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# Clouds of Care: Developing EEG-based endpoints for brain function quantification in rare pediatric diseases

About Clouds of Care

Clouds of Care NV is an ISO 13485:2016 and ISO 27001:2022-certified MedTech company, offering CE-marked and FDA-cleared electrophysiology applications for clinicians and clinical development solutions for biopharma. The company specializes in EEG, ERP, and PSG signal processing and consulting services within clinical trials in epilepsy, rare pediatric disorders, Alzheimer's Disease, Parkinson's Disease, and other neurodegenerative indications. Their mission is to develop biomarkers that enhance the probability of success in CNS clinical development.

Clouds of Care champions in data-sharing, collaboration, and innovation, providing a curated network of digital health solutions to advance CNS endpoint discovery and enable better care through multimodal insights, starting from electrophysiology.
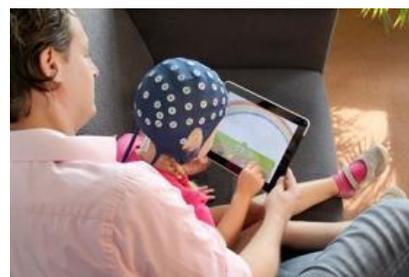
The opportunity

Unlocking the "black box" of pediatric cognition with objective biomarkers.

- Event-related potentials (ERPs), recorded with EEG, provide a non-invasive, user-friendly and standardized way to assess cognitive and socio-emotional development in rare pediatric CNS disorders where objective assessments are often lacking.

- By capturing the brain's neural response to sensory, cognitive, and motor stimuli in real-time via ERPs, this technology allows clinicians to measure information-processing dysfunctions objectively, even in pre-verbal or minimally communicative patients who cannot participate in traditional testing.

The challenge

In rare pediatric CNS disorders, assessing cognitive and socio-emotional development is notoriously difficult.

- Reliable endpoints require protocols that can accommodate children who may be unable to follow instructions or tolerate long setup times.

- While the science of ERPs is well-established, translating it into reliable clinical trial endpoints for rare diseases involves significant operational hurdles.

- Delivering high-quality ERP endpoints demands development and age-appropriate acquisition protocols, carefully selected paradigms and tasks, and appropriate EEG hardware and setup to address technical and operational challenges.

The approach

- Clouds of Care's solution involves designing the ERP paradigm around relevant components, using fit-for-purpose EEG equipment, training technicians, and combining automated ERP extraction with expert verification to ensure data quality.

- By selecting and deploying EEG equipment specifically suited for pediatric use, Clouds of Care addressed the unique physical and compliance challenges of the patient population.

- Specific ERP components derived from auditory and visual paradigms can provide insights into sensory discrimination, attention, and cognitive processing, and can act as **biomarkers of disease progression and treatment response,** as they are sensitive to subtle neural changes.

The impact

✔ By successfully implementing this rigorous ERP framework, sponsors can access a new class of objective endpoints for disease progression and treatment response, which can ultimately speed up the clinical development and delivery of new treatment options for pediatric patients.

✔ This method provides a viable path to measure efficacy in the most challenging populations—pre-verbal and non-communicative children—ensuring they are not excluded from clinical trials due to measurement limitations.

" We see EEG as a powerful yet underutilized tool for delivering objective, quantifiable insights into brain function. Integrating these signals alongside other digital measures can improve endpoint sensitivity, reduce trial burden, and ultimately increase the probability of success in clinical development."

— Pieter van Mierlo
Chief Scientific Officer, Clouds of Care