



FREEDOM
FROM DISEASE IN PSORIASIS

Job code: **CP-362887**
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OVERVIEW

1. Why Janssen initiated the Freedom from Disease study
2. The current psoriasis landscape
3. The Delphi consensus method
4. Results from key stages of the Delphi consensus
5. Achievements and next steps

WHY JANSSEN INITIATED THE FREEDOM FROM DISEASE STUDY

Janssen is a key advocate for people living with psoriasis in Europe

The primary aim of this effort was to define what freedom from disease means in today's psoriasis landscape and to establish the concept as a potential treatment target in psoriasis¹

Why is this important to people with psoriasis?



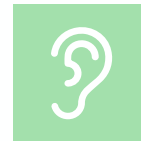
TREATMENT^{2,3}

Changing the treatment paradigm will enable all people with psoriasis to benefit from the full potential of new therapies



NEEDS^{2,3}

A better understanding of the needs of people with psoriasis can serve to ensure that individual needs are better met



VOICE^{2,4}

Listening to and amplifying the voice of people with psoriasis will further improve standards of care



CLINICAL TOOLS⁴

New ways of assessing severity and measuring clinical response will facilitate new standards in freedom from disease

THE CURRENT PSORIASIS LANDSCAPE



PSORIASIS IS A CHRONIC DISEASE WITH HIGH DISEASE BURDEN AND AFFECTS PEOPLE IN SEVERAL WAYS¹

Physical¹⁻³

- Scaling
- Itching
- Erythema
- Common comorbidities:
 - Arthritis
 - Cardiovascular diseases
 - Metabolic syndrome
 - Inflammatory bowel disease
 - Uveitis

Social^{1,2,4}

- Friends and family
- Education
- Professional career

Psychological²⁻⁴

- Fatigue
- Embarrassment
- Anxiety
- Depression

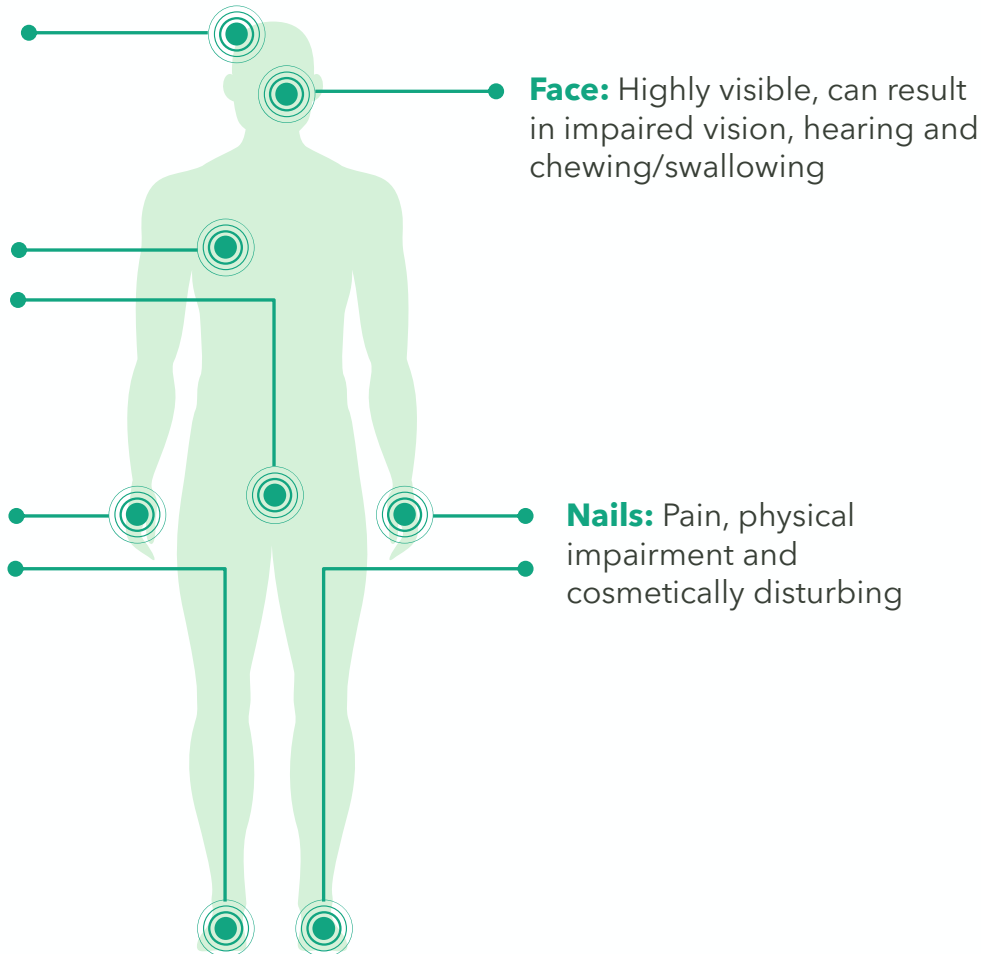


UNDERDIAGNOSED AND UNDERTREATED PSORIASIS IN IMPORTANT AREAS CAN HAVE A DISPROPORTIONATE IMPACT ON QOL¹

Scalp: Itching, bleeding, embarrassment, and choice of clothing limited

Intertriginous: Itching, irritation, soreness and decreased sexual health

Soles and palms: High levels of pain, difficulty in walking and using hands



- Psoriasis of the scalp, face, intertriginous areas, genitals, hands, feet and nails is often underdiagnosed
- Disease management can be challenging
- Patients affected by psoriasis in these locations have disproportionate levels of physical impairment and emotional distress

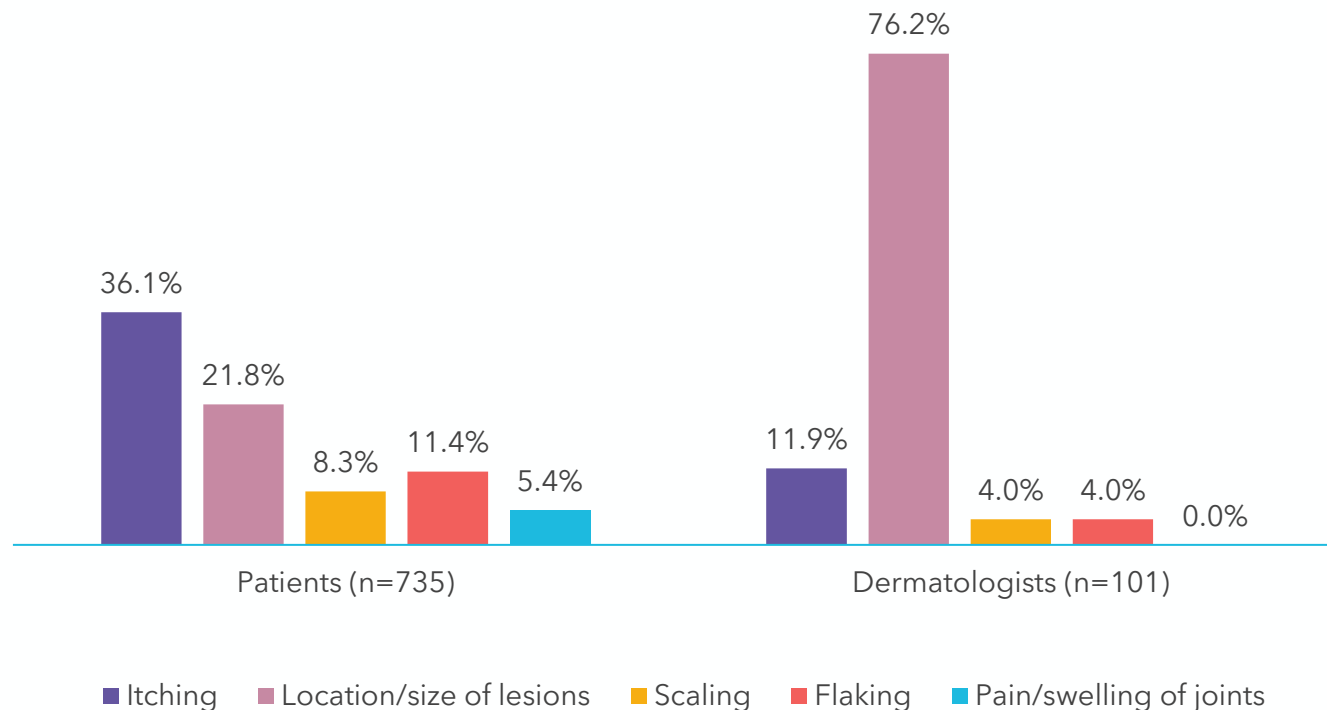


The disproportionate impact of psoriasis in important areas is not captured in current outcome measures such as PASI

