, heavy regulation, and a culture of scientific rigor. Mistakes in AI could have grave consequences: biased algorithms might harm patients, “black-box” models could undermine regulatory trust, or poor data could lead to invalid predictions. The industry motto remains patient safety above all. As one thought leader observes, “In pharma, the ultimate KPI isn’t operational efficiency—it’s trust” (solutionsreview.com). Consequently, adopting AI in pharma requires not just new tools, but *new processes, controls, and mindsets* to ensure the technology enhances – not compromises – safety, efficacy, and equity.

Evolution of AI in Pharma

Recent years have seen renewed momentum: advances in deep learning (e.g. AlphaFold’s protein folding breakthrough) and cloud computing have made AI more accessible. Tech giants (Alphabet, Amazon, Microsoft) have partnered with pharma, and specialized AI startups (e.g. Insilico Medicine, Atomwise, Recursion) are

attracting multibillion-dollar deals (www.genengnews.com) (www.pharmtech.com).

In 2023-2025, generative AI (like large language models) further ignited interest. Pharma is exploring applications from automated report writing to molecule design, but also grappling with data confidentiality. One survey found **65% of top pharma** had banned tools like ChatGPT due to leak concerns (www.fiercepharma.com). At the same time, the executive narrative shifted positively: by 2025, three-quarters of pharma C-suite said AI projects were under way and budget was increasing (www.fiercepharma.com) (www.axios.com). However, analysts caution that many AI pilots remain in silos and lack scale. Arnold & Porter's November 2024 report identifies governance as lagging behind AI implementation (original report). This combination of rapid adoption and procedural immaturity underscores the need for structured readiness assessments.

Why a "Readiness Assessment" and 90-Day Framework

Given the stakes, top pharmaceutical firms cannot rely on ad-hoc AI experiments. They need a clear view of *where they stand*: Do they have the right data infrastructure? Trained AI teams? Governance and ethics boards? Strategic AI use cases aligned with business goals? A thorough **AI readiness assessment** diagnoses strengths and gaps across these dimensions. Industry experts have highlighted analogous needs: a Strategy& report advised pharma companies to "assess and build organizational structures" for delivery, establish innovation incubators, and adopt top-down adoption programs (www.strategyand.pwc.com). Similarly, consultants emphasize foundational layers of "people, processes, and platforms" as prerequisites for sustainable AI (www.intellishore.dk).

This report adopts a **90-day diagnostic framework** to provide an actionable path. The 90-day timeframe is inspired by common consulting roadmaps (akin to 100-day digital transformation plans) and allows for an intensive, phased review. In roughly three months one can inventory data assets, interview stakeholders, pilot small use cases, and draft a strategic action plan. For example, in healthcare supply-chain consulting, a 90-day AI playbook begins with data collection (Days 0–14), moves to quick cost-savings fixes (Days 15–60), and culminates in governance frameworks (by Day 90) (diligize.pe). In pharma, a similar approach can reveal immediate AI opportunities while aligning departmental readiness for the longer term.

The sections that follow will explore each aspect of AI readiness in depth, citing studies and real-world examples. We include tables summarizing key dimensions and project timelines. Ultimately, this diagnostic is meant to leave no stone unturned: it examines technical, organizational, regulatory, ethical, and strategic angles so that pharma leaders can move from AI aspirations to **responsible execution**.

The Current AI Landscape in Pharma

Adoption Trends and Investments

Recent surveys paint a picture of an industry marching toward AI adoption at scale. A 2025 FiercePharma report (surveying 16 of the top 20 pharma companies) found **70% of leaders** call AI an "immediate priority" (rising to 85% among the top-20) (www.fiercepharma.com). Consequently, **over 80%** of respondents said their

companies are **increasing AI budgets**, while only 15% held budgets constant (www.fiercepharma.com). These investments target both cost efficiencies and new capabilities: for many executives, “low-risk, high-efficacy” use cases like medical writing and automation are seen as early wins (www.fiercepharma.com). Notably, outside partnerships are growing: the survey noted a split between in-house development vs. external/vendor alliances, signaling that internal teams are increasingly open to collaborations (www.fiercepharma.com).

Similar conclusions emerge from life-sciences executive polls. A Nov 2024 Axios report citing an Arnold & Porter law-firm survey found **75% of pharma life-sciences executives** said their organizations began implementing AI within the last two years, and **86%** plan to deploy AI tools within the next two years (www.axios.com). But the same source highlights gaps: only about half have formal AI policies or regular audits in place even now (www.axios.com).

Statistically, big pharma’s readiness also varies by company. A 2023 *Statista* index ranked Roche as *highest* in AI readiness among major pharmas (scoring on talent, innovation, execution) (www.statista.com). The report noted that many firms are shoring up readiness through strategic acquisitions of innovative AI startups (www.statista.com). However, other large players lag behind: even leading companies are still only at early stages of AI integration. A related signin survey (ZoomRx, 2024) found that **over 80%** of life-sciences companies had some AI use cases in production, leaving only 8% completely without any – yet 83% still called AI “overrated,” indicating a disconnect between usage and confidence (www.fiercepharma.com). This mixed attitude underscores that while technical adoption is spreading, organizational and cultural readiness may not have kept pace.

Across commercial and technical domains, pharma companies report many active AI initiatives. Strategic applications include:

- **Drug Discovery & R&D:** AI is used to predict molecular targets, repurpose existing compounds, and sift genomic or proteomic data. For example, **Eli Lilly** announced a major $100M+ collaboration (2025) with Insilico Medicine to use AI-driven chemistry to discover new drugs (www.genengnews.com). Lilly also built one of the world’s largest in-house AI platforms (1,016 GPUs) for genomics and molecular design (www.genengnews.com).
- **Clinical Trials:** AI is applied for patient recruitment (mining EHR data for eligibility), adaptive trial designs, and real-time monitoring. Case studies from CROs show predictive analytics can accelerate trial matching, though ensuring fairness and data security remains challenging (solutionsreview.com).
- **Manufacturing & Supply Chain:** AI-driven optimization (scheduling, predictive maintenance, anomaly detection) is emerging, especially in planning and quality control. Big impacts are possible: one source notes AI applications in manufacturing/supply chain were projected to contribute ~40% of the $250B potential value in pharma (scw.ai). (Yet currently only a fraction of factories employ AI schedulers or vision-based inspection).
- **Commercial & Operations:** AI is transforming marketing and sales through dynamic territory planning, segmentation, and content personalization. Many commercial teams use machine learning models to optimize HCP (healthcare provider) outreach. For instance, AI tools now assist in targeting key opinion leaders and in content recommendation to physicians (though regulations on using patient or private data in marketing require strict controls).

- **Support Functions:** Corporate functions (finance, HR, regulatory affairs) are adopting AI for process automation. Routine reporting, regulatory text analysis, and internal help-desk chatbots are common lower-risk pilots that free up human time.

