# Review

# The EULAR Outcome Measures Library: development and an example from a systematic review for systemic lupus erythematous instruments

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**ABSTRACT**

**Objective.** *Patient reported outcomes (PROs) are relevant in rheumatology. Variable accessibility and validity of commonly used PROs are obstacles to homogeneity in evidence synthesis. The objective of this project was to provide a comprehensive library of "validated PROs".*

**Methods.** *A launch meeting with rheumatologists, PROs methodological experts, and patients, was held to define the library's aims and scope, and basic requirements. To feed the library we performed systematic reviews on selected diseases and domains. Relevant information on PROs was collected using standardised data collection forms based on the COSMIN checklist.*

**Results.** *The EULAR Outcomes Measures Library (OML), whose aims are to provide and to advise on PROs on a user-friendly manner albeit based on scientific grounds, has been launched and made accessible to all. PROs currently included cover any domain and, are generic or specifically target to the following diseases: rheumatoid arthritis, osteoarthritis, spondyloarthritis, low back pain, systemic lupus erythematosus, gout, osteoporosis, juvenile idiopathic arthritis, and fibromyalgia. Up to 236 instruments (106 generic and 130 specific) have been identified, evaluated, and included. The systematic review for SLE, which yielded 10 specific instruments, is presented here as an example. The OML website includes, for each PRO, information on the construct being measured and the extent of validation, recommendations for use, and available versions; it also contains a glossary on common validation terms.*

**Conclusion.** *The OML is an in progress library led by rheumatologists, related professionals and patients, that will help to better understand and apply PROs in rheumatic and musculoskeletal diseases.*

## Introduction

In rheumatology, many instruments have been developed to assess disease activity and other critical domains (*i.e.* clinimetrics). These indices are frequently used in clinical trials and some of them even in daily practice, as they help guiding clinical decisions and evaluating treatment response. Some of these indices include the patient's perspective and are therefore called patient reported outcomes (PROs). Patient perspective has become an integral part of evaluation in rheumatic diseases as recognised by OMERACT (1). PROs are useful not only to measure disease impact, but they also have a significant role in the development and evaluation of new therapies (2). However, despite PROs being increasingly recognised as important measures, they have been reported with great heterogeneity in recently published trials in rheumatoid arthritis (RA) (3). PROs have also variable accessibility; with different versions and modifications used in different studies throughout different countries and thus compromising homogeneity.

A workshop on EULAR priorities in PROs, held in Zurich in November 2009, highlighted the difficulty in accessing validated PROs, the heterogeneity in its use, and probable application of non-fully validated instruments (4) (http://www.omeract.org/resources.html). This led to a consensus by which

European rheumatologists, health professionals, methodologists and patients should be acquainted with all cross-cultural validated PROs in rheumatic and musculoskeletal diseases (RMD). On these grounds, the group proposed the development of a library, catalogue, or toolbox, with all available instruments freely accessible on the EULAR website. Such a library could act as an on-going clearinghouse, which helps taking informed decisions on PROs' selection. This initiative would also be useful to detect major gaps concerning instruments, as for example the need for cross-cultural adaptation, and may improve the knowledge and interest of the European rheumatology community on quantitative measurement and validation.

The main objective of this project was to develop a structured and functional Outcomes Measure Library (OML) freely available online that included a comprehensive database of validated PROs (indices, questionnaires, scales, or others) used in rheumatology.

**Material and methods**

The project was approved by the EULAR Standing Committee on Epidemiology and Health Services Research in September 2011. The proposal was designed to have an effect on several important strategic aspects as reducing PROs variability, helping to increase the awareness of researchers outside the field of rheumatology and educating the rheumatology community on the concepts of measure and validation of instruments using the right tool in the appropriate way.

The library was created in two different steps: 1. development of the library and 2. library feed.

*Development of the library*

A one-day meeting was organised with 15 methodological collaborators including rheumatologists and related professionals, PROs experts, and a patient. The objective of this meeting was to reach a consensus on:

1. the scope, aims and users of the library,
2. the items to include for each instrument in the library, and methodology to collect them;
3. the requirements for a web-based tool;
4. task planning and functions.

In a second phase, after several exchanges for agreement through teleconferences, a web-developer was contacted to design a web-based solution based on the pre-specified requirements and fields of the library.

