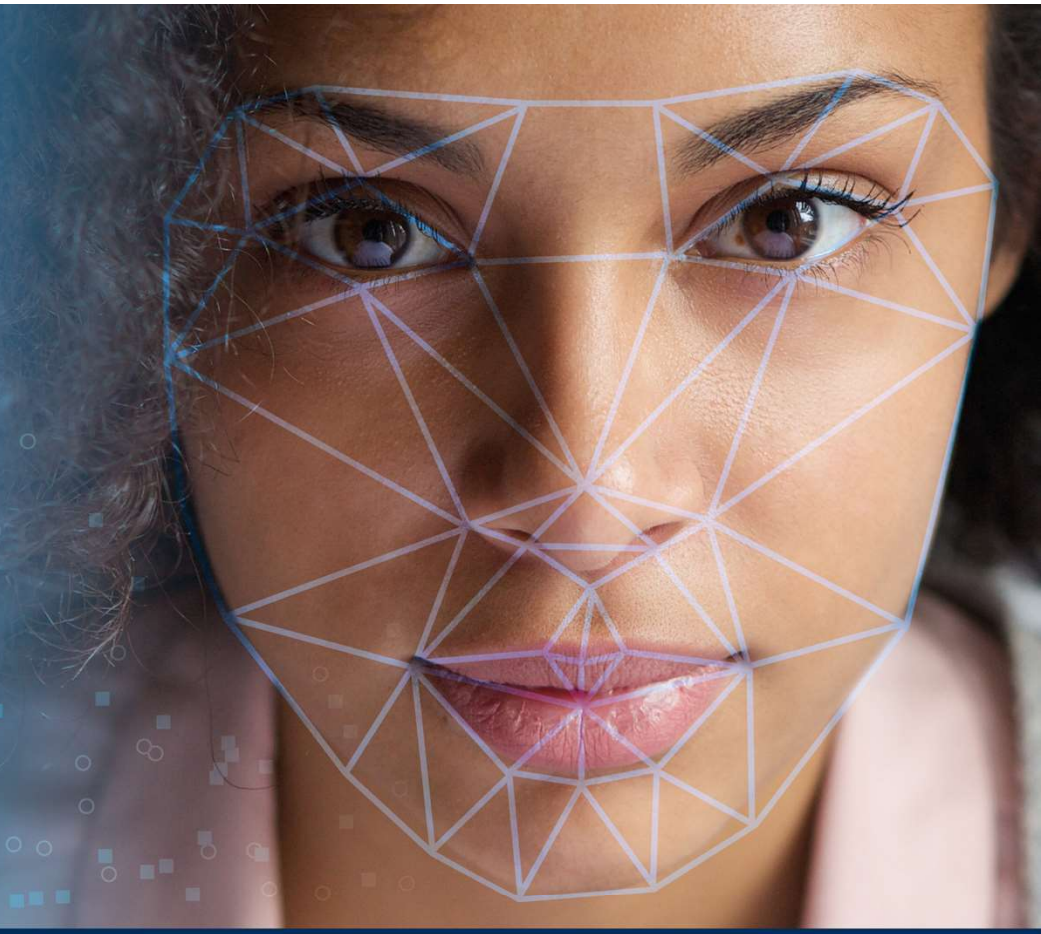
Consideration of Available Safeguards in ADHD



Presentation to OMB July 25, 2024

Danielle Vaeth, Qbtech
Mikkel Hansen, M.D. Qbtech
Angie LaRosa, M.D. Developmental Behavioral Pediatrician
Jennie Byrne, M.D. Adult Psychiatrist, Constellation PLLC.,

Qbtech

Balance of safety and access through recognized, evidence based, objective data

There is a risk of disruption of care, yet solutions are available and being actively being utilized to address these concerns.

The anxiety reported by some clinicians around prescribing ADHD treatment has been described as palpable.

Considerations around evaluation of currently available, FDA cleared, validated data to improve treatment monitoring in telehealth for ADHD should be made.

