european cancer ORGANISATION

Taking a global lead on patient-reported outcome measures: What's holding Europe back?

An ECO Policy Action Report



Acknowledgements

This report draws on the input of experts from across Europe and beyond, and their presentations, contributions and recommendations shared during the European Cancer Organisation (ECO) Community 365[a] Roundtable Meeting, 'Taking a global lead on patient-reported outcome measures. What's holding Europe back?', held online on 13 July 2026.[b]

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b. Find more information concerning the report here: https://www.europeancancer.org/events/445:community365-roundtable-proms-2026

c. European Cancer Organisation's Policy Decision Making Process: www.europeancancer.org/content/policy-decision-making

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Glossary

Common Terminology Criteria for Adverse Effects (CTCAE) – A set of criteria for standardised classification when recording adverse events of drugs and treatments.

EQ-5D – A standardised measure of health-related quality of life developed by the EuroQol Group. It provides a simple, generic questionnaire for use in clinical and economic appraisal and population health surveys.

Electronic health record (EHR) – A digital record of a patient's health and care information which can be accessed and updated by authorised healthcare professionals.

Electronic patient-reported outcome measure (ePROM) – A PROM completed electronically by a patient, for example through an online platform, application or digital health system.

EuroACT – European Atlas of Clinical Trials in Cancer and Haematology

Health-related quality of life (HRQoL) – The aspects of quality of life affected by a person's health, disease or treatment, including physical, emotional, social and functional wellbeing.

Health Technology Assessment (HTA) – A multidisciplinary process used to assess the relative value of a health technology and inform decisions concerning its use and reimbursement.

Patient experience data – Information capturing patients' experiences, needs, preferences and perspectives in relation to their health, disease, treatment or care.

Patient-reported outcome (PRO) – Information about a patient's health status that comes directly from the patient, without interpretation by a clinician or another person.

Patient-reported outcome measure (PROM) – A questionnaire or other structured instrument used to measure a patient-reported outcome.

Quality of life (QoL) – A broad concept reflecting an individual's perception of their wellbeing and ability to live the life they value.

Responder analysis – An analysis examining the proportion of patients whose score changes by an amount considered clinically or personally meaningful, rather than comparing only average changes between groups.

Improving adoption of PROMs in European cancer care

From the case studies, discussions and expert presentations conducted during the Community 365 roundtable event, seven key principles for improved implementation of PROMs in cancer care were identified:



1. Recognise PROMs as a core component of high-quality, person-centred care, research, and decision-making.

Patient-reported information should be considered alongside traditional clinical endpoints to provide a fuller understanding of symptoms, treatment tolerability, functioning, and health-related quality of life, and should not be treated as optional or unreliable data.



2. Make patients and patient organisations partners throughout the PROM lifecycle.

Meaningful involvement of patients and patient organisations should be included in key decisions throughout the processes of:

- Identifying and prioritising what matters
- Selecting appropriate measures
- Methodological design and harmonisation, including trial protocol design
- Implementation and data collection
- Interpretation, communication, and use of the results



3. Collect PROM data with a clear purpose and plan.

The purpose for which information is collected should determine the instrument, timing, methodology, analysis, means of administration, and approach to communicating the results. Because a patient's wellbeing and symptoms change over time, PROMs should be measured repeatedly, including into long-term survivorship, and not treated as a one-off exercise.

During the Roundtable, the following uses and main stakeholders were underlined for clinical practice:

- **Screening** (e.g. for depression or frailty) – of particular interest to clinical teams
- **Monitoring** symptoms over time – of interest to clinical teams, researchers
- **Assessing** outcomes – of interest to researchers
- **Supporting** quality assurance and resource allocation – of interest for healthcare provider management



4. Support clinicians and patients in the uptake and continued use of PROMs by making them fit for purpose, patient-friendly, and meaningful.

PROMs should capture outcomes that matter to patients (e.g. symptoms, functioning, return to work and financial burden, impact on mental and social health), while being accessible and proportionate to the burden of reporting.

- PROMs should be established as a clear part of the clinical process, and not an add-on.
- Concerns from clinicians and patients must be considered, and the relevant safeguards should be built into the process.
- Patient safety must be explicitly protected: systems should include fail-safe mechanisms (e.g. telling patients when their responses will be reviewed and how to seek urgent help).



5. Ensure PROM evidence is robust, transparent, and usable.

- PROM data should be analysed, interpreted, and communicated transparently, including clear consideration of missing data, methodological limitations and uncertainty.
- Imperfect data should not be treated as automatically unusable: limitations and their implications should be described so that the evidence can be used appropriately for the decision at hand.
- Findings should be accessible to the people who need to use them, including patients, clinicians, researchers, regulators, health technology assessment (HTA) bodies , and pricing and reimbursement authorities. When accessible to entities other than the patients and clinicians, PROM evidence should be anonymised.



6. Strengthen European collaboration, interoperability, and alignment in the generation and use of PROM evidence.

- Stakeholders should work together towards greater consistency in standards, methodologies, data infrastructure, and evidence requirements. This includes psychometric interoperability, allowing different instruments to produce comparable information about the same health concept, and alignment with the European Health Data Space to support secure reuse of PROM data across care and research. Sufficient flexibility should remain to reflect different diseases, settings, and patient needs.
- Collaboration is also needed to reduce geographic inequalities in PROM use and research activity across Europe.



7. Make PROMs equitable and inclusive by design.

PROMs should capture the experience of everyone affected by cancer, not only those most able to complete them.

- Instruments, languages, formats and collection methods should be accessible to older adults, people with cognitive impairment or disability, people with limited literacy or digital access, and people who do not speak the dominant national language.
- Completion rates and missing data should be monitored across population groups, so that under-reporting does not become under-recognition of need.

Executive Summary of Recommendations

The recommendations below set out, in brief, the priority calls to action arising from the roundtable. Please find a more detailed version of each recommendation in the respective session.



On embedding PROMs in clinical practice

Recommendations for clinical practitioners, healthcare providers, and health system leaders and commissioners

- Implement PROMs and ePROMs programmes into routine cancer care with a clearly defined purpose and pathway for action.
- Integrate ePROMs with electronic health records and establish clear management and safety protocols for information reported by patients, including fail-safe mechanisms promoting patient safety.
- Design PROM systems with patients and around the realities of patients' lives: ensure that tools are relevant, proportionate, and accessible, that the added value of PROMs is seen throughout the care pathway, and that PROMs are measured repeatedly over time.
- Support clinical teams' adoption of PROMs through engagement, training, clinical champions, and built-in responses to any concerns.
- Implement PROM methodologies and common data standards to ensure interoperability, including psychometric interoperability, and reduce burden.
- Make PROMs programmes inclusive by design, offering validated translations, accessible and non-digital formats and assisted completion, and monitoring completion across population groups to detect and address inequalities.

On strengthening clinical trials through PROMs

Recommendations for trial sponsors, researchers, and regulators

- Build fit-for-purpose PROM strategies into cancer clinical trials from the design stage.
- Use patient-friendly, fit-for-purpose approaches to PROM collection, aligned with the objectives and context of the study and, where possible, with PROMs used in routine care, so that patients are not asked the same questions twice.
- Strengthen the analysis and interpretation of PROM data by reporting the proportion of patients experiencing meaningful improvement or deterioration of their HRQoL. Where relevant, further discuss and involve caregivers who can describe the impact of the deterioration.
- Ensure that PROM findings are reported alongside the principal efficacy and safety findings of cancer trials, where they are important for interpreting benefit and harm.
- Improve the accessibility and transparency of European clinical-trial data, including information on PROM use and reporting.
- Where possible, link PROMs used and collected in clinical practice and clinical trials, limiting duplication.
- Ensure PROM evidence from trials reflects the populations who will receive the treatment, including older adults and groups currently under-represented in European cancer research.

