CLARINESS

Digital patient recruitment and pre-screening methods

for atopic dermatitis June 2022 Digital patient recruitment **Atopic dermatitis**

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Abstract

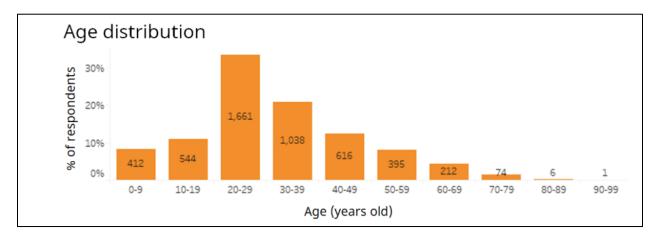
This whitepaper on atopic dermatitis patient recruitment explores the challenges faced by sponsors, CROs and study sites in enrolling sufficient numbers of patients for their clinical trials. Drawing on current literature and our own 16 years of experience in atopic dermatitis patient recruitment, we present approaches to reach, recruit and retain atopic dermatitis patients.

Request a proposal for the patient recruitment campaign for your local and international atopic dermatitis study here

Introduction

Atopic dermatitis (AD) is a common chronic inflammatory skin disease with a complex pathophysiology that <u>underlies a wide spectrum</u> of clinical phenotypes. It affects almost one in four children and 10% of adults in industrialized countries, yet there are <u>big differences</u> in prevalence between industrialized countries, regions, ages and groups. With prevalence rates in developed countries rising significantly over the past decades, some researchers go as far as claiming that there is an <u>'atopic dermatitis epidemic'</u>.

Researchers estimate that 40% of patients with atopic dermatitis have from moderate-to-severe disease (Chiesa Fuxench et al., 2019). As recent studies and our own surveys highlight, people with moderate-to-severe atopic dermatitis are also more likely to have higher medical costs, miss work, and are less satisfied with their treatment.



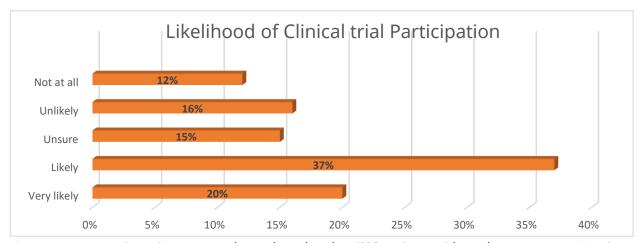
Overview of the age of respondents to a questionnaire with 4,700 patients with moderate to severe atopic dermatitis we conducted in 2021. The other data used in this whitepaper comes from this questionnaire.

The high medical need for <u>better treatment options</u> is reflected by ongoing medical research and the amount of clinical studies currently investigating new drugs and treatment options for moderate-to-severe atopic dermatitis specifically. For

example, <u>a review published in *Nature*</u> estimates that over 70 new medications and therapies are being in development in 2021.

In fact, currently **over 500 dermatology clinical trials are underway (2021)**, meaning that there is intense "competition" between organizers to find eligible patients among trials. This is a big factor contributing to the steady rise of atopic dermatitis clinical trials that are stopped. According to <u>a study published in the British Journal of Dermatology</u>, in 2020 alone, approximately 5% of atopic dermatitis trials are terminated before starting and the overall discontinuation rate is 14%.

One clear cause of this problem is that organizers of atopic dermatitis clinical trials often fail to reach a diverse group of patients. For example, many studies struggle to reach younger and older adults, ethnic and racial minorities, rural residents, and those with low socioeconomic status.



Answers to a questionnaire we recently conducted under 4700 patients with moderate to severe Atopic Dermatitis worldwide.

