Real-World Evidence in post-authorization studies: Review of European databases in the ENCePP EU PAS register® between 2010 – 2023

RWD178

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Background

According to the European legislation a post-authorization study (PAS) is conducted on approved medicinal products to assess potential risks, evaluate the missing safety information and provide additional knowledge on the product's effectiveness and utilization [1]. The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP®) was created by the European Medicines Agency (EMA) to facilitate the conduct of high quality studies and provide a platform for scientific collaboration and development. The European Union electronic Register of Post-Authorization Studies (EU PAS Register®) is a publicly available register of non-interventional PAS with the purpose to provide transparency and promote compliance with the EU pharmacovigilance legislation. This study aimed to perform a review of the most frequently used databases in the EU PAS Register® and to stratify those by geographical distribution and therapeutic area.

Methods

This study reviewed the finalized observational studies registered in the EU PAS register® that are publicly available via the ENCePP® website. All studies registered from the registry's inception until the 20th of January 2023 were taken into consideration. Only PAS conducted in European countries with established databases were included. Studies conducted via primary data collection, prospective data collection, surveys, medical chart abstractions were excluded (*Figure 1*). The information provided on the website was used to retrieve the data sources and the countries the studies had been conducted in. If the data source name was not enlisted, or a data source did not match the country, the information was verified using the study protocol/results. The authors independently performed name harmonization for the data sources. Population databases within the same country were considered as a single national database if linkage through a unique identification number could or is routinely performed.

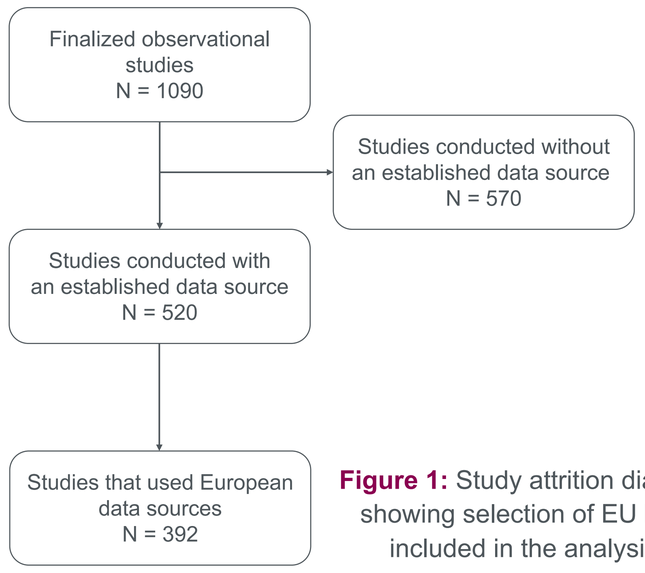

Figure 1: Study attrition diagram showing selection of EU PAS included in the analysis.

Results

We have identified 1090 finalized observational studies registered in the EU PAS register® from the start of the register until 20th January 2023. Of those, 392 have been conducted using established European databases (*Figure 1*). United Kingdom (UK) remains the most utilized source of Real-World Data (RWD) for PAS, followed by Germany and France, while the Nordic countries (Sweden, Denmark, Finland, Norway) provide a significant source of RWD for PAS (*Figure 2*). UK primary care electronic medical records (EMR) databases and Nordic health registries are the most commonly utilized databases in PAS. Other commonly used databases include German, French, Spanish & Dutch EMR; German statutory health insurance claims; Italian regional administrative claims (*Figure 3*). Most frequent use of databases in PAS is supporting studies focusing in General Medicine, followed by Neuroscience, Infectious diseases & Vaccines, Inflammation & Immunology and Oncology (*Figure 4*).

