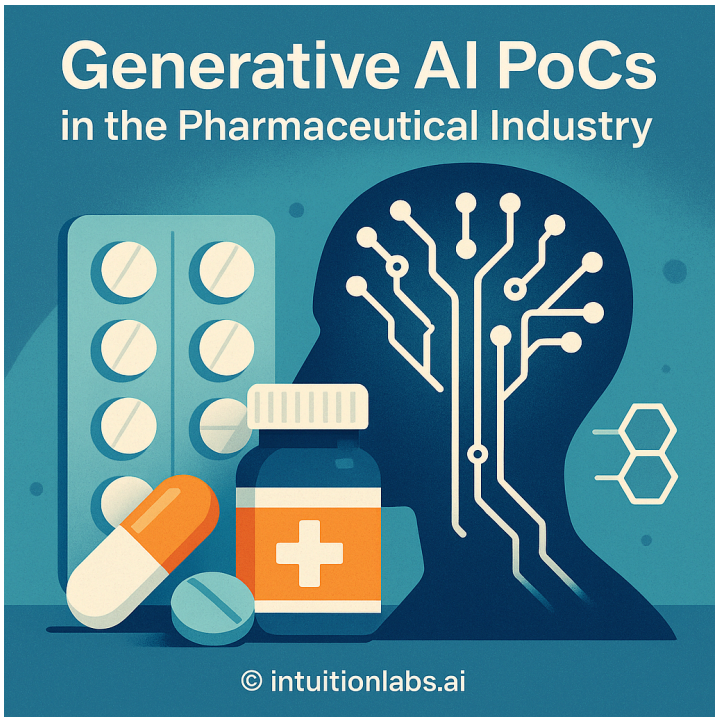
GenAI Proof of Concept in Pharma: Accelerating Drug Discovery and Development

By IntuitionLabs • 4/18/2025 • 25 min read

generative-ai pharmaceutical drug-discovery clinical-trials proof-of-concept machine-learning artificial-intelligence research-and-development data-analytics molecular-modeling protein-folding clinical-data-analysis



Generative AI PoCs in the Pharmaceutical Industry (Comprehensive Overview)

Generative AI (GenAI) is making inroads across the pharma value chain. Below is an exhaustive list of **publicly disclosed** proof-of-concept (PoC) projects and prototypes involving GenAI in the pharmaceutical sector, organized by domain. Each entry details the project, the organizations involved, its purpose, the GenAI technology used, and current status or outcomes. We focus on U.S.-based initiatives or those highly relevant to the U.S. market, spanning drug discovery, clinical development, regulatory operations, medical affairs, pharmacovigilance, and commercial applications.

Drug Discovery and Preclinical Research

GenAI is accelerating early R&D by designing novel molecules (small and large) and identifying new drug candidates faster than traditional methods. Pharmaceutical companies and biotech startups have launched numerous PoCs using generative models (e.g. deep generative chemistry models, protein generators, large language models for biomedical data) to create drug candidates in silico. Notable initiatives include:

- **Insilico Medicine – AI-Designed IPF Drug (ISM001-055):** Insilico's AI-driven platform ("Pharma.AI") **generated a novel small-molecule** for idiopathic pulmonary fibrosis (IPF) – ISM001-055 – which advanced to clinical trials (Insilico Plans Pivotal Trial for AI-Based IPF Candidate) (Insilico Plans Pivotal Trial for AI-Based IPF Candidate). This molecule was **designed entirely using generative AI** models (generative chemistry and deep learning) to target a novel pathway. *Status:* Successfully completed a Phase **IIa** trial in 2024 with positive results (improved lung function in IPF patients) (Insilico Plans Pivotal Trial for AI-Based IPF Candidate) (Insilico Plans Pivotal Trial for AI-Based IPF Candidate). Insilico is now planning a Phase IIb pivotal trial (Insilico Plans Pivotal Trial for AI-Based IPF Candidate) (Insilico Plans Pivotal Trial for AI-Based IPF Candidate), making ISM001-055 one of the first AI-discovered drugs to reach this stage.

- **Exscientia & Sumitomo – Generative AI Drug Pipeline:** UK-based Exscientia (Nasdaq: EXAI) has pioneered **AI-guided drug design** with multiple compounds created via its generative design platform. In partnership with Sumitomo Pharma, Exscientia produced **DSP-1181**, a long-acting 5-HT1A agonist for obsessive-compulsive disorder, which in 2020 became *the world's first AI-designed drug to enter Phase I trials* (DSP-1181: drug created using AI enters clinical trials). They followed with additional AI-designed candidates: e.g. **DSP-2033 and DSP-2342** (a dual 5-HT2A/5-HT7 antagonist for psychiatric disease) – the *third AI-generated molecule* from the Sumitomo collaboration now in **Phase I (U.S.)** (Exscientia - Exscientia Announces Sixth Molecule Created Through Generative AI Platform to Enter Clinical Stage). Beyond Sumitomo, Exscientia advanced **at least six AI-designed molecules into clinical stages** by 2023 (How Exscientia Reduces Drug Discovery Time With Gen AI - CIO.inc), including an A2A receptor antagonist and a CDK7 inhibitor with Bristol Myers Squibb (Exscientia - Exscientia Announces Sixth Molecule Created Through Generative AI Platform to Enter Clinical Stage). *Status:* Several compounds in Phase I; one oncology candidate is in Phase I/II. (Notably, in 2024 Exscientia agreed to **merge with U.S.-based Recursion Pharmaceuticals** to form a leading AI drug discovery firm (Exscientia Business Update for Second Quarter and First Half 2024) (Exscientia Business Update for Second Quarter and First Half 2024), reflecting consolidation in this space.)

