



The Role of Clinical Trials with AI in the Herbal Industry & Modern Healthcare

Khushi A. Nilawar, Om R. Raghawar, Miss. Manisha G. Suryavanshi

Hi-Tech College of Pharmacy, Padoli Phata, Nagpur Highway, Morwa, Chandrapur 442406

Corresponding author Email: nilawarkhushi@gmail.com

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Abstract

Herbal medicine, deeply rooted in traditional healing system such as ayurveda, siddha, and Unani is experiencing a transformative shift towards scientific validation through clinical trials. This review examines the evolving role of clinical trials in herbal industry, emphasizing India's rich heritage within a global context. It highlights key challenges including phytochemical complexity, variability of raw materials, placebo design, regulatory fragmentation, and funding limitation. The integration of advanced technologies like artificial intelligence and blockchain is explored as a means to enhance trial design, standardization, and traceability. Clinical trials are essential for establishing safety, efficacy, regulatory compliance, and market credibility, thereby bridging traditional knowledge with modern evidence-based healthcare. Future direction focuses on harmonized international standard personalized herbal medicine, innovative delivery system, and culturally sensitive trial models to ensure the global acceptance and scientific. The evolution of position clinical trials as the cornerstone for transforming traditional herbal wisdom into validated, globally integrated healthcare solutions. AI serves as bridge, converting traditional knowledge into data driven procedure, even as traditional trials frequently struggle with the multi-component, multi-target, character of herbs.

Keywords: Herbal medicine, Clinical trials, Standardization, Regulatory frameworks, Modern Healthcare, Artificial Intelligence

Introduction

Herbal medicine has long been a cornerstone of traditional healthcare systems across the globe, particularly in India, where Ayurveda, Siddha, and Unani practices continue to influence public health. With over 70% of the population relying on plant-based remedies for primary care, the therapeutic relevance of herbal formulations is well established. However, the transition from traditional use to mainstream acceptance demands rigorous scientific validation. In recent years, clinical trials have emerged as a critical tool for evaluating the safety, efficacy, and pharmacological mechanisms of herbal products, aligning them with evidence-based medical standards. India's rich heritage of traditional medicine, particularly Ayurveda, Siddha, and Unani systems, has positioned it as a global leader in the herbal industry. The increasing demand for plant-based therapeutics, both domestically and internationally, has catalysed the growth of this sector.[1] Despite the widespread use of herbal products, their integration into evidence-based healthcare remains limited due to insufficient clinical validation. The global herbal medicinal products market is expanding rapidly, driven by consumer preference for natural therapies and the increasing burden of chronic diseases. Yet, despite their widespread use, many herbal formulations lack robust clinical data, limiting their integration into formal healthcare systems. A descriptive analysis of over 1,500 herbal clinical trials revealed that most studies employed randomized, double-blind designs, with capsules being the most common dosage form and sample sizes ranging from 50 to 240 participants across trial phases. These findings underscore the growing methodological rigor in herbal research, but also highlight persistent challenges such as standardization, placebo design, and regulatory fragmentation. Clinical trials serve as the cornerstone of modern drug development, offering a systematic framework to assess safety, efficacy, and pharmacological properties. In the context of herbal medicine, these trials are essential not only for regulatory approval but also for establishing

scientific credibility. However, conducting clinical trials on herbal formulations presents unique challenges, including phytochemical complexity, variability in raw materials, and difficulties in placebo design.[2]

The Indian government has taken significant steps to promote research in this domain through initiatives led by the Ministry of AYUSH, the Central Council for Research in Ayurvedic Sciences (CCRAS), and the Clinical Trials Registry - India (CTRI). Yet, a large proportion of herbal products still enter the market without rigorous clinical evaluation,

raising concerns about consumer safety and therapeutic reliability (World Journal of Pharmaceutical and Medical Research, 2024). [3]

Artificial intelligence is a subfield of computer science that focuses solely on problem-solving and building computers that can carry out jobs that would otherwise require human intelligence and operators. In this context, artificial intelligence (AI) is widely defined as a field that deals with the creation and application of algorithms for information analysis, learning, and interpretation. AI, also referred to as "computational intelligence," includes a variety of machine learning subfields, logic and probabilistic theories, pattern recognition, and biologically inspired techniques like neural networks, evolutionary computing, or fuzzy models.[29]

