
Charles Shinaver, PhD

Nov, 2017

Agenda

- Pearson Clinical Trials Processes
- When you need a license, submit a license request
- Expediting Clinical Trials: Limited Permission Agreements.
- Expediting Clinical Trials: Master License Agreements (MLAs)
- Pearson, A World Leader in Assessments
- Where to find information about Pearson Tests
- Qualifications & Rater Training
- Top Pearson Assessments in Clinical Trials
- Which Assessments & Which Disorders/Diseases?
- Summary

Pearson has made a renewed & deepened commitment to Pharma…

Intent: To be your trusted partner through the process of clinical trials.
So, Pearson reviewed and expedited our processes for Pharma.

Recent additions & trained contract specialist to legal staff dedicated to Licensing for Pharmaceutical clinical trials.

New full-time staff member: Manager of Business Development: Charles Shinaver, PhD.

There will be continued evaluation & revision of processes to decrease time from application to an executed license. This includes clearer communication to you, the customer, about our processes (e.g., this webinar!)

Expedited completion of licenses through limited permission agreements & master licensing agreements (MLAs).

We have reviewed our rater training services and continue to clarify, enhance and expand available training.
Pearson Processes Related to Clinical Trials.

Purchase or License Pearson Tests for Trial?

Which will you need for your clinical trial?

When is a license required?
Need modifications of the test(s)? You need a license.

Primary modifications requiring a license:
1. Need for a translation to a foreign language.
2. Putting the product into a digital format.
   (Necessary to put our tests onto proprietary electronic devices of contract research organizations (CRO’s) to deliver our tests in a manner required by the specific study. CRO’s often manage clinical trials of Pharma companies.)
3. Adding headers or footers to either paper or digital administration.
Purchase Pearson Products “straight off the shelf”

No modifications needed? No license needed. Buy the tests “straight off the shelf”.

Quotes for “straight off the shelf” Pearson tests for Pharma contact:
Deborah Vance: deborah.vance@pearson.com, 210-339-8430. San Antonio, TX 78259 (800) 627-7271 Clinical Assessment Customer Support

This is Deborah’s specific role related to Pharma purchases. This expedites acquisition of the tests for YOU (e.g. qualification issues). She does NOT process licenses, though….

If you do need a license: Submit a License Request.

General license agreements are commonly used to conduct INDIVIDUAL clinical trials.

Go to our Pharma landing page here: https://www.pearsonclinical.com/pharma-licensing.html

Click here “Submit a License Request” & get the word document to complete.

You then click this: Licensing Request Form (MS Word)

You can return it to: pharma-licensing@pearson.com

Questions? 210-339-5328

Pearson Clinical Trial License Application:

We believe this has been reduced to typically 4-6 weeks
Some Issues addressed in the Pearson Clinical Trial License Application

- Which tests?
- Reproduction/Administrations:
  - Paper copy? Audio? Online web admin? On screen local admin, other?
  - Translations? Languages? Countries/Territories?
  - Record Form adaptation/translations?
- Which type will you use? Will you adapt the entire record form?
- Examiner manual?
- Stimulus book?
- Other?
- Methodology of study?
  - # of subjects?
  - Total number of record forms?
  - Other reproductions/translations?
  - Method of administration?
  - Site locations?
  - Scoring locations?

Licensing Quote: Debrale Graywolf, Proposal Administrator, Pharma Licensing

To get a licensing quote: You must submit the license request form aka "Pearson Clinical Trial License Application" to: pharma-licensing@pearson.com.

KEY STAFF: Debrale Graywolf, Proposal Administrator, Pharma Licensing Pearson
Clinical Assessment will receive your request. You can reach her here with any questions: (210) 339-5328 or pharma-licensing@pearson.com.

If information is incomplete on the license request or Debrale doesn't have a license request she will give a "preliminary quote", but it cannot account for all expenses.

CRITICAL: If you have questions before submitting your license request contact Debrale.

NEED A LICENSING QUOTE?
YOU MUST SUBMIT THE LICENSE APPLICATION.

