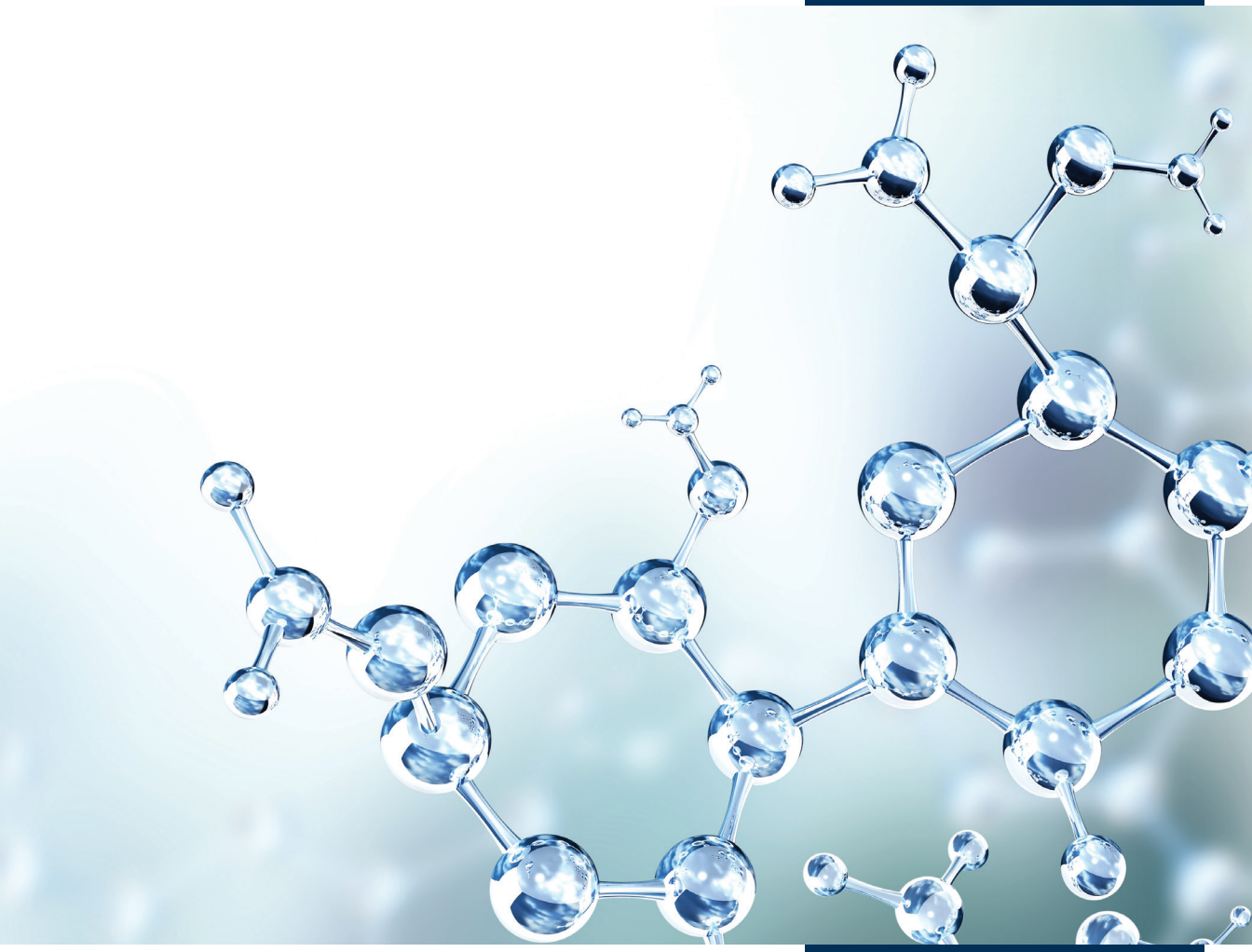
Pharma Research Services

2025
GUIDE
UNITED KINGDOM



Pearson

Content

Research-backed reliable, accurate, and valid COAs are just the beginning

Are you looking for a partner for your clinical trials? You've come to the right place!

