POSITION PAPER

Enrollment Without Compromise:

The Case for Latin American Dermatology Sites in High-Quality Clinical Trials

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Executive Summary

The clinical research industry has long treated Latin American sites as an afterthought, valued for speed and cost, but viewed with skepticism on data quality. For dermatology sponsors, this perception is both outdated and costly. The more important and largely overlooked story is this: Latin America harbors one of the largest untapped reservoirs of treatment-naive dermatology patients in the world. Patients who have never received a biologic, never enrolled in a prior study, and present with clean, unmodified disease histories that translate directly into lower screen failure rates, simpler protocols, and higher-quality data.

Precefi, Inc. operates a curated network of dermatology investigative sites in the Dominican Republic and Honduras, Panama, El Salvador and Ecuador. These sites that have demonstrated measurable, documented quality in active and past trials. In a current case study presented in this paper, two Precefi Dominican Republic sites outperformed 15 established Australian sites on the most demanding subgroup requirement in the protocol. This paper presents the evidence and makes the case that Latin American enrollment is not a quality trade-off It is a quality advantage.

1. The Enrollment Problem Sponsors Face

Patient recruitment remains the single most-cited cause of clinical trial delays. In dermatology specifically, several factors compound this challenge:

- Biopsy consent rates remain a persistent barrier in atopic dermatitis, psoriasis, and other inflammatory indications
- Phenotypic diversity requirements, particularly Fitzpatrick skin types IV through VI are difficult to achieve in predominantly Caucasian U.S. and European patient pools
- Site saturation in major metropolitan research hubs drives up screen failure rates and lengthens enrollment timelines
- Rising patient stipend expectations and competing trial availability reduce per-site yield in top-tier U.S. markets
- Treatment-naive patients are increasingly scarce in saturated U.S. and European markets patients in major research hubs have frequently been enrolled in prior studies, received biologics, or are concurrently screened for competing trials, all of which create washout requirements, screen failures, and data complexity that inflate timelines and cost.

> *85% of clinical trials fail to meet their initial enrollment timelines, with patient recruitment cited as the primary cause. Source: Tufts Center for the Study of Drug Development; LeapCure, February 2025.*

Latin American sites address each of these pain points with a structural advantage that established markets simply cannot replicate: an enormous, largely untapped population of dermatology patients who have never participated in a clinical trial, never received a biologic, and are actively seeking access to innovative therapies. In Latin America, treatment-naive dermatology patients are not a recruitment challenge, they are a recruitment opportunity available at scale.

2. The Quality Concern - and Why It Is Outdated

The skepticism around Latin American data quality is not without historical context. In the 1990s and early 2000s, under-resourced sites, inconsistent regulatory oversight, and limited EDC adoption created genuine data integrity challenges in certain markets. Those experiences understandably shaped sponsor risk frameworks.

The landscape has fundamentally changed. In the Dominican Republic and Honduras, two of countries where Precefi operates, the following conditions now exist:

- Regulatory bodies aligned with ICH GCP E6(R2) standards and FDA/EMA expectations for foreign clinical data
- Investigators with formal GCP certification, IRB-governed protocols, and multi-cycle audit experience
- EDC and eSource adoption that supports real-time remote monitoring, equivalent to U.S. standards
- Patient populations with high protocol compliance and low dropout rates due to limited access to investigational therapies outside of trials
- FDA audit history with no findings, multiple Precefi Latin American sites have undergone U.S. Food and Drug Administration inspections and emerged with zero findings, the highest possible validation of data quality and GCP compliance a site can receive

> *FDA inspectors do not grade on a curve for geography. When a Latin American site survives an FDA audit with no findings, it has met exactly the same standard as any site in Boston or San Diego. Precefi's Dominican Republic investigators have done exactly that.*

Sponsors who continue to apply 2005-era quality assumptions to 2026 Latin American sites are not managing risk; they are creating it by excluding high-performing sites from their networks.

3. The Precefi Model: Built for Quality From Day One

Precefi was purpose-built to eliminate the friction and variability that sponsors associate with multi-country site networks. Three structural elements differentiate our quality approach:

1 Contract. 1 Price. 1 Standard.

Our "1 Contract, 1 Price" model means every Precefi site, whether in the United States, the Dominican Republic, or Honduras, operates under a single, unified contract framework with consistent budget terms, SOP alignment, and quality expectations. Sponsors do not manage separate country agreements, separate IRB packages, or separate training protocols. This structural uniformity itself is a quality control mechanism.

