

Title:

Real-world evidence of clinical outcomes of the use of the adalimumab biosimilar SB5 in rheumatic and digestive IMIDs: 12-month data from the PERFUSE study

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Supplementary Table S8: STROBE cohort checklist.

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Manuscript Mapping
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	“Real-world evidence of clinical outcomes of the long-term use” Provided.
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Done – 1. Introduction
Objectives	3	State specific objectives, including any prespecified hypotheses	Done – 1. Introduction (Final paragraph) Expanded upon in 2.1. Study Design
Methods			
Study design	4	Present key elements of study design early in the paper	Done – 2.1. Study Design
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Done – 2.1. Study Design 2.2. Data Collection
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	Done – 2.1. Study Design 2.2. Data Collection Done for SNDS Matching – 2.2.2. SB5 Treatment Persistence
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Done – 2.2. Data Collection
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Done – 2.2. Data Collection
Bias	9	Describe any efforts to address potential sources of bias	Done – 2.3. Statistical Analysis
Study size	10	Explain how the study size was arrived at	Done – 2.3. Statistical Analysis This is an observational study, and the sample was also limited by recruitment capacity and time constraints.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Done – 2.3. Statistical Analysis
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine	Done – 2.3. Statistical Analysis Done – 2.3. Statistical Analysis

subgroups and interactions

(c) Explain how missing data were addressed Done – 2.3. Statistical Analysis

(d) If applicable, explain how loss to follow-up was addressed Done – 2.3. Statistical Analysis

(e) Describe any sensitivity analyses Done – 2.3. Statistical Analysis

Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Done – 3.1. and Fig. 1
		(b) Give reasons for non-participation at each stage	Done – 3.1. and Fig. 1
		(c) Consider use of a flow diagram	Done – Fig. 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Done – 3.1. and Tables 1 & 2
		(b) Indicate number of participants with missing data for each variable of interest	Done – Data Density is reported for each analysis performed
		(c) Summarise follow-up time (eg, average and total amount)	Done – Persistence Analysis presented in 3.3.
Outcome data	15*	Report numbers of outcome events or summary measures over time	Done – Persistence Analysis presented in 3.3.
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Done – All results are reported as appropriate for type and density of data.
		(b) Report category boundaries when continuous variables were categorized	Done – All results are reported as appropriate for type and density of data.
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Multivariate Analysis presents odds ratios as is appropriate for this type of data.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Done – All results are reported as appropriate for type and density of data for subgroup analyses also.

Discussion

Key results	18	Summarise key results with reference to study objectives	Done – Key results are summarised in the opening paragraph.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Done – Both methodological and data-related limitations are discussed with regard to available literature.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and	Done – Results are discussed with regard to available literature.

other relevant evidence			
Generalisability	21	Discuss the generalisability (external validity) of the study results	Done – Results are discussed with regard to available literature.
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Done – Declarations Section completed.

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.