Key Initiatives

1. Prioritize ADHD under proposed rule
2. Qbtech's role as a leading experienced authority for assessment and treatment monitoring
3. Taking care of those with ADHD: Done response
4. Recommendation:
    1. Priority is access to care
    2. Safety and the evaluation of required safeguards

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Recent Relevant Evidence

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QbTest in the clinical assessment of attention deficit hyperactivity disorder: a review of the evidence

- The purpose of this evidence-based review was two-fold.
  1. A review of studies designed to evaluate the impact of including QbTest in the clinical workflow as a diagnostic support tool in the clinical assessment of ADHD.
  2. A review of evidence of the classification ability of QbTest of ADHD in clinical populations.
- Review of Literature published between 2004 to 2023.
- 11 articles were included for appraisal.
- A weighted average sensitivity and specificity analysis was made, based on composite Q-scores (largest composition available; Q-scores from the QbTest or a composite of Q-scores and rating scales if available.
- The weighted average (for sensitivity and specificity) ranges from 0 to 1 (which can also be expressed as 0% to 100%) with higher values indicating better accuracy.

	Sensitivity	Specificity
Normative Controls (four studies pooled)	**0.89** (0.85-0.93)	**0.87** (0.84-0.90)
Differential Diagnosis (at secondary and tertiary clinical setting) (six studies pooled)	**0.79** (0.75-0.83)	**0.71** (0.65-0.77)
Overall Analysis (ten studies pooled)	**0.84** (0.81-0.87)	**0.84** (0.81-0.87)

Weighted average (95% confidence interval)

Conclusion

The addition of a QbTest reduced the time to a diagnostic decision without compromising diagnostic accuracy in one randomized control trial. In the studies where QbTest was evaluated for discriminatory ability, an overall satisfactory weighted average sensitivity and specificity was found across both normative and clinical comparators.

U. Gustafsson and M. Hansen, *Mental Health Science*, 2023: 1; 270-281.

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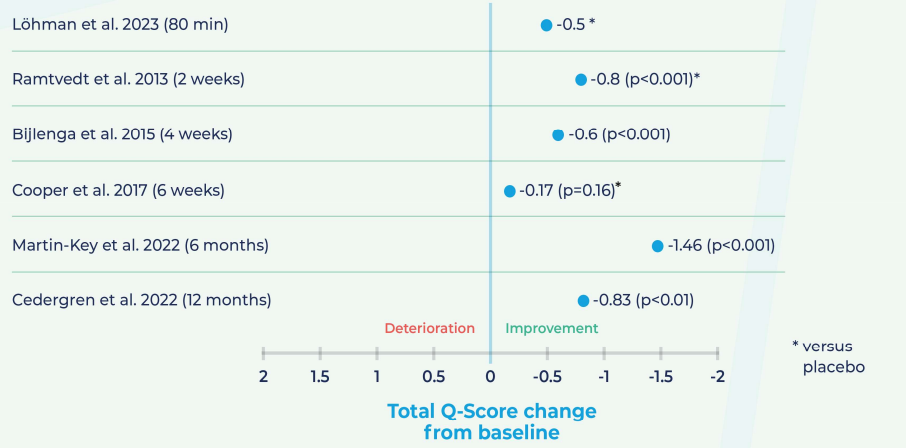
QbTest for monitoring medication treatment response in ADHD: a systematic review

- A literature review was conducted for the use of objective measure QbTest when monitoring medication treatment response in ADHD.
- 15 articles were included for appraisal.
- Changes in QbTest data of Q-scores, effect size or improvement / deterioration of QbTest variables were evaluated.
- A clinically relevant decrease in QbTest Q-scores was found in the majority of studies when treated with any type of ADHD medication.



U. Gustafsson and M. Hansen 2023

Conclusion

QbTest can distinguish pharmacological treatment effect within hours of pharmacological titration and can be used for monitoring of long-term treatment of ADHD.

