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ISPOR Special Interest Group

Using Clinical Outcome Assessments (COAs) in Your Research Study Does Not Necessarily Make It Patient-Centric

Presented by ISPOR:

- Clinical Outcome Assessment Special Interest Group
- Patient-Centered Special Interest Group

ISPOR 2023

Tuesday, May 9, 2023

11:45 AM – 12:45 PM EDT

Moderator:

- Hoda Fotovvat, PhD, Evidera, Bethesda, MD, USA
  - Mixed-method research
  - Implementation Science
  - Patient- Reported Outcome

Agenda

Welcome

The True Meaning of Patient-Centricity

Some Clinical Outcome Assessments Are Better Than Others: How Did We Get Here?

Building Better Outcomes

Open Discussion and Q&A

1

Introduction to Speakers

Speakers:

1. **Eleanor M Perfetto, PhD, RPh, MS,** University of Maryland School of Pharmacy, Venice, FL, USA
2. **Katja Rudell, PhD, MSc,** Parexel International, London, LON, UK
3. **Kathy Wyrwich, PhD,** Bristol Myers Squibb, St. Louis, MO, USA

Eleanor Perfetto, PhD, RPh, MS

Professor, Department of Pharmaceutical Health Services Research
University of Maryland

Patient centered:

Any process, program or decision focused on patients in which *patients play an active role as meaningfully engaged participants*, and the central focus is on optimizing use of patient-provided information. Doing things WITH – not FOR or TO – patients.

Patient-centered outcomes:

Outcomes reported by patients as *important to them* in the way they experience a disease or treatments for that disease.

- Can only be identified by patients
- Can be outcomes, but also broader

https://nationalhealthcouncil.org/additional-resources/glossary-of-patient-engagement-terms/

Patient-Centered Outcomes Research Institute Methodology Standards

RQ-6: Measure outcomes that people (representing the population of interest) notice and care about.

Identify and include outcomes the population of interest notices and cares about (e.g., survival, functioning, symptoms, health-related quality of life) and that inform an identified health decision. Define outcomes clearly, especially for complex conditions or outcomes that may not have established clinical criteria. Provide information that supports the selection of outcomes as meeting the criteria of "patient centered" and "relevant to decision makers," such as patient and decision- maker input from meetings, surveys, or published studies. Select outcomes that reflect both beneficial and harmful effects, based on input from patient informants and people representative of the population of interest.

https://www.pcori.org/research/about-our-research/research-methodology/pcori-methodology-standards

Patient reported (information):

Information that comes directly from the patient; includes outcomes and other information.

Patient-reported outcome:

A measure based on a report that comes directly from the patient about the status of the patient's health condition (how they feel and/or function) without amendment or interpretation of the patient's response by a clinician or anyone else.

https://nationalhealthcouncil.org/additional-resources/glossary-of-patient-engagement-terms/
https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-patient-reported-outcomes-and-other-clinical-outcome-assessments

- **Patient experience data**: Captures patients' experiences, perspectives, needs, and priorities related to (but not limited to): 1) symptoms of their condition and its natural history; 2) impact of the conditions on their functioning and quality of life; 3) experience with treatments; 4) input on which outcomes are important to them; 5) patient preferences for outcomes and treatments; and 6) relative importance of any issue as defined by patients.
- **Patient focused (patient centered):** Ensuring PED is meaningfully incorporated into decisions and activities related to their health and well-being.

https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-patient-reported-outcomes-and-other-clinical-outcome-assessments
https://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary#:~:text=Patient%20experience%20data%20can%20be,of%20life%3B%203)%20their%20experience

Patient-focused drug development (PFDD) (also called patient-focused medical product development):

A systematic approach to ensure patients' experiences, perspectives, needs, and priorities (PED) are captured and meaningfully incorporated into the development and evaluation of medical products throughout the medical-product lifecycle.

https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-patient-reported-outcomes-and-other-clinical-outcome-assessments


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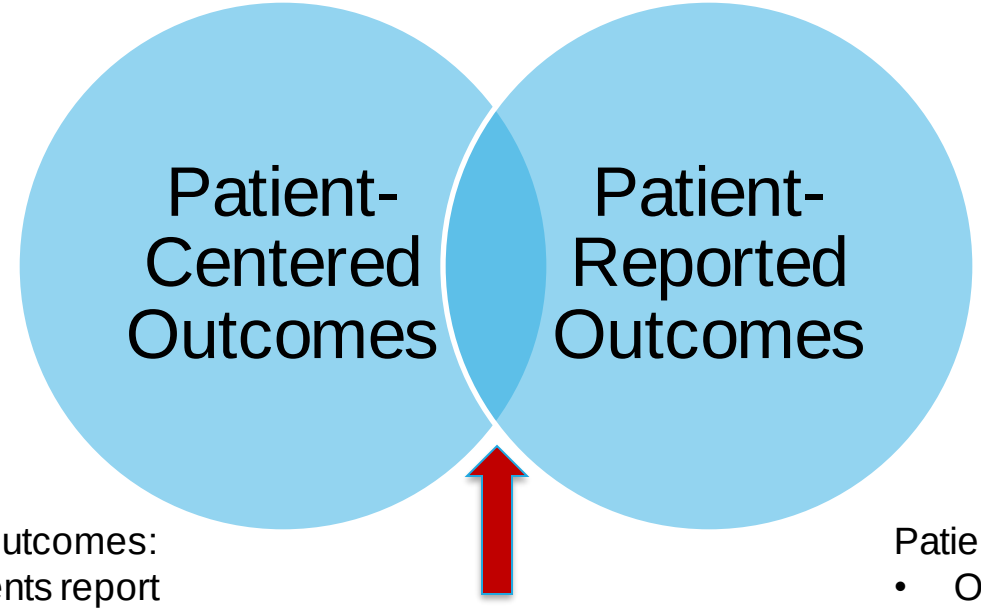
Plan for Issuance of Patient-Focused Drug Development Guidance.
Guidance 1: Collecting Comprehensive and Representative Input
Guidance 2: Methods to Identify What is Important to Patients
Guidance 3: Selecting, Developing or Modifying Fit-for-Purpose Clinical Outcomes Assessments
Guidance 4: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making

Patient-Centered *and* Patient-Reported Outcomes



Patient-Centered Outcomes:

- Outcomes patients report as important to them

Patient-Reported Outcomes:

- Outcomes that can only be reported by patients about how they feel and/or function

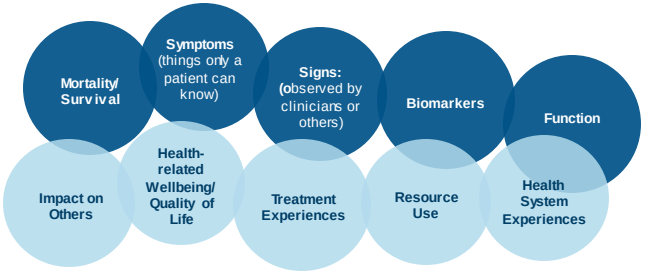
A Framework for Developing Disease-Specific Patient-Centered Core Impact Sets (PC-CIS)

Stakeholder Engagement
Impacts that matters to other stakeholders

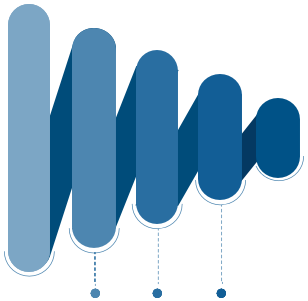
Environmental Scan
Impacts, outcomes, measures and endpoints studied or need to be studied

Pool of Potentially Important Impacts

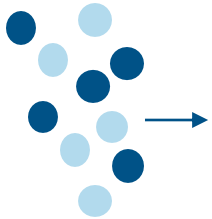
Examples of the wide range of things patients might report as important about the impact a disease or treatment has on their life.



