Science 37





BACKGROUND

One result of the COVID-19 pandemic has been a greatly accelerated adoption of the decentralized clinical trial (DCT) strategy. The adoption of this model in psychiatry has been tempered by concern regarding the conduct of clinician-reported outcomes conducted by centralized raters. This is despite a history of successful deployment across a variety of psychiatric indications. There are a number of reasons why the centralized rater strategy could confer advantages to clinical trials:

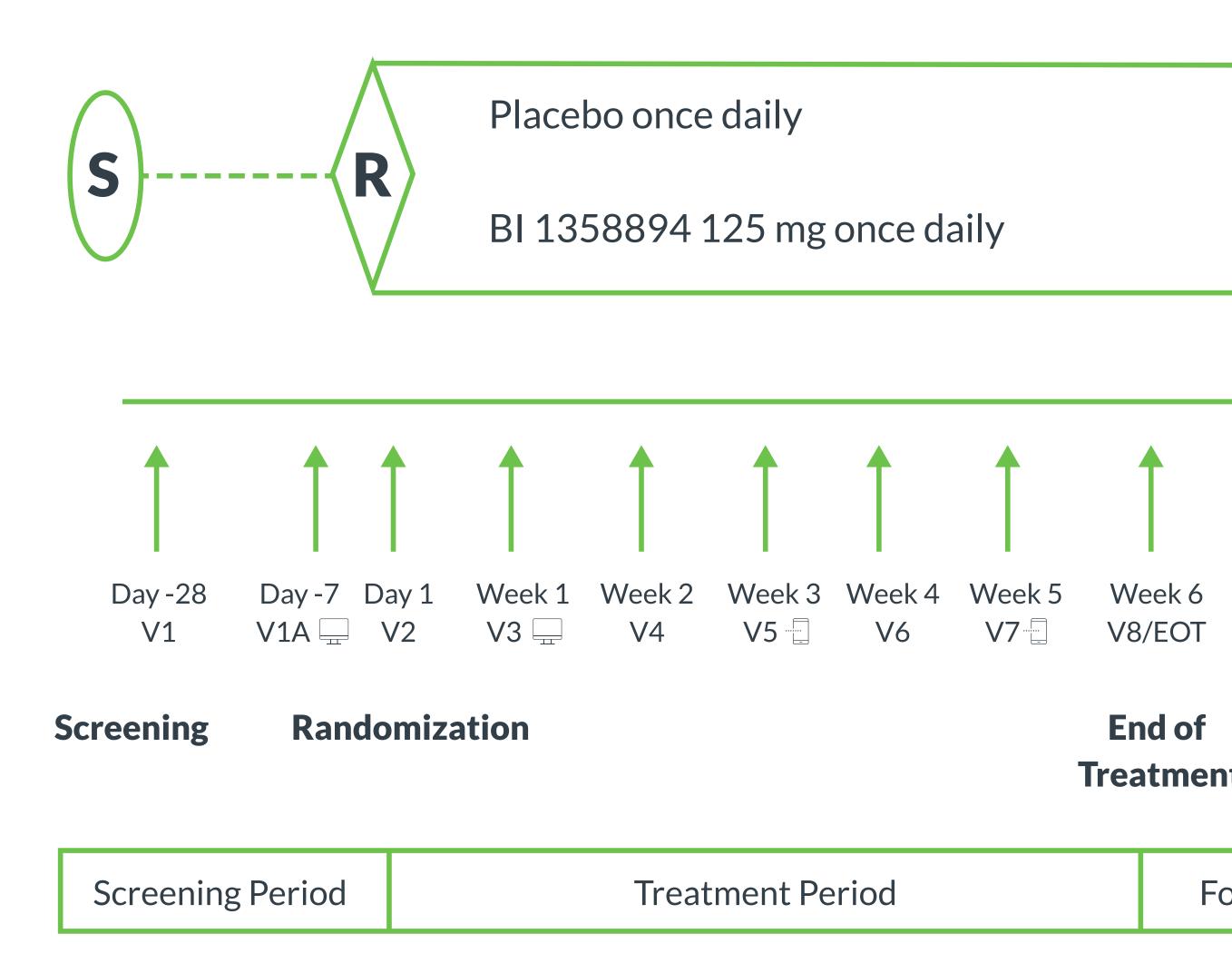
- . Fewer total raters to train and monitor
- 2. Higher volume per rater
- 3. Lower rater turnover
- 4. More flexibility to accommodate participant schedules resulting in fewer missed ratings
- 5. Less opportunity for social interactions to influence rating

Boehringer Ingelheim (BI) partnered with Science 37 to conduct the first-ever fully decentralized trial studying BI 1358894 in treatment-resistant major depression (DCT). Concurrently, BI conducted a nearly identical global site-based trial (TRAD). This offered a unique opportunity to compare the performance of the Science 37 centralized raters to the site-based raters.