*Library feed*

It was decided to feed the library following systematic review and critical appraisal of the PROs, using standardised forms. The first approach was to identify collaborators to carry out the systematic reviews of the literature (SRL) on the most relevant clinical measures in rheumatology, including questionnaires, scales and indices. The initial domains and diseases to be included were selected under consensus during the initial meeting.

Before performing all the SRLs an initial testing review was performed to test the search strategy and materials. The pilot test was the SLE review (included in this report as an example). Finally, all reviews were performed and specific forms completed.

*Systematic literature search with an example in systemic lupus erythematosus*

Studies on PROs for patients with SLE were identified by a comprehensive search in Medline via PubMed, Embase and the Cochrane Library from January 1950 to March 2012. The search strategy was designed to capture all studies in which the study population were adult patients with SLE, and dealt with any aspect of validity (construct validity, feasibility, reliability or responsiveness) of any instrument (the PubMed strategy is available as online supplementary material).

One reviewer (IC) screened the titles and abstracts excluding articles that were clearly unrelated. All other articles were reviewed in detail, and references were added via hand search or by expert recommendation.

*Data extraction*

Forms were designed to summarise relevant information on each identified PRO. These comprised:

1. name and abbreviation of the instrument,
2. construct/domain,
3. population or disease in which the instrument was initially developed and languages in which the instrument is available,
4. relevant references and developer contact information,
5. description of the instrument including type of measure, brief description, range, recommendations to score, score interpretation and time to complete,
6. psychometric properties and information on validity based on the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) checklist (5).

The quality aspects assessed included: reliability, validity, responsiveness, and interpretability. Guidelines to interpret these validation aspects were provided as a glossary which was also included in the OML website. Reliability embraces the concept that the repeated administration of a measurement tool in stable subjects will yield the same results; therefore, it measures the instrument stability. Reliability also includes the internal consistency of the instrument measured by Cronbach's alpha (<0.70 indicate that individual items are providing an inadequate contribution to the overall scale and values >0.90 suggest redundancy). Validity is defined as the degree to which an instrument measures what it is intended to measure and includes evaluation of content validity, criterion validity, and construct validity. Content validity is the appropriateness of an instrument for a particular task and is generally assessed by having experts and/or patients with the target condition review the instrument. Criterion validity is the comparison of a novel instrument to a potential "gold standard" or an instrument previously used and validated to measure the same construct. Criterion validity can be examined using correlations, ROC curves if the score is continuous or by sensitivity and specificity if the score is dichotomous. Construct validity is demonstrated when an instrument behaved in accordance with underlying theories, whether the measure is comparable to other measures of

a similar construct (convergent validity) and whether the measure is able to differentiate between persons with dissimilar conditions (discriminant validity). Responsiveness, also called sensitivity to change, is defined as the ability of an instrument to accurately detect change when it has occurred. It measures whether the instrument really captures when the patient has improved or worsened. It implies that an intervention with an effect of known direction is given to the studied patients. It can be quantified by multiples methods as for example the effect size (ES) or the standardised response mean (SRM). Interpretability includes the evaluation of floor and ceiling effects and the determination of the minimally important clinical difference.

We recommended all collaborators to contact the developer of each instrument to collect all available language versions and to allow developers to review the data collection forms.

*First feed: website testing*

Once the systematic reviews were completed, the data were uploaded in the library. The preliminary version for the website was double tested independently by IC and LG to detect problems and to ensure that the website was user friendly enough.

## Results

*Aims, scope, and users of the library*

The initial meeting took place in Madrid in December 2011 where it was decided the library's aims, scope and basic requirements. During the meeting three examples of similarly developed outcomes measures libraries (OML) were presented to the participants: BiblioPRO (http://www.biblio-pro.org/), PROQoLid from MAPI Research (http://www.proqolid.org/), and CATALINA from the Spanish Society of Rheumatology (http://www.ser.es/catalina/).

During interactive discussion, it was agreed on the aim of the EULAR OML to provide and to advise on PROs on a user-friendly manner albeit based on sound scientific measurement principles. Ideally, the OML should comply with the ICF (International Classification of Functioning) (6) framework and the COSMIN statement (5).

The intended users of the library are rheumatologists, health professionals, patients, researchers, practitioners or any potential user of PROs in the rheumatology field.