Important Considerations: Equity, Representativeness, SDOH, Health literacy & numeracy, Culture, Religion, Baseline characteristics, etc.



Patient/Carer/ Family Engagement
to get to the most important impacts

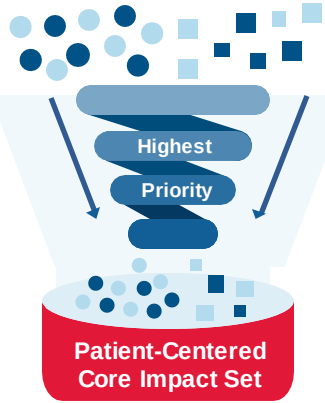


Most Important Impacts
reported by patients/carers/ families

Prioritization Process

✓ Structured ✓ Transparent ✓ Multi-stakeholder

Pool of Important Impacts from all Stakeholders



Align Possible Downstream Uses

+ Clinical Trials
+ RWE/RWD Studies
+ Product Development
+ Clinical Outcome Assessment Development
+ Core Outcome Sets
+ Audit
+ Quality Measurement
+ Value Assessment
+ Value-Based Arrangements
+ Clinical Decision Support
+ Regulatory Decisions

- From Patients: Direct Impacts on Health/Health Outcomes
- From Other Stakeholders: Direct Impacts on Health/Health Outcomes
- From Patients: Other Meaningful Impacts
- From Other Stakeholders: Other Meaningful Impacts

RWD = Real-Word Data
RWE = Real-World Evidence
SDOH = Social Determinants of Health

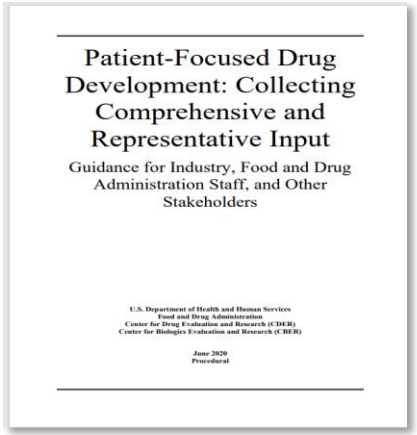
Katja Rudell, PhD

Clinical Outcomes Assessment Team Lead
Parexel Access Consulting

The COA Regulatory considerations from the FDA

- Background
- Regulators increasingly want to see the impact of a drug on patient relevant endpoints, which can include PRO assessments:

2020



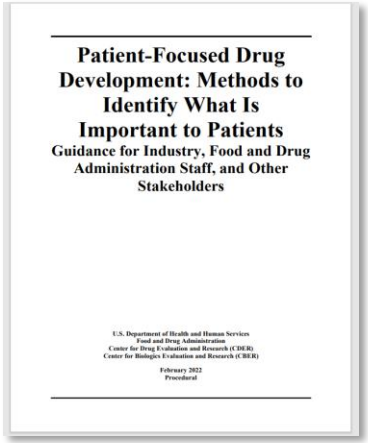
Patient-Focused Drug Development: Collecting Comprehensive and Representative Input

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

June 2020
Procedural

2022



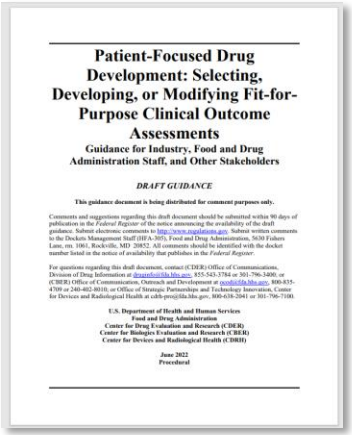
Patient-Focused Drug Development: Methods to Identify What Is Important to Patients

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2022
Procedural

2022



Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

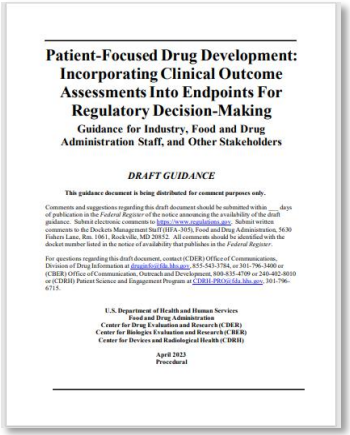
DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

June 2022
Procedural

2023



Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints For Regulatory Decision-Making

