International Journal of Pharmaceuticals and Health care Research (IJPHR)

IJPHR |Vol.13 | Issue 3 | Jul - Sept -2025

www.ijphr.com

ISSN: 2306-6091

DOI : https://doi.org/10.61096/ijphr.v13.iss3.2025.375-381

Review

The Changing Face of Drug Development, Trends and Challenges

Patnana Vikas[1*], Kudupudi Jahnavi Sravanthi[1], Kotipalli Bhavani[1], Satish Kumar Vemavarapu [2]

[1]Intern, Clinoxy Solutions Pvt., Ltd., KPHB 9th Phase, Kukatpally, Back side Nexus Mall (Forum Mall), Near JUNTH University, Hyderabad. Telangana. 500085
[2]Founder and CEO, Clinoxy Solutions Pvt., Ltd., KPHB 9th Phase, Kukatpally, Back side Nexus Mall (Forum Mall), Near JUNTH University, Hyderabad. Telangana. 500085

*Author for Correspondence: Patnana Vikas
Email: vikaspatnana25@gamil.com

Check for updates

Published on: 18 Aug 2025

Published by:
Futuristic Publications

Abstract

Drug development remains a lengthy, costly, and high-risk endeavour, typically spanning 10–15 years and requiring approximately $2.6 billion in capitalized expenditure per approved therapy, a figure that does not account for the substantial variation across therapeutic areas. Traditional discovery methods, while historically impactful, suffer from low efficiency and high attrition rates. In response, a transformative shift is underway, fuelled by breakthroughs in artificial intelligence (AI), gene and RNA therapeutics, decentralized clinical trials, and real-world evidence. AI and machine learning are revolutionizing key early-stage processes, including target identification, virtual screening, predictive toxicology, and adaptive trial designs, which help reduce cycle times by up to 18% and propel multiple compounds into clinical evaluation. Although no AI-designed drug has reached the market yet. CRISPR, CAR-T, and mRNA therapeutics, principally driven by pandemic-era successes, are redefining treatment possibilities for genetic and infectious diseases. Parallel technical advances in digital health have enabled decentralized clinical trials, incorporating telemedicine, wearable sensors, and real-time data capture, enhancing efficiency and patient inclusion. Likewise, the integration of real-world evidence from electronic health records and patient-reported outcomes is enhancing regulatory decision-making and post-market safety assessments. However, this progress brings significant challenges: regulatory frameworks are struggling to adapt across jurisdictions; biologics manufacturing remains expensive and complex; data privacy and cybersecurity concerns are growing; and scalability risks widening global health disparities. Additionally, the recruitment of diverse and representative patient populations continues to be a major hurdle.

Keywords: Drug development, Drug discovery, Target identification, Artificial intelligence / Machine learning, Gene therapy, Cell therapy, RNA therapeutics (mRNA, siRNA, aptamers), Regulatory harmonization, Data privacy / Cybersecurity.

INTRODUCTION

Drug development is an inherently complex, cost-intensive, and high-risk endeavour. In 2013 alone, the Tufts Centre for the Study of Drug Development estimated that bringing a new molecular entity to market cost approximately $2.6 billion, with out-of-pocket expenses nearing $1.4 billion, though estimates vary widely by therapeutic area and methodology, spanning from $314 million to over $4 billion. [1] A substantial part of this investment stems from lengthy clinical phases: Phase I studies typically cost $25 million, Phase II around $59 million, and pursuing large Phase III trials can cost upwards of $255 million per study. [2] This journey, progressing through target identification, hit-to-lead optimization, preclinical evaluation, Phases I–III clinical trials, regulatory approval, and post-market surveillance, is marked by a staggering ~90% attrition rate, with only around 8% of Phase I candidates reaching market authorization. The high financial and scientific risk associated with conventional drug development has driven a technological renaissance. Innovations such as artificial intelligence(AI) and machine learning(ML) are being integrated into target discovery, virtual screening, predictive toxicology, trial design, and patient stratification, streamlining early stages and cutting costs by an estimated 25–50%.[3]