PATIENTS AND DERMATOLOGISTS ASSESS PSORIASIS DISEASE SEVERITY DIFFERENTLY¹

Top 5 most important factors contributing to disease severity

Findings from the USA*



- Lesion location and size was most important to dermatologists
- However, itching was most important to people living with psoriasis

CURRENT OUTCOME MEASURES DO NOT ALWAYS CAPTURE THE NEEDS AND PRIORITIES OF PEOPLE WITH PSORIASIS¹⁻³

Physician-reported outcomes

Measure reduction in disease severity and lesion size

Example:

PASI

75/90%
reduction in PASI shows reduced disease activity

PSORIASIS AREA AND SEVERITY INDEX (PASI) WORKSHEET

HOSPITAL NO.: _____
 PATIENT NAME: _____
 DATE OF VISIT: _____

The Psoriasis Area and Severity Index (PASI) is a quantitative rating score for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

| Plaque characteristics: | Lesion score | Head | Upper Limbs | Trunk | Lower Limbs |
|--|---|------|-------------|-------|-------------|
| Erythema | 0 = None 1 = Slight 2 = Moderate 3 = Severe 4 = Very severe | | | | |
| Induration/Thickness | | | | | |
| Scaling | | | | | |
| Add together each of the 3 scores for each body region to give 4 separate sums (A) | | | | | |
| Lesion Score Sum (A) | | | | | |
| Percentage area affected | Area score | Head | Upper Limbs | Trunk | Lower Limbs |
| 0 = 0% 1 = 1% - 5% 2 = 5% - 20% 3 = 20% - 40% 4 = 40% - 60% 5 = 60% - 80% 6 = 80% - 100% | | | | | |
| Multiply Lesion Score Sum (A) by Area Score (B) for each body region, to give 4 separate sums (C) | | | | | |
| Multiply each of the Subtotals (C) by amount of body surface area represented by that region, i.e. x 0.1 for head, x 0.2 for upper limbs, x 0.3 for trunk, and x 0.4 for lower limbs | | | | | |
| Subtotal (C) | | | | | |
| Total (D) | | | | | |
| Add together each of the scores for each body region to give the final PASI Score | | | | | |
| PASI Score = <input type="text"/> | | | | | |

Patient-reported outcomes

Measure subjective disease severity alongside physical and mental well-being

Example:

DLQI

Low DLQI score (e.g., DLQI 0/1) suggests minimal impact of disease on quality of life

DERMATOLOGY LIFE QUALITY INDEX (DLQI)

Hospital No.: _____
 Name: _____
 Address: _____

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick (✓) one box for each question.

1. Over the last week, how embarrassed or self-conscious have you been because of your skin?
 Very much A lot A little Not at all

2. Over the last week, how much has your skin interfered with your ability to go to work or college?
 Very much A lot A little Not at all

3. Over the last week, how much has your skin interfered with your ability to go to social or leisure activities?
 Very much A lot A little Not at all

4. Over the last week, how much has your skin interfered with your ability to do any work?
 Very much A lot A little Not at all

5. Over the last week, how much has your skin interfered with your ability to do any work or study?
 Very much A lot A little Not at all

6. Over the last week, how much has your skin interfered with your ability to do any work or study?
 Very much A lot A little Not at all

7. Over the last week, how much has your skin interfered with your ability to do any work or study?
 Very much A lot A little Not at all

8. Over the last week, how much has your skin interfered with your ability to do any work or study?
 Very much A lot A little Not at all

9. Over the last week, how much has your skin interfered with your ability to do any work or study?
 Very much A lot A little Not at all

10. Over the last week, how much has your skin interfered with your ability to do any work or study?
 Very much A lot A little Not at all

Please check you have answered EVERY question. Thank you.

DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index.

1. Feldman SR, et al. Am Rheum Dis. 2005;64 Suppl 2(Suppl 2):ii65-ii68; 2. Gordon KB, et al. Semin Cutan Med Surg. 2018;37(2S):S44-S47; 3. Strober BE, et al. Dermatol Ther. 2019; 9(1):5-18.

Even after achieving treatment success according to PASI and DLQI, people with psoriasis may not feel that treatment success has been achieved

Need to achieve consensus from people with psoriasis and HCPs on how to define the concept of freedom from disease

DELPHI STUDIES GENERALLY DO NOT GIVE PEOPLE WITH PSORIASIS A SUBSTANTIAL VOICE

| | | | | |
|---------------------------|--|---|--|--|
| Study description | International Psoriasis Council Delphi consensus ¹ | Delphi consensus on defining drug-free remission ² | Belgian Delphi consensus on defining treat-to-target outcomes ³ | Delphi consensus on minimal disease activity ⁴ |
| Objective | To develop a consensus statement on the classification of psoriasis severity | To develop a practical definition of drug-free remission of skin disease for plaque psoriasis | To define a treat-to-target outcome for moderate-to-severe psoriasis vulgaris | To generate an operational definition to adequately reflect 'Minimal Disease Activity' |
| Panel participants | 74 participants from the International Psoriasis Council | 8 dermatologists from the USA | 7 key opinion leaders from Belgium | Included both 8 dermatologists and 2 people with psoriasis |
| | No representation from community dermatologists or people with psoriasis | No representation from community dermatologists or people with psoriasis | People with psoriasis were included as a focus group for feedback on topic selection and outcome but were not part of the Delphi panel | Only Delphi panel so far to include people with psoriasis |

CONSENSUS MEETINGS CAN AID IN APPROPRIATELY ASSESSING RELEVANT ASPECTS OF DISEASE

- WHO global report on psoriasis highlighted the need for people-centred care¹
- Current physician-reported and patient-reported measures do not always adequately capture needs and priorities²



