

## Review Article

# Enhancing dermatology clinical trials: optimizing sites and strategies for success in India

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**Received:** 16 June 2025

**Accepted:** 07 October 2025

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## ABSTRACT

India's diverse patient population, cost-effective ecosystem and high prevalence of dermatological conditions like chronic inflammatory skin diseases, pigmentary disorders, alopecia and infectious diseases, etc. make it a prime destination for global clinical trials. This article is based on author's experience in dermatology clinical research, web-based information from public domain including clinical trial registries, regulatory guidelines, review of literature, feasibility templates from sponsors and key industry conferences. It is the first of its kind to outline strategic approaches for optimizing dermatology clinical trial in India. This paper recapitulates importance of advanced diagnostic tools, site setup, infrastructure, regulatory compliance, ethical governance and institutional ethics committee (IEC) in enhancing site's credibility and attracting sponsors. Additionally, it highlights the research gaps in dermatology and provides a roadmap for sponsors, CROs and investigators aiming to conduct ethical, efficient and impactful dermatology trials in India. These insights aim to equip Indian dermatology sites to attract and manage high-quality clinical trials across all phases.

**Keywords:** Clinical trial site, CROs, Dermatology clinical research, Institutional ethics committee, Regulatory compliance, Sponsors

## INTRODUCTION

The global dermatology clinical research market is experiencing rapid growth, driven by the increasing demand for improved healthcare outcomes. National and international research initiatives are expanding, aiming to deliver better treatment solutions for a wide range of skin conditions such as pigmentary disorders, acne, dermatitis, inflammatory skin diseases, alopecia and other hair disorders, as well as skin cancer, particularly in skin of color. To address the growing need for innovative therapies, sponsors are conducting more multicentre studies across the world, placing greater pressure on clinical sites to meet evolving expectations. Success hinges on the efficient patient recruitment, retention and operational excellence.

This article offers an overview of strategies for optimizing dermatology clinical research sites, enhance

patient engagement and boost trial acquisition through improved infrastructure, technology and sponsor collaboration, particularly in the Indian market. This article summarizes data obtained from publicly available resources and the practical experience of the authors in dermatology clinical research in the Indian healthcare system, using a narrative review approach. Public Sources of Information: Data was gathered from the websites of Indian and global regulatory agencies and clinical trial registries (CTRI, CDSCO, ICMR), as well as publications and conference presentations. These sources assisted in establishing the understanding of existing benchmarks regarding trial feasibility, infrastructural regulations and compliance metrics.

## REVIEW

A broad literature scan using PubMed, Google Scholar and regulatory databases was done for peer-reviewed

journal articles, industry guidelines and dermatology articles. This shaped emerging practices in the conduct of clinical trials, patient recruitment, site infrastructure development and stratified patient care in dermatology.

### **Feasibility tools and templates**

Standard feasibility questionnaires provided by sponsors and CROs were studied to determine the minimum requirements regarding infrastructure, operations and staff for dermatology clinical trial sites.

### **Authors' experience**

The content reflects the real-world insights of the authors, who have significant experience managing dermatology clinical research operations in India. First-hand knowledge of site selection visits, ethics committee interactions, feasibility assessments and sponsor communications informed practical recommendations.

### **Professional conferences and industry events**

Important clinical research and dermatology conferences such as IADVL Dermacon, DIA India, ISCR, ACRP and SCOPE Summit which provided valuable direction on site-sponsor engagement, strategic networking and capability development.

### **Regulatory guidelines and national registries**

The review incorporated provisions from the New Drugs and Clinical Trials (NDCT) Rules, 2019; ICMR Guidelines (2017); and NABH accreditation standards. Protocol registration practices from CTRI were also reviewed to illustrate compliance and transparency.

## **IMPORTANCE OF CLINICAL RESEARCH SITES IN DERMATOLOGY TRIALS**

Clinical research sites are crucial for conducting high-quality dermatology trials, ensuring strict adherence to ethical guidelines, Good Clinical Practice (GCP) and regulatory standards.<sup>1-3</sup> A well-equipped site with experienced investigators, trained staff and access to diverse patient populations leads to reliable data, patient safety and study integrity.<sup>4-6</sup>

