EMA
EUROPEAN MEDICINES AGENCY

DARWIN EU

DARWIN EU® study

Background incidence rates of selected vaccine AESIs in Europe

Why is this study needed?

Rapid regulatory response to vaccine safety concerns is crucial to maintain public confidence. Background incidence rates (BGRs) of adverse events of special interest (AESIs) support this response, with use in observed-to-expected analyses as an essential initial step in the continuum of safety signal evaluation.

How were the results used?

These findings constitute preparatory work that can be used in observed-to-expected analyses to support faster response and for contextualisation of vaccine safety signals.

How was this conducted?

The AESI list was developed based on knowledge of most representative AESIs for a variety of vaccines (incl. COVID-19) and consultation with EMA and PRAC experts. This was a population-level cohort study in 5 European databases, which estimated BGRs per 100,000 person-years and stratified by calendar month, year, age group and sex.

Why do these results matter?

While multiple studies have generated BGRs, estimates are heterogeneous across data sources, with variable granularity in terms of population groups and factors such as seasonality. In addition, this study highlights the importance of regularly updated evidence to support preparedness and regulatory decision-making.

More information

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