There is a current need to:²

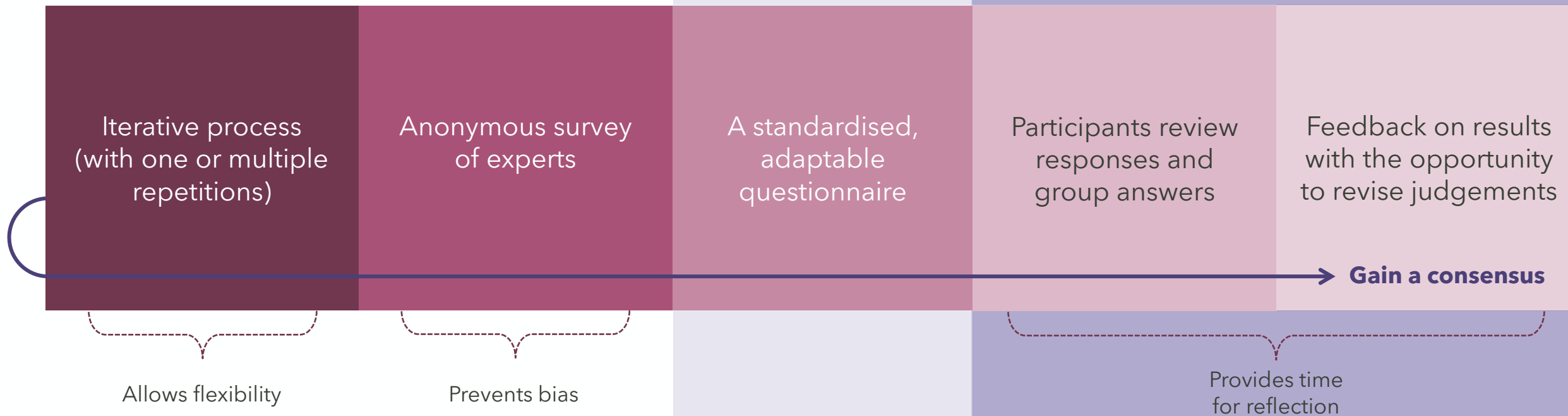
- Go beyond traditional concepts of clinical remission and QoL measures
- Include goals of people with psoriasis, nurses and dermatologists across multiple countries

THE DELPHI CONSENSUS METHOD



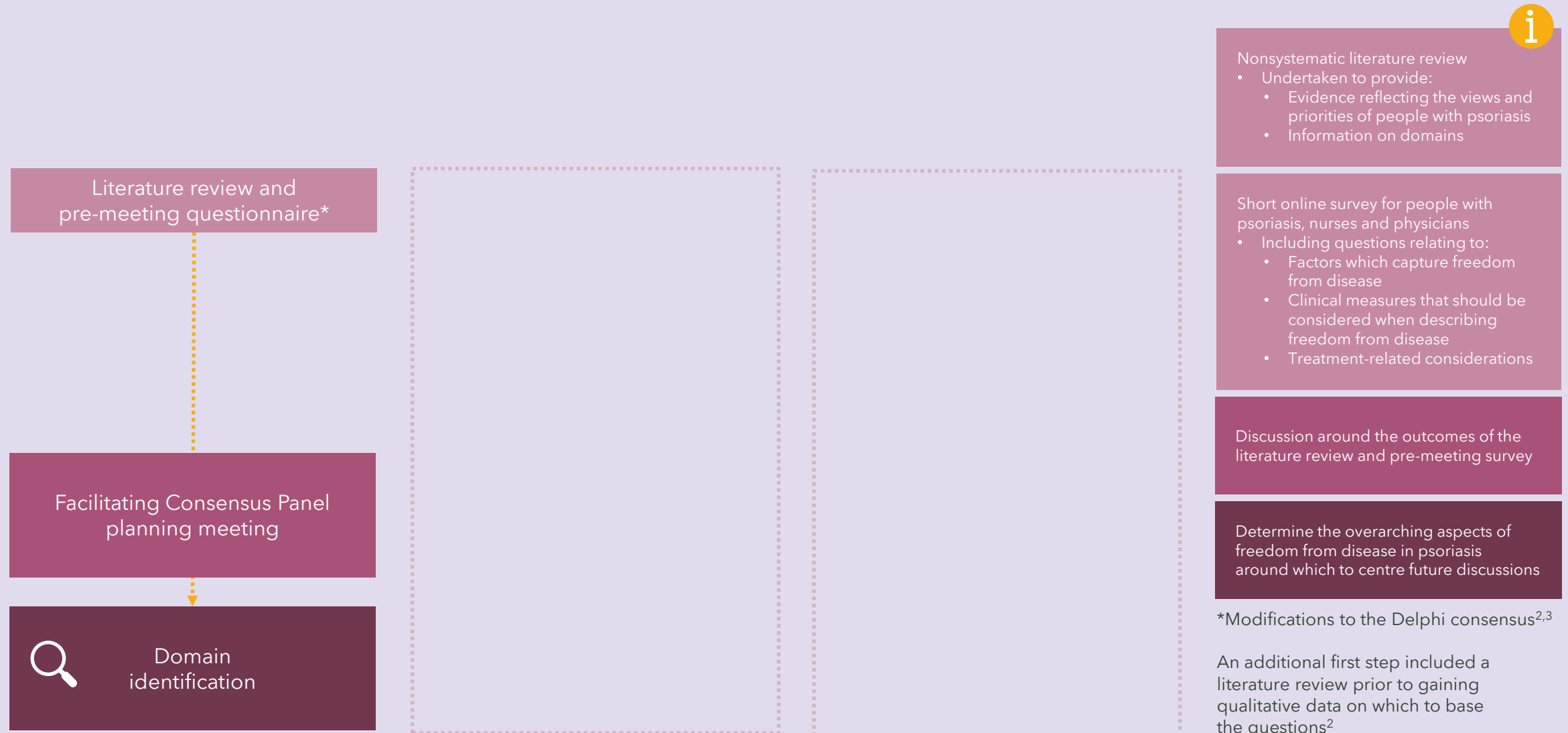
WHAT IS A DELPHI CONSENSUS?¹⁻³

The Delphi method is a well-established and reliable approach to gaining expert consensus on a topic^{1,3}