Appiell: Real-Time Data Visibility

Precefi's proprietary virtual data capture platform, Appiell, provides sponsors and CROs with real-time access to trial data across all sites, including Latin American locations. Remote SDV, query resolution tracking, and protocol deviation flagging happen on the same timeline as U.S. sites. There is no data visibility gap.

Curated, Audited Investigator Network

Precefi does not aggregate sites, we qualify them. Each Latin American investigator in our network has been evaluated for GCP training status, prior trial experience, staff capacity, and patient database depth. Sites are onboarded with full SOP training aligned to our 22-SOP Master Binder, and they operate under active oversight from Precefi's clinical operations team.

4. Performance Data: What Our Sites Actually Deliver

The most compelling argument for Latin American site quality is not structural, it is empirical. The data below are drawn from a confidential Phase II atopic dermatitis study conducted by a U.S. based biotech sponsor. The study did not begin with Precefi or Latin America and that context is essential to understanding what the results mean.

The Backstory: 15 Australian Sites Couldn't Solve It

The study was initially launched in Australia, engaging 15 investigative sites across the country. The protocol presented two compounding challenges: first, identifying patients with moderate atopic dermatitis meeting strict inclusion criteria; second and most critically enrolling a subgroup of 36 patients with confirmed active Staphylococcus aureus skin infections, a key biomarker population central to the study's scientific hypothesis.

Australian sites struggled on both fronts. Moderate AD patients meeting the protocol's inclusion criteria proved difficult to identify at the required volume across all 15 sites combined. The staph-infected subgroup was even more elusive 15 sites collectively enrolled only a handful of qualifying patients against a target of 36.

> *15 Australian sites. 1 protocol requirement: 36 patients with active staph infections. Result: a few patients enrolled across the entire network.*

The Result: 2 Dominican Republic Sites Changed Everything

The sponsor engaged Precefi and activated two investigative sites in the Dominican Republic. What followed was not incremental progress. It was a decisive demonstration of what the right patient population, in the right market, with the right site infrastructure can accomplish.

Ninety total patients were enrolled across both sites in approximately four months, a period that included a two-week December holiday closure, making effective active enrollment closer to three and a half months. Of the 36 required staph-infected patients, the two Dominican Republic sites enrolled 32, nearly the entire subgroup target on their own.

Metric	15 Australian Sites	2 Precefi DR Sites
Number of sites	**15**	**2**
Staph-infected patients enrolled	**A few**	**32 of 36 target**
Total patients enrolled	**Limited**	**90**
Active enrollment period	**Extended**	**~3.5 months***
Screen failure rate	**N/A**	**10%**
Patient retention rate	**N/A**	**95%**

*4-month calendar period including 2-week December holiday closure at both sites.

90	32/36	95%
Patients Enrolled	**Staph Subgroup Enrolled**	**Patient Retention Rate**
2 DR sites in ~3.5 months	*vs. a handful across 15 AU sites*	*10% screen failure rate*

IRB Approval Timeline	Time to First Patient In	Total Enrollment Duration
6-8 weeks from submission to approval (Dominican Republic)	7 days from IRB approval to first patient enrolled	4 months, including 2-week holiday site closure

> "*The data coming from Precefi's Dominican Republic sites has been indistinguishable in quality from our U.S. locations and they enrolled faster.*"

> *[Sponsor Representative, confidential Phase II AD study, to be confirmed for attribution]*

These figures are not aspirational benchmarks, they are documented outcomes from an ongoing, actively monitored study. Sponsors evaluating Latin American site options are encouraged to request more information from Precefi.

5. The Enrollment Advantages That Compound Quality

Beyond quality parity, Precefi's Latin American sites deliver enrollment advantages that established U.S. and European networks structurally cannot match. These are not marginal improvements, they are categorical differences rooted in population demographics, disease epidemiology, and research participation history.

An Untapped Ocean of Treatment-Naive Patients

This is the single most important and least discussed advantage of Latin American dermatology sites. In the United States and Western Europe, research-active dermatology patients are a known and increasingly finite pool. Major academic and community research sites draw from the same databases, compete for the same patients, and manage the same downstream complications: prior biologic exposure requiring washout, concurrent trial participation requiring exclusion, and patients whose disease has been modified by years of systemic therapy.

In the Latin American countries, that dynamic does not exist. The vast majority of dermatology patients, including those with moderate-to-severe atopic dermatitis, psoriasis, alopecia areata, and fungal conditions have never received a biologic, never enrolled in a clinical trial, and have limited access to the advanced therapies that would otherwise disqualify them from participation. They are not a niche subpopulation. They are the mainstream.