- **Sanofi & Exscientia – 15-Drug AI Discovery Partnership:** In a major 2022 deal, **Sanofi** (with a large U.S. R&D presence) partnered with Exscientia to leverage generative AI for up to *15* novel small-molecule drug candidates in oncology and immunology (Sanofi partners with AI firm Exscientia to develop up to 15 new drugs - Reuters). Exscientia applies its AI platform to design molecules, which Sanofi will develop clinically. The deal is valued up to **$5.2 B** in milestones (Sanofi partners with AI firm Exscientia to develop up to 15 new drugs - Reuters), with $100 M upfront, underscoring Big Pharma's commitment to AI-driven discovery. *Status:* Ongoing – multiple AI-designed compounds are in discovery; if any reach the clinic, Exscientia earns milestones and royalties (Sanofi partners with AI firm Exscientia to develop up to 15 new drugs - Reuters).

- **Isomorphic Labs (DeepMind) with Lilly & Novartis – Generative AI for Drug Design:** Alphabet's **Isomorphic Labs** (an AI drug discovery spinout built around DeepMind's AlphaFold) inked landmark agreements in **Jan 2024** with **Eli Lilly** and **Novartis**, each worth up to ~$1+ B, to apply AI in discovering new therapies (DeepMind's Isomorphic Inks $3B Worth of Deals with Lilly and Novartis in One Day - Inside Precision Medicine) (DeepMind's Isomorphic Inks $3B Worth of Deals with Lilly and Novartis in One Day - Inside Precision Medicine). These collaborations use Isomorphic's next-gen AlphaFold-based models and generative approaches to design *small-molecule drugs* for undisclosed targets. For example, Lilly paid $45 M upfront (with up to $1.7 B in milestones) to have Isomorphic generate candidates for certain targets (DeepMind's Isomorphic Inks $3B Worth of Deals with Lilly and Novartis in One Day - Inside Precision Medicine). Novartis likewise paid $37.5 M upfront (up to $1.2 B in milestones) for AI-designed compounds against three targets (DeepMind's Isomorphic Inks $3B Worth of Deals with Lilly and Novartis in One Day - Inside Precision Medicine). *Status:* Early-stage – target selection and AI design in progress as of 2024; success would move candidates into preclinical testing.

- **Novartis & Generate:Biomedicines – Protein Therapeutics via Generative AI:** In Sept 2024, Novartis entered a multi-target collaboration with Boston-based startup **Generate:Biomedicines** to create *protein therapeutics de novo* using GenAI (Generate:Biomedicines Announces Multi-Target Collaboration with Novartis to Discover and Develop Protein Therapeutics with Generative AI). Generate's platform uses generative models to **"program" novel proteins** (e.g. enzymes, cytokines, antibodies) from scratch (Generate:Biomedicines Announces Multi-Target Collaboration with Novartis to Discover and Develop Protein Therapeutics with Generative AI). Novartis brings target biology and development expertise, while Generate produces optimized protein drug candidates with its AI-driven system (Generate:Biomedicines Announces Multi-Target Collaboration with Novartis to Discover and Develop Protein Therapeutics with Generative AI). The deal included **$65 M upfront** and up to **$1 B+** in milestone payments (Generate:Biomedicines Announces Multi-Target Collaboration with Novartis to Discover and Develop Protein Therapeutics with Generative AI) (Generate:Biomedicines Announces Multi-Target Collaboration with Novartis to Discover and Develop Protein Therapeutics with Generative AI). *Status:* Ongoing PoC – novel protein leads are being designed for multiple disease areas (specific targets undisclosed).

- **Merck & Co. & Absci – Generative Biologics Design (Enzymes & Antibodies):** U.S. pharma Merck (MSD) partnered with **Absci** (a Vancouver, WA-based AI biotech) to leverage Absci's *generative AI drug creation platform* for up to **3 targets**. The 2022 deal is worth up to **$610 M** (milestones) (MERCK DIVES DEEP INTO AI WITH $610 MILLION+ ABSCI PACT ...). Absci's technology includes **zero-shot generative models** that can design new biologic drugs (e.g. enzymes with non-standard amino acids, or antibodies) without massive training data (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace). Merck can nominate targets and use Absci's GenAI to create novel protein drug candidates. *Status:* Absci began work on the collaboration in 2023 ([PDF] CORPORATE PRESENTATION SEPTEMBER 2023); progress on designed candidates has not yet been publicly detailed.