Digital patient recruitment offers a fast and cost-efficient way to reach a diverse group of patients with atopic dermatitis from all ages. At Clariness, we have supported over <u>22 atopic dermatitis studies</u> in the past years (from Phase I-IV). This has allowed us to identify common issues as strict inclusion criteria and

comorbidities and bottlenecks with recruitment for atopic dermatitis. For example, some outreach tactics work or don't work for certain local patient populations and a data-driven understanding of the reasons why patients do not qualify or eventually drop-out makes us able to address patient's concerns. Based on the study protocol, we identify challenges up front and adjust our digital patient recruitment strategies over 40 possible channels including our own database.

1. Identifying and understanding local atopic dermatitis patient populations

Atopic dermatitis (AD) is the most common chronic inflammatory skin disease in developed countries. With about 80% of cases starting in infancy or childhood and 95% of patients experiencing onset before 5 years of age, the condition has historically been considered a pediatric disease. At the same time it should be noted that the total prevalence of the condition is about 15 to 25% in children, with the rest being adults, including those who developed the condition in their childhood.

Atopic dermatitis (AD) <u>varies starkly</u> in clinical phenotype by age, severity and ethnic background and its general course. Even individual trajectories are unpredictable, making researchers <u>still struggle with defining and mapping</u> the patient population.

Some scientists have concluded that the condition prevalence is especially high in Northern European countries as Germany and the United States and low in "Africa". Yet, large-scale national and international studies have shown that these generalizations only partly work for creating a recruitment strategy for international clinical trials. For example, the largest study to date, with 256,410 children aged 6 to 7 years and 458,623 children aged 13 to 14 years, showed that prevalence was for instance 1 to 2% in Albania and Iran yet 17% in both Nigeria and Sweden.

Recent studies therefore have argued that its crucial to identify differences on both national and regional level to make patient recruitment for largescale international studies successful. For example, <u>recently published data</u> shows significant differences with higher prevalence in cities compared to rural areas and higher socioeconomic status neighborhoods are linked to an increased prevalence compared to lower economic status areas, having an increased severity.



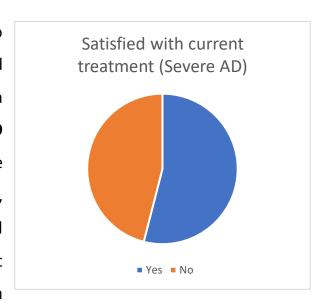
At Clariness, <u>our digital outreach campaigns</u> for local and largescale international trials are therefore based on a combination of **qualitative knowledge of the local context** and **data-driven methods** to know which patients are likely to qualify or not.

Yet, as <u>data from Germany shows</u>, it is crucial to understand that these do not apply to every region. In Germany for instance, prevalence is higher in cities located in the eastern part of the country, with rates being the lowest in rural Bavaria and Northern Germany (Schleswig-Holstein). With Eastern Germany still being significantly less developed and wealthy (Gross income is €3,070/month in Western Germany and €2,320/month in Eastern), this directly contrast the findings of other studies that link prevalence to higher economic status.

Therefore even global clinical trials for atopic dermatitis depend on knowledge of the specific study populations in the proximity to a research center. For example, based on our experience we know that successful recruitment campaigns can take into account the local and seasonally increased levels of specific pollen species (many atopic dermatitis patients are sensitive to environmental allergens).

2. Patient surveys: understanding atopic dermatitis patients' needs

At Clariness we conduct regular surveys to understand patient populations needs and motivation for potentially participating in a clinical trial. In a 2020 survey with 4,959 participants, we examined specifically the relation between symptom experience, medication and treatment satisfaction and motivation for gaining information on atopic dermatitis including potential participation in clinical trials.



One of our key findings was that patients with moderate-to-severe atopic dermatitis typically have high patient burden with limited positive treatment outcomes. Survey participants with severe disease reported more frequently to be 'dissatisfied' or 'very dissatisfied' (54%) while patients with mild disease reported the lowest proportion (26.7%).

