YPrime

Clinical Trials Run on Certainty

Optimizing Dermatology Trials: Your eCOA Platform Playbook

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Introduction

Dermatology trials place unique demands on sponsors because of the volume, frequency, and subjectivity of the data being collected. Endpoints often combine investigator scoring, patient-reported symptoms such as itch or pain, and visual assessments of symptoms that may change over time.

Because skin conditions can change rapidly and differ widely in presentation, sponsors must manage variability in assessments, ensure protocol adherence, and maintain continuity in how data is captured throughout the study. This makes operational execution, site alignment, and ongoing oversight central to trial success in dermatology programs.

Skin conditions are visible, dynamic, and deeply tied to quality of life. From psoriasis and atopic dermatitis to alopecia and hereditary angioedema, dermatologic endpoints rely on both patient perception and investigator observation.

In this environment, electronic Clinical Outcome Assessments (eCOA) have become essential. eCOA enables sponsors to capture what patients experience in a consistent, validated, and regulatory-compliant manner—reducing burden for sites and participants while improving data quality and audit readiness.

Yet, not all eCOA platforms are designed for dermatology's unique demands. Many dermatology studies incorporate photographic references to support and standardize investigator grading of disease severity, redness, lesion characteristics, or treatment response, often alongside visual scoring and frequent symptom diaries that must remain tightly aligned with protocol design. To ensure high-quality, reliable data, sponsors need an eCOA platform that is flexible, scalable, and intuitive for every user—patients, sites, and monitors alike.

The Reality of Modern Dermatology Trials

Patient-centered outcomes have long been foundational to dermatology research, reflecting how visible disease and symptoms influence daily comfort, functioning, and quality of life. As trial designs have evolved, so have expectations for how these experiences are documented, with increasing emphasis on standardized capture, attribution, and auditability across diverse study settings.

Today's Dermatology Trials Face Challenges Such As:

- Integration of investigator grading, symptom-based PROs, and photographic representations to support consistent assessment of visible disease.
- Execution across diverse geographic regions, requiring validated translations and culturally appropriate symptom frameworks.
- Increasing use of remote photography to support decentralized participation.
- Variability in disease presentation across skin tones and phototypes, with implications for scale selection and visual interpretation.

Legacy systems—and especially paper—cannot keep pace. Sponsors need an eCOA platform that adapts in real time, maintains audit-ready traceability, and scales globally without compromising scientific quality.

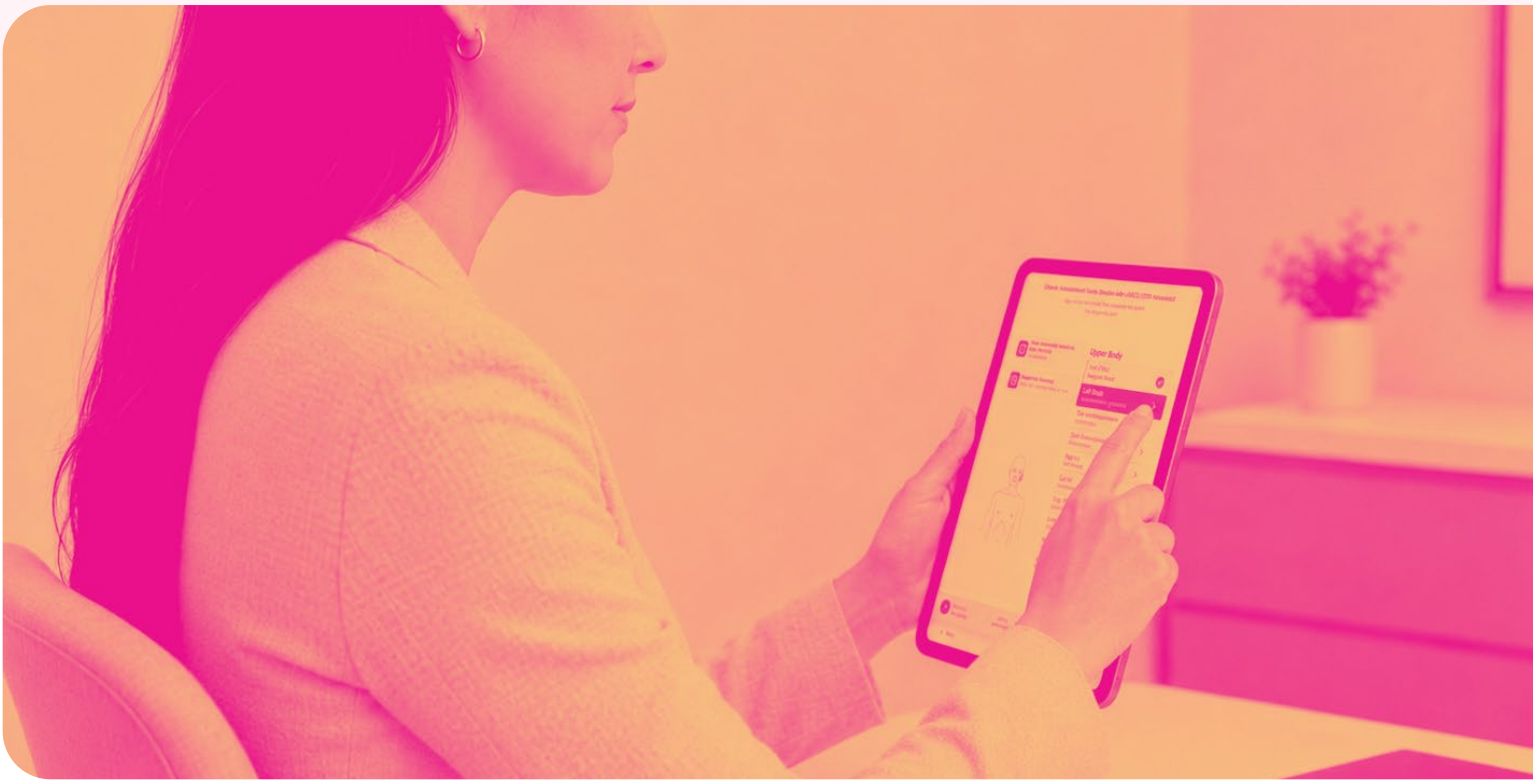
Why eCOA is a Scientific and Operational Imperative for Dermatology Trials

