

Signant understands the unique challenges that pediatric clinical trials bring.

And we're adept at helping sponsors navigate them effectively.

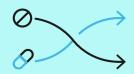


CLINICAL EVIDENCE

IN PEDIATRIC TRIALS

COA SELECTION AND VERSIONING

Our scientists advise on when to use self-completion, proxy, and observer versions. Our solutions simplify in-trial transition between age-related versions of scales.



PLACEBO RESPONSE MITIGATION

Pediatric trials are often associated with the highest placebo response rates. We work with site staff, raters, caregivers, and patients to minimize the placebo response associated with study assessments.



<u>~</u>

AGE-APPROPRIATE PROTOCOL DESIGN

Our clinicians consult on study visit schedules of assessments and settings to ensure measurement strategies drive endpoint reliability and accuracy without overly tiring young participants.



RECRUITMENT AND RETENTION

We understand that recruitment and retention can be challenging in paediatric studies. Our inhouse clinicians and scientists help sponsors to identify optimal approaches including decentralization to simplify participation.

Why choose Signant Health for your pediatric trial?

- Design studies with our in-house experts who lead industry thinking in pediatric trials through their roles in working groups and professional societies, and their peer-to-peer relationships with academic opinion leaders.
- O2 Leverage our feature-rich technology solutions, specially adapted to the needs of pediatric studies.
- Benefit from industry-leading rater training and placebo response mitigation planning to drive the highest quality clinical evidence.
- 04 Leverage our experience of trial conduct to help identify and select high performing sites in terms of data quality.



LEVERAGE OUR FULL SOLUTION SET FOR PEDIATRIC TRIALS







eCONSENT



CLINICIAN RATINGS



STUDY DESIGN CONSULTING

Easily switch in-trial between age-related patient-reported outcomes versions

Implement proxy and observer scales

Select optimal ePRO collection modality

Leverage gamification and engagement content thoughtfully and appropriately

Enable both patient assent and legally authorised representative consent

Provide age-appropriate study information content for different users

Enable remote access to reduce the need to travel, as appropriate

Custom and specialized rater training for pediatric measures to standardize data

Placebo response mitigation planning and training

Electronic rating including prompts to drive measure standardization

Optimize protocols for pediatric populations including splitting visits to reduce visit fatigue

Leverage technology to decentralize aspects of the study, as appropriate, to reduce travel time and burden

Support ethics and regulatory review

EXPERIENCED IN PEDIATRIC TRIALS ACROSS A BROAD RANGE OF DISEASES



- Vaccine research
- Rare / Orphan diseases
- Eczema / Atopic dermatitis
- **Psoriasis**
- Allergy

- **Epilepsy**
- Hemophilia
- Type 1 diabetes
- Migraine
- Ulcerative colitis
- Overactive bladder

- Bipolar disorder
- Schizophrenia
- Generalized anxiety disorder
- Major depressive disorder
- Tourette Syndrome
- Autism spectrum disorder
- ADHD
- Multiple sclerosis
- Neurodevelopmental disorders
- Duchenne Muscular

Dystrophy

- Growth hormone deficiency
- Fragile X
- Niemann Pick Disease
- Lennox-Gastaut Syndrome

...and dozens of others

WHO IS SIGNANT HEALTH?

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes - including all Top 20 pharma - have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.