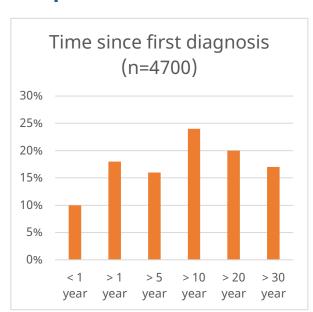
While it might sound not very surprising that people with severe atopic dermatitis more often are unsatisfied, it is remarkable that 40% of the German patients with

severe atopic dermatitis in the survey said to currently not take treatment. This compared to for example only 25% of the responses in Russia.¹

By better understanding patients' mindsets with regards to clinical trials, their satisfaction with existing treatment and sources of influence, we can engage patients based on an understanding of their treatment wishes and needs. This enabled us to successfully support over 30+ atopic dermatitis trials in the past years. Request more information <a href="https://example.com/here-needed-to-support-needed-

3. Undiagnosed or misdiagnosed atopic dermatitis

As there are no standardized tests to diagnose atopic dermatitis, researchers suggest that it is likely that many affected people remain undiagnosed. Whereas there are no European studies that estimate how many people remain undiagnosed, a large-scale 2007 study in the United States estimated that this is the case for almost 18 million persons. In a 2021 report, the US



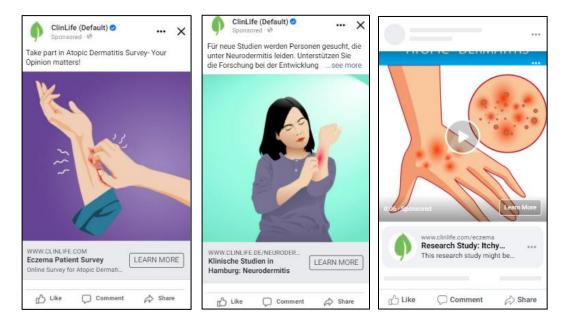
National Eczema Association similarly estimates that at least the half of people with atopic dermatitis are undiagnosed.

Furthermore, because doctors and dermatologists often base their diagnosis of atopic dermatitis on a visual analysis, they <u>often misdiagnose</u> atopic dermatitis as psoriasis as both conditions have a similar appearance. As a 2015 <u>study highlights</u>,

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¹ For information about the survey contact us here.

this especially occurs with infants and children as "scaling is often less prominent and the distribution of lesions more often includes the face".



Example of some digital advertisements on Facebook used in our digital patient recruitment campaigns. Facebook is one of 40 channels Clariness successfully employs for atopic dermatitis patient recruitment.

As the prevalence of atopic dermatitis is significantly higher in people of color compared to white children (17 versus 11%), it is <u>important to recognize</u> that symptoms of atopic dermatitis show differently in people with black or brown skin. For example, eczema in people of color looks brown or gray instead of red and people with darker skin are "more likely to develop small bumps on the arms, legs, and torso and around the hair follicles". As the <u>National Eczema Association</u> notes, it is therefore crucial that both doctors and organizers of clinical trials are aware of these differences and adjust protocols and patient recruitment accordingly.



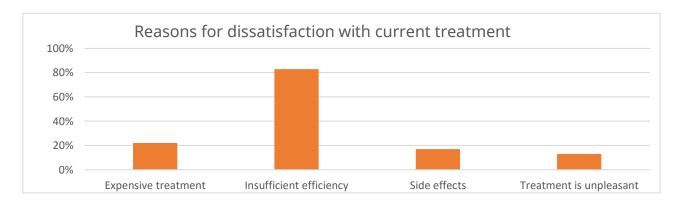
For patient recruitment campaigns this means that we at Clariness opt to reach an as large as possible patient population with atopic dermatitis related symptoms or interests. This way we ensure that even people who are not yet diagnosed yet can potentially take part. Our innovative and data-driven pre-screener at the same time increases the likelihood that only patients who qualify are referred to the study center.

Request more information **here**.

