

Insights from the European Organisation for Research and Treatment of Cancer

Session 3: Building the Evidence Base for Patient-Centred Clinical Cancer Research

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Disclosures

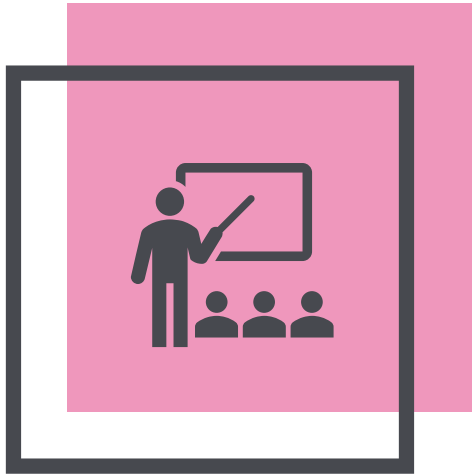
- *No conflicts of interest to disclose*

EORTG history, mission, & activities

- European Organisation for Research and Treatment of Cancer (EORTC) founded in 1962 with mission to **coordinate and conduct international translational and clinical research to improve the standard of cancer treatment for patients**
 - Aim **to increase survival and quality of life**
 - Non-governmental, non-profit
 - Academic independence
 - International network (35+ countries, >1000 institutions, 3000+ members)
 - Multi-disciplinary/multi-tumour:
 - Disease-Oriented Groups (e.g., breast, brain, lung, sarcoma)
 - Cross-Discipline Groups (e.g., elderly task force, **quality of life group**)

