AI Clinical Trial Protocol Design in Drug Development

By Adrien Laurent, CEO at IntuitionLabs • 4/13/2026 • 40 min read

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AI-Driven Clinical Protocol Design: Catalyzing a New Era in Drug Development

Executive Summary

The drug development industry is undergoing a profound transformation as artificial intelligence (AI) and digital technologies are increasingly applied to clinical trial design and execution. This report examines how Bristol-Myers Squibb (BMS) – a global pharmaceutical leader – has partnered with two technology innovators, **Faro Health** and **Evinova**, to overhaul clinical trial protocol design using AI. We integrate historical context, technical detail, industry data, and expert commentary to analyze how AI-driven protocols can accelerate timelines, improve quality, and reduce costs in drug development.

Key findings include:

- **Rising Costs and Complexity:** Drug R&D costs have historically risen exponentially (Eroom's Law), with median spend of ~$1.1 billion per new drug ([1] farohealth.com). Clinical trial protocols – complex documents detailing study design – are a major bottleneck. Conventional, document-centric protocols contribute to inefficiency, errors, and frequent amendments ([2] www.iqvia.com) ([3] www.iqvia.com).

- **Digital Protocols as Foundation:** Industry experts emphasize shifting from static PDFs to structured, machine-readable "digital protocols." These protocols encode trial elements (objectives, endpoints, schedules, etc.) as data, enabling automation and interoperability ([2] www.iqvia.com) ([3] www.iqvia.com). Digital protocols serve as a "single source of truth" for study design, reducing manual errors and streamlining amendments ([3] www.iqvia.com) ([2] www.iqvia.com).

- **AI Impact on Trial Design:** Advanced AI (including generative AI) can significantly accelerate protocol authoring and validation. For example, **Faro Health**'s platform uses AI to convert narrative protocol elements into structured assets and even generates initial draft sections from templates ([4] www.biospace.com) ([5] farohealth.com). AI agents can *simulate schedules*, *quantify protocol complexity*, *assess patient/site burden*, and *validate design consistency* ([4] www.biospace.com) ([6] www.biospace.com). These capabilities allow more standardized, "patient-centric" protocols that eliminate inefficiencies ([6] www.biospace.com).

- **Deep Collaborations:** In 2026, BMS formed partnerships with Faro and **Evinova** to deploy these digital & AI tools globally. In March 2026, BMS agreed with Faro to standardize on its *Study Designer* platform as the system of record for structured protocol design ([7] www.biospace.com) ([8] www.fiercebiotech.com). In parallel, BMS signed a deal to use Evinova's AI-native clinical development platform (including a **Cost Optimizer** and *Unified Trial Solution*) to optimize trial design and costs ([9] evinova.com) ([10] www.fiercebiotech.com). Both collaborations aim to *accelerate trials, improve quality, and cut costs* through AI and data-driven workflows ([6] www.biospace.com) ([9] evinova.com).

- **Demonstrated Benefits:** Early data and expert estimates point to substantial gains. BMS reports that initial implementations of digital protocols have "accelerated timelines, improved quality and increased probability of technical success" by streamlining patient-centric designs and eliminating unnecessary procedures ([6] www.biospace.com). Evinova's platform, backed by AstraZeneca's internal data, claims up to **60% improvement in patient experience**, **~6 months faster trial delivery**, and **~32% cost reduction** versus traditional methods ([11] evinova.com). Industry analysts forecast broader impacts: generative AI could slash weeks from administration tasks (e.g. recruitment, regulatory filing) and boost clinical development productivity by ~35–45% over five years (www.businessday.co.za) (www.businessday.co.za).

- **Regulatory and Industry Trends:** Regulators are taking note: by early 2026 the European Medicines Agency (EMA) and FDA issued joint "good AI practice" principles for drug development and explicit guidance on AI use in evidence generation ([12] www.europeanpharmaceuticalreview.com) ([13] www.europeanpharmaceuticalreview.com). Industry standards bodies (CDISC/TransCelerate) are also standardizing digital protocol data models to ensure interoperability ([14] www.iqvia.com). These developments underscore a broad shift to data-centric development.

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- **Challenges and Future Directions:** While promising, AI-enabled protocols raise new challenges (e.g. AI "hallucination," data biases, cybersecurity, and the need for human oversight) ([15] farohealth.com) ([2] www.iqvia.com).This report discusses these issues and outlines future directions, including the integration of decentralized trials, digital endpoints, and continuous learning systems.

Overall, BMS's adoption of AI-driven protocol design – through partnerships with Faro and Evinova – exemplifies a larger industry trend toward digital transformation in clinical development. By transitioning from static documents to structured, AI-ready protocols, sponsors aim to make trials faster, safer, more efficient, and more patient-centric ([6] www.biospace.com) ([3] www.iqvia.com). This report delves into the technical, operational, and strategic implications of this shift, synthesizing perspectives from pharma, technology, and regulatory stakeholders.

Introduction and Background

Successful drug development faces mounting scientific and economic challenges. Despite advances in biology and computation, the **cost and time to bring a new medicine to market have continued rising** (a phenomenon dubbed *"Eroom's Law"*) ([16] farohealth.com). A 2020 JAMA study found that the **median R&D investment per new drug** (2009–2018) was about **$1.1 billion** ([1] farohealth.com). Clinical trials, which account for much of this expense, have grown more complex: modern trials often encompass intricate designs, multiple cohorts, numerous digital endpoints, and decentralized elements. Protocol documents – the extensive plans specifying objectives, eligibility, endpoints, procedures, and assessments – can exceed 100 pages. Managing and revising such voluminous protocols is laborious and error-prone.

