

# ASSURE-CSU CANADIAN RESULTS: ASSESSING HEALTH UTILITY IN CHRONIC SPONTANEOUS/IDIOPATHIC URTICARIA USING THE EQ-5D

# PRS35

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## INTRODUCTION

- Chronic spontaneous (also known as idiopathic) urticaria (CSU/CIU) is the occurrence of wheals (hives), angioedema or both for 6 weeks or longer due to known or unknown causes<sup>1</sup>
- CSU/CIU is associated with a significant yet underestimated socio-economic burden that, in several respects, is comparable to the impairment suffered by patients with atopic dermatitis and psoriasis<sup>2</sup>
- Although CSU/CIU is not life threatening, when not controlled by medication it has an impact on patients' life. Patients experience disturbing itch, intermittent pain, lack of sleep, occupational disabilities and social isolation which result in a negative impact on their daily function, and a dramatically lowered health-related quality of life (HRQoL)<sup>3-5</sup>
- However, data on the humanistic burden associated with symptomatic persistent CSU/CIU is scarce<sup>5-6</sup>

## OBJECTIVE

- The ASSURE-CSU study (ASsessment of the Economic and humanistic burden of Chronic Spontaneous/Idiopathic Urticaria PatiEnts) was an observational, non-interventional, multinational, and multicenter study conducted in Canada, France, Germany, Italy, United Kingdom, Spain and the Netherlands to identify and quantify the humanistic and economic burden of illness in CSU/CIU patients
- Here we present the results of the Canadian cohort analysis on utility values, measured using Euro Qol (EQ)-5D-3L and stratified by disease severity as per Urticaria Activity Scores

## METHODOLOGY

### Study Design

- Study design was based on a combination of retrospective patient medical record abstraction, a cross-sectional patient survey, and a 7-day patient diary
- EQ-5D-3L and visual analogue scale (VAS) utility values were derived from patient surveys. This was further stratified according to disease severity
- Data on urticaria severity was assessed over the 7 days following enrolment, using the Urticaria Activity Score (UAS7)

### Patient Population

- Clinician-confirmed, guideline-defined and diagnosed adult (≥18 years) CSU/CIU patients with at least one treatment course of an H<sub>1</sub>-antihistamine and with symptoms for more than 12 months were eligible to be part of the study

### Instruments

- EQ-5D-3L is a generic health status instrument which comprises 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. A single utility score can be derived with a range from 0 (death) to 1 (perfect health). The VAS, is also completed by the patient who rates his or her own health state on the day, on a scale of 0 (worst imaginable health), to 100 (best imaginable health)
- Urticaria severity was assessed prospectively over the 7 days following enrolment using a patient diary, from which daily UAS and weekly UAS7 scores were derived. A weekly score (UAS7) was calculated as the sum of daily itch and hives scores ranging from 0 to 42 (highest severity)
- Based on UAS7 scores, five disease severity levels can be described (Table 1)

Table 1. Five CSU disease health states were defined using UAS7 scores

UAS7 Score	Urticaria Severity Level
28-42	SEVERE urticaria (intense itch and >50 hives daily or almost daily over 7 days or confluent hives)
16-27	MODERATE urticaria (troublesome itch and <50 hives daily or almost daily over 7 days)
7-15	MILD urticaria (mild itch and around 20 hives over 7 days)
1-6	WELL-CONTROLLED urticaria (mild itch and no hives or fewer than 20 hives over 7 days)
0	URTICARIA-FREE: Itch free and Hive free

UAS7 = Weekly Urticaria Activity Score

### Analysis

- Descriptive analyses were used for different dimensions of the EQ-5D-3L. Data were summarized descriptively using mean values and standard deviations for continuous variables and counts and proportions for categorical variables
- The total number of patients varied between analysis data because not all patients completed the patient survey or the patient diary