Need to move faster?
WE CAN EXPEDITE

The need to expedite access to our tests often occurs in proposed clinical trials. We have two ways of doing this:

Limited Permission Agreements for individual studies.

Master License Agreements (MLA’s) for multiple studies.
Limited Permission Agreements:

Normally a licensing agreement must first be signed “before any use of our materials, in a form other than as-published, is allowed.” However, Limited Permission Agreements allow some adjustment to that.

Limited Permission Agreements: Fee: $2,500. This can offer you the opportunity to begin translations & form adaptation (e.g., adding headers or footers, building the test into an electronic format, etc.) prior to the full license.

NOTE: Watermarked versions of tests to use in IRB (Internal Review Board)/Ethics Committees or other reviews can be provided without a Limited Permission Agreement. This can allow that process to get started sooner. Again, don’t have to wait until the full license is ready.

Key Staff: Debrale Graywolf, (210) 339-5328 or pharma-licensing@pearson.com

Expediting multiple clinical trials: Master License Agreement (MLA).

Why an MLA? An MLA will set the legal terms of all following clinical trials. This means that legally you don't need to reinvent the wheel with each trial. Initially setting up an MLA will take some time, but after that is done permission for individual studies moves very rapidly. After the MLA is executed each individual study will use a “PNF” Project Notification Form. This facilitates faster turn-around time for individual studies. How much faster?

PNF’s are executed in 2-4 days vs. weeks for general license agreements.

MLA one-time fee: $5,000. Individual study fee: $7,500 (versus $12,000 for a standard license)

Other Advantages?

MLA has several built-in economic advantages. These are reduced fees in a number of areas: agreements fees, individual study fees, content delivery, freezing test costs for a period of time and amendment fees. This approach helps us become your trusted advisor for several clinical trials. The 2-4 day turn around time is a great benefit!

Contact me for details Charles.shinaver@pearson.com 317-641-7794.

MLA’s Facilitate Effective & Efficient Clinical Trials.

1. Expeditious. MLA’s set the general terms for our contractual agreement and removes the need to ‘reinvent the wheel’ with every study/agreement. This means legal does not need to be as exhaustively involved. Saves time. Individual studies can then move through our process more rapidly.

2. Long-term relationships. We will better understand each other’s processes and key people. This will facilitate your ability to deliver more effective and efficient clinical trials. We become better acquainted with each other and deepen our role as trusted advisor.

3. Win/win for our customers and Pearson.
Beyond improved processes and additional staff to meet your needs, Pearson is a world leader in assessments.

Pearson Clinical Assessments.

With more than 80 years of experience in the assessment field, we are proud of our leadership role in assessment.

We have a comprehensive portfolio of research-based instruments that are valid, reliable and represent the highest technical quality in assessments today.

We are particularly noted for our gold-standard assessment contributions in cognitive/ability, memory, neuropsychology, behavior, mental health, personality/psychopathology, achievement and speech/language.

We are a resource for your as you develop and implement your clinical trials.

Pearson, a recognized world leader in clinical assessment development and publishing

Some areas of functioning assessed by Pearson Clinical Assessments:

- Anxiety
- Academic Functioning
- Attention Deficit Disorder
- Cognitive Functioning
- Depression
- Development
- Dementia/Alzheimer's
- Executive Functioning
- Memory
- Mild Cognitive Impairment
- Many More...
### Some Relevant Clinical Trial Therapeutic Areas for Pearson Tests

<table>
<thead>
<tr>
<th>Neurology</th>
<th>CNS</th>
<th>Psychiatry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>Oncology</td>
<td>Cardiovascular</td>
</tr>
</tbody>
</table>

- **Neurology**
  - Depression
  - Anxiety
  - PTSD
  - Psychotic, psychosis
  - Autism
- **CNS**
  - Childhood development disorder
  - Parkinson's
  - Neurologic disorders
  - Mood disorder
- **Psychiatry**
  - Development
  - Substance use
  - Alzheimer's
  - ADHD
  - Cognitive ability
  - Stress
  - Cancer
  - Mentally handicapped
  - Traumatic brain injury
- **Diabetes**
  - Cardiovascular disease
  - Multiple Sclerosis
  - Cognitive Disorders
- **Oncology**
  - Cancer
  - Dementia
- **Cardiovascular**
  - Depression
  - Heart disease
  - Stroke

