



Bracket

Science. Technology. Service.



eCOA

electronic Clinical Outcomes Assessments

Case Study: Bracket Revolutionizes Vineland Adaptive Behavior Scale with eCOA Technology

Bracket's proprietary electronic clinical outcomes assessment (eCOA) solution for Pearson's Vineland Adaptive Behavior Scale, Second Edition (Vineland™-II) drives precision, efficiencies, and compliance.

Overview

The Vineland Adaptive Behavior Scale, Second Edition (Vineland™-II), published by Pearson, is a gold standard measure of adaptive functioning in clinical trials of children and special needs adults. Used internationally, this tool measures function in communication, socialization, daily living, and motor skills, and also measures aspects of

maladaptive behavior. Traditionally, Vineland-II administration has been limited to paper-and-pencil until recently, when Bracket introduced an advanced eCOA solution that aims to bring better treatments to the market by reliably measuring their effectiveness in clinical research trials.

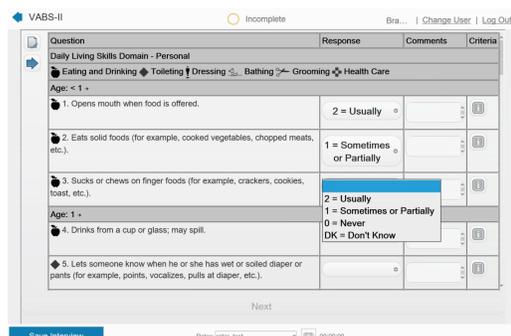
The Challenge

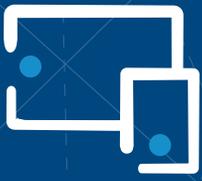
Used repeatedly in a variety of clinical trials for mental health research, the scale's traditional paper-and-pencil administration format presented an opportunity for improvement. Among the many challenges associated with clinicians writing responses on long forms at busy sites, often with young children present, was the need for clinicians to refer to the Vineland II's substantial Appendix, which provides critical guidance for properly scoring and assessing hundreds of queries.

Located in the back of the Vineland-II manual, the Appendix is often bypassed when administering the test simply because the test is time-consuming and at clinical trials sites there is often a variety of additional procedures that need to occur. When the Appendix is utilized, the exercise of referring to it interrupts the Vineland-II query administration, which could be frustrating to the participants being interviewed. Bracket learned that many clinicians did not

check the Appendix, which potentially caused noise in the data and affected scoring of the additional items. Completing the initial scoring of the individual items also posed challenges as the clinician was required to refer to tables for each score domain that converted the initial (raw) scores into age normed scores, and then, had to convert the normed scores into final composite scores. The potential for errors anywhere in the process was high.

- Appendix is difficult to refer to during a clinical trials interview
- Testing environments can be time-pressured, resulting in short-cuts that can lead to imprecise data
- Scoring conversion tables present opportunity for human error and inaccurate outcomes





The Solution

At the forefront of digitization in clinical trials, Bracket partnered with Pearson to develop and release an interactive Rater Station eCOA solution for the Vineland-II, helping to combat its challenges and evolve the assessment to meet the unique clinician, rater, and patient needs of today.

Highly customizable, interactive, and user-friendly, the digital solution is enabled on tablet devices and replicates the exact process and language of the paper document. This not only provides comfort to the clinicians and raters administering the survey, but will also help drive adoption of the platform on a global scale.

The interface embeds the Appendix guidance for items directly into the relevant scale item at the time the item is asked about. Rather than to manually look up a specific definition or rating criterion, the guidance is provided in an easy to access pop-up window as the question is asked. The interface then automatically calculates all of the normed scores and composite scores.

The Results

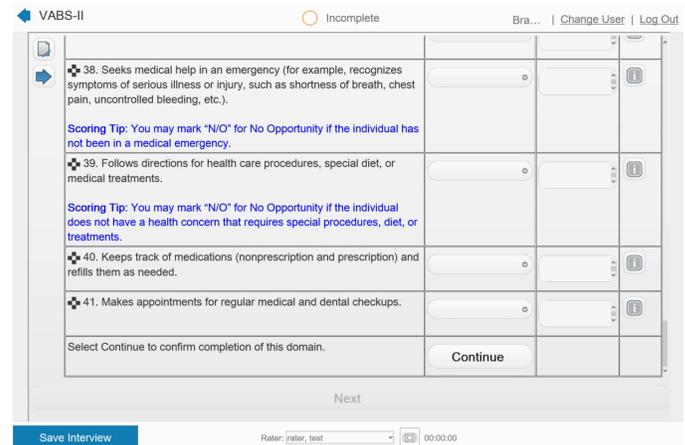
Since its release, the eCOA solution has improved efficiency, productivity, and accuracy, helping to make a clinician's time with a patient more effective. A major advance to this time-honored and widely recognized scale, the platform's automated guidance and score conversion capability has greatly reduced the overall administration and scoring time.

The automation has not just helped eliminate human error and save time and money on monitoring the data, but has instilled even more confidence in the data from all parties. Moreover, the platform allows both the clinician and the family members being questioned to wholly attend to the questions, rather than to administrative details and paperwork.

Ultimately, the Rater Station eCOA solution for the Vineland-II is a collaborative effort among Bracket, Pearson, pharmaceutical companies, clinicians, and patients to help improve reliable data collection so as to bring better treatments to market.

“By partnering with Pearson to introduce an electronic version of the Vineland-II, we aim to provide clinicians, parents, and caregivers with a precise and modernized method for administering this comprehensive measure.”

– Jeff Kinell, CEO of Bracket



- ✓ Dramatically reduces the overall administration and scoring time
- ✓ Saves time, money, and human error and amasses more confidence in the data
- ✓ Helps clinicians accomplish their jobs in a more streamlined fashion



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