AutoCruitment

DERMATOLOGY CLINICAL TRIAL PATIENT RECRUITMENT

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INTRODUCTION

Patient Recruitment for Dermatology Clinical Trials: **Understanding Patient Perspectives**

At any point in time, skin conditions are estimated to affect nearly two billion individuals worldwide. In the next 12 months, over 80 Dermatology clinical trials will begin, and there are hundreds more that are already recruiting participants.

Clinical research plays a crucial part in understanding and approving treatment options for conditions across the therapeutic area. The patient profile is variable based on age, gender, ethnicity, genetics, lifestyle factors, medical history, environmental factors, psychological factors.

There are six indications that are that make up over 60% of the planned trial starts and 55% of the trials already recruiting patients: Atopic Dermatitis, Chronic Urticaria (Hives), Acne, Alopecia, Hidradenitis Suppurativa, and Psoriasis.

This therapeutic area brief provides a look at the patient profile for each of the five conditions and highlights why Direct-to-patient advertising is an ideal approach for recruiting patients for clinical research in these conditions.

PATIENT PROFILE: *ATOPIC DERMATITIS*

Atopic dermatitis (AD) is a common, chronically relapsing skin condition that affects individuals of all ages in 2.4% of the global population, but its prevalence varies greatly among countries. It is more common in developed countries and urban areas. Approximately 60% of AD cases develop within the first year of life, and up to 20% of children and 10% of adults are impacted.

Medical History: Genetics, allergies, Immune dysregulation
A family history of Atopic Dermatitis, allergic rhinitis, and asthma increases the risk of developing the condition. The connection between allergic rhinitis and asthma suggests that there is a common underlying allergic predisposition.

Lifestyle Factors: Environmental irritants, climate
Exposure to irritants and allergens in the environment, such as harsh soaps, detergents, wool, and certain foods, can trigger or exacerbate AD symptoms. Dry and cold climates can worsen AD symptoms, whereas warm and humid climates may provide relief for some individuals.

Psychosocial Factors: Quality of life, social stigma
There is no suggestion that AD stems from psychosocial factors; however, they are impacted by the condition. Symptoms such as itchiness, pain, and sleep disturbance can impact quality of life. The presence of skin lesions and scratching behaviors associated with AD could lead to social stigma and negatively affect self-esteem in affected individuals.

Environmental Factors: Indoor environment, pollution
Indoor allergens such as dust mites, pet dander, and mold can trigger AD symptoms, especially in individuals with allergic sensitivities. At the same time, outdoor allergens, such as air pollution, including particulate matter and volatile organic compounds (VOCs), may contribute to AD development or worsening of symptoms.

PATIENT PROFILE: *CHRONIC URTICARIA*

Chronic urticaria can affect individuals of all ages, races, and genders, and it is estimated to impact approximately 0.5% to 1% of the population. Women are affected more frequently than men, with a female-to-male ratio of approximately 2:1.

Medical History: Allergies, autoimmune diseases, thyroid disorders
While acute urticaria is often triggered by allergens, chronic urticaria is less frequently associated with specific allergic triggers. However, some individuals with chronic urticaria may have underlying allergies or sensitivities. Approximately 30-50% of cases of chronic urticaria are associated with autoimmune mechanisms, such as autoantibodies targeting mast cells or basophils. Finally, thyroid autoimmunity, particularly Hashimoto's thyroiditis, is commonly associated with chronic urticaria.

Lifestyle Factors: Stress, medications
Psychological factors such as emotional stress and anxiety can exacerbate chronic urticaria symptoms in some individuals. Medication is an additional contributor, and certain medications, such as nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and ACE inhibitors, may trigger or worsen chronic urticaria in susceptible individuals.

Psychosocial Factors: Quality of life, social isolation
Chronic urticaria can have a significant negative impact on quality of life due to the unpredictable nature of flare-ups, itching, and sleep disturbances. Individuals with chronic urticaria can also face social isolation due to fear of embarrassment or stigma associated with visible hives.

Environmental Factors: temperature changes, physical stimuli
Exposure to extreme temperatures, such as heat or cold, can trigger or exacerbate chronic urticaria symptoms in some individuals. Physical stimuli such as pressure, vibration, or friction may induce or worsen hives in individuals with physical urticaria subtypes.

PATIENT PROFILE: *ACNE*

In the US, **acne** affects close to 50 million people annually, and approximately 85% of adolescents worldwide are impacted by acne and acne-related conditions. Acne vulgaris is most common during adolescence and early adulthood and impacts individuals across all races and ethnicities. While peak prevalence occurs between 12 and 24 years of age and acne tends to decrease with age, over 25% of women and 12% of men in their 40s report having acne. Both male and female adolescents are impacted; however, the severity and pattern of distribution may differ between sexes.