### Top Pearson Tests in Clinical Trials: Beck Depression Inventory-II (BDI-II)

**1,008 Clinical Trials as of 10/25/2017**.

**Overview**: Assess Depression.

**Qualification Level**: B

- Age range: 13 through 80 years
- Administration: 5 minutes, self-administered or verbally by a trained administrator
- Scoring Options: Manual Scoring or Q-global® Scoring & Reporting

*NOTE: The source of the clinical trials information is [www.clinicaltrials.gov](http://www.clinicaltrials.gov). While this database has been in use since 2000 the requirement for most clinical trials to be listed on this site did not occur until January, 2017. So, these numbers are actually an under-estimation.

### Beck Anxiety Inventory® (BAI®)

**252 Clinical Trials as of 10/25/2017**.

**Overview**: Measure anxiety levels.

**Qualification Level**: B

- Age Range: 17 through 80 years
- Administration: 5 to 10 minutes, self-administered or verbally by a trained administrator
- Scoring Options: Manual scoring or Q-global® Scoring & Reporting
Bayley Scales of Infant and Toddler Development: BAYLEY- III:

187 Clinical Trials as of 10/25/2017.
Overview: Examine all the facets of a young child’s Development.
Qualification Level: C
Age Range: 1 to 42 months
Administration Time: 30 to 90 minutes (depending upon age of child)
Norms: Norm-referenced
Scores/Interpretation: Index scores and Subtest Scaled scores
Publication Date: 2005

Symptom Checklist (SCL-90-R)

175 Clinical Trials as of 10/25/2017.
Overview: The Symptom Checklist-90-R (SCL-90-R) instrument helps evaluate a broad range of psychological problems and symptoms of psychopathology. The instrument is also useful in measuring patient progress or treatment outcomes.
Qualification Level: B
Age Range: Individuals 13 years and older
Administration: 12-15 minutes (90 items; 5-point rating scale)
Scoring Options: Q-global™ Scoring & Reporting, Q Local™ Software, Mail-in Scoring Service, or Manual Scoring
Publication Date: 1994

Brief Symptom Inventory (BSI)

154 Clinical Trials as of 10/25/2017.
Overview: provides patient-reported data to help support clinical decision-making at intake and during the course of treatment in multiple settings.
Qualification Level: B
Age Range: Individuals 13 years and older
Reading Level: 6th grade
Other Languages: English, Spanish
Administration Time: 8–10 minutes (53 items; 5-point rating scale)
Scoring Options: Q-global™ Scoring & Reporting, Q Local™ Software, Mail-in Scoring Service, and Manual Scoring
Publication Date: 1983
Vineland Adaptive Behavioral Scales, Third Edition (Vineland-III)

132 Clinical Trials as of 10/25/2017.

NOTE: Vineland-II is much more popular with clinical trials. There are many more translations and it is often used in preliminary studies.

Overview: Measure of adaptive behavior from birth to adulthood.

Qualification Level: B

Age Range: Birth-90


Administration: Online using Q-global, and paper and pencil

Forms: Birth-90 years old: Interview and Parent/Caregiver Form; 3-21 years old: Teacher Form

Scoring Options: Q-global and Manual Scoring

Publication Date: 2016

Wechsler Adult Intelligence Scale (WAIS-IV)

87 Clinical Trials as of 10/25/2017.

Overview: WAIS-IV was developed to provide you with the most advanced measure of cognitive ability and results you can trust when addressing the changing clinical landscape.

Qualification Level: C

Age Range: Individuals 16:0–90:11


Administration: Pencil-and-Paper or web-based (Q-interactive)

Completion Time: 60-90 minutes for core subtests

Scores/Interpretation: FSIQ, Index scores, subtest level scaled scores

Scoring Options: Q-interactive® Web-based Administration and Scoring, Manual scoring, Scoring Assistant® and Report Writer software

Report Options: Score Report, Client Report and Interpretive Report

Publication Date: 2008

California Verbal Learning Test® - Second Edition (CVLT®2)

86 Clinical Trials since 10/25/2017.

Overview: An assessment of verbal learning and memory deficits in adults.