Concerning the scope of the library it was understood that the library would need some framing. Accordingly, it was decided that: a) the library would include only PROs defined as measure constructs important to patients, being questionnaires, scales, or profiles, or part of a composite measure; b) the PROs to be included would cover any domain, with an emphasis on those framed on the ICF, whether they are generic or specific; targeting all rheumatic diseases, with an initial focus on RA, osteoarthritis (OA), spondylarthritis (SPA), low back pain (LBP), SLE, gout, osteoporosis (OP), and fibromyalgia (FM). A search for paediatric measures was subsequently incorporated; c) since the tool-box would be a repository of instruments available in EULAR countries, the PROs included should have been validated in at least any of the EULAR languages, and it was recommended that at least a communication version in English were published; d) a PRO included should have some evidence of documented validity on a peer reviewed journal.

Each instrument included in the library should be informative with respect to: the construct being measured, conditions of use, a guide on its utility in clinical practice versus research, information about frequency of use, if feasible, and reliable to be used in clinical practice, references with at least one publication in English, information about scoring and interpretation of values, diseases for which it may be used, if the instrument could be considered generic or applicable in all diseases and a list of measured domains.

The library website should also provide all language versions of the instrument to be downloaded if freely available. In case the instrument was not freely available, the author's contact details would be provided.

Completeness and appropriateness of metric properties (reliability, construct validity, responsiveness, and interpretability) should be also included in the library based on the COSMIN checklist (5).

Another aspect discussed during the meeting was the educational aspect. The library would be mainly ecstatic, without formal support besides revising the contents. It was agreed that the educational support would cover different aspects as the glossary including explanations on the different psychometric concepts. The proposal of a central facility to help researchers methodologically was not supported.

Concerning the sustainability of the toolbox it was thought useful establishing a system for feeding and updating the library. This system would imply developing clear instructions and identifying contacts, which may be responsible for keeping updated a domain or a disease. For the recruitment of contacts it would be used a snowballing technique, starting with the participants in the initial meeting.

Some technical aspects for the IT solution were also discussed during the meeting. The searchable terms (diseases, domains, and languages) as come in drop-down menus ready to add new terms by an administrator. It was established as necessary to have a list of FAQ and an administrator. The library would ideally link to the national societies' web pages and other catalogues.

*Systematic reviews*

A total of 236 instruments were identified in nine systematic reviews (106 generic and 130 specific for a RMD). Specifically for SLE, the search strategy retrieved 704 references. After title/abstract screening 532 manuscripts were excluded and 37 articles were retrieved for full paper review, of which 19 references fulfilled the inclusion criteria, covering 10 PROs specifically developed for SLE patients (Fig. 1). The included studies are listed in Table I (7-24), along with a description of the study design, description of the population and PROs evaluated.

The SLE PROs included were created to evaluate: disease activity (n=1), lupus symptoms (n=1), quality of life (n=3), damage (n=2), patients' needs

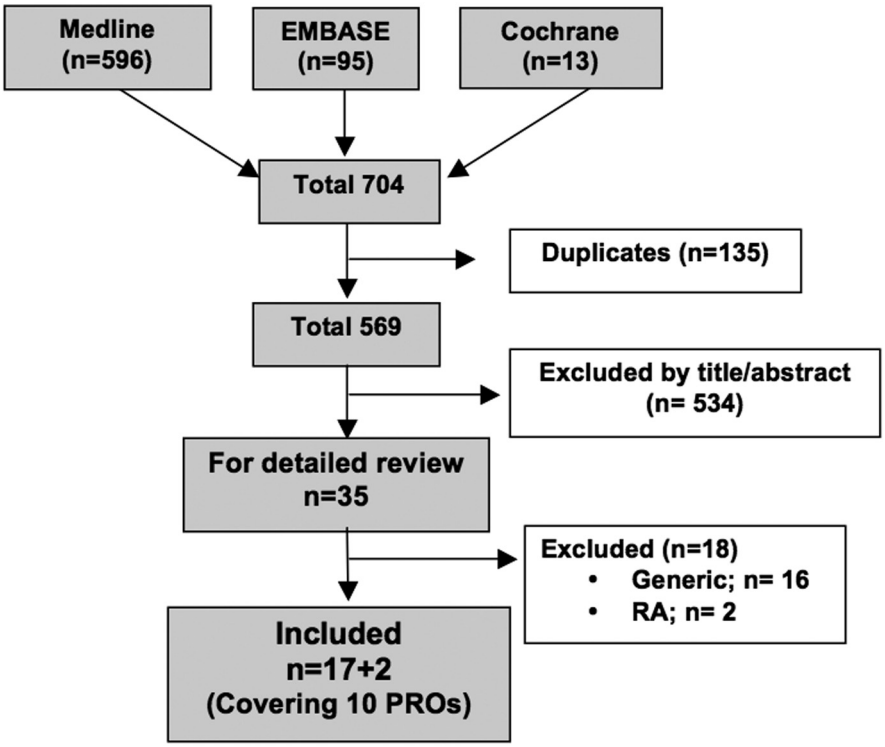


**Fig. 1.** Results of the literature search and disposition of the potentially relevant studies. After detailed review, 19 references were included for analysis covering 10 PRO for lupus.

