

A flexible approach to

# Clinical Trials in Special Populations

**QPS EXCELS IN TRIALS INVOLVING HIGHLY  
SPECIFIC PATIENT POPULATIONS, RARE DISEASES,  
AND DEMANDING PROTOCOLS.**

The QPS experience combines flexibility, agility and speed, with proven procedures, networks and a scientific approach to support success at every milestone.

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TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.  
CONTACT THE QPS BUSINESS DEVELOPMENT TEAM TODAY!

CALL +1 512 350 2827 EMAIL [infobd@qps.com](mailto:infobd@qps.com)



## Why is QPS well positioned for these trials?

As part of a full service CRO, the QPS Clinical Research Division supports research in every clinical stage. QPS has extensive clinical experience across multiple Therapeutic Areas, including: CNS, Dermatology, Diabetes, Gynecology, Infectious Disease, Inflammation, Metabolic Disorders, Neurology, Pain, Respiratory, Urology, Vaccines, and Rare Diseases.

Trials enrolling special patient populations like the elderly, children, pregnant women, breastfeeding women and others, require a higher level of experience and attention to adequately address the associated risks and challenges. However, there might also be benefits for these populations, like access to newer treatments and general medical care. It is the task of the CRO to efficiently leverage these

benefits in order to ensure an optimum performance of the study.

Furthermore, certain patient populations require specific doses and/or treatment schedules. Depending on the specific patient population, the schedules of families, caregivers or other parties involved need to be considered appropriately. Otherwise, patient recruitment and/or patient retention may become a significant challenge.

Customized clinical trial advertising, using social media and other web-based tools is usually appropriate to efficiently target special patient populations. Digitally savy recruitment experts and a reasonable budget are essential prerequisites to effectively maximize these channels.

## Two Examples of At Risk Populations

### Clinical Trials in Elderly

The success of trials within the elderly population often depends on the involvement of caregivers, the existence of a favorable patient pathway and an age-appropriate informed consent procedure. Furthermore, trials in elderly people must carefully consider the frequency of underlying diseases, as well as a higher level of concomitant medication use, which causes an increased risk of medicines interactions.

### Clinical Trials in Children

There is a need for data obtained in children, since this population has physiological, developmental and psychological differences from other populations. This population is particularly vulnerable, and for the purposes of clinical trials, children are subdivided according to their age. To better protect this population, there is legislation to prevent

unnecessary trials involving children. Consequently, one of the main tasks prior to starting a trial is to diligently investigate the risk and burden to be placed on participating children during the trial. The consent procedure in pediatric trials requires careful attention. By definition, children are unable to legally consent, but they should be involved in the process of informed consent, to the extent possible, through the use of age-appropriate materials. Finally, national and study related differences need to be carefully considered (e.g. in some countries the will of a child to participate in a clinical trial is a legal requirement).

The QPS Team consists of people with the appropriate knowledge, expertise, attitude and diligence to run trials in many different special populations, fulfilling the needs of patients, sponsors and investigators.



**AGILITY. FLEXIBILITY. SPEED.**

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**EMAIL** [infobd@qps.com](mailto:infobd@qps.com)

**QPS is a Global CRO**  
with locations around the world  
to serve the evolving needs of the  
Pharmaceutical and Biotech industries