Qualification Level: C

Age Range: Individuals 16:0–90:0


Administration: Digital (Q-interactive®), or paper and pencil

Completion Time: Standard and alternate forms: 30 minutes, plus 30-minute delay.

Scoring Options: Q-global®

Publication Date: 2017
Repeatable Battery for the Assessment of Neuropsychological Status Update (RBANS® Update)

75 Clinical Trials as of 10/25/2017.
Overview: RBANS Update provides a brief, individually administered battery to measure cognitive decline or improvement across these domains: immediate memory, visual spatial/constructional, Language, Attention, Delayed Memory.

Qualification Level: C
Age Range: 12:0 - 89:11 years
Four Forms A-D
Other Languages: Spanish (Forms A and B)*. (Translations: https://www.pearsonclinical.com/pharmaceutical-content-and-translations.html)
Administration: Digital or Paper-and-pencil
Completion Time: 30 minutes
Scores/Interpretation: Index standard scores, sub-test standard scores, total score
Scoring Options: Q-interactive® Web-based Administration and Scoring or Manual Scoring
Publication Date: 2012

Wechsler Memory Scale – Fourth Edition (WMS-IV)

66 Clinical Trials as of 10/25/2017.
Overview: The most widely used scale of adult memory has been revised and enhanced to provide you with the most advanced measure and results you can trust.

Qualification Level: C
Age Range: 16:0 to 90:11 years
Scores/Interpretation: Contrast Scores
Publication Date: 2009

Wechsler Intelligence Scale for Children (WISC-V)

52 Clinical Trials as of 10/25/2017.
Overview: Measure a child’s intellectual ability.

Discover the Power of V: WISC-V.com
Qualification Level: C
Age Range: Children aged 6:0–16:11
Administration: Paper-and-pencil or digital
Completion Time: Core subtests ~60 minutes
Scores/Interpretation: FSIQ, Primary Index Scores and Ancillary Index Scores
Scoring Options: Q-interactive® Web-based Administration and Scoring, Q-global™ Scoring & Reporting or Manual Scoring
Publication Date: 2014
Where do I find information about Pearson tests?

Search for our tests.
Product Details, Resources, Training Information, FAQs, etc.

https://www.pearsonclinical.com/

Our Pharma Licensing website has information more specific to the Pharma industry, like languages available, a list of more commonly used tests in Pharma, a link to submit a License Request, etc:

https://www.pearsonclinical.com/pharma-licensing.html

Pearson Clinical Pharma Licensing Landing page.
https://www.pearsonclinical.com/pharma-licensing.html

“Content & Translations” includes many of our frequently licensed products or tests and the list of the availability of the most asked for translations. If you find the language you seek in that list you can license the use of the test in that language. Ask us about the availability of other languages you need; we frequently acquire more.

Accessing lists of translations of tests.

3 ways to access translations of our tests.

1. You find the test in our list of existing translations & you obtain a license to use it. Go here: https://www.pearsonclinical.com/pharma-licensing/content-and-translations.html

   NOTE: This is not an exhaustive list and confirming the availability of the translation with Debrale Graywolf is advised: pharma-licensing@pearson.com.

2. Translation you require exists but it is published by another Pearson entity in the world (e.g. in another country). Debrale Graywolf will advise if you need to engage with another Pearson entity directly to purchase the test. No license is required to do this.

3. You commission a translation of the test. You can commission your own translation of that test, but the following is required.

   1) A license.
   2) A Certificate of Language Validity from the translator which is then submitted to Pearson.
   3) Submit the translation to Pearson which becomes Pearson’s intellectual property.
Difference between a “Published Translation” and a “Research Translation”

Published Translation: A “published translation” is one that is complete and accessible for consumers to buy. Pearson will not allow customers to translate into the same language as a “published translation” of the test. These translations are found here: [https://www.pearsonclinical.com](https://www.pearsonclinical.com)

Research Translation: A test has been translated into a foreign language but not “published” (typically this comes from companies commissioning the test to be translated.) These are found here: [https://www.pearsonclinical.com/pharma/licensing/content-and-translations.html](https://www.pearsonclinical.com/pharma/licensing/content-and-translations.html). This test CAN be translated another entity with a license.