In dermatology, the participant experience is central to therapeutic benefits. Symptoms like itching, burning, pain, and social embarrassment are highly subjective, yet critical to evaluating treatment efficacy.

eCOA enables sponsors to:

- Capture real-time patient-reported outcomes on itch, pain, sleep disruption, and emotional impact (including depression and suicidal ideation when relevant).
- Standardize workflows and ensure consistent image display and visual aids for scoring and grading.
- Provide timestamped, audit-ready data for inspection and submission.
- Ensure global data consistency across languages, devices, and regions.
- Improve adherence and accuracy through reminders, intuitive workflows, and user-centric design.

Both the FDA[1] and the EMA[2] encourage electronic capture of PROs and ClinROs to ensure reliability, completeness, and auditability—key factors in visually assessed or self-reported endpoints.



A Platform Designed for Dermatology's Unique Demands

YPrime's eCOA platform is engineered to handle the full complexity of dermatology studies—from high-frequency symptom diaries to photographic ClinRO assessments, body-mapping interfaces, and complex visit structures.

Key Capabilities Include:

01

Image Capture and Validation

- YPrime's eCOA platform enables secure, protocol-aligned image capture that integrates seamlessly into site-based workflows while preserving patient privacy and data integrity. Images are captured according to protocol-defined anatomical regions, ensuring consistency, traceability, and inspection readiness.
- Built-in quality checks ensure required image capture so that images are referenceable, allowing for additional rater review or assessment of severity over time.
- Every image is fully traceable, with audit trails linking it to the associated visit, assessment, questionnaire administrator, device, and timestamp. YPrime enables consistent visual documentation that supports investigator grading, longitudinal comparison, and inspection-ready traceability across sites and regions.

02

Visual Scoring and ClinRO Integration

- Support for standard dermatology scales such as PASI, EASI, and IGA, ensuring reliable investigator scoring.
- Ability to embed reference images and radio-button visual selections directly within forms—providing consistent grading across sites.
- Clinician specific access that aligns photographic references and patient-reported data for a holistic view.

03

Patient-Centered UX/UI Design

- Developed in partnership with YPrime's UX team, the eCOA interface enables intuitive body-map selection and image-based symptom reporting.
- Supports 50+ unique selection points for precise region-specific data capture.
- Event-driven data entry allows patients to log flares or symptom spikes in real time.