Arnold & Porter's November 2024 report describes AI adoption across the life-sciences product lifecycle (original report).

These numbers attest to **high usage** of AI tools, but they do not guarantee success. The preliminary MIT NANDA report on enterprise GenAI describes its deployment estimates as directional findings from individual interviews rather than official company reporting (MIT NANDA report). The shortcomings often stem not from technology per se, but from planning, data, and change management issues (e.g. teams tackling "intellectual problems" instead of on-floor bottlenecks (www.pda.org)). Recognizing this, our framework emphasizes diagnostics of organizational readiness *before* embarking on largescale AI programs.

Drivers of AI Adoption and Barriers

Pharma's AI push is driven by multiple factors:

- **Competitive pressure:** As AI acceleration happens in biotech, tech, and among competitors, laggards risk losing edge. A VC report warns that pharma's future will be decided in the next 12–24 months by who embeds AI into core workflows with tangible ROI (www.fiercepharma.com). Companies like Genentech publicly describe AI as an "effectiveness amplifier" for commercial operations (www.fiercepharma.com), reinforcing the message that leaders are increasing adoption.
- **Cost and efficiency needs:** Drug development costs have soared (often >$2B per approved drug) and timeframes lengthen. AI promises to cut waste – for example, Insilico reports achieving candidate identification in ~1 year where traditional routes might take 3–6 years (www.genengnews.com). PwC found AI could address the largest cost pools (manufacturing and supply chain) and thus deliver 39% of the total value by 2030 (www.strategyand.pwc.com). Companies under pricing and regulatory pressure also see AI as a means to do more with less (e.g. fewer development failures, optimized pipelines).
- **Data availability:** The digitization of data (electronic health records, omics databases, real-world evidence) has created raw fuel for AI. Many organizations now have vast troves of proprietary and public data that could be leveraged. This data bounty partly explains why major deals (e.g. Roche–Flatiron, 2018 (Roche)) have occurred to secure data-driven insights in oncology and supplies more impetus for readiness.

However, **barriers** remain formidable:

- **Regulatory uncertainty:** Unlike retail or social media, pharma is tightly regulated. For medical uses, data and algorithms must meet standards of explainability, robustness, and validation. Regulators (FDA, EMA, PMDA, etc.) are still defining how to oversee AI tools, though guidance is emerging. For instance, the FDA and global agencies issued **Good Machine Learning Practice (GMLP)** principles in 2025 for AI/ML as medical devices (www.fda.gov). Under the European Commission's AI Act explanation, high-risk classification depends on intended purpose: relevant routes include specified Annex III uses and

Annex I products or safety components subject to third-party assessment under the applicable product legislation. Healthcare use alone does not establish high-risk status. The Commission gives 2 December 2027 for high-risk rules and 2 August 2028 for AI embedded in regulated products, including qualifying medical devices. Map each use case and obligation to its applicable date.

- **Data and IT gaps:** Despite data abundance, enterprises often suffer data "debt": fragmented legacy systems, poor metadata, and unstandardized formats. A common refrain is that AI efforts stall on poor data quality. The regulatory Good Practice (GxP) framework also requires complete tracability of data (origin, transformations), which many AI teams overlook. Solutionsreview notes: *"In pharma, data integrity is not just a best practice—it's a non-negotiable"* (solutionsreview.com). Building out data pipelines, enforcing data governance, and integrating AI platforms with existing IT (cloud, LIMS, LLMops) are urgent prerequisites.
- **Skills and cultural resistance:** AI requires new roles and mindsets. Many pharma staff lack AI expertise, and there is apprehension about job impacts. Surveys of healthcare organizations (outside pharma) highlight big skill gaps even amid enthusiasm (www.techradar.com). Internal silos also inhibit progress: R&D teams may prototype AI in isolation without linking to commercial or manufacturing stakeholders. Culture surveys indicate that trust in AI varies; executives repeatedly note that humans must retain "final authority" over AI-driven decisions (solutionsreview.com). Embedding "human-in-the-loop" processes and educating the workforce are therefore critical readiness elements.
- **Ethical and social concerns:** Pharma must guard against AI biases that could worsen disparities. For example, an AI model for trial recruitment or dosing could inadvertently exclude underrepresented subjects if trained on skewed data (solutionsreview.com). Public sensitivity around health data is high; a generative AI leak of patient info could ruin trust instantaneously. These issues are driving leaders to form AI governance committees (over 80% of surveyed firms have done so) and to focus governance on ethics, safety, and compliance (www.fiercepharma.com). Readiness therefore means having explicit frameworks (e.g. privacy-preserving methods) to build ethical AI processes.

In summary, while the **imperative for AI** in pharma is clear – from efficiencies to breakthroughs – the **path to adoption** is complex. Extensive technology is available, but harnessing it safely and effectively requires diagnosing one's starting point. The next sections outline the multi-faceted assessment needed to answer "Are we ready?"

Dimensions of AI Readiness in Pharma

Adapting AI in pharma involves many interdependent dimensions. Our framework organizes readiness into key domains, each with specific criteria and checkpoints. These domains often overlap, but for analysis we treat them separately:

- **Regulatory & Governance Readiness**: Alignment with medical regulations, ethical oversight, compliance infrastructure.
- **Data and Technical Infrastructure**: Quality, accessibility and safety of data; computing platforms; integration with IT systems.

- **Organizational and Talent Readiness**: Leadership vision and strategy; skills and culture; change-management processes.
- **Scientific and Clinical Integrity**: Ensuring AI augments (not undermines) biomedical science through transparency, validation, and ethics.
- **Commercial and Operations Alignment**: Identifying valid use cases in commercial operations, supply chain, manufacturing, and ensuring integration into existing workflows.

We examine each in turn, citing best practices and evidence-based guidelines. Within sections, we present frameworks, sub-lists of factors, and examples of metrics or approaches.

Regulatory, Ethical & Governance Readiness

Pharma must navigate an evolving regulatory landscape that treats AI tools akin to medical products. Readiness in this area means having solid compliance processes **built into AI lifecycles**, not as an afterthought. Key considerations include:

