

Building a COA strategy in chronic rhinosinusitis with (CRSwNP) or without nasal polyps (CRSsNP): Patient experiences and clinical outcome assessments from the literature

PCR254

Brittany Klooster<sup>1</sup>, Kaitlin Chatterton<sup>1</sup>, Madi Bernstein<sup>1</sup>, Nazifa Ibrahim<sup>1</sup>, Alan Shields<sup>1</sup>, Veleka Allen<sup>2</sup>  
<sup>1</sup>Adelphi Values Patient-Centered Outcomes, Boston, MA, United States, <sup>2</sup>Sanofi, Bridgewater, NJ, United States

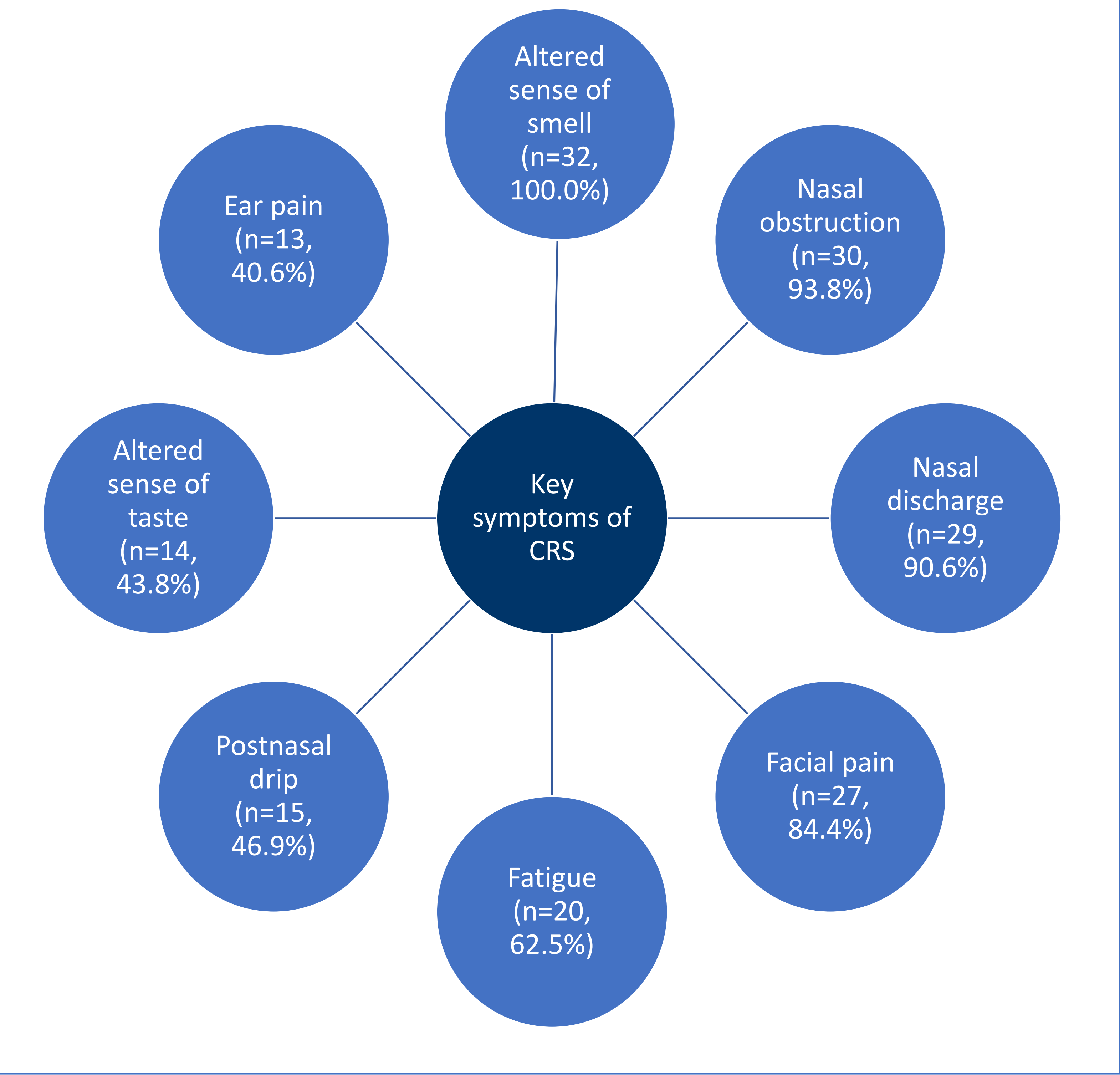
Introduction

- > Chronic rhinosinusitis (CRS) causes chronic inflammation of the nose and paranasal sinuses, with nasal polyps (CRSwNP) or without (CRSsNP).<sup>1,2,3</sup>
- > The goal of this work was to document the (1) key disease-related symptoms and impacts that individuals living with CRSwNP and CRSsNP experience, (2) important outcomes to consider when developing new treatments, and (3) clinical outcome assessments (COAs) available to measure those outcomes.

