

Clinical relevance of disease activity scores from the patient perspective in chronic spontaneous urticaria

Sarah Sauchelli¹; Diane Whalley¹; Panagiotis Orfanos²; Ravneet Kaur Kohli³; Maria-Magdalena Balp²

¹RTI Health Solutions, Manchester, United Kingdom; ²Novartis Pharma AG, Basel, Switzerland; ³Novartis Healthcare Private Limited, Hyderabad, India

KEY FINDINGS & CONCLUSIONS

- From the patient perspective, UAS7 scores ≥ 16 reflect urticaria not sufficiently controlled by treatment, causing discomfort, disrupting sleep, and impacting daily life
- In contrast, UAS7 scores ≤ 6 were considered to reflect well-controlled urticaria, with meaningful benefits in discomfort experienced, impact on daily life, and the need for additional rescue treatment
- Such differences between UAS7 scores are reflected in meaningful differences in scores on patient-reported assessments of symptom severity, urticaria control, HRQOL, sleep and activity interference, and rescue medication use

This study is funded by Novartis Pharma AG
Poster presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), Barcelona, Spain, 17-20 November 2024

INTRODUCTION

- The weekly score from the twice-daily Urticaria Activity Score (the UAS7) administered as part of the Urticaria Patient Daily Diary is widely used to assess disease activity in chronic spontaneous urticaria (CSU) clinical trials^{1,2}
- UAS7 score categories are used to define disease activity states: 0 = urticaria free; 1-6 = well-controlled disease activity; 7-15 = mild activity; 16-27 = moderate activity; 28-42 = severe activity³

OBJECTIVE

- This study sought to evaluate the clinical relevance of UAS7 ≥ 16 to define moderate-to-severe urticaria activity and UAS7 ≤ 6 to define controlled urticaria