04

Global Language and Translation Expertise

- AI-powered migration across all languages, combined with YPrime's strong relationships with licensing and translation partners.
- Deep experience navigating copyrighted instrument licensing, screenshot review processes, and regulatory translation requirements.

03

Seamless Integration and Real-Time Oversight

- Direct interoperability with IRT, EDC, and connected devices/wearables for unified trial management.
- Configurable dashboards and alerts flag missing data or late entries.
- Study teams can intervene proactively to maintain high data quality and site compliance throughout execution.

Real-Time Visibility. Confident Oversight

In dermatology trials, endpoint integrity depends on more than structured data capture. Sponsors need clear visibility into scoring patterns, image capture, diary compliance, and site performance across regions.

YPrime delivers centralized reporting and data visualization that allow study teams to monitor assessment trends, identify variability early, and proactively address risk. Integrated dashboards surface key metrics such as PASI scoring consistency, missing image alerts, participant diary adherence, and site-level performance signals.

By connecting dermatology assessments directly to reporting and portfolio-level data views, sponsors move beyond passive data collection and into active study oversight. The result is faster insight, reduced downstream reconciliation, and stronger inspection confidence without adding operational burden at the site level.

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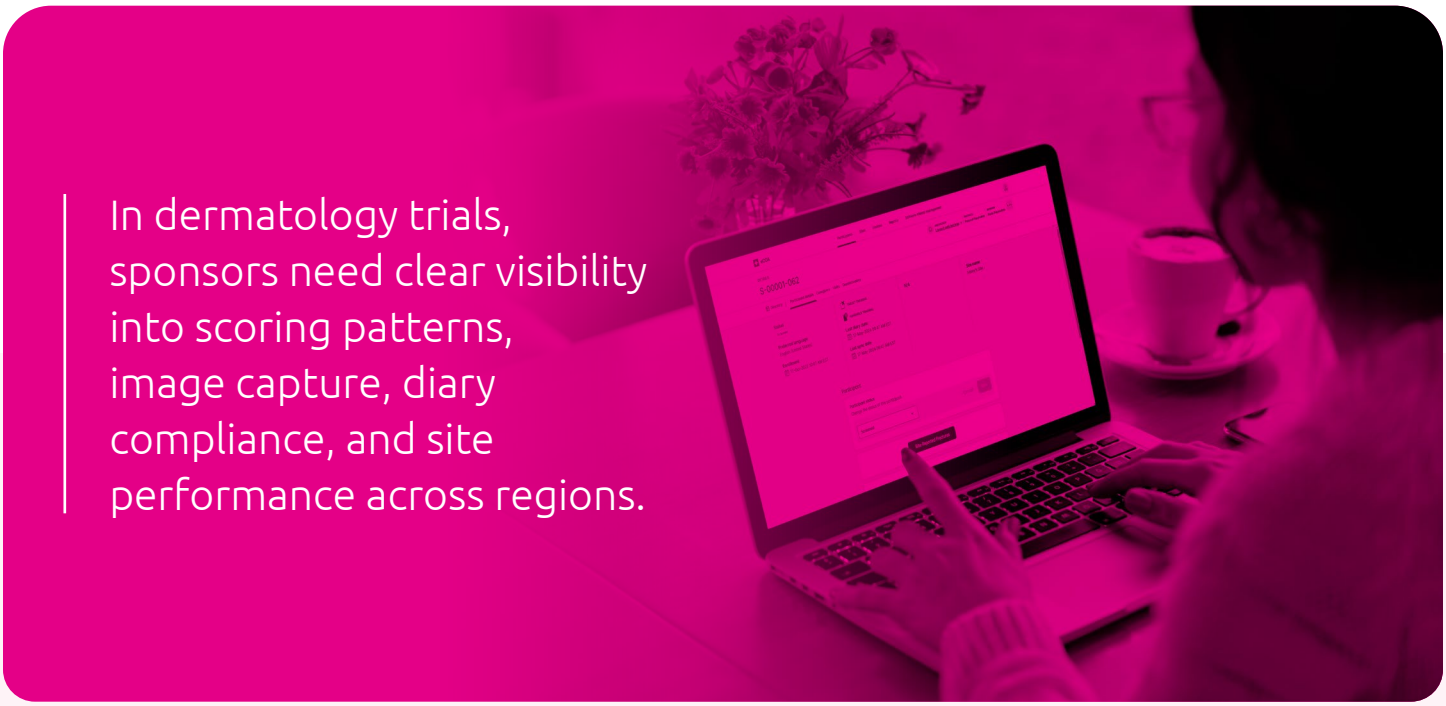


YPrime's eCOA platform delivers:

- Timestamped entries and version control for every assessment.
- Audit trails for all image uploads.
- Access permissions and review tracking for sponsor and CRO oversight.
- Validated data lineage from source to submission, aligned with GCP and FDA/EMA expectations.