- **Regulatory Frameworks**: Does the organization map its AI initiatives to relevant regulations? For example, in the US, AI used in medical contexts may count as a **medical device** under the FDA's Software as a Medical Device (SaMD) rubric. International bodies (FDA, EMA, Health Canada, etc.) have issued **Good Machine Learning Practice (GMLP)** guidelines (www.fda.gov) and FDA's **Transparency for ML-enabled devices** principles, which call for thorough documentation of data origins, intended use cases, monitoring plans, and change management. For EU projects, document the intended purpose and applicable classification route before selecting conformity-assessment requirements. The Commission explains that independent assessment depends on the type of high-risk system. Treat a broader internal high-risk designation as an optional precaution, rather than a legal classification. Use the obligation-specific implementation schedule when planning compliance.
- **Quality Management & Validation**: AI systems used in regulated pharma processes should integrate with existing Quality Management Systems (QMS) and cGxP (current Good Practices) procedures. For drug and biologic submissions, the FDA's January 2025 announcement describes draft guidance proposing a risk-based approach to AI model credibility for a particular context of use. As an internal diagnostic recommendation, document model and dataset versions, validation evidence and change controls appropriate to that context. The Strategy& report emphasizes that only a few leading companies have begun operationalizing AI at scale; those organizations set up hybrid governance models combining cloud partners and internal QA teams (www.strategyand.pwc.com). An AI readiness assessment should verify whether data pipelines and models are subject to routine audits and whether AI outcomes are benchmarked against gold-standard performance metrics (ROC-AUC, etc.) before deployment (solutionsreview.com).
- **Ethical Governance**: Many pharma firms now institute dedicated AI ethics committees or control boards, which scrutinize AI proposals for bias, privacy, and patient impact. In the Define Ventures study, **80%** of companies reported having or establishing such governance structures (and focusing 80% of their mandates on ethics and safety) (www.fiercepharma.com). Readiness requires clear policies: data privacy controls must meet HIPAA/GDPR standards; procedures should evaluate AI trained on patient

data for consent and de-identification (see *Patient Privacy* below). Standard operating procedures (SOPs) for AI should cover areas like “informed consent for AI”, “algorithmic bias auditing”, and rapid incident response if an AI output harms patients. The SolutionsReview framework notes, for example, ensuring models are explainable and traceable so that regulators can “challenge and verify AI outputs – especially for high-risk decisions” (solutionsreview.com).

- **Training and Roles**: A crucial aspect is preparedness of the personnel: do regulatory affairs teams understand AI? Are there roles (e.g. AI Compliance Officer) responsible for maintaining oversight? Many companies plan to train or hire staff fluent in FDA guidance on digital health. In readiness diagnostics, one would interview stakeholders in compliance, legal and quality units to see if they have documented processes for AI. As the FiercePharma article noted, companies are quickly working on governance (with 100% of surveyed top pharmas either having or drafting ethics boards) (www.fiercepharma.com). An AI readiness report should check if these functions have real authority and clear mandates tied to AI initiatives.
- **Future-Proofing**: Because regulations are still catching up, readiness includes ‘horizon scanning’ capabilities: monitoring rule changes in regions of operation (e.g. the anticipated FDA AI regulation, updates to EU MDR for software, or country-specific AI laws). Organizations may adopt a precautionary principle (e.g. treating any AI output used in patient care as if it would be classed high-risk). Use the Commission’s implementation schedule to distinguish obligations already applicable from high-risk rules scheduled for 2 December 2027 and product-related high-risk rules scheduled for 2 August 2028. In practice, readiness means drafting an AI Quality Manual that folds in GMLP and AI-Act checkpoints, prior to solution roll-outs.

In summary, regulatory readiness in pharma requires that *every* AI project be scoped for compliance and ethics from Day 1. It also demands integration of AI into the overall quality culture. By the end of a 90-day diagnosis, an organization should have:

- Mapped all existing/proposed AI tools to relevant risk categories (SaMD guidelines, AI Act, GDPR, etc.).
- Verified documentation procedures for model validation, data lineage tracking, and explainability.
- Confirmed existence of an AI governance body or process.
- Assessed workforce training needs in GxP and AI ethics.

These checks ensure that AI will not be a regulatory blind spot.

Scientific Integrity and Clinical Use Cases

Maintaining scientific rigor is the core of pharma’s value proposition, and the **same standards** must apply when AI enters R&D or clinical operations. The SolutionsReview framework emphasizes *“Scientific Integrity & AI-Augmented Discovery”* as a pillar of readiness (solutionsreview.com). And indeed, an AI readiness audit must examine how AI models are validated scientifically. Key aspects include:

- **Transparency and Explainability:** Are compound or target predictions from AI supported by underlying biology? Black-box leaps without rationale undermine trust. Readiness entails requirement that any AI-generated hypothesis (e.g. a new drug target) be accompanied by explanations of how genomic,

structural, or literature data lead to its suggestion. For example, SolutionsReview suggests *"Algorithmic Transparency: Researchers and reviewers must understand how AI models generate results. Black-box predictions... must be explainable and backed by biological plausibility"* (solutionsreview.com).

- **Peer Review and Validation:** AI-discovered leads or trial designs should be vetted through traditional scientific processes before advancing. The guideline is that an AI hypothesis must undergo **peer review** just like a human one (solutionsreview.com). In practice, a readiness assessment checks: has the company defined SOPs for "AI to human handoff" in R&D? Are newly proposed molecules followed by lab testing? Are data scientists and medicinal chemists collaborating on interpreting results? The intent is that *"Any compound, target, or pathway flagged by an AI system should be vetted through traditional peer review before moving down the pipeline"* (solutionsreview.com).
- **Reproducibility:** A hallmark of pharma science is reproducibility of experiments. An AI system's predictions must similarly be reproducible. Readiness requires logging all model details — architecture, random seeds, training data versions — so that another researcher could regenerate results (solutionsreview.com). For example, if an AI tool proposes a new drug candidate, the workflows that led to that prediction (data cleaning steps, hyperparameters, etc.) should be auditable. The SolutionsReview checklist calls for "Reproducibility Standards: teams must document model architecture, input features, training methods, and random seed states" (solutionsreview.com).
- **Responsible Use of Synthetic Data:** AI can generate virtual patient cohorts or molecular variations (synthetic data). While valuable, readiness means managing this carefully. The framework advises clear flagging of synthetic vs. real data (solutionsreview.com). For example, if a clinical outcomes model is trained in part on simulated patients, this must be documented and justified. Companies should have policies to track and label any AI-generated data, avoid unseen biases from such data, and disclose usage in regulatory submissions.
- **Patient-Level Safeguards:** When AI is used in patient-facing contexts (e.g. diagnostic support, trial eligibility), scientific oversight extends to **privacy, consent, and safety** (solutionsreview.com). Readiness in this "patient data governance" domain (detailed next) is an essential sub-dimension.

Collectively, these measures preserve "faith in the science" even as it is automated. Training programs, internal policies, and documentation standards should adapt to incorporate AI into pharma's existing R&D protocols. By Day 90, an organization's AI readiness blueprint would identify which research areas have pilot AI tools and whether those pilots have built-in scientific safeguards (peer review, validation data benches, etc.). Establishing an AI review board that includes senior scientists can be a practical step.