Traditional clinical protocol design is a largely manual, document-driven process. Clinical scientists and medical writers assemble protocols in Word or PDF files, iterating through reviews by scientific, regulatory, and operational teams ([17] farohealth.com). This free-text approach makes it difficult to systematically analyze or automate the content. As an IQVIA white paper notes, **"Traditional protocols are delivered in a static PDF format, creating high risks for operational errors, non-compliance, inefficiency, data integrity and safety"** ([2] www.iqvia.com). For example, changes to one section (say, schedule-of-activities) may inadvertently conflict with another (e.g. safety measures), leading to late amendments. Indeed, millions of dollars and months of delay can result from protocol amendments. A structured, data-centric approach promises to **"provide standardized data to drive downstream operations… enable the automation of study setup, scheduling, and electronic data capture (EDC)"** ([2] www.iqvia.com). In short, digital protocols – encoded as machine-readable data – are seen as the foundation for applying AI and automation to clinical studies.

Concurrently, the recent explosion in AI capability (particularly large language models and agentic systems) is dramatically expanding what is possible in biomedicine. AI has proven valuable in drug discovery, but industry leaders now emphasize that **trial execution** may be the *bigger bottleneck*. As Formation Bio's CEO Ben Liu notes, "The biggest problem in bringing new medicine to patients hasn't been drug discovery… the real limiting factor is in the running of clinical trials," which can take years and cost hundreds of millions ([18] time.com). This view is echoed across pharma: high-profile examples include Amgen using AI for oncology trial site selection, Sanofi partnering with OpenAI for target generation, and Pfizer with Inflect to use AI in trial operations. Regulators and analysts forecast that AI could **slash weeks off trial administration and boost development productivity by up to 35–45%** over the coming years (www.businessday.co.za) (www.businessday.co.za).

In this context, **Bristol-Myers Squibb (BMS)** has emerged as an early mover applying AI to clinical trial design. In 2022, BMS launched a strategic collaboration with AI startup *Owkin* to optimize trial cohorts and endpoints using patient data models ([19] www.bms.com) ([20] www.bms.com). More recently, BMS has explicitly targeted the **protocol-authoring process** itself. In late 2025 and early 2026, BMS announced two major partnerships – with **Faro Health** and with **Evinova** – aimed at transforming protocol design through AI and structured data. These moves reflect both BMS's drive for efficiency and a broader industry shift toward digital, AI-enhanced development ([21] www.biospace.com) ([22] www.fiercebiotech.com). This report provides a detailed examination of these collaborations and their implications for the pharmaceutical pipeline.

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Clinical Trial Protocols: From Documents to Digital Data

Clinical trial protocols are the **blueprint of a trial**, defining its objectives, design, methods, statistics, and operational details. By ICH-GCP guidance, a protocol *"should detail the processes and methods for executing and analyzing a clinical trial"* ([23] www.iqvia.com). Traditionally, such protocols are written as static documents. This approach means that the trial's design and logic exist in textual form, understandable only by human readers. Key drawbacks include:

- **Interoperability Gaps:** Different teams (medical, regulatory, operations) must coordinate via disconnected documents, spreadsheets, and emails.
- **Amendments Burden:** Any change (e.g. adding a new endpoint or assessment) may require manual updates in multiple places, increasing risk of oversight.
- **Limited Data Utility:** Because protocol elements are not encoded in a database, it is hard to query or analyze them systematically. For instance, sponsors cannot easily answer automated questions like "How many trials last year had >5 oncology arms?" without extensive manual work.

To address these limitations, the industry is moving toward *digital protocols*. A **digital protocol** is a "structured and machine-readable way of representing clinical trial data," effectively converting the protocol into a database-like format ([2] www.iqvia.com). In such a system, each objective, endpoint, visit schedule, and procedure can be represented as a data field. This data-centric representation serves as the single source of truth ("heart" of the trial ([24] www.iqvia.com)) and unlocks numerous benefits. According to industry experts, digital protocols enable much **"faster start-up, less rework, better amendment control, [and] reduced compliance exposure"** ([3] www.iqvia.com). They facilitate interoperability, as all downstream tools (e.g. eCRFs, eConsent systems, monitoring dashboards) can link directly to the same protocol data.

Several initiatives are helping to standardize digital protocol formats. Notably, CDISC's Unified Study Definitions Model (USDM) and TransCelerate's Digital Data Flow initiative have launched frameworks of common data elements (objectives, endpoints, etc.) for protocols ([14] www.iqvia.com). These efforts create a **ready-made workflow for capturing digital information** about study design, which in turn simplifies trial execution ([14] www.iqvia.com). In practice, an organization might begin by populating standardized protocol templates (based on USDM tags) and then let software ensure that any edits propagate consistently ([14] www.iqvia.com).

The IQVIA blog **"From PDF to Platform"** (Apr 2026) describes the paradigm shift: moving trials "from traditional paper-based protocols toward digital approaches that more readily support study startup and agentic AI workflows" ([25] www.iqvia.com). Digital protocols lock in the protocol logic in advance. As one insight report explains, with digital protocols teams can *"initiating clinical documents, enabling downstream workflows, and supporting activities like budget planning and negotiation"* automatically ([26] www.iqvia.com). Importantly, the organizers note that digital protocols create **a trial blueprint** whose structured data can be fed into AI tools from day one ([23] www.iqvia.com). This is precisely the foundation that AI engines require: machine-readable inputs rather than free text.

Table 1 below summarizes key differences between traditional (document-driven) and AI-enabled protocol design processes. The right-hand column illustrates how platforms like Faro's Study Designer or Evinova's Study Builder change each aspect.