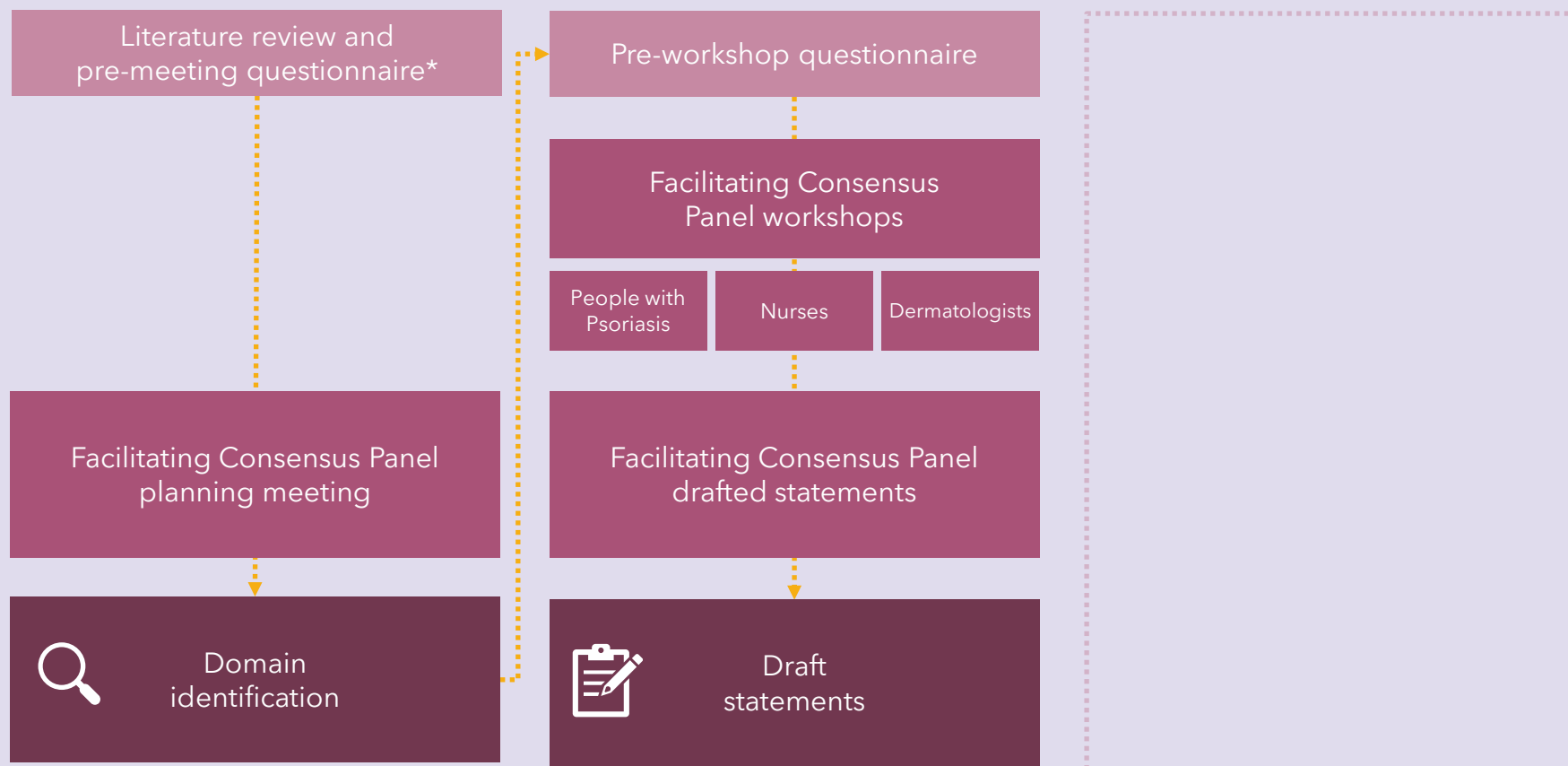


1. Barrett D, et al. Evid Based Nurs. 2020;23(3):68-69; 2. McKillen K. What is a Delphi process? Available at: <https://www.whatisseries.co.uk/product/what-is-a-delphi-process/> (Accessed: February 2022); 3. Eubank BH, et al. BMC Med Res Methodol. 2016;16:56.

THE MODIFIED DELPHI CONSENSUS PROCESS¹



THE MODIFIED DELPHI CONSENSUS PROCESS¹



Separate workshops were conducted to encourage individuals to speak more openly without worrying how other groups might interpret their opinions

Workshop questions included questions regarding:

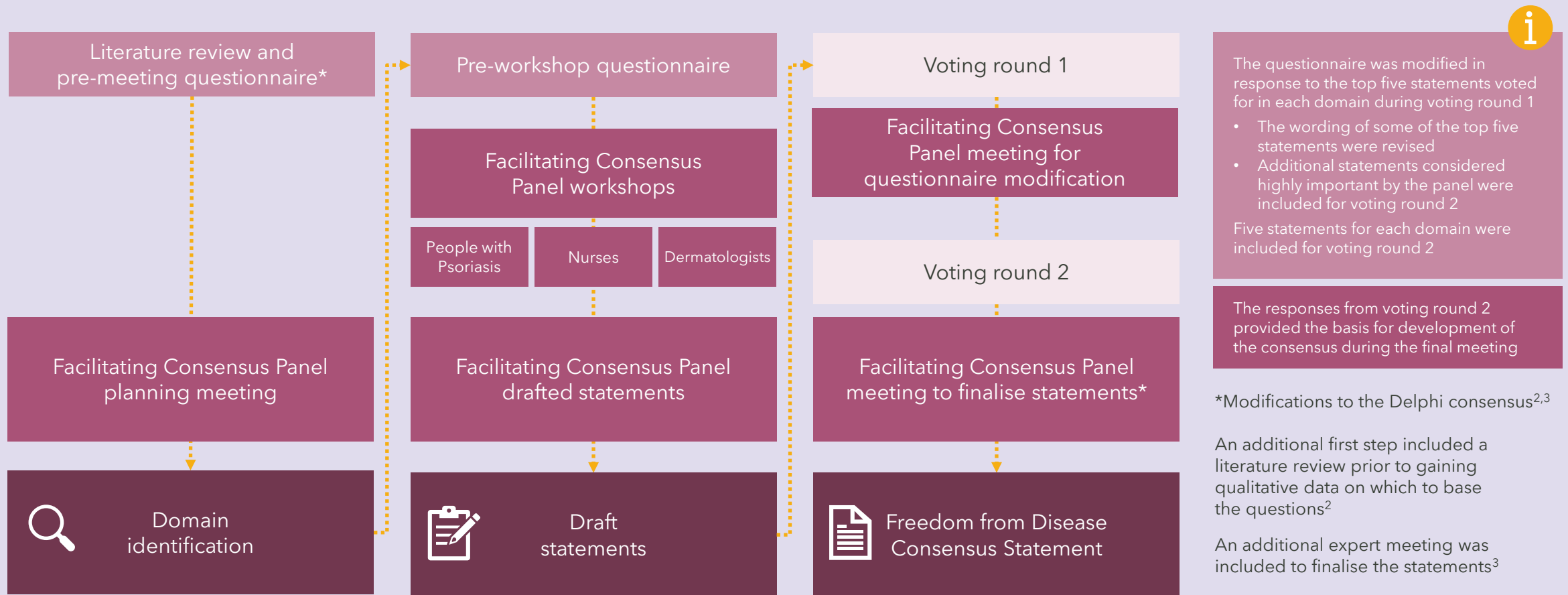
- Goals
- What freedom from disease means
- How freedom from disease can be achieved
- What having clear skin means
- What the physical and emotional impact is
- What the challenges are
- Communication between people with psoriasis and health care professionals on measuring success

Based on the results from the workshop, the Facilitating Consensus Panel selected draft statements to be rated by the voting group via an online questionnaire

*Modifications to the Delphi consensus^{2,3}

An additional first step included a literature review prior to gaining qualitative data on which to base the questions²

THE MODIFIED DELPHI CONSENSUS PROCESS¹



CHOOSING A DIVERSE AND GEOGRAPHICALLY HETEROGENEOUS PANEL

Dermatologists and nurses

- Experience in psoriasis as assessed by:
 - Publications
 - Citations
 - Presentations
 - Participation in guideline development

People with psoriasis

- Recruited through patient advocacy groups

Drive content of programme

Facilitating consensus group

Voting consensus panel

Vote and provide consensus on the content produced by facilitating consensus group

RESULTS FROM KEY STAGES OF THE DELPHI CONSENSUS



WE RECEIVED AN UNPRECEDENTED LEVEL OF ENGAGEMENT

Voting group across Europe: responses received from 15 countries

21 dermatologists



21 dermatologists

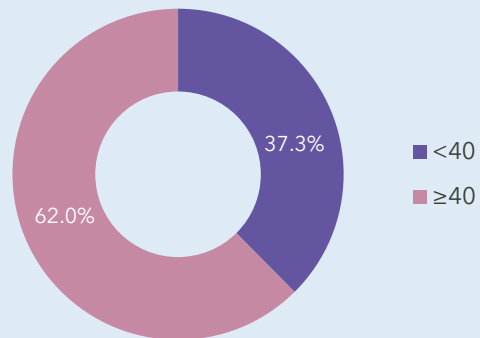


- Belgium
- Croatia
- Denmark
- France
- Germany
- Hungary
- Ireland
- Italy
- Netherlands
- Poland
- Portugal
- Romania
- Spain
- Switzerland
- United Kingdom