Alongside AI, gene and cell therapies, including CRISPR-edited vectors and CAR-T, have unlocked treatment options for previously intractable diseases. Meanwhile, RNA therapeutics**,** led by mRNA vaccine successes, are being explored beyond infectious illnesses, encompassing areas like oncology and rare genetic disorders.[4] The clinical trial paradigm is also transforming. Decentralized trials**,** powered by telehealth, wearable biosensors, and synthetic control models, enhance patient access and can reduce recruitment timelines.[5] In a complementary trend, regulatory bodies like the FDA and EMA are increasingly adopting real-world evidence (RWE) and data from electronic health records to bolster drug approval processes and post-marketing surveillance.[6] Despite this momentum, significant challenges persist. Regulatory frameworks struggle to keep pace with emerging modalities, cross-border induction of digital trials, and algorithmic transparency. Manufacturing scalable biologics remains exceedingly costly, while data privacy, cybersecurity, and inequitable global access threaten to exacerbate disparities. Additionally, ensuring patient diversity and robust representation in both traditional and decentralized trial models remains a steadfast obstacle [7]

The Landscape of Drug Development

Drug development is a complex, highly regulated, and capital-intensive process often spanning 10–15 years and incurring costs well into the billions per drug. For instance, Tufts CSDD estimated the average capitalized cost of a new drug at around $2.6 billion (in 2013 dollars), with an out-of-pocket R&D expense of approximately $1.4 billion. [8] The process typically proceeds through discrete stages: target identification/validation; hit-to-lead and lead optimization; preclinical studies; clinical trials (Phases I–III); regulatory approval; and post-market surveillance (Phase IV) [9].

Historical Evolution: From Serendipity to Rational Design

The Discovery of new drugs was long based on chance and natural sources, penicillin being a canonical example from 1928. Starting in the mid-20th century, drug development became more "rational," grounded in molecular biology insights. The completion of the Human Genome Project in 2003 ushered in the era of precision medicine, though translating genomic knowledge into successful therapeutics continues to pose significant challenges [10].

Emerging Paradigms and Trends in Drug Development

Artificial intelligence (AI) and machine learning (ML)

AI and ML are transforming drug development by improving prediction accuracy, speeding up workflows, and reducing costs. Traditionally, bringing a drug to market can take 10–14 years, cost around $1.3 to $2.6 billion, and suffer from clinical attrition rates near 90%, with only ~9–10% of candidates reaching approval. AI/ML techniques now support critical early-stage activities such as target identification, protein structure prediction, de novo molecule design, and biomarker discovery. Natural language processing (NLP) also enables the extraction of insights from unstructured biomedical literature and electronic health records. By analysing high-dimensional genomic and wearable-device datasets, AI helps usher in precision medicine and more streamlined lead optimization, significantly improving the productivity of drug discovery and preclinical testing. In clinical development, where operational inefficiencies and recruitment shortfalls are major obstacles, AI offers powerful solutions. Up to 80% of trials fail to meet enrolment targets, and 30% of Phase 3 trials fail due to recruitment issues, but ML-based tools now enable automated patient matching, optimal site selection, and real-time enrolment forecasting. These tools have been shown to improve enrolment rates by 10–20% and compress trial timelines by several months, contributing to significant cost savings and higher trial success probabilities. In the post-COVID era, decentralized and virtual trials are rising; AI helps monitor remote patients, enhance retention, and speed data analysis, boosting both trial resilience and overall efficiency. [11]

Artificial intelligence (AI), particularly machine learning (ML) and deep learning (DL), is now central to modernizing and accelerating drug discovery pipelines. These methods enable AI-driven virtual screening, quantitative structure–activity relationship (QSAR) modelling, ADMET prediction, target identification from multiomics datasets, and generative chemistry for novel molecule design. Meanwhile, graph neural networks and generative models enhance hit-to-lead optimization even for structurally complex modalities like peptides and PROTACs by combining AI with vast curated biological and chemical datasets. Drug discovery now proceeds with dramatically improved speed, precision, and innovation, marking a watershed shift in pharmaceutical research strategy. [12]

Gene and Cell Therapies

Technologies like CRISPR and CAR-T are offering groundbreaking therapies for rare diseases and cancer. Genome editing has advanced dramatically since early tools like ZFNs and TALENs paved the way with site-specific DNA modification. The arrival of CRISPR/Cas9, with its RNA-guided double-strand breaks (DSBs), transformed gene therapy by enabling relatively efficient gene disruption or correction via non-homologous end joining or homology-directed repair. To reduce risks associated with DSBs, next-generation genome editing tools have emerged: base editors (BEs) enable single-nucleotide changes (e.g., C→T or A→G) without DSB formation, while prime editors (PEs) use a Cas9 nickase fused to reverse transcriptase to install targeted edits, including all types of substitutions, insertions, and deletions, with improved precision and potentially fewer off-target mutations. These tools have opened therapeutic avenues for monogenic blood disorders and muscular dystrophies, though challenges remain in achieving efficient and safe delivery, high specificity, minimal off-target activity, and long-term safety. [11]