## RESULTS

- In Canada, 9 sites (7 were specialist centers, 1 was specialist center and a hospital, and 1 was other) participated in the study, and medical records were abstracted for 99 patients presenting with CSU/CIU as defined by the eligibility criteria
- Of the 99 patients included in the analysis, 88 (89%) completed the EQ-5D-3L and 86 (87%) the patient diary. Among the 88 patients with EQ-5D-3L data, 4 patients had missing data on the severity scores (2 patients did not have patient diary data while 2 were not assigned a health state due to 3 or more missing daily UAS). At baseline, one patient was itch free or hive free (UAS7=0), and was excluded from the analysis
- The demographic and baseline characteristics for the study cohort are described in Table 2
- The mean age of patients at enrolment was 50.8 years, while the mean age of symptom onset was 42.9 years and the mean age at diagnosis was 45.8 years. The majority of enrolled patients were female (77.8%) and Caucasian (80.8%)

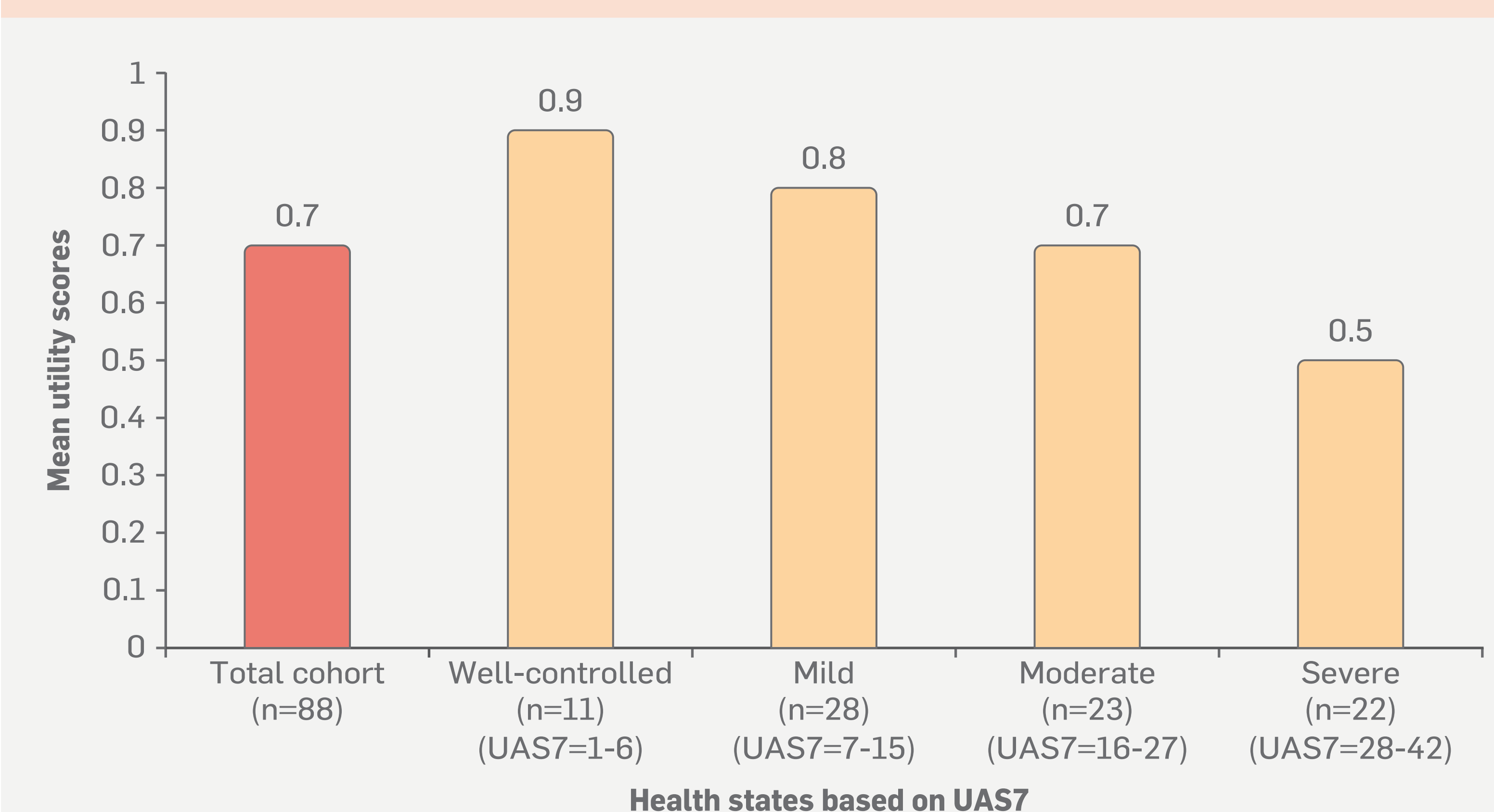
Table 2. Demographic and baseline characteristics