Data, Security and Technical Infrastructure

AI in pharma is critically dependent on data. Yet data in life sciences is often siloed, heterogeneous, and regulated. Readiness in this domain assesses whether the organization has the **data foundation** needed to support AI:

- **Data Quality and Integration:** Does the company have accurate, standardized datasets? Are there gaps or biases in patient records, lab measurements, genomic repositories, etc.? Pharma's regulatory environment treats data with exceptional rigor: Good Manufacturing/Clinical/Laboratory Practice (GxP) require traceability and audit trails (solutionsreview.com). AI projects often fall short by ignoring legacy inconsistencies (e.g. unit mismatches, missing timestamps). An AI readiness review must include a data audit: inventory of key data sources (EHRs, clinical trial databases, omics data, manufacturing records), assessment of completeness, and plans to harmonize formats. One goal is to ensure datasets are "FAIR" (findable, accessible, interoperable, reusable) as industry experts advocate (www.pharmtech.com).
- **Lineage and Version Control:** Readiness means building lineage-tracking from Day 1. Any data fed to models should have metadata recording *when, where, and how* it was collected and processed. Solutionsreview stresses the need for *"every dataset used in training or inference [to] have an auditable chain of custody — from source to preprocessing to model input"* (solutionsreview.com). Tools like data catalogs or blockchain-based logs may be used. Similarly, models themselves must be versioned: if a model is retrained or updated, that event should trigger a re-validation and archival of the prior model (the regulatory goal is reproducibility (solutionsreview.com)).
- **Bias and Fairness Audits:** Pharmaceutical data often underrepresents certain groups (elderly, minorities, etc.). If unaddressed, this imbalance can cause algorithms to perform poorly or unfairly (e.g. toxicity predictions may be less accurate for under-sampled patients). Readiness protocols should include bias detection: carry out demographic analysis on training sets (e.g. check for missing portrait of non-European populations in a genomic dataset) and conduct "stress tests" on model outputs to detect skew (solutionsreview.com). Automated tools now exist for fairness audits that we recommend incorporating into a 90-day plan: for each AI use case, run a bias assessment at the outset.
- **Technology Stack & Compute Resources:** Does the organization have adequate computing infrastructure? As Lilly's example shows, modern drug design may require massive GPUs or cloud platforms (www.genengnews.com). Readiness should catalog existing hardware (on-premise servers, cloud accounts, third-party services) and compare to projected AI projects. Some organizations create "AI Hubs" or partnerships with hyperscalers. We may include in our diagnostic: an inventory of AI tools, vendors, and internal platforms, and identify gaps (e.g. no standardized ML Ops environment, no GPU clusters). Adequate security controls for these systems (TB-scale data encryption, VPN access, etc.) are also a concern. The Intellishore guidance notes that migrating legacy systems to the cloud can enhance security and scale (www.intellishore.dk), so a readiness step might be to evaluate cloud transition plans.
- **Privacy and Cybersecurity:** Healthcare data is highly sensitive. Readiness must consider whether data is secured in compliance with regulations (HIPAA, GDPR) and if de-identification/pseudonymization techniques are robust. For example, many AI initiatives need patient-level data (EHRs, genomics). A maturity assessment should check if PHI is protected end-to-end (storage, transmission, model training). Employee training on data handling and penetration testing of systems may be part of this domain. Solutionsreview specifically mentions *"end-to-end encryption and privacy-by-design"* measures (like federated learning or differential privacy) for models dealing with patient data (solutionsreview.com). A readiness check includes confirming such methods for any tool intended to use live patient data.

- **Data Governance:** Overarching the above is the practice of data governance. Does the company have clear data ownership, stewardship roles, and policies for AI datasets? Many enterprises find they must create a **Data Governance Board** or include data governance in the AI governance forum. Key tasks include defining what data can be used where, documented data quality rules, and a change-control process for data. In a 90-day diagnostic, one should verify that these structures exist, and if not, plan their creation.

In sum, technical readiness is scored on how well data and compute are organized for AI. A company may find that, for instance, most data relevant to a given use case is locked in siloed databases or written in incompatible formats. The diagnostic would then recommend steps like creating a unified data lake or adopting an interoperability standard (FHIR for health records, etc.). Quantifiable indicators of readiness in this domain include the percentage of critical data sources deemed "AI-ready" (cleaned, labeled) and the presence of monitored production pipelines for feeding models.

Organizational Capability, Culture, and Strategy

AI is as much a people question as a technology one. Readiness here examines **strategy alignment, talent, and culture**:

- **Executive Vision and Alignment:** Is there a clear strategic imperative for AI at the executive level? Readiness demands that C-suite and board buy-in is established. We check for an AI strategy document or roadmap endorsed by leadership. The ODAIA readiness pillars (for commercial functions) explicitly include *"Strategic Foundation & Alignment"*: having defined business objectives for AI and cross-team sponsorship (www.odaia.ai). For example, a company might conduct initial leadership workshops to identify top business challenges (e.g. "reduce time-to-market by 20%", "improve adherence prediction in post-approval studies") and confirm how AI could help. The 90-day plan should aim to validate or revise the AI vision through stakeholder interviews. If leaders see AI only as a buzzword, readiness is low. Indicators to gather: number of business units with documented AI initiatives, or existence of a central AI portfolio prioritization process.
- **Organizational Structure:** Are there enterprise-wide teams or centers of excellence for AI, or is work done in isolated pockets? Readiness evaluation should map roles: data science teams, clinical informatics, regulatory specialists, IT, and business owners must coordinate. Mature organizations often appoint a Chief AI Officer or create cross-functional squads. The Strategy& report noted that hybrid delivery models (using external AI partners with internal oversight) succeeded in some cases (www.strategyand.pwc.com). In readiness terms, one should document whether such hybrid squads exist, and whether internal and external players have well-defined collaboration processes. A scoring might be "AI initiatives are enterprise prioritized vs. ad-hoc initiated" (high vs low maturity).
- **Skills and Personnel:** We assess whether the company has or can recruit the necessary talent: Machine Learning engineers, data scientists, bioinformaticians, and AI-savvy project managers. In many pharma companies, these roles are still scarce. A readiness check would involve an inventory of skill gaps. For instance, are R&D scientists being upskilled on ML basics? Are statisticians and biostats

teams prepared to validate AI workflows? Past surveys (e.g. by Deloitte) have flagged lack of AI expertise as a key barrier in life sciences. The diagnostics should recommend training plans or partnerships with academic labs if gaps are identified.

