In the Call to Action: Pre-Registration of Protocols published recently, the HMA-EMA catalogue for RWD studies was mentioned as being one of the possible places for the registration of protocols. However, it gave the impression that this was limited to studies imposed by regulators and performed within Europe only.

In fact, this catalogue has been launched in February 2024, following a complete restructuring of the former version named EU PAS register, that was in action for more than 10 years. Although at that time, the catalogue was mainly used for studies conducted in Europe for regulatory purpose, the register never restricted submissions and has always been open to pre-registration of any type of studies. In line with one of the key principles of the European Medicines Agency (EMA) — upholding transparency — the catalogues can be used by any party who strives to uphold the FAIR principles.

The change of the name, from EU PAS Register to HMA-EMA catalogue for RWD studies, has also been an important development to emphasize this. With the deletion of "EU", we want to change the perceived understanding that the primary focus is on EU-related studies and data sources. The deletion of "PAS" highlights that the catalogue is now for all types of studies and no longer limited to the Post-Authorisation Studies (PAS).

A lot of improvements have been implemented to ensure it follows the FAIR principles (with an updated structure) and to make it more user-friendly (with enhanced search filters). One of the key functions is now the link of the Catalogue of RWD studies with the Catalogue of RWD data sources, so that you can find more information on the data source(s) used in one study, or you can search for studies that have used the data of a specific data source.

This open-access source continues to growth every month with a steady increase in the number of records and includes now information on more than 3,100 RWD studies. Amongst these studies, close to 63% used European data sources only, 23% non-European data sources only, and 14% data sources from Europe and outside Europe.

As regulators, we consider it essential to share study information by registering all studies performed, whether these are mandated by regulators or not, together with the study protocol and study report to support the evaluation, interpretation, and reproducibility of results. The HMA-EMA Catalogue of RWD studies is one of the options available to achieve this aim.

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