- **AstraZeneca & Absci – AI-Generated Antibody for Oncology:** In Dec 2023, **AstraZeneca** (through its U.S. subsidiary and Alexion division) signed a partnership with Absci to **design an antibody** therapeutic for an unspecified oncology target (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace) (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace). Using Absci's generative AI platform, the goal is to create a *"de novo" antibody* that meets AZ's target profile. The deal provides Absci with R&D funding and milestones totaling **$247 M** (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace). AZ's SVP of biologics noted this will apply Absci's *"first-of-its-kind zero-shot generative AI model"* for antibody creation (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace). *Status:* PoC stage – AI models are generating antibody candidates; wet-lab validation will follow (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace).

- **BenevolentAI & AstraZeneca – AI-Generated Target Identification:** Since 2019, AZ has collaborated with **BenevolentAI** (an AI platform company) to find new drug targets using AI **knowledge graphs and generative models**. This effort (AZ's largest AI collaboration) has produced multiple novel targets that AZ added to its portfolio (BenevolentAI Achieves Further Milestones In AI-Enabled Target ...) (BenevolentAI and AstraZeneca collaboration finds novel heart ...). For example, in 2022 AZ selected AI-discovered targets for **systemic lupus erythematosus** and **heart failure**, triggering milestone payments to BenevolentAI (BenevolentAI and AstraZeneca collaboration yields continued ...). While this is target discovery (upstream of molecule design), it showcases GenAI in generating testable scientific hypotheses. *Status:* Several AI-proposed targets have been validated preclinically by AZ (BenevolentAI and AstraZeneca collaboration yields continued ...); the partnership was expanded in 2022 to cover more diseases ([PDF] BenevolentAI Preliminary results for year ended 31 December 2022).

- **Moderna & IBM – Generative AI for mRNA Design:** mRNA pioneer **Moderna** teamed up with IBM in 2023 to apply *genAI and even quantum computing* to **advance mRNA vaccine and therapy design** (Moderna and IBM to use AI, quantum computing on mRNA vaccines) (Moderna and IBM use generative AI to advance mRNA tech). Generative AI can help **optimize mRNA sequences** and lipid nanoparticles by analyzing vast datasets and proposing new designs. Moderna's CEO noted plans to integrate these AI capabilities to accelerate R&D. *Status:* PoC – ongoing exploration of AI for mRNA "design space" expansion. By 2024, Moderna also partnered with **OpenAI** to deploy GPT-4 internally, with *"mChat"* and **750+ AI assistants** aiding researchers across tasks like analyzing genetic data and designing experiments (Moderna banks on OpenAI to accelerate mRNA research - pharmaphorum) (Moderna banks on OpenAI to accelerate mRNA research - pharmaphorum). (This broad adoption reflects Moderna's "digital-first" approach.)

Summary – Drug Discovery: GenAI is **prototyped widely in drug discovery**, from **small molecule generation** (Insilico, Exscientia, Isomorphic Labs) to **biologic drug design** (Absci, Generate:Biomedicines). Many top pharma companies (e.g. Sanofi, Lilly, Novartis, Merck, AZ) have **active PoCs or partnerships** to incorporate generative models into their discovery pipelines. Several AI-designed molecules have already reached **clinical trials (Phase I/II)** (DSP-1181: drug created using AI enters clinical trials) (Exscientia - Exscientia Announces Sixth Molecule Created Through Generative AI Platform to Enter Clinical Stage), and one (Insilico's) has demonstrated Phase II efficacy (Insilico Plans Pivotal Trial for AI-Based IPF Candidate). The table below summarizes key GenAI projects in discovery:

Project / Compound	Organizations Involved	GenAI Focus	Status (as of 2024-25)
ISM001-055 (IPF drug) – Insilico Medicine (Insilico Plans Pivotal Trial for AI-Based IPF Candidate)	Insilico Medicine (AI biotech)	Generative design of novel small molecule for fibrosis (IPF)	Phase IIa **completed** – positive efficacy (Insilico Plans Pivotal Trial for AI-Based IPF Candidate) (Insilico Plans Pivotal Trial for

Project / Compound	Organizations Involved	GenAI Focus	Status (as of 2024-25)
			AI-Based IPF Candidate); Phase IIb planned
DSP-1181 & pipeline molecules – Exscientia (DSP-1181: drug created using AI enters clinical trials) (Exscientia - Exscientia Announces Sixth Molecule Created Through Generative AI Platform to Enter Clinical Stage)	Exscientia + Sumitomo Pharma (OCD, psych, etc.)	AI-generated **small molecules** (multiple targets)	**Multiple Phase I trials** (OCD drug in 2020 (DSP-1181: drug created using AI enters clinical trials); 6 AI-designed molecules in clinic by 2023)
Multi-target AI deal – Sanofi & Exscientia (Sanofi partners with AI firm Exscientia to develop up to 15 new drugs - Reuters)	Sanofi + Exscientia (strategic collab)	Generative design for up to **15** small-molecule drugs	Ongoing discovery; up to $5.2B in milestones (Sanofi partners with AI firm Exscientia to develop up to 15 new drugs - Reuters) (preclinical stage)
Lilly & Isomorphic Labs (AlphaFold AI) (DeepMind's Isomorphic Inks $3B Worth of Deals with Lilly and Novartis in One Day - Inside Precision Medicine)	Eli Lilly + Isomorphic (DeepMind)	Generative AI for **small-molecule** drug design (multi-target)	PoC stage – AI designing candidates; $45M upfront, up to $1.7B milestones (DeepMind's Isomorphic Inks $3B Worth of Deals with Lilly and Novartis in One Day - Inside Precision Medicine)
Novartis & Isomorphic Labs (DeepMind's Isomorphic Inks $3B Worth of Deals with Lilly and Novartis in	Novartis + Isomorphic Labs	Generative AI for **small-molecule** drug design (3 targets)	PoC stage – $37.5M upfront; up to $1.2B milestones (DeepMind's Isomorphic Inks $3B Worth of Deals with