On using PROMs to inform policy and decision-making

Recommendations for regulatory bodies, decision-makers, HTA bodies and payers

- Systematically consider PROM and wider patient experience evidence in regulatory, HTA and reimbursement decisions where relevant and where data are fit for purpose.
- Strengthen alignment between regulatory and HTA approaches to PROMs and alternative endpoints.
- Make meaningful patient-reported findings visible and understandable in regulatory and HTA assessments and related patient-facing information.
- Incorporate PROM data into national cancer quality registers, using common data standards, and explore links with existing national and European data initiatives such as the European Health Data Space (EHDS).
- Characterise and communicate uncertainty in PROM evidence rather than treating imperfect data as automatically unusable.
- Assess whether PROM evidence represents the patients who will use the treatment, and report gaps for under-represented groups, including older adults.



Introduction and background

On 13 July 2026, the European Cancer Organisation (ECO) convened over 150 participants for its Community 365 Roundtable 'Taking a global lead on patient-reported outcome measurement. What's holding Europe back?'. Building on a 2023 ECO Roundtable on patient reported outcome measures (PROMs), the session reflected on how the European landscape has developed since, and what still needs to happen in order to make the development and use of PROMs a widespread reality.

The Roundtable focused on the integration of PROMs and patient-reported outcomes (PROs) in three settings: routine clinical practice, clinical trials, and policy decisions, including regulatory, health technology assessment (HTA), and reimbursement. The purpose was threefold:

- Understand and reaffirm the value of PROMs in these environments.
- Identify what still precludes their meaningful implementation across Europe.
- Reflect on what different actors can do to close this gap.

An important distinction must be underlined: PROs are reports of a patient's health status provided directly by the patient, without interpretation by a clinician or anyone else. PROMs are the instruments used to collect them. Depending on their purpose, PROMs may capture symptoms, functional status, health-related quality of life (HRQoL), treatment burden, or other aspects of a patient's experience. Electronic PROMs (ePROMs) allow these data to be collected digitally and, where the systems are appropriately designed, integrated into care pathways and electronic health records (EHRs).

Dr Nicolò Battisti
Board Member, European Cancer Organisation
Co-Chair, Inequalities Network, European Cancer Organisation



Dr Monica Racovita
Access and Policy Manager, Myeloma Patients Europe)



> **PROMs are not 'soft data': they are clinical data, the way we bring the patient's own voice into the way we treat, run clinical trials, and make decisions about access to treatments. Survival matters, but so do patients' symptoms, quality of life, emotional well-being, and the ability to carry on with the things that make life worth living.**
>
> **Dr Nicolò Battisti**

> **Patient-centred care means ensuring that quality of life and treatment experiences are considered alongside clinical outcomes. Europe now needs a shared approach that embeds PROMs in clinical practice, in clinical trials and in decision-making.**
>
> **Dr Monica Racovita**

Session 1: Embedding PROMs in Clinical Practice

*Co-chaired by **Dr Nicolò Battisti** (Treasurer and Board Member, European Cancer Organisation; Co-Chair, Inequalities Network; Consultant Medical Oncologist, Breast Unit, Royal Marsden NHS Foundation Trust) and **Dr Francesco Fusco** (Director, Health Economics and Outcomes Research (HEOR), Regeneron)*

The first panel focused on how PROMs can be embedded into routine care in ways that improve patient-clinician communication and decision-making. **Dr Battisti** and **Dr Fusco** opened the discussion by highlighting the challenge of translating the growing range of available PROMs into practical tools that can be used effectively in routine clinical care, without overwhelming patients or clinicians.

Embedding ePROMs in Clinical Practice: the Christie example

Prof. Janelle Yorke, Chair Professor of Nursing, Hong Kong Polytechnic University; Honorary Professor, University of Manchester

Prof Janelle Yorke opened the panel with the example of The Christie's ePROM programme, reflecting on how ePROMs can support both patients and clinical teams when embedded into routine care. Prof Yorke chaired the implementation of the programme, which was launched in 2019 to improve communication between patients and their care teams. By 2026, ePROMs had been integrated across 50 services, with more than 40,000 patients having submitted an ePROM, and over 140,000 ePROMs in the EHR.

To collect an ePROM, the patient first receives an electronic invitation from the hospital, usually a text message or an email prompting them to complete the questionnaire. Their responses are then automatically uploaded into the EHR. Based on the model and its complexity, the clinical team may either receive the information in real time or review it ahead of the patient's next consultation.

There are three levels of complexity in ePROMs programmes:

- **Low-complexity 'Asynchronous Model'**: Patient receives and completes the ePROM a few days before an outpatient appointment, and the information is made available to the clinician alongside other clinical information ahead of the consultation. Patients are clearly informed that the questionnaire is not

There are a number of guiding questions that must be decided on when implementing an ePROMs programme:

1. What do you want the ePROM to tell you? (e.g. capture a broad HRQoL profile, monitor treatment-related symptoms, monitor impact of ePROM collection on patients' functioning and wellbeing etc)
2. What is the target patient group?
3. What is the target clinical pathway? (stage of disease, type of treatment)
4. What type of ePROM to use and when? (e.g. at home, a few days before the outpatient appointment)
5. How will data be used? (e.g. clinical decision-making, data analytics)

In addition, a successful programme needs executive and financial support, digital capabilities, project resources, staff, and clinical and patient champions.

monitored, and that urgent symptoms must be reported through the usual clinical routes.

- **Medium-complexity 'Clinician-Supervised Model'**: Patient receives and completes an ePROM a few days before the appointment. A trained member of the clinical team reviews the submission to determine whether the patient requires a face-to-face consultation, a telephone review, or whether the scheduled appointment can be deferred.
- **High-complexity 'Real-time Clinician-Supervised Model'**: Patient submits an ePROM ad-hoc or at set times, and an alert is sent to the clinical team to contact the patient within a set timeframe in case of any concerning symptoms. This type is the most common one in randomised controlled trials including ePROMs for patient monitoring.