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

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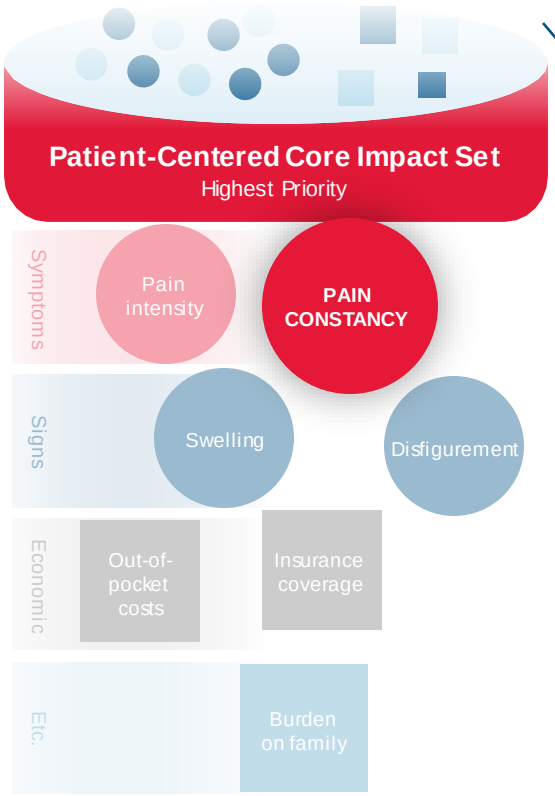
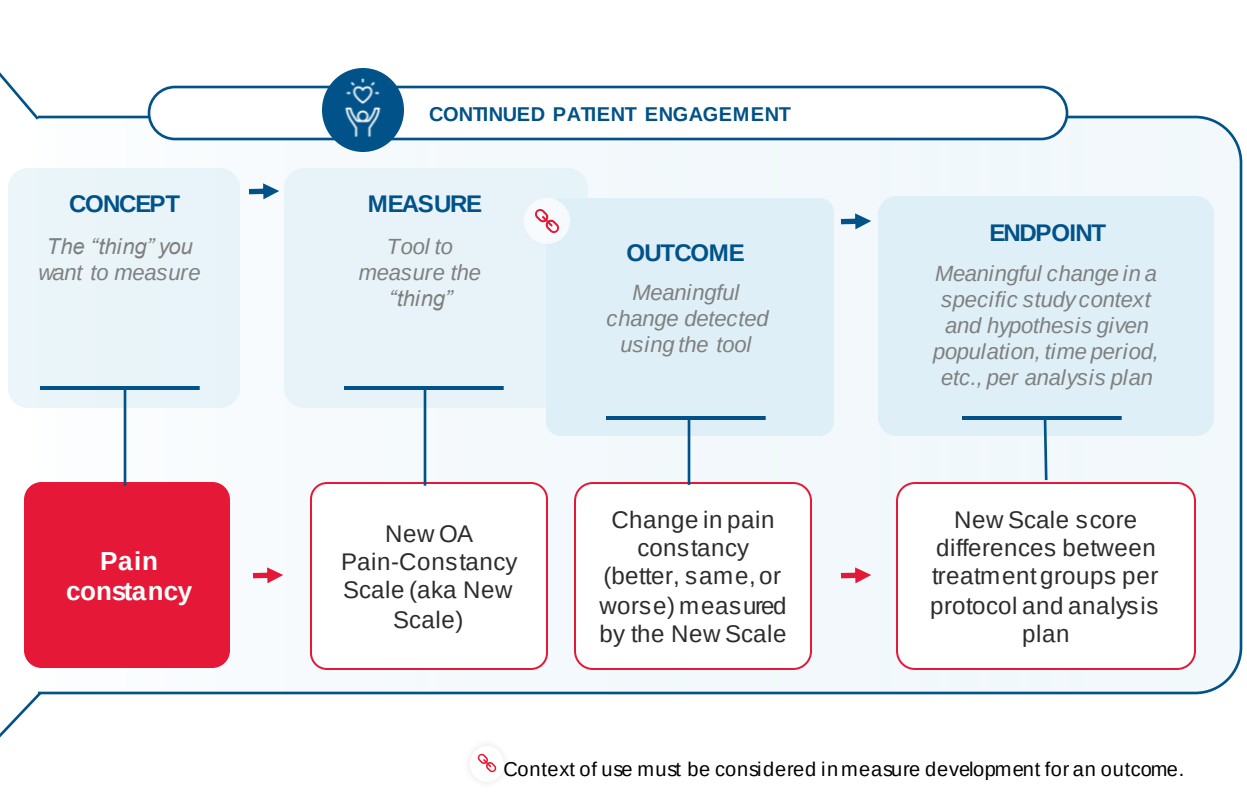
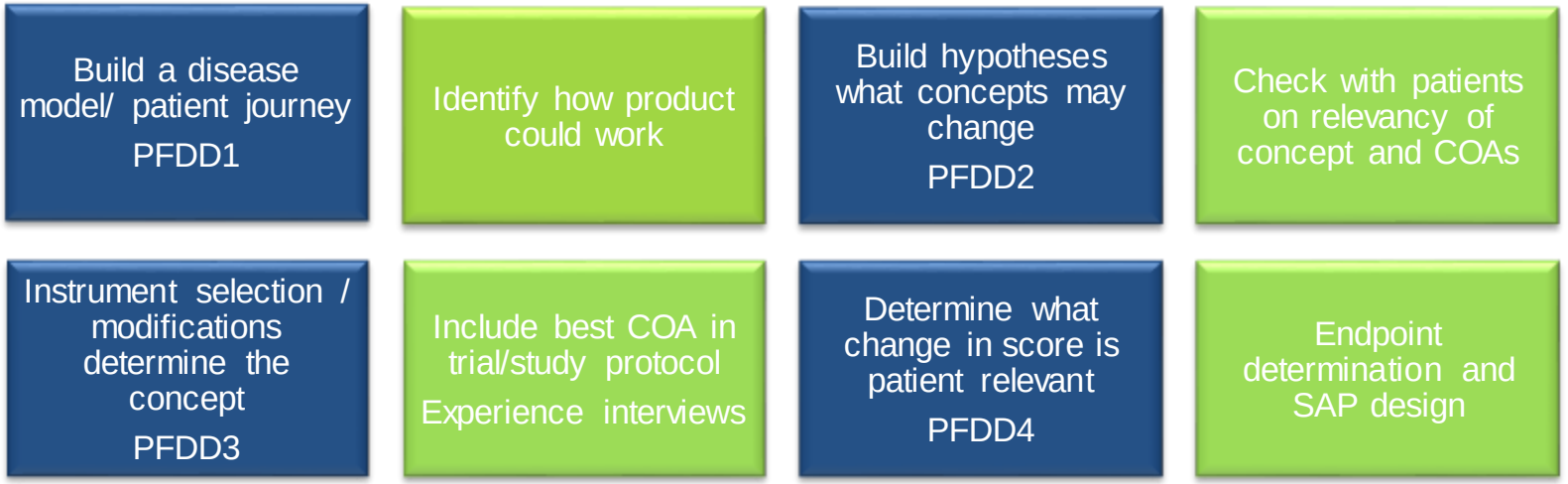
Impact to Endpoint Pathway: An Osteoarthritis (OA) PRO Example

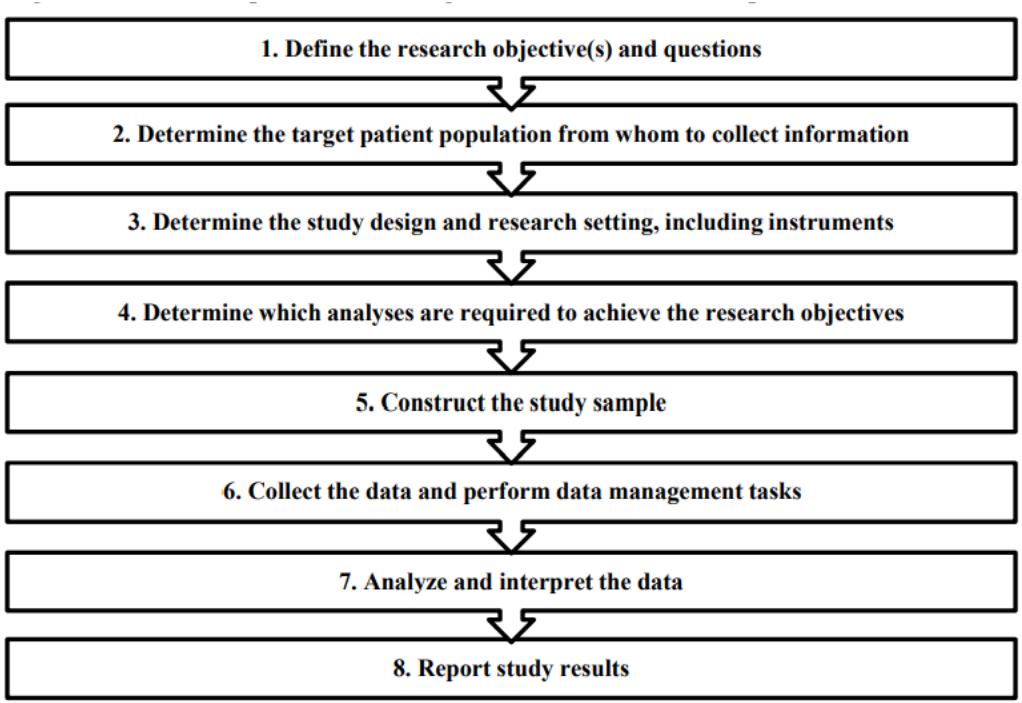




PFDD – Interaction with Pharmaceutical Product Design/ Consultancy



PFDD 1 - General considerations for conducting studies about patient experience data