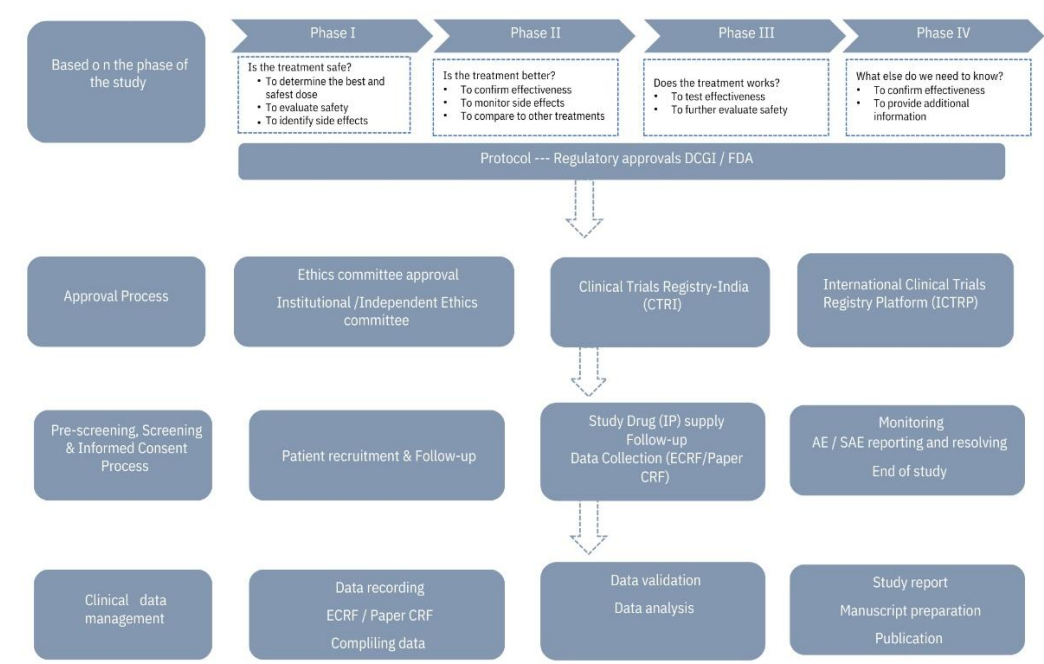
In dermatology, specialized knowledge in diagnosing and managing skin conditions, as well as the use of advanced diagnostic tools, is vital.

Research sites that implement effective patient recruitment strategies, utilize electronic data capture systems and ensure strict adherence to protocols can enhance trial efficiency and data accuracy.<sup>7</sup>

Collaboration with regulatory authorities and ongoing staff training further boosts the site's credibility positioning it as a preferred choice for sponsors and contract research organizations (CROs). Additionally, building strong relationships with sponsors, pharmaceutical companies and CROs increases opportunities trial acquisition (Table 1).

## **OPTIMIZING DERMATOLOGY CLINICAL RESEARCH SITES**

Workflow illustrating the key steps and processes involved in optimizing a dermatology clinical research site for efficient trial execution and patient engagement is depicted in Figure 1.



**Figure 1: Workflow of an optimized dermatology clinical research site.**

Table 1: Steps to build strong sponsor relationships.

Steps	Action
Proactive communication	Regularly engage with sponsors to express site capabilities
Maintain high-quality data	Provide reliable and accurate clinical trial results
Demonstrate strong enrolment	Show a history of meeting recruitment targets
Participate in conferences	Network at dermatology research events
Collaborate with CROs	Expand access to potential clinical trials

Table 2: Key infrastructure improvements for dermatology clinical research sites.

Infrastructure component	Improvement strategy
Dedicated clinical research space	Allocate exclusive rooms for documentation, monitoring, drug storage, patient visits and archival
Specialized tools and equipment	Include dermatoscopes, biopsy kits, calibrated scales, ECGs and centrifuges
Diagnostic laboratory	Establish access to NABL accredited labs, either in-house or via third-party tie-ups
Latest technology diagnostic tools	Ensure accurate assessments with AI-based skin analyzers, trichoscopy and dermal imaging
Digital imaging systems	Enhance documentation of treatment responses through high-resolution, standardized photography
Electronic data capture (EDC)	Improve data accuracy and regulatory compliance with integrated, real-time eCRFs
Telemedicine tools	Facilitate remote patient monitoring and virtual follow-ups to reduce dropout rates
Secure cloud-based storage	Protect patient data and streamline record-keeping using encrypted, HIPAA-compliant platforms

ENHANCING SITE INFRASTRUCTURE AND TECHNOLOGY

Investing in the right infrastructure and technology is key to meeting the demands of modern dermatology trials (Table 2).