4. Patient recruitment for moderate or severe atopic dermatitis

Patients with atopic dermatitis experience unpredictable and highly variable signs and symptoms. Some review-studies suggest that >40% of patients with atopic dermatitis have moderate to severe disease intensity. Those with moderate-to-severe atopic dermatitis are also more likely to have higher medical costs, miss work, and be less satisfied with their treatment. While does not necessarily mean

they are more likely to participate in clinical trials compared to patients wild mild atopic dermatitis.



As atopic dermatitis diagnosed in childhood often improves over time (by 15 years of age, over 50% do not have symptoms any more or less frequent), it is especially adults who receive an diagnosis that have a more severe and frequently-occurring-atopic dermatitis.

A closer look at treatment satisfaction in relation to atopic dermatitis severity showed that as severity increases, the patient's satisfaction with the current medication decreases.

	Mild	Moderate	Severe	Uncertain
Very satisfied	2,71 %	6,91 %	16,64 %	5,80 %
Dissatisfied	23,96 %	37,98 %	37,23 %	24,64 %
Unsure	5,83 %	7,69 %	6,10 %	18,84 %
Satisfied	55,42 %	41,11 %	30,81 %	43,48 %
Very satisfied	12,08 %	6,32 %	9,23 %	7,25 %

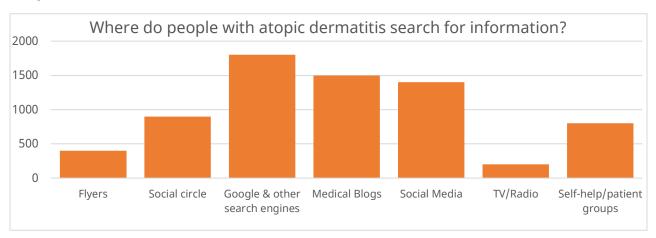
5. Digital patient recruitment for atopic dermatitis studies

Digital patient recruitment can be conducted via two options:

First, data-driven, "direct" outreach to patients, their families, caregivers, and friends with advertisements for specific atopic dermatitis studies.

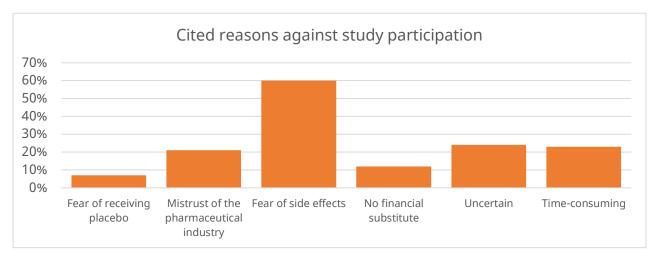
Second, "indirect" outreach via a platform that allows proactive patients to find studies through online searches, indication-based marketing, collaboration with patient organizations and subscription-based databases.

At Clariness, we take the following 4-step approach to patient recruitment for atopic dermatitis.



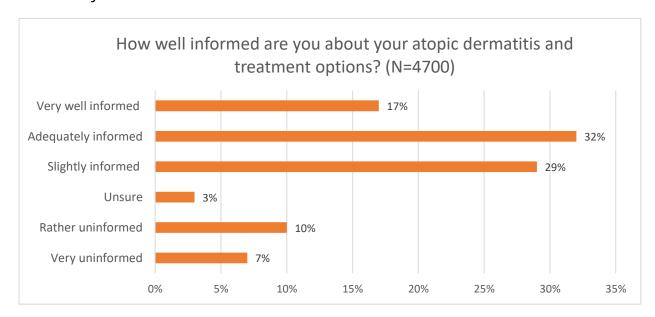
- **1. Adjusting the patient profile based on specific criteria of the study.** For studies focusing on children or elderly people with atopic dermatitis, we also look for ways to identify the caregivers.
 - Through analysis of social media responses and questions, large-scale surveys and qualitative interviews, our Patient's Insight team forms an overview of the needs and wishes of the local patient group.

