Gac Sanit. 2025;39(S2):174

Gaceta Sanitaria

https://www.gacetasanitaria.org

651 - DATA ANALYSIS AND REAL-WORLD INTERROGATION NETWORK (DARWIN EU®): A SUCCESSFUL EXAMPLE OF SIDIAP USE FOR REGULATORY PURPOSES

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Resumen

Background/Objectives: Real-World Data (RWD) is essential for decision-making in medicines regulation, enabling the identification of patterns in disease incidence or medicines use, evaluation of safety and effect of interventions, and rapid response to emerging issues. It is crucial to continue strengthening the collection and analysis of RWD to better address future crises with greater efficiency.

Methods: In this context, the European Medicines Agency (EMA) and the European Medicines Regulatory Network have established a network led by a coordination centre to provide timely and reliable evidence on the use, safety, and effectiveness of medicines from real-world healthcare databases across the European Union (EU). This initiative is called the Data Analysis and Real-World Interrogation Network (DARWIN EU®). The development of DARWIN EU® included the integration of European health databases, the establishment of standardized analytical frameworks using the common data model of the Observational Medical Outcomes Partnership (OMOP), and the implementation of processes to ensure data quality and safety.

Results: The project began in 2022 and currently has 30 data partners from 16 European countries, including 6 from Spain. During the first year (implementation phase), 4 studies were conducted, and by 2025, about 100 studies are expected to be initiated. The Information System for Primary Care Research Development (SIDIAP) is a database of pseudonymized data recorded in primary care centres in Catalonia, Spain, with records from over 8 million people since 2006. SIDIAP was the first primary care Spanish database to join DARWIN EU® and has already participated in 39 studies. Of these studies, 28 were simple descriptive studies, 9 were complex, and 2 were routine repeated studies. These studies have supported European drug regulation and have focused on disease epidemiology, drug safety and treatment effectiveness. A successful example of DARWIN EU® outputs with SIDIAP's involvement is the safety study requested during the review of doxycycline use and its association with suicidality ideation. After assessing all available evidence, including the results of the DARWIN EU RWD study, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) concluded that there was insufficient evidence to establish a causal relationship. SIDIAP's contribution supported this conclusion and ensured informed decisions regarding the safety of the drug.

Conclusions/Recommendations: The use of RWD through initiatives like DARWIN EU® has been

crucial for evaluating the use, safety and effectiveness of medicines, improving public health in the EU. SIDIAP's participation provided timely and reliable evidence, such as in the doxycycline case, supporting informed regulatory decisions.