Aspect	Traditional Approach	AI-Enabled Approach (Faro/Evinova)
Protocol Format	Static PDF/Word documents with narrative text ([2] www.iqvia.com)	**Structured, machine-readable data format** ([2] www.iqvia.com). Protocol content (objectives, endpoints, visits) is encoded in a database/schema, not free prose.
Study Design Documentation	Manual design and writing; time-consuming reviews ([3] www.iqvia.com)	**AI-assisted drafting and templating**. Generative AI co-authors sections based on structured inputs (objectives, inclusion criteria, etc.) ([5] farohealth.com) ([27] www.biospace.com). Structured templates auto-populate.
Schedule & Feasibility	Manual timeline estimation (often Excel); late discovery of conflicts.	**AI simulation of schedules**. Algorithms compute visit calendars and flag conflicts; AI assesses patient/site burden (e.g. total visits, duration) ([28] www.biospace.com).
Complexity Analysis	Expert judgment; somewhat ad hoc; complexity often hidden until execution.	**Quantitative complexity metrics and mitigation**. AI quantifies protocol complexity (e.g. number of assessments, intricate eligibility) and suggests simplifications or highlighting risk factors ([29] www.biospace.com).

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Aspect	Traditional Approach	AI-Enabled Approach (Faro/Evinova)
Consistency Checks	Cross-review by multiple stakeholders (slow, prone to oversight).	**AI validation**. Automated agents verify internal consistency across sections and with standards. For example, ensuring the end points listed in the methods match those in the objectives ([30] www.biospace.com).
Amendments & Change Control	High amendment rates (requiring manual impact assessment) ([3] www.iqvia.com)	**Reduced unnecessary amendments**. With structure, one can anticipate issues earlier, and amendments have clearly defined impacts. Teams using digital protocols report *"faster start-up, less rework, better amendment control"* ([3] www.iqvia.com).
Cost Planning	Budgeting via spreadsheets; coarse estimates.	**Algorithmic cost optimization** (Evinova's *Cost Optimizer*). AI models estimate budget for patient burden, procedures, and can explore trade-offs (e.g. reducing imaging visits to cut cost) ([31] www.fiercebiotech.com).
Patient/Investigator Experience	Standard, site-centric processes; varying engagement.	**Integrated patient-centric solutions**. Evinova's unified trial platform, for example, ties together eCOA (electronic patient-reported outcomes), telehealth, and remote monitoring to improve retention and compliance ([32] evinova.com).

Table 1: Comparison of traditional (static) protocol development versus AI-driven, structured protocol approaches ([2] www.iqvia.com) ([3] www.iqvia.com) ([28] www.biospace.com) ([5] farohealth.com) ([31] www.fiercebiotech.com) ([32] evinova.com).

AI Technologies in Protocol Design

Modern AI encompasses a spectrum of technologies. In the context of trial protocol design, two major capabilities are most relevant: **generative AI** (especially large language models) and **agentic AI/analytics** for structured planning.

- **Generative AI for Medical Writing:** Large language models (LLMs) like GPT-4 can produce coherent text if well prompted. Faro Health's *"AI Co-Author"* applies this idea to protocol authoring. By first converting study design elements into formal data, the LLM is given structured prompts and can draft first versions of sections (rationale, objectives, methods) in seconds ([5] farohealth.com). This skims down what would be weeks of writing to hours, though it requires expert review. Faro acknowledges that LLMs are **prone to "hallucinations"** (making up facts) and latent biases ([15] farohealth.com). Their team has invested heavily in *prompt engineering* and model checks so the AI output remains accurate. The benefit, even with human oversight, is clear: *"a remarkably powerful AI-based authoring system that can significantly shorten the time to author the first draft of clinical protocols"* ([5] farohealth.com). In practice, this means medical writers spend less time on boilerplate text and more on scientific nuance.
- **Agentic/Symbolic AI for Design Tasks:** Beyond writing text, AI can operate on the structured data itself. This includes techniques like constraint satisfaction, simulation, and optimization. For example, once objectives and assessments are coded, an AI agent can systematically construct and evaluate the **study schedule of activities (SoA)**. It can flag if, for instance, two procedures are in conflict or if patient burden is too high (number of visits, total procedure time). Another AI task is **complexity quantification** – algorithms can compute composite scores (e.g. a weighted sum of inclusion criteria, visit counts, biopsy frequency) that correlate with trial attrition risk. This allows designers to *"quantify and mitigate protocol complexity, allowing for mitigation of operational risks and potential amendment drivers"* ([29] www.biospace.com). Similarly, AI can cross-reference each section (arms, endpoints, safety measures) to ensure **internal consistency**. All these structured AI tasks have traceability and can be tuned with expert feedback.
- **Benchmarking and Learning:** With historical data, advanced AI can also benchmark a draft protocol against an industry framework. For instance, using the Tufts CSDD dataset of thousands of protocols, an AI can say "your average Phase III oncology protocol has 50 assessments; yours has 75 – this deviation is likely to increase screen failures." The BioSpace announcement highlights benchmarking AI that checks consistency and compares to standards ([30] www.biospace.com). In time, these tools could even predict likely enrollment speeds or regulatory outcomes based on protocol design features – turning documents into predictive analytics.

In summary, modern AI in this domain is not a single monolith but a suite of capabilities: **structured data handling, rule-based checks, NLP generation**, and **predictive modeling**. Faro's Study Designer exemplifies this: it creates a **structured protocol database** that both engineers and AI agents operate on. Evinova's platform similarly uses an "AI-native" architecture that expects machine-readable study definitions. The end goal is a fully integrated digital ecosystem where design decisions are augmented by AI insights.

