

# SPECIAL AND PATIENT POPULATIONS

As clinical trials become more complex and the use of biologics becomes more widespread, protocols increasingly require recruitment of special and patient populations. Altasciences has the advanced level of clinical expertise required to successfully recruit and conduct clinical trials involving special and patient populations.

The key to the recruitment of special and patient populations is **effective screening**. Clinical pharmacology units must be able to quickly identify viable study participants based on protocol inclusion/exclusion criteria. In addition, recruiting populations for clinical research trials requires a **strategic approach** that combines market research, knowledge of the local media, target population information, cultural concerns, geographic considerations, as well as a **thorough understanding of the clinical trial process**.

Altasciences has been conducting clinical trials in special and patient populations, as well as in healthy normal patients, for over 30 years. Our **dedicated recruitment team** is highly trained to carefully pre-screen participants before scheduling them for an office screening appointment, where they meet with one of our full-time healthcare professionals; thus reducing study start-up timelines.

### **Distinctive Recruitment Strategies**

**Community outreach and thorough pre-screening** have helped us build a sizable database of potential study participants. Additionally, our **marketing strategies** provide a constant source of new participants. The **full-time, in-house recruitment team** is essential to the effective and efficient recruitment strategies designed to reliably meet your targeted milestones.

### **Regulatory Complexities**

We have **vast experience** working with a central Institutional Review Board (IRB) and we understand the requirements for study document approval. Our internal protocol review ensures the **protocol is IRB-submission ready**, minimizes the risk of amendments and shortens study start-up time for trials that involve special and patient populations.

### **Dedicated Research Physicians**

Our Principal Investigators are intricately involved in all aspects of the clinical trial process, ensuring that proper medical and technical procedures are completed to the highest degree of quality. Significant physician involvement is a key element for successfully conducting trials involving special and patient populations due to the often highly complex nature of these trials.

### **Specialized Pharmacy**

Our **robust pharmacy capabilities** include extemporaneous and intravenous preparation (including biologics). Our **full-time pharmacists** have extensive experience in preparing and dosing studies via oral, sublingual, intranasal and parenteral routes. Our pharmacy is secured with electronic key fob access, video monitoring and facial recognition security.

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## **Special and Patient Populations**

Over the past 30+ years, Altasciences has designed and conducted clinical trials in the following special and patient populations:

- Allergy
- Asian Ethnobridging
- Asthma
- ADHD
- Atopic Dermatitis
- Anxiety Disorders
- Binge Eating Disorder
- COPD
- Constipation
- Depression
- Diabetes
- Dyslipidemia
- Elderly
- Epilepsy
- Eye Disorder
- Fibromyalgia

- Genotyped Individuals
- GERD
- Gout
- Glaucoma
- Hepatic Impairment
- Hepatitis
- Hypercholesterolemia
- Hypertension
- Hypogonadal Men
- Lupus
- Migraine
- Nonalcoholic Fatty Liver Disease (NAFLD)
- Nonalcoholic Steatohepatitis
- NASH
- Osteoarthritis

- Osteopenia
- Overactive Bladder
- Overweight and Obese
- Pain and Inflammation
- Panic Disorder
- Post-Menopausal Women
- Premenstrual Dysphoric
  Disorder
- Psoriasis
- Recreational Drug Users
- Renal Impairment
- Restless Legs Syndrome
- Rheumatoid Arthritis
- Sleep Disorders
- Substance Abuse Disorder

#### **Local Partnerships**

To expand our Phase I/II capabilities and support sponsors with trials earlier in the drug development process, we partner with local research teams and hospitals. This gives us access to extensive patient pools in key therapeutic areas, providing an extended network of clinical research experience.