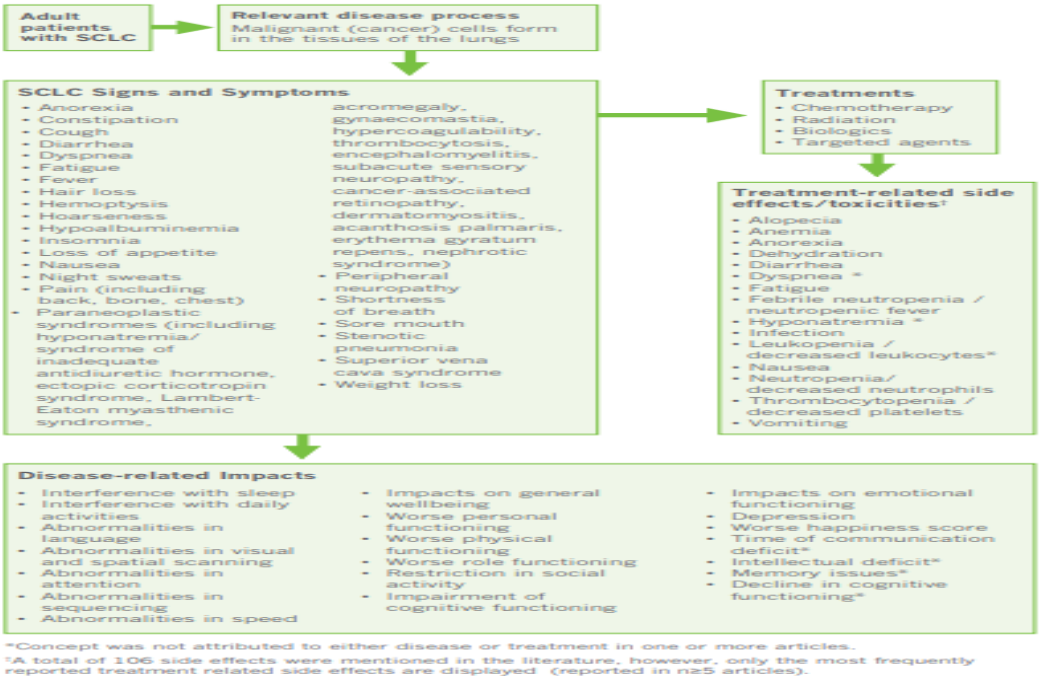


Key takeaways:

- FDA recommends patient experience data is directly reported from patients unless they are unable to reliably report
- Consult existing literature and subject matter experts when determining appropriate research questions, sampling, when patient reporting is limited, and study design.
- If the sample size is limited, the research objectives and/or methods should be adjusted accordingly, and any limitations should be noted

PFDD 1: SCLC EXAMPLE – 2016 – Ojo et al

Figure 2: Literature-centric SCLC conceptual model



*Concept was not attributed to either disease or treatment in one or more articles.
†A total of 106 side effects were mentioned in the literature, however, only the most frequently reported treatment related side effects are displayed (reported in n≥5 articles).

Table 1: SCLC disease-related symptom description table: Disease-related symptoms

Concept	Concept Description
Fatigue	Feeling tired, weak or exhausted (Riemsma et al. 2010, Zikos et al. 2014, Huber and Tufman 2012)
Pain	Pain is a feeling triggered in the nervous system. Pain may be sharp or dull. It may come and go, or it may be constant.[1] It may occur in the back, bone, and/or chest (Ellis et al. 2014, Riemsma et al. 2010, Zikos et al. 2014)
Cough	A reflex that keeps the throat and airways clear (Riemsma et al. 2010, Huber and Tufman 2012)
Dyspnea	An intense tightening in the chest, air hunger or a feeling of suffocation (Zikos et al. 2014, Huber and Tufman 2012).
Hemoptysis	Coughing up blood, the spitting up of blood or bloody mucus from the lungs and throat (respiratory tract) (Riemsma et al 2010, Huber and Tufman 2012)
Loss of appetite/ anorexia	A decreased appetite or abnormal loss of appetite for food;[3] the desire to eat is reduced (Riemsma et al. 2010, Zikos et al. 2014)
Weight loss	Unexplained weight loss, or losing weight without trying (Riemsma et al. 2010, Huber and Tufman 2012)

PFFD 2 – What is Important to Patients

Objective: Describes how stakeholders can collect and submit patient experience data and other information from patients and caregivers for medical product development and regulatory decision making

Qualitative methods:	Quantitative methods:	Mixed methods:
Interviews and focus groups to understand patient experience, perspective, preferences, etc.	Quantifiable data collection (e.g., surveys) and statistical methods to summarize patient experience data	Combination of qualitative and quantitative approaches (e.g., survey with open-ended and fixed response options)

PFDD 2 - Conceptual Model design – SCLC Altman 2022 /23

Development of a Conceptual Mo
Patient Experience in Small-Cell
(SCLC): A Qualitative Interview

Danielle Altman[1], An-Chen Fu[2], Patrick Marquis[1], Alissa Rams[1], Jessica Baldasaro
Samir Ali Ahmad[1], Michael Schlichting[3], Xinke Zhang*[2]
[1]Modus Outcomes, a Division of THREAD, Boston, MA, USA
[2]EMD Serono, Billerica, MA, USA
[3]the healthcare business of Merck KGaA, Darmstadt, Germany
*presenting author

CONCLUSIONS

- In this study, we addressed a gap in the literature by specifically interviewing patients with SCLC, instead of lung cancer more broadly, and creating a conceptual model of the SCLC patient experience focused on clinical treatment benefit
- To our knowledge, this is the first qualitative study of the lung cancer patient experience in which the sample was comprised only of patients with SCLC
- Participants rep impacts of SCLC
- The conceptual used to support items for an SC (PRO) instrume guidance on cor physical and rol PROs in oncolog