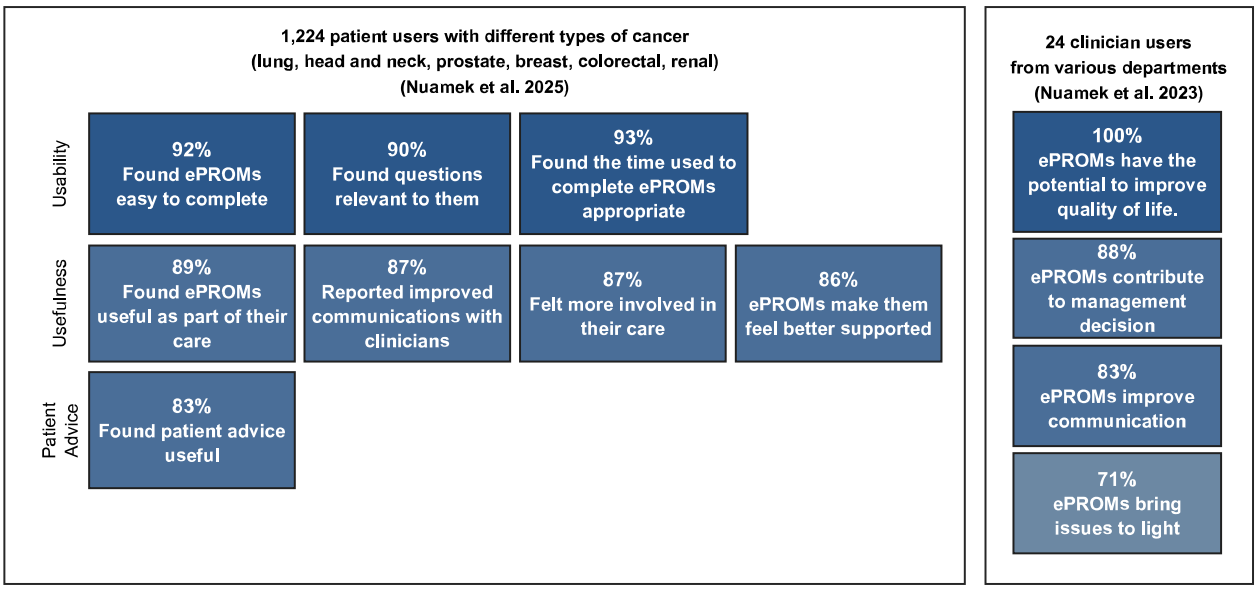
The Christie programme focuses particularly on symptoms related to acute and long-term treatment-related toxicity. A broad item pool was developed based on the Common Terminology Criteria for Adverse Events (CTCAE),[1] from which clinical teams could select the questions most relevant to their patients. The EQ-5D[2] measure was also included to create a common dataset that could support wider assessment of HRQoL, economic evaluations (i.e. cost-effectiveness analyses) and health economic analysis across disease groups. To support more accurate patient reporting, pictograms were also added to some questions.

Reflecting on the successful uptake and continued use of ePROMs, Prof Yorke highlighted the importance of **ownership and practical feasibility for patients and clinicians**.

- For patients: Patients may discontinue completion of the questionnaire if they feel that the data is not being used to improve their care, or if the process is too long or burdensome.
- For clinicians: To reduce the burden, ePROMs should be integrated into the clinical workflow, enabling clinicians to use them as part of routine care, rather than treating them as an add-on.

At the Christie Hospital, ePROM responses are integrated into and displayed within the patient's EHR, alongside blood test results, scan results, and other clinical information. This allows clinicians to track changes in the patient's symptoms and their severity over time, alongside other aspects of their clinical history. Feedback from both patients and clinicians on ePROM use has been highly positive.

Patient Care - Patient and Clinician Reported Experiences



1 CTCAE is a set of criteria for standardised classification when recording adverse events of drugs and treatments.

2 EQ-5D is a standardised measure of health-related quality of life developed by the EuroQol Group. It provides a simple, generic questionnaire for use in clinical and economic appraisal and population health surveys.

Beyond their role in patient care, ePROMs also offer an opportunity to build a real-world dataset linking PROs with clinical data. Prof Yorke described emerging work using these linked data in prognostic models, including models predicting treatment completion and survival. She noted that adding patient-reported symptoms and QoL information could improve predictive performance, illustrating the potential secondary value of high-quality routine data.

Learnings from the Charité Centre for PRO Research

Prof Matthias Rose, Chair, Department of Psychosomatic Medicine, Charité Centre for PRO Research

The Christie example illustrated the practical considerations involved in embedding ePROMs into routine clinical care. Building on this, **Prof Matthias Rose** discussed the experience and learnings of the Charité Centre for PRO Research in selecting and designing PROMs programmes. His key message was that **the choice of PROM should follow what the programme is intended to achieve**. For clinical practice, these may be distinguished into four main uses:

- Screening (e.g. for depression or frailty) – of particular interest to clinical teams
- Monitoring symptoms over time – of interest to clinical teams, researchers
- Assessing outcomes – of interest to researchers
- Supporting quality assurance and resource allocation – of interest for healthcare provider management

These different purposes may require different tools, levels of methodological rigour, and approaches to implementation. Successful PROMs programmes need to address these perspectives simultaneously, without requiring patients to repeatedly provide overlapping information. The Charité approach combines regular assessment of eight health domains across physical, mental and social health, in accordance with the PROMIS system[3], to create a core patient-reported dataset, with additional targeted measures where clinically required (e.g. for precision oncology).

Rather than requiring every setting to use an identical instrument, Prof Rose drew attention to **psychometric interoperability**: the ability to use different instruments and produce comparable information about the same underlying health concept. For example, item banks can link different questions that measure the same aspect of health. This approach allows PROMs to be adapted to different clinical settings and patient needs while maintaining the ability to compare results across instruments or populations. Without such interoperability, using different tools for the same concepts limits comparison across settings and studies. This can lead to duplication of efforts not only for the collector, but also for the patients, who may be asked overlapping questions repeatedly, increasing the burden of reporting.

Similarly, for digital systems, PROM information should be integrated into **EHRs and made interoperable across clinical and research environments**, rather than requiring patients to repeatedly submit overlapping information through disconnected platforms. However, digital capacity varies considerably between healthcare providers, making **common data standards** essential for wider implementation.



3 The Patient-Reported Outcomes Measurement Information System (PROMIS) initiative developed new ways to measure PROs and their impact on quality of life across a variety of chronic diseases.

The patient perspective on the use of PROMs in clinical practice

Gilliosa Spurrier-Bernard, Board Member and Co-Chair of the Patient Advisory Committee, European Cancer Organisation & Vice-President, Melanoma Patients Network Europe

Gilliosa Spurrier-Bernard drew on her personal experience and her advocacy work within the melanoma patient community to reflect on the sue of PROMs and patient experience data in practice. She noted that, although there has been positive change over time, significant differences remain between **what affects patients during diagnosis, treatment and survivorship and what is captured by healthcare professionals and other stakeholders**.

Spurrier-Bernard described her husband's experience participating in a trial for metastatic melanoma. The validated PRO tool, based on extensive patient reporting, showed no difference between the placebo and treatment arms, despite more than half of the participants discontinuing due to treatment-related toxicity. The example illustrated that **extensive patient reporting does not offer insight into the patient experience if the right questions are not asked at the right time, or if they do not cover the right information**.

She also reflected on the **difficulties of translating complex lived experiences into standardised reporting categories**. Patients and healthcare professionals may be required to fit symptoms and their impact on everyday life into predetermined frameworks which do not necessarily reflect what patients themselves consider most burdensome. Symptoms classified as relatively low-grade from a clinical perspective may have a significant cumulative effect on work, family responsibilities, relationships, and day-to-day functioning.

At the same time, **patients may under-report treatment effects if reporting becomes burdensome or appears unlikely to result in meaningful action**. If patient reporting systems are difficult to use, poorly timed or disconnected from practical support, the resulting evidence can underestimate the real burden of treatment. To combat this, **patient-reporting systems should be built around accessibility, privacy, simplicity, and agency over own data**. Long-term and cumulative toxicity must also be considered, including treatment effects which may persist well beyond the period traditionally captured in a clinical trial.

