Indivi and Clouds of Care Partner to Advance Deep Phenotyping in Early Alzheimer's and Parkinson's Drug Development

Basel, Switzerland – October 15, 2025 – Indivi and Clouds of Care, two independent TechBio companies, today announced a strategic partnership to advance the use of precision medicine tools in early-phase neuroscience drug development, targeting Alzheimer's and Parkinson's disease.

The field of neurodegeneration remains one of the toughest challenges in medicine, with a historically low probability of technical and regulatory success (PTRS). The highest attrition occurs between First-in-Human and Proof-of-Concept studies, where conventional endpoints lack the sensitivity needed to detect early treatment effects.

"*Age being the principal risk factor for neurodegenerative diseases, we are facing a global pandemic*," says **Michel Vounatsos, Chair of the Board of Directors of Clouds of Care.** "*Deep phenotyping technologies will be essential to improve drug development success in Alzheimer's and Parkinson's Disease and extend healthy brain ageing across the lifespan*."

The partnership will integrate world-class expertise in neuro-electrophysiology (resting-state EEG, event-related potentials, and polysomnography) with digital health technology tools. Together, they aim to establish a unified R&D framework for multimodal deep phenotyping, combining biological (electrophysiology-based) and functional (cognitive and motor behavior) measures to deliver earlier, more definitive Proof-of-Biology (PoB) and Proof-of-Concept (PoC) signals in early drug development trials.

This collaboration creates a technology-integrated value proposition, which de-risks early clinical development, by increasing the signal-to-noise ratio of PoB-PoC endpoints, thereby enhancing the PTRS, and potentially improving the risk-adjusted Net Present Value (rNPV) and accelerating time-to-market for biopharmaceutical partners.

The initiative aligns with the European Medicines Agency's (EMA) recent call for updated guidelines on early Alzheimer's trials, emphasizing the need for more responsive and clinically meaningful endpoints in early clinical phases.

"*It is not just about bringing deep phenotyping technologies together*," says **Shibeshih Mitiku Belachew, Chief Medical Officer of Indivi.** "*It is about creating a true symbiosis between clinical development and the science of enabling technologies to design smarter, faster, and more successful trials*."

About Indivi *& Deep Phenotyping Measures of Cognitive and Motor Functions for Proof-of-Concept Demonstration of Disease Modification:*

Indivi is an ISO 13485 and ISO 27001-certified TechBio company headquartered in Basel (CH) and developing future-proof functional biomarkers derived from Digital Health Technology (DHT) tools measuring key disability concepts of importance (motion and cognition) for drug development trials in neuroscience.

- Indivi developed the most comprehensive suite of smartphone-based assessments (N=20) of motor and cognitive functions, including **Konectom**[1,2], a digital biomarker platform in-licensed from Biogen in 2024.
- **CoGames**[3] is a proprietary battery of smartphone-based gamified and user-adaptive cognitive assessments (ACA).
- **CoGames** entails a unique system of dynamic difficulty adaptation to individual performance, which enables personalizing the difficulty of each cognitive assessment for each subject, at trial baseline.
- **Publications** : https://indivi.io/insights

About Clouds of Care *& Deep Phenotyping Measures of Brain Activity for Proof-of-Biology Demonstration of Disease Modification:*

Clouds of Care NV is an ISO 13485 and ISO 27001-certified TechBio company in Ghent, Belgium, housing CE-marked and FDA-cleared electrophysiology applications for clinicians and tailor-made clinical development solutions for biopharmaceutical companies. Through its comprehensive *CNS platform* and strategic network of partners, Clouds of Care is revolutionizing care for people with Central Nervous System disorders.

- **Resting-state EEG during wakefulness and sleep** measures direct and indirect effects of active compounds on brain activity as a pharmaco-dynamic readout of therapeutic response at the level of neuronal biology.
- **Event-related potentials (ERPs)**, recorded using scalp EEG, offer a non-invasive, high-temporal-resolution method for assessing cognitive and socio-emotional activity of neurons in response to sensory and cognitive stimuli. ERPs enable the quantification of biological dysfunctions in information processing, even in minimally communicative patients. Sensitivity to subtle neural changes makes ERPs valuable PoB endpoints for early-stage clinical trials.

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[1] https://konectom.com
[2] Llorens-Arenas R et al. Smartphone-based digital assessments in the LUMA trial of BIIB122/DNL151 for early-stage Parkinson's disease. International Congress of Parkinson's Disease and Movement Disorders, 2025, Poster P860, October 7, Hawaii, USA
[3] Rodríguez-Romero A et al. Biomarkers of Alzheimer's disease modification using adaptive cognitive assessments to improve responsiveness - a simulation study. *Front. Neurosci*. 2025, 19:1653261.

- The proprietary **Electrical Source Imaging (ESI)** of Clouds of Care estimates the 3D spatial distribution of the brain activity source localization (using an electromagnetic model built from the subject-level brain MRI), which is essential to capture spatially heterogeneous disease signatures as those observed in Alzheimer's and Parkinson's diseases.
- **Publications** : https://www.cloudsofcare.com/publications

More Information:

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