INTRODUCTION

- SCLC represents nearly 15% of all lung cancers. SCLC occurs primarily in smokers and is a more aggressive type of lung cancer[1]
- PROs are important tools in clinical management and drug development as diseases and treatments may impact patients' lives in ways that are only known by the patients
- While PRO questionnaires exist for lung cancer, none of these are SCLC-specific
- To inform PRO assessments in clinical trials of patients with SCLC and under the FDA patient-focused drug development guidance, it is vital to understand SCLC symptoms and the impacts of SCLC on QoL from the perspective of patients with SCLC[2]
- However, the patient experience of SCLC is not well documented in qualitative lung cancer literature, with most studies reflecting the lung cancer experience more broadly or the non-small cell lung cancer experience specifically
- It is important to fill this gap in the literature by collecting information directly from patients with SCLC on the symptoms and daily life impacts they experience

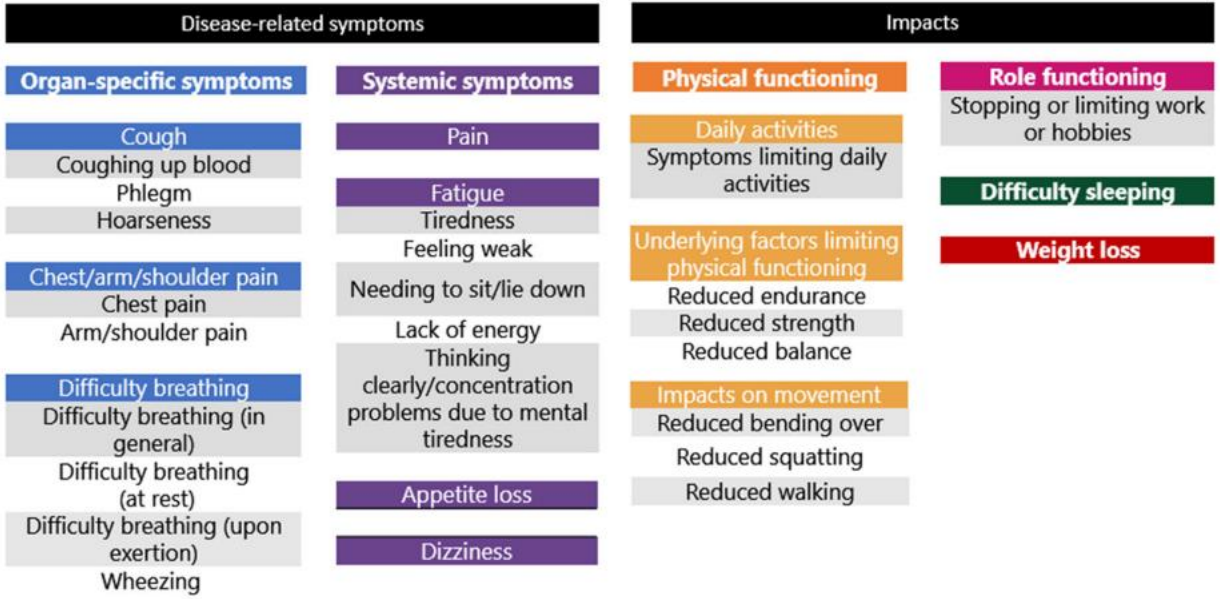


Fig. 1 Conceptual model of clinical treatment benefit

PFDD 3 and 4 - Provide Rationale for Each COA Selection + Endpoint Design

Concept of Interest: "the aspect of an individual's experience or clinical, biological, physical, or functional state that the assessment is intended to capture (reflect)"

- In a clinical trial, it is important to carefully select concepts that, when measured adequately:
  - Reflect an aspect of health that is **important to patients**
  - Have the ability to be modified by the investigational treatment
  - Could demonstrate **clinically meaningful differences** between study arms within the time frame of the planned clinical trial
- Patient and/or caregiver input can be used to identify which aspect(s) of a **concept is most impactful for patients**. This input will help sponsors in selecting or developing a COA that measures what is important to patients.

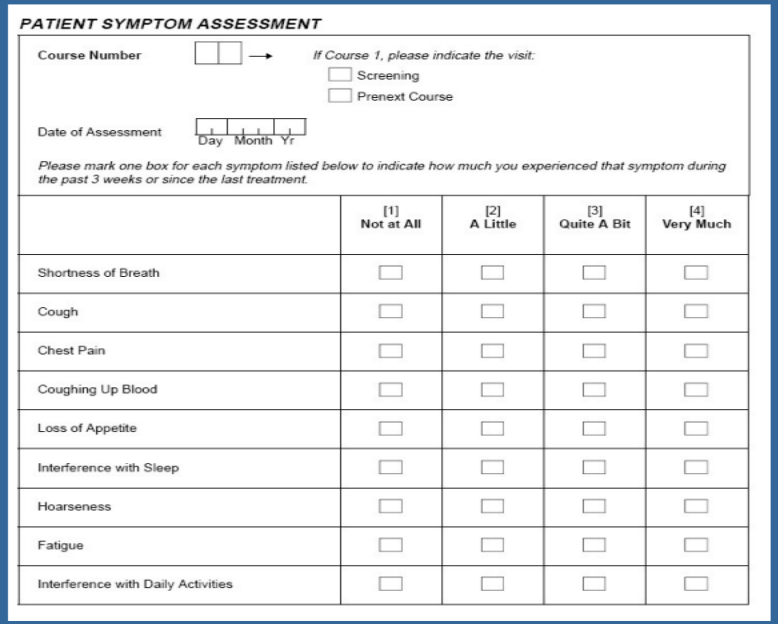
Context of Use: Specifies the way COA scores will be used as the basis for an endpoint, including the purpose of their use in a medical product development program

- Context of use considerations may include:
  - **Use of the COA:** Clinical trial objectives and how COA will be used to support COA-based endpoints
  - **Target population:** Disease/condition; participant selection criteria
  - **Study context:** Clinical trial design
  - **Timing:** When assessment(s) of the COA is/are conducted; total amount of time COAs take
  - **COA implementation:** Method of administration, setting, and who the COA will be collected by (e.g., patient, investigator, caregiver, etc.)

PFDD 3 - Instrument Patient Assessment of Lung Cancer Chen et al, 2007

INTRODUCTION (cont'd)

- PSALC instrument
  - Contains nine symptoms
  - Each symptom is evaluated on a 4-point ordinal scale
    - 1: not at all
    - 2: a little
    - 3: quite a bit
    - 4: very much
  - Total score is calculated as the sum of nine symptom scores
  - The higher the total score, the worse the symptoms are



PATIENT SYMPTOM ASSESSMENT

Course Number ☐☐ → *If Course 1, please indicate the visit:*
☐ Screening
☐ Prenext Course

Date of Assessment ☐☐ ☐☐ ☐☐ Day Month Yr

Please mark one box for each symptom listed below to indicate how much you experienced that symptom during the past 3 weeks or since the last treatment.