- **Culture and Change Management:** A culturally ready organization encourages experimentation but also critical evaluation. Metrics here could include the presence of training programs on AI literacy, internal forums to discuss AI ethics, and change champions. The PDA article warns that unchecked excitement about GenAI can lead to pursuing "overly complex" problems; it advises starting small on concrete bottlenecks (www.pda.org). Our readiness framework therefore looks for processes that enforce gradual adoption and learning: e.g. having pilot projects with clear success criteria and requiring human approval of AI outputs (human-in-loop policy (www.pda.org)). Qualitative interviews may reveal resistance: do older scientists distrust AI, is there fear of job loss, or confusion about new roles? Addressing such morale issues is part of readiness.
- **Governance and Accountability:** We earlier discussed formal governance; here we focus on accountability lines: when an AI-affecting decision is made, who is responsible? Good readiness ensures that each AI system has a defined sponsor and reviewer, so that if an AI recommendation leads to an adverse outcome, investigation and remediation roles are clear. For example, if an AI model mis-classifies a batch as uncontaminated, is there clarity on who reviews that error? The SolutionsReview admonition *"Investigators must retain ultimate decision-making authority"* (solutionsreview.com) underscores this need.
- **Use Case Prioritization:** Strategy alignment extends to selecting the right problems for AI. Readiness assessments often advise building a use-case portfolio ranked by business value and feasibility. Frameworks suggest identifying a mix of short-term ROI pilots (often in commercial or manufacturing) and longer-term R&D bets. For example, the Intellishore article counsels prioritizing "targeted initiatives to increase digital maturity" rather than chasing every AI hype (www.intellishore.dk). The PDA roadmap (which we cite) also starts with "Define scope and success metrics" (www.pda.org), emphasizing measurable pain points. A readiness questionnaire might catalog candidate use cases for AI and check if they have clear leads and data readiness.
- **Metrics and KPIs:** Finally, organizational readiness includes having performance metrics for AI adoption. These go beyond technical metrics (like model accuracy) to business outcomes: e.g. reduction in trial timeline, cost savings in production, or increase in patient enrollment rate. The PDA article proposes tracking metrics such as CAPA closure times or audit pass rates (www.pda.org). In practice, readiness is higher when initial AI projects define and track such KPIs.

In essence, this domain ensures that AI is embedded into the company's strategy and workflows, rather than being a toy project. By Day 90, findings may include an updated org chart showing AI-related roles, a skills gap analysis, and a prioritized roadmap of AI initiatives. Board-level oversight of AI (via a charter or steering committee) is a strong signal of maturity.

Clinical Trials and Patient-centric Considerations

This sub-section intersects the above domains but focuses on the patient-facing side of pharma – the testing and post-market phases – which have their own readiness facets.

- **Clinical Trial Design & Optimization:** AI's promise to speed up trials (through better protocol design, patient matching, and monitoring) also carries ethical responsibilities. Readiness here means having safeguards to prevent algorithmic bias or consent violations in trials. For example, if AI is used to select trial participants from EHR data, we ask: *"Are underrepresented groups being excluded inadvertently?"* (solutionsreview.com). An assessment should review how AI models for recruitment are validated: do they use diverse training data? Are outputs reviewed by clinicians? The SolutionsReview checklist specifically highlights checking models for fairness in recruitment and ensuring investigators understand AI criteria (solutionsreview.com).
- **Informed Consent and Transparency:** If AI is used to explain trial protocols to patients (for example, using AI chatbots to answer questions), organizations must validate that the information is accurate and understandable (solutionsreview.com). Assess study consent, privacy authorization, transparency and any other lawful processing basis separately, in light of the jurisdiction, protocol, ethics review and use case. HHS explains that a covered entity may use or disclose protected health information for research under a documented IRB or Privacy Board waiver of authorization when the required conditions are met (HHS). Determine any AI-specific disclosures or additional permissions through that review. The PDA author Preeya Beczek comments on missed AI use cases: automating regulatory document writing or answering authority queries – implicitly warning that such automation must keep humans "focused on value-added activities" (www.pharmtech.com); analogously, patients should too remain active partners, not passive data miners.
- **Post-Market Monitoring (Pharmacovigilance):** After drugs are approved, AI can monitor real-world data (e.g. EHR, social media) to detect adverse effects more rapidly than traditional reporting systems. But misuse can lead to privacy violations. Readiness should assess lawful, purpose-specific data access, data minimization and access controls, with pharmacovigilance experts reviewing AI-generated alerts. Distinguish de-identified analytics datasets from regulated safety-case processing. For reports submitted to EudraVigilance, follow the EMA masking instructions, preserving the specified identifiers or quasi-identifiers needed for signal management, duplicate detection and case processing. Like pre-market trials, these systems should have audit trails linking AI predictions with source data (to allow regulators to investigate if needed).
- **Patient Privacy and Safety (General):** A major theme in the SolutionsReview content is that *"pharmaceutical companies bear an extraordinary ethical burden"* given they use sensitive health data (solutionsreview.com). AI readiness must narrowly enforce privacy. For instance, feasible steps include: implementing state-of-the-art de-identification, conducting Privacy Impact Assessments (PIAs) on AI projects, and using privacy-enhancing technologies. The framework's guidance goes further: dynamic consent models (where patients can change their data-sharing preferences for AI use over time) (solutionsreview.com), privacy-by-design (federated learning so raw patient data never leaves hospital networks) (solutionsreview.com), and explicit patient disclosures whenever AI is involved in a medical

decision (solutionsreview.com). An assessment should note whether the pharma's clinical trial system or post-market surveillance has such controls. If AI chatbots deliver patient education or dosing advice, they must pass risk assessments akin to medical devices, with override options for physicians.

- **Equity and Accessibility:** We must also consider whether AI is perpetuating or reducing health inequities. AI readiness might include analysis of model performance across demographic segments and making plans to remediate disparities. Though not often explicitly stated in corporate reports, this is an ethical expectation (and will likely be regulatory soon). Checklists may not yet exist, but readiness calls for at least documenting demographic coverage of data and any fairness evaluations done.

Overall, **patient-centric readiness** in pharma revolves around guaranteeing that AI-driven interactions (whether trial enrollment or clinical decision support) preserve informed consent, privacy, and safety. The organization should map all AI touchpoints that involve patient data or therapy and treat them as potential high-risk systems in the AI Act sense. By the end of assessment, there should be a checklist of each patient-affecting AI application and the ethical controls placed around it.

Manufacturing and Supply Chain

Pharmaceutical manufacturing is strictly controlled (cGMP), and there are emerging regulatory expectations for "AI in manufacturing." A readiness review in this area touches on:

- **Audit Readiness:** The PDA article argues that rather than "scramble" for quality audits, manufacturers can deploy AI to maintain continuous compliance (www.pda.org). Practical examples include using Natural Language Processing (NLP) to scan change controls or audit logs for compliance breaches. Table 1 in that article (reproduced below) illustrates how AI tools can augment the "People, Processes, Assets" pillars of quality systems (www.pda.org). For readiness, companies should audit which quality processes have (or could have) AI support. Do manufacturing QA teams have active AI-driven dashboards for CAPA tracking or document consistency? If not, this might be a quick improvement area.

Pillar	AI Application Examples	Benefit / Impact
People	Audit-simulating chatbots; AI-driven training and competency tracking; automated regulatory update alerts (www.pda.org)	Staff remain current on SOPs and audit-ready.
Processes	Automated CAPA storyboards; risk-prioritized backlog reviews; gap assessment via AI (www.pda.org)	Transparent oversight and proactive remediation.
Assets	Predictive equipment maintenance (sensor data on line performance) (www.pda.org)	Equipment stays compliant with maintenance evidence.

This table (adapted from PDA (www.pda.org)) exemplifies how AI can be woven into quality and operations. A 90-day roadmap might include quick pilots of such tools, as has happened in some "Industry 4.0" initiatives.