(n=1), health (n=1) and family functioning (n=1). All of them are self-administered by definition. Internal consistency was studied in all with Cronbach's alpha ranging from 0.71 to 0.96. Validity, examined by means of convergence with other instruments, was generally similar between indices. Responsiveness was tested in SLAQ, SLEQOL, with a standardised response mean ranging from 0.12 to 0.44 and, by other statistics in SSC and LupusPRO. Interpretability was only tested in SLEQOL, LupusQoL and LupusPRO, with similar floor and ceiling effects (Table II).

Emails were sent to the developers to ask for additional language versions, to give the opportunity to review the forms on their instruments, and to inform them about this initiative. Fifty per cent of developers answered. All except one reviewed the data collection form and provided new versions and additional references.

*On-going and permanent feed*

The basis for the permanent feed of the toolbox was established during the initial meeting. The proposal addressed different approaches: a) review the results of a sentinel search strategy in PubMed to alert annually on new validated tools and b) to create a network of volunteers interested on PROs across Europe, who were willing to participate including new instruments or reviewing the available information.

*Website launch at EULAR 2013*

The final version for the OML is now available online (http://oml.eular.org/) for the community to use and to build on. A glossary with a list and definition for each validation aspect has been included in this website for educational support.

## Discussion

This paper describes the development of the EULAR OML as an in-progress library led by rheumatologists, related professionals, and patients that should contribute to a better knowledge of PROs in RMD. Compared to other available PRO catalogues, this library is more restrictive in terms of instruments because only those used in the rheumatology field are included. The EULAR OML includes relevant information about PROs in a standardised format but provides neither an opinion on each instrument nor specific recommendations about which one to use in each clinical setting. The main goal of the toolbox is to summarise all available information about each PRO and to provide different language versions -mainly in European languages but also in other languages if appropriately validated- to help taking informed decisions on PROs utilisation.

We exemplified the development of the EULAR OML with the literature review for PROs specific for SLE. After an extensive literature research we found 10 instruments assessing different domains with a special emphasis on quality of life. The majority of these instruments went through an extensive validation being reliability and validity the most extensive evaluated properties and responsiveness the less frequent reported aspect. Most of them showed an acceptable reliability and validity. SLEQOL was the only measure evaluated for each aspect of the validation.

We anticipate that the EULAR OML will be extensively used for different reasons. The library website is freely available and connected to the main EULAR website. It offers the opportunity to authors, collaborators, and experts to update the information included allowing the detection of potential gaps existing on certain diseases, domains, or validation completeness. It also provides the opportunity to educate the rheumatology community on the validation process providing an explanation on each validation aspect.

Such an initiative will have an effect on several important strategic aspects as to reduce variability in the use of PROs not only within Europe, hopefully around the world. As the OML shows, there are numerous instruments available with a potential overlap in constructs that they cover. To further investigate their content coverage, linking the instruments to the ICF by applying established linking rules is suggested. The use of instruments in research based on scientific grounds will improve the scientific level of projects, and will reduce variability among countries with lower development or

