

Background

- Clinicians participating in Rare Disease clinical trials range in their level of experience with specific outcome measures.
 - Some measures require an advanced degree and some are completed by junior staff
- The Vineland Adaptive Behavior Scale, Third Edition (Vineland-3) is a caregiver interview commonly used in Rare Disease trials, specifically developmental disabilities trials
 - Often administered by research assistants and study coordinators
 - Training in the accurate administration and scoring is imperative
- High quality data in Rare Disease trials is critical given the sample sizes
- Clinician training can be burdensome and historically, in-person and trial-specific

Objective

Develop an efficient yet effective fully remote model for training clinician on common clinical assessments used in clinical trial, here the Vineland-3.

Method



Clinicians participating in four Rare Disease trials completed a comprehensive training program on the Vineland-3

Total training time was 90 minutes

Didactic Training

- Web-based, interactive module covering: clinical rapport, administration practices, and scoring
- Includes interactive knowledge checks, video demonstrations, and case examples

Mock Admin

- Clinicians completed a Vineland-3 with a mock caregiver
- Audio recording and record form submitted for review

Review & Feedback

- Neuropsychologist reviews each administration ; provides written feedback about admin & scoring
- If errors identified, 1:1 training call held with neuropsychologist to review errors prior to providing another mock administration.
- After successful mock administration with no errors, clinician is certified for the trials.

To monitor quality, 25% of in-study administrations were expert reviewed using this method

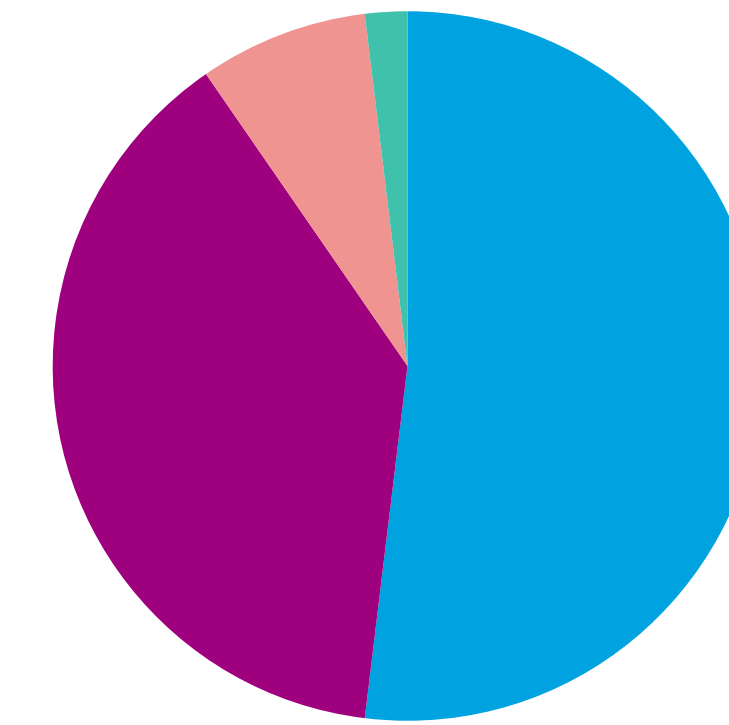
Results

52 clinicians completed the Rater Academy training program for the Vineland-3

Of these clinicians, **48** completed a practice administration accurately on the first submission and **4** clinicians required a 1:1 phone call with a neuropsychologist to individually review accurate administration and scoring

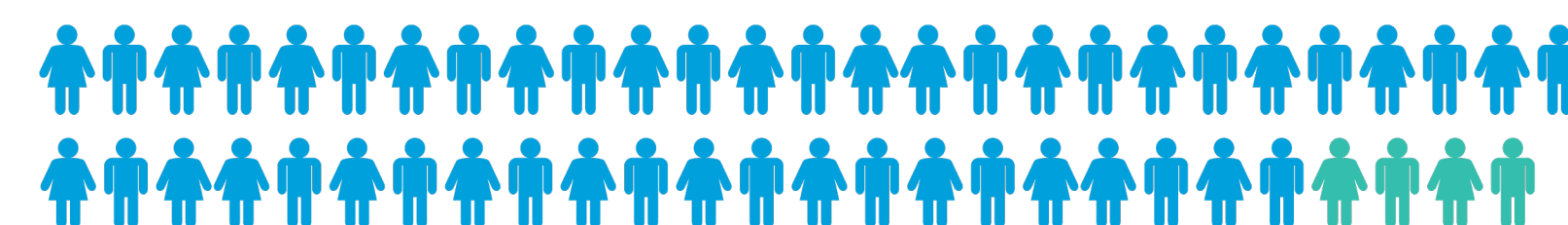
Following certification:

- 27 clinicians participated in 1 trial
- 20 participated in 2 trials
- 4 participated in 3 trials
- 1 participated in all 4 possible trials



138 Vineland-3 administrations were conducted across these clinicians

Of these administered, 53 administrations were reviewed



Four administrations had significant errors that compromised the validity of the assessment.

- One clinician did not introduce the assessment and did not sufficiently probe for details for accurate scoring.
- One clinician did not accurately score 3 items.
- One clinician, on two administrations, did not probe to elicit sufficient information to score the items.
 - Following the first problematic administration, the clinician received written feedback and had a 1:1 phone call with a neuropsychologist.
 - After the second administration, the neuropsychologist had a call with the PI.
 - Subsequent two administrations were accurate

Conclusions

As the number of clinical trials in Rare Disease trials grow, so does the need to develop high quality yet more efficient models to train clinicians



Rater Academy was highly successful

- Trained **52** clinicians across **4** trials
- **138** total administrations
- **53** were reviewed and only **4** included significant errors
 - Triggered escalation of follow-up and further monitoring
- Total training time was **90** minutes
- Led to certification across **4** trials, reducing training time by **25%**

- Expanding this model will support scalability of Rare Disease trials
- Future work can compare the efficacy and error-rate of this model with more traditional in-person and study-specific training model

References

Sparrow, S., Cicchetti, D., and Saulnier, S. (2016). Vineland Adaptive Behavior Scales, Third Edition. Pearson.

Acknowledgements

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