Spurrier-Bernard welcomed the growing recognition of the importance of **mixed-method approaches, social science methodologies and meaningful patient engagement** in research. For patient experience and PRO data to inform implementation and system change, they need to be clear, robust and representative. Patient organisations can play a significant role in this process, through their trusted relationships with patient communities and growing experience collecting patient experience data.

To conclude, Spurrier-Bernard stressed the need for **collaboration across the whole community**. As health systems are complex, non-linear, and constantly adapting, all stakeholders need to understand their complexity and work across organisational borders.

> **With meaningful collaboration, all stakeholders can find the solutions to anchor equity and patient-centred lived experiences in cancer care.**
>
> **Gilliosa Spurrier-Bernard**

Discussion

The following Q&A discussion focused on the practical conditions needed to implement PROMs successfully.

In **tackling scepticism among healthcare professionals**, Prof. Yorke stressed the importance of listening to clinicians' concerns and adapting implementation accordingly. Concerns often relate to workload, patient safety, and medico-legal responsibility. For example, in an asynchronous model, a patient could report a serious symptom through an electronic questionnaire which was not intended to be monitored immediately. To tackle this, the programme explicitly informed patients when their ePROM would be reviewed and instructed them to use usual clinical routes for urgent concerns. Clinical ownership was also important to enhance trust: for this, clinical teams were able to decide when questionnaires should be sent and which questions were most relevant to their patient group.

Prof. Rose returned to the question of **validation and usability**. Instruments developed for research may be too extensive for frequent use in routine care, and different requirements can therefore apply depending on the purpose of data collection.

The panel also discussed the use of real-world PROM data for research. Prof. Yorke acknowledged that routine real-world data may not always be subject to the same validation procedures as data collected through research studies. However, she stressed that the Christie programme was primarily designed to support symptom reporting and clinical decision-making, with research use as a secondary objective. Prof. Rose agreed that **primary clinical use should come first**, adding that useful secondary research applications are unlikely to emerge if the system does not first work in routine care.

Spurrier-Bernard highlighted the importance of ensuring that digital systems include **management protocols, clear follow-up responsibilities, next steps and documentation of action**, so that information consistently loops back towards an appropriate and timely response for the individual patient.

The networks of comprehensive cancer centres and breast units (e.g. EUSOMA, ECIBC) have been highlighted by relevant stakeholders as important settings for the collection of routine PROMs in clinical practice. These centres have multidisciplinary teams and established data-collection processes, which can help embed PROMs in the clinical workflow. A shared approach across such networks could also make PROM data comparable between sites, supporting benchmarking, quality improvement and, where relevant, national cancer quality registers.

SPOTLIGHT: The EUonQoL Project

EUonQoL

Funded by the European Union

The European Cancer Organisation is a member of the EUonQoL project, coordinated by the Fondazione IRCCS Istituto Nazionale dei Tumori (INT) in Milan, Italy, and running between January 2023 and December 2026. This European Union-funded research initiative is developing, piloting and validating the EUonQoL-Kit, a digital set of questionnaires for assessing the QoL of cancer patients undergoing active treatment, cancer survivors, and cancer patients receiving palliative care, covering their physical, social, and overall health, and psychological wellbeing.

RECOMMENDATIONS ON EMBEDDING PROMS IN CLINICAL PRACTICE

- **Implement PROMs and ePROMs programmes into routine cancer care with a clearly defined purpose and pathway for action**. Healthcare providers should select the appropriate PROM and timing considering its intended purpose, the target patient group and clinical pathway, the stakeholders interested in the information, the type of PROM, and the subsequent use of data. Patients contributing data may also benefit directly: more data can support better-informed decisions and lead to better health outcomes.
- **Integrate ePROMs with electronic health records and establish clear management and safety protocols for information reported by patients, including fail-safe mechanisms promoting patient safety**. Systems should identify who reviews the information, how concerns are followed up, what action is required and how that action is recorded.
- **Design PROM systems with patients and around the realities of patients' lives**.
  a. Tools should be relevant, accessible and proportionate in length and frequency, with patient organisations involved in identifying what matters and how information can realistically be collected.
  b. Patients should feel the added value of PROMs on their care pathway and see the results of the data they contribute; the PROM should reflect what truly matters for their quality of life, including return to work and financial burden.
  c. PROMs should be measured repeatedly over time, including long-term survivorship.
- **Support clinical teams' adoption of PROMs through engagement, training, clinical champions, and built-in responses to any concerns**. Implementation should actively address concerns around workload, safety and medico-legal responsibility, involve clinicians in designing workflows, and use experienced clinical champions to support wider uptake.
- **Implement PROM methodologies and common data standards, promoting psychometric interoperability**. Ensure that PROM information is interoperable to avoid duplication and unnecessary burdens on patients and clinicians. Interoperability applies both to systems, through common data standards that allow PROM information to be exchanged and reused, and to the instruments themselves, through psychometric interoperability, which allows results from different tools to be compared.
- **Make PROMs programmes inclusive by design**. PROM programmes should offer validated translations and accessible formats, support assisted completion or, where appropriate, clearly identified proxy completion, and monitor completion and missing data by age, sex, socioeconomic status, language, geography, or other relevant characteristics, in line with data protection requirements. Non-digital options should be maintained alongside ePROMs (e.g. for older patients or where digital access is limited). Nevertheless, where possible, promote the use of ePROMs, given their easier integration into the systems.

Session 2: Strengthening Clinical Trials Through PROMs

*Co-chaired by **Dr Nicolò Battisti** (Board Member & Co-Chair of the Inequalities Network, European Cancer Organisation; Consultant Medical Oncologist, Breast Unit, Royal Marsden NHS Foundation Trust) and **Dr Monica Racovita** (Access and Policy Manager, Myeloma Patients Europe)*

