Clinical Outcome Assessments (COA) Qualification Program
DDT COA #000111: Hidradenitis Suppurativa Quality of Life (HiSQOL)
Letter of Intent

Administrative Structure:

Description of the submitter including, but not limited to, principal investigator(s), working group member(s), institutions, and contact information not contained within the cover letter.

The submitting group is a multi-stakeholder, international assembly of clinicians, researchers, and people with the condition of interest (hidradenitis suppurativa [HS]). The principal investigators are Joslyn Kirby and Linnea Thorlacius, co-investigators are Bente Villumsen, Amit Garg, and John Ingram, and senior investigators are Jerry Tan and Gregor Jemec. The group members, their institutions, and contact information are listed below.

North America: Joslyn S. Kirby[1], Amit Garg[2], Jerry Tan[3,4]

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Denmark: Linnea Thorlacius[5], Bente Villumsen,[6] Gregor B.E. Jemec[5]

5) *Zealand University Hospital, Department of Dermatology, Roskilde; Health Sciences Faculty, University of Copenhagen, Denmark*
6) *Patient Representative, The Patients' Association HS Denmark, Denmark*

United Kingdom: John Ingram[7]

7) *University Hospital of Wales, Institute of Infection & Immunity, Heath Park, Cardiff, UK*

Concept(s) of Interest (COI) for Meaningful Treatment Benefit:

A description of the meaningful aspect of patient experience that will represent the intended benefit of treatment (e.g., presence/severity of symptoms, limitations in performance of daily activities).

Provide a conceptual framework for the COA(s)

The HiSQOL is intended to assess the impact of HS on patients' health-related quality of life (HRQOL) during a clinical trial. These impacts include severity of HS-related symptoms, limitations in performance of activities, and psychosocial effects. Hidradenitis suppurativa (HS) is a chronic, inflammatory skin disease of unknown etiology that causes painful swollen nodules, draining abscesses, and disfiguring scars of the skin folds that make walking, sitting, and working difficult or impossible and also causes malodorous drainage that can be humiliating and uncomfortable.[1,2] HS has a large negative impact on HRQOL.[3-5] Several generic dermatologic HRQOL scales exist and have shown that patients with HS have a lower HRQOL than patients with eczema, chronic urticaria, psoriasis or psoriatic arthritis.[2,3] However, generic HRQOL

measures do not assess the unique and likely serious ways in which HS affects patients because of the distinctive locations and symptoms of the condition. In addition, an international multi-stakeholder group reached consensus on a core outcome set of domains for HS clinical trials and HS–specific HRQOL was one of the final recommended domains.[6]

The HiSQOL was developed to assess the symptoms, emotions, and functional impairments for a patent due to HS. Conceptual models of HRQOL informed the development of the HiSQOL beginning with semi-structured interviews that included: symptoms, functions, perceptions, environmental impacts, as well as emotional and social influences.[7] The structure of the HiSQOL was informed by the extant literature as well as people with HS and focused on the development of sub-scales for symptoms, especially pain, psychosocial, and function impacts.[8]

Context of Use for COA Qualification:

Targeted study population including a definition of the disease and selection criteria for clinical trials (e.g., baseline symptom severity, patient demographics, comorbidities, language/culture groups).

The targeted study population includes adults, with HS, the ability to read and comprehend English, who are participating in a clinical trial. HS is defined by chronic outbreaks of boils or nodules over 6 or more months with a minimum of at least two boils in the axilla, groin, genitals, under the breasts, perianal, neck, and/or abdomen.[9]

***Targeted study design and statistical analysis plan (includes the role of the planned COA in future drug development clinical trials, including the planned set of primary and secondary endpoints with hierarchy, if appropriate*).**

Because HS, like many diseases, has more than one consequence, efficacy may not be established on a single endpoint. Thus, the HiSQOL is being developed for use as a primary or secondary outcome measure in HS clinical trials to demonstrate an improvement in HS-related quality of life. In addition, each of the three sub-scales could be used to demonstrate a reduction in HS-related symptoms or other impact. Design of future clinical trials that incorporate the HiSQOL as one of multiple endpoints would benefit from recommendations on management of multiple endpoints.[10]

Applicable study settings for future clinical trials

- ***Geographic location with language/culture groups***
- ***Other study setting specifics (e.g., inpatient versus outpatient)***

The applicable study settings for future clinical trials include English-speaking out-patient populations in North America. Members of the investigative team have been working in parallel in Denmark to develop a version of the HiSQOL in Danish for adult out-patients. The investigative team feels is it important to develop the HiSQOL in other languages given the globalization of clinical research and, thus, the need for the HiSQOL to be linguistically and culturally adapted to meet the needs of other populations.[11]

COA Type: PRO

References:

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11. Acquadro C, Patrick DL, Eremenco S, et al. Emerging good practices for Translatability Assessment (TA) of Patient-Reported Outcome (PRO) measures. *Journal of patient-reported outcomes.* 2017;2(1):8.