Our pharma research team includes experts in the fields of clinical practice, test development, and psychometric analysis. Our goal is to support you in assessing the efficacy and safety of therapeutic treatments and provide the highest level of customer service in scale licensing, translations, scientific consultation, and rater training.

Wherever you are in your trial-planning journey, we will be with you every step of the way!

Supporting clinical research with an 80-year history in measurement science

Get connected to a comprehensive portfolio of research-based instruments that are psychometrically validated, reliable, and represent the highest technical quality in Clinical Outcome Assessments (COAs).

"At Pearson, we can help identify which COA best fits the trial design," says Lynsey Psimas, Ph.D., director of sales and pharma services. "Our COA portfolio includes reliable and valid PRO, ClinRO, ObsRO, and performance measures used by pharmaceutical, biotech and medical device companies conducting clinical research." Pearson is particularly noted for our proven and trusted assessments in cognitive ability, memory, neuropsychology, behavior, personality/psychopathology, achievement, and speech/language.

"Our COA portfolio includes reliable and valid PRO, ClinRO, ObsRO, and performance measures used by pharmaceutical, biotech and medical device companies conducting clinical research."

Discover more about Pharma Research Services.

It all starts with a conversation

Meet your team of experts

Lynsey Psimas, PhD

Director of Business Development

Dr. Psimas is a Licensed Clinical Psychologist with extensive experience in the assessment of children, adolescents, and adults. She has worked in private practice, therapeutic schools, and as a professor. She specializes in neuropsychological assessment, autism, ADHD, and learning disabilities.

> None of the advancements in medicine that eradicate, treat, and cure our illnesses and progressive diseases would make it into the hands of those who need them without the validation of your clinical trials. We understand that the tests you use in those trials need to be built with the same rigor as the research behind the novel treatment options that are being tested — and they need to be reliable."