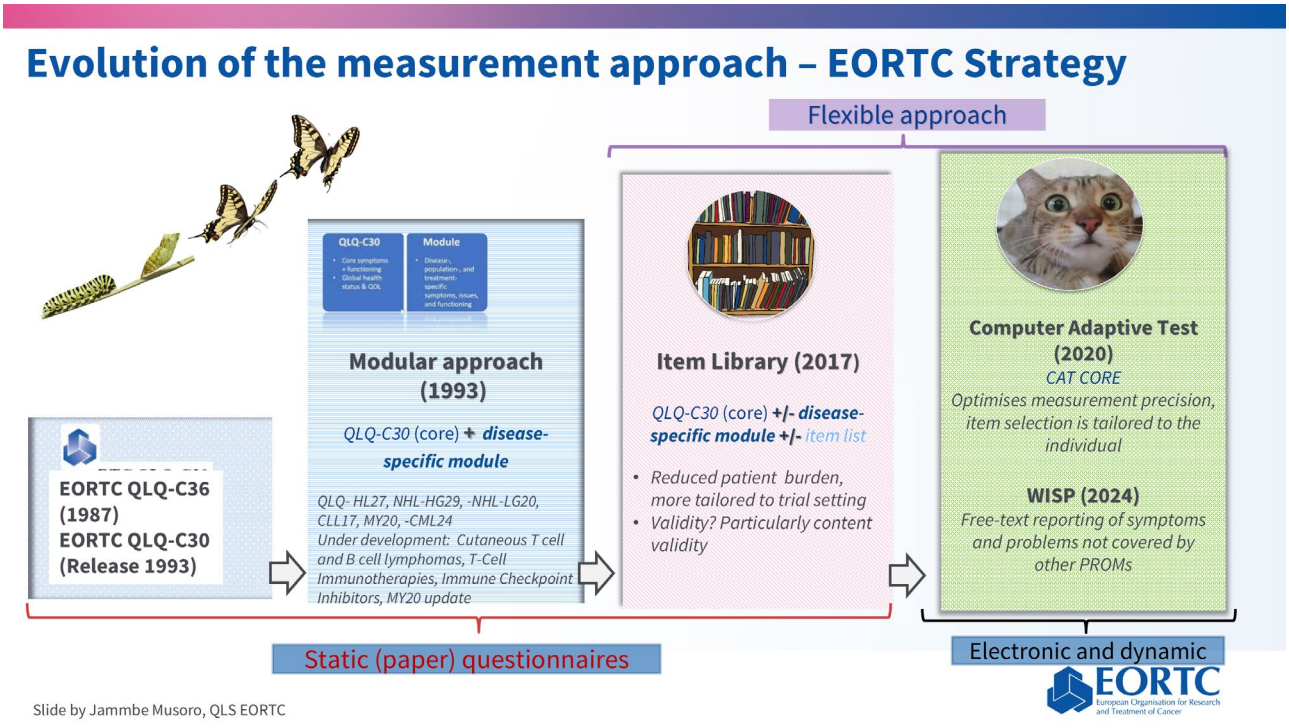
Introducing the second session, **Dr Monica Racovita** emphasised that clinical trials are one of the first major opportunities to collect patient-reported evidence for a new treatment. She noted that the issue concerns both pre-authorisation clinical trials and post-authorisation research and framed the session around two questions: **how PROMs can be built strongly into trial design and how the resulting data can subsequently be used meaningfully**.

Why PROMs are so useful and important in clinical trials – the story in Europe so far

Prof. Dr Bernhard Holzner, Founder and Leader, Patient-Reported Outcomes Working Group, Medical University of Innsbruck

> **Outcomes cannot always be fully assessed by clinicians alone – we need the voice of the patient to capture information about symptoms, functioning, health-related quality of life and treatment burden.**
>
> **Prof. Bernhard Holzner**

Prof. Bernhard Holzner provided an overview of the development of PROMs in cancer research and stressed that the rationale is essentially the same in trials as in routine care.



The European Organisation for Research and Treatment of Cancer (EORTC) has been a highly important institution for developing standardised PROM questionnaires for clinical trials. Amongst others, the EORTC created the **EORTC QLQ-C30** (released in 1993), assessing physical, social, cognitive and emotional functioning alongside important cancer symptoms across cancer types. This is widely used worldwide in oncological clinical studies.

To complement the core questionnaire, the EORTC subsequently developed **disease-specific modules,** an **item library** of over 400 validated items, and two electronic and dynamic approaches.

The use of QoL endpoints in EORTC clinical trials has increased substantially over time: from 28% between 2000-2009, to 91% between 2020-2026. In the 2020-2026 period, the core questionnaire was used in all trials, over half used a disease-specific module, and 76% included an item list.

Trial data on PROs and QoL may then impact decision-making:

- Regulatory decision-making and label claims: confirmatory or supporting evidence for risk-benefit assessments
- Reimbursement decisions
- ESMO Magnitude of Clinical Benefit Scale score: contribute to measuring the value of anti-cancer therapies
- Facilitate shared clinician-patient decision-making
- Use by patient organisations for informing patients and strategic planning

Prof. Holzner then highlighted two of EORTC's initiatives in this field. Firstly, the **SISAQOL-IMI initiative** has sought to create international, multistakeholder consensus on the use of HRQoL and PRO data in cancer clinical trials, and to improve their statistical analysis, reporting and interpretation. This work contributes to an overall better use of data for regulatory approvals, HTA assessments, and shared decision-making. To support implementation, the EORTC has developed a final publication, an interactive table with recommendations based on PRO endpoint and objective, and other tools including a guidebook with detailed information, a patient checklist, and educational videos.

Secondly, the **CTCAE+PRO project** examined whether the inclusion of graphical PRO feedback in clinical studies could improve the assessment and grading of treatment-related side effects using CTCAE. In the study, clinicians were shown graphical feedback based on patient-reported symptom information. The results showed improved agreement between raters for most of the symptoms examined, illustrating that PRO information does not need to remain hidden from clinicians until a trial is completed. Patient-reported evidence can also potentially be fed back during research and contribute to the assessment and management of adverse events.

To conclude, Prof. Holzner summarised the value of PROMs for clinical trials: gaining a more comprehensive evaluation of treatment effectiveness and treatment tolerability, facilitating comparisons between therapies, and generating evidence relevant to regulators, payers, clinicians, and patients.

How PROM and QoL data are analysed and communicated in clinical trials

Prof. Ian Tannock, Emeritus Professor, Princess Margaret Cancer Centre; Founding Member, Common Sense Oncology

Continuing the discussions, **Prof. Ian Tannock** reflected on how QoL results are analysed and communicated in cancer trials.

He questioned the frequent reliance on **mean changes in QoL scores** between treatment groups. Average values can conceal considerable variation: one group of patients may experience meaningful improvement while another deteriorates, even where the mean difference between the groups appears small.

Prof. Tannock therefore pointed to a recent study conducted by the EORTC and Common Sense Oncology, advocating for the use of responder criteria to evaluate QoL in clinical trials.

This would allow findings to show the proportion of patients experiencing a meaningful improvement or deterioration, which can be particularly useful for communication with patients.

> **It is much easier to approach a patient and say: 'With this treatment, the clinical trials suggest you have perhaps a 30% chance that your quality of life will substantially improve.'**
>
> **Prof. Ian Tannock**

A forthcoming publication will focus on the importance of patient-reported information in the adjuvant treatment setting: patients in these trials may have few or no symptoms from their cancer but experience toxicity from treatment. Where treatment produces a relatively small absolute benefit, he argued that patients should also have clear information about the likelihood of important QoL effects.

