

Development of the NICS Multi-Informant Clinical Formulation Toolkit

A Multi-Informant Approach to Characterizing Dysregulation Drivers Relevant to ND

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What is the Methodological Issue Being Addressed? Current CNS trial outcome measures rely heavily on aggregate symptom scales that fail to disentangle core neurodevelopmental pathology from contextual drivers (e.g., environmental mismatch, physiological states, sensory dysregulation). The NICS toolkit introduces a novel, structured, multi-informant formulation framework (NEEDS model) to decompose contributors to dysregulation and improve signal detection in clinical trials.

Introduction Traditional trial designs in neurodevelopmental CNS disorders are limited by heterogeneous populations and nonspecific outcome measures. The NICS framework proposes a paradigm shift from single-score severity ratings to multidomain, informant-integrated profiling. This design enables identification of mechanistic drivers of symptoms, potentially improving patient stratification and outcome sensitivity.

Methods The NICS toolkit includes five informant-specific instruments (clinician, caregiver, child, adult, short form) using a 0–3 anchored scoring system with an “insufficient information” option. Domains include Neurotype, Environmental Fit, Education, Medical/Physiological factors, Sleep/Sensory regulation, and Interoception. Planned validation includes staged assessment: content validity (expert review), feasibility and inter-rater reliability testing, and construct validation in neurodevelopmental trial populations. Unsourced Overlay Modules are added as well. Target sample sizes will be determined per phase (e.g., ~50–100 for reliability; larger cohorts for construct validation).

Results Preliminary development demonstrates feasibility of a multidomain, multi-informant approach with structured scoring and profile outputs rather than a single severity metric. An illustrative case shows differential domain contributions (e.g., high interoceptive and environmental drivers), supporting the toolkit’s ability to identify non-core contributors to dysregulation. Projected validation studies are expected to show improved signal separation and reduced measurement noise.

Conclusion The NICS toolkit represents a novel methodological approach for CNS trials, shifting from symptom severity to structured clinical formulation. This approach may enhance patient stratification, reduce confounding, and improve detection of treatment effects. If validated, NICS

could address a major source of failure in neurodevelopmental clinical trials by aligning outcome measurement with underlying mechanisms

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Keywords

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Guidelines I have read and understand the Poster Guidelines

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