Supplementary Material 1: detailed methods

Patients followed at the Unit of Immunology, Rheumatology, Allergy and Rare Diseases of the San Raffaele Hospital, Milan, Italy for rheumatic diseases or primary immunodeficiencies and who received a two-dose course of the BNT162b2 (Comirnaty®) vaccine were consecutively enrolled. The ongoing Italian COVID-19 vaccination campaign prioritised the administration of anti-SARS-CoV-2 vaccines to healthcare professionals and people of older age, due to their increased risk of developing COVID-19 and its complications. Therefore, the majority of patients enrolled were health professional with enhanced risk of exposure to subjects with COVID-19. Written informed consent under the Panimmuno research protocol (conforming to the declaration of Helsinki and approved by the hospital ethics committee with reference code 22/INT/2018) was obtained from all participants. The study was conducted during the third SARS-CoV-2 surge that stroke the Milan urban area and the observation timeframe spanned from December 31st, 2020 to March 26th, 2021.

Demographics, general clinical features including immune-mediated disease history and comorbidities as well as current treatments were recorded during clinical consultation or by reviewing patients’ charts. Disease remission at time of vaccination was defined as the absence of clinical signs of active disease (independent of possible laboratory alterations) or of recent treatment changes due to incomplete disease control within one month before vaccination. A previous history of COVID-19 and/or evidence of positive SARS-CoV-2 antigen swab for routine hospital surveillance were also actively investigated. Direct or phone-based interviews were performed and any clinical manifestation occurring after the first and second vaccine doses was recorded. In particular, the following definitions were applied: allergic reaction (“hypersensitivity reaction initiated by immunological mechanisms”) [1]; anaphylaxis (“severe life-threatening generalized or systemic hypersensitivity reaction”) [2]; fever (raise in body temperature above 37.5°C); fatigue (“difficulty in initiation of or sustaining voluntary activities”) [3]; drowsiness (increased need for sleep); malaise (“an indefinite feeling of debility or lack of health”) [4]. Adverse reactions were also classified into mild or severe based on the need for hospitalisation, and into immediate or delayed based on whether signs and symptoms occurred within one or more hours after vaccine injection [5].
Categorical variables were reciprocally compared by using the chi-square test with Fisher's exact correction. Variations in quantitative continuous variables among two or more groups were analysed by using the Mann-Whitney U test or the Kruskal-Wallis' test, respectively. Statistical analysis was performed with Statacorp STATA® version 15. Data are expressed as median (interquartile range, IQR) unless otherwise specified.

REFERENCES