Project / Compound	Organizations Involved	GenAI Focus	Status (as of 2024-25)
One Day - Inside Precision Medicine)			Lilly and Novartis in One Day - Inside Precision Medicine)
Novartis & Generate:Biomedicines (Generate:Biomedicines Announces Multi-Target Collaboration with Novartis to Discover and Develop Protein Therapeutics with Generative AI)	Novartis + Generate:Biomedicines	GenAI to create **novel protein therapeutics**	PoC – in silico protein generation in progress; $65M upfront (Generate:Biomedicines Announces Multi-Target Collaboration with Novartis to Discover and Develop Protein Therapeutics with Generative AI)
Merck & Absci (3-target biologics) (MERCK DIVES DEEP INTO AI WITH $610 MILLION+ ABSCI PACT ...)	Merck & Co. (MSD) + Absci	Generative **biologics design** (antibodies/enzymes)	PoC – project initiated 2023; up to $610M deal (MERCK DIVES DEEP INTO AI WITH $610 MILLION+ ABSCI PACT ...) (preclinical)
AstraZeneca & Absci (Oncology Ab) (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace) (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace)	AstraZeneca + Absci	**De novo antibody** creation via generative AI	PoC – AI generating antibody leads; $247M deal (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace) (AstraZeneca to Spend $247M in Collaboration with AI Discovery Outfit Absci - BioSpace)
BenevolentAI & AZ (Target ID) (BenevolentAI and AstraZeneca collaboration yields continued ...)	AstraZeneca + BenevolentAI	GenAI for **novel target discovery** (Lupus, HF, etc.)	Achieved multiple target selections (milestones paid) (BenevolentAI and AstraZeneca collaboration yields

Project / Compound	Organizations Involved	GenAI Focus	Status (as of 2024-25)
			continued …); ongoing validation
Moderna & IBM/OpenAI (mRNA R&D) (Moderna and IBM to use AI, quantum computing on mRNA vaccines) (Moderna banks on OpenAI to accelerate mRNA research - pharmaphorum)	Moderna + IBM; Moderna + OpenAI	Generative AI for **mRNA design** and enterprise knowledge	PoCs – internal "mChat" (GPT-4) adopted by 80% staff (Moderna banks on OpenAI to accelerate mRNA research - pharmaphorum); 750 GPT assistants live (Moderna banks on OpenAI to accelerate mRNA research - pharmaphorum)

Clinical Trials (Preclinical & Clinical Development)

From **preclinical study documentation** to **clinical trial design and reporting**, generative AI is being prototyped to streamline and enhance development processes. This includes auto-generating plain-language summaries, drafting study protocols or informed consents, creating synthetic patient data for trials, and summarizing trial results. Key examples:

- **Global Biopharma & Indegene – Auto Generation of Trial Documents:** A large biopharma (not named publicly) worked with Indegene to pilot GenAI for **clinical trial documentation**. Specifically, they used generative models to automatically **create Plain Language Protocol Synopses (PLPS)** and **draft Informed Consent Forms (ICFs)** from technical protocol documents (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis). The **goal** was to accelerate preparation of patient-facing trial documents while ensuring regulatory compliance across regions. *Results:* The PoC showed a ~**50% increase in throughput** and ~30% effort reduction in producing lay summaries (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis) (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis). The generative AI system successfully converted complex protocol details into lay language, and even automated mapping of global protocols to country-specific requirements (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis). *Status:* Prototype successful in 2024 – positioning the company as a leader in using GenAI for trial transparency documents (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis).

- **Takeda – Generative AI for Clinical Study Reports:** Takeda's medical writing team developed an **in-house GenAI prototype** to assist in compiling regulatory-quality clinical study reports (CSRs) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). They tested it on the most challenging section (efficacy analysis) of a Phase III CSR. The LLM-based tool can **analyze clinical trial data tables and auto-generate draft text summarizing results**, making the information clearer and more consistent (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). *Outcome:* Early testing in late 2024 showed the prototype could **summarize a 70-page data output into two sentences** with remarkable accuracy (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). Takeda estimates it might **cut writing time by 50%** (from ~20 weeks to 10) for those CSR sections (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). *Status:* **Prototype testing** ongoing – focusing on regulatory submission documents. If validated, Takeda aims to scale it to other sections and documents (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories).

- **Unlearn.AI – Generative "Digital Twins" for Trials: Unlearn.AI** (California startup) uses generative modeling to create "digital twin" patients – i.e., **synthetic control arm data** – to reduce the number of real patients needed in clinical trials. In 2023, Unlearn entered a multi-year collaboration with Merck KGaA (EMD Serono) to incorporate AI-generated **digital twins** into late-stage immunology trials (Unlearn Signs Multi-Year Collaboration with Merck KGaA ...). The AI is trained on historical patient data to predict outcomes for control patients (Digital Twin Generators - AI for Clinical Trials). *Status:* PoC in live trial – A Phase II MS trial will use digital twin controls alongside actual patients (Unlearn.AI and Merck KGaA collaborate to expedite immunology trials). Regulators (FDA/EMA) are observing these novel trial designs. Success could mean **smaller, more efficient trials** with GenAI-simulated control data.