Gustafsson U, Hansen M. QbTest for Monitoring Medication Treatment Response in ADHD: A Systematic Review. Clin Pract Epidemiol Ment Health. 2023 Nov 1;19:e17450179276630. doi: 10.2174/0117450179276630231030093814. PMID: 38164455; PMCID: PMC10758132.

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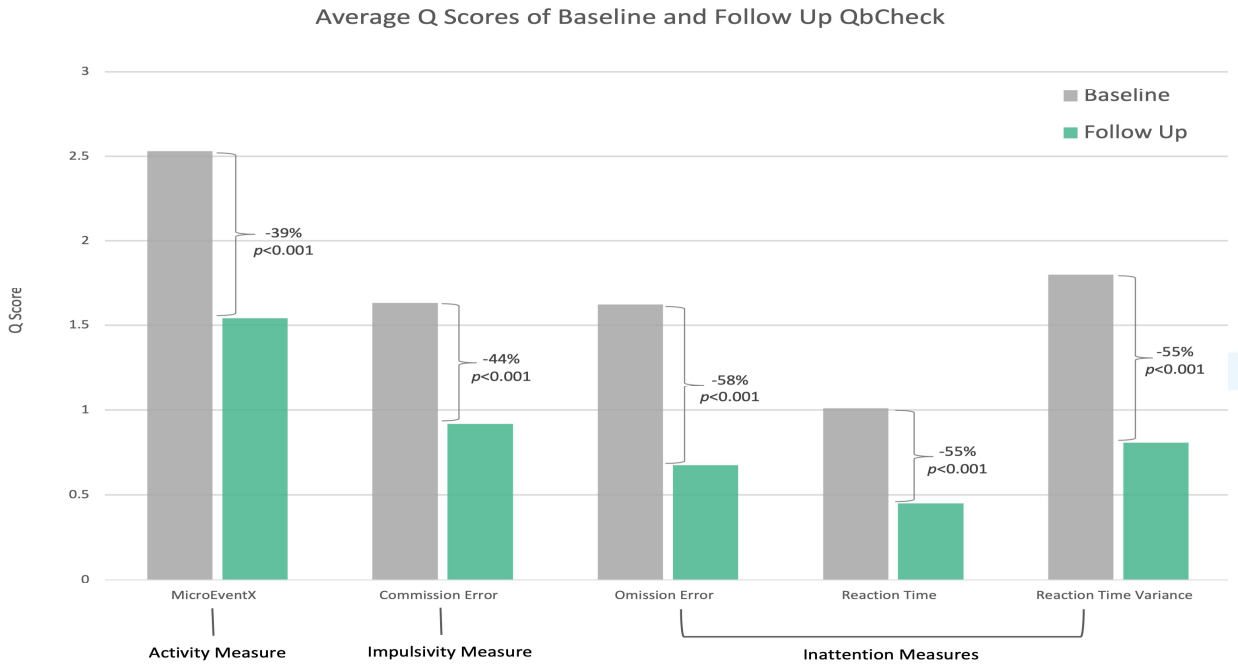
Utilizing remote objective ADHD testing to monitor symptom improvement following medication treatment

Analysis focused on changes in pre and post pharmacological treatment



n = 114
Avg age = 29.51

Significant improvement in all 5 parameters

Sanyal RY, Nolen R, Gustafsson U, et al. Utilizing Remote Objective ADHD Testing to Monitor Symptom Improvement Following Medication Treatment. Int J Psychiatry Res 2024; 7(3): 1-6.

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NICE MIB318 and NICE Recommendation

The National Institute for Clinical Excellence (NICE) published its Medtech innovation briefing [MIB318] for QbTest March 2023

NICE Recommendation of QbTest completed July 2024

The report highlights several positive findings, namely that QbTest saves clinician time, improves clinical confidence and NHS funds when used as part of ADHD assessments – with no loss of accuracy.

