

Trailblazing Clinical Drug Development In Dermatology

The dermatology pharmaceutical sector is undergoing a profound transformation. Recent FDA activity, including a notable rise in Fast Track designations for dermatology programmes, reflects both accelerating innovation and an urgent need for more effective, personalised treatments. This momentum is driving a fundamental rethink of how clinical trials are designed, conducted, and measured, with growing emphasis on biomarkers, earlier inclusion of patient cohorts, i.e. Phase 1b studies, artificial intelligence (AI), and advanced imaging technologies to modernise assessments and improve outcomes.

Refining Traditional Endpoints

For decades, dermatology trials have relied on established visual scoring systems such as the Psoriasis Area and Severity Index (PASI), the Eczema Area and Severity Index (EASI), the Hidradenitis Suppurativa Clinical Response (HiSCR), and the Investigator's Global Assessment (IGA). These tools have provided standardised frameworks for assessing disease severity and treatment response and they remain the gold standard across all programmes.

However, widely used does not always mean fully fit-for-purpose in today's development landscape. A key limitation is subjectivity: two clinicians may score the same patient differently, introducing variability. This inter-rater variability becomes especially challenging in multi-site trials, where consistent evaluation across investigators, geographies, and patient populations is critical.

Sensitivity is another constraint. Visual scoring can miss subtle but clinically meaningful changes in skin condition, particularly in early-phase trials or when studying novel mechanisms of action. These small changes may provide the earliest signals of therapeutic effect. When they are overlooked, decisions may be delayed, studies prolonged, or the true potential of promising therapies obscured. Together, these challenges underscore the need for assessment tools that are more objective, reproducible, and sensitive.

The Promise of Biomarkers, AI, and High-Resolution Imaging

This is where the integration of AI with standardised, high-resolution photography can deliver an important solution. High-quality imaging can capture lesion morphology, texture, and surface features in far greater detail than conventional visual inspection alone, enabling a more comprehensive view of disease evolution over time.

When paired with AI, the impact increases further. Algorithms trained on large image datasets can segment lesions, quantify affected area, track subtle changes longitudinally, and identify early signals of progression or response. Instead of relying solely on subjective visual judgment, AI-assisted workflows can generate quantifiable, reproducible metrics. This helps to reduce variability between clinicians and across trial sites.

Equally important is the growing role of wet biomarkers, including skin punch biopsies, tape strips, and blood-based biomarkers. These mechanistic readouts can provide evidence of target engagement and pharmacologic activity in both tissue and circulation. When integrated with pharmacokinetics (PK) and clinical endpoints, they enable a more complete picture of PK/PD relationships. This foundational understanding is essential for robust go/no-go decisions and for dose selection ahead of larger Phase 2a studies.

Extending Dermatology Trials Beyond the Clinic

The advantages of AI and imaging extend beyond controlled clinic settings. Smartphone-based and portable imaging tools increasingly allow patients to capture high-quality images at home, reducing the need for frequent site visits. With AI-assisted analysis, clinicians and study teams can monitor patients more continuously, detect flares earlier, and tailor interventions more responsively.

This shift supports more patient-friendly trial participation and enables hybrid or decentralised trial designs. In turn, it can improve recruitment and retention, reduce participation burden, and expand access for underrepresented populations. This represents an important step toward more generalisable evidence.

Toward a Smarter Future in Dermatology

The integration of biomarkers, AI, and high-resolution imaging represents more than a technology upgrade; it signals a broader paradigm shift in how dermatologic diseases are assessed, studied, and treated. By addressing the subjectivity and sensitivity limitations of traditional methods, these approaches can accelerate development timelines while strengthening scientific rigor and patient-centricity.

Widespread adoption will depend on collaboration and standardisation. Shared datasets, cross-institutional validation, and harmonised imaging and biomarker protocols will be critical to ensure reliability and comparability across studies. Regulators are increasingly receptive to digital measures and tissue-based biomarkers when they are rigorously validated and clinically meaningful.

Ultimately, the pace of innovation in dermatology drug development demands equally innovative approaches to measurement. With biomarkers, AI, and advanced imaging leading the way, dermatology trials can become not only faster and more precise, but also more informative, bringing better treatments to patients sooner.