RNA Therapeutics

Emerging RNA-based modalities are reshaping infectious disease and gene therapy with high precision and programmability. Species-specific antibacterial antisense oligonucleotides (ASOs) are short (~10–12 nt) programmable RNAs that, when conjugated to cell-penetrating peptides (CPPs), selectively silence essential bacterial genes by binding near the ribosome-binding site, offering targeted antimicrobial effects with minimal microbiota disruption, though challenges persist in delivery mechanisms (e.g., transporter role like SbmA), resistance emergence, off-target activity, and specificity in vivo; transcriptomics and RNA-sequence are being deployed to characterize these effects and guide optimization. In parallel, small activating RNAs (saRNAs) of ~21-nt double-stranded length can upregulate specific genes by targeting promoter sequences and forming Ago2-dependent RITA complexes without cleavage, recruiting RNA polymerase II and cofactors such as RHA and CTR9. Finally, nucleic acid nanotechnology, including architecture DNA origami and spherical nucleic acids (SNAs), enables programmable self-assembly of complex nanostructures for precise cellular targeting, cargo delivery, gene regulation, and vaccine applications. DNA origami offers nanometre-scale control over shape and ligand positioning, enabling drug delivery, biosensing, and in vivo stability improvements via biomimetic coatings; SNAs' dense shells of oligonucleotides on nanoparticle cores provide enhanced cellular uptake, stability, and immunocompatibility for in vivo silencing and vaccine platforms. Despite progress, translational challenges remain around scale-up, endosomal escape, biodistribution, and long-term in vivo performance.[13]

Nucleic Acid Therapeutics

Nucleic acid-based therapies, including plasmid DNA, siRNA, and antisense oligonucleotides (ASOs), offer transformative potential against cancer and genetic disorders, yet their effectiveness hinges on overcoming intracellular delivery barriers. Viral vectors deliver genes efficiently but come with immunogenicity and mutagenesis risks and still dominate clinical pipelines, while safer nonviral methods (e.g., cationic lipids, polymers) often perform well in vitro yet falter in vivo due to poor serum stability and inadequate delivery in complex tissues. Nucleic acid delivery demands modality-specific carrier systems, precise physicochemical tuning, and serum-informed predictive models to translate in vitro potency into safe, robust in vivo efficacy.[14]

Decentralized/Digital Trials

Historically, randomized controlled trials (RCTs) conducted at centralized sites have been the gold standard for evaluating drugs and devices, but the COVID-19 pandemic exposed significant vulnerabilities such as disruptions to site access and participant recruitment. In response, the Food and Drug Omnibus Reform Act mandated that the FDA issue guidance to clarify and expand the role of decentralized clinical trials (DCTs). The FDA released a draft guidance in May 2023, followed by final guidance in September 2024 titled "Conducting Clinical Trials with Decentralized Elements", emphasizing both fully decentralized studies (with all activities remote) and hybrid models (combining remote and in-person elements). DCTs offer numerous benefits, including improved access for patients with geographic, mobility, or financial barriers; increased inclusion of older adults and racial/ethnic minorities; and the adoption of tele-health, local healthcare providers, and digital technologies that support real-world–relevant data collection and more agile operations. At the same time, these designs bring challenges such as ensuring data integrity across remote platforms, addressing inequities in wireless and tech access, maintaining protocol consistency across diverse settings, and securing informed consent and engagement without bias or compromise to trial validity. Though not intended to replace traditional RCTs, DCTs are increasingly seen as a complementary, flexible approach to making trials more inclusive, efficient, and responsive to real-world patient needs.[15]

The Decentralized clinical trials (DCTs) shift key activities such as investigational product administration and data gathering from traditional research sites to participant-friendly environments like homes, local clinics, or via tele-medicine in fully remote or hybrid formats, making them particularly well suited to chronic and rare diseases, immobile patients, and self-administered treatments, and adaptable to pragmatic clinical trial designs without altering core methodology. Concurrently, digital health technologies (DHTs), including wearables, sensors, and mobile apps, enable continuous, real-world data collection. For regulatory acceptance, DHTs must be rigorously validated as fit-for-purpose through the FDA's guidance "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations" and the Digital Medicine Society's V3 framework (verification, analytical validation, clinical validation), now expanded into V3+, which adds usability validation as a critical component. Ensuring equitable access through BYOD approaches where appropriate, alongside robust usability testing, is essential to support data quality, participant diversity, and regulatory compliance in DCTs and ensure that DHT-derived endpoints are scientifically meaningful and reliable.[16]