	[1] Not at All	[2] A Little	[3] Quite A Bit	[4] Very Much
Shortness of Breath	☐	☐	☐	☐
Cough	☐	☐	☐	☐
Chest Pain	☐	☐	☐	☐
Coughing Up Blood	☐	☐	☐	☐
Loss of Appetite	☐	☐	☐	☐
Interference with Sleep	☐	☐	☐	☐
Hoarseness	☐	☐	☐	☐
Fatigue	☐	☐	☐	☐
Interference with Daily Activities	☐	☐	☐	☐

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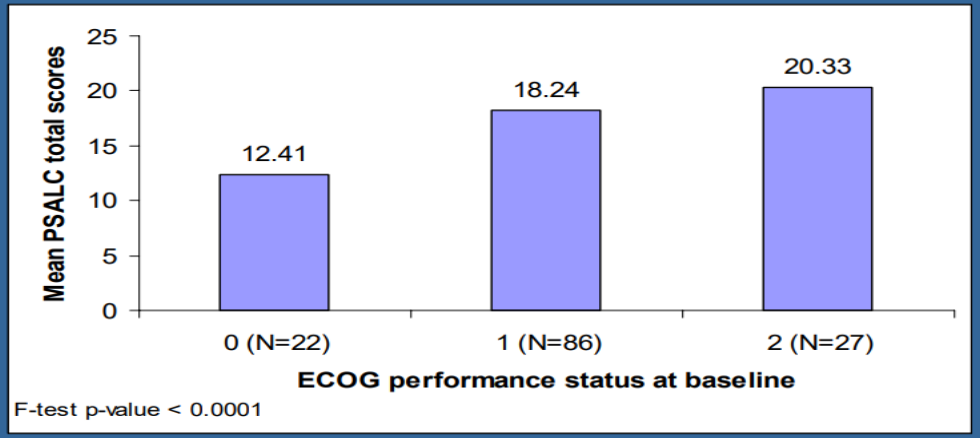
PFDD 4 - Meaningful change estimates – Anchor based approach

- Patients with higher ECOG scores (ie, lower performance status) on average had higher PSALC total scores (ie, worse symptoms) compared to patients with lower ECOG scores



Note: Only patients with both ECOG and PSALC scores at baseline were included in this analysis.

ECOG performance status: 0 = Normal activity, asymptomatic; 1 = Symptomatic, but fully ambulatory; 2 = Symptomatic, in bed in less than 50% of normal daytime.

The moral of the story is…

- Always, always **check the ISPOR database for COA materials**. Many companies have published materials for you to use and peruse
- **Talk to the COA experts** and consultants available to you in your company, CRO and or standalone COA consultancy
- **Some instruments** were developed prior to recent guidelines, but may still be relevant and meet standard KPI for COA development and validation.
- Follow where possible **guidance from the regulatory agencies** – they have more knowledge and insights into the process….
- And finally….

Decision Making on Patient Relevant COA Selection? Common KPI from 20 years experience

K-KPI	PRO/ ObsRO	ClinRO	PERF-O
Patient Relevancy	Has been developed with patients/ caregiver input?	Has the ClinRO been developed with patient and clinician input?	Can be performed by patient?
Burden Time for Administration	Does the administration take longer than human attention spans?	Needs limited clinician training + recalibration?	Is performing test time causing pain?
Interpretability	Is the score relevant to patients?	Is the score relevant to clinicians and patients?	Is the score relevant to patients and testers?
Readability /Complexity	Can patients understand the questions? (Double Barrel check)?	Can clinicians understand the instructions?	Is the task – ecologically valid?
Cross-cultural validity	Is the concept valid in all countries?	Is the clinical test used/trained in medical schools of the countries?	Does the performance test work in all countries?

- While some flaws can be overcome by modifications, **critically flawed COAs are best left behind**

Kathy Wyrwich, PhD

Senior Director, Patient-Reported Outcomes Assessment Team
Bristol Myers Squibb

What is Alopecia Areata?

Alopecia areata (AA) is an autoimmune disease that causes individuals to lose hair on:

- scalp
- eyebrows
- eyelashes
- face
- body

It affects ~2% of the world's population

A Case Study:
Incorporating the Patient Voice in the Development of COAs for Severe Alopecia Areata

Kathy Wyrwich, PhD

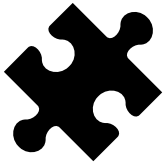
Senior Director, WW HEOR Advanced Scientific Capabilities, Patient-Reported Outcomes Assessment (PROA)

The Setting: 2017

- No approved systemic treatment for alopecia areata (AA)
- The Severity of Alopecia Tool (SALT; Olsen 2004) is widely clinician-reported outcome measure used to assess the extent of scalp-hair loss in patients with (AA)

  SALT score of **0** = **No** scalp hair loss
  SALT score of **100** = **Complete** scalp hair loss
- Guidelines defined AA treatment success as a 50% SALT improvement
  - However, there was no clinical consensus on these endpoints, and patient perspectives on treatment success were unknown
- No standardized method to assess eyebrow or eyelash hair loss
- Several open-label clinical studies reported success in hair regrowth using Janus kinase (JAK) inhibitors

The Challenge: Understand the Outcomes of Priority to Persons with Severe AA (SALT ≥ 50)

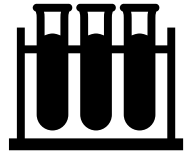


- Is scalp hair loss the most important AA concern? Eyebrows? Eyelashes? Other?

- Should there be a composite scoring measurement process that incorporates the importance of AA hair loss in other areas besides the scalp?

- How to best address the assessment need for:
  - Appropriate ClinRO and PRO tools?
  - Meaningful change thresholds that assess what is most important to patients seeking treatment?

The Solution: Listening to Clinicians and Patients



- Conducted noninterventional, cross-sectional, qualitative interview study to understand:
  - clinicians'
  - patients'

  perspectives and expectations of a clinically meaningful treatment outcome
- Developed a content-valid Investigator's Global Assessment (IGA) to measure distinct and clinically relevant gradations of scalp-hair loss support the definition of treatment success
- Later, developed a content valid:
  - Patient-reported outcome (PRO) measure of scalp hair loss
  - ClinRO and PRO measures to assess eyebrow, eyelash and nails
  - Adapted PRO measure for AA (Skindex-16 AA)

What We Heard: Listening to Clinicians

Ten expert dermatologists who regularly treated patients with AA characterized AA by scalp-hair loss to varying extents:

- Many patients with AA experience scalp-hair loss only
- In nearly every case, they 'treated to the scalp'

  -Other areas (e.g., eyebrows, eyelashes and body-hair loss) targeted only if the absence of hair was bothersome to the patient

