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WHITE PAPER

Winning multiregional approvals in a diverse dermatology landscape

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Executive summary

As dermatology programs grow increasingly global, navigating diverse regulatory expectations becomes ever more complex. While certain requirements align, significant differences remain between agencies such as the FDA, EMA, and Asia Pacific (APAC) authorities (e.g. NMPA, PMDA, CDSCO) - particularly regarding demands for local data and the nuances of data standards and submission processes. This paper provides clarity on these evolving requirements, highlighting where strategies must adapt to meet regional expectations, and underscoring that regulatory planning and execution must go hand in hand to ensure successful approval across all markets.

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Introduction

The dermatology field in late 2025 stands out as a hub of innovation and scientific progress with breakthroughs in treatments for established conditions such as atopic dermatitis, alongside advances in addressing emerging infectious and immune-mediated skin disorders. Dermatology is one of the top ten most active trial areas across all indications currently monitored in the GlobalData clinical trials platform, with over 16,000 trials completed, ongoing or planned as of December 2025.

Globally, the traditional hubs for dermatology-focused trials are North America and Western Europe (especially the UK, Germany, and France), and parts of East Asia, notably Japan and South Korea. Recent years have also seen emerging markets in Eastern Europe and Asia-Pacific contributing swathes of new studies, especially for indications which have a high regional burden.

For instance, GlobalData epidemiologists estimate that there were 818.35 million total diagnosed prevalent cases of dermatophytosis in 2024, which is expected to slightly increase to 830.78 million diagnosed prevalent cases by 2029. The highest prevalence occurs in India, closely followed by China[i].

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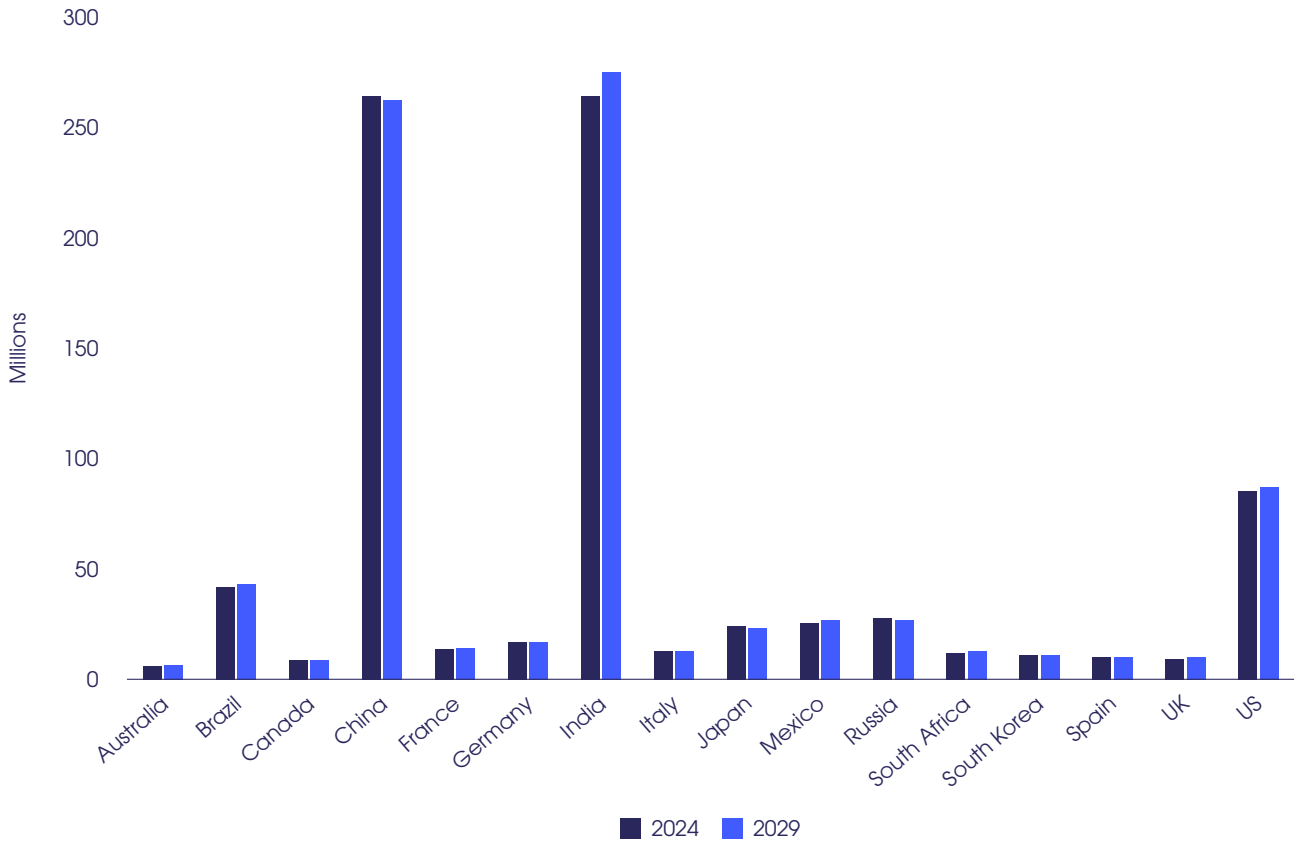
Figure 1: Diagnosed prevalent cases of dermatophytosis in 2024 and projected in 2029



