THE SIGNAL
BLOG BY SIGNANT HEALTH

VISIT THE SIGNAL

Simplifying the Vineland-3: Assisting Raters, Reducing Burden, and Improving Data Quality

Joan Busner, PhD; Margot Oakley, MSN; Elizabeth Jones, MA; Samantha Silverman, MS, MPH

The Vineland Adaptive Behavior Scales – Third Edition (VABS-3) is a widely used standardized, semi-structured interview that assesses adaptive behavior skills (Communication, Daily Living Skills, Socialization) from birth to age 90+. The scale is a gold standard in clinical trials for autism spectrum disorder, developmental epileptic encephalopathies, and other conditions involving cognitive or developmental delays. The scale is administered via interview with an informant, typically a parent or caregiver, who has direct knowledge of the participant's daily life functioning.

The scale is designed to be administered by raters who are trained psychometricians, typically psychologists. **However, the paper-and-pencil format of this scale is complicated to administer correctly and score, even for highly experienced raters**. Like its predecessor, the Vineland-II, each component of the paper-and-pencil Vineland-3, for example, requires a separate multi-step, age-based calculation formula to derive standardized scores. In addition, although accurate administration and scoring of the scale requires frequent reference to a separate, large, scoring manual, this step is often bypassed by busy raters, thus jeopardizing scoring precision and validity.

Electronic Vineland-II and Vineland-3: Focusing on the Informant by Easing Rater Burden

To address these problems, Signant Health, in consultation and collaboration with Pearson, developed a widely acclaimed, user-friendly electronic Vineland-II. We first introduced the electronic Vineland-II in 2016 and presented additional data via poster at the 2019 ASCP Annual meeting (download the poster here).

With the publication of the revised paper-and-pencil Vineland-3, Signant again worked with Pearson to create an electronic Vineland-3. Both the Vineland-II and the Vineland-3 have been utilized successfully by sponsors for US, UK, and European populations,

administered using our Electronic Clinician Ratings platform. We describe below some of the features of Signant Health's Vineland-3.

- **Built-in prompts:** The Signant Health electronic Vineland-3 includes item-specific open-ended prompts, as well as item-specific scoring criteria
- **Built-in item-by-item scoring guidance:** Rather than needing to repeatedly reference the paper manual during an administration, raters receive individual item-level scoring guidance, enhancing scoring accuracy, improving the administration experience for raters and informants, and improving ratings reliability.
- **Built-in scoring:** The rater need only enter item-level scoring. The Signant Health electronic Vineland-3 reminds the rater as to basal and ceiling rules for each subdomain, and then notifies the rater when basal and ceiling rules for each subdomain have been met; the system also notifies the rater if required item-level scores are missing. The Signant Health electronic Vineland-3 calculates all required raw and standardized scores including all age specific normative score look-ups (e.g. v-Scale Score, Domain Standard Score, Adaptive Behavior Composite). This greatly reduces time and burden for the site rater, as well as reducing human error that can occur in fully scoring the Vineland-3.

Additional Advantages of the Electronic Vineland-3

Customizability

Although the Signant Health electronic Vineland-3 mimics the paper scale, it is flexible and can be tailored to any protocol. For example, certain age-specified subdomains will not be displayed to avoid inadvertent administration of items. In addition, depending on sponsor needs, participant age can be locked to that of the baseline visit for repeat administrations (holding the norming tables constant) or can be allowed to advance as the participant moves through the trial. The two optional sections of the Vineland-3, Motor Skills (Gross and Fine) and Maladaptive Behavior (Internal, External, Maladaptive) are available for studies where these areas of functioning are of interest.

Audio & Video Capture

Signant Health has robust methods of training site raters and monitoring data throughout the life span of a study. To ensure site raters are conducting the Vineland-3 interview appropriately and scoring items per Vineland-3 conventions, we engage with an international team of Central Quality Reviewers (CQRs), who provide expert review of Vineland-3 administration and scoring, to provide insight into site/rater performance and to remediate issues identified. Signant's Rater StationTM has the capability of capturing both audio and video administration of the Vineland-3 to support such reviews.

Central Ratings Capabilities

Sponsors may also choose to utilize Central Raters to reduce rater variance during the course of a study. Signant Health's Rater Station™ can support this data collection methodology for the Vineland-3 with our expert Central Raters. Central Raters are fully trained and monitored, and undergo calibration or recalibration throughout their role as a Central Rater in a study.

Blinded Data Analysis

Signant provides an enhanced view of Vineland-3 study data, near real time with its proprietary Blinded Data Analysis (BDA) service. Using its extensive international database, BDA tracks study-specific data trends, identifies country, site, and rater anomalies, and allows for informed, actionable clinical recommendations.

In summary, data quality in any trial is paramount. Complex rating instruments such as the Vineland-3 may be administered and scored differently from rater to rater, introducing opportunities for errors and unwanted variability. Signant Health's electronic Vineland-3 is the only validated version of this scale available from an eCOA provider, and offers a scientifically robust solution for reducing rater burden and enhancing scoring accuracy in clinical trials. With built-in prompts, automated scoring, and customizable options to accommodate protocol or patient population needs, we ensure reliable endpoint data—a critical need in trials assessing cognitive and developmental delays. In addition, support from expert Central Raters and tools like Blinded Data Analytics, Signant provides unmatched precision and oversight throughout the study lifecycle.

To learn how Signant can support your protocol with our validated electronic Vineland-3, contact us today.

About the Authors

Elizabeth Jones is a Program Manager in eCOA Clinical Science at Signant Health, with 14 years of experience in clinical trials. She holds a Master's in Forensic Psychology and has extensive clinical experience across various settings. At Signant Health since 2011, Elizabeth has worked as a Clinical Lead, focusing on rater training and monitoring, particularly with the Rater Station™ platform. Her expertise spans pediatric, adult, and geriatric CNS and neurological indications.

Samantha Silverman holds Master's degrees in Health Psychology and Public Health. She joined Signant Health in 2013 and serves as both a Senior Clinical Scientist and eCOA Clinical Scientist in the Digital Health Science Department. In her role, she works across various indications and acts as a liaison between clinical and technical teams for studies using Signant's Rater Station™ learning management platform.

Margot Oakley is a Masters-level Registered Nurse with a diverse clinical background. Her extensive nursing experience covers various medical diagnoses and settings. She has prior experience in clinical trial work at research sites and as a Clinical Research Associate for a CRO. For the past 16 years with Signant Health, she focuses on pediatric and adult CNS clinical studies, with recent emphasis on pediatric rare diseases.

Dr. Busner has over 35 years of experience as an academic psychiatric researcher, serving as Principal Investigator for 49 clinical trials and Sub-Investigator for 35 more. She has authored or co-authored over 140 peer-reviewed articles and presentations. Before joining Signant Health, she directed psychiatric clinical trials at two major medical schools and served on University IRBs for 20 years. Currently an Affiliate Associate Professor of Psychiatry at Virginia Commonwealth University, Dr. Busner leads studies at Signant on pediatric, rare, and psychiatric disorders, and has trained thousands of clinical trial investigators worldwide.

Interested in reading more blogs from The Signal?

SUBSCRIBE

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at **www.signanthealth.com**.