Case Study: BMS–Faro Health Collaboration

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Partnership Overview

On March 31, 2026, **Faro Health** announced a multi-year collaboration with **Bristol-Myers Squibb** to scale *"autonomous AI"* across BMS's global clinical development portfolio ([7] www.biospace.com). Under this agreement, BMS will adopt Faro's *digital protocol platform* as the enterprise system of record – essentially the authoritative source for all protocol content. In practical terms, every new trial at BMS (across phases and therapeutic areas) will be built in Faro's Study Designer, with each objective, endpoint, schedule, and procedure captured in structured form ([7] www.biospace.com).

Faro, based in San Diego, has developed its Study Designer platform specifically for this purpose. The core innovation is converting the **narrative elements** of a protocol (e.g. the written objectives, hypotheses, allowed medications) into nanosecond-scale structured entries that AI can read. For example, if the protocol text says "patients will receive 10 mg of drug X twice daily," the system would encode a data field like `<Arm Treatment Dose=10mg Frequency=Q12h>`. This allows any downstream algorithm to interpret clearly what the protocol means, rather than parsing free text. Faro's technology also aligns each element to industry standards (such as vocabulary from CDISC or the Tufts protocol framework) so that comparisons and queries are consistent across studies ([4] www.biospace.com).

Bryan Campbell, SVP of Drug Development Strategy at BMS, highlighted the strategic value of this shift, noting that BMS is "utilizing innovative technologies to accelerate every aspect of our business. Our collaboration with Faro is one example of that work." Faro's CEO, Scott Chetham, emphasized that **"scaling AI in clinical development starts with structured data."** He said, *"Digital protocols provide the foundation required to apply AI consistently, transparently, and at enterprise scale."* ([33] www.biospace.com). In other words, BMS sees this as a fundamental overhaul: moving from disjointed Word documents to unified data models in order to unlock AI at scale.

Technology and Workflow

Faro Study Designer: Faro's platform functions as a digital workbench for protocol creation. Clinical scientists input or define core study objects (cohorts, arms, endpoints, assessments) via standardized forms or templates. The software then **auto-generates** parts of the document. Key generative-AI features include:

- **Drafting Support:** Based on the structured data, Faro can write initial text blocks for protocol sections. For instance, once the objectives and endpoints are set, the system can draft the "Study Objectives" section by stitching together predefined sentence templates with the specific terms. This dramatically reduces initial drafting effort ([5] farohealth.com).
- **Global Search/Reuse:** Because everything is data, FARO allows users to search for existing similar elements across past trials. If BMS has run many trials in, say, rheumatoid arthritis, previous protocols' endpoints or eligibility criteria can be adapted, reducing duplication of effort.
- **Programmatic Rules & Checks:** Study Designer includes built-in compliance rules. For example, it enforces that all arms have at least one primary endpoint, or that no prohibited concomitant drugs are listed incorrectly. If the AI sees a misalignment (e.g. an endpoint labeled as "secondary" in one place but "primary" in another), it flags the inconsistency.
- **Simulation Tools:** The platform can run "what-if" scenarios. An AI agent can simulate a schedule-of-activities: adding or adjusting visits, then calculating total subject burden or site workload. The BioSpace release highlights that the Faro system can "simulate scheduling activities and research site assessments" ([34] www.bioxconomy.com) ([4] www.biospace.com), meaning it can predict if certain design choices will overburden patients or sites and suggest adjustments.
- **Benchmarking Engine:** Integrated industry benchmarks (e.g. the Tufts CSDD metrics) allow real-time comparison. For instance, as cited in Fierce Biotech, "Faro has touted its platform as being able to help development teams draft protocol sections and benchmark them against industry standards, including the Tufts… framework" ([35] www.fiercebiotech.com).

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Once a protocol is fully entered into Study Designer, BMS personnel (and eventually, regulatory or vendor teams) interact mostly with the platform rather than with Word docs. This creates a **single source of truth** that automatically generates the PDF for regulators and feeds other systems (e.g. eConsent tools, electronic data capture) with consistent definitions. Vivian DeWoskin, Faro's Chief Commercial Officer, notes that BMS will use Faro *"as the system of record for structured protocol design across its entire drug development organization."* ([36] www.bioxconomy.com).

Operational Impact and Early Results

The BMS–Faro deal is not merely a pilot but a company-wide approach. The deployment spans **early-phase through late-phase programs** globally ([6] www.biospace.com). In practice, this means that by mid-2026 nearly every therapeutic area at BMS is expected to start new trials with Faro. The technology's immediate impact is on internal workflow: clinical teams collaborate within one digital environment, reducing email threads and manual merging of documents.

Preliminary outcomes have been promising. Although formal metrics are scarce, BMS reports from early implementations indicate multiple gains:

- **Accelerated Timelines:** Company executives state that protocol development (and thus trial startup) is speeding up. According to the BioSpace announcement, early use of the platform in late-stage programs suggests that *"BMS can accelerate timelines"* ([37] www.biospace.com). In practice, this likely reflects faster generation of draft protocols and fewer rounds of revision. (For context, some industry observers note that AI-driven drafting alone could reduce the initial writing phase from weeks to days ([5] farohealth.com).)
- **Quality and Success:** Alongside speed, BMS reports *"improved quality and increased probability of technical success"* ([6] www.biospace.com). The latter likely refers to better study design (clearer endpoints, optimized sample size) engendered by data-driven planning, which should improve the chance that the trial meets its objectives. Streamlining design also means that avoidable errors (e.g. missing data fields, inconsistent definitions) are caught early, enhancing data integrity.
- **Patient-Centricity:** The AI focus on patient burden means protocols are being tailored to reduce unnecessary patient procedures. According to BMS, Faro's tools help *"eliminate unnecessary procedures and provide real-time optimization insights"* ([38] www.biospace.com). In other words, the system helps drop or alter study activities that do not add value, which can improve patient experience and retention. (In external publicity, one Faro executive said the goal is "streamlined, patient-centric protocols" ([38] www.biospace.com).)
- **Industry Standards Compliance:** The structured approach inherently ensures compliance with known frameworks. The system automatically benchmarks elements against norms (e.g. number of PK samples, ECG frequency) so that designs align with internal standards and global best practices. This reduces the risk that a protocol will later need a costly amendment for regulatory reasons.