Source: GlobalData, Pharma Intelligence Center, Epidemiology & Market Size Database; based on peer-reviewed literature, disease registries, and primary research. *Note: Cases represent 2024 and 2029 total diagnosed prevalent cases of dermatophytosis for both men and women.*

As a result, dermatology is a red-hot research area in emerging markets. Overall dermatology clinical trials in the APAC region (nearly 8,000) now dwarf those in both North America and Europe (just under 4,000 each) as of December 2025. In India, studies span a broad range of skin diseases (including atopic dermatitis, alopecia, fungal and bacterial infections, vitiligo, acne, and urticaria), encompass both interventional and observational designs, and include products ranging from well-established pharmaceuticals (e.g., minoxidil, tacrolimus, terbinafine) to ayurvedic and herbal formulations. Sponsors span leading pharma companies, research institutes, hospitals and medical colleges. In China, a mixture of Western pharmaceuticals and traditional Chinese medicine therapies dominate, often with multi-center and large planned enrollments. NMPA oversees authorization, conduct, and inspections of all clinical research conducted in China. The CDE, a division within NMPA, specifically handles technical reviews of clinical trial applications and new drug submissions.

Additionally, the latest data from GlobalData's *Atopic Dermatitis Competitor Landscape Trackers* saw new phase II and III studies initiated in North America, Europe and Asia in Q2-Q3, 2025.

Together, these trends underscore both the global growth of dermatological research and the vital need for ongoing innovation to meet patients' evolving challenges in a diverse, multiregional landscape.

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Chapter 1: Regulatory nuances and inclusive planning

Regulatory approaches concerning dermatology therapies and research differ notably between the FDA (US), EMA (Europe) and APAC regions, yet there is a growing trend towards global convergence and collaborative review models. For instance, the FDA is recognized for its streamlined and predictable regulatory pathway, especially in areas of high unmet medical need e.g. orphan drugs. This can result in faster approvals, as seen in instances where the US has granted accelerated access to innovative therapies that may still be under prolonged review within Europe[ii].

The EMA, in comparison, often exercises stricter scrutiny on clinical evidence and has more conservative requirements, especially regarding safety endpoints and long-term data[iii]. For companies seeking to introduce new dermatological treatments, expanding into the European market remains complex because of these stricter expectations and nuances in overall regulatory requirements.

Across APAC, regulatory frameworks can be less harmonized compared to the US and Europe, although countries like Japan and Australia are increasingly working towards mutual recognition and international benchmarks. Other regulatory agencies within the APAC region are aligning more closely with FDA and EMA standards, and collaborative initiatives are evident, such as draft guidance papers designed to streamline biosimilar approval requirements by factoring in drug mechanism of action and trial design harmonization[iv]. This helps reduce unnecessary duplication, especially for multinational studies, a critical factor in the globalization of dermatology trials.