Patient Characteristics	Total cohort (N=99)
	Mean (SD)
Age at enrolment (years)	50.8 (15.0)
Age at symptom onset (years)	42.9 (16.9)
Age at diagnosis (years)	45.8 (15.6)
Disease duration since diagnosis to enrolment (years)	5.2 (6.8)
	n (%)
Female	77 (77.8)
Race and ethnicity	
Caucasian/white	80 (80.8)
Black	4 (4.0)
Asian	10 (10.1)
Other	3 (3.0)
Data not available	2 (2.0)

SD=Standard Deviation

- The overall mean (SD) EQ-5D-3L utility value was 0.7 (0.3) for the total cohort (Figure 1)
- With increasing severity of CSU/CIU, there was a consistent decrease in the mean utility scores

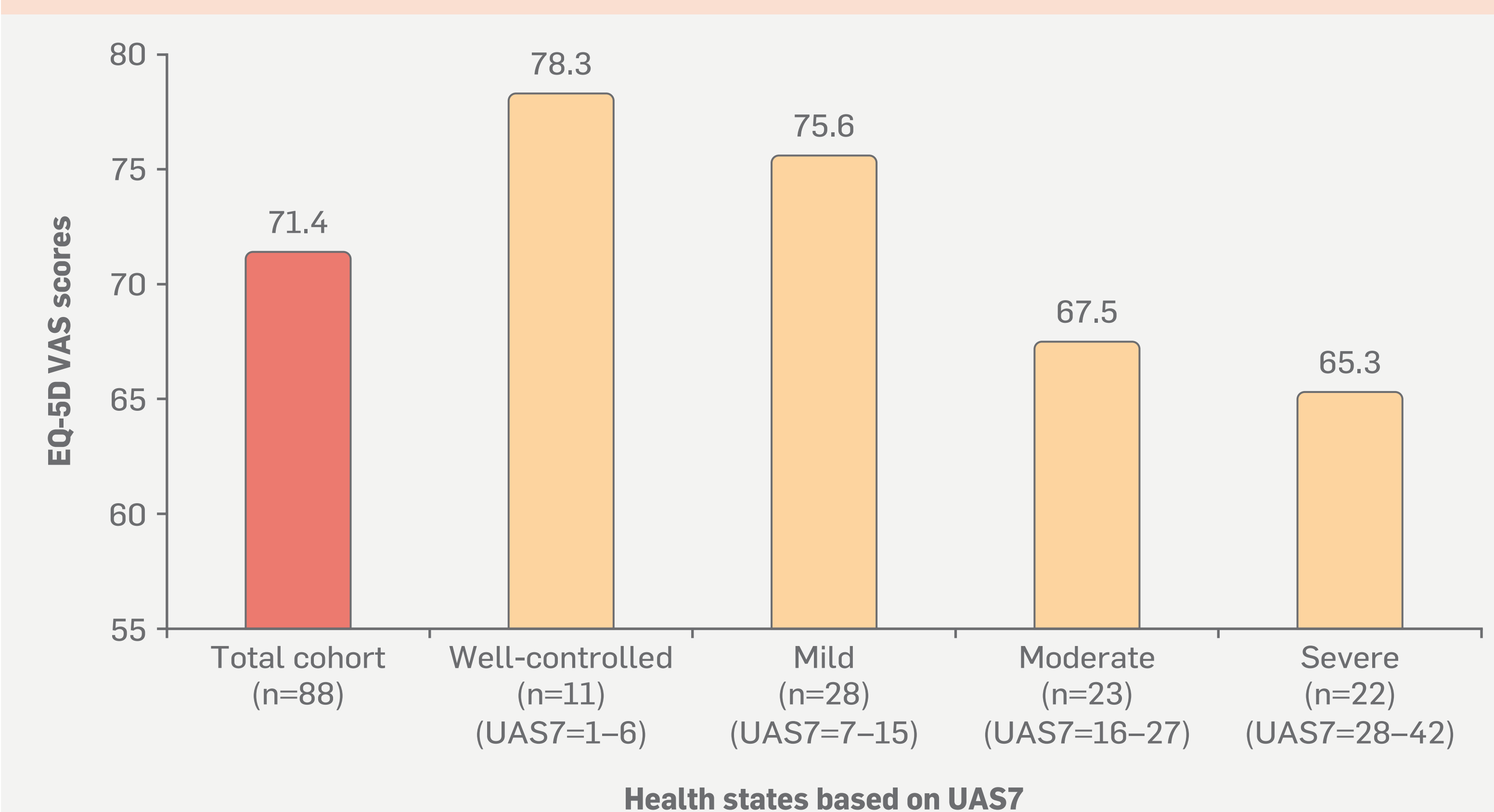
Figure 1. Mean EQ-5D-3L utility values according to the health states based on UAS7 scores