Key findings include:

1. **Experts recognise QbTest as an addition to routine clinical assessment of ADHD**
2. **The NICE evidence review and ADHD experts confirm that QbTest helps clinicians make accurate decisions, saving time and money**
3. **NICE reports reduced ADHD waiting list achieved through the use of QbTest**

NICE recommends digital technology to help diagnose ADHD in children and young people

A digital technology that will help healthcare professionals provide a quicker diagnosis to people with attention deficit hyperactivity disorder (ADHD) can be used by the NHS, NICE has said in draft guidance.

News 16 July 2024

https://www.nice.org.uk/news/articles/nice-recommends-digital-technology-to-help-diagnose-adhd-in-children-and-young-people

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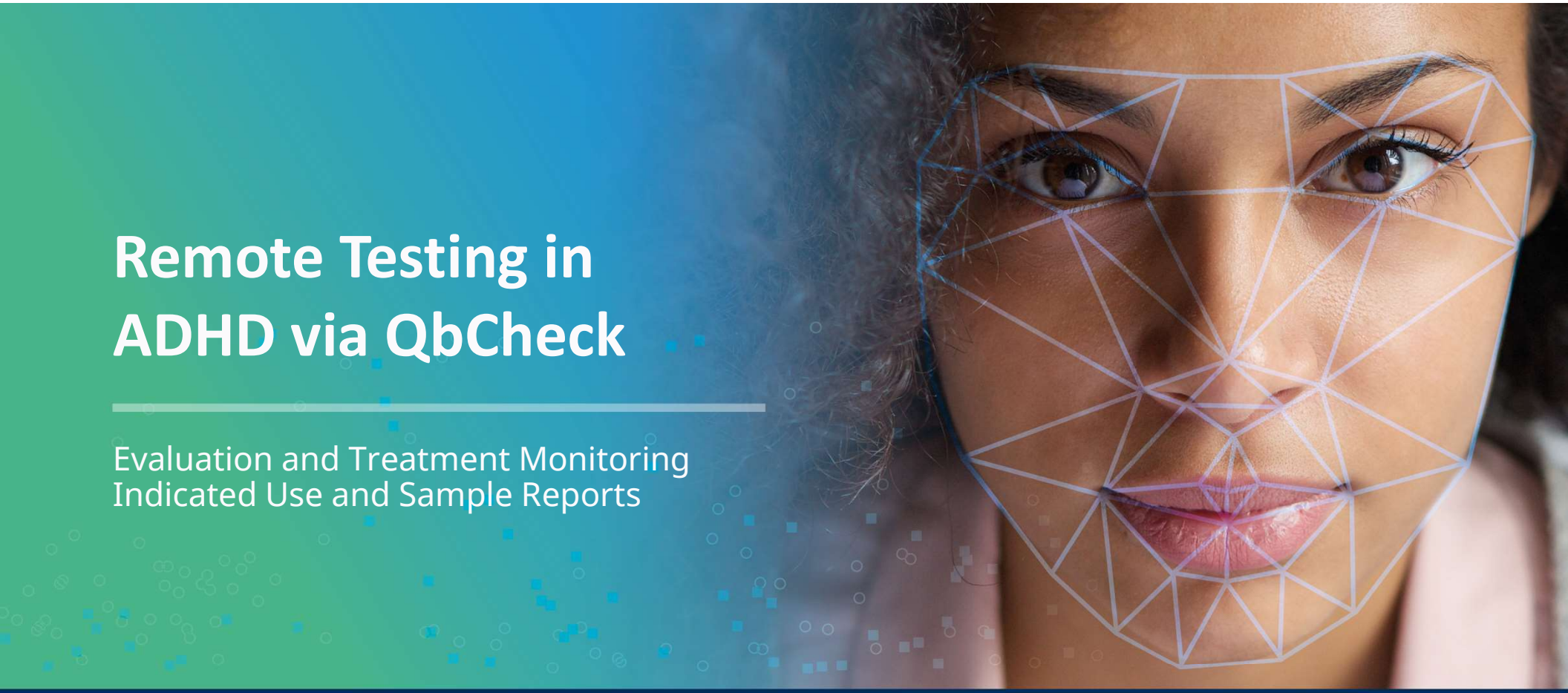
Remote Testing in ADHD via QbCheck

Evaluation and Treatment Monitoring
Indicated Use and Sample Reports



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QbCheck

QbCheck is a CE marked, FDA-cleared and TGA-registered medical device supporting the assessment and treatment of ADHD in individuals aged 6-60 years old.