Guideline adoption in dermatology also varies. US dermatologists often follow the American Academy of Dermatology and other national organizations. Meanwhile, European dermatologists look to the European Dermatology Forum, and national guidance such as NICE in the UK, whereas Japan utilises the Japanese Dermatological Association standards. Each region emphasizes different treatment algorithms and cultural preferences, reflecting local patient populations and regulatory priorities.

To summarize, it is essential to efficiently manage the differences in global regulatory requirements and practices throughout your study to minimize risk of success for your regulatory submissions.

The importance of diversity

Equally critical to dermatology research and therapy development is the inclusion of diverse skin phototypes- both skin color and genetic backgrounds- and an understanding of cultural factors. Dermatological diseases can manifest differently across skin types, and responses to both topical and systemic treatments may vary. Historically, many clinical trials and product developments have been based disproportionately on lighter skin types, leading to gaps in understanding efficacy and side effects in patients with darker phototypes. Addressing these disparities through better representation improves patient outcomes and enhances the reliability of research results.

Further, cultural factors influence both the prevalence and the perception of skin diseases, as well as adherence to prescribed therapies. For example, traditional medicines or cosmetics may interact with clinical treatments, while cultural attitudes towards conditions such as eczema or vitiligo can impact willingness to seek care and/or participate in trials. According to the National Eczema Association, African American patients represent 13.3% of the US population but only make up 5% of patients enrolled in clinical trials[v]. This is a major consideration for including patients of African descent into non-US trials. Only by embracing these differences can researchers and companies ensure that new products are both effective and truly accessible in the global market.

How do researchers harmonize overlapping challenges around navigating global regulatory pathways, promoting inclusivity and diversity in dermatology, and ensuring that research can benefit diverse populations worldwide?

Chapter 2: Overcoming multi-regional barriers in clinical trials

Multi-regional trials are essential for global drug development but face many challenges, including inconsistent endpoints and varying regulations. To overcome these multiregional barriers, sponsors can adopt three key strategies: unified endpoints and imaging methods, smart country/site mixes, and strict submission hygiene. These approaches align the trial's design and conduct across regions while pre-empting last-mile surprises in regulatory review.

Unified endpoints and imaging methods

Success in multi-country studies depends on measuring outcomes in a consistent way across all regions. Variability in criteria, technology, or expertise can make trial data heterogeneous and hard to interpret, potentially undermining the validity of results. Standardizing endpoints and the methods used to assess them, for example using the same diagnostic protocols, ensures that findings are truly comparable across sites.
This is especially crucial for imaging-based endpoints, where differences in equipment or image interpretation can skew results. The use of centralized imaging protocols or core laboratories establishes uniform standards for image acquisition and analysis, minimizing variability. Training all site personnel and employing central readers further enhances consistency, making multi-regional data more reliable and credible.

Smart country and site mixes

Careful selection of countries and sites - a smart mix - can pre-empt many multi-regional pitfalls. Select countries where trials are aligned with regulatory plans, considering local requirements for product approval and post-study access. Evaluate regional differences in patient characteristics and medical practices to ensure comparability or stratify enrollment accordingly. Include sites in key markets and prioritize diverse patient populations to support global approval and broad applicability of results.

Finally, choose experienced sites and provide unified protocol training to maintain high-quality, consistent data across all locations. By thoughtfully mixing countries and sites in this way, sponsors can maximize data quality and regulatory acceptability. The goal is a trial population that is broad enough to satisfy global regulators, but not so heterogeneous or uneven that it jeopardizes data integrity. Smart country selection also removes the risk of needing costly bridging studies post-trial.

Submission hygiene

Submission hygiene refers to the practice of keeping data, documentation, and regulatory plans clean and in order, so that nothing derails the final approval process. In a multi-regional context, this means anticipating and meeting the requirements of multiple agencies in advance. Key elements of submission hygiene include:

- Analyzing efficacy and safety for consistency across all geographical subsets and planning ahead for subgroup analyses and proactively investigating any unexpected differences. This reassures agencies that new therapies are effective both globally and locally.
- Addressing each region's regulatory requirements early. Obtain required plans or relevant waivers before key trials commence. Completing all region-specific commitments in advance helps to prevent last-minute submission barriers.
- Standardize data formats and documentation across sites by using unified electronic systems and aligning with international standards. Early engagement with regulators enables alignment on trial expectations, reducing surprises and ensuring your dossier is coherent, complete, and ready for inspection.