Medical History: Family history, hormonal factors, and underlying medical conditions.
Individuals with a family history of acne are more likely to develop the condition. Hormonal changes, especially those occurring during puberty, menstruation, pregnancy, and with polycystic ovarian syndrome (PCOS) can make acne worse.

Lifestyle Factors: Diet, skincare habits, and smoking
High glycemic index diets and dairy consumption have been associated with exacerbation of acne. Poor skincare practices and the use of comedogenic cosmetics or harsh cleansing products can contribute to acne prevalence, and smoking has been linked to more severe acne in some clinical studies.

Psychosocial Factors
Psychological stress can exacerbate acne through hormonal pathways, and it is a double-edged sword as many individuals with acne face increased psychological stressors: decreased self-esteem, increased depression and anxiety, social withdrawal, and bullying. Acne-related stigma may be a contributing factor to acne itself.

Environmental Factors: Climate and Pollution
Hot and humid climates result in increased sweat production and pore-clogging, and poor air quality may contribute to inflammation and worsening of acne, specifically due to particulate matter.

PATIENT PROFILE: *ANDROGENIC ALOPECIA*

Androgenic alopecia (AGA) affects both men and women, but it is more common and typically more severe in men, and its prevalence increases with age. By age 50, nearly 50% of men and 25% of women will experience some degree of hair loss, and it is more common amongst those of Caucasian descent.

Medical History: Genetic predisposition, hormonal factors, medical conditions
AGA is genetically determined and due to an excessive response to androgen. A family history of early-onset hair loss increases the risk of an individual developing AGA. Hormonal factors, specifically dihydrotestosterone play a key role in the pathogenesis of Androgenic Alopecia. There are, however, medical conditions, like polycystic ovarian syndrome and thyroid disorders that may contribute to the development of AGA.

Lifestyle Factors: Smoking, Diet
While the genetic component to AGA is the driving factor, smoking has been associated with an increased risk, and can exacerbate hair loss in those who are predisposed to the condition. Poor nutrition can also contribute to hair loss.

Psychosocial Factors: Self-esteem, psychological distress
Psychological factors do not cause AGA; however, it can significantly impact self-esteem and body image, and lead to feelings of embarrassment, self-consciousness, and decreased confidence. Additionally, individuals with AGA can experience anxiety, depression, or social withdrawal because of concerns about their appearance.

Environmental Factors: Hormonal changes, stress
Changes in hormonal levels such as those occurring during puberty, pregnancy, and menopause can influence AGA progression. Additionally, chronic stress could exacerbate hair loss in those who are genetically predisposed to AGA.

PATIENT PROFILE *HIDRADENITIS SUPPURATIVA*

Hidradenitis Suppurativa (HS), a chronic inflammatory skin condition, varies in prevalence worldwide. In the US, it affects approximately 1-4% of the population. Globally, prevalence rates range from 0.1% to 4%, demonstrating its significant impact across diverse regions and populations. HS typically starts in young adults, peaking in an individual's 20s and 30s.

Medical History: Family history, hormonal factors, and associated conditions
Genetics play a substantial role, with up to 40% of individuals affected by HS having a family history of the condition. Hormonal changes, such as those during puberty, menstruation, pregnancy, or menopause, can also impact the severity of HS symptoms. Additionally, HS is commonly associated with other medical conditions including obesity, metabolic syndrome, inflammatory bowel disease, and spondyloarthropathies.

Lifestyle Factors: Impaired quality of life, depression and anxiety
Chronic pain, along with malodorous discharge and social embarrassment stemming from the condition, significantly diminishes daily functioning and overall well-being. Additionally, individuals with HS experience higher rates of psychiatric comorbidities such as depression and anxiety compared to the general population.

Psychosocial Factors: Impaired quality of life, depression and anxiety
Chronic pain, along with malodorous discharge and social embarrassment stemming from the condition, significantly diminishes daily functioning and overall well-being. Additionally, individuals with HS experience higher rates of psychiatric comorbidities such as depression and anxiety compared to the general population.

Environmental Factors: Friction, sweating and microbial colonization
Excessive sweating and friction in skin folds and areas affected by HS can intensify inflammation and discomfort. Furthermore, microbial colonization, notably by Staphylococcus aureus and other bacteria, contributes to triggering or worsening HS flares.

