Clinician Global Impression of Severity and Change Scales for Cutaneous Lupus Erythematosus: Cognitive Debriefing Evidence Supporting Clinical Utility

Tina O'Donnell, *Josephine Park*, Patricia Koochaki, Ufuk Coşkun, Denise Bury, *Paul Kamudoni*

This work was sponsored by Merck Healthcare KGaA, Darmstadt, Germany (ROR ID: https://ror.org/04vpzfb52).
Authors in italics are/were employees of Merck Healthcare KGaA, Darmstadt, Germany, or its affiliates at the time the work was carried out.
Please scan the QR code below for author affiliations and disclosures.

CO231

SCAN TO VIEW RELATED POSTERS

For personal use only and may not be reproduced without written permission from the authors

RESEARCH IN CONTEXT

1. **The Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity Score (CLASI-A) is a widely used measure of cutaneous disease activity in lupus trials. Thresholds for clinically meaningful changes in CLASI-A scores have been established in prior work. Additional data relying on anchor-based methodology would strengthen the evidence base.**
2. **The Cutaneous Lupus Disease Activity Physician Global Impression of Severity (CDA-PGIS) and Physician Global Impression of Change (CDA-PGIC) may serve as clinician-reported anchors alongside the CLASI-A for interpreting clinically meaningful changes in cutaneous disease activity in lupus trials.**

OBJECTIVES

To evaluate the content validity and clinical utility of two novel clinician-reported global scales—CDA-PGIS and CDA-PGIC were developed to support interpretation of meaningful within-person change in Clinician-Reported Outcomes (ClinROs) for cutaneous disease activity in lupus trials.

INTRODUCTION

Rationale and background: Well-developed and **interpretable anchors** are needed to support understanding of **clinical meaningfulness of cutaneous disease activity in lupus trials**.

Clinician-reported global scales:

- **CDA-PGIS is a 4-point** clinician-reported measure of current disease **severity**.
- **CDA-PGIC is a 7-point** measure of **change** since study start.
- **Both capture disease activity**, including erythema, scale/hypertrophy, mucosal membrane lesions, hair loss, and alopecia.

METHODS

Draft items

CDA-PGIS and **CDA-PGIC** drafted based on patient input and clinician input.

Cognitive debriefing

- **18 clinicians** (dermatologists/ rheumatologists, ≥5 years managing CLE and/or SLE).
- **Semi-structured Interviews** led by experienced moderators.

Evaluation

- **Comprehension** and ease of completion.
- **Recall** period
- **Response** options.
- Estimates of **meaningful** within-person **change**.

Finalized items

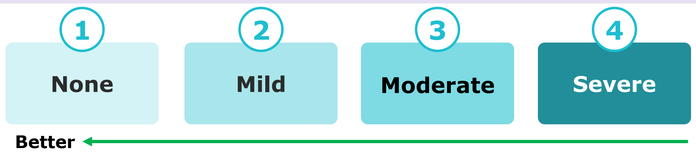
Wording of **clinician-reported anchors refined** alongside the CLASI-A.

Note: Study limitations are provided in the supplementary material

RESULTS

CDA-PGIS global scale | Current severity (points 1-4)

"How would you describe the overall severity of the patient's cutaneous lupus disease activity[a] at the present time?"

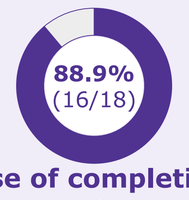


CDA-PGIC global scale | Change since study start (points 0-6)

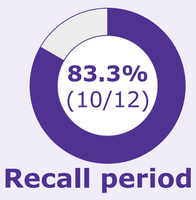
"Please choose the response below that best describes the overall change in the patient's cutaneous lupus disease activity."



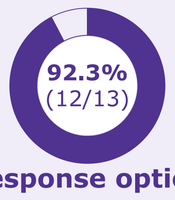
CDA-PGIS | Cognitive debriefing interview summaries



Ease of completion
Clinicians found the CDA-PGIS easy to complete



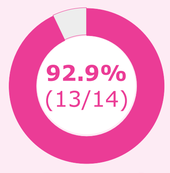
Recall period
Clinicians found recall period clear and suitable



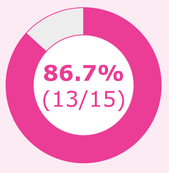
Response option
Clinicians found response options suitable

11/18 clinicians judged a 1-point improvement in CDA-PGIS as clinically meaningful change*

CDA-PGIC | Cognitive debriefing interview summaries



Ease of completion
Clinicians found the CDA-PGIC easy to complete



Response option
Clinicians found response options appropriate

Used alongside CDA-PGIS to capture change from baseline providing complementary clinical context

[a]Erythema, scale/hypertrophy, mucosal membrane lesions, hair loss and alopecia.
*Independently supported by post-hoc analysis of patient-level data.