Katrina Bengtson

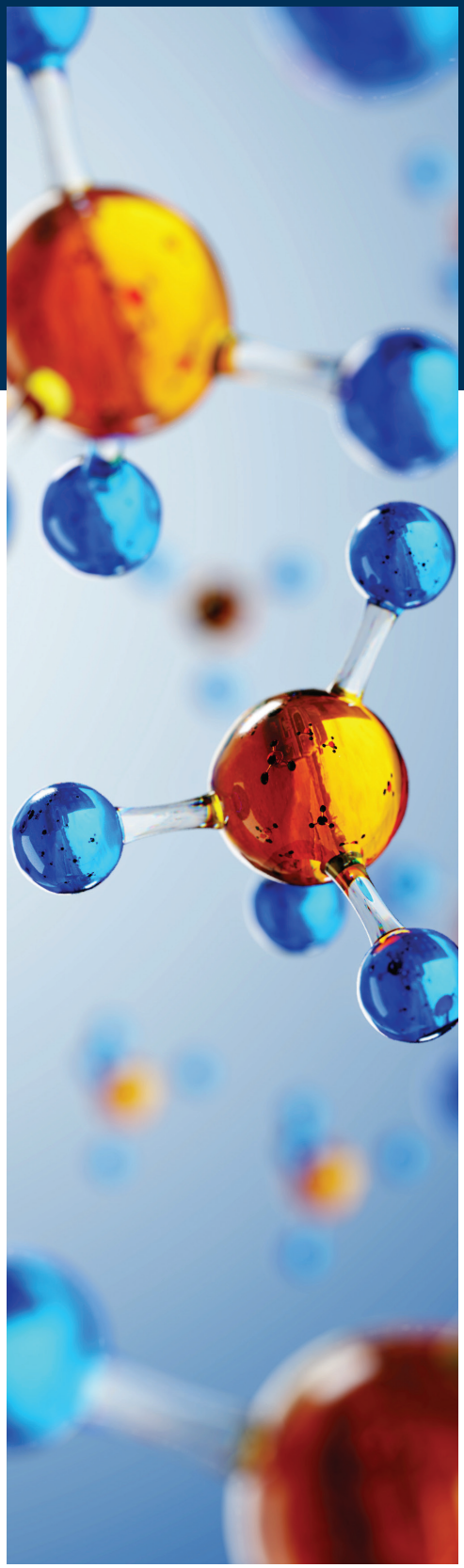
Account Manager

Katrina joins the Pearson Pharma Team with a background in Clinical Trial Management and Psychometry expertise. Prior to Pearson, Katrina worked in Pharmaceutical Clinical Operations specializing in study start-up at a Clinical Research Organization. Ka

trina gained familiarity with the Pearson Assessments from her time as a Psychometrist conducting neurocognitive evaluations at the Anschutz Medical Campus in Colorado.

Pearson's vast catalog of Clinical Outcome Assessments (COAs) have been proven reliable through decades of research and are suitable for a wide range of ages with norms that reflect today's population."

Complete the Request a Consultation form to get connected with one of us.



We are your one-stop shop for clinical endpoints

We are here to support you and your needs throughout your clinical journey. From training and consultation to translations and eCOA migration, we have got you covered.

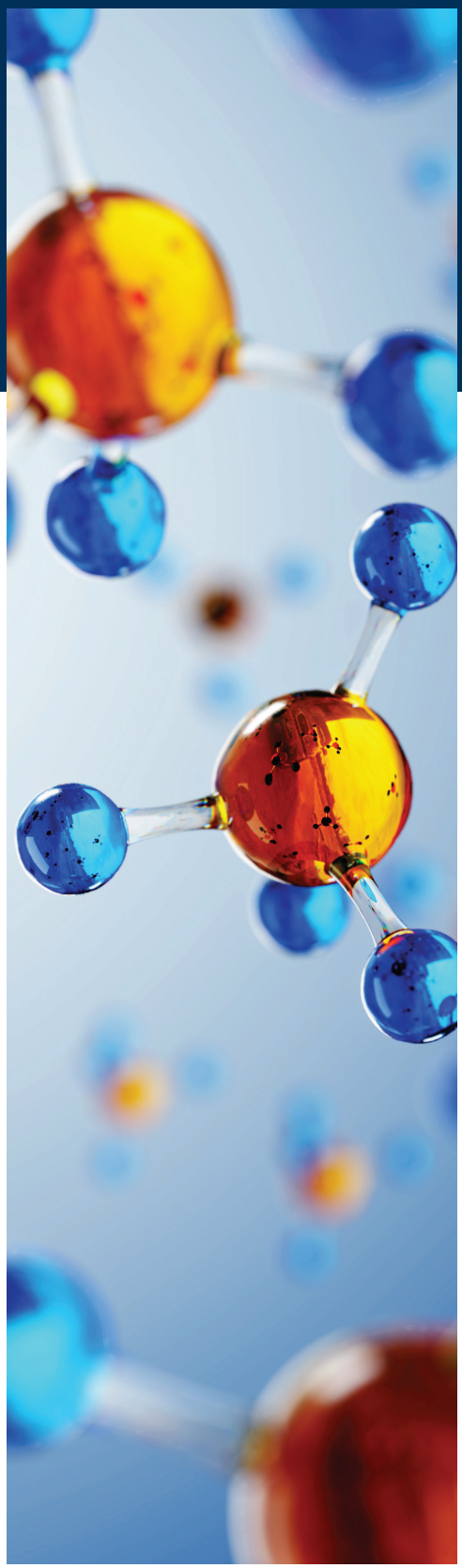
Rater Training

Get expert training straight from the source.

Let us support you with rater training for your Clinical Outcome Assessments (COAs). Our experienced training team includes psychologists and clinical practitioners with expertise in clinical endpoints, psychometrics, and e-learning to ensure standardized administration and scoring.

