Critical Evaluation of Vineland™-II and Vineland™-3 as Outcome Measures for ASD Clinical Trials

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Financial Disclosures All authors report no financial disclosures.

Objectives

• Identification of reliable and valid measures of social communication challenges which are sensitive to change in ASD trials, and to assess the efficacy of new behavioral and pharmaceutical interventions for autism spectrum disorder (ASD).

• To determine which social communication measures are available for Vineland™-II and Vineland™-3 and evaluate the advantages and disadvantages of each with respect to precision of valid and sensitive measures of social communication in ASD.

Methods

• To report decision-making around the selection of tools for future clinical research, we reviewed the content, context, and other clinical studies available for Vineland™-II and Vineland™-3 and evaluated the advantages and disadvantages of each with respect to precision of valid and sensitive measures of social communication in ASD.

Conclusions

• In VINELAND, 3 is an updated and potentially improved scale, with the added layers of scale validity and evidence of sensitivity to change in ASD populations indicating that Vineland™-3 is still a valuable measure for clinical development programs.

• White Vineland™-3 is an updated and potentially improved scale, with the added layers of scale validity and evidence of sensitivity to change in ASD populations indicating that Vineland™-3 is still a valuable measure for clinical development programs.

Background

Social Communication Challenges Are Part of the Core Symptoms of ASD

• ASD is a complex, heterogeneous neurodevelopmental disorder characterized by impairments in social communication and interaction, as well as restricted behaviors and restricted interests.

• Adaptive functioning, including social communication skills, is an important factor to be taken into consideration when assessing the outcomes of ASD with VABS-2 and Vineland™-3, and improving adaptive abilities is a desirable treatment goal.

• Adaptive behaviour skills include three core domains of adaptive behaviour: communication, socialization and daily living skills.

The Vineland™-II and Vineland™-3 Have Good to Excellent Reliability

• The Vineland™-II and Vineland™-3 have been used extensively in multiple clinical settings, including pharmaceutical trials (e.g., ANXIETY (NCT00754941), Vineland (NCT00249457) and psychiatry (NCT01041451)).

• The Vineland™-II has been validated in multiple settings, including clinical trials (e.g., Vineland (NCT00754941)).

• The Vineland™-II has been used as a primary endpoint in a placebo-controlled trial (NCT00360461).

• The Vineland™-III is an updated version of the scale that has recently been used in some ASD trials, including the ongoing registration trial (NCT01524131).

• The Vineland™-II has updated content that reflects changes in skills related to everyday life (e.g., new technologies such as smartphones), and adapted norms carrying in temporal period developmental norms.

Results

Reliability Across Vineland™ Scores

• Internal consistency.

• Test-retest reliability.

• Interrater reliability.

• Total test reliability.

• Outcome Measures for ASD Clinical Trials

Conclusions

The Vineland™-II and Vineland™-3 Have a Proven Record of Success

• Vineland™-II and Vineland™-3 are well-established and internationally validated tools for measuring adaptive behavior in individuals with ASD.

• The Vineland™-II and Vineland™-3 have been used extensively in multiple clinical settings, including pharmaceutical trials.

• The Vineland™-II and Vineland™-3 have been validated in multiple settings, including clinical trials.

• The Vineland™-II has been used as a primary endpoint in a placebo-controlled trial.

• The Vineland™-III is an updated version of the scale that has recently been used in some ASD trials, including the ongoing registration trial.

• The Vineland™-II has updated content that reflects changes in skills related to everyday life (e.g., new technologies such as smartphones), and adapted norms carrying in temporal period developmental norms.

References

1. Dawson G, Wiltsie T, Reading KH, Sanders S, and Smith J*. Critical Evaluation of Vineland™-II and Vineland™-3 as Outcome Measures for ASD Clinical Trials. Presented at the International Conference on Clinical Trials and Methodology – 2020 Autumn Conference, 6-7 September 2020, Copenhagen, Denmark (Index of joint day with the European College of Neuropsychopharmacology).

2. Dawson G, Wiltsie T, Reading KH, Sanders S, and Smith J*. Critical Evaluation of Vineland™-II and Vineland™-3 as Outcome Measures for ASD Clinical Trials. Presented at the International Conference on Clinical Trials and Methodology – 2020 Autumn Conference, 6-7 September 2020, Copenhagen, Denmark (Index of joint day with the European College of Neuropsychopharmacology).