<https://www.eortc.org/our-mission/>

Patient involvement at the EORTC



**Training opportunities,
e.g., EORTC
Patient Days**



**EORTC patient
panel advisory
board**



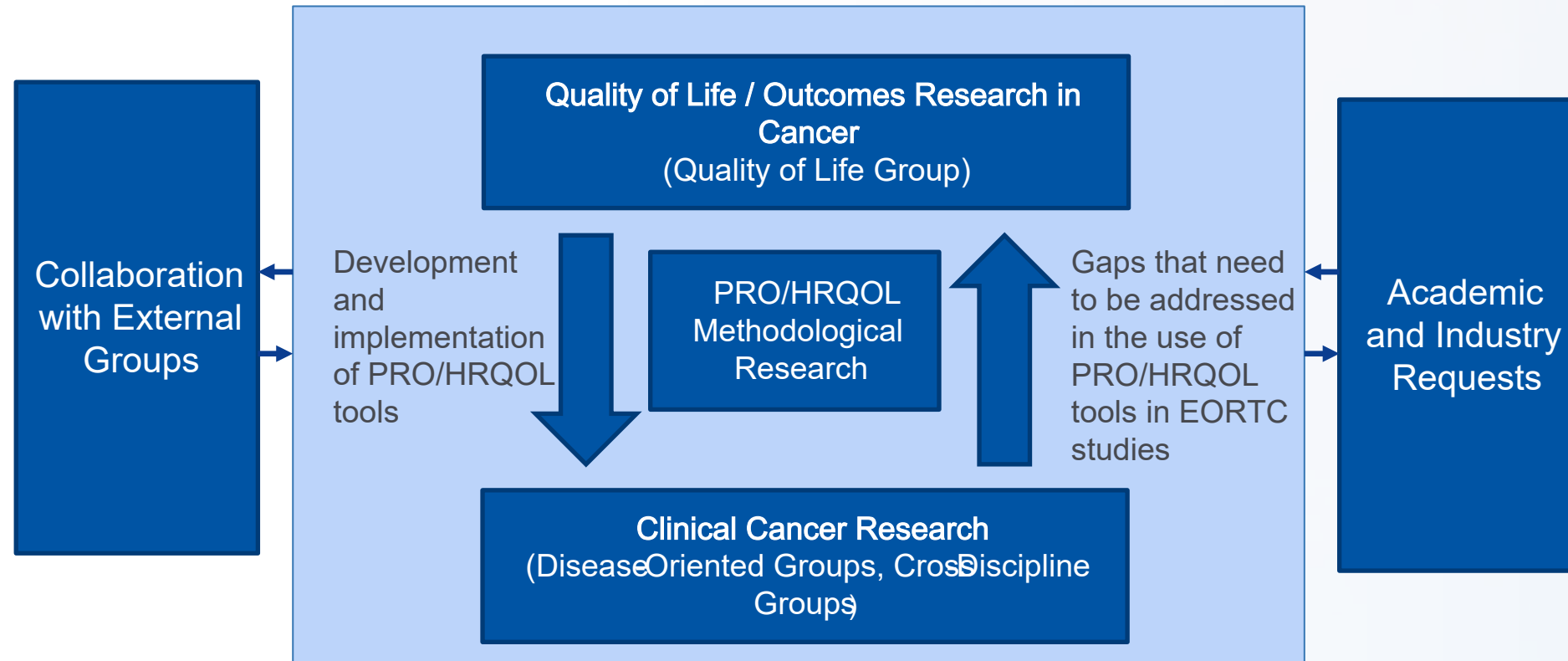
**EORTC group of
patient partners**



**Independent
data monitoring
committee**

<https://www.eortc.org/patient-involvement/>

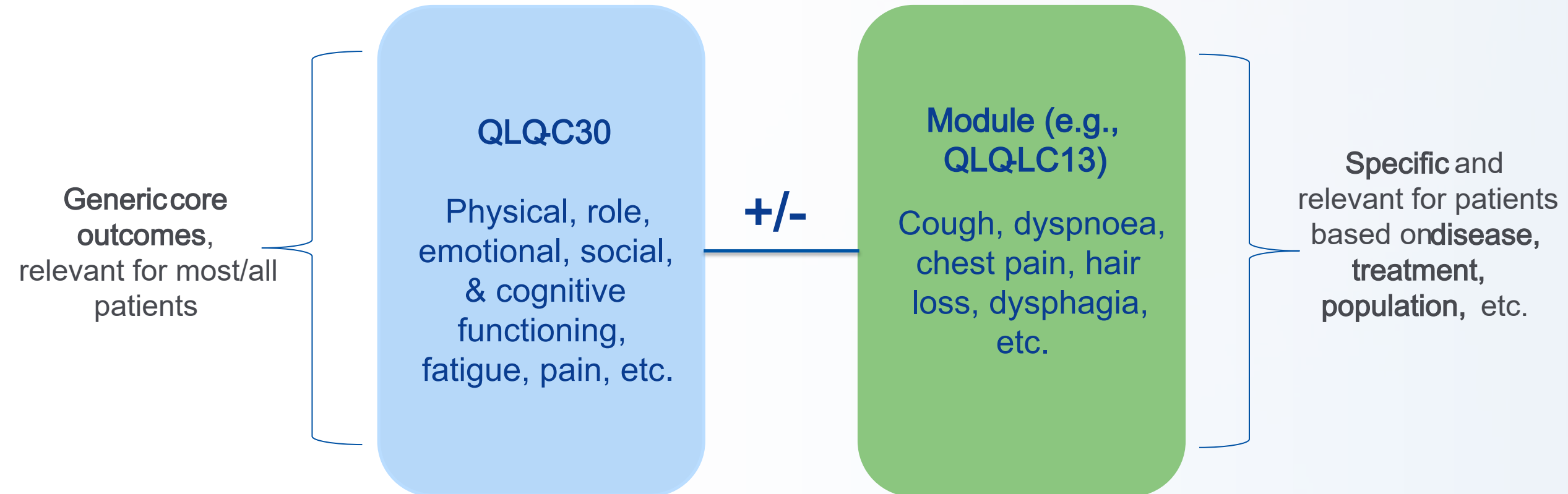
PRO/HRQOL research at the EORTC overview of activities



EORTC PRO/HRQOL measurement strategy built and continues to evolve based on these components

<https://qol.eortc.org/>

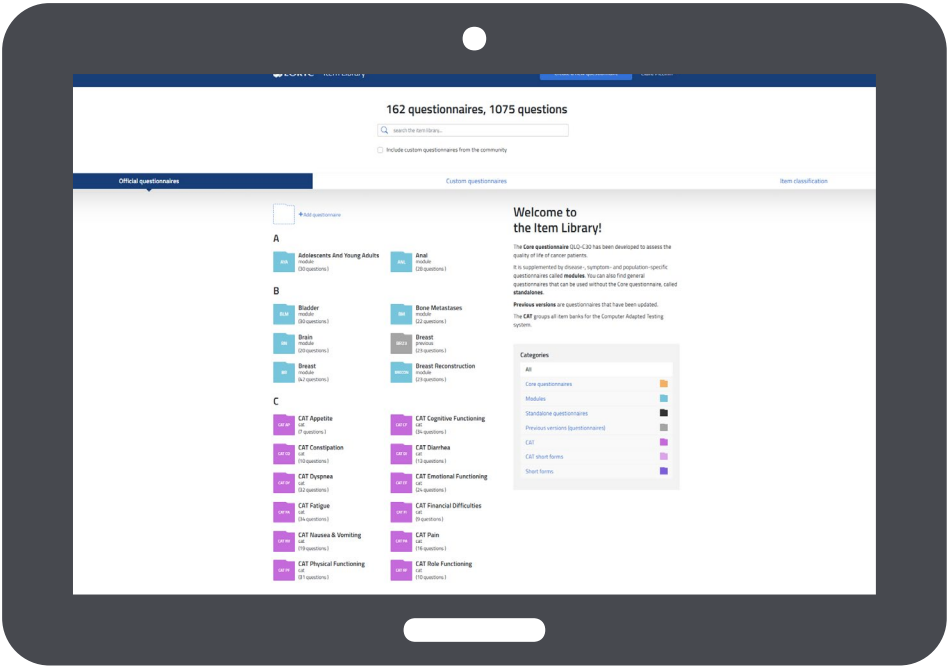
EORTC modular approach to PRO/HRQOL measurement