This transparency enables sponsors to stand behind every data point with confidence during inspections.

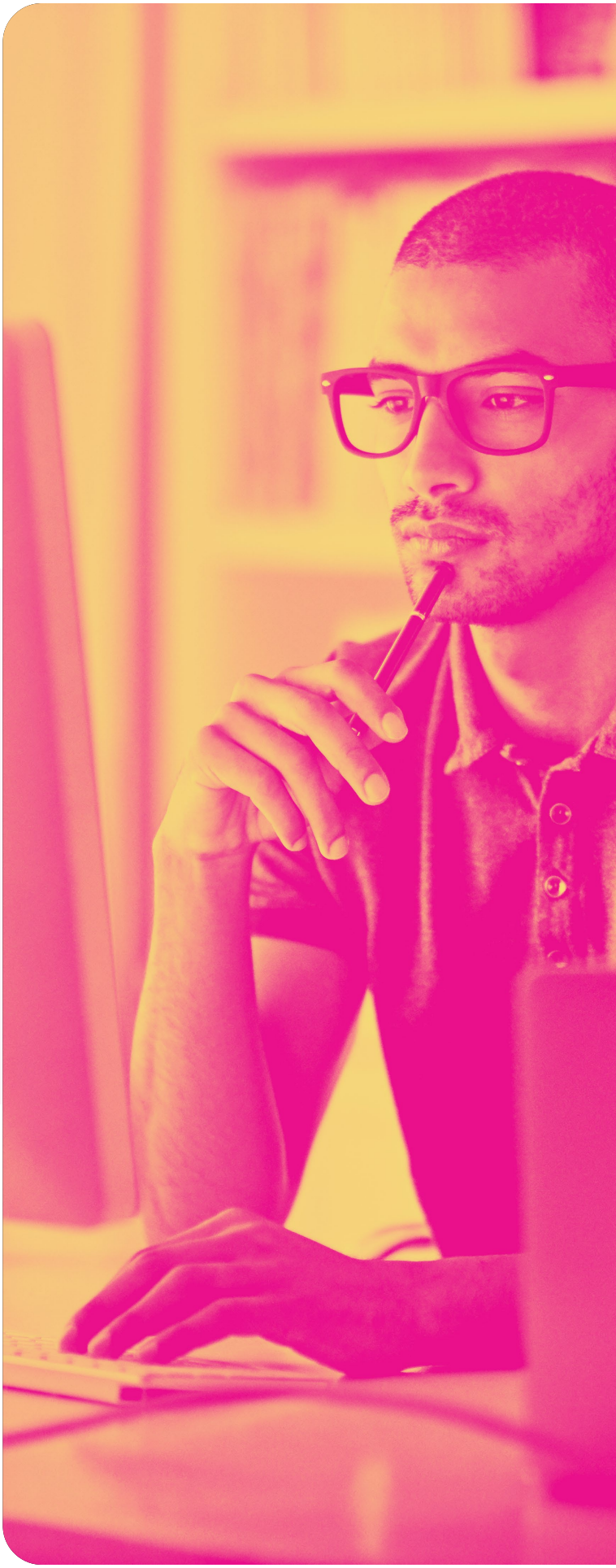
YPrime's Dermatology Experience

YPrime has supported a wide range of dermatology studies—from common inflammatory conditions such as atopic dermatitis and psoriasis to pigmentary disorders like vitiligo and a variety of rarer and emerging indications. Many of these studies have been initiated in recent years, reflecting both the depth and continued growth of YPrime's dermatology experience.

Our teams understand:

- How PASI, EASI, IGA, DLQI, NRS, and many other measures are deployed day-to-day.
- How suicidality or depression assessments (such as C-SSRS, PHQ-8 or PHQ-9) are often layered into dermatology protocols.
- How to maintain image consistency and data integrity across sites and device types.
- How to manage the practical challenges of translation, licensing, and screenshot reviews that delay study startup elsewhere.

Experience matters in dermatology. YPrime's platform, processes, and partnerships are designed to make complex studies easily deployable, accurate, and scalable.