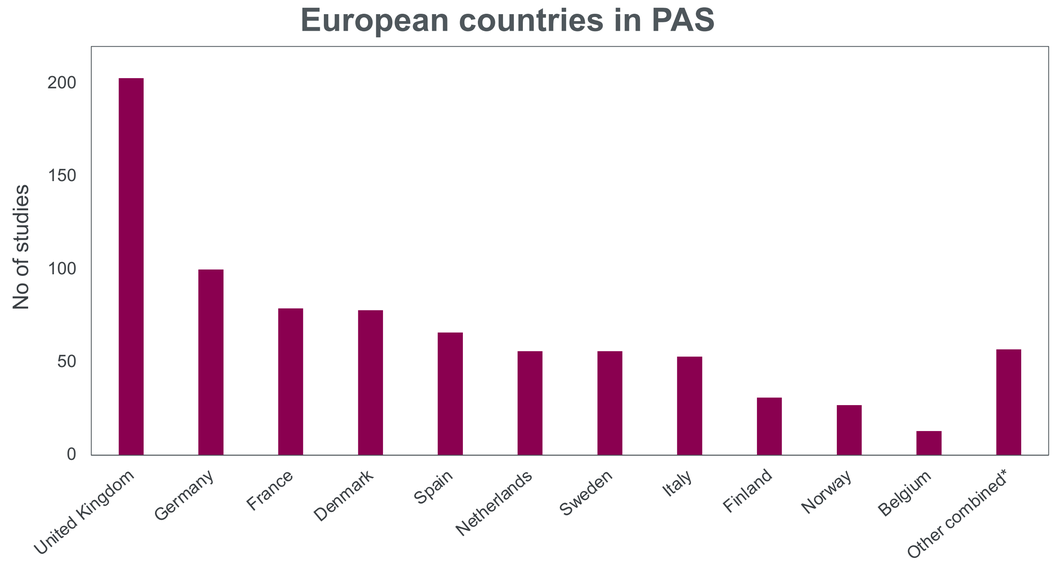

Figure 2: Frequency of European countries contributing to RWD studies registered in EU PAS register®. *All other countries combined, where less than 10 studies have been completed

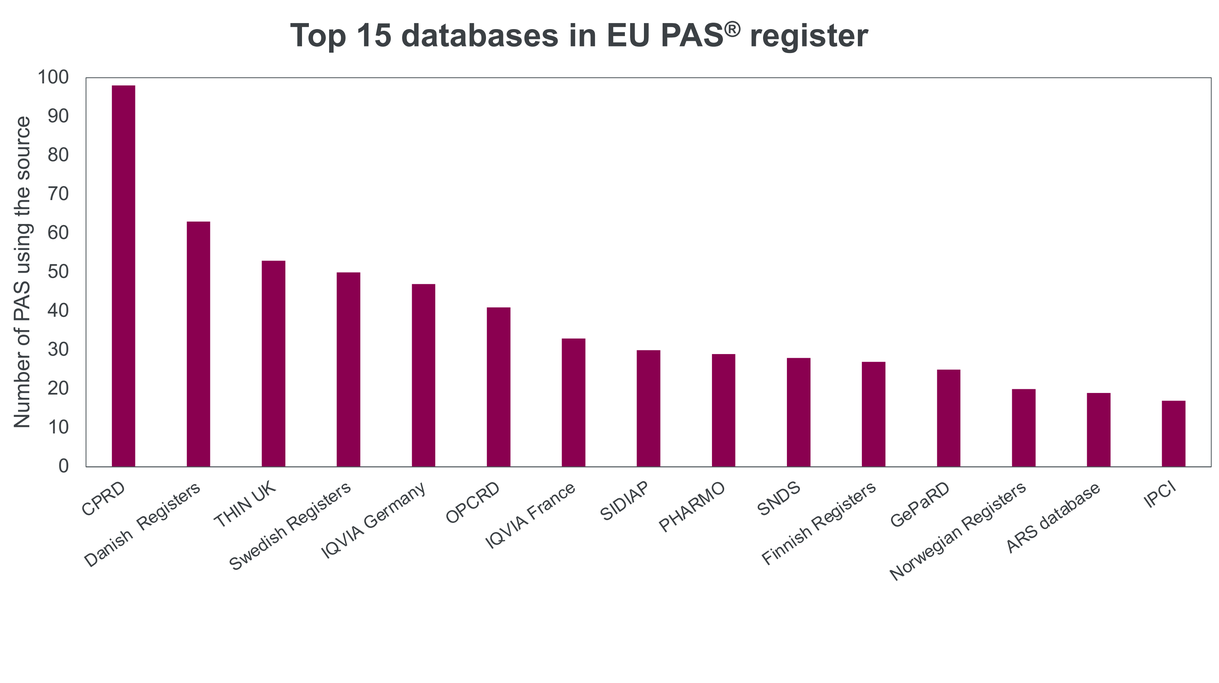

Figure 3: Frequency of European databases contributing to RWD studies in EU PAS register®