Raters will be armed with the most up-to-date and valid administration and scoring guidance. Training content will be tailored to meet your needs. Rater training is available to CROs and Sponsors in a variety of formats, including in-person training, virtual sessions, and on-demand training modules to support your clinical trial.

Contact us for more information and pricing.



Scientific consultation

Maximize your data analysis efforts

As data analysis and clinical endpoint questions arise, let our pharma experts help you find the answers. Our team of scientists have expertise in clinical practice, test development, and psychometric data analysis. Scientific Consultation is tailored to meet your needs.

We are here to provide unique and additional insights that your researchers need to effectively detect treatment changes. Our experts can provide guidance on topics including:

- COA endpoint selection
- Scale licensing
- Data analysis
- Growth Scale Values (GSVs)
- Preparation for FDA submissions
- Out-of-level testing

Contact us for more information and pricing.

Strategic partnerships

Get more access to the resources you need for your clinical trials.

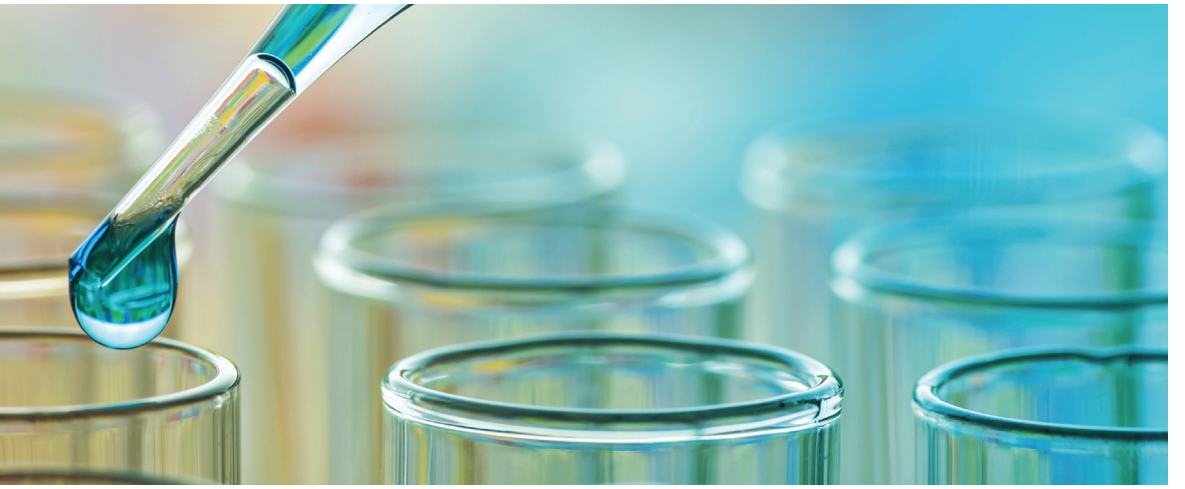
Decades of experience have shown that the best way to support our Pharma partners is working across the industry to provide you with more access to the assessments and resources you need for upcoming clinical trials. Our partnerships with MHS and Lionbridge make this possible!

MHS

You can now license MHS assessments through Pearson.

Multi-Health Systems Inc. (MHS) is a leading publisher of scientifically validated assessments for more than 30 years. MHS serves clients in educational, clinical, corporate, public safety, government, military, pharmaceutical, and research settings

Contact us for scale availability or visit our partnership page for additional insight.



Lionbridge

We partnered with Lionbridge for their expertise in translations and eCOA migration.

Lionbridge has over 25 years of experience with translation and localization projects across the globe. Lionbridge has a proven track record of translating all types of Clinical Oucome Assessments (COAs) into the language you need for your clinical trial.

What this means for you:

- Error-free translations
- 350+ languages supported
- On-time deliverables and on-time in-full deliveries
- ISO compliant linguistic resources
- Conceptual equivalence to the original instrument
- Comparability across languages and cultures
- Access to linguists across the globe to ensure accuracy of translations

Visit the partnership page.

What are Clinical Outcome Assessments?

