

Indication-Specific Outcome Measure Considerations in Neurodevelopmental Disorder Trials



Indication-Specific Outcome Measures

Increase specificity

- Disease/symptom specific

Increase sensitivity

- More granular approach

Role of Cogstate in Trials Using Indication Specific Outcome Measures

Development of outcome measures: Expert in disease areas

Validation of outcome measures

Training and reliability of clinical trial raters;
oversight of data quality

Clinical meaningfulness of change



A photograph of a woman with long dark hair smiling warmly while holding a young child. The child is also smiling and looking towards the camera. The scene is set in what appears to be a hospital or clinic, with a table and some equipment visible in the foreground. The entire image is overlaid with a semi-transparent blue filter.

Meaningful Within-Patient Change



Meaningful Within-Patient Change

- Data-driven, statistical approaches
- Exit interviews from early phase trials
 - Asking caregivers/patients:
 - *What changed?*
 - *Was the magnitude of change meaningful?*
- Mixed quantitative/qualitative approach with direct input from key stakeholders



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