QbCheck must be incorporated with a comprehensive diagnostic evaluation, subjective data and interpreted by a trained QHP.

- Objectively measures 3 core symptoms
  - Sustained attention and impulsivity
  - Facial recognition technology to measure activity
- A subjective rating scale aligned with DSM-5

Indicates how a patient's performance compares to peers

QbCheck adjusts for age/sex and compares results against a group of individuals with and without a clinical diagnosis of ADHD.

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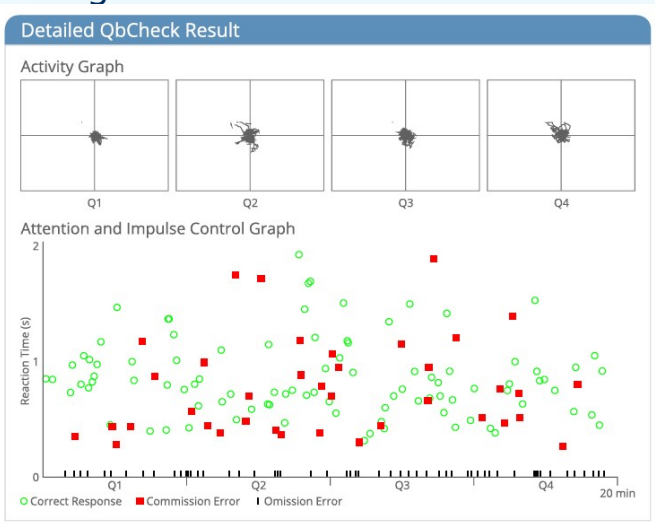
Detailed QbCheck Result and Sample Case

To contextualize the 5 variables and further support test interpretation, the QbCheck report also contains a Detailed QbCheck Result and Sample Case.

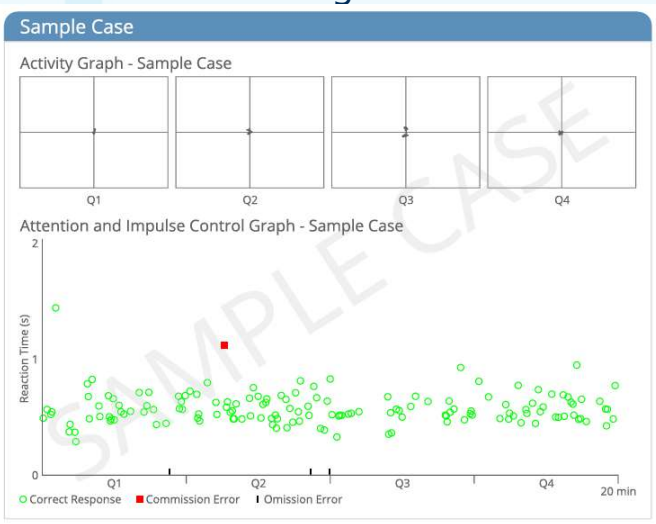
Detailed QbCheck Result

Graphic representation of the test taker's activity levels and performance during the test.



Sample Case

Graphic representation of a norm group sample result: an age and sex matched individual without a clinical diagnosis of ADHD.



