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Use of EORTC item lists for patient-reported outcome measurement in industry-sponsored research: A three-year snapshot of study characteristics

CONTACT

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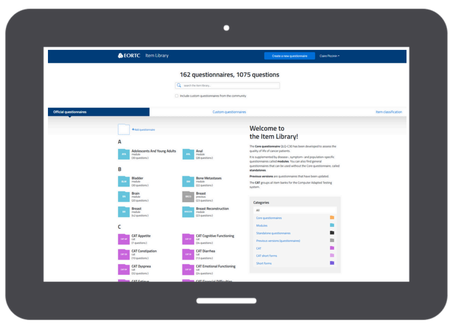
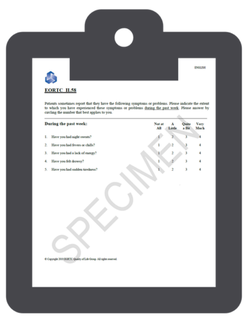
BACKGROUND & AIMS



EORTC Item Library[a]

Interactive online platform that stores all validated EORTC patient-reported outcome measures (PROMs), supports smart search functionalities, and allows for creation of customised item lists from pool of available items to, e.g., supplement standard core and disease-specific measures



Item list

Customised questionnaire created using select items from an item library to, e.g., capture missing symptoms/adverse events and support flexible patient-reported outcome (PRO) assessment in cases where standard PROMs are not available or fit-for-purpose → current EORTC PRO measurement strategy highlights use of **core +/- module +/- item list** where relevant[b]

Aims

Evaluate use of EORTC item lists in industry-sponsored studies (based on EORTC licensing agreements) over a 3-year period to highlight study attributes and trends and shed light on possible rationales for item list use

METHODS

1 Database creation

Database created to assess item list use over time and summarise key characteristics per study related to design, experimental treatment, population, & PRO measurement strategy

2 Data extraction

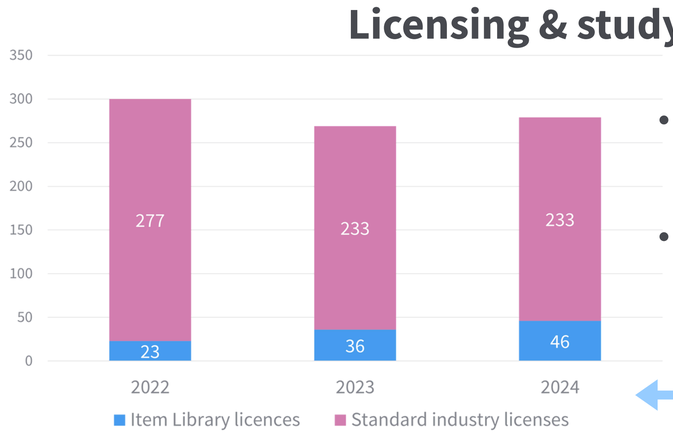
Data anonymously extracted per license/study from EORTC licensing documents executed from January 2022 through December 2024 and verified in online clinical trials registries where relevant/available. Licenses/studies divided among 3 raters who carried out data extraction

3 Review & consolidation

Data reviewed by 3 raters to verify accuracy and completeness and discuss any inconsistences or challenges. In cases of uncertainty, raters reviewed license/study to reach an agreement & finalise database. All data summarised descriptively

RESULTS

Licensing & study design



- 105/848 (12%) commercial licenses (i.e., studies) from 2022 through 2024 included at least one item list
- Proportion of commercial licenses including item lists increased each year, from 23/277 (8%) in 2022 to 46/233 (17%) in 2024