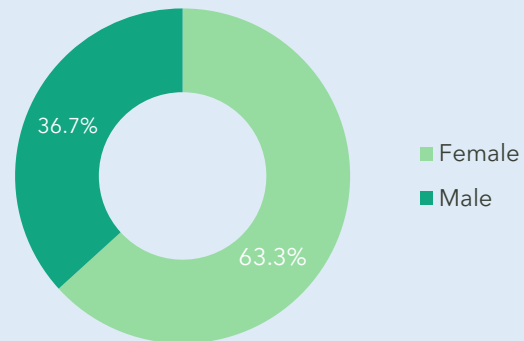
FURTHER CHARACTERISTICS

Voting round 1

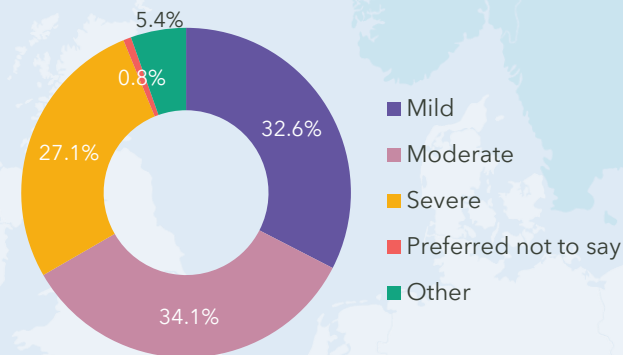
Age (all responders; n=166)



Gender (all responders; n=166)

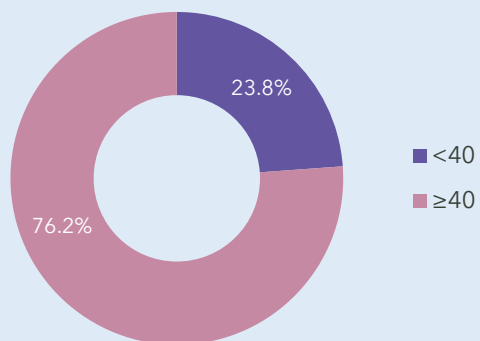


Disease severity (people with psoriasis; n=129)

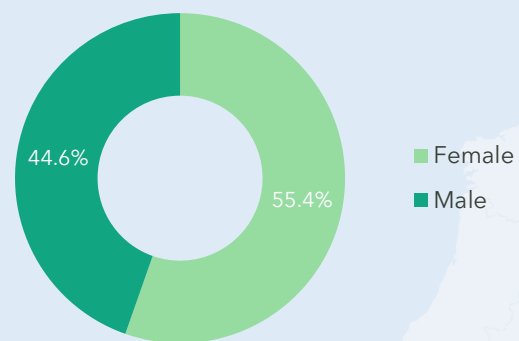


Voting round 2

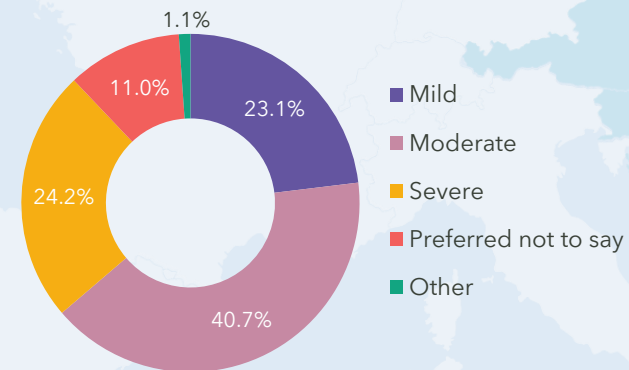
Age (all responders; n=130)



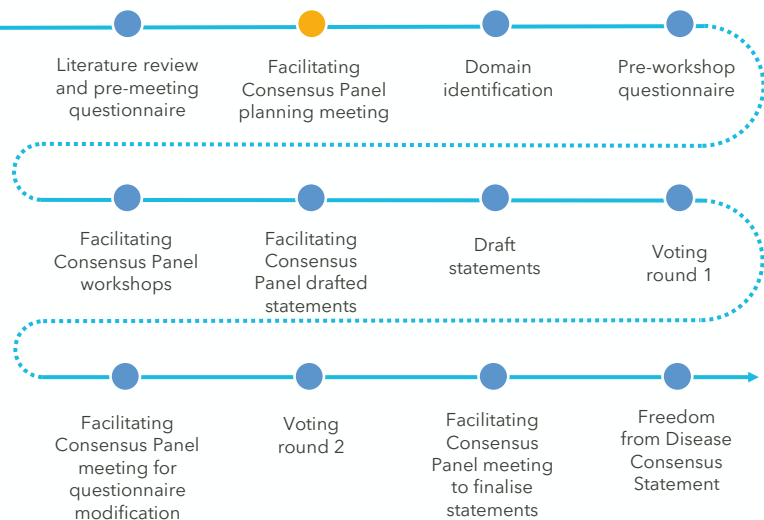
Gender (all responder; n=130)



Disease severity (people with psoriasis; n=91)



KEY CONCLUSIONS FROM THE VIRTUAL PLANNING MEETING



There is a paucity of published consensus psoriasis papers based on the opinions of people with psoriasis and healthcare professionals, including nurses

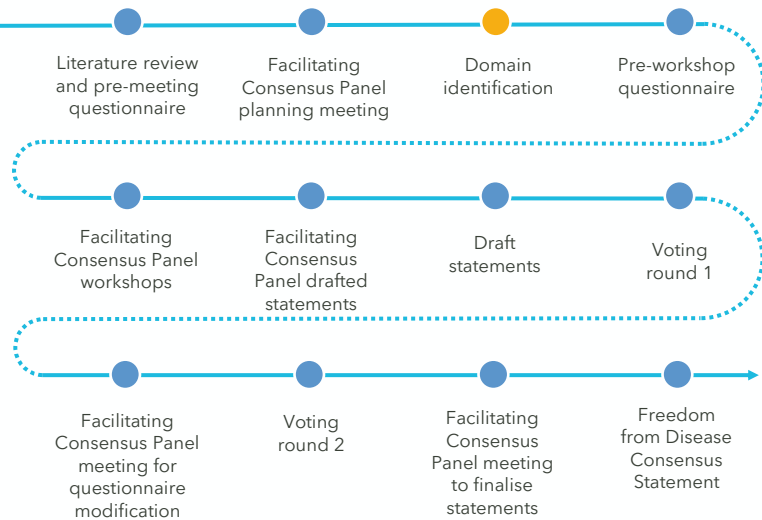
Current clinical assessment tools are insufficient for describing the full impact of psoriasis on individuals (e.g., DLQI correlates poorly with PASI outside of clinical trial settings)

No single patient reported outcome measure can be used as a gold standard

The consensus statement should place importance on patient-related factors

The consensus statement should be developed in a stepwise manner

DEVELOPMENT OF MULTI-DIMENSIONAL DOMAINS



WELL-BEING

- To be able to lead a normal everyday life
- To experience a greater enjoyment of life
- To be able to engage in normal leisure activities
- To be less of a burden to relatives and friends
- To be more productive in everyday life
- To be able to lead a normal working life

TREATMENT BURDEN

- To need less time for daily treatment
- To be less dependent on doctor visits
- To have fewer side effects
- To have fewer out-of-pocket expenses

QUALITY OF CARE

- To have confidence in therapy
- To find a clear diagnosis and therapy

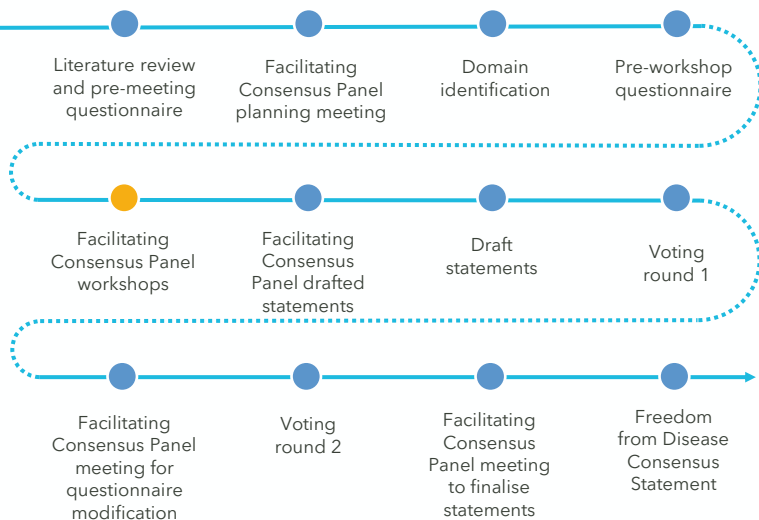
BEYOND SKIN

- To have no fear that the disease will become worse
- To be comfortable showing yourself in public
- To be able to have more contact with other people
- To be less burdened in your partnership
- To be able to have a normal sex life
- To feel less depressed
- To be able to sleep better