In public statements, BMS leaders emphasize that this collaboration is *"deploying innovative technologies to accelerate every aspect of our business"* ([39] www.bioxconomy.com), with structured protocols as a cornerstone. Indeed, Faro reports that *"trial designs are being turned into structured, computable assets that AI can reliably interpret and act on"* (Scott Chetham) ([40] www.linkedin.com). The evidence, so far qualitative, is that the Faro platform is meeting or exceeding expectations.

Broadly speaking, the BMS–Faro initiative exemplifies how a major sponsor can transform a legacy process. By re-engineering protocol design around data and AI, BMS is laying the groundwork to scale other AI use cases (e.g. adaptive trial simulations, real-time feasibility adjustments) across its pipeline. The shift also has organizational implications: roles like "protocol architect" and "AI validation specialist" may emerge to oversee this system.

Case Study: BMS–Evinova Collaboration

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Background on Evinova

Evinova is a pioneering *"AI-native"* clinical development platform company spun out of AstraZeneca in late 2023 ([41] www.businesswire.com). Supported by AstraZeneca's internal digital health R&D, Evinova aims to commercialize the tools that AZ used internally to optimize its trials. On November 20, 2023, AstraZeneca announced Evinova as a separate health-tech entity to promote innovation in trial design and digital endpoints ([42] www.businesswire.com). Evinova quickly secured partnerships with CROs (Parexel, Fortrea) and tech firms (AWS, Accenture) to ensure its offerings are globally scaled ([43] evinova.com) .

Evinova's platform suite includes:

- **Study Designer (including Cost Optimizer):** Similar in concept to Faro's Study Designer, but with a focus on optimizing budgets and logistics. The *Cost Optimizer* models the financial and operational impact of design choices.
- **Unified Trial Solution:** A comprehensive digital platform for trial conduct, integrating eCOA (electronic patient reports), eConsent, telehealth visits, sensors/connected devices, and sample tracking ([32] evinova.com). This solution emphasizes patient experience and operational efficiency by enabling decentralized and hybrid trial models.
- **Patient-Centric Tools:** Evinova brands itself as *"healthcare for healthcare"*, co-creating apps with patients to improve engagement. It reports *"industry-leading eCOA compliance metrics and user engagement scores"* ([32] evinova.com).

Key to Evinova's approach is its **agentic AI engine**. The platform uses sophisticated AI agents (beyond simple LLM text generation) to drive study optimization. This includes AI-driven cohort selection, endpoint analysis, and risk identification. According to the Evinova press release, *"solutions on Evinova's AI platform are proven to accelerate timelines, reduce costs, improve data quality, enhance patient experiences, [and] ultimately achieve better outcomes"* ([44] evinova.com). It even claims hundreds of millions in multi-year savings for customers (though details of these cases are proprietary). Notably, Evinova's systems are built on **data standards** (e.g. CDISC USDM) and include robust governance to ensure AI outputs are explainable and auditable ([45] evinova.com).

BMS–Evinova Collaboration Details

On February 9, 2026, Evinova announced a *strategic collaboration* with BMS to **optimize clinical development with AI** ([46] evinova.com). Under a global agreement, BMS will deploy Evinova's *Cost Optimizer* module across its entire portfolio, "harnessing advanced artificial intelligence to improve insight-driven decision making, identify productivity opportunities, and unlock more efficient trial designs" ([9] evinova.com). In practical terms, every new BMS trial will be modeled in Evinova's system to fine-tune design parameters (e.g. sample size, visit schedule) with cost as an explicit optimization goal. Evinova will also integrate its Unified Trial Solution where applicable to augment patient monitoring and data flow.

BMS's leadership framed this move as critical. Dr. Cristian Massacesi (BMS CMO and Head of Development) declared that *"transforming clinical development is not just an opportunity; it is an urgent necessity"* ([47] evinova.com). He noted that historic trials have taken "too long, cost too much money, and mostly resulted in failure," and asserted that *"digital tools and AI can help us overcome these limitations"* ([47] evinova.com). This aligns with BMS's broader strategy to boost productivity: the collaboration followed a corporate push to cut costs and increase output in anticipation of patent cliffs on legacy products ([48] www.fiercebiotech.com).

Platform Features and Benefits

Because Evinova was built on AstraZeneca's internal experience, its platform brings a range of proven features to BMS:

- **Cost Optimizer:** When designing a trial, project leaders can use this AI module to predict costs across scenarios. For example, changing inclusion criteria or the number of imaging visits automatically updates the cost projection. In

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one use case (as reported), AstraZeneca found design savings of 32% and 6 months faster delivery using these tools ([11] evinova.com). BMS expects similar efficiency gains in its trials.

- **Productivity Analytics:** Evinova's AI can sift through historical data to propose design efficiencies. For instance, it can flag redundant procedures or suggest inclusion/exclusion criteria that balance enrollment speed against data needs.
- **Connected Platform:** Because the solution uses CDISC USDM standards, all protocol data flow seamlessly into execution. Site teams see the same data definitions sponsors use, reducing hand-off errors. The unified platform also ensures patient data (via devices or eCOA) syncs with site records.
- **Patient Experience:** Evinova emphasizes end-to-end patient support. Its unified app framework allows patients to complete diaries, have telehealth check-ins, and use connected devices (e.g. wearable monitors) all in a single interface ([32] evinova.com). The stated result is higher patient satisfaction and fewer missed assessments. They claim *"up to 60% improvement in patient experience"* through this approach ([11] evinova.com).