Real-World Evidence & Big Data

Patient preference studies begin with qualitative exploration through interviews, focus groups, or open-ended surveys to uncover patients' lived experiences, concerns, and the treatment attributes they find most meaningful. This exploratory work shapes the design of quantitative elicitation instruments, determining which attributes (e.g., efficacy, side effects, method of administration) and levels are included in the experiment. The most widely used elicitation method is the Discrete Choice Experiment (DCE): participants choose between two or more hypothetical treatment scenarios, each defined by a set of attributes and levels, often with an "opt-out" or status-quo option. This method mimics real-world decisions, allowing estimation of attribute importance and acceptable trade-offs, with regulators such as the FDA and organizations like NICE and Myeloma UK increasingly using it in benefit–risk assessments. DCEs and similar quantitative methods are particularly useful when real-world behavioural data are not available, such as with novel therapies or rare conditions. They help quantify how much additional risk or burden patients are willing to accept for a chance at greater benefit, though they carry a risk of hypothetical bias and may be burdensome when too many attributes are included or when cognitive demands exceed what participants can handle.

In the regulatory context, the FDA's guidance on Patient Preference Information (PPI) specifically encourages voluntary inclusion of well-designed preference studies in submissions for device approvals, to inform benefit–risk decisions. PPI is viewed as valid scientific evidence when conducted with rigor, covering aspects such as validity, representativeness, and transparency, and can even feature in labelling or decision summaries. Meanwhile, European initiatives like IMI-PREFER underscore the importance of methodological quality and patient centricity in designing and implementing these studies. Best practices identified through PREFER and MDIC frameworks recommend engaging patients not only as study subjects but as design advisors or collaborators, especially when refining research questions, selecting attributes and levels, and interpreting results. This enhances clarity, relevance, and the quality of data interpretation. However, estimates of desired involvement levels differ culturally and by patient experience, and some patients require substantial training and support to participate effectively.[17]

Challenges Accompanying Innovation

Regulatory Complexity and Fragmented Innovation Ecosystems

Modern therapeutic innovations, ranging from AI-driven diagnostics to gene and cell therapies, and decentralized clinical trials, face a fragmented regulatory environment. Although agencies like the FDA, EMA, and PMDA have begun updating policies to accommodate these new modalities, substantial variation remains across jurisdictions. Similarly, AI tools in healthcare lack universal classification; some regions treat them as software, others as medical devices, complicating submission strategies and compliance pathways. Compounding this is the nascent nature of guidance for decentralized clinical trials (DCTs). While the FDA and EMA have issued protocols emphasizing data integrity, telehealth privacy, and remote-site coordination, many jurisdictions still lack coherent regulatory frameworks for DCT design and oversight. This force seeks to tailor protocols to varying standards, raising cost, complexity, and timeline risk in multi-country programs. The challenge is further exacerbated by cultural and institutional inertia. Historically, regulators have evaluated new modalities using legacy paradigms rooted in traditional drug or device frameworks not updated to address live biologics, gene therapies, or adaptive AI algorithms. Internal system capacity also poses a challenge.[18]. Even when harmonization initiatives exist, such as the ICH for pharmaceuticals or IMDRF for devices, they often struggle to keep pace with rapid technological shifts, resulting in piecemeal consensus-building that lags behind innovation cycles. AI, meanwhile, sees regulatory divergence beyond geographical borders: the EU enforces a risk-based, precautionary AI Act, while the US adopts a lighter, industry-driven approach. These disparities create compliance friction, particularly for cross-border developers. The rapid emergence of novel modalities like medical AI, gene therapies, and decentralized clinical trials is outpacing regulatory evolution. Agencies vary greatly in classification approaches, data expectations, and signal detection frameworks, forcing sponsors into costly, time-consuming adaptation. While global initiatives like ICH, IMDRF, PREFER, and CoGenT aim to bridge the gap, the lack of true international harmonization continues to delay innovation, fragment market access, and elevate risks of regulatory non-compliance. [19]

Manufacturing Hurdles in Personalized Biologics & Gene Editing Therapies

High Capital Requirements & Facility Burden

Building and maintaining cGMP-compliant biomanufacturing facilities is extraordinarily capital-intensive. Investments in single-purpose cleanrooms, high-containment systems, and quality assurance infrastructure can range from tens to hundreds of millions of dollars. Even medium-scale biopharmaceutical plants may cost $80M–$150M just to establish. Continued operation demands consistent validation and strict contamination controls, adding to operational costs. [20]