This review aims to synthesize current trends, challenges, and future directions in the clinical evaluation of herbal formulations. By examining documented trials of key Indian herbs—such as Ashwagandha, Turmeric, Giloy, Neem, and Triphala and exploring innovations like AI-assisted trial design and blockchain-based traceability, the article seeks to bridge traditional wisdom with modern scientific frameworks. Ultimately, it advocates for a harmonized, interdisciplinary approach to herbal clinical research that meets both regulatory expectations and global healthcare needs. [1]

The branch of research where cognitive activities, like promoting learning, reasoning, and self-correction, are carried out by machines or computer system to make robot behaves ad though they knew human behaviour is known as AI, and traditional complementary, and integrative medicine (TCIM). AI has the potential to completely transform healthcare through data-driven decision-making, individualized care, and analytical strategies.

Global Trends In Herbal Medications

The global herbal medicinal products market is experiencing robust growth, projected to reach USD 224.51 billion by 2030, with a compound annual growth rate (CAGR) of 7.58%. This expansion is driven by increasing consumer preference for plant-based therapies, particularly for general wellness, immunity, and chronic disease management. Tablets and capsules remain the dominant formulation types, accounting for over 46% of global revenue, while innovations such as nano formulations, standardized extracts, and combination therapies are gaining traction.

Traditional systems like Ayurveda, Traditional Chinese Medicine (TCM), and African herbal practices are influencing global product development. Regulatory frameworks vary significantly across regions—herbal products are classified as dietary supplements in the United States, traditional medicines in the European Union, and therapeutic agents in countries like India and China.

Emerging trends include AI-enabled phytochemical discovery, blockchain-based traceability, and personalized herbal medicine tailored to genetic and lifestyle profiles. Additionally, the rise of wellness tourism and demand for sustainable, ethically sourced botanicals are reshaping consumer expectations and industry practices. [9-10]

Artificial intelligence has enormous potential to improve patient care and lessen the workload for medical staff. By minimising errors and boosting precision, AI can drastically increase the efficiency and efficacy of healthcare delivery.

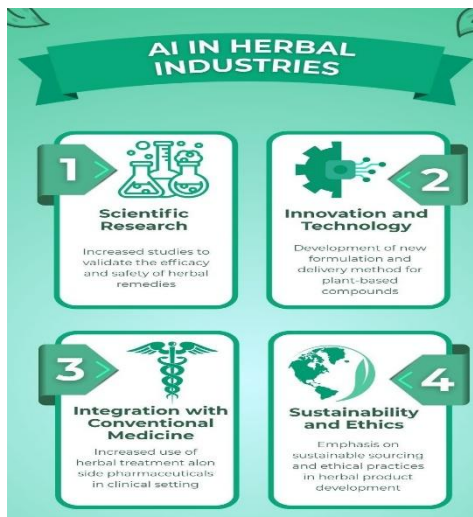


Figure 1: AI in herbal industries

Additionally, the application of AI may improve current clinical recommendations and broaden medical knowledge, propelling further developments in the sector. These potential for transformation is not without difficulties, though. A fundamental change in perspective about data sharing is required to overcome the crucial obstacle of obtaining extensive datasets required for training precise algorithms, promoting the advancement of this revolutionary technology. [30-31]

Background Of Clinical Trials In Healthcare And Herbal Medication



Figure 2: Clinical trials in healthcare

The global resurgence of interest in herbal medicine has prompted a critical need for scientific validation of traditional remedies. Herbal formulations, long used in systems such as Ayurveda, Traditional Chinese Medicine (TCM), and African ethnomedicine, are increasingly being integrated into modern healthcare. However, their acceptance within evidence-based medicine hinges on rigorous clinical evaluation.

Clinical trials in herbal medicine aim to assess the safety, efficacy, and pharmacological properties of plant-based products. Unlike synthetic drugs, herbal formulations often contain multiple bioactive compounds, making their evaluation complex. A descriptive analysis of published studies between 2019 and 2022 revealed that most herbal clinical trials employed randomized, double-blind, parallel designs, with capsules being the most common dosage form. Sample sizes varied across trial phases, ranging from 50 participants in Phase I to 240 in Phase IV.

Historically, the lack of standardized methodologies and regulatory oversight limited the credibility of herbal trials. In many developing countries, where traditional medicine is widely practiced, regulatory frameworks are still evolving. Meanwhile, countries like the United States and members of the European Union have refined their laws to accommodate herbal products, recognizing their therapeutic potential while ensuring safety and quality.