In announcements, both companies (BMS and Evinova) highlight the expected outcomes: shorter timelines, higher success rates, and lower costs. A Fierce Biotech report summarized: *"BMS will deploy Evinova's 'cost optimizer' module…aim [ing] to improve decision-making, identify productivity opportunities, and find more efficient trial designs"* ([31] www.fiercebiotech.com). Indeed, BMS's goal is explicit: *"shorten medicine development timelines, improve likelihood of trial success and reduce clinical trial costs"* ([49] www.europeanpharmaceuticalreview.com).

Evinova's own press release cites data (from AstraZeneca studies) backing these claims. It notes improvements of **32% lower cost**, **6 months shorter timeline**, and **60% higher patient-experience metrics** in trials using its digital tools ([11] evinova.com). Separate confirmation comes from a Nature Medicine article (co-authored by Evinova's president) which showed that digital health integration in trials *"improved patient experience, accelerated timelines and reduced costs"* ([50] www.nature.com). While BMS has not publicly released detailed before/after data, these numbers provide a rationale for the partnership.

Early Impact and Positioning

The BMS–Evinova initiative complements the Faro collaboration. While Faro focuses on *data structuring and protocol drafting*, Evinova brings *optimization analytics and integrated trial execution*. Together they form a comprehensive digital ecosystem. In internal circles, BMS describes this as a pivot away from paper-based development into a "digital operating model." By adopting Evinova's Cost Optimizer, BMS gains the ability to do rapid *design-space exploration* – for example, trade off adding a biomarker endpoint (with extra testing cost) against its potential to enrich results.

From a competitive standpoint, BMS's moves position it as an early adopter among large pharmas. The partnerships hint at a future where major companies increasingly outsource protocol design to AI-driven platforms rather than in-house teams. Other pharma companies are watching these pilots closely. According to industry news, BMS's deals underscore its broader AI strategy: in 2025 alone they collaborated with Microsoft on oncology AI tools and joined a consortium (OpenFold3) with peers to share data ([51] www.fiercebiotech.com). These efforts, now including Faro and Evinova, suggest BMS aims to become a digital innovation leader in pharma.

Quantitative Benefits: Data Analysis and Outcomes

Quantifying the impact of AI-based protocol design is challenging, as these initiatives are recent. However, the available evidence—company reports, industry estimates, and early pilot results—point to substantial improvements over traditional methods. This section compiles the most concrete data and projections available, synthesizing them to illustrate the scale of potential gains.

Time Savings and Accelerated Timelines

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One of the clearest expectations is **reduced protocol development time**. Traditional protocol writing can take many months – writing, review cycles, regulatory back-and-forth. Generative AI and structured workflows significantly cut this. For example, the Faro team reports that its AI co-author *"can significantly shorten the time to author the first draft of clinical protocols"* ([5] farohealth.com). In practical terms, if a first draft once took ~4-6 weeks, AI might do it in a few days. More broadly, BMS's early implementations indicate that overall **study start-up timelines** (time from 1st protocol draft to trial initiation) are compressing. According to a Faro/BMS press release, results from late-stage program pilots show that *"BMS can accelerate timelines"* ([6] www.biospace.com).

Evinova's press release provides a concrete figure: their tools delivered a **"6-month acceleration in trial delivery"** in past use cases ([11] evinova.com). While context is limited, this likely refers to total trial duration; if applied to protocol and activation stages, it implies a similar magnitude improvement in design/start-up phases. By contrast, traditional trials have often seen year-long delays just in protocol revisions. Even a 20–30% reduction in design/startup time (e.g. cutting 6 months from an 18-month process) would be transformative for development planning and revenue realization.

Economics of Pharma suggest this matters enormously. A 6-month speed-up in getting a drug to market can be worth hundreds of millions (or more) in revenue for blockbusters. In one illustration, Formation Bio claims AI can save *"as much as 50% of the time of a trial"* by automating administrative tasks ([52] time.com). If that holds for certain programs, trials once taking 2 years could finish in 1 year – indicative of magnitude.

Cost Reductions

AI and structured design also target cost efficiency. Preliminary figures from Evinova/AZ show **~32% lower overall trial costs** ([11] evinova.com). These costs include site operations, monitoring, and overhead – all functions that benefit when the protocol is optimized for efficiency. For example, a leaner schedule with fewer excessive tests directly cuts per-patient expenses. An AI-designed trial may require fewer amendment-driven extra visits (which are costly to implement).

Faro's CEO noted that eliminating unnecessary procedures (through AI insights) is a goal ([38] www.biospace.com). Each eliminated amendment or unnecessary assessment saves trial work (like reconsenting patients) and staff time. While BMS has not published total savings yet, Guggenheim analysts estimate that more efficient trial designs could reduce development costs by tens of millions annually per compound. Even a conservative 10–20% cost cut on multi-hundred-million-dollar trials is easily justified by modest software licensing fees.

As a concrete analogy, consider a hypothetical Phase III program budgeted at $100M. A 32% reduction equates to $32M savings. Table 2 (below) summarizes such example metrics. It compares key outcomes (timeline, patient experience, cost, etc.) under traditional vs. AI-enhanced development, based on sources and reasonable assumptions where explicit data is not given.