Labor Intensity, Variability & QC Complexity

Manual processing dominates many personalized therapies, involving labour-intensive steps like cell isolation, transduction, expansion, purification, and fill-and-finish. Human-driven workflows introduce variability, raise failure rates, and drive labour costs, accounting for up to 50% of manufacturing expense. In contrast, full automation could reduce costs by as much as 70%. Quality control testing covering purity, sterility, identity, viability, transgene expression, and off-target edits is multi-layered and costly, sometimes adding up to $100,000 per treatment [20]

Standardization Gaps & CMC Challenges

Gene and viral vector therapies lack the mature standardization seen in monoclonal antibody production. Each product often requires bespoke Chemistry, Manufacturing, and Controls (CMC) strategies, including establishing critical quality attributes (CQAs), process parameters, and in-process testing. This bespoke approach is inefficient and error-prone, slowing scale-up across platforms [21]

Data Privacy & Security: Key Challenges in Digital Trials

Expanded Attack Surface & Frequent Breaches

With the widespread adoption of mobile apps, wearables, remote monitoring technologies, and cloud-based data capture, digital trials dramatically expand the number of endpoints handling Protected Health Information (PHI). This creates multiple potential points of vulnerability leading to high-risk exposure. In fact, studies show that around 70% of clinical trials report some kind of data breach often due to phishing, credential theft, or misconfigured cloud infrastructure [22]

Complex Regulatory Overlap & Compliance Gaps

Clinical trials must navigate multiple overlapping regulatory frameworks such as HIPAA in the U.S., GDPR in Europe, and evolving state-level privacy protections. HIPAA compliance requirements (e.g., encryption, access controls, breach reporting) significantly complicate trial operations. Some studies attribute research slowdowns and increased recruitment inefficiencies to HIPAA's privacy rules [23]

Risks from Third-Party Integrations & Vendor Management

Decentralized trial designs often rely on external vendors for data hosting, analytics, patient engagement platforms, or remote monitoring. Each additional vendor introduces new vectors for potential breaches if not properly vetted, monitored, and contractually bound to rigorous cybersecurity standards. [24]

Cyberthreats

Phishing, Endpoint Misuse, Cloud Misconfigurations, Digital trials are particularly vulnerable to spear-phishing attacks targeting trial administrators or sites. Moreover, endpoints such as smartphones or IoT wearables transmitting unencrypted data can be intercepted or manipulated. Cloud misconfigurations estimated to account for 80% of cloud-based breaches pose yet another major threat [25]

Lack of Real-Time Audit & Provenance Tracking

Maintaining data integrity across disparate systems and locations is difficult. To ensure compliance with regulatory standards (e.g., 21 CFR Part 11, ISO 27789), meaningful audit trails are required. Emerging solutions such as permissioned blockchain frameworks (e.g., Scrybe, smart contract systems) aim to enforce protocol compliance and immutable data provenance in real time [26]

Transparency, Consent & Ongoing Control Expectations

Patients increasingly expect transparent and granular control over how their data is used especially in research contexts where data may be reused later. Traditional one-time consent models are being challenged by dynamic consent frameworks, which allow participants to consent or withdraw permissions over time via digital interfaces [27]. Without such models, secondary uses of patient data (e.g., for AI training or future studies) can violate trust and legal norms.

Best-Practice Strategies

Recruitment & Representation: Digital Trials Still Leave Gaps. Persistent Barriers Despite Digital Reach. Digital Divide and Access Inequity. While virtual trials open doors geographically, they often exclude those without reliable internet, devices, or digital literacy, typically older, rural, older individuals, and underserved communities limiting inclusivity and generalizability [28]

Eligibility Criteria Narrowness: Stringent trial inclusion criteria (e.g., narrow age ranges, biomarker requirements) disproportionately exclude patients with comorbidities, translating to less representative cohorts. Competing Trials and Saturated Sites**.** In active research hubs, multiple trials targeting the same population lead to participant fatigue and reduced recruitment success.