Note: Health state is determined by the patient's Urticaria Activity Score over 7 days as calculated from the Patient Diary. Utility index scores range from 0, representing death, to 1, representing full health. A negative value indicates a health state worse than death. Among the 88 patients with data on EQ-5D-3L, 4 patients were missing on the severity scores.

- The overall mean (SD) EQ-5D-VAS utility score was 71.4 (19.2) for the total cohort
- Similar to the EQ-5D-3L scores, there was a consistent decrease in EQ-5D-VAS utility values as patient severity of urticaria increased (Figure 2)

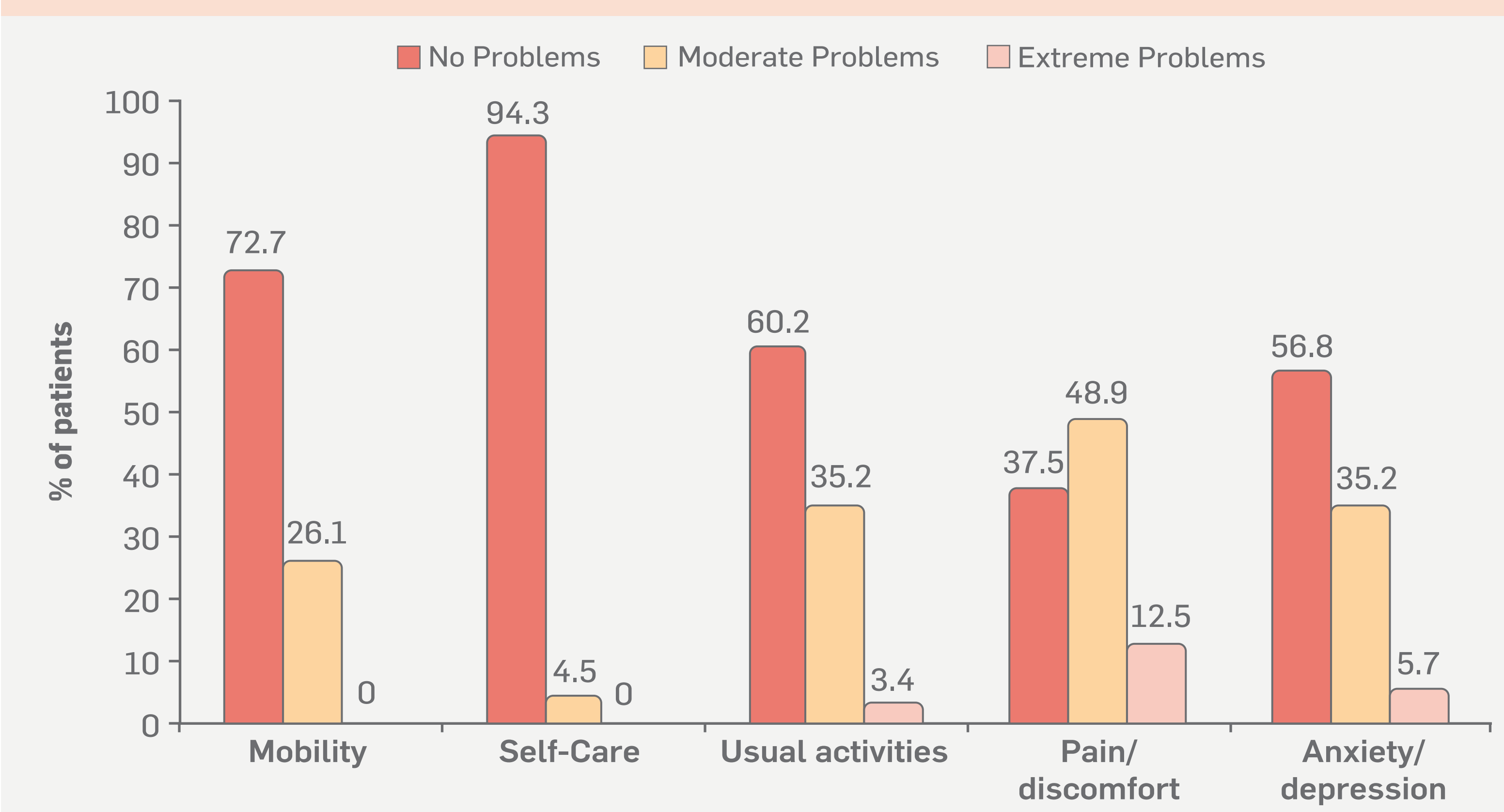
Figure 2. Mean EQ-5D-VAS scores according to the health states based on UAS7 scores