**Table I.** Description of the 19 included studies in chronological order.

| Author & Year | Type of study and population | Patient reported outcome | Brief description |
|---|---|---|---|
| Karlson 2003(7) | 93 SLE patients | SLAQ (Systemic Lupus Activity Questionnaire) | A patient self-reported measure of disease activity in SLE |
| Grootscholten 2003 (8) | Cross-sectional study 100 lupus patients with stable disease | SSC (SLE Symptom Checklist questionnaire) | Lupus specific questionnaire to assess the presence and burden of 38 treatment and related symptoms |
| Leong 2005 (9) | Cross-sectional study 100 lupus patients recruited in a single institution | SLEQOL (Systemic lupus erythematosus-specific quality-of-life instrument) | Quality of life measure specific for lupus patients |
| McElhone 2007 (10) | Multi-center cross-sectional study | LupusQoL (Lupus quality of life) | Disease-specific health-related quality of life |
| Moses 2007 (11) | Cross-sectional study 32 lupus patients | SLENQ (SLE needs questionnaire) | Self-administered needs assessment questionnaire for lupus patients |
| Kong 2007 (12) | Longitudinal cohort in a single institution | SLEQOL-C (Chinese version) | Quality of life measure specific for lupus patients in Chinese |
| Freire 2007 (13) | Cross-sectional study 107 lupus patients with stable disease | SSC-P (SLE Symptom Checklist questionnaire Portuguese version) | Lupus specific questionnaire to assess the presence and burden of 38 treatment and related symptoms |
| Yazdany 2008 (14) | Large Observational cohort 982 English-speaking SLE patients | SLAQ (Systemic Lupus Activity Questionnaire) | A patient self-reported measure of disease activity in SLE |
| Pons-Estel 2009 (15) | 887 SLE patients | LDIQ (Lupus Damage Index Questionnaire) | Versions in Spanish, Portuguese and French |
| Doward 2009 (16) | 50 SLE patients from two different Hospitals in UK | L-QoL (Lupus quality of life) | Quality of life measure for lupus patients |
| Costembader 2010 (17) | Multicenter study including 569 SLE patients | LDIQ (Lupus Damage Index Questionnaire) | Self-assessed organ damage instrument for lupus patients |
| Gonzalez-Rodriguez 2010 (18) | 115 SLE patients | LupusQoL (Lupus Quality of life) Spanish version | Disease-specific health-related quality of life in Spanish |
| Jolly 2010 (19) | 185 SLE patients | LupusQoL-US: US version | Specific version for US patients |
| Freire 2010 (13) | 107 SLE patients | SLEQOL-Portuguese | Quality of life measure specific for lupus patients. Portuguese version |
| Yazdany 2011 (20) | 81 patients from 2 university-affiliated SLE clinics | BILD (Brief Index of Lupus Damage) | A patient self-reported measure of damage in SLE |
| Jolly 2012 (21) | 18 SLE patients from an outpatient clinic | LupusPRO (Lupus Patient-Reported Outcome tool) | Disease-targeted patient-reported health outcome tool |
| Hassett 2012 (22) | 52 SLE patients from a single Rheumatology clinic | SLE-FAMILY | Family role functioning |
| Kasitanon 2013 (23) | 109 SLE patients from a single Rheumatology clinic | SLEQOL-TH (Thai version) | Thai version of Systemic Lupus Erythematosus Quality of Life |
| Jolly 2013 (24) | 211 SLE Hispanic ancestry | LupusPRO | Spanish version of LupusPRO |

support on methodological matters. It would be also important to increase transparency. The methodology for including instruments is explicit, and a way to capture instruments with validation in all European languages has been designed. This catalogue would help to increase the awareness of researchers outside the field of rheumatology. EULAR would have the opportunity to become a leader on the evaluation and dissemination of PROs, with the advantage of open access to the library. We also expect with this initiative to educate the rheumatology community on the concepts of measure and validation of instruments, and on the importance of using the right tool in the appropriate way.

The EULAR OML has some limitations. Although an extensive arsenal of measurement instruments have been developed for rheumatic diseases, only PROs are initially included. Even though we limited the selection to PROs, we are aware of the enormous number of existing measures and future measures under development. We tried to perform the most complete systematic review to capture all potential PROs, but there might be potential missing PROs. For this reason all users of the OML are explicitly invited to contribute and complete any relevant missing information.

Another limitation is that although the

**Table II.** Summary of the results of the validity of the 10 different SLE instruments retrieved in the search strategy.