RESULTS

Qualitative Interviews

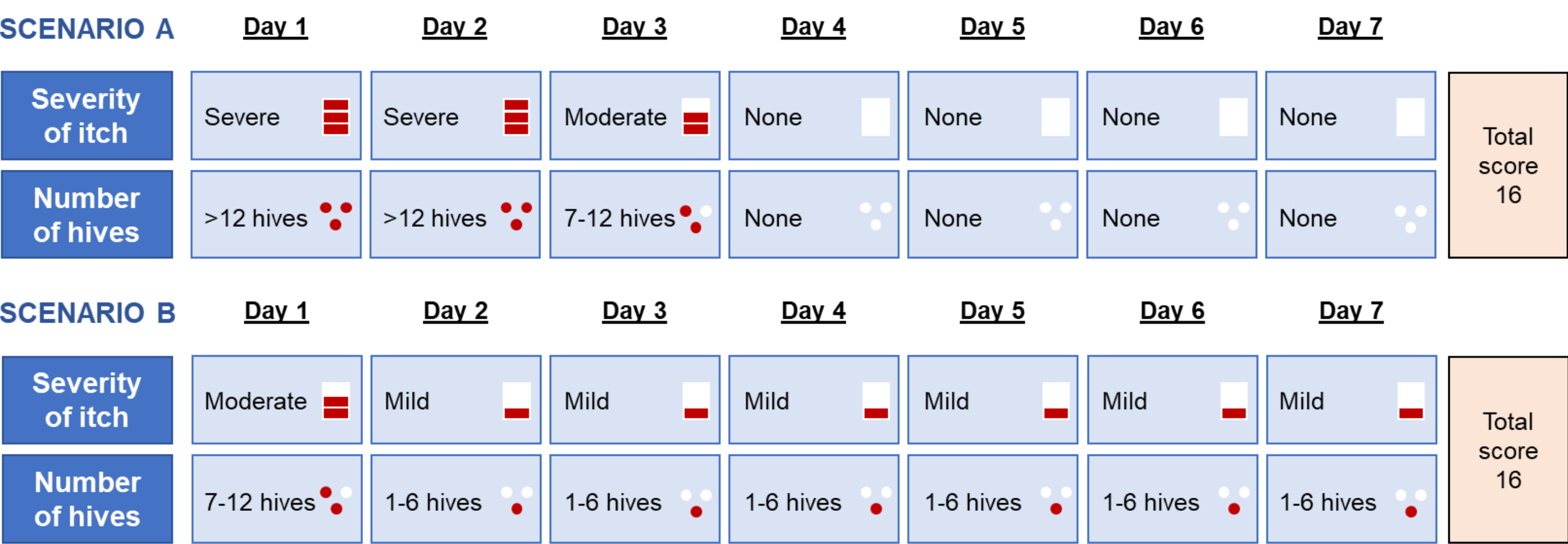
Interview Sample

- Fifteen adults (n = 13 female) aged 21 to 68 years (mean [standard deviation (SD)] = 42.7 [13.1]) participated in the interviews
- Most participants identified as White (n = 12) and were in full-time employment (n = 11). All participants (n = 15) had a college degree or higher

Meaningfulness of UAS7 = 16

- Two scenarios were presented to illustrate response patterns for UAS7 = 16 (**Figure 1**)
- Scenario A (more severe symptoms on fewer days) was described as a “bad week” (n = 8)
- Scenario B (milder symptoms spread across more days) was described as “tolerable” symptoms (n = 10) but still impacting daily life
- Most participants (n = 10) considered these scenarios to represent symptoms not controlled by routine treatment and noticeably interfering with daily life (**Table 1**)

Figure 1. Scenarios Illustrating Response Patterns for UAS7 = 16



UAS7: weekly Urticaria Activity Score.

Table 1. Participants’ Feedback on UAS7 = 16 Scenarios

Scenario	Descriptions of scenarios	Example quotations
Scenario A: moderate or severe itch and hives on 3 days	<ul style="list-style-type: none">▪ Noticeable physical discomfort▪ Disruption of daily activities and sleep▪ Feelings of anxiety, confusion, annoyance, and/or disappointment by the unpredictability of symptoms	<ul style="list-style-type: none">▪ <i>I would still consider it a bad week. [...] I think any week where you have a flare, especially a severe flare can really impact your day-to-day, which can also impact the rest of your week and how you interact with your daily activities. [...] I would still be very frustrated and would be trying to go to a doctor to figure out how to manage it. (ID4)</i>
Scenario B: mild or moderate itch and hives on 7 days	<ul style="list-style-type: none">▪ Constantly aware of symptoms▪ Not committing to too many activities▪ Being tired throughout the week▪ Feeling frustrated and irritated by the perseverance of symptoms▪ Wanting greater control over symptoms	<ul style="list-style-type: none">▪ <i>This [mild-to-moderate itch and hives every day] would just be a constant source of aggravation. I think it's like borderline discomfort, like a constant discomfort. (ID14)</i>▪ <i>Well, during the first part, it wouldn't be good because that's nighttime, [it] is worse for me or while I'm sleeping [...]. So I'm scratching all the time and I wake myself up and cause myself to bleed so there can be scares attached to that. (ID11)</i>

UAS7: weekly Urticaria Activity Score.