- **2. Individualized targeting method:** We select different channels and categories that we know from experience and surveys could be of interest to atopic dermatitis patients.
 - Examples are certain associations, groups and keywords that are for example (often very indirectly) related to possible symptoms and air quality.
 - We also work closely with patient organizations such as Bundesverband für Neurodermitis in Germany and inform our database subscribers about new studies.
- **3. Behavioral targeting:** targeting people with similar behavior to those who registered for the study or people who visited the study site but did not register.



- **4. Lay-friendly information and study material:** At Clariness, we pay a lot of attention to creating lay-friendly educational content that explains the importance of clinical trials for the patient population, but also explain the study process. This leads to significant higher participation rates and lower dropout rates.
 - With our ClinLife patient blog we explain clinical research and give clinical trials a human face by interviews with the researchers and study doctors.

For example, our surveys highlight that many people with atopic dermatitis
do not know that medicines are tested for years before they are administered
in clinical trials, and that clinical research consists of several phases with strict
safety checks and reviews.

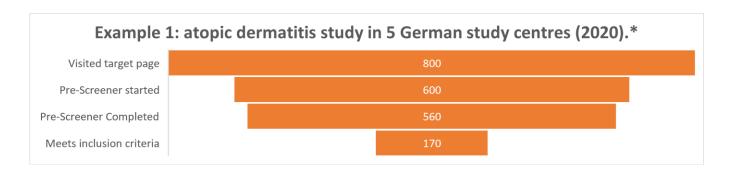


6. Example: Patient recruitment for local study (2021)

Based on our experience with more than 20 German and international clinical trials for atopic dermatitis from phase I to phase III, we developed the following approach for a patient recruitment campaign for a phase III trial conducted in Germany last year.



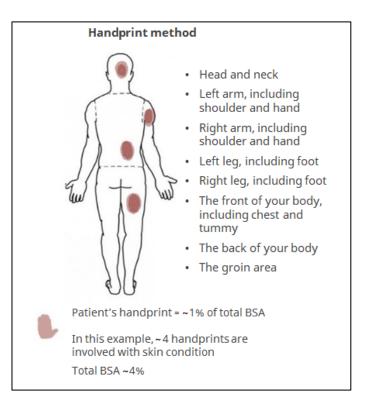
A hypothetical example of a digital target range for a study centre in Lübeck (Germany), which is only looking for patients who have to travel a maximum of 15 kilometres for a very demanding study.



The difference between the amount of people starting and qualifying for the study is relatively small, which shows the quality of our patient profile, outreach methods and our in-house developed pre-screening technique.

7. Digital screening techniques for atopic dermatitis

One of the key eligibility criteria for almost all atopic dermatitis clinical trials is knowing the body surface area (BSA) affected by the disease which has traditionally been difficult for patients to accurately self-identify. For this reason, Clariness developed a unique handprint screening technique to quickly identify eligible patients ahead of referring them to sites. and thus increasing patient enrollment numbers.



This BSA screening technique allows patients to better self-identify symptom severity during the completion of both phone and online screeners, with a

customizable threshold adapted for screening as per the trial protocol's requirements.

8. On ClinLife, our patient friendly clinical trials databank

ClinLife was developed in direct collaboration with patients and lists studies of different sponsors, CRO's, SMOs and single sites. The platform enables patients to learn more about clinical trials, test their eligibility for studies and apply to participate in them.

What sites say:

"We struggled to get the number of participants we wanted and spent a lot of time and effort recruiting participants. Since we published our study on ClinLife we don't have to do anything and suddenly we have a list of interested people!"

Dr Laura Blauth, FHWS (Germany)

What patients say:

"I usually never click on ads, but this ad about a clinical trial really appealed to me, so I applied right away. The research center was only 2 km away, so the personal approach was optimal."

2021 Patient's Voice Participant

Read more about Patient's Voice:

Request a demo for a patient recruitment campaign for your atopic dermatitis study here