Key Contact Person: Debrale Graywolf

Examples of Available Languages & Beck Depression Inventory, 2nd edition

The BDI–II consists of 21 items to assess the intensity of depression in clinical and normal patients. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression. [On our Pearsonclinical.com website](https://www.pearsonclinical.com) you will only find other languages: Spanish. This is a “published translation”.

Below are listed “research translations” available to Pharma which are considered doing research with clinical trials. The Pharma landing page is where you find “research translations”.

Languages Available:

1. English 7. Korean
2. Portuguese (Bz) 8. Croatian
4. French (France) 10. Dutch
5. Spanish (Argentina) 11. Danish
6. Italian 12. Norwegian
13. Swedish
14. German 15. French (Canada)
16. Spanish (Spain)
17. Hebrew
18. Finnish
19. Romanian

Find information about Pearson tests in clinical trials:

Go to [https://www.Clinicaltrials.gov](https://www.Clinicaltrials.gov) and search.

ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA required the U.S. Department of Health and Human Services (HHS), through NIH, to establish a registry of clinical trials information for both federally and privately funded trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for serious or life-threatening diseases or conditions. NIH and the Food and Drug Administration (FDA) worked together to develop the site, which was made available to the public in February 2000.

However, the regulation to register clinical trials only started in January, 2017. [Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)](https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/PostmarketSafetyInformation/PostmarketApprovalRequirements/UCM446937.pdf) clarifying and expanding the registration and results information submission requirements of FDAMA.

Key Contact Person: Debrale Graywolf
Go to https://www.clinicaltrials.gov

Click on “Advanced Search”

Want to know which Pearson tests in which studies with which disorders?  
Put the name of our tests into “outcome measures”

Addressing the Issue of Qualification Levels & Rater Training

In the case of Clinical Trials we do not require Pharma companies or CRO’s to go through the normal confirmation of credentials process before purchasing our tests.

The “straight off the shelf” process expedites the purchases of our tests.

However, what if your raters do not have the expected level of credential or training that we normally require for the administration and scoring of our tests?

Qualification Levels & Rater Training Caveat...

We realize that often in trials that there may not be raters that meet our standard level of qualification.

If this is the case then we will require higher levels of rater training which we can provide and will be discussed in following slides.

For example, face to face training may be necessary in such cases instead of online training.

We do have the capacity to certify raters once they have meet our criteria for training on our specific tools.
Qualification Level B
& the typical process of purchasing Pearson Tests

Master's Degree: psychology, education, occupational therapy, social work, counseling, or in a field closely related to the intended use of the assessment, and formal training in the ethical administration, scoring, and interpretation of clinical assessments.

OR
Certification by or full active membership in a professional organization (such as ASHA, AOTA, AERA, ACA, AMA, CEC, AEA, AAA, EAA, NAEYC, NBCC) that requires training and experience in the relevant area of assessment.

OR
A degree or license to practice in the healthcare or allied healthcare field.

OR
Formal, supervised mental health, speech/language, occupational therapy, social work, counseling, and/or educational training specific to assessing children, or in infant and child development, and formal training in the ethical administration, scoring, and interpretation of clinical assessments.

Qualification Level C
& the typical process of Purchasing Pearson Tests

Doctoral Degree: in psychology, education, or closely related field with formal training in the ethical administration, scoring, and interpretation of clinical assessments related to the intended use of the assessment.

OR
Licensure or certification to practice in your state in a field related to the purchase.

OR
Certification by or full active membership in a professional organization (such as APA, NASP, NAN, NS) that requires training and experience in the relevant area of assessment.

Pearson Top 11 in Clinical Trials as of 10/25/2017
Note the credentialing trend...