Wyrwich et al 2020

What We Heard: Listening to Clinicians on Meaningful Treatment Success

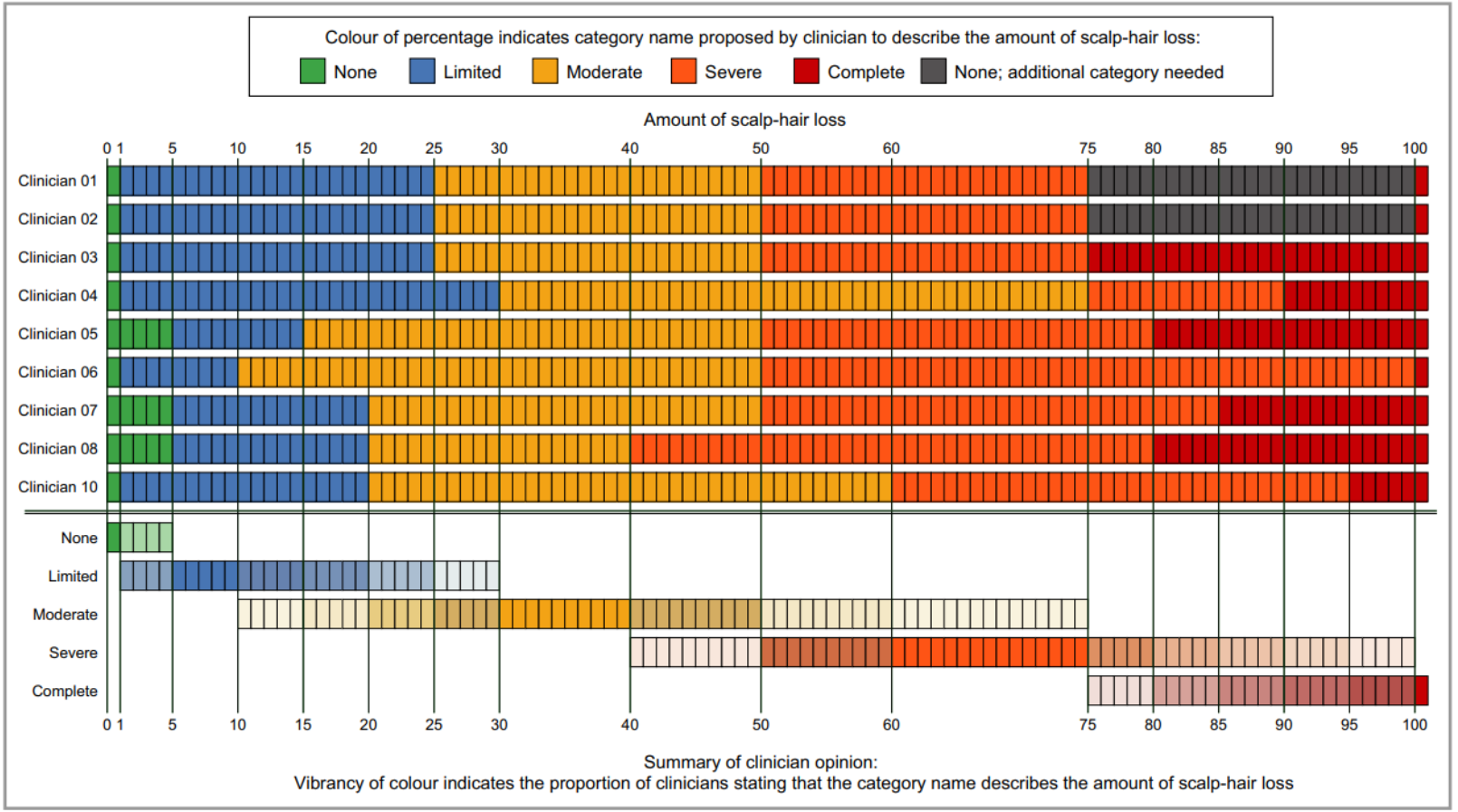
- The 10 clinicians emphasized that clinically meaningful treatment success was a combination of the amount of scalp-hair growth, density, location and quality, with *an emphasis on amount*
- When asked to describe **the amount of scalp hair** indicative of treatment success for patients with severe AA, responses were:

  90% (n = 1 clinician)
  80% (n = 5 clinicians)
  75% (n = 3 clinicians)

  1 clinician strongly preferred a ≥ 50% change metric vs. a static amount

Wyrwich et al 2020

What We Heard: Listening to Clinicians



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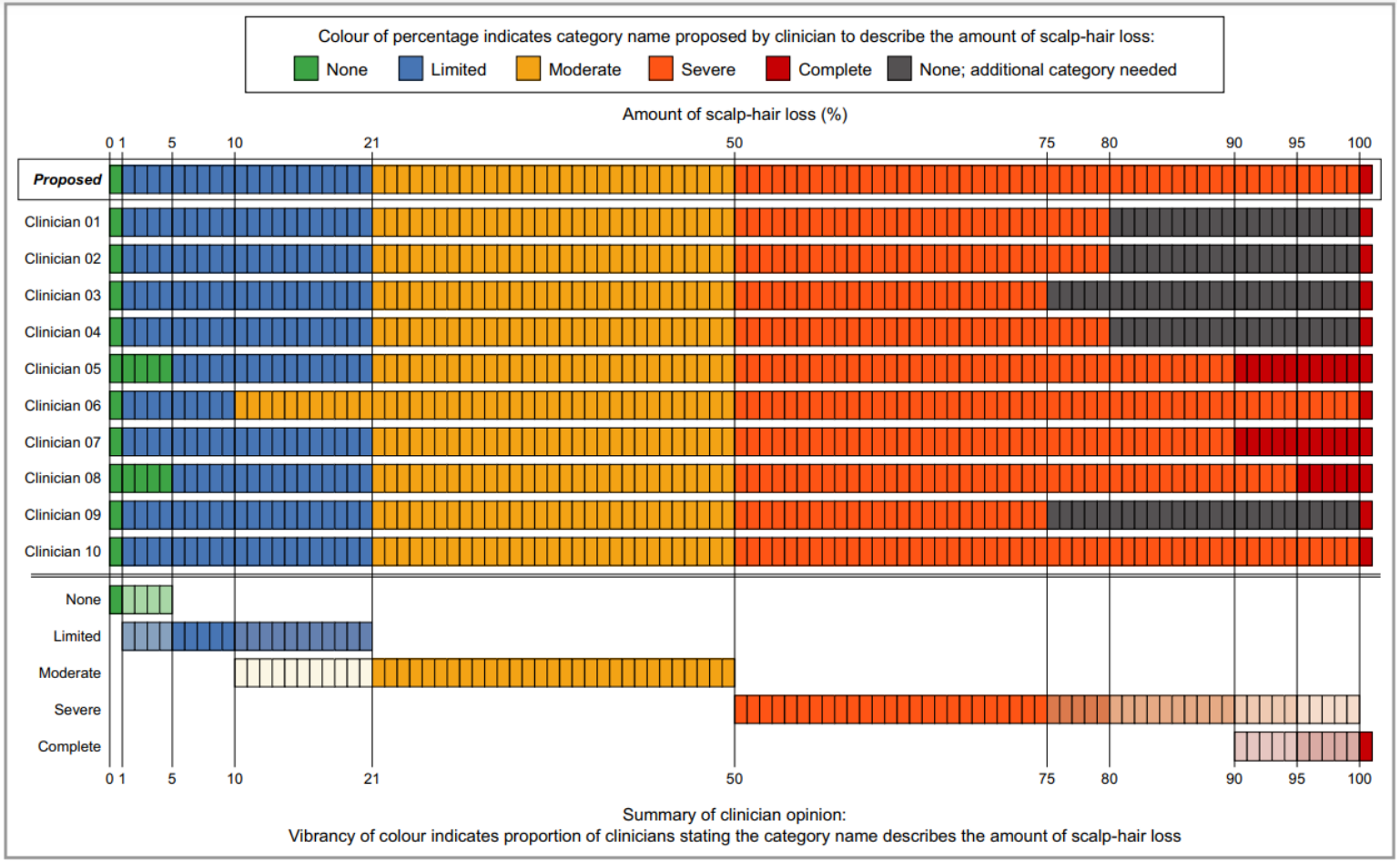
What We Heard: Clinicians and Proposed Percentages



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Before Listening to Patient: The Draft AA-IGA™

- Clinician Panel reviewed the detailed clinician data with a focus on the larger hair-loss range, and proposed that the fifth category descriptor (Very Severe)
- 'Very Severe' include nearly complete scalp-hair loss (95–99% hair loss), a patient presentation that is clinically very similar to 100% scalp-hair loss.