Key infrastructure enhancements

Specialized dermatology tools

Sites equipped with dermatoscopy, along with the latest advancements and modifications in dermoscopy, AI-assisted diagnostic tools (e.g., DermaSensor), skin imaging systems for psoriasis and pigmentation disorders and hair analysis technologies for diagnostic accuracy, particularly for conditions like alopecia.<sup>8-11</sup>

Aesthetic and energy-based devices

Incorporating FDA-approved devices, such as fractional CO<sub>2</sub> lasers, pulsed dye lasers, Nd:YAG lasers and intense pulsed light (IPL), can significantly improve treatment outcomes for conditions like vitiligo, psoriasis and hair loss.

Energy-based devices, such as radiofrequency, high-intensity focused ultrasound (HIFU) and FMS (Functional Muscle Stimulation) devices, also contribute to effective treatments.<sup>12-16</sup>

Clinical trial readiness facilities

Dedicated rooms for documentation, investigational medicinal product (IMP) storage with controlled temperature (room temperature; 2°C to 8°C), aseptic drug preparation areas and access to calibrated equipment (centrifuges, ECGs, deep freezers, thermohygrometer etc) ensure readiness for trials involving pharmacokinetics, biopsies or long-term follow-up.

Electronic data capture systems

Integration with EDC and eCRF platforms enables real-time, accurate data collection. Coupled with EMRs and secure cloud storage, this supports regulatory compliance (e.g., HIPAA) and facilitates remote monitoring.<sup>17</sup>

Site support capabilities

Access to ICU beds, radiology, clinical laboratories with NABL accreditation and patient archival systems underlines operational maturity.

Data security and compliance

Cloud-based storage and encrypted communication safeguard patient data while ensuring regulatory compliance, such as HIPAA.

LEVERAGING PATIENT POOL AND INDICATION DIVERSITY IN SITE FEASIBILITY

A dermatology clinical research site’s most valuable asset is its patient population not just in terms of numbers, but also in terms of clinical diversity, demographic representation and diagnostic clarity.<sup>18</sup> In site feasibility assessments, sponsors are increasingly evaluating a site's ability to recruit across a broad spectrum of dermatologic conditions and to support inclusive trial designs.

Understanding the site’s patient pool

Sites with a steady monthly footfall of patients for common and complex dermatologic disorders such as alopecia areata (AA), androgenetic alopecia, psoriasis, vitiligo, acne, melasma, atopic dermatitis and lichen planus are naturally more attractive for multi-centre trials.

For example: A site that sees 50–100 AA patients per month, with 15–20 meeting specific SALT score ranges, demonstrates strong recruitment potential.

Patient registries can provide real-time data on sub-categories, such as severity of disease, Fitzpatrick skin types, gender distribution, treatment-naïve status and history of systemic or topical therapy.

Diversity of dermatology indications: clinical breadth matters

Sites that manage a broad dermatology caseload signal two strengths.

Diagnostic and interventional capability

The ability to differentiate between similar presentations (e.g., scarring vs non-scarring alopecia, pigmentary disorders, inflammatory dermatoses) improves inclusion accuracy and minimizes screen failures.

Flexibility for future studies

Sites handling diverse indications are well-positioned to support trials beyond one condition making them long-term partners for sponsors across multiple pipelines.

IMPROVING PATIENT RECRUITMENT AND RETENTION STRATEGIES

Effective recruitment and retention are key to the success of dermatology clinical trials. Dermatology trials face unique challenges in attracting suitable participants, so targeted strategies are essential.<sup>19</sup> Table 3 presents a comparison between traditional and digital recruitment methods.

Table 3: Comparison of traditional vs digital recruitment methods.

Aspect	Traditional recruitment	Digital recruitment
Reach	Limited to local clinics, newspapers and referrals	Global reach via social media, websites and online ads
Speed	Slower due to manual processes and paperwork	Faster with automated screening and online applications
Cost	Higher due to printing, staff involvement and outreach efforts	Lower with targeted online ads and automation
Targeting	Broad and less specific	Highly targeted based on demographics and interests
Engagement	Passive, relying on patients to respond	Interactive with real-time engagement through digital platforms
Data collection	Manual data entry, prone to errors	Automated data collection, reducing errors
Compliance & security	Traditional documentation and in-person verification	Digital consent forms with encryption and secure storage

Table 4: Roles and responsibilities of clinical research team.