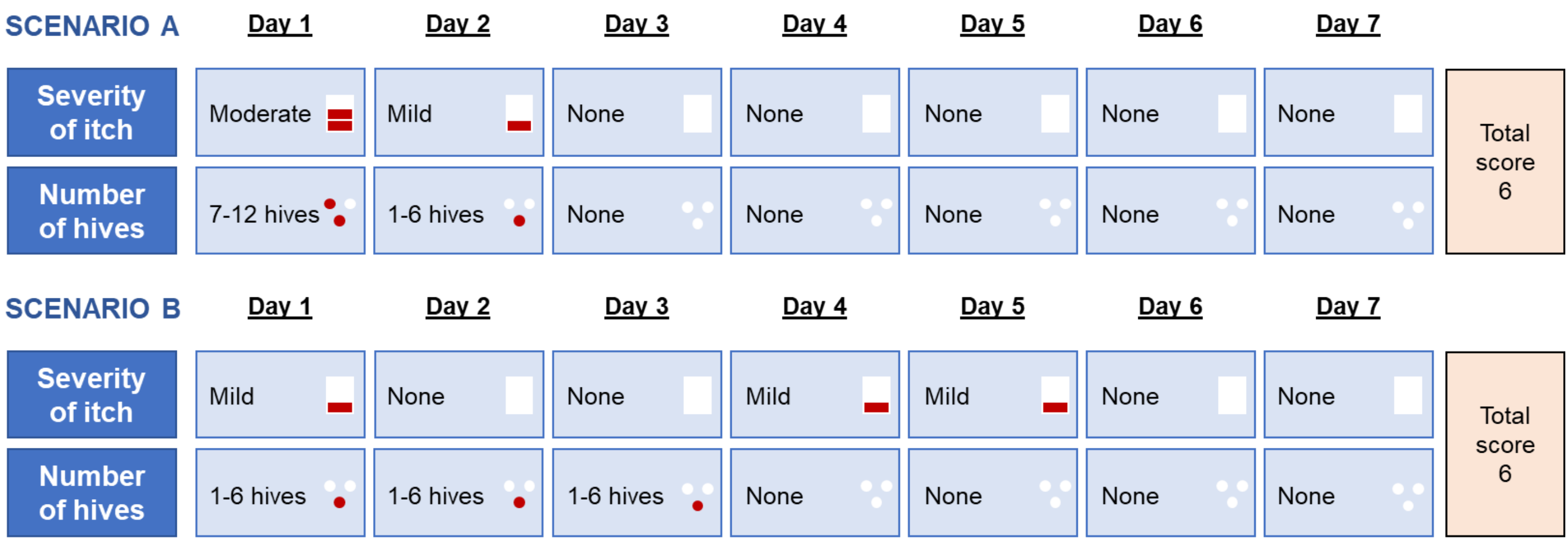
Meaningfulness of UAS7 = 6

- Two scenarios were presented to illustrate response patterns for a UAS7 score of 6 (**Figure 2**)
- Both Scenario A (more severe symptoms on fewer days) and Scenario B (milder symptoms spread across more days) were described as a “good week” (n = 12), characterized by manageable symptoms with no or minimal impact on daily life (**Table 2**)
- Almost all participants (n = 14) felt that an improvement from UAS7 = 16 to UAS7 = 6 would be meaningful; symptoms would be more stable, tolerable, and appropriately controlled by routine treatment, and any sleep disruption would have negligible impact

METHODS

- This mixed-methods study comprised:
 - Qualitative, semi structured interviews with English-speaking adults in the United States with a physician-confirmed diagnosis of CSU who were symptomatic and taking H1-antihistamines
 - Participants’ feedback on scenarios of itch and hives associated with different UAS7 scores were analyzed using deductive content analysis methods
 - Secondary analysis of initial data from two phase 3 clinical trials (REMIX-1 [NCT05030311] and REMIX-2 [NCT05032157])
 - Scores at weeks 2 and 12 on the Dermatology Life Quality Index (DLQI), Urticaria Control Test 7-day recall version (UCT7), Patient Global Impression of Severity (PGIS), weekly activity (AIS7) and sleep interference (SIS7), and rescue medication use were compared across UAS7 score categories (analysis of variance and chi-squared tests)

Figure 2. Scenarios Illustrating Response Patterns for UAS7 = 6



UAS7: weekly Urticaria Activity Score.

Table 2. Participants’ Feedback on UAS7 = 6 Scenarios

Scenario	Descriptions of scenarios	Example quotations
Scenario A: mild or moderate itch and hives on 2 days	<ul style="list-style-type: none">▪ Negligible physical discomfort▪ Minor disruptions in sleep and activities (e.g., being more cautious, wearing looser clothing)	<ul style="list-style-type: none">▪ <i>This would be very, very mild. This would be a good week. This wouldn't affect me in any way as far as doing anything or going anywhere or...(ID6)</i>▪ <i>That this is easily controlled with taking medication when I need to. And that I would be happy with this week. (ID14)</i>▪ <i>And again, sleep, I'd be able to sleep, so that's important. So it'd be a good week. (ID7)</i>
Scenario B: mild itch and/or hives on 5 days	<ul style="list-style-type: none">▪ Impact limited to the symptomatic days	

UAS7: weekly Urticaria Activity Score.