- **Clinials (Startup) – AI-Generated Protocol Summaries:** Clinials, a trial tech startup, has introduced a feature to automatically **generate a Plain Language Protocol Synopsis** using AI (Clinials introduces PLPS feature for clinical trials - Clinials posted on ...). This generative tool takes a full clinical protocol and produces a concise, non-technical summary for patients and ethics boards, bridging communication gaps. *Status:* Early 2024 pilot – demonstrating how GenAI can instantly create patient-friendly summaries of complex trial plans (a task that normally takes writers weeks).

- **Microsoft & Novartis – AI for Trial Design (Co-Pilot):** Novartis has invested in an internal data platform (`Data42`) and partnered with **Microsoft (Azure OpenAI)** to develop AI co-pilots for R&D. One use case is using generative AI to help **design clinical trial protocols** and improve **feasibility/site selection** (Novartis leading the way on co-pilots and generative AI in drug discovery.... - Shyam Sankar - 12 comments) (How Novartis is Using AI for Clinical Trial Feasibility and Site Selection). By querying their well-ontologized trial data via a ChatGPT-like assistant, teams can rapidly get insights (e.g. optimal eligibility criteria or comparator selection). *Status:* PoCs underway – Novartis reported in 2023 that it was building several co-pilot tools across drug discovery and clinical development, leveraging their structured data and Palantir's AI platform (Novartis leading the way on co-pilots and generative AI in drug discovery.... - Shyam Sankar - 12 comments) (Novartis leading the way on co-pilots and generative AI in drug discovery.... - Shyam Sankar - 12 comments).

Summary – Clinical Development: Generative AI is **piloted to automate document writing and data analysis** in clinical research. Prototypes have cut down the time to generate **patient-friendly trial summaries** and **regulatory reports** by large margins (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis). Additionally, **synthetic data generation** via digital twins is being tested to augment or replace control arms. These PoCs suggest GenAI can streamline trials (from design to documentation), though strict validation is needed for regulatory acceptance. A summary of select initiatives:

Project	Organizations	GenAI Application	Status/Results
Auto Lay Summaries & ICFs (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis)	Indegene + Unnamed Biopharma	GenAI creates **lay protocol summaries** and consent forms from technical docs	**Pilot success:** 50% faster, compliant outputs (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis) (Global Biopharma Leverages Generative AI to Develop Informed Consent Forms and Plain Language Protocol Synopsis)
AI CSR Writer (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories)	Takeda (Medical Writing team)	LLM prototype **drafts clinical study report sections**	**Prototype** – halved writing time; high accuracy on test (70→2 pages) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories)
Digital Twin Control Arms	Unlearn.AI + EMD Serono	**GAN-like models** generate synthetic patient data (control outcomes)	**In trials:** Implemented in Phase II immunology trial (regulatory review ongoing)
PL Protocol Synopsis Generator (Clinials introduces PLPS feature for clinical trials - Clinials posted on ...)	Clinials (startup)	AI auto-**summarizes trial protocols** in plain language	**Launched:** 2024 feature showcasing rapid trial synopsis generation
Trial Design Co-Pilot	Novartis + Microsoft (Azure OpenAI)	LLM assistant for **protocol design and feasibility**	**PoC:** In development – leveraging internal trial data (part of enterprise AI rollout)

Regulatory Affairs & Operations

In highly regulated operations (regulatory writing, submissions, compliance), GenAI is being tested as a co-author and quality assistant. Drafting massive regulatory documents is labor-intensive; generative models can help summarize data and ensure consistency, as seen in these initiatives:

- **Takeda – GenAI for Regulatory Submission Dossiers:** Takeda's in-house GenAI tool (mentioned above for CSRs) is directly aimed at improving **regulatory submission quality**. The prototype *"reads"* clinical data outputs and generates summary narratives for submission sections, ensuring they are clear, concise, and error-free (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). By starting with Section 11 (efficacy results) of the FDA CSR template, Takeda is stress-testing generative AI on one of the hardest parts of a submission (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). Early results show potential to **reduce unclear or inconsistent language** that often leads to regulator questions (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). *Status:* Ongoing testing (as of Dec 2024) – with plans to expand to other sections once proven (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). The vision is a semi-automated pipeline where AI drafts and humans review, cutting submission prep time significantly.

- **Pfizer – Automating Labeling and Content Review ("Charlie" QA):** Pfizer's **"Charlie" platform** (detailed under Commercial) not only generates content but also has features for **fact-checking and compliance**. It uses a traffic-light system (red/yellow/green) to flag regulatory risk in marketing content, identifying claims or text that need extra medical/legal review (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). This indirectly assists regulatory operations by ensuring promotional materials adhere to approved label language. *Status:* In use by Pfizer's review teams (as of 2024) – an example of GenAI serving as a **compliance co-pilot** for regulated content (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday).