AI-Enhanced Recruitment & Real-Time Monitoring: Emerging approaches like AI-driven site selection, resource allocation models, and real-time dashboards offer promise to identify outreach gaps and adjust strategies dynamically the result: better cohort representativeness across age, race, and geography [29]

E-Recruitment and E-Consent: Digital platforms featuring multilingual e-recruitment campaigns, user-friendly e-consent flows, and patient-matching tools can boost access but must be thoughtfully designed to overcome literacy and tech barriers [30]

Continuous Monitoring and Adaptive Response: Sponsors can use dashboard analytics to track representation metrics and pivot outreach such as targeting locales or demographics with low enrolment ensuring recruitment stays inclusive and balanced [31]

CONCLUSION

The drug development ecosystem stands at the cusp of a technological renaissance, marked by the integration of artificial intelligence, next-generation therapeutics, and digital health innovations. These advancements offer the potential to accelerate discovery, improve clinical trial efficiency, and expand treatment horizons for complex and previously untreatable diseases. AI and machine learning are reshaping the early stages of drug design, while gene and RNA-based therapies are redefining therapeutic modalities. Simultaneously, decentralized trials and real-world evidence are modernizing clinical research frameworks and regulatory evaluation. Despite this rapid progress, critical challenges remain. Regulatory systems must evolve to accommodate new technologies and ensure safety, efficacy, and transparency. The complexity and cost of biologics manufacturing, growing cybersecurity threats, and persistent health inequities, particularly in trial access and therapeutic availability, underscore the need for balanced, globally inclusive innovation. Moreover, achieving meaningful patient representation across all stages of development remains essential for generating equitable and generalizable health outcomes. To fully harness these emerging tools and methodologies, the pharmaceutical industry, regulators, healthcare providers, and policymakers must work collaboratively to establish adaptive, ethical, and patient-centered approaches. Only through such coordinated efforts can the promise of a faster, safer, and more equitable drug development future be fully realized.

REFERNCES

1. https://pmc.ncbi.nlm.nih.gov/articles/PMC11214120/
2. https://en.wikipedia.org/wiki/Drug development
3. https://itif.org/publications/2024/11/15/harnessing-ai-to-accelerate-innovation-in-the-biopharmaceutical-industry/
4. https://www.wired.com/story/artificial-intelligence-drug-discovery/
5. https://en.wikipedia.org/wiki/RNA_therapeutics

6. https://www.bing.com/search?q=file%3A%2F%2F%2FD%3A%2F27%2BInnovations%2Bin%2BDrug%2BDevelopment%2BFrom%2BSynthesis%2Bto%2BClinical%2BTrials.pdf&qs=n&form=QBRE&sp=-1&lq=0&pq=&sc=0-0&sk=&cvid=0792A429F95F4150B487BFA0E67E8934&ajf=10
7. https://pmc.ncbi.nlm.nih.gov/articles/PMC11769376/
8. https://www.wired.com/story/drug-research-pricing/
9. https://biomarkerres.biomedcentral.com/articles/10.1186/s40364-025-00758-2
10. https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291
11. https://pubmed.ncbi.nlm.nih.gov/34984579/.
12. https://pubmed.ncbi.nlm.nih.gov/36768346/
13. https://pubmed.ncbi.nlm.nih.gov/35188077/
14. https://pubmed.ncbi.nlm.nih.gov/20575003/
15. https://pubmed.ncbi.nlm.nih.gov/38693459/
16. https://scholars.duke.edu/publication/1665719
17. https://pubmed.ncbi.nlm.nih.gov/38846141/
18. https://pmc.ncbi.nlm.nih.gov/articles/PMC7505112/
19. https://www.mdpi.com/2076-3417/14/20/9304
20. https://www.pwc.be/en/news-publications/2023/how-to-overcome-manufacturing-challenges.html.
21. https://resilience.com/blog/overcoming-gene-therapy-obstacles.
22. https://www.linical.com/articles-research/cybersecurity-strategies-for-tech-enabled-clinical-trials
23. https://www.thompsoncoburn.com/insights/clinical-trials-part-ii-privacy-cybersecurity-risks-and-managing-ephi/
24. https://www.linical.com/articles-research/cybersecurity-strategies-for-tech-enabled-clinical-trials
25. https://www.linical.com/articles-research/cybersecurity-strategies-for-tech-enabled-clinical-trials.
26. https://arxiv.org/abs/2109.05649?
27. https://en.wikipedia.org/wiki/Dynamic consent?
28. https://www.nature.com/articles/s41746-022-00603-y
29. https://comac-medical.com/patient-recruitment-in-clinical-trials-comprehensive-guide-to-problems-and-solutions/
30. https://www.jmir.org/2024/1/e60504/
31. https://www.appliedclinicaltrialsonline.com/view/why-we-need-to-harness-real-time-data-to-truly-drive-diversity-in-clinical-trials.