Signant Health provided training for raters in both trials and conducted ongoing review throughout the conduct of both. Part of this process included review of the interview quality as well as the item scoring, either of which could result in raters being contacted if performance was judged to have deviated from administration/scoring guidelines. The study design is shown in Figure 1. The primary outcome measure was the Montgomery Asberg Depression Rating Scale (MADRS), which was completed at screening and during Visits 2, 3, 4, 6 and 8.

Remote administration of MADRS is comparable in quality to in-person administration: **Evidence from two parallel depression trials.**

Figure 1: The study design



METHODS

The Science 37 study (DCT) was conducted in 2020 and 2021, enrolling 86 subjects and randomizing 44. The TRAD study was conducted globally with 64 sites worldwide and is ongoing. For the purposes of this analysis, subjects who had completed the study in August 2022 were included (286 enrolled, 147 randomized). In addition to the Cronbach's alpha (α) analysis that was conducted to compare the two studies on quality, the TRAD and DCT were compared on MADRS administration and scoring errors flagged by Signant Health's Central Quality Reviewers.

RESULTS

Figure 2 shows Cronbach's alpha (α) for baseline (V1) showed DCT α = 0.82 and TRAD α = 0.71. Subsequent visits showed steady increase for both: DCT α = 0.91 and TRAD α = 0.89 at V8.

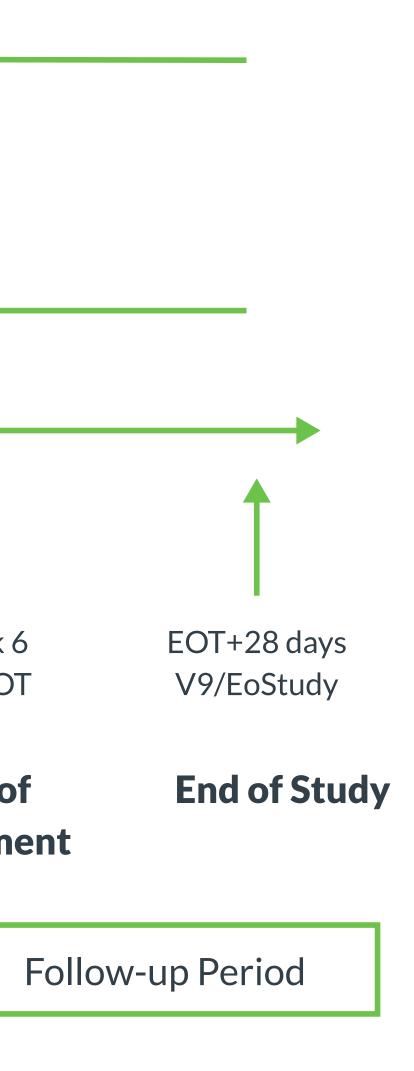
The percentage of MADRS administration and scoring errors flagged by Signant Health Central Quality Reviewers in the TRAD study and in DCT is shown in Figure 3. DCT had 11.5% error rate (21 hits out of 183 visits), which positions it at the end of the first tertile when compared with the TRAD sites.

Christopher Reist, MD, MBA Science 37 Chris.Reist@Science37.com

> Marcela Roy Signant Health

Thuy Le Nguyen **Boehringer Ingelheim** Pharmaceuticals, Inc.

