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MELBOURNE, AUSTRALIA, April 28, 2025 /EINPresswire.com/ -- [iNGENū CRO](https://www.ingenucro.com), a full-service contract research organization headquartered in Australia, has announced its strategic focus and growing leadership in complex paediatric clinical trials, specifically involving profoundly intellectually and physically disabled children with rare neurodevelopmental conditions.



This specialized domain—regarded as one of the most operationally and ethically challenging areas of clinical research—is one that only a select few CROs globally have the capability to support. iNGENū is currently conducting multinational, multicentre trials across Australia and the

Asia-Pacific region in Rett Syndrome and Autism Spectrum Disorder (ASD), both of which demand highly tailored trial designs, specialised medical oversight, and nuanced understanding of paediatric neurobiology.

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“These are not conventional paediatric studies. They involve children who are often non-verbal, have severe functional impairments, and require complex behavioural and physiological endpoints,” said [Dr. Sud Agarwal](#), Chief Medical Officer of iNGENū CRO.

“Designing and operationalizing these trials requires deep

fluency in paediatric neuropsychiatry, neurodevelopmental trajectory analysis, and precision

consent frameworks that engage both caregivers and specialist physicians. It is one of the highest bars in clinical research methodology.”

[iNGENū’s](#) studies in Rett Syndrome—an X-linked disorder marked by profound psychomotor regression and autonomic dysregulation—require integration of caregiver-based assessments, EEG biomarkers, and serial developmental tracking across multiple languages and cultural contexts.

Simultaneously, its ASD program involves a basket trial structure using CBD-based interventions stratified by functional phenotypes, integrating adaptive trial designs and centralized digital assessments.

The CRO partners with leading developmental paediatricians, specialist disability services, and experienced site investigators, and employs a dedicated internal team trained in paediatric Good Clinical Practice (GCP), non-verbal patient engagement, and neurocognitive outcome assessment.

“Few CROs possess the clinical governance, technical infrastructure, and frontline experience required to deliver trials in this population,” said Dr. Agarwal. “At iNGENū, we have built a fit-for-purpose platform to ensure that the most vulnerable children—those typically excluded from clinical trials—can be included in a way that is both scientifically valid and ethically robust.”

With an expanding pipeline in rare and complex paediatric disorders, iNGENū CRO. continues to shape the future of child-focused drug development across the Asia-Pacific region.

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