Aaronson NK et al. The European organization for research and treatment of cancer (EORTC) quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst. 1993;
<https://doi.org/10.1093/jnci/85.5.365>

Bergman B et al. The EORTC QLQ-13: a Modular Supplement to the EORTC Core Quality of Life Questionnaire (QLQ-C30) for Use in Lung Cancer Clinical Trials. Eur J Cancer. 1994;
[https://doi.org/10.1016/0959-8049\(94\)90535-4](https://doi.org/10.1016/0959-8049(94)90535-4)

Current EORTC PRO/HRQOL measurement strategy



EORTC Item Library–online platform

Smart search functionalities

Search results for "cough":

- Q90 - coughing - Have you coughed?
- Q395 - problem coughing - Have you had problems with coughing?
- Q411 - dry cough - Have you had a dry cough?
- Q470 - cough blood - Have you coughed up blood?
- SS85 - coughing - Coughing - scale



Q90 - coughing

Question - Direction: negative - Issue: coughing

expectoration | pulmonary symptoms | cough | coughing

Translated into 108 languages

English

Recommended wording

Have you coughed?

From: Head & Neck, Lung, Oesophago-Gastric and 1 other...

Other wordings

How much did you cough?

From: Lung

Detailed item view

Standard classification | CTCAE classification

- + Cardiac disorders (6)
- + Ear and labyrinth disorders (5)
- + Endocrine disorders (3)
- + Eye disorders (85)
- + Gastrointestinal disorders (304)

Adverse event mapping

Computerised adaptive testing (CAT) core item banks

CAT AP cat (7 questions)	CAT CF cat (34 questions)
CAT CO cat (10 questions)	CAT DI cat (13 questions)
CAT DY cat (32 questions)	CAT EF cat (24 questions)

Customised questionnaires (item lists)

IL46 standalone (1 question)	IL47 module (1 question)
IL5 module (36 questions)	IL50 itemlist (25 questions)
IL53 module (8 questions)	IL54 itemlist (9 questions)

Opened reporting of additional symptoms/problems

Write In three Symptoms or Problems

WISP 1

GENDER Neutral | TYPE Module | CONTACT itemlibrary@eortc.org

1. Have you had any other significant symptoms or problems that have not been mentioned in the questions above?

<https://itemlibrary.eortc.org/>
Piccinin C et al. Flexibility in patient-reported outcome and health-related quality of life measurement: The EORTC Quality of Life Group measurement strategy. European Journal of Cancer. <https://doi.org/10.1016/j.ejca.2025.115392>

EORTC PRO/HRQOL research projects

EORTC Quality of Life Group funded projects

Support for QLQ-C30 & Modules

Support for computerised adaptive testing (CAT)

Support for utility measures

Support for Item Library

Long-term follow-up / survivors

Reviews / meta-analyses

<https://qol.eortc.org/qlg-funded-projects/>
<https://qol.eortc.org/other-projects/>

Additional projects / collaborations



<https://www.sisqol-imi.org/>
<https://euonqol.eu/>
<https://strongaya.eu/>

PRO data for regulatory & HTA assessmentthe European landscape

European-level

Regulatory

When?

Across drug development lifecycle/clinical research continuum

Why?

For benefit/risk assessment, product labeling, patient experience, supportive evidence

How?

Validated & fit-for-purpose PRO measures; consideration of statistical robustness, interpretation thresholds, appropriate endpoints, timing, etc.

VS



HTA

When?

Generally, later in drug development lifecycle (post approval) but joint clinical assessment possible in earlier stages via EU regulation (2021/2282)

Why?

To determine “added benefit” & value, inform cost effectiveness & reimbursement decisions, ensure patient-centredness

How?

Validated & fit-for-purpose PRO & health utility measures; need to compare with standard of care & ensure sufficiently long-term data collection, etc.