PATIENT PROFILE *PSORIASIS*

Psoriasis, a chronic autoimmune skin condition, impacts a significant number of individuals worldwide. In the United States alone, approximately 7.5 million people are affected . Globally, the condition affects an estimated 2-3% of the population. Psoriasis can manifest at any age, but it most commonly appears between 15 and 35 years old. It affects both men and women equally, showing no substantial gender preference. Prevalence rates vary across ethnic groups, with higher incidences observed among Caucasians compared to other racial and ethnic populations

Medical History: Family history, autoimmune disease
Family history plays a significant role, with about one-third of individuals affected by psoriasis reporting a family history of the condition, indicating a strong genetic component. Furthermore, psoriasis is commonly linked to autoimmune diseases such as psoriatic arthritis, rheumatoid arthritis, and inflammatory bowel disease.

Lifestyle Factors: Smoking, obesity
Cigarette smoking and obesity are significant risk factors for psoriasis. Smoking is linked to more severe disease and reduced treatment response. Similarly, obesity increases the risk of developing psoriasis and is associated with more severe forms of the disease and poorer treatment outcomes.

Psychosocial Factors: Impaired quality of life, depression and anxiety
The visibility of psoriasis lesions can lead to social discomfort and reduced self-esteem, contributing to a considerable negative impact on daily life. Additionally, individuals with psoriasis are more prone to experiencing depression, anxiety, and other psychological disorders than the general population.

Environmental Factors: Stress, climate
Psychological stress has been shown to exacerbate psoriasis symptoms and trigger flares in individuals susceptible to the condition. Climate also plays a role, as cold weather, dry air, and low humidity conditions can worsen psoriasis symptoms for many individuals. Conversely, sunlight exposure and warmer climates may provide relief and improve symptoms for some individuals with psoriasis

STANDARD DIAGNOSTIC & TREATMENT PATH

Individuals seeking care for almost all skin-related conditions will begin with their Primary Care Physician. If they're already under the care of a Dermatologist, they are likely to begin there.

The treatment of the condition varies greatly based on the condition itself, but typically involves oral or topical medication. Patients might, however, express interest in clinical trials because the current treatment options are no longer addressing their existing concerns, or they are not effective in treating newer dermatological conditions, like Hidradenitis Suppurativa or Chronic Urticaria.

For many dermatological conditions, individuals may try over-the-counter topicals or explore natural remedies like changing their diet, addressing (where possible) environmental contributors, and/or putting measures into place to address their existing environmental and climate constraints.

PATIENT HESITANCY & CONCERNS

There are millions of individuals worldwide who suffer from any number of skin conditions, with differing degrees of severity. While most individuals will seek treatment (when they have access to appropriate medical care) for dermatological conditions, they are likely to express hesitation in seeking care outside of their current or the standard treatment pathways.

For some, this might be due to previous negative experiences or flares in their condition when washing out of and then beginning a new treatment. For others, they might fear being placed in the placebo arm of a study. A commonly held concern about clinical research is the frequency of documentation and visits required. In reality, clinical trials typically require only 5-20 visits spread out over 1-3 years, accommodating participants' lifestyles while they receive new therapies.

Initially, visits may be monthly to monitor biomarkers, viral load, or inflammatory markers, later transitioning to every three months. Whether opting for traditional physician-led care or participating in clinical research, individuals typically invest a comparable amount of time in treatment.

THERAPEUTIC ADVANCEMENTS

Depending on the therapeutic area, different types of treatment or routes of administration have been the ‘gold standard’; however, clinical research and drug development are designed to improve and constantly push that gold standard forward. Biologics and targeted therapies that were previously administered via IV infusion in a clinical or hospital can now be taken orally or subcutaneously. Topical treatments, typically used for conditions like Acne and Atopic Dermatitis are formulated now to be better absorbing and can be coupled with microneedling to ensure the topical can penetrate deeper into the skin.

ACNE

It can be assumed that there has been a change in formulation to enable better absorption, less side effects, and more stability. Topicals (better absorption now with encapsulation, nanoparticles, and microneedling).

There also more access to laser and light therapies, chemical peels, and PDT that can improve the condition of the skin non pharmacologically.

ATOPIC DERMATITIS

With over 25 new biologics in development, treatments are becoming more personalized and targeting specific parts of the immune system, offering better results with fewer side effects.

ALOPECIA AREATA

Treatments for hair loss have evolved from systemic and invasive options to more targeted, less invasive therapies. Current treatments emphasize minimizing systemic effects while improving efficacy and patient compliance.