What are clinical outcome assessments?

Clinical Outcome Assessments, also known as COAs, are standardized questionnaires/ assessments that are used to collect patient experience data such as disease symptoms, treatment side effects, or how symptoms impact quality of life.

Expand your Pharma vocabulary

Here are some commonly used acronyms and their meaning:

1. Patient-reported outcome (PRO): patient self-report
   - For example, the (ex. Beck Depression Inventory, Beck Anxiety Inventory)
2. Clinician-reported outcome (ClinRO): report by a clinician
   - For example, the PANSS (Positive and Negative Syndrome Scale)
3. Observer-reported outcome (ObsRO): report by a caregiver/parent
   - For example, the Vineland Adaptive Behavior Scales, Third Edition
4. Performance outcome (PerfO): tasks performed by a patient under the instruction of a clinician/healthcare professional.
   - For example, the Bayley Scales of Infant and Toddler Development or the Wechsler Family of Assessments

FAQs: Licensing with Pearson

Q: How long does it take to obtain a license agreement?

Your dedicated Account Manager will email you an Intake Form to identify key components of your study. After they review the form, they will schedule a Discovery Call to gather any additional information needed to move forward with your license agreement.

Pearson will then conduct an internal audit of our existing Intellectual Property (Certified Research Translations and International Publications). For any components that require translation, Pearson will work on your behalf to obtain a translation quote. All details will be integrated into a Statement of Work (SOW). Please know a Master License Agreement (MLA) must be in place prior to executing a SOW. Learn more about licensing **here**.

Q: When do I need a license agreement?

For published tests that require no adaptations or modifications, you may purchase off-the-shelf test kits for which your Account Manager can help you obtain a quote. For content that will be modified, you will need a license agreement.

Q: What is considered a modification?

Any change made to the originally published format of an assessment is considered a modification and requires a license to proceed (Ex. Inclusion in eCOA, eCRF, Digitization, Adaptation, Translation, headers, footers, etc.).

Q: Where can I find pricing?

Please contact your Account Manager or Submit an Inquiry **here** to obtain pricing for published COAs, certified research translations with a Certificate of Translation, and/or initiating new translations. Review the general fees on our website.

PearsonClinical.co.uk/Pharma

Q: Which languages are available?

Many of the assessments that we offer are available in a wide variety of languages, and your Account Manager will be able to provide you with availability. If we do not have an International Publication or Certified Research Translation available, Pearson will work with our exclusive translation vendor to obtain the translations you require.

Q: Which languages can I use in each country?

Pearson does not provide guidance regarding which languages should be used in specific countries. It will be up to your study team to determine whether additional languages are appropriate in your research study.

Q: What is Pearson's signatory process?

Once an agreement is ready for both parties to sign, it is Pearson's policy for the other party to sign the agreement first and then return the partially executed agreement to Pearson for electronic signature. Our legal team will be copied to facilitate the signatory process (Isr-XXXX).

FAQs: Translations

Q: Can I translate Pearson COAs?

No. Pearson oversees all translations of Intellectual Property to ensure the quality and content meets our standards. You will be provided with a Certificate of Translation for all research translations.

Q: How long will my translation take?

Translation timelines vary based on the scope of your project, requested languages, and features of the COA(s) selected. You will receive an estimated delivery timeline on your Statement of Work.

Q: What is the difference between an "International Publication" and a "Certified Research Translation"?

A published scale published scale has been normed, standardized, and commercialized for use in a specific geography and language. Based on the rigorous validity studies to determine lingustuc and cultural equivalence of an international publication, these scales are not accompanied by a Certificate of Translation. All psychometric data can be found in test manuals. Certified Research Translations are trans-adaptations based on an English source file. Trans-adaptations are aligned with industry guidance and best practices and recommended by regulatory bodies (FDA, EMA, ISPOR, C-Path PRO and ePRO Consortia, ISOQOL) to ensure a high-quality, valid, and localized translation.

Q: Why doesn't my published clinical outcome assessment (COA) include a Certificate of Translation?