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Trials</th>
<th>Age</th>
<th>Credential Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory [BDI]</td>
<td>1008</td>
<td>13-80</td>
<td>B</td>
</tr>
<tr>
<td>Beck Anxiety Inventory [BAI]</td>
<td>252</td>
<td>17-80</td>
<td>B</td>
</tr>
<tr>
<td>Bayley Scales of Infant and Toddler Development</td>
<td>187</td>
<td>1-42 mos.</td>
<td>C</td>
</tr>
<tr>
<td>Symptom Checklist SCL-90-R</td>
<td>175</td>
<td>13 years &amp; older</td>
<td>B</td>
</tr>
<tr>
<td>Brief Symptom Inventory [BSI]</td>
<td>154</td>
<td>13 years &amp; older</td>
<td>B</td>
</tr>
<tr>
<td>Vineland Adaptive Behavior Scales</td>
<td>132</td>
<td>Birth-90 years</td>
<td>B</td>
</tr>
</tbody>
</table>
Pearson Top 11, continued
Note the trend with cognitive assessments & level C

<table>
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<tr>
<th>Assessment</th>
<th>Trials</th>
<th>Age</th>
<th>Credential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wechsler Adult Intelligence Scale (WAIS-IV)</td>
<td>87</td>
<td>16:00-90:11</td>
<td>C</td>
</tr>
<tr>
<td>CVLT-II (California Verbal Learning Test - Second Edition)</td>
<td>86</td>
<td>14 to 89</td>
<td>C</td>
</tr>
<tr>
<td>Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)</td>
<td>75</td>
<td>12:00-88:11</td>
<td>C</td>
</tr>
<tr>
<td>WMS-IV ('Wechsler Memory Scale' - Fourth Edition)</td>
<td>64</td>
<td>16:00-90:11</td>
<td>C</td>
</tr>
<tr>
<td>Wechsler Intelligence Scale for children (WISC-V)</td>
<td>52</td>
<td>6:0-16:11</td>
<td>C</td>
</tr>
</tbody>
</table>

Rater Training: Ensure Proper Administration and Scoring of Pearson Tests.

**Existing online training**

1. Existing online training: Go to: https://www.pearsonclinical.com. Search for the test of interest and then click on the ‘training’ tab after scrolling down the page. If there is no ‘training’ tab then there is no training at that site for this tool. Usually there is training that includes the following formats:
2. Recorded webinars.
3. Live Webinars.

**Additional Rater Training with the possibility of specificity to your particular project.**

1. **Face to Face Investigator Meeting:** This training includes onsite training anywhere in the world you would like training.
2. **Live Webinar:** Rater location logistics may prevent a face to face investigator meeting or limit access of some raters. This option can be used instead.
3. **Consultation:** A consultation package can be developed which will allow you to access our staff through conference calls or video chats. This may involve regular meetings as you see fit.
4. **Recorded Webinar:** Online on demand training from anywhere that has internet access:
   a. Pearson Clinical Training Campus.net
   b. Brainshark

**NOTE:** A services agreement quote of fees will be provided after you provide a detailed request for the training you prefer.
On demand Pearson Training  
Requiring credential confirmation:
PearsonClinical.TrainingCampus.net


Or Type "PearsonClinical.trainingcampus.net" into the search bar.

NOTE: This format of training will require a confirmation of Education & Training

Requisites: License number, Licensing Body

- Field, Highest Degree, Year Earned Degree, Institution

- Professional organization membership:
  - Name of organization (e.g. APA, ACA, AOTA, ASHA, etc).
  - Member number, Member type.

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PearsonClinical.TrainingCampus.net
Assessment Training Available

Beck Depression Inventory® – II Administration, Scoring, Interpretation
Contains both the Administration and Scoring, and Interpretation modules.

Using the WISC-V to Understand Learning Difficulties: APA CE Tests

Neuropsychological Assessment of Cognitive Functions in Individuals with TBI
- Delis, Part 1 & 2

MCMI-IV Independent Study Training Program: APA CE Tests

MMPI-2-RF Introductory Training SERIES APA CE Tests

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Brain Shark Recorded Training Webinars
Can include project specifics.

