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# AUTISM CLINICAL TRIAL PATIENT RECRUITMENT





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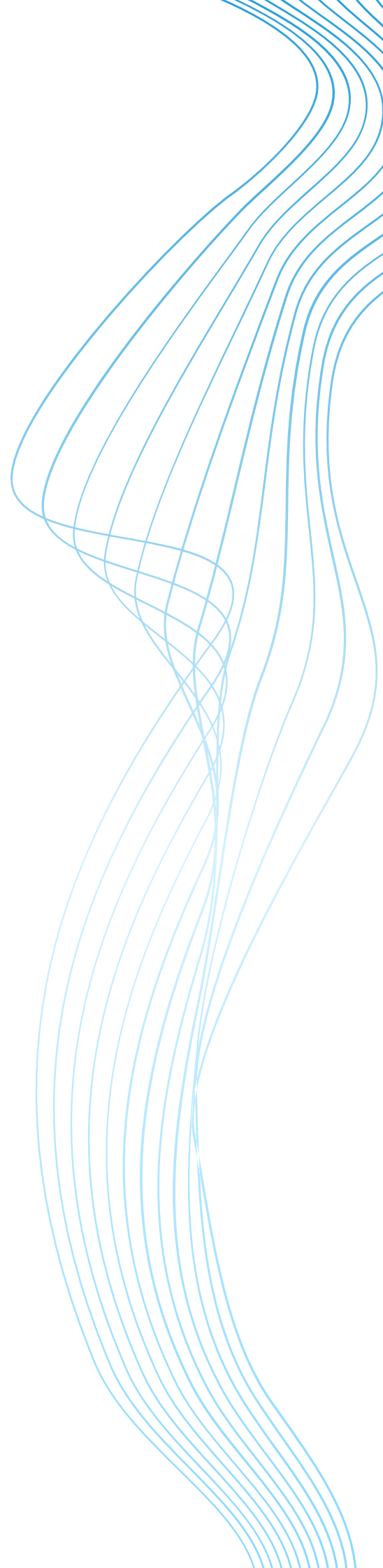
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# INTRODUCTION



## Patient Recruitment for Autism Clinical Trials: **Understanding Patient Perspectives**

Autism Spectrum Disorder (ASD) is estimated to affect more than 75 million individuals worldwide, and it is known to affect 1 in 100 children. Thirteen ASD trials are expected to start in the next 12 months, and more than 120 are currently recruiting patients.

Clinical research plays a crucial part in understanding and approving treatment options for individuals with ASD, and the patient profile is nuanced with respect to age, gender, ethnicity, genetics, lifestyle factors, medical history, environmental factors, and psychosocial factors. This therapeutic area brief provides a look at the patient profile for Autism Spectrum Disorder and highlights why Direct-to-Patient advertising is an ideal approach for recruiting patients for clinical research in these conditions.

# TYPICAL PATIENT PROFILE

**Autism Spectrum Disorder (ASD) is typically diagnosed in early childhood, often around 2-3 years of age when symptoms are first noticed by parents or caregivers.**

**It is more commonly diagnosed in males, with a male-to-female ratio of about 4:1 in clinical settings. While prevalence rates are generally similar across different ethnic and racial groups, there can be variations in access to diagnosis and services.**

## **Medical History: Genetics, prenatal factors**

There is a significant genetic component to ASD, and there is a higher likelihood of ASD in siblings of children already diagnosed with the disorder. In addition to the genetic component, there are prenatal factors that have been associated with an increased risk, including maternal infections and exposure to certain medications.

## **Lifestyle Factors: Diet, prenatal exposure**

Some studies indicate that certain dietary factors, such as maternal folic acid intake, may reduce the risk of ASD. Additionally, prenatal exposure to environmental pollutants, including air pollutants and pesticides, has been explored as a potential risk factor for ASD.

## **Psychosocial Factors: Social interaction, communication, behavioral patterns**

Individuals with Autism Spectrum Disorder often experience difficulties in social communication and interaction, which are core characteristics of the condition. These challenges influence how they engage with others and understand social cues. Additionally, people with ASD frequently exhibit repetitive behaviors and have focused interests, often leading to established routines or an intense concentration on particular subjects or objects.

## **Environmental Factors: Socioeconomic status, urban vs. rural**

Socioeconomic factors can play a role in determining the availability and accessibility of early intervention services for individuals with Autism Spectrum Disorder. Moreover, some studies have explored how living in urban versus rural areas might affect the prevalence of ASD and the access to necessary services.



# STANDARD DIAGNOSTIC & TREATMENT PATH

Individuals with Autism Spectrum Disorder follow a fairly standard diagnostic and treatment pathway which typically begins with either the Primary Care Provider or the Pediatrician. From there, a more comprehensive assessment is undertaken by a Neuropsychiatrist, Child Psychiatrist, or Psychologist.

The treatment planning often involves a Speech Language Pathologist and Occupational Therapist depending on how ASD is impacting the individual. After diagnosis, individuals with ASD will typically engage in various interventions through Special Education Services or Behavioral Therapies and will be followed and supported in an ongoing fashion.