> *Latin America does not just have more dermatology patients; it has the right kind of dermatology patients. Treatment-naive, protocol-eligible, and motivated. For sponsors designing studies that require clean baselines and uncontaminated disease histories, this is not a secondary benefit. It is the primary one.*

The practical impact is direct and measurable: lower screen failure rates, shorter washout periods, simpler medical histories, and cleaner baseline data. The 10% screen failure rate achieved in this Phase II study, against a U.S. dermatology average of 30–40%, is not a coincidence. It is the predictable result of recruiting from a population that has not been pre-treated, pre-screened, or pre-enrolled.

- **Fitzpatrick types IV–VI are significantly more prevalent in Latin America, meeting FDA guidance on diversity in clinical trials without targeted recruitment campaigns** Phenotypic diversity:
- **Atopic dermatitis including the moderate, staph-infected subtype carries higher population prevalence in Latin American markets. A recent Phase II study required 36 staph-infected AD patients. Fifteen Australian sites enrolled a handful. Two Precefi DR sites enrolled 32.** Disease prevalence and phenotype:
- **IRB/ethics review and regulatory approval in the Dominican Republic ran 10 weeks from submission to approval and sites were ready to enroll within 7 days of that approval** Regulatory timeline:
- **Principal investigators at Precefi sites maintain dedicated research staff, protocol-trained coordinators, and active patient databases, not a secondary research program layered onto a busy private practice** Investigator commitment:

6. A Strategic Regulatory Advantage: No IND Required

Beyond enrollment speed and patient quality, Latin America offers a regulatory structure that many sponsors have not fully considered and that creates strategic opportunities unavailable in the United States.

How the Regulatory Process Actually Works

In the United States, initiating a clinical trial with an investigational drug requires an active Investigational New Drug (IND) application on file with the FDA. The IND process involves chemistry, manufacturing, and controls data, preclinical safety summaries, investigator information, and a protocol submission before a single patient can be consented. It is a rigorous and time-consuming process by design.

In the Dominican Republic and Honduras, there is no FDA. There is no IND requirement. The path to initiating a clinical study runs entirely through the local Institutional Review Board and the country IRB (Conabios), the ethics committees responsible for protecting patient safety and rights under their SOP. Once both the IRB’s have approved the protocol and documentation package, the study can begin. The regulatory pathway is leaner, faster, and does not require a sponsor to have committed to a full IND strategy before generating human data.

This model is directly analogous to how Australia has operated for decades. Australia's well-established Clinical Trial Notification scheme allows sponsors to initiate studies with only ethics committee approval, without advance regulatory authority review, making it one of the most popular destinations globally for early-phase and exploratory clinical work. Latin America, through Precefi's network, offers the same fundamental advantage: IRB is the only obstacle between a sponsor and first patient in.

> *In Latin America, the IRB is the gateway not the FDA. Once ethics committee approval is in hand, the study is authorized to begin. No IND. No FDA review clock. No pre-IND meeting. Just a qualified site, a consented patient, and*

> *clean data.*

Strategic Use Case #1: Proof of Concept Without IND Commitment

For sponsors with early-stage compounds particularly those in dermatology where clinical signal in skin is critical before committing to a full IND development program, Latin American sites offer a pathway to generate meaningful human proof-of-concept data at a fraction of the regulatory cost and timeline of a U.S. IND study.

A sponsor who is not yet ready to file an IND, perhaps because the preclinical package is not fully assembled, because internal go/no-go decisions are still pending, or because the risk profile of the compound warrants exploratory human data before committing to full development can conduct a properly IRB-approved, GCP-compliant study in Latin America and generate the clinical signal data needed to make that decision with confidence.

The data generated at Precefi's Latin American sites is collected under ICH GCP E6(R2) standards, monitored in real time through EDC, and fully defensible for use in a subsequent IND submission or regulatory package. Proof-of-concept data from a well-run, IRB-approved Latin American study is not a compromise, it is a strategic asset.

Strategic Use Case #2: New Indication Exploration for Approved or Late-Stage Drugs

The second use case is equally compelling for a different type of sponsor: one who already has an approved drug or a compound in late-stage clinical development and wants to explore whether it has efficacy in an adjacent or entirely new dermatology indication before committing to a full IND-governed label expansion study.

Filing a supplemental IND or a new IND for a label expansion indication is not a trivial undertaking. It involves regulatory strategy decisions, CMC considerations, and a significant investment of time and internal resources all before a sponsor knows whether the drug actually works in the new indication. For a sponsor trying to make a go/no-go decision on a potential label expansion, running an exploratory study at Latin American sites under IRB governance only without triggering a full supplemental IND process can provide the clinical intelligence needed to justify that investment, or save the cost of making it prematurely.