Alopecia Areata Investigator Global Assessment™ (AA-IGA™)

	None 0	Limited 1	Moderate 2	Severe 3	Very Severe 4
Please rate the patient's **scalp hair loss**, as it looks **today**.	0%	1-20%	21-49%	50-94%	95-100%

The Severity of Alopecia Tool (SALT; Olsen et al 2004) is recommended to assess the extent (0-100%) of scalp hair loss.

Wyrwich et al 2020

What We Heard: Listening to Patients

30 US patients participated; 25 adults (ages 18-72) and 5 adolescents (ages 15-17)

All had prior experience with severe AA (SALT ≥ 50)
24 patients (80%) had eyebrow and/or eyelash involvement
18 patients (60%) were currently or previously treated with oral JAK inhibitor
13 patients (43%) were receiving no AA treatment at the time of interview

Results

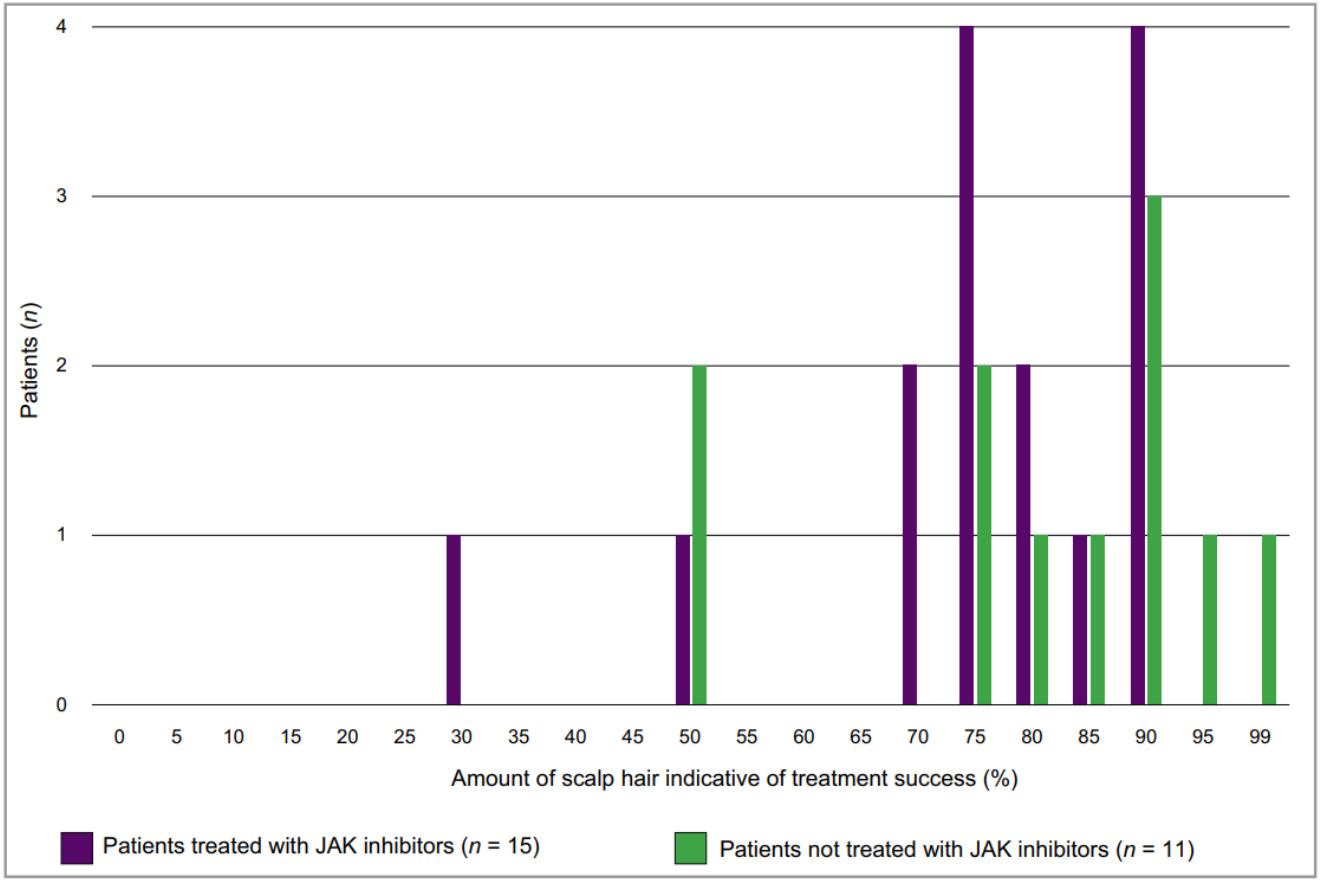
Scalp-hair loss was the most bothersome AA sign/symptom for 77% (n = 23)

Patients with SALT scores < 100% (n = 19) described their current scalp hair:

- amount of scalp hair (n = 18)
- hair density (n = 9)
- length (n = 6)

Wyrwich et al 2020

What We Heard From Patients: *What amount of scalp hair – short of 100% –would you consider a treatment success?*



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What We Heard: Patients' Review of the Draft AA-IGA™

Alopecia Areata Investigator Global Assessment™ (AA-IGA™)

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All 30 patients confirmed the appropriateness of the AA-IGA and the gradations

6 patients spontaneously commented on the clinician accuracy in answering

- trained in assessing scalp hair loss
- can view the whole head

Achieving "Limited" (1–20% hair loss) would be a treatment success

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What We Learned: Clinicians Then Patients Interviews

- When reviewed with clinicians and patients, the AA-IGA™ was supported as a meaningful ClinRO of scalp hair loss

- A qualitative investigation of a quantifiable treatment success threshold for a ClinRO is possible through a well-designed interview process with expert clinicians and the appropriate patient population…especially when new treatments requires a patient- centric solution!

- The depth of our gratitude
- Both clinicians and patients provided honest and numerically intense insights that yielded alignment reflective of the patient voice

Wyrwich et al 2020

SECTION

2

Open Discussion

Moderated by:
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Research Associate III
Evidera

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THANK YOU!