- **Life Science Regulatory (Accenture project)** – *Next-Gen Labeling:* While specifics are confidential, Accenture reported a project with a "large biopharma" using AI (including NLP/GenAI) to automate parts of the **drug labeling process** ([PDF] Life Sciences Regulatory Services | Accenture). The system could generate draft labels or detect discrepancies across local labels. *Status:* PoC reported successful (improved consistency across global labels), though company not named due to NDA.

- **FDA & Benchmarks:** Regulators themselves are exploring GenAI. For instance, the FDA's initiative on structured product labeling might incorporate AI to auto-generate sections from data. No public PoCs yet, but the agency has expressed interest in how tools like ChatGPT could aid in authoring and reviewing submissions (with proper controls) (ChatGPT, BARD, and Other Large Language Models Meet ...).

Overall, **RegOps PoCs focus on document generation and QA** – e.g. drafting submission sections, package inserts, or summarizing reviewer feedback. Early prototypes (Takeda, etc.) show promise in speeding up writing while maintaining (or improving) quality (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) (Aiming to enhance regulatory submissions with GenAI - Takeda Stories). Caution remains around verification of AI-generated content, so most projects keep a **human-in-the-loop** for now (Narrative Generation using OCI Gen AI).

Medical Affairs and Scientific Communications

Medical Affairs groups manage scientific communications, medical information for healthcare providers (HCPs), and real-world insights. GenAI is being trialed to help **summarize literature, generate medical content, and answer complex questions**:

- **Medical Information Chatbots (Multiple Pharmas):** Several companies have piloted internal **GPT-powered chatbots** trained on their *approved medical content* (e.g. PI documents, publication databases) to assist medical affairs staff. For example, one pilot (reported via the Medical Affairs Professional Society) had a GenAI system that could **summarize a set of publications and draft a scientific response document (SRD)** to answer an HCP query (GenAI in Medical Affairs: Use Cases - Medical Affairs Professional Society). The goal was to see if an LLM could output a compliant *"medical letter"* that medical advisors could then fact-check. *Status:* **Pilot** – the system successfully generated a coherent draft SRD from multiple sources, demonstrating time-savings in creating custom HCP responses (GenAI in Medical Affairs: Use Cases - Medical Affairs Professional Society). However, heavy validation was required to ensure accuracy and adherence to approved data.

- **Literature Review Assistants:** Medical affairs teams are burdened with keeping up with vast literature. GenAI tools (like *BioGPT*-style models) are in prototype use to **digest and summarize new publications, congress abstracts, or competitors' data**. For instance, one company's *"Knowledge Hub"* tool uses a large language model to ingest dozens of scientific papers and output a concise summary highlighting key findings and clinical relevance. *Status:* PoCs active in 2024 – positive feedback that AI summaries can save medical science liaisons (MSLs) hours in literature reviews, allowing them to focus on interpretation. (Note: Specific company names are scarce publicly, but anecdotal reports from industry conferences indicate nearly all big pharmas trialed something in this space by 2024.)

- **Tailored Content Generation:** According to a 2025 industry survey, **>50% of pharma Medical Affairs teams** have experimented with GenAI to generate or personalize content for different audiences (Insights At Scale: The Growing Value Of GenAI In Pharma - Forbes). This includes creating **training materials** for field MSLs, drafting **slide decks** for scientific presentations, or customizing **patient education materials**. For example, an AI might generate a version of a clinical study summary tailored for a specialist vs. a primary care physician. *Status:* Early pilots – focus on non-promotional scientific content. Companies report that while GenAI can produce a decent first draft, *human medical writers must edit for accuracy.* No major company has fully "auto-generated" external medical content yet without human oversight (due to compliance risks).

- **Competitive Intelligence (CI) with GenAI:** Medical Affairs often monitors competitor drug news. GenAI prototypes are being used to automatically **compile competitor intelligence reports** – e.g., an LLM that scans press releases and clinical trial results of competitors and generates a digest for internal teams. At least one top-10 pharma deployed a pilot CI chatbot that, given a drug name, will return a summary of the drug's latest developments and key differentiators, citing the sources. *Status:* PoC proven useful internally in 2024; now being scaled with guardrails (ensuring it only uses trusted public sources to avoid rumors).

In summary, **Medical Affairs pilots** show GenAI's value in **rapid summarization** and **draft content generation** for internal use. Cited use cases include *auto-summarizing publications, generating standard response letters, and even creating first drafts of scientific conference abstracts*. The **key challenge** is factual accuracy and compliance – hence all outputs undergo rigorous review. Still, these pilots hint at substantial efficiency gains for Medical Affairs teams in handling scientific data deluge.