The increasing global demand for herbal products—driven by consumer preference for natural therapies—has accelerated the need for well-designed clinical trials. These trials not only validate therapeutic claims but also help in standardizing formulations, identifying adverse effects, and facilitating regulatory approval. As herbal medicine continues to gain traction, clinical trials serve as a vital bridge between traditional wisdom and modern scientific rigor. [11-12]

Healthcare and biomedical research trends are steadily changing as AI gets more and more integrated with medicine in a variety of domains. AI is being rapidly adopted by the traditional medical industry, including complementary and alternative medicine (CAM). artificial intelligence has the potential to improve the detection and quality mapping of traditional herbal remedies, resulting in more sophisticated techniques for their identification and verification. The best herbal combinations for treating conditions including Alzheimer's, asthma, and atherosclerosis can be accurately predicted using the TCMFP methodology, an inventive method for predicting traditional Chinese medicine formulae. This method combines network science algorithms and artificial intelligence with the fundamentals of traditional Chinese medicine. [34-35]

Neural networks and other artificial intelligence techniques can analyse botanical data, interactions, and medicinal results to produce herbal compositions that are optimised. As an illustration of the possibility for better patient outcomes in cardiovascular health, AI-generated drugs for blood pressure regulation have been developed to increase efficacy and decrease negative effects. AI can provide a clearer understanding of how medications interact with herbal remedies and uncover potential links that may provide dangers. Additionally, it can predict standard curves for herbal therapies with an astounding accuracy of 95.67%, improving the accuracy and efficacy of standardising these natural treatments.[29]

The Role and Scope Of Clinical Trials

In Herbal Industries

The herbal industry is undergoing a transformative shift, propelled by rising global demand for plant-based therapeutics and an increasing emphasis on scientific validation. While traditional systems such as Ayurveda, Unani, and Siddha have long relied on empirical knowledge, the modern herbal sector must align with evidence-based standards to ensure product safety, efficacy, and regulatory compliance. Clinical trials serve as the cornerstone of this transition, offering a structured framework to evaluate herbal formulations under controlled conditions and substantiate therapeutic claims.

Unlike synthetic pharmaceuticals, herbal products often contain multiple bioactive constituents, making their pharmacological assessment inherently complex. Clinical trials address this challenge by employing randomized controlled designs, blinding techniques, and placebo comparisons to generate reliable data. A descriptive analysis of herbal medicine trials revealed that most studies adopted randomized, double-blind, parallel designs, with capsules being the most common dosage form.



Figure 3: Role of clinical trials

In industrial contexts, clinical trials play a pivotal role in several key areas:

- 1. Product Standardization:** Trials help define optimal dosage, formulation consistency, and delivery mechanisms—critical for mass production and consumer safety.
- 2. Regulatory Approval:** Herbal products must meet the requirements of agencies such as CDSCO (India), EMA (Europe), and FDA (USA). Clinical data is often mandatory for market authorization and export clearance.
- 3. Market Credibility:** Evidence-backed products gain consumer trust and competitive advantage, especially in global markets where herbal medicine is often viewed with scepticism.
- 4. Innovation and R&D:** Trials encourage innovation by validating new combinations, delivery systems, and therapeutic applications of herbs, fostering growth in industrial research pipelines.
- 5. Safety and Efficacy Profiling:** Clinical trials help identify adverse effects, contraindications, and herb-drug interactions, dispelling the misconception that herbal medicines are inherently safe.

Despite these benefits, the scope of clinical trials in the herbal industry remains constrained by challenges such as lack of standardized protocols, variability in raw materials, and limited funding. Harmonization of international standards and increased government support—such as initiatives by the Ministry of AYUSH—are essential to expanding the reach and impact of herbal clinical research.

As the herbal sector continues to evolve, clinical trials offer a scientific bridge between traditional wisdom and modern medicine. They not only enhance consumer confidence but also support the integration of herbal products into evidence-based healthcare systems, ensuring that these formulations are not only culturally significant but also clinically reliable. [23, 26-27]

Regulatory Importance of Clinical Trials

In Formulations and Healthcare



Figure 4: Regulation through clinical trials

Clinical trials are a regulatory cornerstone in the development and commercialization of herbal formulations. While traditional systems like Ayurveda and Siddha rely on centuries of empirical use, modern regulatory frameworks demand scientific validation to ensure safety, efficacy, and quality. In this context, clinical trials serve as the primary mechanism through which herbal products can transition from traditional remedies to evidence-based therapeutics from a regulatory standpoint, clinical trials fulfil several critical functions:

1.Safety and Efficacy Validation: Regulatory bodies such as the CDSCO (India), FDA (USA), and EMA (Europe) require clinical data to assess the therapeutic claims and risk profiles of herbal products. Without such data, products may be restricted to use as dietary supplements or traditional medicines, limiting their market scope.