Note: Health state is determined by the patient's Urticaria Activity Score over 7 days as calculated from the Patient Diary. VAS ratings range from 0, representing worst imaginable health, to 100, representing best imaginable health. Among the 88 patients with data on EQ-5D-VAS, 4 patients were missing on the severity scores.

- Among the different components of EQ-5D-3L, the dimensions most affected were pain/discomfort and anxiety/depression (Figure 3):
  - Pain/discomfort: 61.4% of patients reported moderate to extreme problems
  - Anxiety/depression: 40.9% of patients reported moderate to extreme problems

Figure 3. Responses to the different EQ-5D-3L dimension



## DISCUSSION

- ASSURE-CSU is the first international study assessing the burden of CSU/CIU on symptomatic patients and the impact on healthcare and society
- The results suggest that utility values derived from the EQ-ED-3L and VAS are similar
- EQ-5D-3L dimension reflecting symptoms (itch and pain) and common comorbidities (anxiety and depression) of CSU/CIU were most affected
- As disease severity and utility values were assessed over the same period, the results suggest as the severity of urticaria increases, utility values decrease
- The results indicate that there is an association between HRQoL and disease severity
- Therefore, improvements in symptoms scores, as measured by the UAS7 may improve HRQoL

## CONCLUSIONS

- The average utility score of an average Canadian population is 0.88<sup>7</sup>, which is above the utility scores obtained in this study, at 0.7
- The results suggest that CSU/CIU has significant impact on the patients' health status and quality of life; patients suffering from moderate to severe CSU/CIU showing a greater impact on patients' health state

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## ACKNOWLEDGEMENT

The authors thank Aneesh George (Novartis) for assistance with poster content and Rajesh Nadella (Novartis) for designing the poster layout

## FUNDING

The study was funded by Novartis Pharma AG, Basel, Switzerland and Genentech, Inc., South San Francisco, CA

## CONFLICT OF INTEREST

Sussman G has acted as a consultant for Novartis and in the past three years, he has conducted studies for Novartis, CSL Behring, Merck, and DBV Technologies. He is also president of the Allergy, Asthma & Immunology Society of Ontario

Wasserman S and Keith P have served on Advisory Boards, Novartis  
Chiva-Razavi S, Chambenoit O, Tian H and MM Balp are employed by Novartis  
Hollis K, McBride D and Westlund R are employed by RTI Health Solutions, which provides consulting and other research services to pharmaceutical, device, government, and non-government organizations. In this salaried position, they work with a variety of companies and organizations. They receive no payment or honoraria directly from these organizations for services rendered.



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