- **Product Quality Monitoring:** AI is increasingly used in process analytical technology (PAT) and visual inspection. For example, computer-vision models now inspect vials for particulates in real time. Readiness involves validating these tools: ensuring their detection thresholds are calibrated and

automating alerts to operators. It also means integrating any AI-driven QC systems into the GMP environment: if an AI camera system fails, is there a fail-safe or fallback?

- **Supply Chain Resilience:** COVID highlighted supply chain fragility. AI is applied to forecasting demand, optimizing shipments, and detecting anomalies (e.g. predicting shortages). Readiness in supply chain AI is about data integration across suppliers and distributors, plus scenario planning. At a minimum, the organization should have mapped critical nodes and the data needed (inventory levels, supplier performance metrics) and plan how AI could enhance visibility.
- **Cyber-physical Security:** As factories become "smarter" with connected sensors and AI controls, cybersecurity becomes a manufacturing issue. Readiness includes evaluating the security of connected equipment and network segmentation. The FDA cybersecurity guidance addresses medical-device design, labeling and premarket submission documentation. Any use of those practices as a reference for pharmaceutical factory security should be identified as an analogy and assessed for relevance.

Manufacturing readiness is partly covered by broader governance and data readiness, but specifically it requires alignment with existing quality systems. For example, in a 90-day diagnostic, one would ask: are there specific quality metrics that AI can improve (e.g. first-pass yield, cycle time), and have engineers validated the AI models on those metrics? In audit scenarios, an inspection readiness AI system might ensure that by Day 90, document retrieval for auditors is faster and reports errors automatically – concrete KPIs to track.

Commercial and Business Operations

While less regulated, commercial operations face their own readiness factors for AI:

- **Go-to-Market Readiness:** AI can optimize marketing and sales, but only if integrated into commercial strategy. Readiness in this area means aligning AI use cases (like HCP predictive targeting, content personalization, call planning) with commercial goals. For example, if a sales force plans to use an AI-driven tool for recommending offices to visit, the readiness check is: *Is the CRM data consistent? Is the field team trained on the model's suggestions?* The ODAIA pillars include "commercial AI capabilities" (though our focus is broad).
- **Data Privacy and Compliance:** Commercial AI often uses sales and prescribing data (e.g. claims or partner data). Readiness includes compliance with patient data laws in marketing contexts (e.g. prescription data privacy). Unauthorised use of patient data for marketing can violate laws (like HIPAA or PDPA), so firms must ensure marketing AI uses aggregated or anonymized data.
- **Vendor and Partner Readiness:** Many commercial functions outsource analytics to agencies. The readiness question: *Are our partners also compliant and aligned?* Pharma companies should audit vendors' data practices and AI capabilities. For instance, if an agency proposes using generative AI to craft marketing emails, the pharma legal team must review for accuracy and regulatory language compliance.
- **Performance Measurement:** Finally, readiness here means having metrics for commercial AI success: e.g. sales uplift from AI-driven segmentation, or ROI on an AI-powered content management system. Establishing these KPIs upfront keeps AI pilots accountable.

Summarily, commercial readiness is about ensuring that AI enhances marketing precision without breaching codes (e.g. FDA advertising regulations, Good Promotion Practice guidelines). Many companies are still exploring what “AI Ready” means in sales – our assessment might find that preparatory steps include cleaning marketing databases and defining “digital skill frameworks” for sales reps.

Framework and Tools for the AI Readiness Assessment

To operationalize this analysis, we propose a **diagnostic framework** subdivided into phases on a 90-day timeline. The goal is to provide both a structure for analysis and concrete deliverables by the end of each phase. A notional breakdown is:

Days 1–30: Discovery and Assessment

- **Kickoff & Stakeholder Interviews:** Identify executive sponsors and assemble a cross-functional diagnosis team (R&D, IT, Quality, Commercial, etc.). Conduct interviews to gather existing perceptions of AI readiness and identify key business objectives.
- **Data & Asset Inventory:** Audit major data sources (clinical, preclinical, operational, etc.), computing resources, and current AI/analytics projects. Use the data maturity questions (e.g. existence of data lakes, use of common identifiers) to assess baseline data governance (solutionsreview.com).
- **Regulatory/Risk Mapping:** Quickly classify any ongoing or planned AI projects by risk level. Review compliance documentation (e.g., if any ML validation has been done).
- **Rapid Use-Case Evaluation:** Identify a shortlist of AI initiatives (current or planned). For each, evaluate basic feasibility (data ready? aligned with goals?).
- **Governance Review:** Check existing governance structures (committees, policies). If absent, assemble a preliminary “AI Oversight” group.

Deliverables by Day 30 might include an **AI Readiness Scorecard** across key dimensions, a prioritized list of data issues, and a first-cut roadmap outline.

Proposed scorecard method: Apply the following editorial rubric to each candidate use case and its intended use. This is a proposed internal decision aid, not a validated maturity benchmark or a regulatory classification. Record the scope, assessment date, accountable owner, evidence location, score, unresolved gaps and next review date for every domain.

Use a 0–3 scale: **0 — unsubstantiated:** no reviewable evidence; **1 — documented:** an owner, baseline and gap list exist, but controls are incomplete or untested; **2 — pilot-ready:** the domain’s agreed controls have been tested on representative samples or in the scoped test environment, results meet pre-agreed acceptance criteria, and a reviewer has signed the evidence; **3 — demonstrated in the intended workflow:** validation records, monitoring results, change controls and incident/fallback exercises demonstrate that the controls operate as intended. Assign the highest level whose evidence requirements are fully met; interviews alone cannot establish a score of 2 or 3.

Domain	Accountable owner	Minimum evidence to review
Regulatory and governance	Quality/regulatory lead, with legal and privacy support	Intended-use statement; jurisdiction-specific obligation and risk assessment; control map; approval and escalation records.
Data and technical infrastructure	Data owner and IT/security lead	Data provenance and permitted-access records; measured completeness/error rates against predefined thresholds; access-control and environment tests for the scoped workload.
Organizational capability and talent	Business sponsor	Named delivery and review roles; training records; user workflow, human-review and fallback responsibilities.
Scientific and clinical integrity	Scientific/clinical lead	Evaluation protocol; relevant baseline/comparator; held-out or otherwise independent evaluation evidence appropriate to the intended use; documented safety, bias and uncertainty review.
Commercial and operations alignment	Operational process owner	Baseline workflow and business metric; agreed pilot success and stop criteria; resource estimate; integration and fallback plan.

Pilot go/no-go: As a proposed internal gate, require every applicable domain to score at least 2, with written approval from the business sponsor, data owner and Quality lead. Document and approve any domain deemed inapplicable. Do not average away a low score or an unresolved critical safety, privacy, security or data-access issue. A no-go decision must identify the missing evidence, remediation owner and reassessment date. Pilot approval authorizes only the agreed test scope; production deployment requires a separate review of validation, applicable obligations, monitoring and change controls. Assess the starting environment before committing to infrastructure delivery dates; where a prerequisite cannot be completed in 90 days, deliver a costed remediation plan instead.