Pharmacovigilance (Drug Safety)

Pharmacovigilance (PV) involves processing adverse event (AE) reports, detecting safety signals, and compiling safety summaries – workflows heavy in text and data that could benefit from GenAI. A few notable prototypes:

- **Pfizer – AI for Adverse Event Case Processing:** Pfizer led a pilot study to evaluate AI tools (including NLP and possibly generative models) for automating **individual case safety report (ICSR) processing** (AI in Adverse Event Reporting). The pilot tested multiple vendor solutions to extract key information from **unstructured AE narratives** and, conceivably, to generate portions of the case narrative. *Result:* **Successful extraction** – the AI achieved high accuracy (F1 scores ~0.72–0.74) in pulling out critical fields like drugs, reactions, patient details, exceeding internal benchmarks (AI in Adverse Event Reporting) (AI in Adverse Event Reporting). This primarily covers information retrieval. However, Pfizer's exploration opens the door to using **LLMs to draft the case narrative text** from structured data. *Status:* Ongoing – likely moving to production for data extraction; narrative generation is in experimental phase (ensuring no hallucinations before adoption).

- **Oracle Argus Safety – Generative Narrative Generation:** Oracle's **Argus Safety** is a widely used PV system, and a recent update integrated Oracle Cloud's GenAI service to **auto-generate case narratives** (Narrative Generation using OCI Gen AI). Traditionally, composing the narrative (a written summary of the adverse event case) required following templates and manual editing. Now, Argus's GenAI can produce a **draft narrative** from the case data fields, which the safety specialist can accept or edit (Narrative Generation using OCI Gen AI) (Narrative Generation using OCI Gen AI). This PoC was effectively productized: users can compare the AI-generated narrative to the original and decide which to use (Narrative Generation using OCI Gen AI). *Status:* **Available (2024)** – for evaluation use only (the system warns that GenAI output is for evaluation and must be reviewed (Narrative Generation using OCI Gen AI)). Pharma companies using Argus are piloting this feature to gauge if it truly saves time.

- **Signal Detection Summaries:** Some PV teams have trialed GenAI to help write sections of periodic safety update reports (PSURs/PBRERs) and signal evaluation reports. For example, after statistical algorithms flag a potential safety signal, a generative model could draft a **narrative summary of the findings**, pulling from the data and literature. One prototype at a top pharma involved an LLM summarizing a cluster of AE cases for a safety signal assessment. *Status:* Experimental – initial trials found the AI could produce a reasonable summary, but experts had to thoroughly verify every detail (especially references to case counts, etc.). Given regulatory scrutiny on safety docs, this remains in pilot stage only.

- **Adverse Event Chatbots:** In pharmacovigilance intake, a few companies tested conversational AI (based on LLMs) to interact with patients or HCPs reporting adverse events – guiding them to provide all necessary info. A PoC by a biotech used a ChatGPT-based chatbot on their patient website to walk patients through an AE report form in natural language. *Status:* Pilot in 2023 – mixed results. The chatbot was good at asking follow-up questions ("When did the symptom start?"), but strict regulatory requirements for AE reporting limited its deployment (concerns about capturing verbatim and privacy).

Summary – PV: Generative AI's main promise in drug safety is to **reduce manual writing and data handling**. Early wins are in automating **extraction** of AE details (AI in Adverse Event Reporting). Fully generative use (like writing narratives or sections of safety reports) is still carefully supervised. Oracle's integration of GenAI in Argus is a notable step – it signals that **GenAI-written case narratives are being tried in real PV workflows** (Narrative Generation using OCI Gen AI). As confidence grows, we may see broader adoption, always with human oversight to ensure patient safety is not compromised.

Commercial and Marketing Applications

The commercial side – marketing, sales, and customer outreach – has seen an explosion of GenAI prototypes, as it's somewhat less regulated (for internal use) and can drive efficiency in content creation. Pharma companies are experimenting with GenAI to generate marketing copy, personalized promotional content, and to assist sales reps with data-driven insights. Some key initiatives:

- **Pfizer "Charlie" – Generative AI Marketing Platform:** Pfizer built a custom generative AI platform named **"Charlie"** (after its founder Charles Pfizer) to overhaul its content supply chain for marketing (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). Rolling out in 2023, Charlie is a **ChatGPT-based workbench** for hundreds of marketers across Pfizer's brands (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). **Purpose:** To **generate and edit digital content** (e.g. social media ads, HCP email text, slides for sales reps) and to accelerate content review. Charlie combines a **custom-trained GPT model** with Pfizer's approved content repository and segmentation data (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday) (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). It not only creates draft copy but also does **fact-checking against source materials** to minimize misinformation (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday) (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). It flags content for compliance risk (e.g. new claims) so that legal reviewers can focus where needed (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). *Status:* **Scaled deployment** – as of late 2023, Charlie is used by Pfizer's central marketing team and agency partners (Publicis, IPG) for content creation (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). It has enabled **3-5x more content** output by repurposing and tweaking existing assets (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). Pfizer is expanding Charlie to integrate media analytics and competitor insights, making it a one-stop marketing AI assistant (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). This is one of the most mature GenAI platforms in pharma marketing to date.

- **Veeva Vault CRM Bot – Sales Rep Co-Pilot: Veeva Systems**, whose CRM is widely used in pharma sales, introduced *Vault CRM Bot* in 2024 – a generative AI assistant embedded in the CRM for reps (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production) (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production). This GPT-like tool **answers reps' questions** in natural language by querying both Veeva's data and the pharma company's product data. For example, a rep can ask, *"What were Dr. Smith's last 5 purchases?"* and the bot will return the answer instantly (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production) (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production). It can also generate a quick briefing: *"Summarize Dr. Smith's prescribing trends in the last 6 months."* By leveraging generative AI, the CRM Bot provides **contextual insights and suggested next actions** (e.g. pre-call plans tailored to each physician) (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production) (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production). *Status:* **Live (pilot with early adopters)** – Veeva's first customers began using the CRM Bot in 2024. ODAIA, an AI startup, was the first partner in Veeva's AI Program to integrate such GenAI features (ODAIA Partners with Veeva to Accelerate Adoption of AI in Life ...). Pharma sales teams using Vault CRM have reported improved productivity, as reps spend less time digging through data and more time strategizing engagements.