Role	Responsibilities
Principal investigator (PI)	Overall responsibility for the trial conduct at the site. Ensure compliance with protocol, GCP and regulatory requirements. Oversee participant safety and well-being. Approve study data and documentation. Lead site team and maintain communication with the sponsor and CRO.
Sub-investigators (Sub-Is)	Assist PI in participant screening and clinical assessments. Ensure data accuracy and adherence to study protocols. Participate in managing adverse events (AEs) and serious adverse events (SAEs).
Clinical research coordinator (CRC)	Administer study procedures and treatments according to protocol. Schedule and conduct patient visits, ensuring proper documentation. Maintain study records and

Continued.

Role	Responsibilities
	ensure regulatory compliance. Collect, verify and report data. Assist with adverse event reporting and ensure participant safety.
<b>Medical writer</b>	Ensure trial data and results are accurately reflected in documents, consistent with source documentation and include proper statistical analysis. Create scientifically accurate documents that are easily understood by stakeholders, translating complex clinical data into clear narratives. Ensure that clinical study documents protect patient confidentiality, safety and rights; review ICFs for clarity and comprehension. Prepare necessary documents for submission to regulatory authorities, ensuring compliance with local, national and international regulations (e.g., Clinical Trial Registries, Safety Reporting)
<b>Site manager</b>	Oversee the operational aspects of the trial at the site. Manage budget, resources and scheduling. Coordinate between PI, CRCs and other staff. Ensure adherence to timelines and milestones.
<b>Regulatory/compliance manager</b>	Prepare and submit regulatory documents to ethics committees and regulatory bodies. Ensure all necessary approvals are obtained before trial start. Monitor ongoing regulatory compliance.
<b>Data manager</b>	Ensure accurate and timely data collection and entry. Resolve discrepancies or missing data. Work with CRC and CRA to ensure proper documentation.
<b>Study nurses &amp; phlebotomist</b>	Administer treatments and study-related procedures. Monitor and assess participant health. Collect biological samples (e.g., blood, urine). Record and report adverse events or health changes.
<b>Photographer</b>	Capture high-quality images of skin conditions at the start and throughout the study to monitor changes. Maintain unaltered images and adhere to data protection regulations to ensure accuracy and compliance. Provide visual documentation to complement clinical data. Adhere to study guidelines and work with the research team to ensure consistency and quality in documentation.

### ***Effective recruitment strategies***

#### ***Community engagement and physician referrals***

Collaborating with local dermatologists helps identify eligible patients and streamline recruitment.

#### ***Digital marketing***

Using platforms like Instagram and Facebook for targeted campaigns increases awareness and participation.

#### ***Patient registries***

Maintaining a patient registry for pre-screening candidates speeds up the recruitment process.

### ***Retention strategies***

#### ***Transparent communication***

Providing clear educational materials helps patients understand trial requirements and stay committed.

#### ***Convenience and comfort***

Offering flexible scheduling and a patient-friendly clinic environment encourages continued participation.

### ***Incentives and Follow-ups***

Offering incentives like transportation reimbursements and meal vouchers, combined with regular follow-up communications, enhances retention.

## **STRENGTHENING THE RESEARCH TEAM**

With the evolving landscape of clinical trials, particularly in India, it is vital to equip the research team, including the principal investigator (PI), study coordinators, scientific officers and co-investigators (Co-Is). Their roles have become more specialized and require continuous professional development and regulatory training.

Keeping the team updated on clinical trial regulations, such as those set by the Central Drugs Standard Control Organization (CDSCO) and the Indian Council of Medical Research (ICMR), ensures efficient trial management and compliance.<sup>1-3</sup> Roles and responsibility of research team is tabulated in Table 4.

## **INSTITUTIONAL ETHICS COMMITTEE**

IEC is an independent entity established to uphold ethical standards in clinical and biomedical research. In India, their formation and functioning are guided by the ICMR Guidelines (2017) for health research and the New Drugs and Clinical Trials (NDCT) Rules, 2019 for regulatory studies.<sup>2,6,20</sup>



**Committee composition**

IECs are multidisciplinary in nature, comprising scientific and non-scientific, as well as medical and non-medical members. These typically include clinicians, researchers, legal experts, social scientists and laypersons. Each IEC must have a written constitution and Standard Operating Procedures (SOPs) that clearly define member roles, appointment terms and quorum requirements.

**Key responsibilities**

Ethical and scientific review of research proposals

Continuous monitoring of trials and assessment of adverse events (AEs). Verification of informed consent procedures, safeguarding participant rights, privacy and well-being. Providing access to CDSCO officials for inspections and addressing regulatory concerns.