Pearson Clinical Assessment international publications are developed in accordance with the caliber defined by the International Test Commission (ITC) Guidelines for Translating and Adapting Tests (second edition, 2017). The guidelines apply to both the translation of items and content, and adaptation to cultural and construct relevance within a particular region. It is imperative to note that adaptation refers to a multitude of activities including modification of the test format. The professional standard is to determine whether a test in one language and culture can successfully measure the same construct in another. Therefore, item content included in an international publication may not be parallel to the English version.

Q: Are internationally published assessments identical to US English published assessments?

Pearson Clinical Assessment international publications are developed in accordance with the caliber defined by the International Test Commission (ITC) Guidelines for Translating and Adapting Tests (second edition, 2017). The guidelines apply to both the translation of items and content, and adaptation to cultural and construct relevance within a particular region. The professional standard is to determine whether a test in one language and culture can successfully measure the same construct in another. Therefore, documents published in English may not directly align with international publications. Should your study team determine that you require a translation parallel to the English version, please work with your Account Manager.

Q: How will my files be delivered?

All published content and Certified Research Translations are delivered in electronic format via Box.com. The licensee on the account will receive an email notification that files are available. You will receive files in PDF format, along with any associated Certificates of Translation (available only with Certified Research Translations).

Q: Does Pearson require eCOA migration and Screenshot review (SSR)?

Yes. When a Sponsor wishes to adapt "paper" COAs for use on an electronic data collection platforms (ePRO/eCOA), Pearson's Translation Support team will work with our exclusive translation vendor, the eCOA provider, the Licensee to facilitate this process.

FAQs: Additional Services

Q: How do I get a quote for physical kits?

Contact your Account Manager or email **PharmaPearsonClinical@pearson.com** to obtain for physical testkits and paper materials.

Q: Can I get watermarks for Pearson's IP?

Pearson will provide English watermarks. Non-English watermarks are currently not available.

Q: Do you offer consultation?

Yes. Pearson offers Scientific Consultation tailored to meet your needs. Our training teams expertise in clinical practice, psychometrics, and e-learning ensures standardized administration and scoring. The training team consists of seasoned psychologists and clinical practitioners familiar with issues related to clinical assessment in the research and healthcare space. Fees may apply.

Q: Do you offer rater training?

Yes. Pearson works with CROs and Sponsors to support rater training, which can be delivered in various formats including in-person, virtual, and on-demand training modules. Training content can be tailored to meet your needs.

Our training team's expertise in clinical practice, psychometrics, and e-learning ensures standardized administration and scoring. The training team consists of seasoned psychologists and clinical practitioners familiar with issues related to clinical assessment in the research and healthcare markets.

Featured research

See how our clinical outcome assessments (COAs) are being used in today's research.

Bayley Scales of Infant and Toddler Development™

The Association between Bronchopulmonary Dysplasia Grade and Risks of Adverse Neurodevelopmental Outcomes among Preterm Infants Born at Less than 30 Weeks of Gestation

This study seeks to quantify the risks of unfavorable neurodevelopmental outcomes for each bronchopulmonary dysplasia (BPD) grade in preterm infantes delivered at less than 30 weeks of gestation. Researchers evaluated infants who received care until at least 36 weeks postmenstrual age and had a rigorous neurodevelopmental assessment using the Bayley Scales for Infant and Toddler Development (BSID) in our infant follow-up clinic. Using descriptive statistics and regression methods, they examined the relationship between BPD grade and unfavorable neurodevelopmental outcomes.

Beck Anxiety Inventory® (BAI®)

The Association between Physical Activity and Anxiety in Aging: A Comparative Analysis

As the world's population ages, there is a greater need to recognize the significance of physical activity in the anxiety of older individuals. The objectives of this study was to analyze anxiety in older adults who engage in physical activity and those who do not. Questions were included from the Beck Anxiety Inventory, BAI, and the Physical Activity Inventory for Older People. The sample data of this study contribute to the conclusion that physical activity influences anxiety levels with 98% certainty, and it is advised that future studies with other designs be added to it.