SYMPTOM CONTROL

- To be healed of all skin defects
- To get better skin quickly
- To be free from itching
- To no longer have burning sensation on skin
- To be free from pain

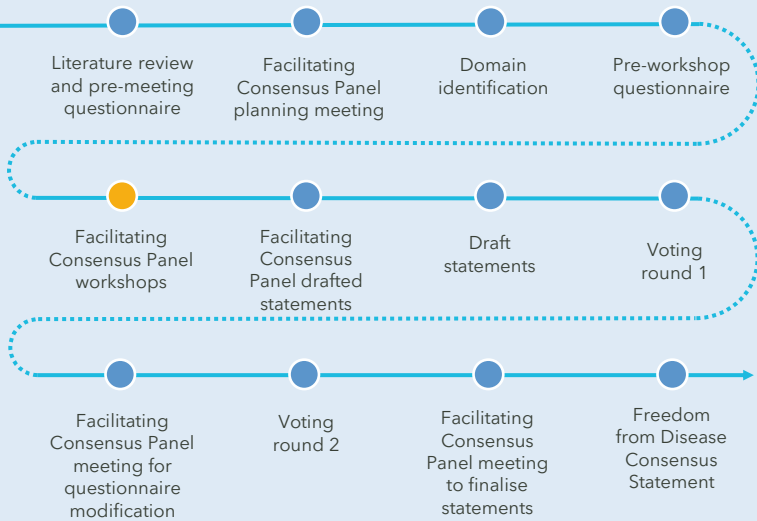
KEY CONCLUSIONS FROM THE WORKSHOP WITH PEOPLE WITH PSORIASIS



The participants used the following language to describe freedom from disease:

| | |
|--|--|
| <p>Living without thinking about my skin</p> | <p>Priorities for people with psoriasis were as follows:</p> <p>Symptom control - to not have pain, itching and flares; to have disease under control; to have clear skin which feels and looks good</p> |
| <p>Not feeling watched and judged</p> | <p>Living a normal life</p> |
| <p>Skin which looks and feels good</p> | <p>Living without embarrassment</p> |
| <p>Well-being - to not think about skin; to feel good, normal; to be able to sleep peacefully and do activities</p> <p>Beyond skin - to live a normal life without fear and embarrassment; to break the cycle of hope and disappointment</p> <p>Treatment burden/quality of care - to reduce the time and effort required for clear skin; to deal with fewer side effects; to be less dependent on others; to be free from hospital visits; to be able to communicate how their psoriasis feels</p> | |

KEY CONCLUSIONS FROM THE WORKSHOP WITH NURSES AND DERMATOLOGISTS



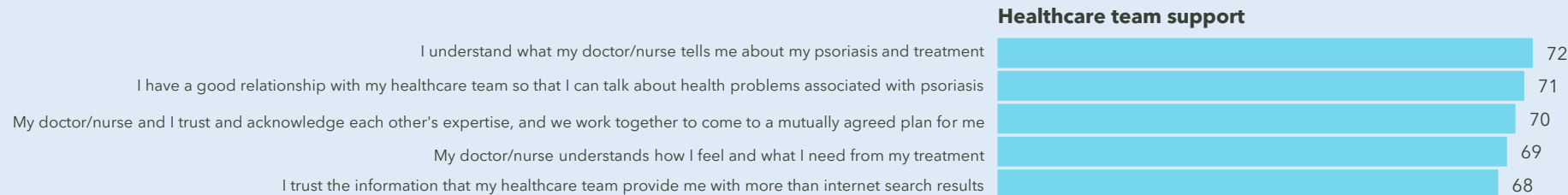
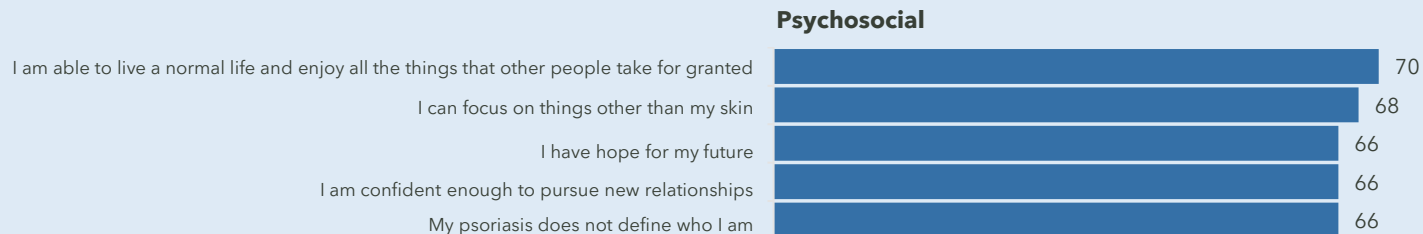
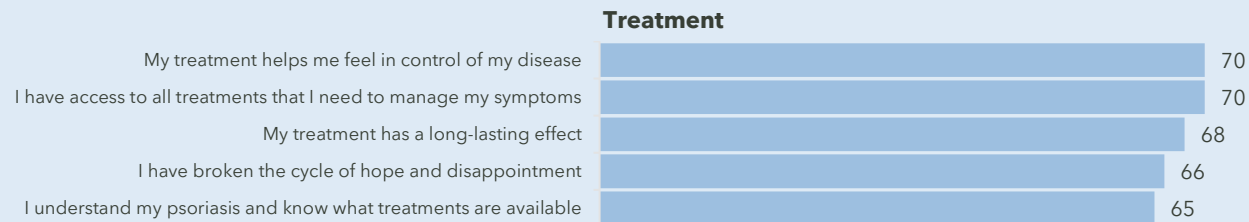
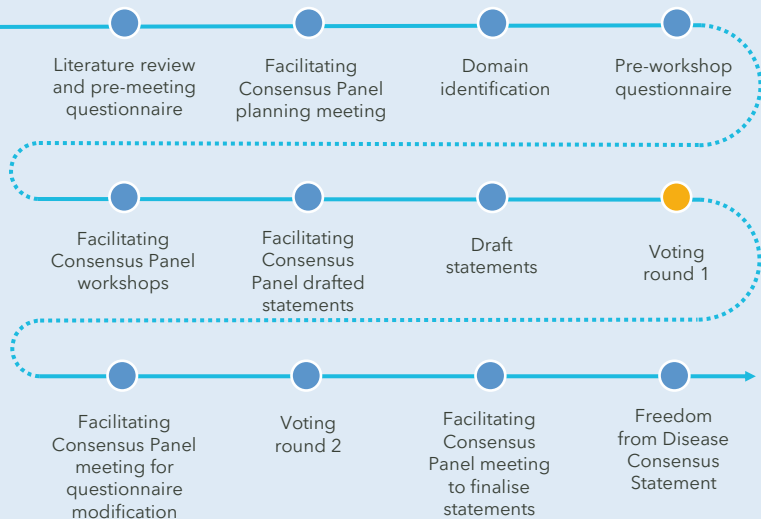
Nurses