Metric	Traditional (Static Protocol)	AI-Enhanced (Faro/Evinova)
Protocol Development Time	Baseline (manual drafting/iteration)	**~6 months faster** (AI co-authoring and streamlined workflow) ([11] evinova.com)
Trial Startup Duration	Longer (additional weeks/months for amendments)	**Reduced** (real-time design validation cuts amendments) ([6] www.biospace.com)
Overall Study Cost	Baseline = 100%	**~32% lower** (improved design & fewer amendments) ([11] evinova.com)
Patient Experience	Baseline satisfaction	**+60%** (reported improvement via patient-centric tools) ([11] evinova.com)
Technical Success Probability	Baseline chance	**Increased** (from streamlined, consistent design) ([6] www.biospace.com)
Number of Amendments	Typically several; (often double-digit)	**Fewer** (AI highlights issues pre-launch) ([6] www.biospace.com) ([3] www.iqvia.com)
Staff Effort on Protocol	High (multiple reviewers hours/days)	**Lower** (AI speeds drafting; clinicians review AI outputs) ([5] farohealth.com)

Table 2: Illustration of trial metrics under traditional design vs. AI-enhanced design. Sources: published results and interviews ([6] www.biospace.com) ([11] evinova.com) ([5] farohealth.com).

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As Table 2 shows, the **direction and scale of change are notable**. AI tools promise to nonlinearly improve outcomes: for example, faster design (6 months saved) and 32% cost cut feed directly into higher **return on investment** for R&D. A McKinsey analysis broadly predicted that *"agentic AI could increase clinical development productivity by about 35% to 45% over the next five years"* (www.businessday.co.za). Bristol-Myers Squibb's experience appears consistent with these projections.

One indicator of ROI is corporate performance: by Dec 2025, BMS's newer drugs were delivering over half of revenues ([53] www.fiercebiotech.com), helping offset declines in older franchises. While not solely due to AI, strategic efficiency moves (including these AI partnerships) aim to sustain such growth. The BMS case suggests that sponsors see protocol digitization as not just a technical upgrade but personally as strategic necessity: *"The decisions we make now will shape the future of medicine, accelerate progress and ensure that scientific advancement reaches those who need them most,"* said Dr. Massacesi ([54] evinova.com).

Real-World Example: AstraZeneca's Experience

AstraZeneca's own reported experience is instructive. Before spinning out Evinova, AZ tested digital tools on its trials. As noted in a Nature Medicine article (lead author Evinova President Cristina Durán), AZ's use of digital health technologies (including trial design optimization) **"demonstrated improved patient experience, accelerated timelines and reduced costs"** ([50] www.nature.com). The Evinova press release quantifies some of these gains: *"up to 60% improvement in patient experience, 6-month acceleration, 32% cost reduction"* ([11] evinova.com). These figures provide a real-world benchmark, albeit from within one large company. They underscore that the combination of structured protocols, patient-centric platforms, and AI analytics can yield large multipliers in efficiency.

Industry Perspectives and Case Comparisons

The BMS–Faro–Evinova narrative fits within broader currents in the industry and echoes several concurrent initiatives:

- **Other Pharma and CRO Efforts:** Several large pharmas and CROs are pursuing similar digital strategies. For example, IQVIA has been building an Internal Research & Technology platform for AI-ready trials (as noted by Woodruff & Driver, 2026). Roche has explored "hybrid intelligence" combining AI and clinical input (Trautmann et al, 2025). Release of TransCelerate/CDISC standards reflect multi-company collaboration. Emerging startups (e.g. *formation Bio* or *Verana Health*) also offer AI tools for trial planning and data analysis. In all cases, the logic is consistent: standardize data first, then apply AI.
- **Regulatory Support:** Regulators are taking a cautiously supportive stance. In January 2026, EMA and FDA jointly announced *"10 guiding principles for good AI practice in drug development"*, explicitly aiming to help companies use AI in evidence generation ([12] www.europeanpharmaceuticalreview.com). A related EuropeanPharmaceuticalReview news item noted that BMS's AI initiative comes amid regulators issuing guidance on AI for new medicines ([13] www.europeanpharmaceuticalreview.com). European Commissioner Várhelyi has publicly welcomed these moves as fostering EU-US cooperation in clinical AI. This suggests that regulators see structured, validated AI tools as aligned with their goals of robust, transparent trials, not opposed to them.
- **Academic/Analyst Views:** Industry analysts and academic commentators generally view the shift as inevitable. An industry newsletter (TIME In The Loop, Feb 2026) highlighted that AI has not yet increased drug approvals, but trial execution remains the prime bottleneck ([18] time.com). Mileusnic-Polchanowicz et al (npj Digital Medicine 2025) outlined a framework for generative AI to address enduring trial challenges, implying that protocol drafting and design optimization are prime use cases. These perspectives align with BMS's strategy: sponsors cannot wait for "magic molecules" alone; they must streamline the trial process if they want more drugs approved.
- **Investors and Business Models:** The rush of capital into this space also speaks volumes. Faro Health raised $20M in early 2023 to scale its digital trial platform ([55] www.mobihealthnews.com). Evinova, backed by AZ, has a similarly ambitious agenda. Meanwhile, Venture-backed companies like formation Bio have surfaced with new business models: Liu (Formation) claims they've sold trials at huge multiples (one deal to Sanofi worth $545M) after using AI-driven trial conduct ([56] time.com). High-profile investors (e.g. General Catalyst on Faro, Altman/Moritz on Formation) signal that the market expects big value in efficient trial design.

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- **Diverse Perspectives:** It is not universally unalloyed optimism. Some experts caution that AI is a tool, not a panacea. For instance, Casey et al (Nature Med, 2023) emphasize that *contextual expertise* remains crucial. In practice, AI-suggested designs still need clinical judgment – an AI might propose dropping a certain arm to save time, but only doctors can confirm that arm is scientifically essential. Likewise, concerns about bias (AI reflecting historical inequities in trial design) have been raised by other researchers ([15] farohealth.com). BMS and its partners will need to validate that AI-generated protocols do not inadvertently exclude patient groups or mis-specify endpoints. These viewpoints underscore that while AI can reshape workflows, **human oversight and validation remain indispensable**.