This is not a regulatory workaround. It is a legitimate and well-established approach to early clinical signal generation, and it is precisely what Precefi's Latin American network is positioned to support: fast activation, naive patients, experienced investigators, clean data and no IND required to get started.

> *Two of the highest-value scenarios in drug development proving a new compound works in humans and expanding a successful drug into a new indication both benefit from a regulatory environment where the IRB, not the FDA, controls the starting line. That is exactly what Latin America offers.*

7. The Operational Complexity of Latin America - Fully Managed by Precefi

Working in Latin America introduces a specific set of operational challenges that sponsors should understand before committing to an international site strategy. These are real complexities and they are precisely why choosing the right SMO partner is not optional. Precefi was built to absorb every one of them, end to end, so that sponsors experience the benefits of Latin American enrollment without inheriting the burden of managing it.

Document Translation - Precefi Handles It

Every clinical trial document operating in the Dominican Republic or Honduras must be available in Spanish: informed consent forms, protocol summaries, patient diaries, site-facing SOPs, regulatory submissions, investigator brochures, and all sponsor correspondence. A full trial document package can run hundreds of pages. Every page must be professionally translated, reviewed for clinical accuracy, and approved by the local ethics committee before a single patient can be consented.

Translation errors in clinical documents are not cosmetic. A mistranslated eligibility criterion or adverse event reporting instruction can create protocol deviations and regulatory findings that follow a study through NDA submission. Precefi provides complete Spanish-language document translation and QC review as a standard service, managed internally, not outsourced to a generic translation vendor. Sponsors deliver their English-language documents. Precefi delivers submission-ready Spanish packages.

Import/Export Licensing and Drug Shipment - Precefi Handles It

Investigational medicinal products cannot be shipped to Latin American sites the way they are distributed domestically within the U.S. Cross-border IMP shipment into Latin America requires import licenses, health authority permits, temperature-controlled freight coordination, customs clearance documentation, and in-country chain-of-custody verification all before a vial reaches a site pharmacist.

Precefi manages the complete import/export process through established local partners in both markets, including obtaining all required licenses and permits, coordinating qualified freight carriers, managing customs documentation, and verifying IMP receipt and storage at the site level. Drug supply timelines are built into the feasibility plan from day one, so sponsors are never caught off guard by a customs hold or permitting delay midway through study startup.

Latin American CRAs - Precefi Provides Them

High enrollment velocity creates a monitoring burden that standard CRA staffing models are not designed to absorb. When two sites enroll 90 patients in 3.5 months, concurrent CRA coverage across both locations is not optional it is a requirement. Multiple monitors must work in parallel to keep pace with source documents, consent forms, eCRF entries, and protocol-required assessments being generated in real time.

Precefi maintains a network of trained, Spanish-speaking Latin American CRAs who are familiar with local regulatory expectations, site documentation practices, and the cultural dynamics of monitoring in these markets. CRA staffing is sized to enrollment projections at the feasibility stage, before the first patient is screened, so that monitoring capacity is never the bottleneck to enrollment speed. Sponsors do not need to source, vet, or manage local monitors. Precefi provides them.

Country-Specific Regulatory Processes - Precefi Knows Them

This is among the most underestimated challenges in Latin American clinical research: every country operates under a distinct regulatory framework, with its own ethics committee structure, health authority submission requirements, approval timelines, and documentation standards. What works in the Dominican Republic does not automatically apply in Honduras. What a sponsor learned from a prior trial in Mexico or Brazil may bear little resemblance to the requirements they will encounter in the markets where Precefi operates.

Sponsors who attempt to navigate this without in-country expertise routinely experience submission errors, requests for additional documentation, and approval delays that were entirely avoidable. Precefi provides precise, country-specific guidance on regulatory pathways and realistic approval timelines for every market in our network. We tell sponsors what to expect, when to expect it, and what to prepare before the clock starts, not after a submission comes back incomplete.

> *Every country in Latin America has a different regulatory body, a different submission process, and a different approval timeline. Precefi removes the anxiety of navigating that complexity with direct, on-the-ground knowledge of each market we operate in. Sponsors get a clear roadmap, not a surprise.*

8. The Real ROI: Speed to Market, Not Line-Item Savings

When sponsors evaluate Latin American sites, the conversation often gravitates toward per-patient costs and site fees. That is the wrong lens. While Precefi's Latin American sites do offer some cost efficiencies relative to comparable U.S. markets, the monetary difference at the per-patient level is not transformative. The transformative value of Latin American enrollment is measured in something far more significant: time.