- The communication with the patient is vital
- Healthcare professionals including nurses need to:
 - Use open-ended questions during the initial discussions with people with psoriasis
 - Tailor treatment according to patient goals
 - Inform people with psoriasis of possible side effects and raise awareness of comorbidities
 - Support and encourage people with psoriasis to feel in control of their disease
- Help relieve emotional burden of disease while managing physical symptoms through personalised treatment plans

Dermatologists need to:

- Empower people with psoriasis to live a completely normal life - physically, emotionally and socially
- Ensure that the information given to people with psoriasis is reliable and within the point of view of the patient
- Interact with people with psoriasis in a meaningful manner by being accessible for people with psoriasis and offering treatment which they will adhere to

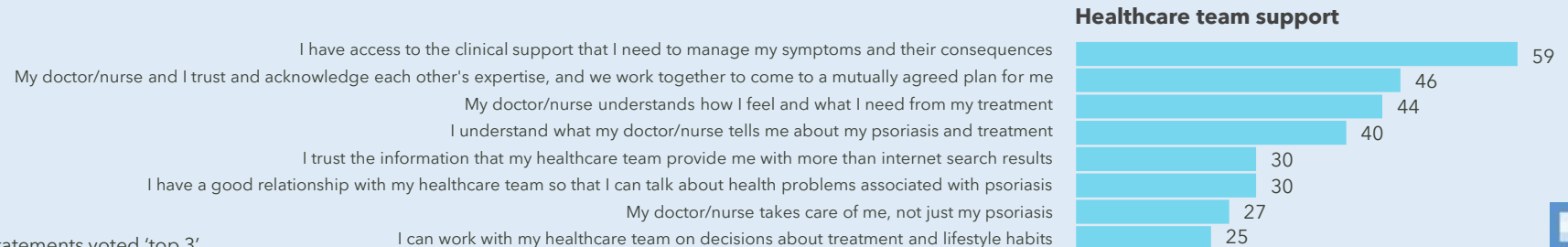
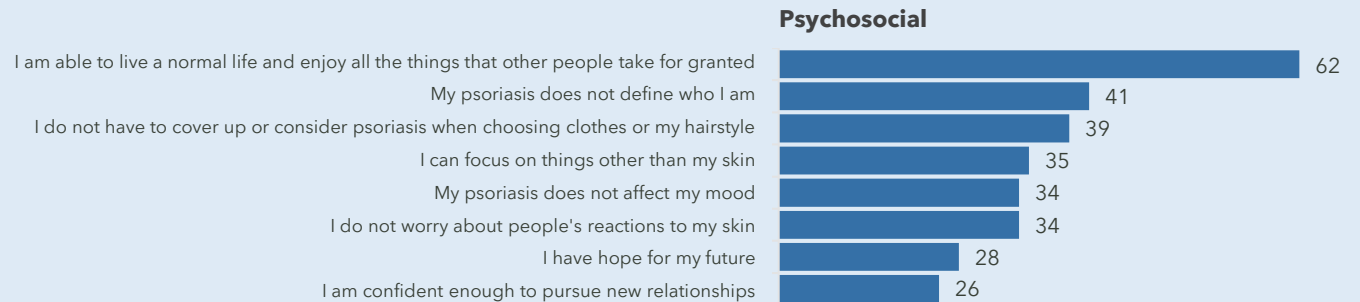
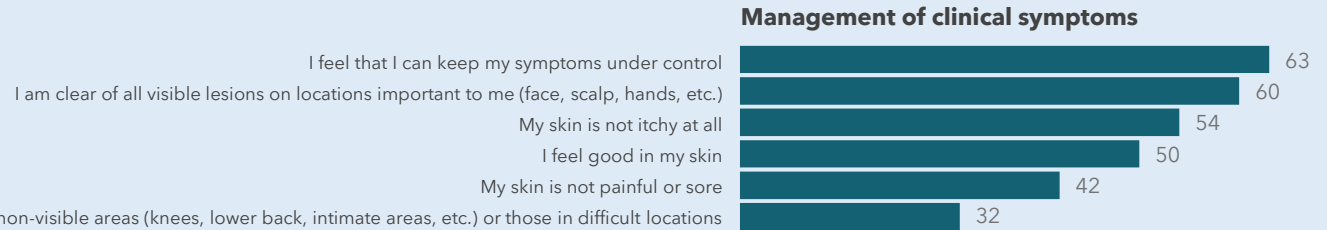
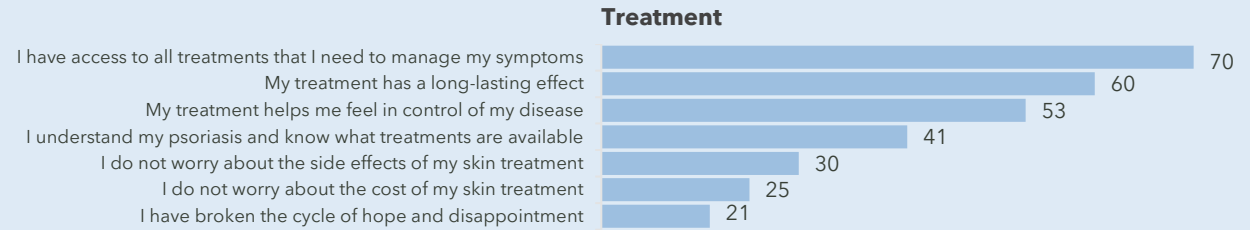
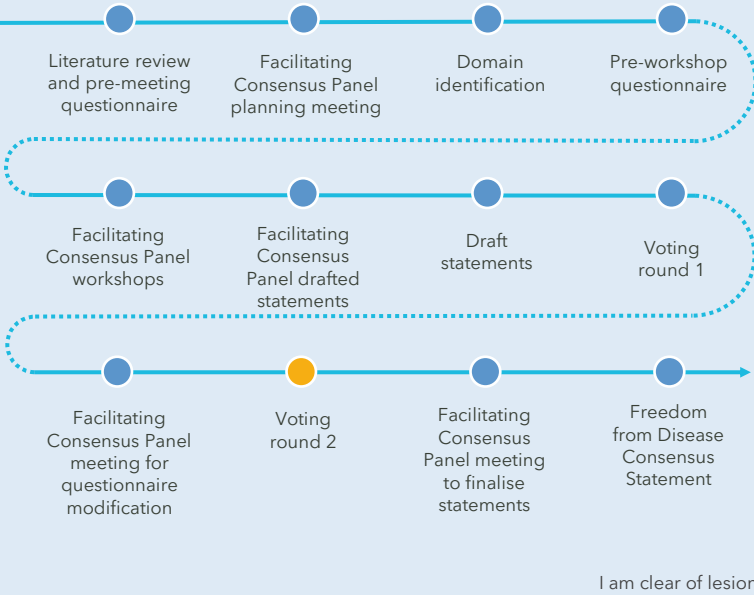
RESULTS FROM ROUND 1*



Percentage of responders (%)

*Delphi questionnaire round 1 output: top five high priority statements scoring 8-10. van Ee I, et al. J Eur Acad Dermatol Venereol. 2022;36(3):403-412.

