

SUPPLEMENTARY MATERIAL

Development of the Cutaneous Dermatomyositis Investigator Global Assessment (CDM-IGA): a de novo IGA of cutaneous manifestations of dermatomyositis

Authors:

Stephanie McKee¹, Jason Xenakis², Harriet Makin¹, Chris Marshall¹, Randall Winnette^{2*}, Rohit Aggarwal³, Sarah L Knight¹

¹ Clinical Outcomes Assessment, Clarivate, London, UK

² Pfizer Inc, New York, US

³ University of Pittsburgh Medical Centre, Pittsburgh, US

*RW is a current employee of Novartis. This research was conducted when RW was an employee at Pfizer Inc.

Corresponding author:

Stephanie McKee: stephanie.mckee@clarivate.com

Table S 1. Overview of CDM-IGA clinical expert review

Clinical expert ID	Version 0.1 of the CDM-IGA	Version 0.2 of the CDM-IGA	Version 0.3 of the CDM-IGA	Version 0.4 of the CDM-IGA	Version 0.5 of the CDM-IGA	Version 1.0 of the CDM-IGA (Via consensus meeting)
CLIN_01	✓	Versions adapted through internal discussion between COA development and validation expert consultants at Clarivate, Pfizer and experienced clinical experts.				
CLIN_02	✓					✓
CLIN_03	✓					
CLIN_04					✓	
CLIN_05					✓	
CLIN_06					✓	✓
CLIN_07					✓	
CLIN_08					✓	
CLIN_09						✓

Abbreviations: CDM-IGA, Cutaneous Dermatomyositis Investigator Global Assessment; CLIN, clinical expert; ID, identification.

Table S 2. Example quotes from clinical experts during the qualitative interviews and consensus meeting

Concept, reported by N (%)	Example quote(s)
Erythema	
DM causes patients to experience erythema on their skin	<i>“Um, so, one of the big – you know, everyone’s not the same, so they’re all different. Um, sometimes they present with a very red erythematous scaly scalp that can be very itchy.” (CLIN_03)</i>
	<i>“And, err, err, the second symptom they – err, that bother patient is, err, redness itself. It, it, err, often, err, a-affects, err, face and their, also, err, trunk, err, including, err, chest and err, back. And err, sometime – oh, err, err, patient usually show – err, no, err, have, err, erythema on the err, err, hands, but the, the, the – it, it, err, is, err, usually, err, symp – err, apus – asymptomatic.” (CLIN_07)</i>
Erythema should be the primary characteristic on the CDM-IGA	<i>“The color of the skin is a very, err, a good indicator for severity” (CLIN_01)</i>
	<i>“Um, so, I guess, are you asking should it be the prime weigher, is that what you’re asking? I: Yeah, so at the moment it’s the first – it’s the primary characteristic, and we’re wondering do you agree that it should influence – it should be the key influencer of the score? Um, I mean, I guess if you have to pick one, then I would say yes.” (CLIN_03)</i>
Secondary changes	
The presence of secondary changes should add +1 point on the patients CDM-IGA score	<i>“[Pause] I think this is always an intrinsic problem with these scales, because you’re always trying to, like, force these gradations [means gradations], but it may be that you need a scale that combines some of these secondary features into, err, you know, a scoring so that they’re not all so discreet. You know, we think scale’s, kind of, important. We think the erosions are important. Maybe the lichenification is important. Maybe there is some sort of – you’d have some sort of secondary characteristics, where there’s, sort of, a mixture of those things and then you get points to try to do it. ‘Cause these, these, these gradations [means gradations] are always so artificial and sometimes they just don’t capture what you’re trying to assess. So, it’d just be one consideration, maybe to collapse some of these categories into some, sort of, sort of, secondary skin changes and then try to have some definitions to help, um, you know, you know, in terms of making those “clear, almost clear, mild, moderate, severe,” and using, maybe, multiple factors. It may be – maybe that’s not the best way to do it, but it may be a consideration, ‘cause I’m just not sure these gradations [means gradations] with respect to the scale of the erosions are really going to really help you.” (CLIN_09)</i>
Erosions/ulcerations can appear slightly differently across body areas	<i>“I think body area – I’m trying to look; you don’t have body area anywhere. Like, a punched-out lesion on the shoulder looks different than a punched out lesion on the MCP, a lot of times. Like, it’s a little bit different. Sometimes it’s looks like a little hole punch. Um, might be reasonable to show them in multiple areas if you, if you had them.” (CLIN_06)</i>
Appearance of erythema on different skin tones	
Erythema can differ depending on a patient’s skin color; a supplementary photo-guide would be useful	<i>“Um, erythema is harder to appreciate on darker skin. Um, if they have the scaliness and the plaques, then you can appreciate it more, um, because it’s not just the color change, it’s the, um, the scale as well. Um, so yes, it can definitely be a lot harder to appreciate. You still can notice, especially if they’re severe, but sometimes, yeah, when they’re subtle or a mild case, they’re definitely harder to pick up on in darker skin. [...] But we see a lot of dark skin, so, um, it also, I think, depends</i>

	on what – how trained people have been on different skin types, too.” (CLIN_03)
	“Um, yes, well, that is a challenge, of course, for people with dark skin, trying to integrate these types of, um [laughs], assessments. So yes, I mean, a person with very white skin and a person with very dark skin will have different appearances to the skin, and in some cases, in fact, the rash in, in African Americans, for example, would be a darkening of their skin in those areas, rather than just a redness or a pinkness.” (CLN_04)
	“Um, y-yes. So, again, as mentioned – as I mentioned earlier, err, the, err, definition of erythema is sometimes, err, difficult to determine in, err, Asian patients compared with, err, Caucasian patients. But err, err, I, I – and err, I think it’s more difficult in, like, err, err, dark skin patients, err, err, like African Americans. So, oh, I, err, generally agree with the, err, definition of erythema, but err, yes, but err, I – um, when we use this, err, err, measurement in the, err, err, clinical settings, err, we may need more, err, precise descriptions. I: Hmmm hmm, and how can we improve this to include the descriptions of erythema on the skin of people who – from Asian ethnicities and African Americans? What kind of words could we use? Err, I think words, words are, are enough, but the, err – I’m – I have, err, very, err, limited experience in, err, Africa American patients. But err, err, in general, I would, err, consider that, err, err, I – err, presenting the, err, examples maybe, and err, these examples, err, is cons – should be considered like, a score one, and err, err, for example, these examples should be considered as, err, score two or three or something like that. I: Okay, so, like photographs? Yes, exactly.” (CLIN_07)
	“...I think if you’re doing it with someone who’s green and hasn’t seen a lot of these patients, I think having a, a photometric scale would probably be useful. Um, I have actually talked, with this scale being developed, about having something like that. I think someone who doesn’t see these all the time might not know what pink, red, deep red look like.” (CLIN_02)

Abbreviations: CDM-IGA, Cutaneous Dermatomyositis Investigator Global Assessment; CLIN, clinical expert; DM, Dermatomyositis; I, interviewer; MCP, metacarpophalangeal.