Secondary Analysis of Trial Data

- The pooled REMIX-1 and REMIX-2 sample included 899 adults with CSU (n = 882 at week 2; n = 743 at week 12)
- Mean (SD) age was 43.4 (14.27) years, 66% female, 55% White, and 84% non-Hispanic or Latino
- At week 12, there were significant differences between the UAS7 score categories on the PGIS, DLQI, UCT7, activity and sleep interference, and rescue medication use ($P < 0.0001$); results at week 2 were similar
 - Median DLQI and UCT7 scores indicated meaningful differences between UAS7 categories based on published guidelines for score interpretation (**Table 3**)
 - More participants categorized as urticaria free or well-controlled on the UAS7 had no or mild symptoms on the PGIS (98% and 89%) compared with participants categorized as moderate or severe activity (23% and 12%)

Table 3. Patient Experience Associated With UAS7 Score Categories Based on Median Scores on Measures at Week 12 in REMIX-1 and REMIX-2

Impact indicated by median scores on study measure (median value)					
Measure (score range)	UAS7 = 0 (urticaria free)	UAS7 = 1-6 (well-controlled)	UAS7 = 7-15 (mild)	UAS7 = 16-27 (moderate)	UAS7 = 28-42 (severe)
DLQI (0-30) ^a	No effect on life (0.0)	No effect on life (1.0)	Mild effect on life (5.0)	Moderate effect on life (7.5)	Very large effect on life (11.0)
UCT7 (0-16) ^b	Completely controlled (16.0)	Well-controlled (13.0)	Not well-controlled (11.0)	Not well-controlled (8.0)	Not well-controlled (6.0)
AIS7 (0-21)	No interference (0.0)	No interference (0.0)	Some interference (5.0)	Some interference (8.0)	Some interference (14.0)
SIS7 (0-21)	No interference (0.0)	No interference (0.0)	Some interference (3.0)	Some interference (7.0)	Some interference (14.0)
Rescue med. over 7 days	No tablets (0.0)	No tablets (0.0)	Some tablets (3.0)	Some tablets (4.0)	Some tablets (8.0)

AIS7: weekly Activity Interference Score; DLQI: Dermatology Life Quality Index; med: medication; SIS7: weekly Sleep Interference Score; UAS7: weekly Urticaria Activity Score; UCT7: Urticaria Control Test 7-day recall version
^aDLQI score bands: 0-1 = no effect; 2-5 = small effect; 6-10 = moderate effect; 11-20 = very large effect; and 21-30 = extremely large effect ⁴
^bUCT7 scores: ≥ 12 = well-controlled disease; ≤ 11 = poor control ^{5,6}

References

1. Mathias SD, Dreskin SC, Kaplan A, Saini SS, Spector S, Rosen KE. Development of a daily diary for patients with chronic idiopathic urticaria. *Ann Allergy Asthma Immunol*. 2010 Aug;105(2):142-8.

2. Mathias SD, Tschosik EA, Zazzali JL. Adaptation and validation of the Urticaria Patient Daily Diary for adolescents. *Allergy Asthma Proc*. 2012 ;33(2):186-90.

3. Stull D, McBride D, Tian H, Gimenez Arnau A, Maurer M, Marsland A, et al. Analysis of disease activity categories in chronic spontaneous/idiopathic urticaria. *Br J Dermatol*. 2017 Oct;177(4):1093-101.

4. Hongbo Y, Thomas CL, Harrison MA, Salek MS, Finlay AY. Translating the science of quality of life into practice: what do Dermatology Life Quality Index scores mean? *J Invest Dermatol*. 2005 Oct;125(4):659-64.

5. Buttgeriet T, Salameh P, Sydorenko O, Zuberbier T, Metz M, Weller K, et al. The 7-day recall period version of the Urticaria Control Test-UCT7. *J Allergy Clin Immunol*. 2023 May 18:S0091-6749(23)00604-8.

6. Weller K, Groffik A, Church MK, Hawro T, Krause K, Metz M, et al. Development and validation of the Urticaria Control Test: a patient-reported outcome instrument for assessing urticaria control. *J Allergy Clin Immunol*. 2014 May;133(5):1365-72, 1372.e1-6.

Acknowledgements

The authors acknowledge Mukhtar Ahmad Dar (Novartis Healthcare Private Limited, Hyderabad) for editorial and medical writing support. The final responsibility for the content lies with the authors.

Disclosures

This study is funded by Novartis Pharma AG, Basel, Switzerland.



Scan to obtain:

Poster
<https://www.medicalcongressposters.com/Default.aspx?doc=53cd2>
Copies of this poster obtained through Quick Response (QR) code are for personal use only and may not be reproduced without permission of the authors.