> **Gary Sachs** Signant Health

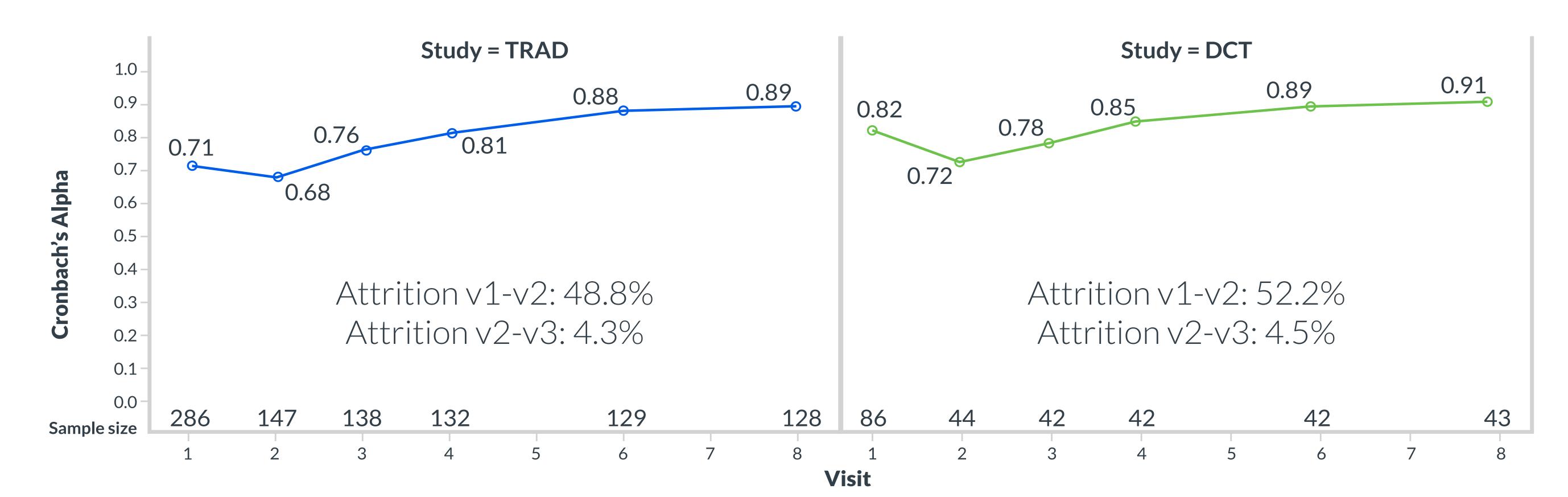


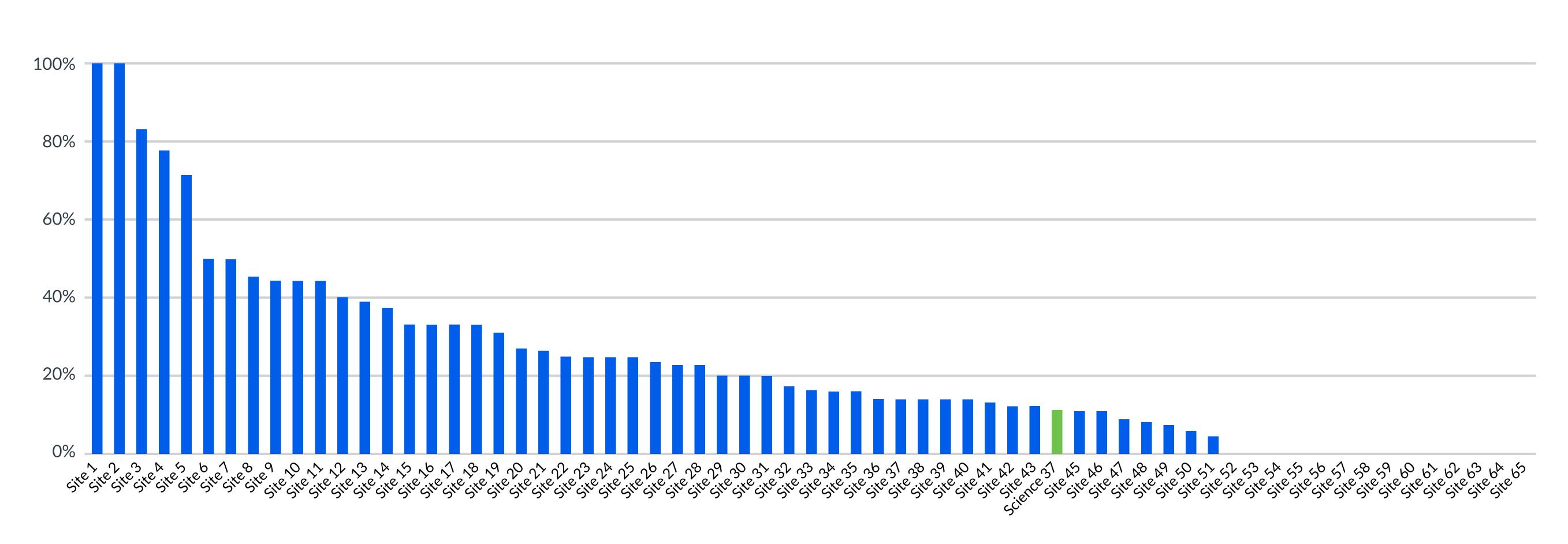
We hypothesized that DCT trial, compared to TRAD, will show better quality for the MADRS as reflected by Cronbach's alpha calculation and will have lower error rate on MADRS administration and scoring.

CONCLUSIONS

This is the first opportunity to report on quality of depression symptom assessment, using MADRS, conducted remotely in comparison to a parallel site-based trial. Our analysis suggests quality in DCT is comparable to face-to-face methods. More research is needed to examine how DCT trials perform against site-based trials on quality; perhaps adding additional quality metrics would make our findings more robust.

Figure 2: Comparison of Cronbach's alpha for MADRS assessments





Vikas Mohan Sharma **Boehringer Ingelheim** International GmbH

> **Jason Bain** Science 37

Jan Wruck **Boehringer Ingelheim** Pharmaceuticals, Inc.

> Xingmei Wang Signant Health

PRESENTERS

Petra Reksoprodjo Signant Health

> Alan Kott Signant Health

Figure 3: Percentage of flagged MADRS administration and scoring errors