Final version: Modifications following cognitive debriefing

Cognitive debriefing feedback	Modification implemented
Disease activity not explicitly defined	Parenthetical explanation added to both items: erythema, scale/hypertrophy, mucosal membrane lesions, hair loss, and alopecia
Terminology not aligned with the disease activity as defined in CLASI[1]	"Scale" revised to "scale/hypertrophy"
Recall period left implicit	"At the present time" added to the CDA-PGIS
Alternative scale range or granularity preferred	No change; isolated preferences not adopted

Relevance and intended use

Both the CDA-PGIS and CDA-PGIC scales were deemed relevant in providing clinician global assessments of CLE disease activity, which can be used to aid with the interpretation of results from other clinician-reported cutaneous disease activity measures.

Selected clinician feedback

CDA-PGIS
Ease of completion
"That's quite easy to do. You can certainly tell the difference between severe and moderate."
— 304R

CDA-PGIS
Response options
"The descriptive wording is better than numerical scoring… described in quite understandable words."
— 307R

CDA-PGIS
Meaningful improvement
"I think in almost every situation, one point would be clinically meaningful if they did go down by one point."
— 301D

CDA-PGIC
Ease and familiarity
"That seven-point scale, people are used to it. So, I think that one's easier to understand."
— 206R

CONCLUSIONS

CDA-PGIS and CDA-PGIC are complementary clinician-reported anchors developed to support interpretation of clinically meaningful changes in ClinROs for cutaneous disease activity in lupus trials.

Cognitive debriefing confirmed that both measures were understandable, relevant, easy to complete, and supported by appropriate response options; a one-category CDA-PGIS improvement was considered clinically meaningful. Minor refinements clarified disease activity, added "hypertrophy," and made the present-time reference explicit.

These findings support the suitability of the CDA-PGIS and CDA-PGIC as clinician-reported anchors to estimate responder thresholds for ClinROs for cutaneous disease activity in lupus trials.

SCAN FOR POSTER PDF AND SUPPLEMENTARY MATERIALS
For personal use only and may not be reproduced without written permission of the authors.

Abbreviations: **CDA-PGIC**, Cutaneous Lupus Disease Activity Physician Global Impression of Change; **CDA-PGIS**, Cutaneous Lupus Disease Activity Physician Global Impression of Severity; **CLASI-A**, Cutaneous Lupus Erythematosus Disease Area and Severity Index–Activity; **CLE**, cutaneous lupus erythematosus; **ClinROs**, clinician-reported outcomes; **SLE**, systemic lupus erythematosus.

References: 1. Albrecht J, et al. J Invest Dermatol. 2005;125(5):889-894.

Presented at ISPOR Europe 2026 | 8 - 11 November | Vienna, Austria

SUPPLEMENTARY MATERIALS

Affiliations

Tina O'Donnell, PhD[1], Josephine Park, MPH, MBA[2], Patricia Koochaki, PhD[1], Ufuk Coşkun, PhD[3] , Denise Bury, MPH, PhD[4], Paul Kamudoni, PhD[5]

1. ICON PLC, Dublin, Ireland
2. EMD Serono Research & Development Institute, Inc., Billerica, MA, USA, an affiliate of Merck KGaA (at the time of the study)
3. Sprout Health Solutions, Los Angeles, CA, USA
4. Independent COA Consultant under contract with Merck Healthcare KGaA, Darmstadt, Germany
5. Merck Healthcare KGaA, Darmstadt, Germany

Disclosures

Tina O'Donnell and **Patricia Koochaki** are employees of ICON, PLC, Dublin, IR.

Josephine Park was an employee of EMD Serono Research & Development Institute, Inc., Billerica, MA, USA, an affiliate of Merck KGaA, at the time the work was carried out.

Ufuk Coşkun was an employee of ICON at the time of this study, and is currently with Sprout Health Solutions, Los Angeles, USA.

Denise Bury is an Independent COA Consultant under contract with Merck Healthcare KGaA, Darmstadt, Germany.

Paul Kamudoni is an employee of Merck Healthcare KGaA, Darmstadt, Germany.

Acknowledgements

Medical writing support was provided by Saranya Kanukollu of Merck Specialties Pvt. Ltd., Bengaluru, India, an affiliate of Merck KGaA.

Limitations

- Semi structured interviews are well suited for exploring content validity; nevertheless, they cannot guarantee content validity nor external validity.
- The sample size, while appropriate for this research, coupled with convenience sampling, cannot guarantee that the findings will be representative of all practicing clinicians.