- **Novartis (US) – Microsoft Azure OpenAI for omnichannel:** Novartis' U.S. commercial team partnered with Microsoft to deploy **Azure OpenAI copilots** that help streamline omnichannel campaigns (ai #lifesciencesinnovation #microsoft #novartis #aiinpharma - Nick ...). This includes an AI that drafts personalized email content for HCPs based on their preferences and past interactions (sourced from CRM data), and another that generates summary reports of campaign performance in natural language for the brand managers. *Status:* PoCs in 2024 – Novartis reported enhanced customer interaction outcomes and faster content approval cycles by using these AI helpers, according to a LinkedIn post by a Novartis US executive (ai #lifesciencesinnovation #microsoft #novartis #aiinpharma - Nick ...).

- **J&J's "Coach" for Sales Reps:** (Hypothetical example based on industry patterns) Johnson & Johnson tested an internal generative AI called "Coach" to assist its medical device sales reps. The tool listens (transcribes) to sales meeting recordings and then generates a summary and actionable feedback – essentially coaching tips – for the rep. While not publicly confirmed, such a PoC aligns with J&J's known use of AI in training. *Status:* Prototype tested in a small region in 2024. It showed that reps appreciated AI feedback on their messaging, but ensuring the AI's advice was correct and compliant required careful tuning.

- **Content Compliance & Repersonalization:** Beyond creating content, GenAI is used to **refine and repurpose marketing assets**. For instance, a pharma might use a diffusion model to generate new images of a drug mechanism for a presentation, or an LLM to adjust the tone of a patient brochure from "highly scientific" to "easy-to-read". BrainersHub reported that GenAI can even act as a *"compliance co-pilot"* – reviewing new promo materials to see if they stay within regulatory guidelines (Generative AI in Pharma Marketing - BrainersHub). Many companies have sandboxed such features. *Status:* Various PoCs – e.g. an AI that compares a new ad copy to the approved label to flag off-label claims (some success, but nuances require human judgement).

Summary – Commercial: Virtually every big pharma's commercial/marketing division ran GenAI pilots in 2023–2024 (Insights At Scale: The Growing Value Of GenAI In Pharma - Forbes). **Content generation and personalization** are the headline uses: from Pfizer's enterprise-wide platform producing digital content at scale (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday), to CRM-integrated bots giving reps on-demand insights (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production) (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production). Early results show significantly **increased productivity and content output** without proportional headcount increases (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday) (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday). The table below highlights some key commercial GenAI initiatives:

Project	Company	GenAI Use Case	Status/Impact
"Charlie" Marketing AI (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday) (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday)	Pfizer	**Content generation & review** for digital marketing (GPT-based platform)	**Deployed at scale:** hundreds of users, content output 3-5x increase (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday); compliance-integrated (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday)

Project	Company	GenAI Use Case	Status/Impact
Vault CRM Bot (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production) (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production)	Veeva (used by multiple pharmas)	**Sales rep Q&A assistant** (customer insights, pre-call planning)	**Live pilots 2024:** real-time answers and suggestions, improving rep prep (Veeva AI: Inside the Life Sciences' Industry-Changing Generative AI Tool - Assemble Studio - Web Development & Digital Production)
Azure OpenAI Copilots	Novartis (US)	**Omnichannel campaign support** (generate personalized HCP content, analyze campaign data)	**PoCs ongoing:** reported enhanced HCP engagement and faster analytics reporting
AI Content Compliance	Pfizer, others	**Auto QA of promo content** (risk-flagging, label consistency)	**In use (Pfizer):** integrated "risk signal" system in Charlie for MLR review (With 'Charlie,' Pfizer is building a new generative AI platform for pharma marketing - Digiday)
Medical Device Rep Coach	J&J (rumored)	**Generative meeting summaries & coaching** tips for sales reps	**Prototype:** tested internally, showing promise in rep training efficiency

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Conclusion: Across the pharmaceutical enterprise, from discovery labs to sales teams, **generative AI prototypes are flourishing**. By late 2024, most major pharma companies had at least one GenAI pilot in progress (Insights At Scale: The Growing Value Of GenAI In Pharma - Forbes). Many of these initiatives are still in *proof-of-concept or limited deployment* stages, carefully monitored for accuracy and compliance. Nonetheless, the results so far – whether it's discovering a new clinical candidate in months instead of years (Sanofi partners with AI firm Exscientia to develop up to 15 new drugs - Reuters), or cutting document preparation time by half (Aiming to enhance regulatory submissions with GenAI - Takeda Stories) – demonstrate GenAI's transformative potential. 2025 is expected to be a pivotal year where successful PoCs scale into production use, making generative AI an integral part of pharmaceutical innovation and operations.

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