2.Compliance with International Standards: Clinical trials help herbal manufacturers align with global regulatory expectations, including Good Clinical Practice (GCP), pharmacovigilance protocols, and post-marketing surveillance. This is essential for export approval and international credibility.

3.Product Classification and Labelling: In jurisdictions like the United States, herbal products may be classified as botanical drugs or dietary supplements depending on the strength of clinical evidence. Trials determine whether a product qualifies for therapeutic claims or must be marketed with limited health indications.

4.Consumer Protection and Transparency: Regulatory agencies emphasize the need for transparent labelling, adverse event reporting, and risk-benefit analysis. Clinical trials provide the data necessary to support these requirements, protecting consumers from misleading claims or unsafe formulations.

5.Facilitating Innovation and Market Access: Clinical validation opens pathways for herbal products to be included in national formularies, insurance coverage, and hospital protocols. It also encourages innovation by allowing companies to explore new indications and delivery systems backed by regulatory approval.

In India, the Ministry of AYUSH and CDSCO have introduced frameworks to support herbal clinical trials, including the AYUSH Research Portal and integration with the Clinical Trials Registry–India (CTRI). However, global harmonization remains a challenge, as regulatory definitions and expectations vary widely across regions. [11, 18-19]

Mainstream Healthcare the holist nature of Traditional and Complementary Medicine (T&CM) is examined in recent research. which emphasizes the importance of herbal medicine and the need to include the views of numerous stakeholders in order to successfully integrate T&CM.it provides strategies for fostering acceptance and integrating herbal therapy with traditional medicine procedure.

Combining complementary, alternative, and modern medicine can improve patient outcomes, reduce cost and increase overall health these discuss the advantages of integrating herbal therapy with conventional pharmaceutical emphasizing which helps in reducing so many Sid effect and improve therapeutic outcome. It highlights the need of an all-encompassing approach in healthcare, emphasizing the benefits for practitioners, patients, and clients.[28]

Challenges in Performing Clinical Trials For Traditional and Modern Medicine



Figure 5: Challenges in integrating traditional and modern medicine

Despite the growing demand for herbal products and their therapeutic potential, conducting clinical trials on herbal formulations presents a unique set of scientific, regulatory, and logistical challenges. These complexities often hinder the generation of robust clinical evidence and limit the integration of herbal medicines into mainstream healthcare.[33]

1. Phytochemical Complexity

Herbal formulations typically contain multiple bioactive compounds, making it difficult to isolate and attribute therapeutic effects to specific constituents. This complexity complicates dose standardization and pharmacokinetic profiling.

2. Variability in Raw Materials

The quality and composition of herbal ingredients can vary significantly due to factors such as soil conditions, climate, harvesting time, and processing methods. Such variability affects reproducibility and consistency across clinical batches.

3. Standardization and Quality Control

Unlike synthetic drugs, herbal products often lack uniform standards for purity, potency, and stability. Ensuring batch-to-batch consistency is a major hurdle, especially in multicentric trials.

4. Blinding and Placebo Design

Herbal formulations often have distinct taste, colour, and aroma, making it difficult to design indistinguishable placebos. This can compromise blinding and introduce bias in randomized controlled trials.

5. Limited Funding and Infrastructure

Herbal clinical trials often receive less funding compared to pharmaceutical trials. Additionally, many institutions lack the infrastructure and trained personnel to conduct rigorous herbal research.

6. Regulatory Ambiguity

Regulatory frameworks for herbal products vary widely across countries. In India, while the Ministry of AYUSH and CDSCO oversee herbal trials, the lack of harmonized international standards creates barriers to global acceptance.