Country-specific

Joint EMA-EORTC workshop to support use of PROs for regulatory decisions



29 February 2024
EMA Headquarters,
hybrid in-person/virtual
workshop



Clinicians, patient
representatives, industry,
academia, independent,
and international
regulatory & HTA groups



1. Understand current global landscape on use of PROs for evaluation of anti -cancer treatments
2. Explore use of validated PRO measures & item libraries
3. Facilitate interactions among relevant interest holders to support international collaboration

Joint EMA-EORTC workshop to support use of PROs for regulatory decisions

Action points

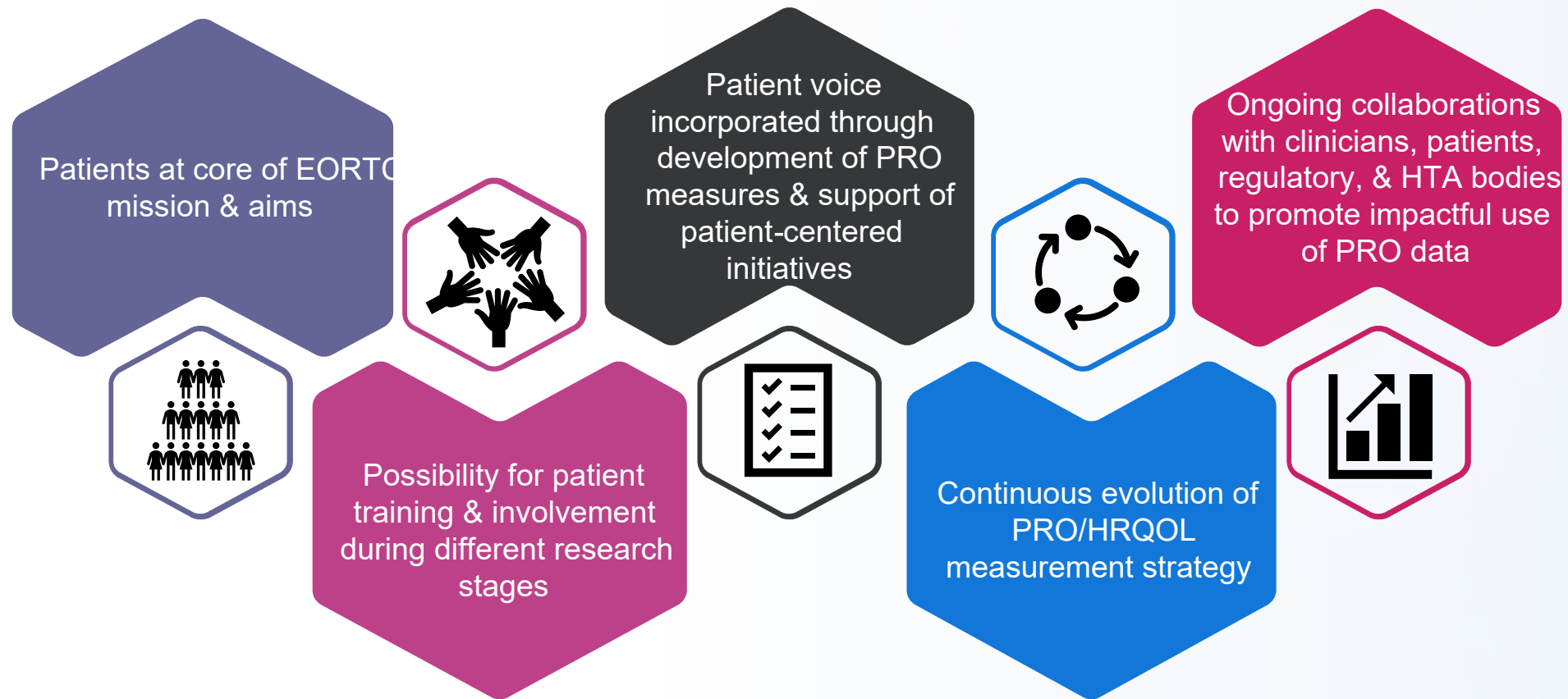
- Need to treat PRO endpoints as any other relevant clinical endpoint
- Implement estimand framework
- Determine meaningful PRO interpretation thresholds
- Adopt SISAQOL-IMI, SPIRIT-PRO, & CONSORT-PRO guidelines
- Harmonise PRO recommendations between international regulatory & HTA bodies



<https://www.ema.europa.eu/en/events/ema-european-organisation-research-treatment-cancer-eortc-workshop-how-can-patient-reported-outcomes-pro-health-related-quality-life-hrqol-data-inform-regulatory-decisions>

Pe M, Voltz Girolt C et al. Using patient-reported outcomes and health-related quality of life data in regulatory decisions on cancer treatment: highlights from an EMA-EORTC workshop. The Lancet Oncology. 2025; [https://doi.org/10.1016/s1473-2149\(25\)00150-0](https://doi.org/10.1016/s1473-2149(25)00150-0)

Summary



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Thank you!

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