Days 31–60: Pilot/Gap Remediation

- **Pilot Projects:** Launch small-scale pilots only after the scorecard go/no-go gate is approved; otherwise use this phase for remediation and reassessment. For example, run a data lineage/trust experiment on a sample dataset, or pilot an AI-enabled QMS dashboard (akin to the PDA AI use in Table 1 (www.pda.org)). Small successes (or problems) reveal readiness gaps.
- **Governance & Policy Development:** Based on compliance findings, draft needed policies (e.g. AI Model Change Control procedure, Ethical AI guidelines). Formalize data governance roles.
- **Talent & Training Initiatives:** Begin any immediate training or hiring (e.g. ML workshop for biostatisticians, GDPR refresher for IT staff). Establish an AI Center of Excellence or working group if not already present.
- **Technical Upgrades:** Scope and, where feasible, address high-priority infrastructure gaps (e.g. secure cloud provisioning, GPU cluster provisioning, data cleaning pipelines) according to the assessed starting environment and approved pilot scope. Document any legacy systems needing integration.
- **Stakeholder Buy-In:** Communicate early pilot outcomes and draft plans with broader teams to build momentum.

By Day 60, record either approved pilot progress or unresolved gate criteria, with named remediation owners and dates; update interim policies and the roadmap.

Days 61–90: Integration and Roadmap Finalization

- **Evaluation & Metrics:** Define KPIs for longer-term projects (e.g. % trial recruitment improvement, model uptime, compliance metrics). For pilots, measure initial results against expectations.
- **Detailed Roadmap:** Finalize a phased AI adoption plan (6-24 months), including projects, budgets, resourcing, and governance checkpoints. Incorporate regulatory change timelines (e.g. EU AI Act implementation).
- **Change Management Plan:** Develop communication and change strategies (how to roll out new AI tools to users, how to maintain data pipelines). Identify internal champions in each business line.
- **Documentation:** Compile an "AI Readiness Report" summarizing findings, risks, and recommended actions in each domain (to present to leadership).

At Day 90's end, leadership receives a comprehensive assessment: a gap analysis plus a 1-year AI launch plan tuned to pharma's risk profile (along with longer-range vision).

Below is one example of how a 90-day governance timeline could be structured (derived from Diligize's supply chain playbook (diligize.pe) and the PDA roadmap (www.pda.org)):

<table> <caption>**Table 2: Sample 90-Day AI Readiness Diagnostic Timeline (Pharma)**</caption> <tr> <th>Day Range</th><th>Main Activities</th><th>Key Deliverables</th></tr> <tr> <td>Days 1–15</td> <td> Assemble cross-functional team; align on objectives. Conduct interviews with R&D, Clinical, IT, Quality, Commercial leads. Inventory AI-related assets (data, tools, budgets). Perform quick data health checks and risk scan. </td> <td> AI Readiness Scorecard (strengths, gaps). List of existing/pipeline AI projects with risk classification. Data map & priority issues (e.g. critical datasets incomplete). Preliminary governance committee formed. </td> </tr> <tr> <td>Days 16–45</td> <td> If the scorecard go/no-go gate is approved, launch 1–2 pilot projects to test capabilities (e.g. ML on lab data, NLP for document review); otherwise prioritize remediation. Define initial AI policies (change control, validation protocols). Start data remediation (clean/merge key data sources). Train identified staff in AI basics and ethics. </td> <td> Pilot results summary (lessons & shortfalls). Draft AI governance framework (roles, processes). Updated roadmap with quick wins (e.g. automate routine tasks). Data capability improvements (some cleaned datasets). </td> </tr> <tr> <td>Days 46–75</td> <td> Implement only the infrastructure changes approved for the scoped pilot, based on the assessed starting environment. Where access, security and validation gates permit, integrate pilot tools into the agreed test workflow. Validate pilot outputs with SMEs and regulators (if applicable). Refine strategy/phasing: prioritize next wave of use cases. </td> <td> Evidence of the agreed pilot environment and scoped data pipelines where feasible; otherwise a costed remediation plan with owners, dependencies and dates. Interim validation report (performance metrics for models). Revised use-case portfolio aligned with business KPIs. Stakeholder adoption plan (communication materials). </td> </tr> <tr> <td>Days 76–90</td> <td> Finalize AI adoption roadmap for 12+ months. Establish monitoring regime (audit trails, metrics tracking). Secure resources (budget, partnerships) for approved projects. Hold executive review and training wrap-up. </td> <td> Final AI Readiness Report with

recommendations. Governance & compliance checklists (regulatory alignment). Operational metrics dashboard prototype. Executive briefing summarizing findings and ROI projections. </td> </tr> </table>

(Sources: Adapted from industry playbooks (diligize.pe) (www.pda.org).)*

The table above is illustrative; actual timelines may vary. The key is that each phase yields tangible artifacts (scorecards, pilot results, policies, roadmaps) and involves iterative feedback with stakeholders.

Readiness Case Studies and Examples

To ground our discussion, we present selected case examples of AI initiatives in pharma. These illustrate both the potential and pitfalls, and highlight readiness factors.

Pfizer and IBM Watson for Drug Discovery (2016 announcement)

In December 2016 Pfizer announced a multi-year collaboration using IBM's Watson for Drug Discovery platform in oncology research (www.pfizer.com). Watson, a cognitive AI system, was tasked to ingest Pfizer's internal data and public literature to surface new immuno-oncology targets and therapy combinations. This case exemplifies early large-scale R&D AI adoption.

Evidence boundary: This case refers to Pfizer's December 1, 2016 announcement (Pfizer).

Diagnostic questions: For a comparable project, ask how scientists will evaluate AI-generated hypotheses and what evidence they will need before advancing them. These are proposed diagnostic steps, rather than verified Pfizer workflows or achieved outcomes.

Eli Lilly and Insilico Medicine AI Partnership (2023–2025)

Eli Lilly has aggressively pursued AI in discovery. In 2023 they first licensed Insilico's generative chemistry platform, and by November 2025 they expanded this into a ~$100M collaboration, committing to co-develop drugs using Insilico's Pharma.AI suite (www.genengnews.com). Insilico identifies Chemistry42 as its small-molecule drug-discovery platform.

Relevance: Lilly's case demonstrates readiness built through partnership. Lilly not only provided data (their target pipelines, research expertise) but also invested in compute infrastructure: notably, LillyPod uses 1,016 NVIDIA Blackwell Ultra GPUs (NVIDIA). This shows preparation of "technology stack" at scale.

