OVERCOMING THE CHALLENGES OF PEDIATRIC CLINICAL RESEARCH

Children are severely underrepresented in the world of clinical research.

This is bad news for kids, even though they have long relied on and often benefitted from off-label use of the vast majority of drugs prescribed to them.

Drugs without proper clinical research in pediatric populations raise the risk of unexpected adverse events, suboptimal therapy, and inappropriate dosing.

211,209 kids to the emergency room were by adverse drug reactions in 2008 alone.®

The FDA granted marketing exclusivity to 189 drug sponsors extending studies to children from 1998-2012.

57% of the 189 drugs granted exclusivity extended studies to the pediatric population.

To Design an Effective Pediatric Clinical Trial, You Must Consider:

- Multiple age groups, as appropriate:
  - Earliest age appropriate for study
  - Adolescents aged 12 or older
- Recruitment, medical techniques, and staff prepared to appropriately manage pediatric patients
- Consent/assent procedures, and trial ethics requirements
- Quality of life, schedule, and number of interventions
- Techniques for recruitment, retention, communication, and comfort for families

FDA Incentive programs have removed some of the hurdles to completing these critical pediatric trials.

The Foundation for the National Institutes of Health offers some trial funding for the study of off-patent drugs in children.®

MAKE YOUR PEDIATRIC CLINICAL RESEARCH A SUCCESS WITH WORLDWIDE CLINICAL TRIALS

Our experts offer unmatched support in the clinical, technical, and regulatory environment understanding pediatric disease development.

Worldwide’s uncommon commitment to pediatric clinical trial solutions.

REFERENCES

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