FACT SHEET BY PREMIER RESEARCH

PEDIATRICS

At Premier Research, we don't try to be everything to everyone. We focus on doing what we do best.

Pediatric studies are substantively different from adult trials in terms of recruitment challenges, operational feasibilities, ethical considerations and regulatory requirements. Premier Research brings to bear an extraordinary depth of experience, insight and capability in pediatric trials with both familiar and extremely rare and complex childhood illnesses.

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PEDIATRICS

Overcoming the number one challenge: successful recruitment of pediatric patients

In both the U.S. and Europe, it has become increasingly challenging and time consuming to find pediatric patients who qualify for study participation in anything but the smallest trial. Direct recruitment of healthy volunteers prior to maturity is not permissible under pediatric ethics guidelines. We also work in Latin America and Southeast Asia/Australia to gain access to large, as-yet-untapped patient populations. First and foremost, though, we design studies that make compliance as straightforward as possible for patients, families, and healthcare providers — for example, by scheduling visits after school hours. We help families understand that what they are doing can have a noticeable effect on the health and wellbeing of both their own child and millions of other children worldwide.

Dealing with often-confusing pediatric regulatory requirements

Current regulations for adult medication approvals in both the U.S. and Europe frequently require pediatric studies or waivers. Although the pediatric regulations are well- intentioned, how to best accomplish pediatric trials is often as provocative a question for regulators as it is for industry sponsors. Regulatory authorities are open to being educated about pediatric-specific considerations that sponsors unearth as they begin to conduct pediatric trials. Premier Research can help demonstrate that the pediatric research they requested needs to be amended to gain meaningful data or that alternatives to the requested work should be factored into a solution.

Our pediatricians and pediatric specialists have conducted 130 trials in the past five years.

We acquired extensive — and diverse — pediatric expertise during our six years as the sole Coordinating Center for the Best Pharmaceuticals for Children Act (BPCA). Working with the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) within the NIH, our mission was to obtain pediatric labeling for high-priority off-patent medications. Our experience encompasses PICUs, NICUs, clinics, ERs and outpatient settings, and the recruitment and retention of neonates, infants, children, and adolescents. We also established close relationships with specialists at many of the 180 North American children's hospitals.

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IT'S WHAT WE DO. BEST.™

North America: +1 919 627 9069 | Europe: +44 118 936 4000 | info@premier-research.com premier-research.com