Evaluation of the Effectiveness of Implementation of Additional Risk Minimization Measures (aRMM) Materials for Xeljanz® (Tofacitinib) / Rheumatoid Arthritis (RA) indication in Nigeria via a Survey among Prescribers: A Non-Interventional Post Authorization Safety Study (PASS).

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000900

Study ID

1000000900

DARWIN EU® study

No

Study countries

Nigeria

Study description

This study is a regulatory, non-interventional post-authorisation safety study (PASS) designed to evaluate the effectiveness of additional risk-minimisation measures (aRMMs) implemented for Xeljanz® (tofacitinib) for the treatment of rheumatoid arthritis in Nigeria, as requested by the National Agency for Food and Drug Administration and Control (NAFDAC). The study assesses whether implementation of the Xeljanz® aRMM materials (including the Prescriber Brochure, Prescriber Treatment Maintenance Checklist, and Patient Alert Card) results in prescriber behaviours and clinical decision-making practices aligned with approved risk-minimisation recommendations that are expected to reduce identified and potential safety risks.

This is a cross-sectional, non-interventional survey conducted among physicians authorised to prescribe Xeljanz® who have received the aRMM materials. The study includes physicians who have prescribed Xeljanz® as well as those who have not yet prescribed the product, reflecting the low utilisation setting and the preventive intent of the risk-minimisation programme. Data are collected through a structured, paper-based questionnaire administered in outpatient clinical settings across Nigeria, with no patient-level data collected.

Primary outcomes assess prescriber implementation of risk-minimisation behaviours, including screening and risk assessment prior to treatment initiation, application of decision rules in high-risk clinical scenarios, and preventive counselling and Patient Alert Card use. Secondary outcomes include prescriber awareness (receipt) and utilisation of aRMM materials and knowledge of key contraindications and safety risks. Predefined effectiveness thresholds are applied to support transparent interpretation of findings. All analyses are

descriptive and conducted at the prescriber level.

Study status

Ongoing

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/02/2026

Actual: 24/03/2026

Study start date

Planned: 21/09/2026

Actual: 14/09/2026

Date of final study report

Planned: 31/01/2027

Study protocol

A3921450_PROTOCOL_ Version 2.0_23MAR2026_SIGNED_Redacted.pdf (524.31 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

Non-interventional cross-sectional survey

Main study objective:

The primary objective of this study is:
To evaluate whether implementation of the Xeljanz® aRMM materials (Patient Alert Card, Prescriber Brochure, and Prescriber Treatment Maintenance Checklist) in Nigeria results in prescriber risk-mitigation behaviours and decision-making practices that are expected to reduce identified and potential safety risks associated with Xeljanz® use in RA (including serious infections/TB, malignancy/NMSC, VTE, MACE, and laboratory abnormalities).

Secondary objectives:
• Evaluate prescriber awareness (receipt) and utilisation of each aRMM component.
• Evaluate prescriber knowledge and comprehension of key contraindications, risks, and risk-minimisation instructions.
• Describe prescriber practice characteristics and barriers/facilitators to implementation.
• Explore descriptive associations between receipt/knowledge and implementation of
risk-mitigation behaviours.

Study Design

Non-interventional study design, other

This study is designed as a cross-sectional, non-interventional survey targeting Health Care Professionals (“HCPs”) specializing in Rheumatology, Internal Medicine, and other relevant disciplines who have been identified by Pfizer as prescribers of Xeljanz®. The survey will be distributed in paper format and the completed questionnaire collected via face-to-face meetings with HCPs. Data from these completed questionnaires will be transcribed into a web platform for subsequent analysis.

Study drug and medical condition

Medicinal product name

XELJANZ

Anatomical Therapeutic Chemical (ATC) code

(L04AF01) tofacitinib

tofacitinib

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

The study population is limited to physicians authorised to prescribe Xeljanz® who have received the additional risk-minimisation measure (aRMM) materials. Therefore, the study population consists of Rheumatologists and other prescribers of Xeljanz®
in Nigeria, (e.g. Internists).

Study design details

Setting

This study will be conducted in Nigeria and will involve a non-interventional, cross-sectional survey of Physicians practising in outpatient clinical settings, including public and private healthcare facilities. The study will not involve direct patient contact, clinical interventions, or collection of patient-level data.

Outcomes

Primary outcomes assess prescriber implementation of risk minimisation behaviours and clinical decision-making practices aligned with aRMM recommendations, including screening, risk assessment, decision-rule application, preventive counselling and Patient Alert Card use. These outcomes will be measured using prescriber responses to predefined behaviour-based and clinical scenario-based questions in a structured, paper-based questionnaire administered face to face, with responses classified according to prespecified criteria aligned with approved aRMM recommendations.

Secondary outcomes include prescriber awareness (receipt) and utilisation of aRMM materials and knowledge of key contraindications and safety risks, measured through structured questionnaire items assessing recall, use, and correct responses to predefined knowledge questions. Key covariates include prescriber professional background and practice characteristics (e.g., specialty, years of practice, practice setting), experience with Xeljanz®, and perceived barriers to implementation of aRMM recommendations, collected via self-reported questionnaire data.

Data analysis plan

All analyses will be descriptive and conducted at the prescriber level, which is the unit of assessment for this study. Categorical variables will be summarised using frequencies and proportions, and continuous variables will be summarised using mean, standard deviation, median, range, and interquartile range (IQR), as appropriate.

Analyses are structured to correspond directly to the study objectives and the variables defined in Section 9.3, and to the questionnaire sections provided in Annex 1.
Given the descriptive, threshold-based nature of the analysis and the number of prescribers exposed to the additional risk-minimisation measure (aRMM) materials, the proposed sample size is sufficient to determine whether predefined adequacy thresholds for awareness, knowledge, and implementation of risk-minimisation behaviours are met, without reliance on formal hypothesis testing.
Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor. The SAP may modify the plans outlined in the protocol; any major modifications of primary endpoint definitions or their analyses would be reflected in a protocol amendment.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Survey among Prescribers

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown