



Best Practice Guide

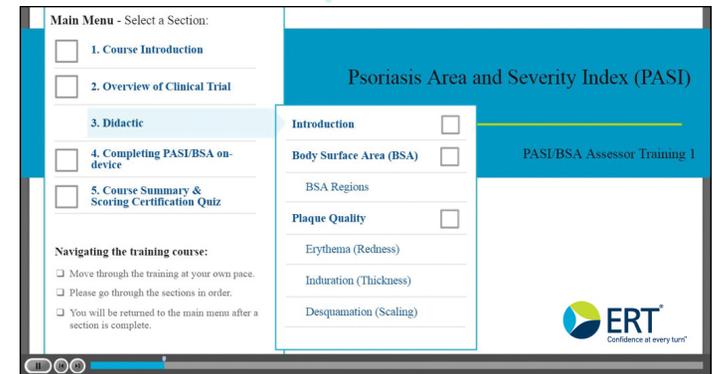
# COLLECTING eCOA IN DERMATOLOGY TRIALS

ERT develops gold standard for training raters on the psoriasis area severity index (PASI)

# CUSTOMIZED RATER TRAINING FOR DERMATOLOGY ASSESSMENTS

Clinician rater training has been shown to be effective in improving rater reliability in dermatology studies.<sup>1</sup> Rater training effectiveness and engagement are enhanced when COA data are collected electronically, with customized assessment training on ERT eCOA tablet and web.

The ERT Clinical Science Team customizes clinician rater training for each dermatology assessment with the expert guidance of Dr. Kristina Callis Duffin, MD. Dr. Callis Duffin practices general dermatology with an emphasis on the care of patients with psoriasis. She has extensive experience in treating psoriasis patients with topical agents, ultraviolet light, systemic medications including biologic agents, and is an investigator on a number of clinical trials for psoriasis. In addition, she has led the effort in psoriasis and psoriatic arthritis rater training by creating the GRAPPA network.<sup>2</sup> Together with ERT clinical psychologists, Dr. Callis Duffin has established a gold standard for training raters on the PASI.



**TRAINING IS BROKEN DOWN INTO A CHAPTER FORMAT FOR EASY REFERENCE AND NAVIGATION**

1. Armstrong, A. et al. 2013. DOI: <http://dx.doi.org/10.1001/jamadermatol.2013.1083>;

2. Salvarani, C. et al. 2016. DOI: <http://dx.doi.org/10.1016/j.semarthrit.2016.06.004>

# THE GOLD STANDARD FOR TRAINING CLINICIAN RATERS

The Psoriasis Area and Severity Index (PASI) is a highly subjective clinician reported outcome. Standardized training for this assessment is crucial as it is the most commonly used and validated disease severity measure for psoriasis clinical trials. Historically, without training, raters have provided scores with a great degree of inter-rater variability. In particular, there is often an overestimation of the body surface area component when determining the extent of the psoriatic lesions.<sup>3</sup>

THERE IS OFTEN AN OVERESTIMATION OF THE EXTENT OF PSORIASIS ON THE PATIENT'S BODY

The screenshot shows a training slide titled "BSA - Head and Neck Example". It features a hand icon on the left and two photographs of a person's head and neck with a blue shaded area representing the affected skin. Below the photos, a calculation is shown: "Number of Palms: 2", "Divide by 10: / 10", "Multiply by 100: x 100", and "Area Score Calculation: = 20%". A red text box states "Head and Neck = 10% BSA = 10 palms". A table titled "Area Scores 0-6" lists the following ranges: 0 = 0 (none), 1 = >0% to <10%, 2 = 10% to <30%, 3 = 30% to <50%, 4 = 50% to <70%, 5 = 70% to <90%, and 6 = 90% to 100%. The slide footer includes the copyright notice: "© 2010-2016 Group for Research and Assessment of Psoriasis and Psoriatic Arthritis. All Rights Reserved."

The screenshot shows a training slide titled "Plaque Quality - Introduction". It contains the text: "This section covers the second component, the measurement of plaque quality. 3 symptom types: Erythema (Redness), Induration (Thickness), and Desquamation (Scaling)". Below the text are three photographs illustrating these symptoms. To the right, a "Scale:" box lists: "0 = None", "1 = Mild (Slight)", "2 = Moderate", and "3 = Marked (Striking)". The slide footer includes the copyright notice: "© 2010-2016 Group for Research and Assessment of Psoriasis and Psoriatic Arthritis. All Rights Reserved."

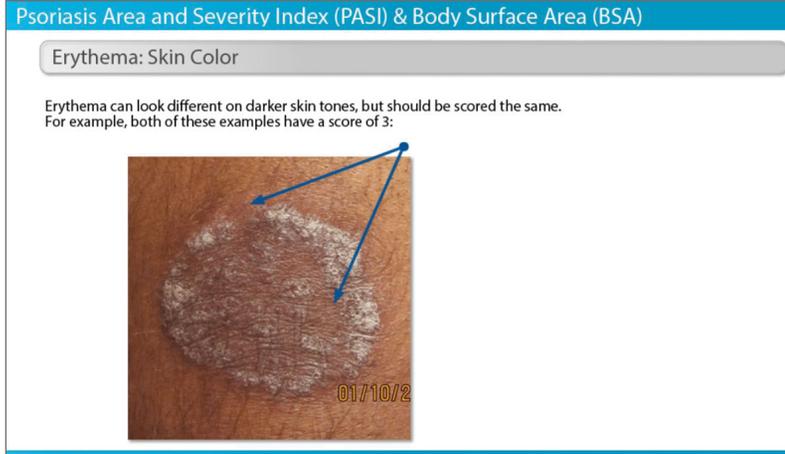
ERT'S GOLD STANDARD TRAINING AND EXAM CAN DECREASE INTER-RATER VARIABILITY ACROSS YOUR PSORIASIS TRIALS

3. Armstrong et al., 2013 Group for Research and assessment of psoriasis and psoriatic arthritis. <http://www.grappanetwork.org/>

## Targeted areas of improvement for clinician rater training

ERT Rater Training for clinicians targets these areas for immediate improvement, supported with detailed guidance and best practices:

- > The ERT PASI training breaks down the body surface area component of the PASI and explains how best to calculate the percentage for each area singularly.
- > There is strong emphasis on the palm-measurement method, resulting in a more quantitative and consistent approach to PASI rating as opposed to only scoring by observation.
- > All training images are of real patients.
- > This training discusses how to score challenging examples, such as central clearing and erythema on different skin tones.

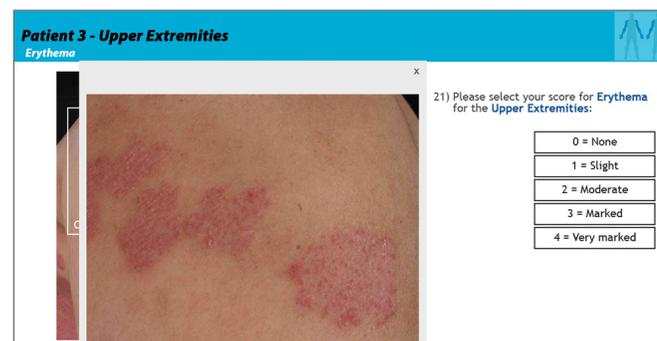


**BEST PRACTICES ON TRAINING TO SCORE CHALLENGING EXAMPLES, INCLUDING CENTRAL CLEARING AND ERYTHEMA ON DIFFERENT SKIN TONES**

# ERT PASI ASSESSMENT QUIZZING AND SCORING

ERT PASI rater training includes interactive quizzes with feedback throughout the module. After learning each concept, clinicians can check their learning and score an actual patient example before advancing to the next section. Quiz-based certification was validated by 16 dermatologists in 2016.

- > PASI assessment scoring complexities are simplified with automated branching, scoring and algorithms, eliminating manual mathematical error. For example, when entering values for each body area void of psoriatic lesions, the device will automatically score a 0 for erythema, induration, and desquamation.
- > Auto-scoring mitigates human scoring error and saves time otherwise wasted with paper entries and redundant information.



## CLINICIANS CAN SCORE ACTUAL PATIENT EXAMPLES BEFORE ADVANCING TO NEXT SECTION

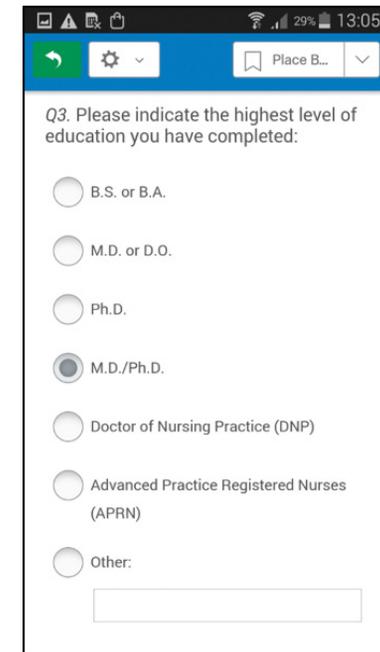


## QUIZ-BASED CERTIFICATION VALIDATED BY PANEL OF DERMATOLOGISTS IN 2016

# ERT PASI ELECTRONIC IMPLEMENTATION TRAINING

In addition to clinician assessment training, ERT PASI training educates raters on the pitfalls of each clinical outcome assessment, including advice on practices for improved, standardized scoring.

- > ERT provides a quick response (QR) code and/or link for clinical raters to easily access the qualification testing area. Nothing is manual; no paper is involved. There are no time delays, nor any subject matter expert (SME) required to review paper data forms.
- > Clinician raters complete the qualification test on their own smartphones. If their score renders them eligible to complete rater training, they will automatically receive email instructions on how to complete their assigned training in ERT Portal.



The screenshot shows a mobile application interface for a qualification test. At the top, there is a status bar with icons for signal, Wi-Fi, and battery (29%), and the time 13:05. Below the status bar is a navigation bar with a back arrow, a settings gear, and a dropdown menu labeled 'Place B...'. The main content area displays the question: 'Q3. Please indicate the highest level of education you have completed:'. Below the question are seven radio button options: 'B.S. or B.A.', 'M.D. or D.O.', 'Ph.D.', 'M.D./Ph.D.', 'Doctor of Nursing Practice (DNP)', 'Advanced Practice Registered Nurses (APRN)', and 'Other:'. The 'M.D./Ph.D.' option is selected. Below the 'Other:' option is an empty text input field.

**AUTOMATED PRE-QUALIFICATION PROCESS CAN BE COMPLETED BY PHONE OR WEB**

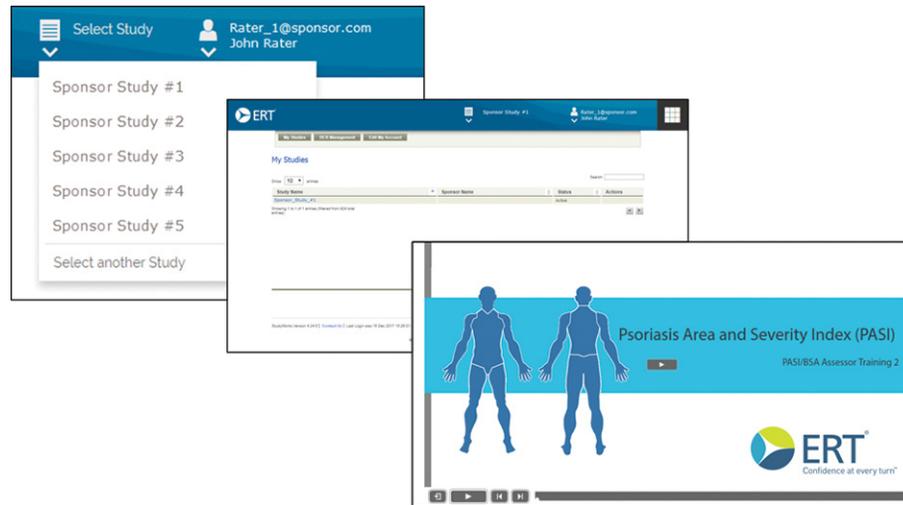
## Qualification management on device

- > Clinician raters are assigned training based on their qualification level — advanced vs beginner raters.
- > Training burden is reduced for advanced raters, who can provide documentation of recent completion of GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis) training, which would make them eligible for exemption from the final certification quiz.
- > After completion of a short pre-qualification survey, unqualified raters are routed to ERT's automated waiver system for final determination.
- > Within the training environment, trainees can zoom to drill down on skin images, and/or use a hand tool for counting affected/unaffected areas.

**AVOID OVER- OR  
UNDER-TRAINING  
INVESTIGATORS WITH  
PRE-QUALIFICATION**

## Single system for rater qualification, rater training and electronic assessment

ERT's PASI rater training is detailed and easy to understand. It can be completed on the same device used to collect the electronic clinical outcome assessments (eCOA) or online using the ERT Portal. A single system is used for rater qualification, rater training and electronic implementation of the assessment; enabling rater gating and electronic data attribution. Thus, clinical raters have a single sign-on for both eCOA and rater training, and reduced burden on site staff. This new Gold Standard can increase inter-rater reliability across all dermatology clinical trials using the PASI.

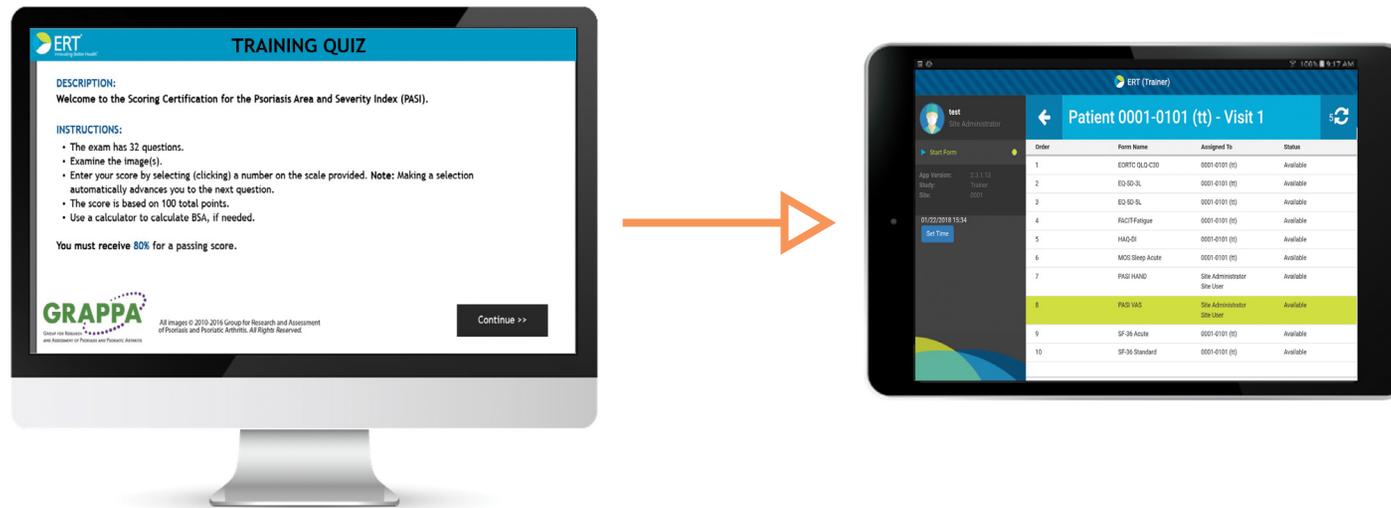


**EASY ACCESS TO TRAINING THROUGH THE ERT STUDY PORTAL**

# GATING: MONITORING THE BRIDGE FROM TRAINING TO THE eCLINRO

Due to ERT's single sign-on platform, gating between training and the eCLINRO is a powerful tool that can be implemented to ensure only qualified raters are providing key endpoint data.

After training and the subsequent training quiz are completed, each rater will receive a unique code. That code is then entered onto the tablet to unlock the PASI assessment. Prior to entry of this code, that rater will not be able to enter data for this assessment. Note: Only assessments tied to training will be locked in this manner; all others will be accessible.



**UPON SUCCESSFUL COMPLETION OF THE TRAINING QUIZ, A UNIQUE CODE WILL BE GENERATED, WHICH WILL UNLOCK THE PASI ASSESSMENT ON THE ELECTRONIC DEVICE**

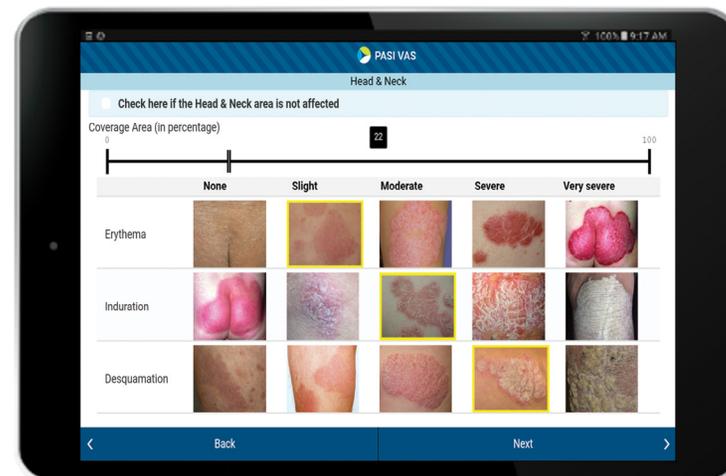
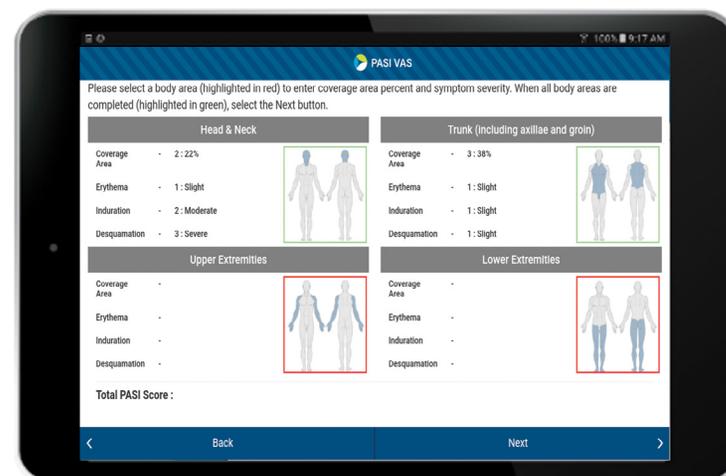
# ERT PASI eCLINRO COMPLEMENTS TRAINING, ENHANCES CONSISTENT DATA

ERT has developed a new and improved PASI eCLINRO design that far surpasses those that have come before. It allows for more intuitive data entry, contains logic checks and is formatted to help raters score this assessment with consistent data.

## Features:

- > Single entry screen to view all 4 areas; body diagrams visible to select which area to start with first.
- > Example patient images for each severity score, validated by an expert dermatologist.
- > 'Clear All' button at the top of each evaluation page, to facilitate efficient entry where there is no psoriasis in one of the body areas.
- > VAS scale from 0 to 100% for body surface area entry. Option to enter the # of handprints instead of % for Body Surface Area.
- > All scores auto-calculated on entry screen.

Learn how ERT accelerates your research with eCOA technology that doesn't get in the way.



**RATER TRAINING EFFECTIVENESS AND  
ENGAGEMENT ARE ENHANCED WHEN COA DATA  
ARE COLLECTED ELECTRONICALLY**

## ABOUT ERT

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move ahead with confidence. With nearly 50 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next, so we can adapt without compromising standards.

Powered by the company's EXPERT® technology platform, ERT's solutions enhance trial oversight, enable site optimization, increase patient engagement and measure the efficacy of new clinical treatments while ensuring patient safety. Since 2014, more than half of all FDA drug approvals came from ERT-supported studies. Pharma companies, biotechs and CROs have relied on ERT solutions in 10,000+ studies spanning more than three million patients to date. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly — and with confidence.