Dermatology Case Study

A Phase 3 Extension Study in Moderate to Severe Plaque Psoriasis

A biotech company developing an oral therapy for moderate to severe plaque psoriasis engaged YPrime to support a large, late-phase dermatology program requiring global scale, operational consistency, and high data integrity. The program required a site-based eCOA model with provisioned devices and a high-touch execution approach to manage global complexity and ongoing program changes.

Key program stats:

1,500+
patients enrolled

270+
sites

11
countries supported

15
languages supported

~315
provisioned tablets deployed

The eCOA solution was designed specifically for psoriasis workflows, supporting assessments that captured affected body surface area and disease severity. To reduce site burden and improve protocol adherence, YPrime implemented automated calculation logic that translated assessment data directly into dosing guidance and next-step decisioning, including whether rescue treatment was required. This approach eliminated manual calculations at the site level, supported consistent clinical decision-making across regions, and preserved full auditability and inspection readiness throughout the program.

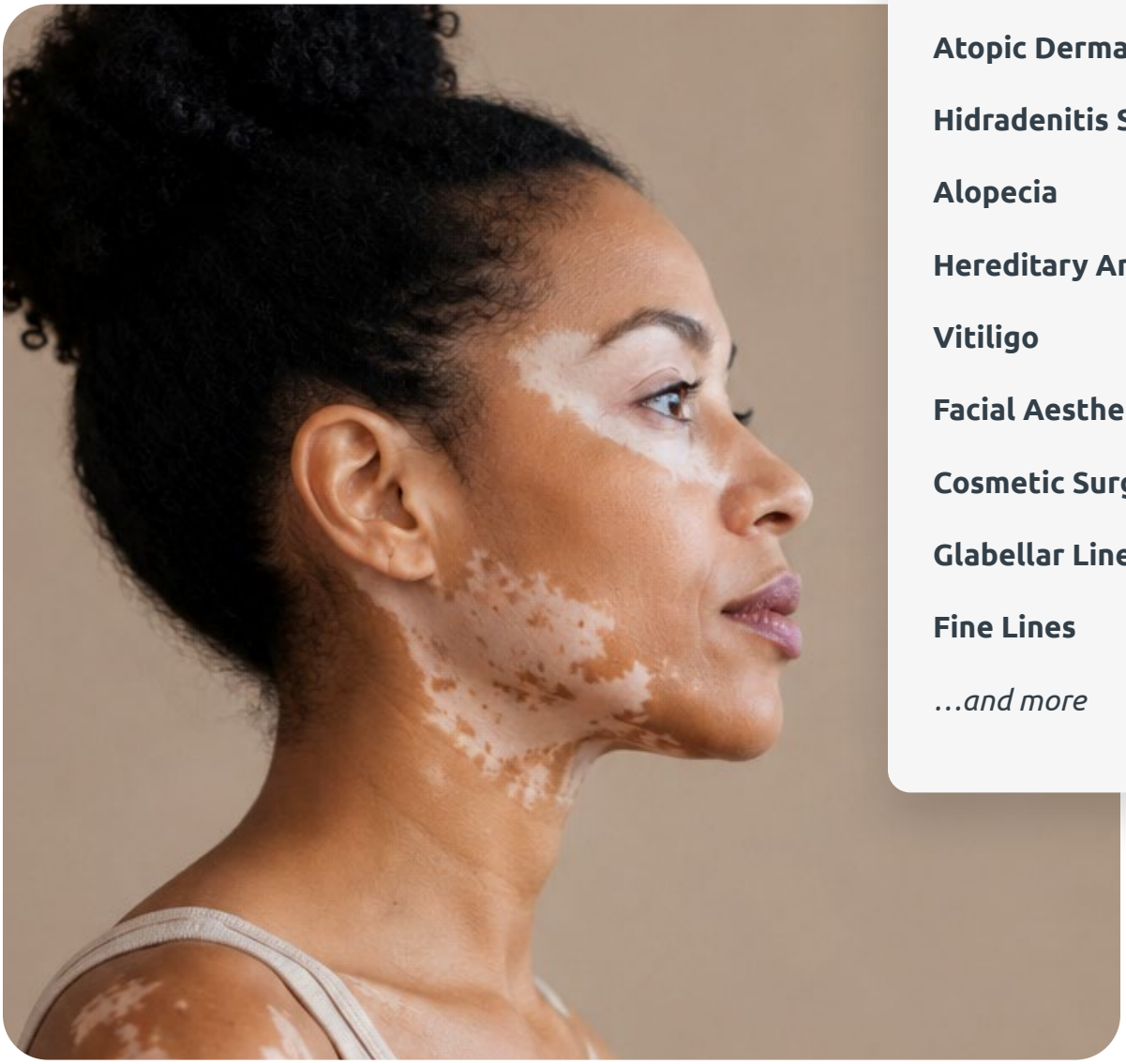
The program met all primary and secondary endpoints with high statistical significance, demonstrating strong efficacy, durability, and consistency across a large, global psoriasis population. Enrollment goals were exceeded, with 1,500+ patients enrolled across 270+ sites. The program completed ahead of schedule, reflecting strong operational execution and site enablement