This is an online training format in which we house recorded webinars.

With any particular project we may need to develop new training materials through this format or we may use existing training materials. This format allows us to develop project specific content if necessary.
To engage in additional rater training (more than what is already at www.pearsonclinical.com or at PearsonClinical.TrainingCampus.net) a services agreement for training is necessary. Once this agreement has been executed the training will begin as it was stipulated in the agreement. Changes in training requests will require an amendment to the original agreement which includes a cost for the amendment and the additionally specified training.

NOTE: Presently this is a distinct process from licensing. It may be integrated into the licensing process at a later date.

CONTACTS: Pearson’s Team Lead, Clinical Training and Consultation Adam Scheller, Ph.D., adam.scheller@pearson.com

Charles Shinaver, PhD, Manager of Business Development – Pharma: 317-379-9083, charles.shinaver@pearson.com

Which Assessments & Which Disorders?

**Beck Depression Inventory (BDI)**

Chronic medical conditions in bold.

Disorders rank ordered by (number of studies) on that disorder in parentheses.

- Depression (369), Major Depressive Disorder (130), Anxiety (124), Post Traumatic stress disorder – PTSD (86), Parkinson Disease (44), Cardiovascular Diseases (44), Multiple Sclerosis (38), Fibromyalgia (38), Bipolar Disorder (25), Substance use disorders (25), Heart Diseases (24), Diabetes (21), Gastrointestinal disorder (21), Traumatic Brain Injury (19), stroke (19), Suicide (19), Arthritis (14), Coronary artery disease (14), Obesity (13).

NOTE: This is NOT an exhaustive list. The list will change from day to day and week to week as new studies are added. This does capture the notable range of disorders, related symptoms and many comorbid disorders.
Which Assessments for Which Disorders?

Beck Anxiety Inventory (BAI)
252 Clinical Trials, Age: 17-80, Credential: B

**Conditions:** Anxiety (100), Depression (81), Post Traumatic Stress Disorder (PTSD) (20), Well being (19), Generalized Anxiety Disorder (16), Sleep (13), Panic Disorder (12), Phobia (12), Social Phobia (9), Cancer (9), Social Anxiety Disorder (7), Agoraphobia (5), Suicide (5), Post Partum Depression (3), Body Dysphoric Disorder (3)

Which Assessments for Which Disorders?

Bayley-III
187 clinical trials with Bayley, 43 Clinical Trials with Bayley-III
Ages: 1-42 mo., Credential: C

**Conditions Assessed:** Development (61), Preterm infants (56), Premature (56), Depression (11), Bronchopulmonary disease (11), congenital heart disease (7), very low birth weight (4), Movement disorder (4), neonatal seizures (3), pain (3), Angelman Syndrome (3)

Which Assessments for Which Disorders?

Symptom Checklist-90-Revised
SCL-90-R 175 studies, Age: 13 & Older, Credential: B

**Conditions Assessed:** Psychotic (113), Depression (50), Mood Disorder (47), Anxiety (30), Stress (19), Personality Disorder (18), Pain (13), Schizophrenia (9), Substance use disorder (8), cardiovascular disease (8), Post Traumatic Stress Disorder (8), Cancer (8), Somatization (6), Attention Deficit Hyperactivity Disorder (6), Distress (6), Alcoholism (5), substance abuse (3), Breast cancer (3), Traumatic brain injury (3), Phobia (3), Obsessive Compulsive Disorder (2)
Which Assessments for Which Disorders?

**Brief Symptom Inventory**

BSI: 154 Clinical Trials. Age: 13 years & older. Credential: B

**Conditions Assessed:** Psychotic (67), mental disorders (67), Depression (24), Cancer (24), Stress (21), Anxiety (18), Pain (16), Post Traumatic Stress Disorder (15), Mood Disorder (15), Brain injuries (16), Schizophrenia (8), Traumatic brain injury (8), Substance use disorder (7), Distress (6), Alcoholism (5), Personality Disorder (5), concussion (4), borderline personality disorder (4), cardiovascular disease (3)

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**Vineland Adaptive Behavior Scales, Second Edition**

