#### **CONTEXT & OBJECTIVES**

Patient-Reported Outcomes (PROs) are more and more used to support health authorities<sup>1,2</sup>. Their identification and selection is thus a critical step in medical research to assess the medical conditions from the patients' perspectives during clinical trials and clinical practices. Nevertheless, due to the wide variety of instruments available, identifying the most suitable PROs to use in a specific context might be complex. There is no consensus on a standardized method to select PROs considering the medical and scientific context and the regulatory recommendations. Patients' perspectives being and more considered in medical product development and in healthcare decision-making, it appears valuable to take into account their preferences during the PRO selection and development process. This research thus aimed at developing a patient-centric method for PROs selection and applied it in a pilot study on lung cancer.

#### PATIENT-CENTRIC APPROACH TO OPTIMIZE PRO SELECTION

**STEP 1: STATE-OF-THE-ART** adapted to the therapeutic area and field of interest

Identification of **PROs most frequently used** in medical & clinical research

Sources: PubMed & clinicaltrial.gov

**STEP 2: MEDICAL REGULATORY RECOMMENDATIONS** 

Identification of **PRO recommended** by Health Authorities, working groups and consortiums Consultation of **medical experts boards** 

Sources: regulatory guidelines & directives of countries of interest, working groups recommendations in therapeutic area of interest, medical review

> LIST OF OUTCOMES COVERED BY PRO AND **RECOMMENDED BY EXPERTS AND AUTHORITIES**

> > PROs SELECTION

# An innovative patient-centric approach to integrate patients' perspectives in the selection of Patient-Reported Outcomes

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**STEP 4: GAP ANALYSIS** between outcomes covered by PRO, authorities and experts' recommendations and important for patients

NEW PROs DESIGN

**GUIDELINES TO ADAPT PRO** SELECTION TO THE CONTEXT

## PRACTICAL APPLICATION OF THE METHOD IN LUNG CANCER

The newly developed method was applied to address the "value in health" in lung cancer (LC) for patients and caregivers, and published in JMIR (2023)<sup>3</sup>.

### ITEM

#### Daily life

Professional life

Physical functioning and well-being

Emotional well-being

Medical care

Treatment care

End-of-life care

Economic burden

Relationship with HCPs

Caregivers' perspectives

### Major domai

Step 4: Results of the gap

- Identification of discrepand experts and those valued by patients and caregivers.
- caregivers' perspective.

# CONCLUSIONS

This new patient-centric approach presents the advantage of considering patients' expectations in the choice of tools. The methodology developed in this pilot showed the importance of considering patients/caregivers' perspectives and profiles to select appropriate PROs for health products and services development and evaluation.

# **REFERENCES - COMMUNICATION**

cal-devices

2-https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims 3- Varriale P., Müller B., Katz G., Dallas L., Aguaron A. Azoulai M., Girard N. Patient Perspectives on Value Dimensions of Lung Cancer Care: Cross-sectional Web-Based Survey. JMIR Form Res. 2023; 7: e37190. https://www.ncbi.nlm.nih. gov/pmc/articles/PMC9912155/

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#### Steps 1 to 3: Identification of domains: (1) covered by frequently used PROs, (2) recommended by experts and (3) most valued by lung cancer patients and caregivers registered on Carenity.com

	<b>PROs</b> (FACT-L, EG5D-5L, QLQ-C30, QLQ-LC13, ICHOM guidelines)	Medical & HEOR experts (n=4)	Patients & caregivers Online questionnaire (n=150)
k			
;			
S			
ain Minor domain		Iomain	Not represented domain
o analysis cies between domains assessed in existing PROs, those valued by medical and HEOR			

• Need of the development of instruments assessing end-of-life care, economic burden, relationship with HCPs and

• Most important outcomes for patients vary according to their profile: gender, age and cancer stage.

# The increasing importance of Health-Related Quality of Life (HR-QoL) in health-

care decision-making reinforces the need to choose relevant PROs instruments.



1- https://www.has-sante.fr/jcms/p\_3284524/en/real-world-studies-for-the-assessment-of-medicinal-products-and-medi-