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What to do when regional authorities want local data

When regulatory bodies require local data, it is important to approach this proactively and strategically.

Plan ahead: Anticipate local data requirements early in the clinical development process. Review regional guidelines and consult with local experts to understand what constitutes local data for each authority.

Include regional subpopulations: Design your trial to enroll adequate numbers of participants from the regions where approval will be sought. This may involve setting specific enrollment targets for key locations.

Select sites strategically: Choose trial sites in each relevant geography to ensure the patient population reflects local demographics, disease characteristics, and standards of care.

Early regulatory engagement: Initiate dialogue with each authority to clarify expectations for local data, discuss acceptable endpoints, and address any questions about trial design and size.

Subgroup analyses: Plan for pre-specified analyses of efficacy and safety in local/regional subgroups. Be prepared to present these results separately, highlighting consistency or addressing any differences.

Address local practices and standards: Ensure that aspects of the study, such as dosing regimens, comparator treatments, or imaging protocols, are relevant and acceptable to local authorities and clinical communities.

Documentation and transparency: Keep thorough records of local data and site conduct to facilitate smooth inspection and regulatory review.

By addressing these steps, you can satisfy regulatory expectations for local data, support timely approvals, and demonstrate the relevance and safety of your product in target markets.

Chapter 3: The CRO advantage

A globally equipped Clinical Research Organization (CRO) provides the central expertise required to transform the complexities of multiregional clinical and regulatory requirements into one streamlined path toward approval. By aligning regulatory strategy across diverse regions, a capable CRO ensures the entire program is built on a shared understanding of local and global expectations and anticipates requirements from regulators such as the FDA, EMA, and those key APAC territories, proactively mitigating fragmentation before it arises.

Experienced CROs can leverage robust international relationships to open doors to the most suitable clinical sites globally, ensuring that patient recruitment encompasses both strategic geographies and the diversity regulators increasingly expect. Their capacity to harmonize training, particularly for visual dermatology endpoints, ensures that principal investigators and site staff have a unified understanding of lesion grading, digital imaging protocols, and endpoint adjudication, regardless of where the trial is run. This is vital in dermatology, where subjective assessments can undermine data comparability without robust central standards in place.

Importantly, a seasoned CRO builds and maintains inspection-ready quality systems that meet the highest expectations for data integrity and documentation, enabling smooth passage through inspections and audits, and prevents any last-minute surprises. While regional rules may start as a patchwork of unique requirements, a truly global CRO weaves them into a coordinated strategy: accelerating development timelines, minimising redundant work, and ultimately turning regulatory complexity into a clear, unified route to market approval.

Caidya: A world-class CRO

Achieving successful global dermatology clinical trials requires a nuanced understanding of regional regulatory landscapes and having in place proactive planning for diverse patient populations. A world-class CRO, such as Caidya, is instrumental in this process, providing the expertise and infrastructure needed to harmonize complex requirements and deliver consistent quality.

With a strategic foothold in North America, Europe, and Asia-Pacific, Caidya is adept at navigating the intricate requirements of clinical research, while its expert team offers bespoke regulatory strategy consulting, ensuring adherence to local regulations. With Caidya as their partner, sponsors can confidently translate regulatory complexity and operational barriers into a coordinated, inspection-ready strategy, accelerating timelines, reducing duplication, and enabling innovative dermatological therapies to reach patients quickly and equitably around the globe.

For sponsors pushing the boundaries of dermatological research, working with the right CRO is the secret ingredient for keeping the pipeline flowing. A multiregional research landscape requires a CRO with multiregional expertise; arrange a consultation with Caidya today to find out what this looks like.

References

[i] GlobalData: Dermatophytosis: Market View, September 2025.

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[iii] https://pmc.ncbi.nlm.nih.gov/articles/PMC6983504/

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