Thousands of individuals have participated in Autism research, either instead of or in addition to the standard treatment methodology. With clinical research, they often receive access to new therapies or treatments, as well as even more comprehensive monitoring and care.

For those with more limited access to healthcare, clinical research opens treatment pathways with a lower financial burden. There is also an understanding that they are contributing to scientific knowledge and advancing treatment possibilities for the condition.



# PATIENT HESITANCY & CONCERNS

Autism Spectrum Disorder is a complex and challenging condition to navigate, and there are several reasons why a patient or their caregiver would hesitate to seek care, either in general or outside of the standard treatment pathway.

Individuals with Autism Spectrum Disorder may be less likely to seek healthcare due to a combination of challenges.

They often struggle to recognize or communicate their healthcare needs, and the sensory overload of medical environments can be overwhelming. Fear, anxiety, and past negative experiences with healthcare providers may also lead to treatment or diagnostic avoidance. Limited access to specialized care, a preference for routine, and a desire for self-management further contribute to their reluctance. Additionally, practical barriers such as financial costs, lack of insurance, and transportation difficulties can make accessing care even more challenging.

When considering care outside of their current path, factors like a preference for familiarity and routine, the importance of trust and relationship building, fear of the unknown, and the scarcity of available options play significant roles. Concerns about transportation, cost, appointment availability, stigma, misunderstanding, and fear of disruption also contribute to their hesitancy in seeking alternative care options.

While thousands do participate in clinical research, there are several reasons that patients hesitate to take this route, many of them similar to the other concerns outlined.

1. **Treatment safety and efficacy:** Concerns about potential side effects, unknown risks, and whether the treatment will be effective in addressing their condition are common.
2. **Impact on Routine and Stability:** Participating in clinical research could disrupt established routines or daily schedules, causing stress or anxiety to individuals who thrive on routine and predictability.
3. **Trust and Communication:** If there is a real or perceived lack of communication or understanding about ASD-specific needs, there may be concerns about trusting providers or researchers involved in the trial.
4. **Financial Considerations:** The cost of participation is a frequently held concern for clinical trial participation as a whole. Some concerns include worry about costs not covered by the trial itself or potential loss of income due to time spent participating or supporting participation.
5. **Lack of Control:** Families may feel a loss of control over the treatment process and decision-making, especially if they are accustomed to being actively involved in managing their child's care.

# 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. While significant research has been done on Autism Spectrum Disorder, there is still much that scientists don't know.



Newer ASD research includes focus on genetic factors, gut biome imbalances, neurological factors, and environmental impact. Early diagnostics and treatment can be extremely helpful to children diagnosed with ASD, so there is advancing research into innovative diagnostic methods. Additionally, there are advancements in biomarker research, looking at commonalities in metabolotypes.

Future studies include those that use cannabis or cannabidiol in treatment, hormone therapies, vitamin supplementation, and non-surgical procedures like Transcranial Magnetic Stimulation and pressure chamber therapy, to name just a few.

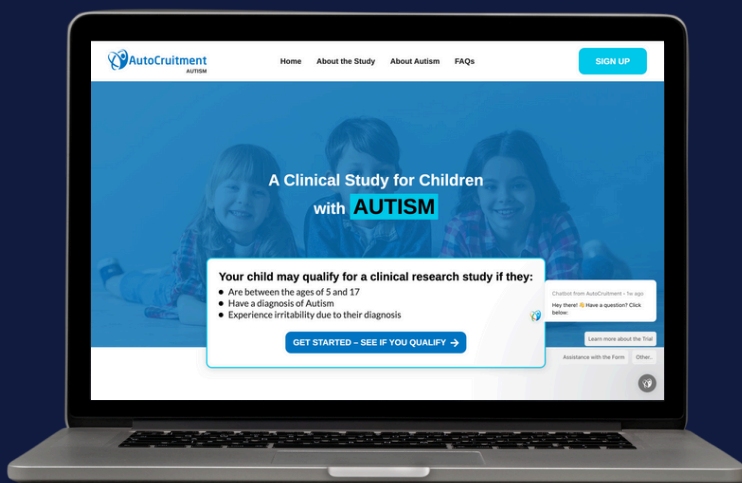
New treatments for Autism Spectrum Disorder (ASD) are increasingly being designed with a patient-centric approach, involving collaboration with the autistic community to co-create interventions that foster a deeper, empathetic understanding of the autistic experience.



# UNLOCKING ACCESS TO INDIVIDUALS WITH ADHD

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

Autism and ASD have been searched, on average, 718,000 times per month for the last year. With this condition, parents and caregivers are often turning first to online sources for information and education about their diagnosed or suspected condition as well as treatment and therapeutic management for the condition.



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 63 CNS Studies

Average increase in enrollment rate: 259%

Average time saved: 10.2 months

Total Randomizations Contributed: 2,501

# 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

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

## Dedicated Engagement Support

## 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.