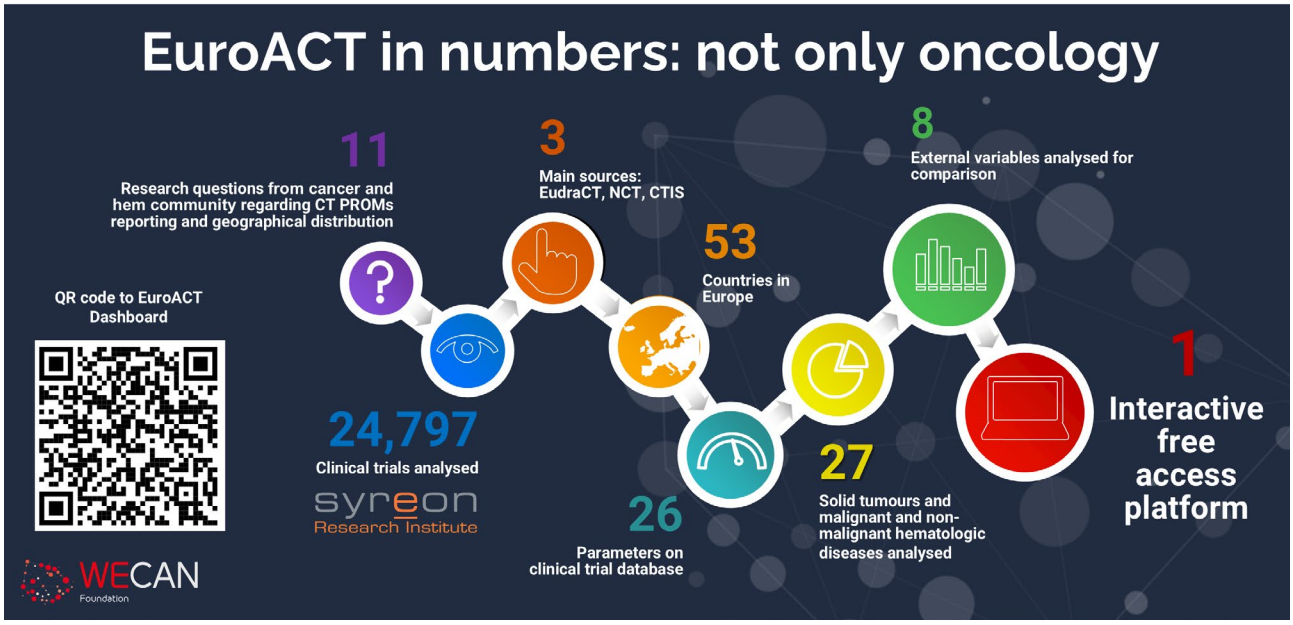
A further concern was **missing data**, as patients whose QoL is deteriorating may be more likely to discontinue treatment or stop completing questionnaires. If this is not properly considered, trial findings can give an incomplete picture; therefore, a sensitivity analysis should be done to account for these participants.

Finally, he argued that where QoL findings are important to understanding the balance of treatment benefits and harms, they **should be reported in the primary trial publication, rather than appearing only later in a secondary paper**.

From data to action: Lessons from EuroACT on PROMs and cancer inequalities in Europe

Dr Lis Puga, Research Manager, EuroACT

Dr Lis Puga presented findings from the **European Atlas of Clinical Trials in Cancer and Haematology (EuroACT)**, a patient-led research initiative run by WECAN and the European haematology community, examining clinical trial activity, PROM inclusion and geographical variation across Europe. The project analysed **more than 24,000 clinical trials,** and the information has been brought together in a free interactive EuroACT dashboard which allows users to compare countries, examine PROM use and reporting, and explore individual disease areas.



The data demonstrate a **highly unequal geographic distribution** of cancer research activity across Europe, with France, Germany, Italy and Spain accounting for almost half of oncology clinical trials initiated in Europe since 2015, while Central and Eastern Europe are markedly underrepresented.[4] While PROM inclusion has increased over recent years, the study revealed that **only 41% of oncology trials initiated in 2024 included PROMs as either primary or secondary endpoints**. This concentration has direct implications for equity. Patients in many Central and Eastern European countries have fewer opportunities to take part in clinical trials, and the patient-reported evidence informing European decisions is generated in a limited number of health systems and populations.

The EuroACT findings were included in the Organisation for Economic Co-operation and Development's (OECD) 'Delivering High Value in Cancer Care', and will also be used for the 2027 EU Country Cancer Profiles, therefore shaping policy and action at European level.

The wider EuroACT evidence base is also being used to inform a white paper and policy recommendations aimed at strengthening PROM use and promoting more equitable cancer research in Europe. **A concrete set of actions based on the evidence collected is being proposed by the EuroACT Steering Committee to European institutions, regulators, and industry**:

- Elevate the importance of PROMs for regulatory decision-making
- Enable flexible, patient-friendly PROM data collection methods
- Align PROM tool selection with study objectives while avoiding excessive burden on patients
- Promote transparent and consistent reporting of PROM methods and results
- Ensure visibility, timely publication, and accessibility of PROM results generated in clinical research

Session discussion

Building on the presentations, the discussion first considered **whether awareness of treatment allocation could influence PROM responses**. Prof. Tannock noted that patients may have different expectations depending on whether they receive active treatment or a control. Additionally, blinded trials may become unblinded when treatments have sufficiently different toxicity profiles for participants to infer which treatment they are receiving.

Participants also discussed the **relevance of PROMs in earlier-stage research**. Prof. Tannock emphasised their importance where large trials identify a relatively modest survival gain but affect a much larger proportion of patients through treatment-associated toxicity. In these situations, understanding the trade-off between benefit and QoL is particularly important for treatment decisions. Dr Puga emphasised the importance of the quality of PROM use and suggested that collecting patient-reported information earlier in clinical development could identify treatments with an unfavourable QoL impact before larger trials.

Closing the session, Dr Battisti stressed that PROM evidence should not simply disappear once a clinical trial ends. Evidence generated in trials can subsequently contribute to **marketing authorisation, Joint Clinical Assessment under the EU HTA Regulation, and national HTA and reimbursement decisions**.

RECOMMENDATIONS ON STRENGTHENING CLINICAL TRIALS THROUGH PROMS

- **Build fit-for-purpose PROM strategies into cancer clinical trials from the design stage**. This should apply across both pre- and post-authorisation evidence generation and should begin with clarity about the purpose of PROM collection. Pre-specify HRQoL domains to be assessed, timings of the measurement and re-measurement, threshold for meaningful change, and approaches to missing data and interpretation.
- **Use patient-friendly, fit-for-purpose approaches to PROM collection**. PROM tools and data collection methods should be aligned with the objectives and context of the study, while using flexible approaches and avoiding unnecessary burden on patients, including by aligning with PROMs used in routine care where possible.
- **Strengthen the analysis and interpretation of PROM data**. Where appropriate, report the proportion of patients experiencing meaningful improvement or deterioration, rather than relying only on average changes, and account for missing data in the analysis. Furthermore, it is suggested that PROM data be considered as a potential requirement of publicly funded clinical trials.
- **Ensure that PROM findings are reported alongside the principal efficacy and safety findings of cancer trials**. Where QoL findings are important for interpreting the overall treatment effect, they should not routinely be deferred to later secondary publications. Include PROMs as co-primary or important secondary endpoints where treatment benefit is modest, toxicity is long-term, or treatment intent is palliative.
- **Improve the accessibility and transparency of European clinical-trial data, including information on PROM use and reporting**. Better public data can help identify geographical and disease-specific gaps and support more equitable clinical research across Europe.
- Where possible, **link PROMs used and collected in clinical practice and clinical trials**, limiting duplication.
- **Ensure PROM evidence reflects the populations who will receive the treatment**. Broaden eligibility and recruitment of under-represented groups, including older adults and people with comorbidities. Include the domains that matter most to them, such as physical function and independence. Extend trial activity beyond the small number of countries where research is concentrated, and report PROM completion and results by relevant subgroups.



Session 3: Using PROMs to Inform Policy and Decision-Making

*Co-chaired by **Dr Monica Racovita** (Access and Policy Manager, Myeloma Patients Europe) and **Jose Diaz**, Lead of Global Health Economics and Outcomes Research – Health Systems Economics & Value of Innovation, Bristol Myers Squibb (BMS)*

The third session examined the role of PROMs and wider patient experience evidence in regulatory, HTA and reimbursement decision-making. In opening the discussion, **Jose Diaz** highlighted the importance of considering the full evidence pathway: information is generated in research, interpreted by regulators and HTA bodies, and ultimately used to make decisions that affect patient access.