**Registration process**

According to Rule 122DD, introduced in 2013, IECs must be registered with the CDSCO via the SUGAM portal ([www.cdsoonline.gov.in](http://www.cdsoonline.gov.in)) before approving any clinical trial protocols. Under the NDCT Rules 2019, registration is valid for 5 years (previously 3 years).

For biomedical and health research, the Department of Health Research (DHR) grants provisional registration for 2 years, followed by final registration for 5 years after evaluation. Failure to comply with registration norms can lead to suspension or cancellation by the licensing authority.

**Accreditation and oversight**

To ensure quality and uniformity in ethics review, the National Accreditation Board for Hospitals and Healthcare Providers (NABH) has been designated by CDSCO to accredit IECs, principal investigators and trial sites.

**TRAINING INITIATIVES**

Ongoing training is essential for the success of dermatology clinical trials.

**Specialized dermatology knowledge**

The PI must be a certified dermatologist with clinical trial experience to ensure accurate study execution.

**Ongoing education**

Continuing Medical Education (CME) programs and Good Clinical Practice (GCP) workshops help staff stay updated on the latest dermatology research, trial methodologies and regulatory compliance.

**ENSURING ETHICAL AND REGULATORY COMPLIANCE**

Maintaining ethical and regulatory standards is crucial to ensure patient safety and trial integrity. Dermatology research sites must adhere to strict documentation, adverse event management protocols and regulatory compliance to guarantee high-quality trials.

**Compliance best practices****Comprehensive documentation**

Keeping up-to-date with EC approvals and informed consent forms ensures audit readiness.

**Adverse event management**

Following clear protocols for reporting adverse events (AEs) and serious adverse events (SAEs) protects patient safety.

**DERMATOLOGY CLINICAL TRIAL OPPORTUNITIES IN INDIA (PHASE I TO IV)**

India presents a dynamic and rapidly growing landscape for dermatology clinical trials, emerging as a key hub for global research across all phases. Sponsors are actively looking to conduct trials in India for: skin of color representation, diverse and high patient volume, availability of skilled dermatologists and investigators. Additionally, its cost-effective environment and evolving regulatory framework further enhance its appeal as a destination for clinical trials.

**Chronic inflammatory skin diseases**

Psoriasis, psoriatic arthritis, atopic dermatitis, vitiligo, urticaria, vasculitis and hidradenitis suppurativa, etc: High disease burden and increasing need for novel biologics, JAK inhibitors and small molecules.<sup>21,22</sup>

**Indian-specific variations**

Research focused on phototherapy responsiveness, genetic markers and immune-modulating therapies in Indian patients' population.

**HIGH-POTENTIAL DERMATOLOGY INDICATIONS****Pigmentary disorders and skin of color research**

Melasma, post-inflammatory hyperpigmentation (PIH), vitiligo need for tailored treatments for skin of color populations. Efficacy and safety studies of newer depigmenting agents, combination therapies, laser-based treatments and surgical treatment modalities.<sup>23,27</sup>

### ***Alopecia and hair disorders***

Androgenetic alopecia (AGA), frontal fibrosing alopecia (FFA), alopecia areata opportunities for stem cell therapies, exosome-based treatments, laser therapy and newer oral/topical interventions (e.g., oral minoxidil, JAK inhibitors).<sup>28-30</sup> Hair loss patterns in Indian populations and response to current treatment modalities.<sup>25,31-33</sup>

### ***Acne and sebaceous gland disorders***

Clinical trials on antibiotic resistance in acne, newer anti-inflammatory agents and personalized treatment approaches.<sup>34-37</sup> Indian skin microbiome studies to optimize probiotic and skincare formulations.

### ***Dermato-oncology***

Non-melanoma skin cancers (BCC, SCC), rare dermatological malignancies and pre-cancerous conditions.<sup>38,39</sup> Potential for Phase 1/2 trials of targeted therapies, immunotherapies and photodynamic therapy in an Indian setting.

### ***Infectious and neglected dermatological diseases***

Leprosy, fungal infections, scabies and cutaneous tuberculosis need for newer antifungals, antimicrobial resistance studies and improved diagnostic methods.<sup>40,41</sup> Impact of climate and environmental factors on emerging dermatological infections.