Vineland-II: 132 studies, "Vineland-II": 20 studies, "Vineland-3": 1 study. Age: Birth – 90 years. Credential: B

**Conditions Assessed:** Autism (72), Child Developmental Disorder (68), Pervasive Developmental Disorder (55), neurologic Disorders (48), Nervous System Disorders (48), Mental Retardation (26), Down syndrome (8), Asperger’s Disorder (7), Fragile X Syndrome (7), Cognitive Dysfunction (4), Sanfilippo Syndrome (4)

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**Wechsler Adult Intelligence Scale**

WAIS-IV: 87 Clinical Trials. WAIS-IV: 30

**Age:** 16:00-90:11, Credential: C

**Conditions Assessed:** Psychosis (47), Cognitive Disorders (25), Cognitive Impairments (17), Dementia (14), AIDS (10), Traumatic Brain Injury (TBI) (9), Alzheimer’s (9), ADHD (8), HIV (6), Schizophrenia (6), Stress (6), Stroke (5), Parkinson’s (5), PTSD (5), healthy Adults (5)
Which Assessments for Which Disorders?

California Verbal Learning Test – Second Edition
CVLT-II: 86 Clinical Trials, CVLT-II: 35
Age: 16-89, Credential: C
Conditions Assessed: Cognition (31), Traumatic Brain Injury (TBI) (12), multiple sclerosis (12), major depression (12), schizophrenia (11), Parkinson Disease (8), Mild cognitive impairment (8), Dementia (7), Bipolar (5), Cognitive ability (5), Down Syndrome (3), intellectual disability (3), Aging (3)

Repeatable Battery for the Assessment of Neuropsychological Status (RBANS): 75 clinical trials, Age: 12:00-89:11, Credential: C
Conditions: Dementia (18), Schizophrenia (17), Cognitive Impairment (16), Alzheimer’s disorder/dementia (16), mild cognitive impairment (8), Depression (7), Delirium (5), Fragile X Syndrome (3), Mania (3)

“Wechsler Memory Scale”-Fourth Edition (WMS-IV): 66 clinical trials, Age: 16:00-90:11, Credential: C
Conditions: Cognitive Decline (22), Cognitive Disorders (21), Dementia (17), Alzheimer Disorder (15), mild cognitive impairment (9), Depression (8), Schizophrenia (7), stroke (4), Parkinson Disease (3), healthy (3), Sepsis (3), PTSD (3), schizoaffective (2), Cancer (2)
GDE6  Suggest formatting a sub-head with the full title of the assessment; I've done a few but don't have time for the rest.
Graywolf, Debrale E, 10/25/2017
### Which Assessments for Which Disorders?


**Age:** 6:00-16:11, Credential: C

**Conditions:** Attention Deficit Hyperactivity Disorder (ADHD) (17), Tumor (6), Cancer (6), Epilepsy (4), Schizophrenia (3), Thyroid (2), Anxiety (2), Fragile X Syndrome (2), depression (2)

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### Which Assessments for Which Disorders?

**“Mullen” Scales of Early Learning-II:** 43 clinical trials, Age: Birth-68 months, Credential: B

**Conditions:** Autism (18), Infant development (5), Rett Syndrome (3), infant cognitive development (2), Batten Disease (2), Parenting (2), Late infantile metachromatic Leukodystrophy (2), Late Infantile Neuronal Ceroid Lipofuscinosis (2), Postpartum Depression(2)

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### Summary

- Pearson’s Renewed & Deepened Commitment to Clinical Trials.
- Buying “straight off the shelf” vs Licensing
- To get a licensing quote submit a competed Clinical Trial License Application.
- Expediting Clinical Trials: Limited License Agreements.
- Expediting Clinical Trials: MLA’s.
- Pearson is a world leader in assessment.
- Cross checking the utilization of assessments in clinical trials can be done at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).
- Qualifications or credentialing is now clear.
- Variety of Rater Training options
- Which assessments for which disorders is broader than you thought!
Straight off the shelf: Deborah Vance
deborah.vance@pearson.com, 210-339-8430. San
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Assessment Customer Support

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