Outcomes: Insilico reports that between 2021-2024 it nominated 20 preclinical candidates using AI, with an average 12–18 month cycle rather than the typical 3–6 years (www.genengnews.com). Two of Insilico's candidates even reached Phase II clinical trials. Lilly's involvement gave credibility and resources: Lilly's venture arm and senior scientists engaged, indicating organizational commitment. Inferring from public info, Lilly likely had to address (and enable) readiness aspects: data sharing agreements, joint project teams, and regulatory planning (since co-developed molecules will enter clinical trials).

Lessons: The Lilly-Insilico story underscores that a well-prepared pharma company can form deep AI partnerships. Lilly's multi-year planning (first licensing AI tools in 2023, then collaborating on discovery) shows a staged approach. They invested in both technology (supercomputing) and culture (internal platform "TuneLab" for AI access) (www.genengnews.com). Importantly, they reported outcomes like accelerated discovery timelines, which can feed back into organizational belief in AI's ROI.

Novartis and Clinical Operations

In its collaboration announcement, Novartis said the initiative would primarily use real-world patient data (Novartis).

Readiness Aspects: For a comparable project, assess data-access permissions, data quality, scientific review and the evidence needed to evaluate the proposed use. These are diagnostic recommendations, rather than documented Novartis implementation steps.

Roche and Early Cancer Detection

Flatiron Health became an independent affiliate of the Roche Group following Roche's acquisition in 2018 (Roche).

Readiness: A diagnostic of a comparable oncology-data project should examine data provenance, permissions, curation, method validation and integration with source systems. Assess those capabilities from project evidence before assigning a readiness score.

Implementation Pitfalls to Avoid

Other failures include in-house pilots that relied on single data sources without metadata control. (E.g. a Google Flu Trends analog in health failed because of shifting web search behavior; for pharma an analogy is a model that only learned a single trial's noisy data and broke when generalized.)

These examples reinforce that readiness must address technical, regulatory, and organizational gaps before or alongside technology roll-out.

Metrics and KPIs for Readiness

How does one *measure* AI readiness? Unlike simple IT metrics, AI readiness is multi-dimensional. Nonetheless, at the end of a diagnostic, organizations can track indicators such as:

- **Governance Maturity Level:** Exists on a spectrum from "none" to "enterprise-wide AI governance with auditing." A mid-level readiness might see an AI oversight committee reviewing all projects.
- **Data Quality Scores:** Proportion of relevant data fields populated and validated. For instance, if recruiting for oncology trials, what percentage of patient records has complete biomarker info?
- **Model Validation Benchmarks:** Fraction of AI use cases that have been validated on hold-out test sets or by medical experts.

- **Adoption Metrics:** Percentage of targeted business units with active AI pilots (vs planning stages). For example, if the goal was to cover 4 functions (R&D, manufacturing, marketing, support), readiness might track how many have at least one defined AI pilot.
- **Budget/Resource Allocation:** AI's share of R&D/IT budgets as a proxy for commitment (e.g. 5% this year, 10% next year), and number of FTEs dedicated to AI initiatives.
- **Regulatory Compliance KPIs:** Number of AI applications formally classified under SaMD or AI-act, and number passing internal audits. By Day 90, perhaps an initial audit checklist is completed.

Collecting baseline values for these KPIs can show progress post-diagnosis.

Future Directions and Implications

Looking ahead, the AI landscape in pharma will continue to evolve rapidly. The following trends are pertinent:

- **Regulatory Evolution:** Maintain an obligation-specific regulatory road map and monitor first-party regulator publications for updates. The Commission's AI Act schedule distinguishes provisions already applicable from high-risk rules beginning 2 December 2027 and product-related high-risk rules beginning 2 August 2028.
- **Advanced AI Technologies:** Generative AI (LLMs, diffusion models) is moving into drug-design (generating new molecules) and even patient support (AI personas for patient education). Incorporating these safely will be crucial. For example, some firms are developing "foundation models for biology" that require novel governance (since their outputs can invent unseen chemical structures). Readiness efforts will have to expand to cover these new paradigms (e.g. model cards, usage logs).
- **Cross-Industry Collaboration:** Pharma may increasingly partner with tech companies and consortia to share best practices (e.g. open challenges on AI in drug discovery, or data collaboratives for rare diseases). A readiness plan might allocate engagement time for such activities.
- **Cultural Shift:** Over time, "AI literacy" will need to be part of the company's DNA. We may anticipate formal programs like pharma AI fellowships, and job postings that blend life-science and ML skills. Metrics like the fraction of clinical or manufacturing hires with ML backgrounds could track success.
- **Ethical AI Leadership:** Patient advocacy groups are becoming stakeholders in AI dialogue. Future implications of readiness include building transparent communication (e.g., patient advisory panels on AI in trials). Companies at the forefront may set industry standards that others follow.

Crucially, the shift is not one-time: as AI tech and regulations advance, readiness is a moving target. Thus, the diagnostic should be repeated periodically, and its outputs monitored as part of continuous improvement.

Conclusion

Pharmaceutical companies stand at a pivotal moment: the convergence of biology and machine intelligence offers unprecedented opportunities to develop better medicines faster, but only if deployments are done right. This report has laid out the foundations for a **90-day AI readiness assessment** specifically tailored to the

unique challenges of Pharma.

By methodically evaluating regulatory compliance, data integrity, technological infrastructure, organizational capability, and ethical considerations, pharma leaders can transform AI from a gambit into a core competency. We have shown that while nearly all major pharma players are eager to embrace AI (www.fiercepharma.com) (www.axios.com), many must still build up their internal discipline around it. Cases like Pfizer and Lilly illustrate both the promise and the path: leveraging partnerships, building platforms, and rigorously validating results.

In practice, we encourage organizations to treat the 90-day diagnostic not as a tick-box audit but as the launch of a transformation journey. It should yield a clear roadmap – with concrete action items for governance, training, data upgrades, pilot scaling, and so on. Progress on the metrics identified (adoption rates, compliance adherence, project ROI) will then indicate how readiness is improving. Our expectation is that firms who invest wisely here will gain not just incremental efficiency, but a sustainable competitive advantage grounded in trust and innovation (solutionsreview.com) (www.intellishore.dk).

Finally, all claims in this report are supported by extensive literature and industry references. We have drawn on expert analyses (www.strategyand.pwc.com) (www.pharmtech.com), surveys (www.fiercepharma.com) (www.axios.com), regulatory guidelines (www.fda.gov) (www.iliomadhealthdata.com), and case studies (iiaai.org) (www.genengnews.com). Our aim is to present a **comprehensive evidence-based** framework. Pharma executives and AI teams should use this report as a guidepost: validate its insights against their own context, gather further data where needed, and proceed with confidence that their strategies rest on best-available knowledge. If done diligently, embedding AI into pharma processes will lead not to broken systems, but to smarter science and safer, more effective medicines for patients worldwide.

Source links

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

1. https://www.strategyand.pwc.com/de/en/industries/pharma-life-sciences/re-inventing-pharma-with-artificial-intelligence.html
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IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore AI enablement, pharma and biotech software development, data engineering and BI, and Veeva services. Contact IntuitionLabs to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

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