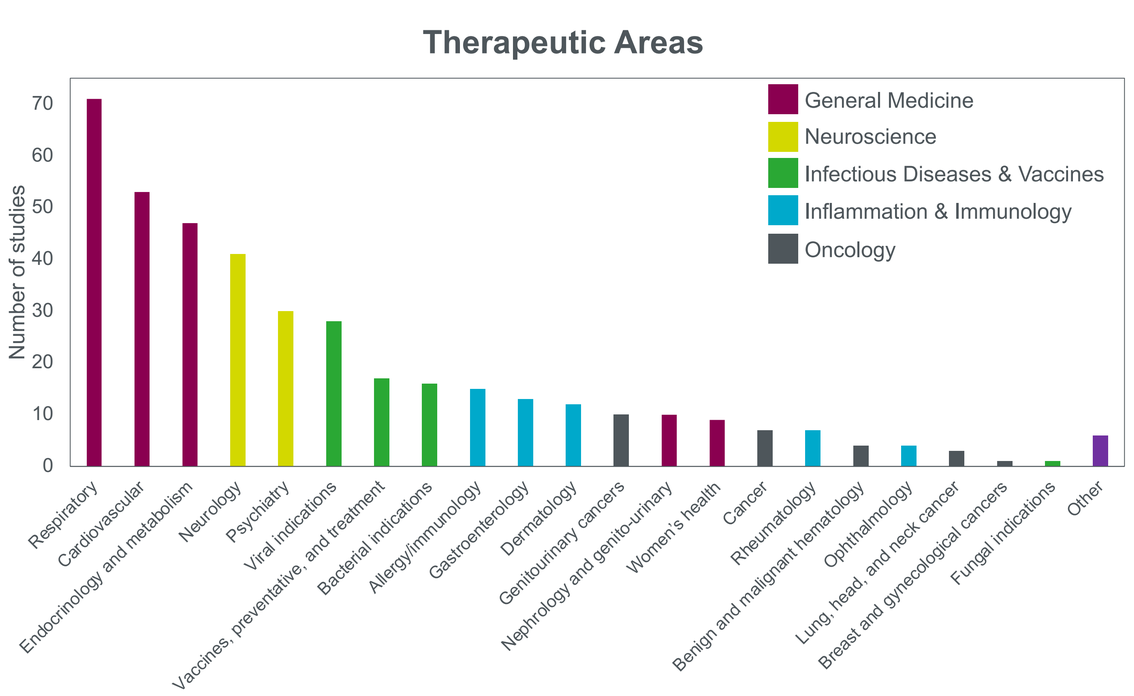

Figure 4: Frequency of therapeutic areas supported by European databases in EU PAS register®

Conclusions

This research is not the first attempt to describe the studies in the EU PAS Register®. Previous studies explored the availability of basic information alongside the availability of a study protocol [2]; searched the studies that evaluated the effectiveness of Risk Minimization Measures [3, 4]; analysed the methodological design in terms of study objectives and therapeutic areas [5]; described the characteristics of the registered PAS [6]. The present study is the latest to assess the content of the EU PAS Register®. Its main focus was to identify the European countries the PAS were conducted in, retrieve the database names and the therapeutic areas covered. It is a comprehensive analysis of the data sources and their respective countries in order to identify the most used data sources for PAS using established databases. The strength of this study is a quantitative analysis of databases usage in PAS, as well as the quantitative analysis of therapeutic areas these databases support.

Only the imposed PAS have an obligation to be recorded in the EU PAS register®. However, the same does not apply for the non-imposed PAS, thus limiting the accurate determination of the databases used across all categories of PAS. Furthermore, the lack of study protocol and/or results alongside the occasional inaccurate information provided on the studies' entries, obstructs the proper logging of databases and countries involved in PAS. The introduction of the metadata RWD catalogue by the EMA Big Data task force will be a step towards contributing to better understanding of the RWD utilization in PAS.

REFERENCES

[1] European Medicines Agency. Guideline on good pharmacovigilance practices (GVP) – Module VIII: Post-authorisation safety studies (Rev 2). Doc. Ref. EMA/813938/2011 Rev 2; August 2016 [online]. Available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129137.pdf

[2] Engel P et al 2017. Lessons learned on the design and the conduct of Post-Authorization Safety Studies: review of 3 years of PRAC oversight. Br J Clin Pharmacol (2017) 83 884–893.

[3] Farcas A et al 2019. Study design, process and outcome indicators of post-authorization studies aimed at evaluating the effectiveness of risk minimization measures in the EU PAS Register. Br J Clin Pharmacol (2019) 85 476–491.

[4] Vora P et al 2018. A review of studies evaluating the effectiveness of risk minimisation measures in Europe using the European Union electronic Register of Post-Authorization Studies. Pharmacoepidemiol Drug Saf. 2018;27:695–706.

[5] Carroll R et al 2017. An analysis of characteristics of post-authorisation studies registered on the ENCePP EU PAS Register [version 2; peer review: 2 approved]. F1000Research 2017, 6:1447.

[6] Sultana J et al 2022. Overview of the European post-authorisation study register post-authorization studies performed in Europe from September 2010 to December 2018. Pharmacoepidemiol Drug Saf. 2022;31(6):689-705.

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