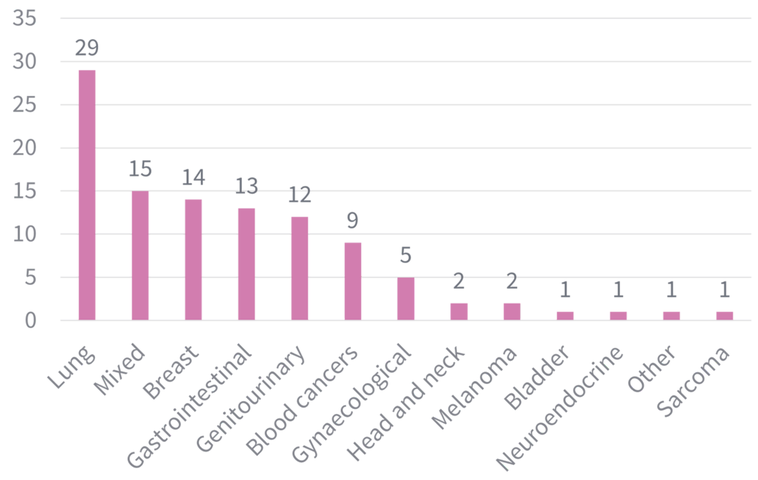
Clinical trial phase	N (%)
III	**55 (52%)**
I-II	**41 (39%)**
II	17 (16%)
I	11 (10%)
Ib/II	5 (5%)
I/II	4 (4%)
Ib	2 (2%)
IIa/IIb	1 (1%)
IIb	1 (1%)
II/III	**2 (2%)**
Master Protocol (basket, umbrella, & platform trials)	**2 (2%)**
N/A (observational studies)	**5 (5%)**
Total	**105 (100%)**

- 100/105 (95%) studies were clinical trials, with 55/105 (52%) studies phase III trials and 41/105 (39%) phase I-II trials
- 30/105 (29%) studies evaluated targeted therapy, 17/105 (16%) immunotherapy, and 16/105 (15%) combination targeted + immunotherapy

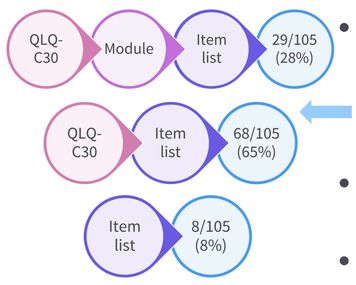
Experimental treatment[c]	N (%)
Targeted therapy	**30 (29%)**
Immunotherapy	**17 (16%)**
Immunotherapy + targeted therapy	**16 (15%)**
Targeted therapy + chemotherapy	**13 (12%)**
Immunotherapy + chemotherapy	**10 (10%)**
Hormone therapy	**6 (6%)**
Targeted therapy + hormone therapy	**5 (5%)**
Targeted therapy + chemotherapy + immunotherapy	**2 (2%)**
Chemotherapy + radiotherapy	**1 (1%)**
Radiation enhancer + chemotherapy + radiotherapy + immunotherapy	**1 (1%)**
Targeted therapy + unspecified anticancer therapies	**1 (1%)**
N/A	**3 (3%)**
Total	**105 (100%)**

[c]Including 2 observational studies investigating specific treatments (i.e., targeted therapy & hormone therapy)

Population & PRO measurement strategy



- 29/105 (28%) studies included patients with lung cancer, 15/105 (14%) with mixed disease types, and 14/105 (13%) with breast cancer
- 60/105 (57%) studies included patients with advanced or metastatic disease



- 97/105 (92%)studies used the QLQ-C30, and 29/105 (28%) used a module
- 78/105 (74%) studies used electronic PROs
- IL46 used in 44/105 (42%) studies

Item list	License/study requests N (%)	Length (# of items)	Concept(s) covered
IL46	**44 (42%)**	**1**	**Q168 – treatment-related side effect burden**
IL172	**15 (14%)**	**12**	**Select QLQ-C30 scales (role, cognitive, emotional, & social functioning; global health status/quality of life)**
IL19	**10 (10%)**	**5**	**QLQ-C30 physical functioning scale**
IL147	**9 (9%)**	**1**	**Q919 – dry eyes**

CONCLUSIONS

- Proportion of commercial licenses integrating item lists continues to increase over time
- Use of item lists in early phase trials and for evaluation of novel treatments underscores their relevance within these settings, pointing to a need for PRO measurement flexibility
- Item lists are most frequently administered electronically alongside the QLQ-C30, highlighting balance of static and flexible approaches and commitment to measuring core outcomes
- Frequent use of IL46 underlines importance of treatment-related side effect burden as a concept

FUTURE DIRECTIONS

- Further investigate rationale for item list use and methods for item list design and implementation through dissemination of survey to users and license holders
- Consider trends in usage to inform validation of frequently used item lists and module updates

KEY REFERENCES

[a]EORTC Item Library - https://itemlibrary.eortc.org/

[b]Piccinin C et al. Flexibility in patient-reported outcome and health-related quality of life measurement: The EORTC QLG measurement strategy. EJC. 2025;220:115392

ACKNOWLEDGEMENTS

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