Beck Depression Inventory® (BDI®)

Distorted Thoughts as a Mediator of Depressive Symptoms in Patients with Major Depressive Disorder: A Longitudinal Study

Over a six-month period, this study sought to determine whether distorted ideas mediate depressive symptoms in Major Depressive Disorder MDD patients. The Hamilton Depression Rating Scale (HAMD-17), the Montgomery-Asberg Depression Rating Scale (MADRS), the Beck Depression Inventory (BDI-II), and the Depression Thoughts Scale (DTS) findings were gathered at weeks 1, 8, 12, and 24. Cognitive distortions were found to be a mediator of depressive symptoms, emphasizing the necessity of early psychological therapies in MDD patients who present these distortions.

Positive and Negative Syndrome Scale (PANSS) and Repeatable Battery for the Assessment of Neuropsychological Status Update (RBANS)

Differences in Inflammatory Marker Profiles and Cognitive Functioning between Deficit and Nondeficit Schizophrenia

The purpose of this study was to investigate the differences in cognitive functioning and plasma levels of C-reactive protein (CRP) and inflammatory cytokines between deficit schizophrenia (DS) patients, nondeficit schizophrenia (NDS) patients, and healthy controls (HCs). To assess clinical symptoms and cognitive performance, the Positive and Negative Syndrome Scale (PANSS) and the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) were utilized.

Vineland Adaptive Behavior Rating Scale, Third Edition

Use of the Vineland-3, a Measure of Adaptive Functioning, in CLN3

Early and frequent signs of CLN3 disease include neurocognitive impairment and progressive visual loss. This emphasizes the importance of neurodevelopmental functioning for the illness but restricts the range of neuropsychological tests. The Vineland-3's connections to the well-established results of verbal IQ (VIQ) and Unified Batten Disease Rating Scale (UBDRS) indicate its convergent validity for use in CLN3. Future longitudinal studies will be crucial to proving the Vineland-3's usefulness for tracking change in CLN3, including replication in other cohorts and evaluation of sensitivity to change.

Wechsler Adult Intelligence Scale (WAIS)

Longitudinal Study of Epigenetic Aging and Its Relationship with Brain Aging and Cognitive Skills in Young Adulthood

This study investigated epigenetic aging during adolescence and young adulthood and assessed its associations with brain aging and cognitive outcomes in a longitudinal study of a prenatal birth cohort. In the late 20s, cognitive abilities were measured using the Wechsler Adult Intelligence Scale (WAIS).

Wechsler Intelligence Scale for Children (WISC)

Network Analysis of ADHD Symptoms and Cognitive Profiles in Children

In this study, using a network method, researchers systematically examined the cognitive profiles and ADHD symptoms of the patents and discovered a number of relationships between these two categories. The WISC-IV was administered to each participant. The full-scale intelligence quotient (FSIQ), verbal comprehension index (VCI), processing speed index (PSI), and working memory index (WMI) scores of the ADHD youngsters in our sample were lower. Academic ability, inattention symptoms, and mood disorder all exhibited direct interaction with the cognitive domains of the WISC-IV among all the core symptoms and comorbid symptoms of ADHD.

Thought leadership

Stay up-to-date on news Pharmaceutical to the Pharma and clinical trial space and read our Featured Articles on BioPharma Dive!

How the right technology and tools can accelerate progress in rare disease clinical trials

Rare diseases, defined as occurring in fewer than one in 2,000 persons, affect more than 300 million people worldwide, with the majority having significant unmet medical requirements.

The need for greater research into rare diseases is obvious, but researchers confront major hurdles, from recruiting individuals with one of the 7,000 different rare diseases to picking meaningful endpoints and making conclusions. Technology has paved the way for increased liklihood of success in clinical trials.