Reports must be interpreted by a qualified healthcare provider, who is trained by Qbtech

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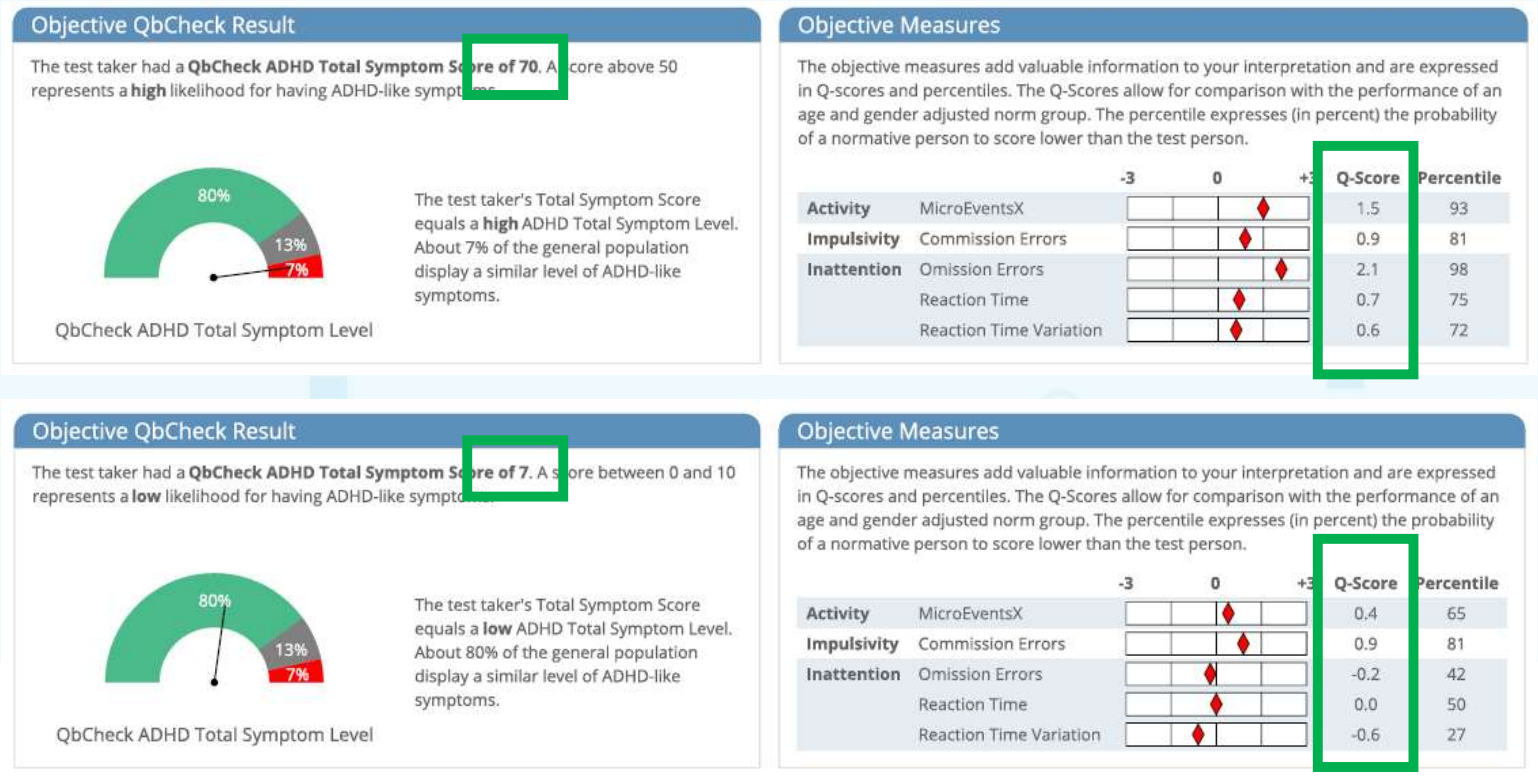
QbCheck Objective Measures in Treatment Management

Treatment effect on the ADHD Total Symptom Score and individual parameters is reflected by a change in likelihood and associated values, where a decrease in values reflects a reduction in ADHD symptoms



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