THERAPEUTIC ADVANCEMENTS

CHRONIC URTICARIA

The basic treatment for Chronic Urticaria is non-sedating antihistamines, with increased dosage as needed.

Newer treatments work by attaching to IgE, which in turn keeps IgE from binding to receptors, thus reducing the activity of these cells and the release of substances that cause inflammation.

HIDRADENITIS SUPPURATIVA

New treatments include topical formulation of therapies used to treat other conditions, hormonal therapeutics, laser treatment, and biologics.

Since HS is a multifactorial condition, new therapeutics, combined with lifestyle adjustments aim to reduce the severity of outbreaks.

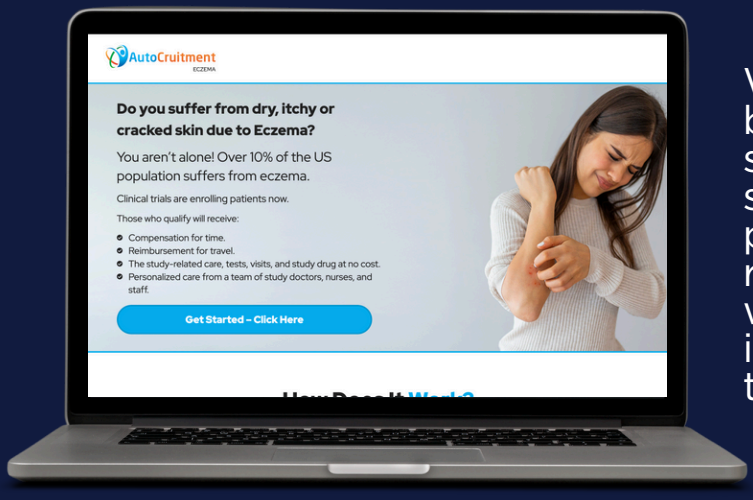
PSORIASIS

Recent advancements focus on novel biologics and small molecule inhibitors targeting specific pathways involved in the disease. Additionally, there is ongoing research into the genetic and environmental factors contributing to psoriasis, aiming to personalize treatment approaches. There is also research on comorbid conditions often associated with psoriasis, such as cardiovascular disease and metabolic syndrome.

UNLOCKING ACCESS TO INDIVIDUALS WITH DERMATOLOGY CONDITIONS

Finding potential Dermatology clinical trial participants can be challenging, but Direct-to-Patient Advertising as a recruitment approach is powerful in this population.

The conditions reviewed in this brief have been searched, on average, 500,000 times per month for the last year. Potential patients are often turning first to online sources and reacting to influencers for information and education about their diagnosed or suspected condition as well as side effect management for their existing treatment.



With that activity, an online profile begins to evolve, and by using sophisticated targeting and screening algorithms, Sponsors can put information about clinical research directly in front of people who are already seeking information outside of the traditional physician-led approach.

Direct-to-patient recruitment builds awareness and empowers patients (or their caregivers) to seek best-fit solutions for the condition.

PATIENT MOTIVATION

Whether or not someone has received a formal diagnosis, their search for information about symptoms or conditions implies a desire for a solution. If they're presented with a clinical trial as a treatment option and take steps to determine their eligibility, the patient is likely to be more engaged and proactive at the start.

Traditional recruitment methods focus on data mining to find potential matches but often overlook the individual's interest or motivation. Direct-to-patient recruitment, however, reaches those actively seeking solutions, placing research opportunities directly in their path.

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THERAPEUTIC AREA SNAPSHOT

AutoCruitment has completed 28 Dermatology Studies in the last 5 years

Average increase in enrollment rate: 154%

Average time saved: 4.1 months

Total Randomizations Contributed: 1,316

AUTOCRUITMENT METHODOLOGY

Targeted Direct-to-Patient Recruitment

- Diverse recruitment channels
- Web-based technology platform
- Proprietary algorithms to hyper-target and identify the right patients

Enhanced Qualification Services

- Sophisticated online screener, customized to protocol
- Second-line clinical phone screening
- AI-powered EMR Capture & Intelligence

Dedicated Engagement Support

- Patient advocates provide support throughout recruitment and enrollment
- Research site support to reduce the patient recruitment/enrollment burden

ABOUT AUTOCRUITMENT

AutoCruitment unlocks access to the 90% of patients who cannot be found through traditional recruitment methodology alone. By targeting and engaging directly with patients, they're at the center of their recruitment journey.

AutoCruitment is the leading direct-to-patient recruitment company, and we help life sciences companies find the right patients for their trials, at exactly the right time.

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