How regulators use patient-reported outcomes

Francesco Pignatti, Scientific Adviser in Oncology, European Medicines Agency

Francesco Pignatti provided an overview of how PROs are currently considered in oncology regulation. Pointing to the 2016 EMA guidance on PROs in cancer drug development, he stressed that current regulatory discussions recognise PROs as relevant evidence in oncology, but their role depends on purpose and evidentiary strength. PROM analyses are frequently included in pivotal oncology trials, commonly as secondary or exploratory endpoints, and PROM evidence may be used by developers to demonstrate improvements or provide evidence that a treatment does not cause a deterioration. Nevertheless, interpretation requires consideration of methodology, including **instrument choice, study design, missing data, and multiplicity.**

Pignatti then pointed to a 2022 review of PROs in EU oncology approvals between 2017-2020, answering the question 'How does EMA account for PROs in regulatory decision-making?'.

He stressed that PROs not featured in the labelling information does not signify they were not included in the assessment. Whether a finding appears in product information depends on several factors, including the **purpose for which the PROM was collected, the quality of the methodology, and whether the finding is appropriate for communication as a formal claim**. PROMs may be collected to support a comparative efficacy claim, but they may also be used to contextualise toxicity or inform the wider therapeutic context considered in benefit-risk assessment.

A **systematic, purpose-driven approach** is therefore necessary: stakeholders should first decide whether patient-reported information is needed and what decision it is intended to inform. The methodology should then be proportionate and fit for that purpose, and the resulting evidence should be communicated transparently. He also referred to EMA's work on **patient experience data**, noting that this extends beyond PROMs to other forms of evidence, including patient preference information and different approaches to patient engagement.

> **The question is not whether PROs matter – they do. For regulators in Europe, the next step is to consider PROM evidence systematically, align the collection methodology to the purpose, and communicate effectively and transparently.**
>
> **Francesco Pignatti**

Recognising the value of alternative endpoints

Sahana Joish, Director, Global Market Access, Bristol Myers Squibb

Sahana Joish presented work from the ongoing **Intrinsic Value of Alternative Endpoints** initiative. She began by noting that cancer treatment has changed substantially: as patients with many cancers are living longer, new treatments may seek not only to extend survival but also to delay disease progression, maintain disease control, preserve QoL and reduce the wider burden experienced by patients and caregivers.

How does EMA account for PROs in regulatory decision-making?

Evidence from EU oncology approvals, 2017–2020

78%	59%	17%
PROs collected	**PROs discussed**	**PRO claim in SmPC**
100 of 128 indications included PRO data in confirmatory trials	EMA assessment reports explicitly discussed PRO evidence for 76 of 128 indications	22 of 128 indications translated PRO evidence into product information

Interpretation

PROs are frequently collected and can inform EMA assessment, but their regulatory impact is selective. Impact on label depends on fit-for-purpose instruments and credible design, conduct and analysis — particularly open-label bias, missing data and PROM selection.

ASSESS ≠ LABEL

Source: Teixeira MM et al. Front Med. 2022;9:968272. Review of PROs in EU oncology approvals (2017–2020).

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Classified as public by the European Medicines Agency

Overall survival remains an important endpoint for demonstrating clinical benefit where it can be established, but may take many years to mature or be difficult to interpret due to treatment crossover, subsequent therapies, or changing standards of care. The initiative therefore aims to understand **when, why and how alternative endpoints may capture benefits that are meaningful to patients and how those benefits can be evaluated alongside survival**.

Joish argued that current assessment frameworks should better reflect patient experiences and preferences, and that alternative endpoints should be considered systematically alongside traditional measures rather than replacing them. The work therefore seeks to develop a more harmonised framework which could improve consistency across HTA bodies, increase transparency and guide evidence generation, and create greater alignment between regulatory and HTA approaches.

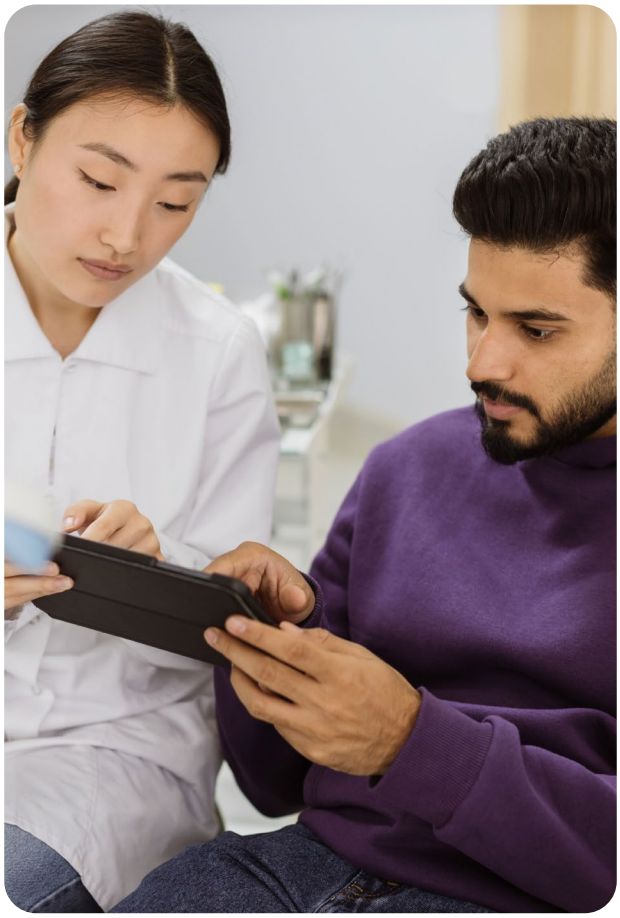
The work involves a multistakeholder expert advisory panel, including patients and patient advocates, clinicians, HTA experts, economists, regulators, methodological experts and academic researchers. It examines what outcomes matter to patients, how disease control is experienced, and how different endpoints relate to aspects of health and wellbeing considered important, such as **maintaining independence, reducing anxiety, preserving QoL, maintaining disease control and being able to plan for the future**. Joish stressed that the project does not seek to prescribe decision-making or advocate for one particular endpoint, but to support more structured and transparent consideration of the different ways treatment benefits can be measured and valued.

Patient perspectives: Putting QoL at the centre of treatment assessment

Susanne Dieroff Hay, President, Swedish Breast Cancer Association; Executive Board Member, Europa Donna

Susanne Dieroff Hay reflected on PROMs from the perspective of people living with breast cancer. As breast cancer survival improves, it is increasingly becoming a long-term condition for many people, but longer survival may be accompanied by prolonged treatment and toxicity. Therefore, while important, survival **is not the only outcome that matters to patients**. Patients experience cancer through its effect on everyday life: their ability to work, sleep, care for family, maintain relationships and live the life they value, which cannot be captured through clinical parameters only. PROMs can therefore generate evidence relevant to treatment decisions, clinical trials, regulatory and reimbursement processes and long-term survivorship care.

Dieroff Hay argued that QoL deserves an important place in clinical trials, as it helps assess treatment benefit alongside its potential harms: a treatment can extend life while also causing toxicity, pain or disability. This applies differently in curative and metastatic settings: in curative treatment, patients may accept significant toxicity in exchange for the possibility of long-term survival. In metastatic disease, where treatment is typically not curative, preserving or improving QoL alongside prolonging life can become particularly important.