| | | | Measurement Properties | | | |
|---|---|---|---|---|---|---|
| SLE PROs | Domain | no. of items and range | Reliability IC/TR/ME | Validity | Responsiveness | Interpretability |
| SLAQ (Systemic Lupus Activity Questionnaire) | Disease Activity | Items: lupus flare, 24 symptoms and DA<br>Range: 0-44 | Cronbach's α=0.87 | SF-36= 0.66<br>SLAM no lab=0.62 | SRM: 0.12 | – |
| SSC (SLE Symptom Checklist questionnaire) | Lupus Symptoms | Items: 38<br>Range: # Symptoms: 30; SLE symptom distress score: 0-152 | Cronbach's α=0.89<br>Pearson correlation (28 pat/1 mo) =0.87 | Pysician´s VAS= 0.26<br>IRGL: -0.54-0.55<br>POMS: -0.25-0.69<br>MOS-SF-36: -0.57-0.01 | Significant changes in nephritis & CFM: no. of symptom s=-2.9<br>Total distress =-9.2 | – |
| SLEQOL (SLE-specific quality-of-life instrument) | Quality of Life | Items: 49<br>Range: 40-280 | Cronbach's α=0.95<br>ICC= 0.83 | SLEDAI: 0.02<br>SLAM: 0.02<br>SLICC: 0.05<br>SF-36: 0.06-0.17 | SRM: 0.44<br>Effect Size: 0.33<br>Guyatt's coeff: 0.37 | Floor: 14.9-44%<br>Ceiling: <2.6% |
| LupusQoL (Lupus quality of life) | Quality of Life | Items: 34<br>Range: 0-100 | Cronbach's α=0.88-0.96<br>ICC = 0.72 -0.93 | SF-36: 0.71-0.79 for the 4 comparable domains | – | Floor: <10.8% (score=0)<br>Ceiling: 4-21% (score=100) |
| SLENQ (SLE needs questionnaire) | Needs | Items: 97<br>Range: Unknown | Cronbach's α = 0.96<br>Cohens kappa = 0.70 | Correlation with SF-36: -61 to -0.31 | – | – |
| LDIQ (Lupus Damage Index Questionnaire) | Damage | Items: 56 in 12 organs<br>Range: 0-22 | Cronbach's α=0.72 | Comorbidity index: r=0.45<br>SF-36 PCS r=0.43<br>Disability status r=0.37 | – | Most commonly reported neuropathy (35%) & arthritis (34.4%) |
| L-QoL (Lupus quality of life) | Quality of Life | Items: 25<br>Range: 0-22 | Cronbach's α=0.92<br>ICC = 0.95 | Nottingham Health Profile = 0.48-0.80 | – | – |
| BILD (Brief Index of Lupus Damage) | Damage | Items: 28<br>Range: 0-33 | – | SDI: 0.64 | – | – |
| LupusPRO (Lupus Patient Reported Outcome tool) | Health-outcome | Items: 44<br>Range: 0-100 | Cronbach's α=0.72 -0.94<br>ICC= 0.55-0.92 | SF-36: 0.50<br>Correlation with DA measures: -0.29 to -0.32 | ↑BILAG correlated with ↓ in lupus symptoms (-0.56), pain-vitality (-0.58), & physical health (-0.53) | Floor: 22.3%<br>Ceiling: 1.2% |
| SLE-FAMILY functioning | Family | Items: 6<br>Range: 1-7 | Cronbach's α=0.71<br>ICC=0.82 (1 week later) | SDS family: rho = 0.67<br>SDS social: rho= 0.60<br>FSS: rho = 0.62<br>SLAQ: rho = 0.68 | – | – |

IC: internal consistency; TR: test retest; ME: measurement error; DA: disease activity; SRM: standardised response mean; pat: patients; mo: months; IRGL: Influence of Rheumatic disease on general health and life style; POMS: Profile of Mood States; CFM: cyclophosphamide; ICC: intraclass correlation coefficient; SDI: SLE Damage Index.

evaluation of the validation process for each PRO was part of the initial project it is not included in the final version. The first approach was to provide a colour grid depending on the quality of the validation, giving different colours according to the quality level reached. Providing a COSMIN-based objective assessment on the validation process for each PRO was a very ambitious task requiring the collaboration of experts on validation. In order to have a more feasible approach it was decided to provide information about validation as presented in the references for each PRO without any judgment.

Concerning the sustainability of the library it was thought useful establishing a system for feeding and updating the tool-box resembling the Cochrane Collaboration. This system would imply developing clear instructions and identifying contacts, which will be responsible for keeping a domain, disease or instrument updated. For the recruitment of contacts a snowballing technique was proposed, starting with the participants in the initial meeting, and probably the members of the EULAR Standing Committee on Epidemiology. If the OML is to become a continuing task this will possibly involve the EULAR Secretariat. Their task will be to remind the contacts of their responsibility to regularly update their assigned PROs on the website.

In summary, we present the new EULAR OML as a freely available website with structured access to a comprehensive database of validated PROs instruments used in rheumatology. This website not only includes a detailed description of each instrument it also includes recommendations and rules for use, information about its validation and the instrument itself with its version in other EU languages. We expect that unified access to the information on PROs will not only contribute to improve research but also enhance the use of these measures in clinical practice.

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