## **RESEARCH GAPS CAN BE ADDRESSED BY INDIAN TRIALS**

### ***Ethnic and skin type-specific studies***

Limited global clinical trial data on Indian skin phototypes (Fitzpatrick Skin Type III to IV). Need for studies on laser therapies, pigmentary disorders and side effects of existing treatments in Indian patients.

### ***Comparative effectiveness research***

Real-world data comparing cost-effectiveness, safety and efficacy of dermatological treatments between generic and branded drugs. Head-to-head trials of lasers, biologics, micro needling, PRP and chemical peels for scarring, pigmentation and skin rejuvenation.

### ***Personalized and precision dermatology***

Genetic, proteomic and metabolomic studies to develop customized treatment approaches. Role of AI and digital health tools in dermatology trials.

### ***Pharmacovigilance and long-term safety studies***

Post-marketing surveillance (Phase 4) for biologics, JAK inhibitors and systemic retinoids in Indian patients. Real-

world monitoring of drug-induced dermatological adverse effects.

## **ENHANCING RESEARCH SITE CLINICAL TRIALS IN DERMATOLOGY: STRATEGY FOR THE INDIAN MARKET**

Establishing strong collaborations with sponsors and contract research organizations (CROs) is a key strategy for increasing the number of clinical trials awarded to dermatology sites in India.

Effective networking serves as the foundation for building these valuable partnerships.

### ***Participate in key clinical research conferences***

Attend high-impact regional and international meetings that serve as touchpoints for CROs, pharma companies and trial networks.

*IADVL Dermacon (India)*: India's flagship dermatology conference.

*DIA India annual meeting*: Focused on regulatory science and drug development

*SCOPE summit*: Global site optimization and engagement

*ACRP India chapter events*: For professional development and site visibility.

*Indian society for clinical research conferences*. For association with Indian clinical research professionals. National and international conferences held by government bodies on drug regulatory authorities. These platforms are ideal for presenting site capabilities, networking with decision-makers and staying updated on sponsor priorities.

## **DIRECT ENGAGEMENT WITH CROS AND SPONSORS**

Proactively approach medical affairs teams and feasibility managers with your site dossier, infrastructure overview and PI credentials. WCreate a professional site capability presentation highlighting: indications handled (e.g., vitiligo, alopecia, psoriasis), monthly patient volumes, biopsy and Pharmacokinetics (PK) readiness, infrastructure and staff readiness, past and ongoing trial performance. Maintain a well-designed, informative website that showcases your research site's capabilities, available dermatology services, infrastructure, PI profiles and contact information. A strong digital presence not only enhances visibility but also builds credibility when CROs or sponsors assess potential sites. Ensure to register trials with the CTRI. This not only demonstrates transparency and regulatory compliance but also

improves visibility among national and international sponsors looking for verified Indian research sites

## REGISTER WITH CRO NETWORKS AND SITE MANAGEMENT ORGANIZATIONS

Many CROs maintain preferred site databases. Example: IQVIA Site Network, Labcorp Drug Development, Parexel Site Partnerships, PPD (Part of Thermo Fisher Scientific), biorasi, Syneos Health, ICON plc, Navitas Life Sciences, etc. Registration ensures visibility for dermatology studies.

## JOIN DERMATOLOGY-SPECIFIC GLOBAL TRIAL NETWORKS

Establish presence in indication-focused global associations. The international federation of dermatology clinical trials networks (IFDCTN). Global Vitiligo Foundation Trial Network–For pigmentation and autoimmune skin trials. International Federation of Psoriasis Associations (IFPA)—connects sites to sponsors targeting inflammatory skin conditions. Explore affiliations with disease registries, advisory boards and real-world evidence platforms relevant to Indian skin types.

## CONCLUSION

Enhancing the performance of dermatology clinical research sites requires strategic investments in infrastructure, technology and staff training, alongside patient-centric recruitment and retention strategies. By strengthening relationship with sponsors and maintaining compliance with ethical and regulatory standards, sites can increase their trial acquisition opportunities and contribute to the advancement of dermatologic treatments. India, with its diverse population and evolving regulatory landscape, presents a promising environment for dermatology trials, offering significant opportunities to address global dermatological needs. Sites that showcase readiness and build relationships through targeted networking are better positioned to attract more dermatology clinical trials and long-term sponsor collaborations.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: Not required*

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**Cite this article as:** Chandrashekar BS, Roopa MS, Narayana NL. Enhancing dermatology clinical trials: optimizing sites and strategies for success in India. *Int J Clin Trials* 2025;12(4):353-61.