Results

- > A total of 39 CRSwNP- (n=20 articles) and CRSsNP-related (n=12 articles) symptoms and 49 impacts across 13 health-related quality of life (HRQoL) domains were identified in the literature.
  - For both conditions, symptoms of altered smell (n=20 and 12, respectively), nasal obstruction (n=19 and 11, respectively), and discharge (n=18 and 11, respectively) and impacts on emotional functioning and sleep were most frequently reported.
  - For CRSwNP, facial pain (n=17) and fatigue (n=13) were also frequently reported.
  - Findings for adolescents were limited (only one article reported data in adolescents aged 16–17 years).
- > Key symptom and impact concepts (i.e., reported in ≥40.0% of reviewed articles) are presented in **Figures 1 and 2**, respectively.
- > At least 15 total COAs were newly identified via the clinical trial, product label, and literature review; nine of these and the six pre-identified COAs (15 in total) were evaluated for conceptual coverage of CRS concepts identified in the literature.
- > **Table 1** presents results of conceptual coverage of key COAs. The Sinonasal Outcome Test (SNOT-22) and Chronic Rhinosinusitis Patient-Reported Outcome (CRS-PRO) demonstrated the broadest conceptual coverage.

Figure 1. Key symptoms of CRS (reported in ≥40.0% of the 32 total reviewed articles)



Conclusions

- > Though limited information is currently available in the literature for adolescent groups, individuals with CRSwNP and CRSsNP experience similar, though not always the same, symptoms with altered smell, nasal discharge, nasal obstruction, facial pain, and fatigue principal among them.
- > Given the impacts these symptoms exert on patients, particularly emotionally and on sleep, results from this research specify several symptom and impact outcomes, that if improved, would reflect benefit for patients living with these conditions.
- > Several of the reviewed COAs demonstrated acceptable conceptual coverage of the conditions and warrant further evaluation for use in clinical trials to support efficacy analysis.

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Methods

- > Independent, though related, literature and clinical trial/product label reviews were conducted to identify symptoms and impacts associated with CRSwNP and CRSsNP among adults and adolescents, as well as COAs used to assess the concepts in clinical trials.
- > Six COAs were previously identified in a search conducted by the Sponsor and included in the review. Additional COAs included in the review were identified from the literature, clinical trial, and product label reviews. COAs were included in concept mapping based on availability of COA item wording and concept relevance.
- > The CRSwNP and CRSsNP concepts identified from the literature were mapped to concepts assessed by the most relevant COAs from the search to demonstrate conceptual coverage.

Results (cont'd)

