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Non-interventional Studies: Different Types - Different Challenges

Scientific and methodological considerations should primarily drive the design and the conduction of Real World Data collection in order to increase available evidences for decision making.

However, running observational studies on drugs in the under-regulated EU environment poses also a number of significant challenges because the regulatory framework is mainly based on guidelines (rather than laws) which very often do not consider the methodological characteristics of the observational research.

As a consequence of this situation, the increasing need of observational research within the industry (before and after marketing authorization) is seriously challenged by the wide heterogeneity existing across EU countries not only on ethical requirements for approval of these studies but even on their formal definition.