achieved remission and those who did not could be clearly separated by the levels of IgA, IgG, rheumatoid factor, and albumin (Figure), whereas those baseline characteristics were mostly overlapped in the late ABT users (cut-off value for predicting remission with sensitivity and specificity in the early ABT users; IgA 342 mg/dL with 83% and 100%, IgG 1880 mg/dL with 50% and 100%, rheumatoid factor 152 IU/mL with 50% and 100%, albumin 3.7 g/dL with 88% and 67%, respectively). The area under the curves of receiver operating characteristic curves to predict remission were 0.833 of IgA and 0.778 of rheumatoid factor titer.

Conclusion: We identified serum IgA titer was the novel predictive factor for response of ABT.

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Figure. Principal component analysis by clinical parameters. RF; rheumatoid factor, HAQ; health assessment questionnaire, EGA; evaluator's global disease activity, PGA; patient global assessment, VAS; visual analog scale

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EVALUATION OF A PROSPECTIVE COHORT EVENT MONITORING MODEL FOR PATIENT-REPORTED ADVERSE DRUG REACTIONS ATTRIBUTED TO BIOLOGICAL DMARDS: VALIDITY OF THE PATIENT-REPORTED INFORMATION AND REPRESENTATIVENESS OF THE PARTICIPANTS

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Background: To gain knowledge on the prevalence, course and treatment of adverse drug reactions (ADRs) attributed to biological DMARDs (bDMARDs) and the experienced impact of ADRs on patients, an ADR-focused online questionnaire system was developed by Netherlands Pharmacovigilance Centre Lareb (*Dutch Biologic Monitor*). 898 consecutive patients of eight centers who used a bDMARD indicated for an inflammatory rheumatic disease were followed between 1 January 2017 and 31 December 2018.

Objectives: Validation of the quality of the patient-reported information in the *Dutch Biologic Monitor* and evaluation of the representativeness of the participants in relation to the source populations.

Methods: Patients of 18 years and older who used a bDMARD indicated for an inflammatory rheumatic disease were included by the participating hospitals. The patient-reported medical information (bDMARD, indication and concomitant DMARDs) of 479 patients with a rheumatic disease (Reade, Amsterdam: N=174; Sint Maartenskliniek, Nijmegen: N=305) was verified by comparing the patient-reported parameters to the patient's electronic health record using percentage agreement and/or Cohen's kappa. Representativeness was tested in 550 patients with an inflammatory rheumatic disease (Reade, Amsterdam: N=192; Sint Maartenskliniek, Nijmegen: N=358) by comparing their grouped age, grouped gender and prescribed bDMARD to the source populations of the respective hospitals using Mann-Whitney U test, Chi-Square Goodness-of-Fit and Fisher's exact test with Monte Carlo simulation.

Results: 95.8% of the tested rheumatic disease patients correctly reported their bDMARD (active substance and brand name). Furthermore, agreement between patients and the electronic health record was strong for the reported indications (90.4% agreement; $\kappa = 0.832$) and moderate for the concomitant therapy (79.7% agreement; $\kappa = 0.725$). The subpopulations were representative for their source populations based on grouped gender (38.4% vs. 38.8% male, $\chi^2(df=1, N=550)=0.038$; $p>0.05$) and bDMARD use (both $p>0.05$). Grouped median age was not representative (58.0 vs. 56.0 years; $U=962872$; $p=0.04$), since the male participants were older (58.5 vs. 55 years; $p=0.001$).

Conclusion: So far, the *Dutch Biologic Monitor* seems to be a valid tool to obtain knowledge on ADRs attributed to bDMARDs, since the reported medical information corresponded to the patients' electronic health records and the participants generally represented their source populations regarding grouped gender and prescribed bDMARD.

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