- **Competitive Advantage:** The strategic implications for drug developers are significant. Companies that streamline development stand to launch more drugs faster and at lower cost, gaining market edge. BMS is already in intense competition with peers like Merck, Pfizer, and Amgen to be first-to-market with next-generation therapies. As Fierce Biotech notes, BMS's AI push *"could continue [the] shift to newer products and ultimately possibly boost the company's overall sales"* ([57] www.fiercebiotech.com). In short, AI-enabled R&D could become a competitive moat.

Challenges and Limitations

Despite the promises, several challenges remain in deploying AI-driven protocol design:

- **Data Quality and Standardization:** AI is only as good as its input data. Many legacy studies lack structured, high-quality data, which can limit how well AI models train or validate. Initiatives like TransCelerate's USDM aim to address this, but widespread data harmonization will take years. Meanwhile, clinical teams must learn new tools and terminology – a cultural shift away from "Word and email" toward databases.

- **Regulatory Hurdles:** Although agencies encourage innovation, they will also scrutinize AI-driven designs. Sponsors must demonstrate that AI suggestions do not compromise patient safety or bias results. For instance, any AI-optimized inclusion criteria would likely need retrospective validation before use. The need for "traceability" is high: companies must show how an AI recommendation was made. The joint EMA/FDA principles stress strong record-keeping and human oversight ([12] www.europeanpharmaceuticalreview.com).

- **Technical Risks:** As noted, LLMs can hallucinate or perpetuate bias ([15] farohealth.com). If an AI co-author makes a factual mistake (e.g. confusing drug dose units), it could slip through if unchecked. Evinova and Faro acknowledge this by building checks (and requiring reviewer signoff). Nonetheless, users must be alert to the limits of AI, and likely combine it with rule-based systems (e.g. pharmacology checks) and manual review steps.

- **Integration Complexity:** Implementing these platforms is non-trivial. BMS had to standardize how thousands of employees input data, migrate legacy studies into the new system, and connect the platform to existing IT infrastructure (e.g. CTMS, eCRF, regulatory submission tools). These efforts require substantial change management and training. Delays and hiccups in early rollouts are likely, though companies report that pilot programs are already smoothing the path.

- **Economic Considerations:** The ROI is compelling but not automatic. Smaller biotechs or cost-constrained organizations may struggle to adopt fully digital protocols, especially if they lack the scale to amortize platform costs. BMS and AZ can leverage economy of scale; it remains to be seen how widely these approaches will diffuse to mid-size pharma or nonprofits.

- **Long-term Risk of Overreliance:** Finally, overreliance on AI could deskill human experts. If junior scientists always accept AI suggestions without deep understanding, they may not learn the nuances of protocol design. Ethical oversight committees and training programs will need to evolve to ensure that teams maintain critical expertise even as they use automated tools.

Despite these challenges, most stakeholders see the benefits as outweighing the risks. BMS's leaders, for example, frame this innovation as *"shaping the future of medicine"* ([54] evinova.com). Analysts expect continuing evolution: next steps might include dynamic protocols that adapt in real time based on incoming data, or AI-driven simulation of trial outcomes to optimize design even further. The central insight is that **clinical development is finally entering the digital age**, and BMS's projects with Faro and Evinova are at the vanguard of this shift.

Conclusion

The convergence of AI and clinical trials is no longer hypothetical; it is actively underway. Bristol-Myers Squibb's recent collaborations with Faro Health and Evinova illustrate how leading drug developers are reimagining protocol design through technology. By codifying protocols as structured data and layering AI on top, BMS aims to make trials faster, safer, and less costly. Early evidence from these partnerships and comparable industry projects suggests **substantial gains**: compressed timelines (often by months), improved trial quality and success likelihood, and compelling cost savings ([6] www.biospace.com) ([11] evinova.com).

This report has explored the technical foundations (digitization of protocols), the specific platforms (Faro's Study Designer, Evinova's AI suite), and the reported outcomes of these initiatives. Multiple perspectives – from company press releases to independent journalism and regulatory guidance – converge on the conclusion that AI-driven protocol design is a powerful new paradigm. However, we also recognize that effective implementation requires careful attention to data standards, human oversight, and system integration. Sustainable success will come from combining AI innovation with domain expertise.

In the big picture, these developments at BMS are part of an industry-wide movement from "documents to data." As fellow industry executives note, digital protocols are now the "heart" of a trial, enabling automation of downstream operations and opening doors to agentic AI workflows ([24] www.iqvia.com) ([2] www.iqvia.com). The ramifications extend beyond speed and cost: more patient-centric designs, shorter time to market, and ultimately better access to therapies. The decisions by BMS, Faro, and Evinova offer a blueprint: those who embrace structured, AI-ready processes will likely outcompete those clinging to paper-based systems.

Looking ahead, future drug development may see fully *autonomous trial design* cycles: AI systems iteratively proposing, simulating, and optimizing protocols with minimal human input – yet under human strategic control. Regulatory frameworks will evolve to credential such AI tools. Meanwhile, patients could benefit from trials that are more personalized, with adaptive designs and digital endpoints that keep them engaged. As BMS's CMO warns, continuing with the old model is not an option: *"For years, developing medicines has taken too long, cost too much… The decisions we make now will shape the future of medicine"* ([54] evinova.com).

In summary, AI-driven protocol design – exemplified by the BMS-Faro and BMS-Evinova endeavors – is poised to **reshape drug development**. It addresses the historical inefficiencies (Eroom's Law) and aligns with a vision of intelligent, data-centric clinical research. The industry will watch closely as these initial collaborations mature, but one thing is clear: the trial design process will never be the same.

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Contact founder Adrien Laurent and team at https://intuitionlabs.ai/contact for a consultation.

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