Together, these results illustrate how dermatology-specific eCOA workflows, paired with automated scoring, dose calculation logic, and high-touch global support, can scale effectively in dermatology programs while maintaining data quality, protocol adherence, and site efficiency.

The Path Forward: Smarter, More Inclusive Dermatology Trials

As endpoints evolve, sponsors need technology that can adapt rapidly, support diverse populations, and provide validated, interpretable data for regulators and payers alike.

YPrime's dermatology-ready eCOA platform delivers this balance—scientific credibility, operational agility, and an exceptional user experience that empowers clinical trials to run on certainty.



Dermatology Indications Supported

Psoriasis

Atopic Dermatitis

Hidradenitis Suppurativa

Alopecia

Hereditary Angioedema

Vitiligo

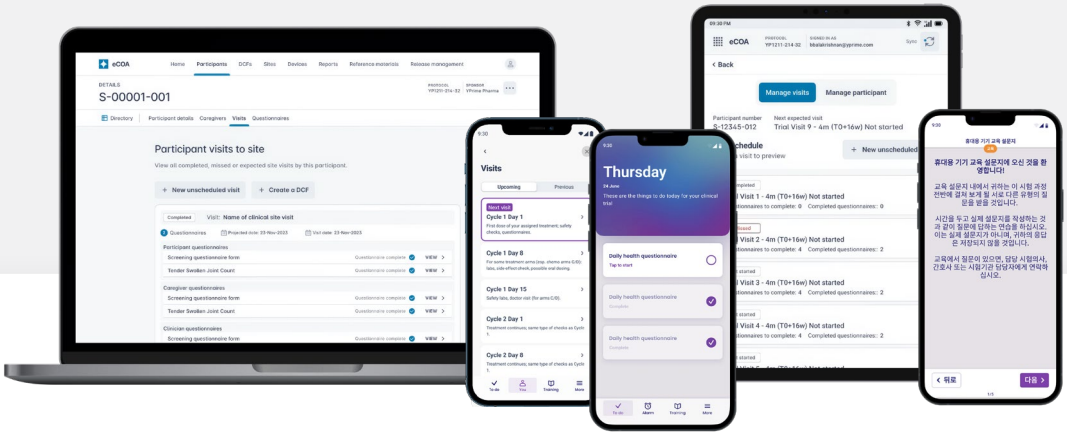
Facial Aesthetics

Cosmetic Surgery

Glabellar Lines

Fine Lines

…and more



Ready to Design Better Dermatology Trials—Faster?

Let’s connect:
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YPrime
Solve with Certainty

About YPrime

YPrime simplifies clinical trials with eCOA, IRT, and eConsent solutions that combine speed, flexibility, and quality. The YPrime eCOA platform enhances participant compliance with an intuitive app and easy-to-use design, streamlines site workflows through a powerful eCOA portal, integrates seamlessly with connected devices, and supports sponsors with real-time dashboards for better decision-making. A pre-validated and configurable eCOA platform delivers study startup 47% faster than industry benchmarks, with AI-supported localization that accelerates globalization. Delivering ~50% faster IRT startup times, eConsent that drives engagement, and quality metrics 55% above industry standards, YPrime is trusted by top pharma leaders and emerging biotech companies alike. With nearly two decades of experience, solutions in 250+ languages, and support in 100+ countries, YPrime is your partner to solve with certainty. Visit www.yprime.com or email marketing@yprime.com.

References:

1. FDA, Electronic Source Data in Clinical Investigations, 2013.
2. EMA. Guidance Documents on Electronic Source Data, 2023.