RESULTS FROM ROUND 2*

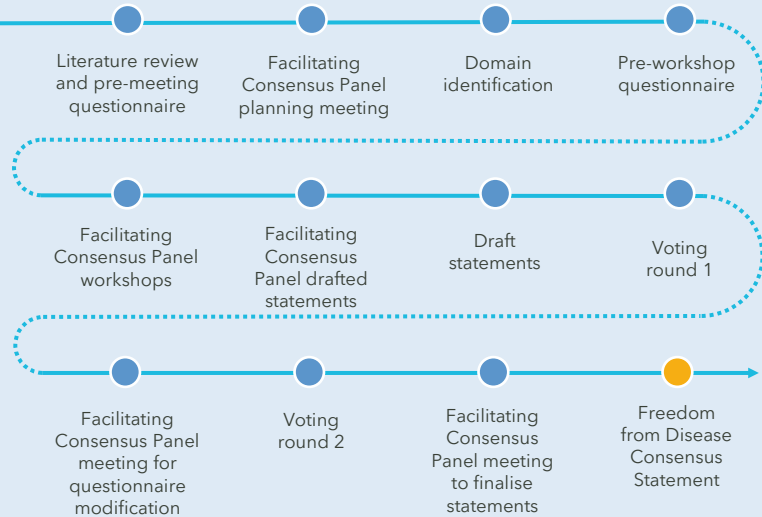


Percentage of responders (%)



*Delphi questionnaire round 2 output: statements voted 'top 3'.
van Ee I, et al. J Eur Acad Dermatol Venereol. 2022;36(3):403-412.

CONSENSUS STATEMENT



Freedom from disease is multifaceted with five core elements. Addressing all five offers individuals with psoriasis a restoration of normality; effective, lasting treatment to manage visible and non-visible clinical symptoms, eliminating the anxiety and fear of losing control, and resulting in no impact of disease owing to treatment management, with treatment meeting the individual's needs and expectations. This reduces psychosocial burden, improving quality of life and well-being, and enabling life to be lived fully with the confidence that psoriasis will not disturb it.



CONSENSUS STATEMENT

1. QoL and well-being

For individuals, control of psoriasis means that their daily routine at home and at work, their relationships and social life, and intimacy are all returned to normal. This enables them to live confidently, without psoriasis impacting their life.

2. Healthcare team support

To address individual expectations and all elements of living with psoriasis, an effective healthcare professional and patient relationship is essential. This is based on trust, time spent on individual needs, open discussion of treatment options, and shared decision-making to agree the optimal treatment plan.

3. Psychosocial elements

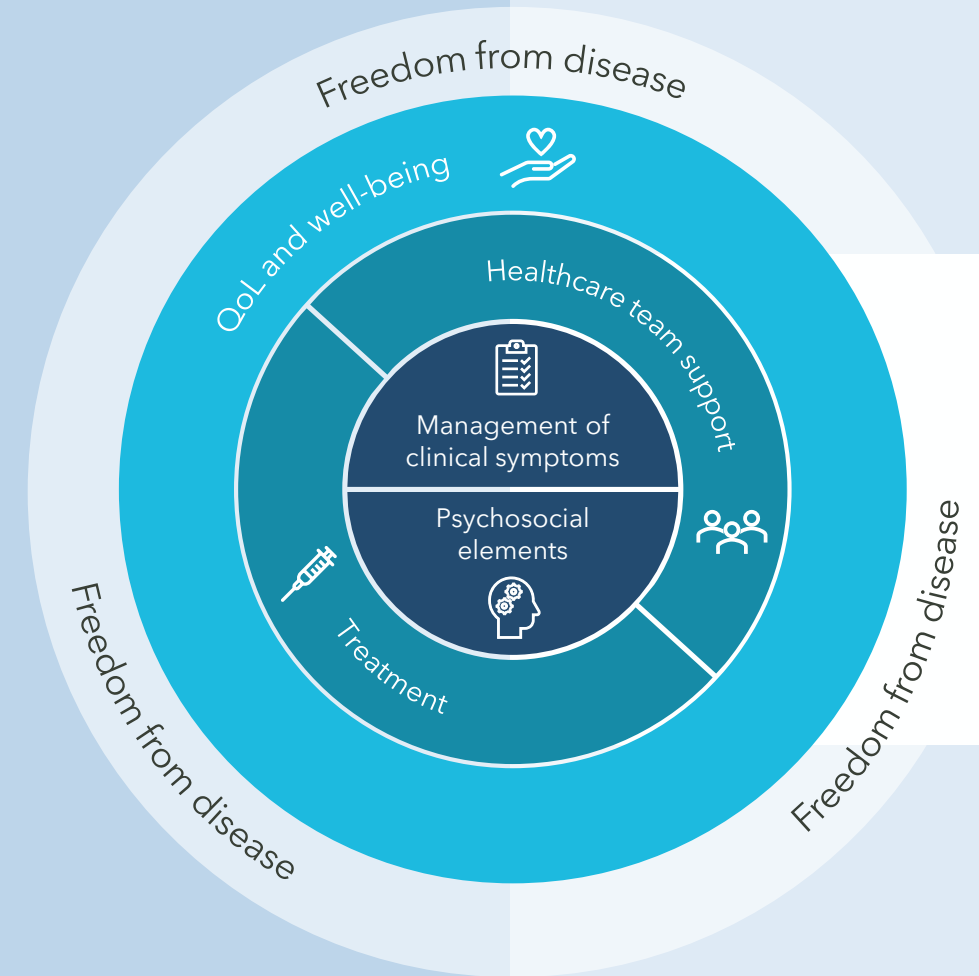
The psychosocial burden of living with psoriasis can be overwhelming, resulting in anxiety and recurrent fear of losing control, leading to reduced confidence and hope and isolation. These feelings can persist even when existing symptoms are controlled.

4. Treatment

Early access to optimal treatment enables effective symptom control. This helps eliminate anxiety and fear due to loss of control, while providing confidence in long-term safe management without the worry of side-effects, and relief from all symptoms of disease.

5. Management of clinical symptoms

Effective symptom control should include clearance of all lesions, particularly those important to individuals, such as those most visible or in sensitive regions. It must also tackle non-visible symptoms such as pain, itch and soreness.



ACHIEVEMENTS AND NEXT STEPS



FREEDOM FROM DISEASE REQUIRES THE NEEDS OF ALL **FIVE** DOMAINS TO BE SUFFICIENTLY ADDRESSED

QoL and well-being

- Having control of their disease
- Improving care and treatment of comorbidities*

Psychosocial

- Not being defined by their psoriasis
- Normality of living

Treatment

- Access to comprehensive information on the available treatments

Management of clinical symptoms

- Clear from visible lesions
- Symptom control (particularly in significant body regions)

Healthcare team support

- Relationship of mutual trust and respect between the individuals with psoriasis and their HCP
- HCPs to understand the needs of the individual with psoriasis

*Freedom from disease in psoriasis also implies freedom from any potential comorbidities, such as:

- Psoriatic arthritis
- Inflammatory bowel disease
- Psychiatric disorders
- Uveitis

THE MODIFIED DELPHI METHODOLOGY USED PROVIDED A BROAD AND PRECISE CONSENSUS

- Largest Delphi consensus to include people with psoriasis at every stage of the process
 - Providing an accurate consensus across those with psoriasis and those involved in treatment
- The rigorous Delphi methodology involved multiple meetings
 - Including separate meetings for the different specialist groups



The consensus achieved for Freedom from Disease represents a new treatment target in psoriasis

TO CONCLUDE: ACHIEVEMENTS AND NEXT STEPS

Largest Delphi consensus to fully incorporate the views of people with psoriasis at the time of its publication (January 2022)

Final consensus statements provide **new insight** into the concept of freedom from disease

Europe-wide response, with input from people with psoriasis, nurses and dermatologists from 15 countries across Europe

Providing an **active voice** to people with psoriasis

Publication strategy and **awareness** campaign to disseminate the novel concept of freedom from disease

Retain and progress panel insights in the form of the proposed **Freedom from Disease Steering Committee**



THANK YOU

FREEDOM
FROM DISEASE IN PSORIASIS