STUDY REPORT
SUMMARY OF CHANGES

Protocol Number	A3921275
Study Report Title:	An Observational Study of Xeljanz® (tofacitinib citrate) and Biologic Rheumatoid Arthritis Treatments to Characterize their General Treatment Patterns, Effectiveness and Safety in a Real-World Taiwanese Population
Study Report Version Date:	25-Mar-2022
Date of Form Completion:	19-Jul-2022

The original approved Study Report (SR) was not amended based on the changes below, as the changes are administrative and do not affect review of study conduct, data interpretation, or overall study conclusions.

Section	Original text	Changes
9.9.8 Change of Conduct of Study	In August 2021, 267 patients in total were enrolled as the study population.	The total number of enrolled patients was 270 instead of 267. 3 patients were not eligible and were discontinued shortly after baseline. Per definition, they are not part of any of the analysis sets listed in section 10.1 participants. They are excluded from all analyses since they were not eligible.
10.6.1.3 Targeted Adverse Events	In the tofacitinib group, 5 patients (3.4%) reported mild TAEs, 7 patients (4.8%) reported moderate TAEs, and 2 patients **(1.4%)** reported severe TAEs.	The percentage of severe TAEs for serious infection for 2 patients should be **1.6%** instead of 1.4%. This was a typo and considered an administrative change.
10.6.1.3 Targeted Adverse Events – Table 26 Targeted Adverse Events-Safety Analysis Set	In the TNFi group a total of n=**3 (2.5%)** patients suffered from the AE "Herpes Zoster".	The total number of patients in the TNFi group with Herpes Zoster should be **n=4 (3.3%) with an unknown severity**. This error was due to a wrong entry in the electronic case report form, which was not identified during the data review.
10.6.1.4. Related Targeted Adverse Events	In the TNFi group in the TAEs category infection, related events were reported for the TAE subcategory serious infections for 3 patients (2.5%), pneumonia for 2 patients **(1.8%)**, herpes zoster infection, other serious infection,	The percentage of 2 patients with pneumonia should be **1.6%** instead of 1.8%. This was a typo and considered an administrative change.

	bone joint infection, cellulitis and opportunistic infection for 1 patient (0.8%) in each TAE subcategory.	
11.1 Key Results and Interpretation	There were 18 tofacitinib users and **3** TNFi users who had a TAE of herpes zoster.	It should be **4** TNFi users who had a TAE of herpes zoster.
Listing 16.2.5-1.1 RA study medication dosing profile (page 100)	Patient 1004-1005 is listed with a starting dose of tofacitinib of 10 mg BID.	It was confirmed by the study site that this was a mistake in the electronic case report form. The patient started with a dose of tofacitinib of 5 mg BID according to the label. The database will not be unlocked to correct this data point since it won't affect the data interpretation or study conclusion.
Listing 16.2.7-1.1 Adverse Events	The AE Herpes Zoster for patient 1003-1039 is listed as not being a TAE.	The AE Herpes Zoster of patient 1003-1039 should be listed as TAE (TAE- yes). It was confirmed that this was a mistake in the electronic case report form which was overlooked and therefore not corrected during data review. The database will not be unlocked to correct this data point since it won't affect the data interpretation or study conclusion.
Listing 16.2.7-1.3 Target Adverse Event Description	The AE Herpes Zoster of patient 1003-1039 is not listed in this listing.	Patient 1003-1039 should be listed in here, because the AE Herpes Zoster should have been documented as a TAE.

Document Approval Record

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Kuo, Edward	20-Jul-2022 05:48:50	Author Approval