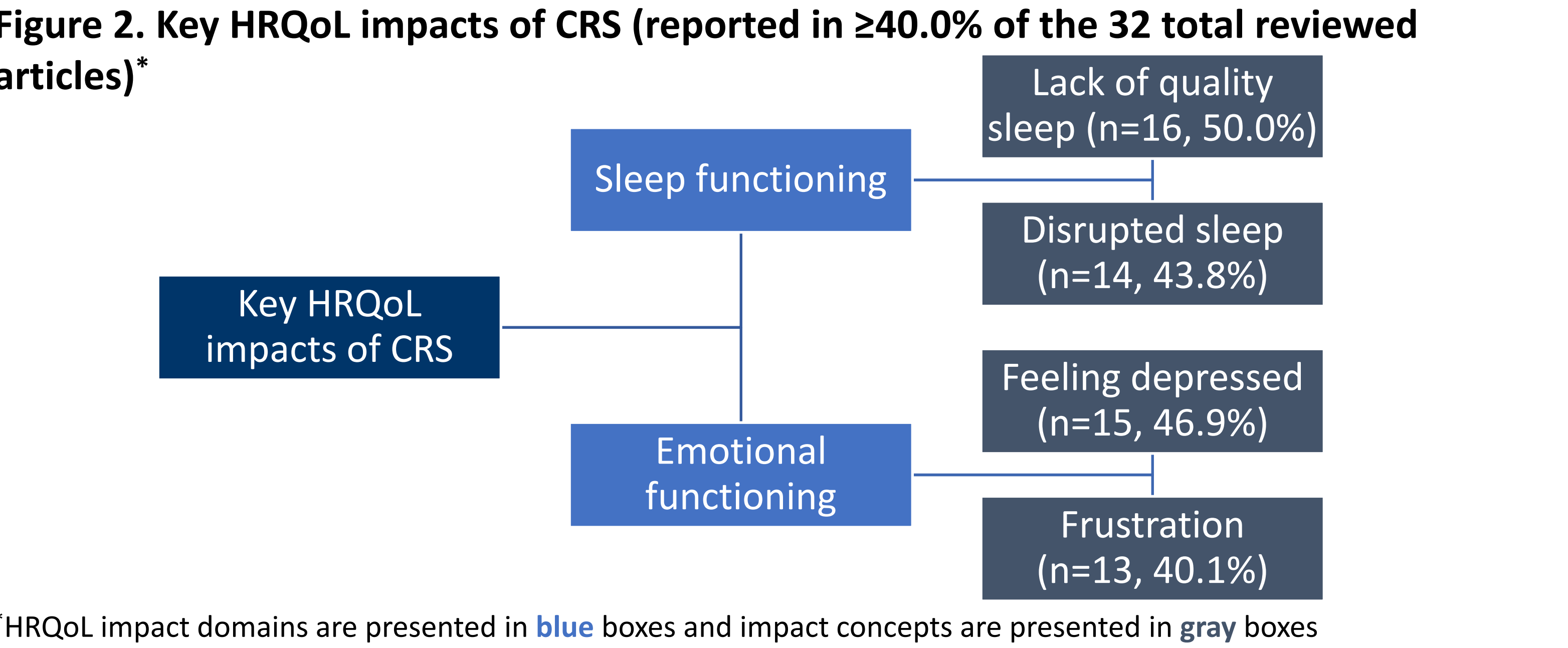


Table 1. Concept mapping of key CRSwNP and CRSsNP symptom and impact concepts				
List of COAs included in evaluation	# of symptom concepts full coverage	# of impact concepts full coverage	Total conceptual coverage	Broadest conceptual coverage
<b>Pre-identified COAs of interest (N=6)</b>				
Sinonasal Outcome Test (SNOT-22)* <sup>4</sup>	6/8	3/4	9/12	✓
Rhinosinusitis Visual Analog Scale (VAS)*	0/8	0/4	0/12	
CRSwNP Nasal Symptom Diary <sup>†</sup>	3/8	0/4	3/12	✓ (symptoms)
CRSsNP Nasal Symptom Diary <sup>‡</sup>	3/8	0/4	3/12	✓ (symptoms)
The University of Pennsylvania Smell Identification Test (UPSIT)* <sup>5</sup>	1/8	0/4	1/12	
Asthma Control Questionnaire (ACQ-6)* <sup>6</sup>	0/8	0/4	0/12	
<b>Additional COAs identified via clinical trial and product label review (N=10)</b>				
Nasal Polyposis Symptom Diary <sup>†</sup>	5/8	1/4	6/12	✓
Asthma Quality of Life Questionnaire (AQLQ) <sup>†7</sup>	0/8	0/4	0/12	
Rhinosinusitis Disability Index (RSDI)* <sup>8</sup>	1/8	3/4	4/12	✓ (impacts)
PROMIS Fatigue Short Form 6a* <sup>9</sup>	1/8	0/4	1/12	
PROMIS Sleep Disturbance Short Form 6a* <sup>10,11</sup>	0/8	1/4	1/12	
PROMIS Pain Interference Short Form 6a* <sup>12</sup>	0/8	0/4	0/12	
PROMIS Satisfaction with Participation in Social Activities Short Form* <sup>13</sup>	0/8	0/4	0/12	
Chronic Rhinosinusitis Patient-Reported Outcome (CRS-PRO) <sup>†14</sup>	6/8	1/4	7/12	✓
Mini-Rhinoconjunctivitis Quality of Life (RQLQ) survey <sup>†15</sup>	3/8	0/4	3/12	✓ (symptoms)
Abbreviations: PROMIS=Patient-Reported Outcomes Measurement Information System				
*Questionnaire/concept identified for both CRSwNP and CRSsNP				
†Questionnaire/concept identified for CRSwNP only				
‡Questionnaire/concept identified for CRSsNP only				