Read the article

3 ways decentralized clinical trials could help advance research on rare diseases

According to the National Organization for Rare Disorders, one out of every ten people in the United States is affected by a rare disease. Despite this, only about 5% of the 7,000 diagnosed rare diseases have an FDA-approved treatment.

Wearable technology, mobile health apps, telemedicine, and a variety of information technologies have all become commonplace in people's daily lives. Dr. Lynsey Psimas explains why decentralized clinical trials are becoming more widely accepted, how they might benefit patients with uncommon diseases, and promote research into these illnesses.

Read the article

5 steps to help increase the odds of clinical trial success

Pharmaceutical businesses must stress clinical trial validity in order to ensure that the findings are relevant and applicable to patients in real-world clinical settings, as well as that the data can survive heightened scrutiny by regulatory bodies.

However, among the most common reasons clinical trials fail include inability to establish efficacy, safety concerns, challenges with inclusion and exclusion criteria, and patient recruitment. Read about the five measures that can improve the chances of a successful clinical trial.

Read the article

GSVs

What are Growth Scale Values (GSVs) and how can they improve precision in research?

In testing and in research, it is critical to have both an effective and reliable way to measure change. The traditional accepted metric for research studies has been age equivalents (AEs) and raw scores. However, the lack of standard deviations, standard errors of measurement, and equal intervals between scores, make AE's imprecise. While raw scores have typically been the go-to to measure change, GSVs are quickly becoming the preferred method.

GSVs in simple terms

GSVs can be thought of as an improved version of raw scores. Both GSVs and raw scores measure underlying ability; as ability increases, they both increase. However, the raw score increases faster or slower depending on how many items there are at a particular region of difficulty. If there are a lot of items, raw score increases quickly as ability increases, because there are many items on which the person can demonstrate their improvement. In a region with few items, raw score increases slowly. What this means is that a given increase in raw score corresponds to different amounts of increase in ability depending on the level of the scale where the change occurs.

GSVs attempt to remove this inconsistency. A GSV is an estimate of the ability level that would most likely have produced an observed raw score. Thus, GSVs adjust for the effects of the uneven distribution of item difficulties. By their nature, they attempt to be "equal interval"; that is, a given change in GSV reflects the same amount of change in ability at all levels.

Of course, GSVs do not perfectly achieve this goal. The Rasch model on which they are based is a simple one in which a person's probability of success on a test item is based on just two things, the item's difficulty, and the person's ability. Nevertheless, they are a fundamental improvement over raw scores because they address the problem caused by the distribution of item difficulties.

Additional GSV-related resources

Mark Daniel's Blog:

An interview with Mark Daniel, author of Growth Scale Value (GSV): Theory, Development, and Applications

Report:

Growth Scale Value (GSV): Theory, Development, and Applications

Blog with featured recording:

Are GSVs a more accurate measure of change?

Exploring optimal protocol outcomes?

Let's start the process together!

We are grateful for the opportunity to partner with you in your clinical trial! Here is a step-by-step look at your Pharma journey:

1. **Customer inquiry**: Each engagement begins with your organization completing the "Request a Consultation" form.
2. **Discovery call:** Organizations should be prepared to discuss the entire scope of the project including timeline, budget, assessments and related endpoints, administration and scoring, languages needed, patient volume, rater training plans, etc.
3. **Confirmation of study details:** Your Account Representative will facilitate communication and planning for any new translation work, API integrations, and rater training requests.
4. **Licensing contract finalization:** Once the details of the study have been confirmed, your Account Manager will share the first draft of the licensing contract for your review.
5. **Contract approval and invoicing:** Your licensing contract will be finalized with signatures from all parties. Payment terms and schedule are set up at this point.
6. **Project execution:** Upon receipt of payment or purchase order, existing Pearson intellectual property will be sent to you electronically.
7. **Receipt of all project deliverables:** Pearson Translation Support will ensure access to, and receipt of, all documented project deliverables as outlined within the statement of work.

Take the first step on your Pharma journey!

800-627-7271 | PearsonClinical.co.uk/Pharma

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