

Launch of a checklist for reporting longitudinal observational drug studies in rheumatology: a EULAR extension of STROBE guidelines based on experience from biologics registries

The advent and increased use of targeted therapies in rheumatology have stimulated the establishment of clinical drug registers. Such registers have evaluated a broad spectrum of outcomes in patients exposed to these uniquely designed, potent and expensive drugs.^{1–8} Although the main focus of most drug registers in rheumatology is drug safety, other important issues include drug usage, real-life effectiveness and economic consequences.

Results from biologics registers have come to play an important role in the evaluation of safety, effectiveness and treatment strategies, contributing significantly to the evidence base that guides clinical practice and shapes policy decisions. It is thus vital that the underlying studies are carefully conducted, analysed and transparently reported. This ensures (a proper appraisal of) the internal and external validity, and thus also the comparability across studies. A EULAR taskforce on biologics registers recently published ‘points to consider’ when analysing and reporting data of biologics registers in rheumatology.⁹ For the section pertaining to analysis and reporting, the taskforce reproduced the STROBE (STrengthening Reporting of OBServational studies in Epidemiology) guidelines to emphasise generic guidelines for the reporting of observational research as a backbone, and appended item-specific points to consider. The parent STROBE statement presents a checklist of 22 items to be addressed when observational epidemiological studies are reported, together with a detailed exposition of its rationale and purpose.¹⁰ The EULAR taskforce on biologics registers added additional points to consider for analysis and reporting for the following sections of the STROBE structure: setting, participant, variable, statistical method, descriptive data, outcome data, main results, other analyses and limitations.

Because of the ever-increasing complexity of analysing and reporting results from biologics registers, the current EULAR Study Group on Longitudinal Observational Registers and Drug Studies decided it may be useful to transform these points into an easy-to-use checklist as an instrument to guide transparent reporting. Several versions of the checklist were discussed in a meeting and by email, and the final version of the checklist was then circulated among members of the study group. Representatives from eight national registers tested its feasibility and usefulness using published studies from biologics registers. Each participant reviewed it against one published study of safety and a second study on another topic, for example, effectiveness. This reflected the focus of safety when developing the ‘points to consider’, and an acknowledgement of the potential wider uses of registers. Based on this feasibility assessment, the checklist was further modified. All respondents found the checklist to be a useful instrument, particularly as a guide for authors when writing publications.

In conclusion, we present the launch of the checklist as an educative tool to assist authors in writing reports of longitudinal observational drug studies in rheumatology, editors and peer reviewers in reviewing manuscripts for publication, and readers in critically appraising published articles. Besides, as an online

supplement to this report, the checklist is also accessible through the study group’s website (http://www.eular.org/index.cfm?framePage=/st_com_epidemiology_checklist_eralods.cfm). We acknowledge that the checklist (or some of its points) may not be applicable to each and every study or study design, and that it may have to be amended to fit the future landscape of Rheumatology drug studies. The article ‘EULAR points to consider when establishing, analysing and reporting safety data of biologics registers in rheumatology’,⁹ provides elucidation and context to the checklist items.

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