7. Ethical and Cultural Sensitivities

Trials involving traditional knowledge must navigate ethical concerns related to intellectual property rights, community consent, and cultural appropriateness of study designs. [11,20-21]

Herbal Formulations With Documented Clinical

Trials. [11, 15-17]

Table1: list of herbs with clinical trials

Herbal Formulation	Botanical Name	Clinical Use	Trial Design	Key Findings
Ashwagandha	<i>Withania somnifera</i>	Stress, anxiety, cognitive function	Randomized, double-blind, placebo-controlled	Significant reduction in stress and cortisol levels; improved sleep quality
Turmeric Piperine	<i>Curcuma longa</i> <i>Piper nigrum</i>	Inflammation, arthritis, metabolic syndrome	Parallel-group, placebo-controlled	Reduced joint pain and inflammatory markers; enhanced bioavailability with piperine
Giloy	<i>Tinospora cordifolia</i>	Immunity, post-viral recovery (COVID-19)	AYUSH-supported observational and interventional	Improved immune markers and recovery rates
Neem	<i>Azadirachta indica</i>	Antimicrobial, anti-diabetic	Small-scale randomized trials	Lowered blood glucose levels; effective against oral pathogens
Triphala	<i>Emblica officinalis</i> , <i>Terminalia chebula</i> , <i>Terminalia bellirica</i>	Digestive health, antioxidant support	Controlled trials with gut microbiota analysis	Improved digestion and antioxidant status; modulated gut flora

Future Directions for Clinical Trials in Herbal Formulations

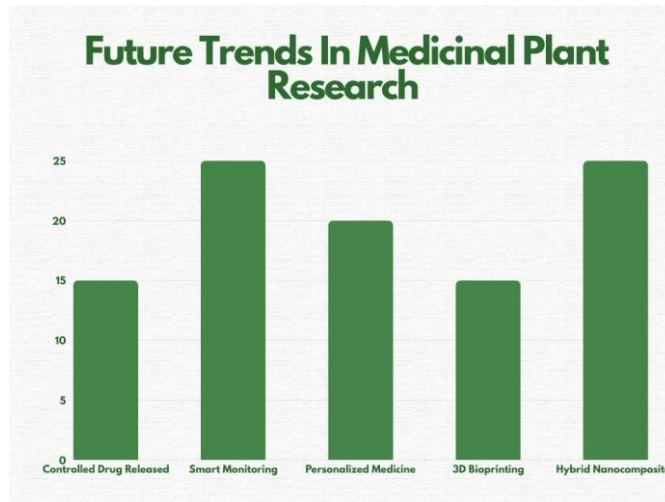


Figure 6: Future trends in medicinal plant research

As herbal medicine continues to gain global traction, future clinical research must evolve to meet scientific, regulatory, and consumer expectations. Several emerging directions are poised to transform the landscape of herbal trials:

1. AI and Machine Learning Integration

Artificial intelligence can optimize trial design, predict herb-drug interactions, and assist in phytochemical profiling. These tools enhance precision and reduce trial costs.

2. Personalized Herbal Medicine

Advances in genomics and microbiome research support the development of individualized herbal therapies. Trials may soon stratify participants based on genetic markers or lifestyle factors.

3. Global Harmonization of Standards

Regulatory convergence between CDSCO, EMA, FDA, and WHO is essential to streamline trial protocols and facilitate international product registration.

4. Advanced Formulation Technologies

Nano formulations, liposomal delivery, and bioenhancers are improving bioavailability and therapeutic efficacy. Clinical trials are increasingly evaluating these novel delivery systems.

5. Real-World Evidence and Digital Surveillance

Mobile apps and wearable devices can collect post-marketing data, enabling Phase IV trials and pharmacovigilance for herbal products.

6. Ethnopharmacological Trial Models

Culturally sensitive trial designs that respect traditional knowledge systems and community practices are gaining importance, especially in indigenous contexts.

7. Blockchain for Trial Integrity and Traceability

Blockchain technology can ensure transparency in trial data, patient consent, and herbal sourcing, enhancing regulatory trust and consumer confidence. [11,22-24]

Conclusion

A key component of connecting traditional knowledge with contemporary evidence-based healthcare is the clinical examination of herbal preparations. Herbal medicine has a long history and is widely used, but in order to prove safety, effectiveness, and regulatory compliance, rigorous clinical trials are still necessary for scientific validation. Regulatory fragmentation, raw material variability, placebo design, and phytochemical complexity are some of the issues that still prevent herbal medications from being fully incorporated into conventional treatment. However, there are encouraging opportunities to improve trial design, standardization, and traceability thanks to developments in technology like blockchain, artificial intelligence, and personalized medicine. Global acceptance and market credibility will be further facilitated by adopting culturally sensitive trial approaches and harmonizing international regulatory norms. The foundation for converting ancient herbal knowledge into proven, dependable, and internationally integrated healthcare solutions is ultimately clinical studies, which guarantee that herbal treatments satisfy modern scientific and consumer standards.

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