

Methodological considerations for rater training and certification in Down Syndrome (DS) clinical trials: overview and initial findings from two DS studies.

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The Methodological Question Being Addressed

Methodological standards for rater training and certification applicable across all CNS indications and scales have not been established, although general recommendations have been proposed (Daniel et al., 2013). Sponsors are therefore responsible for customizing rater training programs based on the study goals and the roles of the scales in the study.

Introduction (Aims)

Ensuring reliable and valid screening and outcome assessments in Down Syndrome (DS) clinical trials is challenging. Scales used in these studies are complex, including psychometric tests, clinical global impression ratings, caregiver interviews, and caregiver-reported outcomes. A further challenge is that many of these assessments require specialized rater skills. This poster summarizes the training methods and results from two DS studies:

- Study A: Observational study with 3 sites in the US, 3 in Spain, 4 in France
- Study B: Phase II study with 10 US sites.

Methods

The customized rater training and certification programs included:

- Rater Experience Survey (RES)
- Didactic training on all scales (see Table 1).
- Certification exercises for psychometric scales and VABS-II: mock scoring exercises, hands-on training at an Investigators' Meeting (IM), and audio-recorded practice administrations of the CMS and VABS-II.
- Rater satisfaction survey

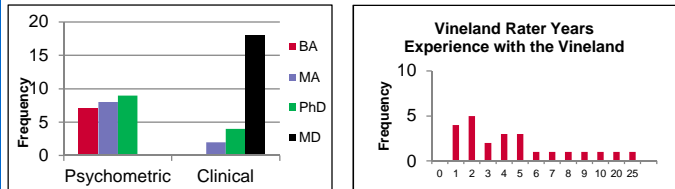
Table 1. List of Scales and Rater Roles

	Scale	Acronym	Rater Role
1.	Leiter International Performance Scale-3rd Edition	Leiter-3	Psychometric
2.	Children's Memory Scale	CMS	Psychometric
3.	Clinical Evaluation of Language Fundamentals-Preschool-2nd Edition	CELF-P-2	Psychometric
4.	Automated Working Memory Assessment-2	AWMA-2	Psychometric
5.	MacArthur Bates Communicative Development Inventories	CDI	Psychometric or Caregiver only
6.	Behavior Rating Inventory of Executive Function-Preschool version	BRIEF-P	Psychometric or Caregiver only
7.	Pediatric Quality of Life Inventory	PedsQL	Psychometric or Caregiver only
8.	Observer Memory Questionnaire-Parent Form	OMQ-PF	Psychometric or Caregiver only
9.	Conners-3rd Edition	Conners	Psychometric or Caregiver only
10.	Anxiety, Depression and Mood Scale	ADAMS	Psychometric or Caregiver only
11.	Vineland Adaptive Behavior Scale-2nd Edition	VABS-II	Psychometric or Vineland only
12.	Clinical Global Impression Scale-Severity and Improvement	CGI-S/I	Clinical

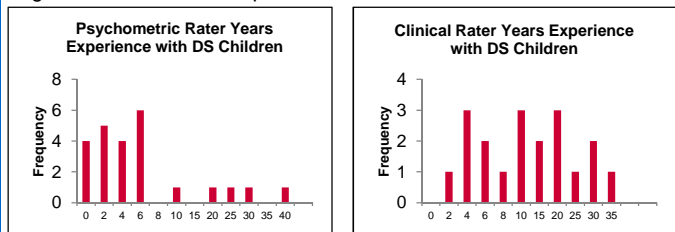
Results: Rater Experience

55 raters from 19 sites have been prequalified (24 psychometric, 24 clinical, and 7 caregiver role only). Figures 1-6 summarize rater experience results. The prevalence of MDs as clinical raters reflects the preference for principal investigators as clinical raters for these studies.

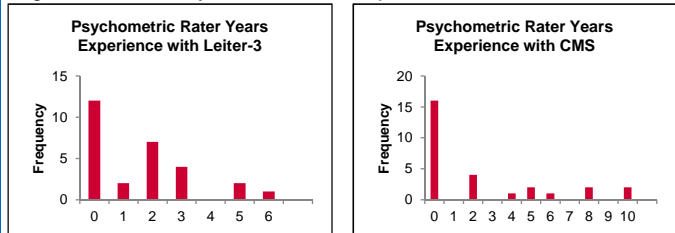
Figure 1. Rater Education by Role. Figure 2. Vineland experience



Figures 3 and 4. Rater experience with DS Children



Figures 5 and 6. Psychometric rater experience with Leiter-3 and CMS



Results: Rater Performance

- 6 raters have completed all certification procedures. All raters performed well on the mock scoring exercises.
- Despite having an advanced degree (Ph.D.), one rater made a considerable number of errors on the practice administration of the CMS which required additional training.

Results: Rater Satisfaction with Training

- Raters reported high levels of satisfaction with training. Two experienced raters expressed concern that the training was too basic but recognized it as necessary for less experienced raters.

Conclusions

- Education level, clinical experience with DS, and experience with specific scales varies considerably across raters at DS research sites.
- Consequently, study-specific certification procedures are required to ensure rater knowledge and competency in administration, recording, and scoring of psychometric scales after comprehensive didactic training.

Reference: Daniel, D., Opler, M., Wise-Rankovic, A., & Kalali, A. (2013). Consensus recommendations on rater training and certification. CNS Summit Rater Training and Certification Workgroup.