Concerningly, however, QoL outcomes remain secondary or exploratory in many trials, sometimes with limited long-term follow-up or incomplete reporting. Dieroff Hay argued that regulators should not simply accept PROM evidence when it happens to be submitted, but should **expect it where relevant, assess its quality and make findings visible in labels, public assessment reports and patient-facing information**. Additionally, because patient wellbeing and symptoms can change over time, she stressed that **PROM measurement should be repeated, not a one-off exercise**. Dieroff Hay set out several specific proposals to strengthen the use of PROM evidence:

- Include PROMs as co-primary or important secondary endpoints where treatment benefit may be modest but the QoL impact is substantial, toxicity is long-term, or treatment intent is palliative
- In trial protocols, pre-specify the QoL domains to be assessed, the timing of measurement, thresholds for meaningful change, approaches to missing data and interpretation
- Require PROMs in publicly funded breast cancer trials
- Include PROM plans in HTA and reimbursement submissions
- Incorporate PROMs into national cancer quality registers
- Publish QoL findings alongside efficacy findings
- Provide lay summaries of PROM results for patients, ensuring that patients providing data can review the results of their contribution
- Invest in digital ePROM systems while maintaining non-digital options
- Involve patient advocates from protocol design through to interpretation of the evidence

Her central message was that assessment should not focus only on whether a treatment works against the tumour, but also on **whether it works for the person living with cancer**.

Session discussion

The discussion first considered the role of caregivers as a source of evidence. Pignatti agreed that caregivers can provide important evidence, particularly in situations where direct patient reporting is difficult. However, they provide a different perspective from the patient, so their information should not be treated as a substitute for patient input.

The discussion then turned to what constitutes sufficiently robust PROM evidence for decision-making. Dr Racovita highlighted the variety of existing instruments, including general and disease-specific measures, and raised the difficulty of using datasets affected by methodological variation and missing information. Pignatti cautioned against describing data quality as an all-or-nothing characteristic. All evidence generated in clinical development contains limitations, resulting from the measurement instrument, context, missing data, study methodology or other factors. The task should therefore be to **characterise the uncertainty created by these limitations**. Some uncertainties can be reduced, while in other cases, decisions may still need to be taken despite them. What matters is that limitations and their implications are handled and communicated transparently. He identified transportability, relevance and internal validity as examples of aspects which may need to be systematically described when assessing whether evidence can support a particular decision.

Dieroff Hay returned to the issue of patient burden. Many questionnaires remain very long and difficult to complete, particularly for people already dealing with cancer and treatment. She called for existing forms to be reconsidered and made easier for patients to answer while still collecting the information required.

Joish added that patient-focused measures can also be incorporated into trials as exploratory endpoints and that evidence generation should not necessarily stop at the boundaries of the pivotal clinical trial. Complementary and supplementary evidence may also contribute to a more complete picture for HTA assessment.

During the course of the consultation, other issues that arose were the extent to which HTA bodies across Europe are following different approaches regarding the utility weights of PROMs, and the possible future relation between PROMs and the European Health Data Space (EHDS). These may be explored further in future ECO work on the subject.

RECOMMENDATIONS ON USING PROMS TO INFORM POLICY AND DECISION-MAKING

- **Systematically consider PROM and wider patient experience evidence in regulatory, HTA and reimbursement decisions where relevant**.
  - Evidence generation should start from a clear understanding of the purpose for which the information is needed, with methodology proportionate to that purpose.
  - Regulators should consider PROM evidence where relevant to assessing treatment benefit, tolerability and the balance between benefits and harms, taking into account the purpose, quality and methodological strength of the evidence.
- **Strengthen alignment between regulatory and HTA approaches to PROMs and alternative endpoints**. Greater consistency and transparency can support evidence generation that addresses the needs of different decision-makers while retaining rigorous standards for assessment.
- **Make meaningful patient-reported findings visible and understandable**. Important QoL evidence should be communicated through appropriate assessment documents and patient-facing summaries, with patients and patient organisations involved in deciding how findings are interpreted and communicated.
- **Incorporate PROM data into national cancer quality registers**, using common data standards, and explore links with existing national and European data initiatives such as the EHDS.
- **Characterise and communicate uncertainty in PROM evidence rather than treating imperfect data as automatically unusable**. Limitations relating to measurement, missing data, methodology, context and transportability should be transparently described together with their implications for the decision being taken.
- **Assess whether PROM evidence represents the patients who will use the treatment**. Regulators and HTA bodies should identify and report gaps in patient-reported evidence for under-represented groups, including older adults, and consider how these gaps can be addressed through post-authorisation evidence generation.

Conclusions

The Roundtable followed patient-reported evidence across three stages of the cancer evidence pathway: **in clinical practice, in clinical trials, and on the decision-maker's table**. Despite the different contexts, several consistent messages emerged.

Firstly, the principal challenge is converting **the wealth of available PROM instruments into systematic and harmonised implementation**. Europe already has established measures, substantial methodological expertise, mature patient organisations and growing practical experience. The remaining barriers relate much more to **implementation, standardisation and follow-through**. In routine care, a PROM that is completed but not reviewed is unlikely to sustain patient engagement. In clinical trials, collecting a questionnaire is insufficient if the wrong domains are measured, important data are missing or the findings are not analysed and reported appropriately. In regulatory and HTA assessment, patient-reported evidence is only useful if its intended purpose and methodological limitations are understood.

Secondly, the **purpose matters at every stage**. Before collecting patient-reported information, stakeholders need to understand what they want to learn and what decision the evidence is intended to support. This should determine the choice of instrument, timing, analytical approach and method of communication.

Thirdly, the speakers repeatedly called for **the patient to remain a partner throughout the process**. Their expertise is needed to identify what matters, whether a measure truly captures their lived experience, whether reporting is realistically manageable, and how the resulting findings should be interpreted. Spurrier-Bernard's account of a validated PROM failing to reflect substantial treatment toxicity and Dieroff Hay's call for regulators to look beyond tumour control illustrate the same underlying issue: **measurement only has value if it reflects outcomes that matter in patients' lives**.

Several contributions also pointed to the risk that PROMs widen rather than narrow inequalities. The groups least able to complete a lengthy digital questionnaire in a national language often carry the highest symptom burden and have the least voice in care and research. These include many older adults, people with limited digital access or health literacy, people with disability or cognitive impairment, and migrant and minority communities. If their responses are missing, systems will underestimate their needs. Equity therefore needs to be designed into instrument selection, collection methods, trial recruitment and the handling of missing data from the outset, in line with ECO's work through its Inequalities Network.

Finally, patient-reported information must ultimately **lead somewhere**. In clinical practice, that means establishing pathways through which reported symptoms can lead to review and action. In clinical trials, it means analysing and publishing PROM findings in ways that allow patients and clinicians to understand treatment trade-offs. In regulatory, HTA and reimbursement processes, it means ensuring that appropriate patient-reported evidence can genuinely contribute to assessment. Comprehensive Cancer Centres and their emerging European networks are well placed to lead routine ePROM implementation and to share infrastructure and learning across countries.

Closing the meeting, Dr Battisti reflected that **PROMs should no longer be regarded as an optional addition to cancer care or research**. The discussion had shown that the instruments largely exist and that attention must now turn to implementation, standardisation, follow-through, equity and partnership with patients from the design of what is measured through to interpretation of what the findings mean.

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