What a Single Day of Delay Actually Costs

For decades, the clinical research industry cited a figure of $4 to 5 million per day of delay in drug development. In May 2024, the Tufts Center for the Study of Drug Development published a rigorous, peer-reviewed analysis in Therapeutic Innovation & Regulatory Science that updated this estimate with current, empirical data across 645 drugs and 409 clinical trial budgets.

The updated figures: each day of delay in drug development costs approximately $500,000 in unrealized prescription drug or biologic sales, plus $40,000 in direct clinical trial operating costs, a combined $540,000 per day. Across all therapeutic areas analyzed, dermatology was specifically identified as one of the highest daily direct-cost categories, with Phase III trials running approximately $55,700 per day in direct costs alone.

> *$500,000 per day in lost drug sales. $40,000 per day in direct trial costs. Dermatology is among the highest cost therapeutic areas. Source: Smith ZP, DiMasi JA, Getz KA. "New Estimates on the Cost of a Delay Day in Drug Development." Therapeutic Innovation & Regulatory Science. May 2024. Tufts Center for the Study of Drug Development.*

Translating Days Into Dollars

Using the Tufts CSDD figures, the math is straightforward. A **three-month** enrollment acceleration, fully achievable, as demonstrated in our Phase II AD case study, is worth approximately **$48.6 million** in combined recovered sales and avoided trial costs. A **six-month** compression, the kind that becomes possible when Latin American sites replace a stalled international network approaches **$97 million.** These are not theoretical projections. They are the direct application of peer-reviewed cost estimates to real enrollment timeline differences.

Timeline Compression	Recovered Sales Value	Combined Value (+ Trial Costs)
1 Month (30 days)	**$15.0M**	**$16.2M**
3 Months (90 days)	**$45.0M**	**$48.6M**
6 Months (180 days)	**$90.0M**	**$97.2M**

Based on Tufts CSDD figures: $500,000/day lost sales + $40,000/day direct trial costs. Smith ZP, DiMasi JA, Getz KA. Therapeutic Innovation & Regulatory Science, May 2024.

First to Market Wins - Especially in Dermatology

In competitive dermatology indications atopic dermatitis, psoriasis, alopecia areata being second to market is not just a revenue disadvantage. It is often a market share disadvantage that persists for the life of the product. Prescribers develop treatment habits early. Payers establish formulary preferences around the first approved agent. Patients who achieve disease control rarely switch.

An enrollment strategy that compresses the Phase II or Phase III timeline by three to six months by activating Latin American sites with genuinely treatment-naive patient populations and the operational infrastructure to move fast, is not a logistics decision: It

is a competitive strategy measured in tens of millions of dollars and years of market position.

> *The savings from Latin American enrollment are real, but per-patient cost differences are not the story. The story is $540,000 per day recovered by getting to market faster. At three months of acceleration, that is nearly $49 million. At six months, it approaches $100 million. That is the ROI of the right site network.*

9. Risk Mitigation: How Precefi Protects Sponsor Data

For sponsors who wish to apply formal risk mitigation to Latin American site inclusion, Precefi offers a structured oversight framework:

- Pre-study site qualification visits and documentation review
- Unified SOP alignment and protocol training prior to first patient in
- Real-time data monitoring through EDC with sponsor-configurable access
- Scheduled remote SDV at a frequency defined in the Monitoring Plan
- Dedicated Precefi clinical operations contact for each sponsor program
- Joint sponsor/Precefi oversight calls on a cadence determined by risk classification

This framework is not an add-on; it is standard for every Precefi engagement, at every site and in every geography.

Conclusion

In Latin American clinical research, speed and quality are not a trade-off; they are a standard. Precefi's sites across the region demonstrate that enrollment velocity and data integrity are mutually reinforcing; they are both achievable and both are amplified by the single most powerful structural asset Latin America offers: droves of treatment-naive dermatology patients who have never been touched by a biologic, a competing trial, or the research saturation that plagues U.S. and European markets.

For dermatology sponsors facing the twin pressures of diverse patient recruitment and accelerated timelines, the question is no longer whether Latin American sites are ready. The question is whether your trial can afford to keep ignoring them.

> *To request more information from Precefi, schedule a feasibility consultation, or discuss protocol-specific enrollment projections for our Latin American network, contact: rich@precefi.com | precefi.com*

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ABOUT PRECEFI, INC.

Precefi, Inc. is a specialty Site Management Organization (SMO) focused exclusively on dermatology, ophthalmology, and aesthetics clinical trials. Operating under a "1 Contract, 1 Price" model across U.S. and Latin American investigative sites. Precefi offers sponsors the reliability they expect, the speed they need and the therapeutic focus and operational standards sponsors rely on. Precefi's proprietary virtual data capture platform, Appiell, supports real-time trial oversight across all geographies.