

# REAL-WORLD DATA

## LEARNING FROM ROUTINE CLINICAL SETTINGS

### WHAT ARE REAL-WORLD DATA (RWD)?

RWD are information reported and collected from real-world medical settings that may show the effectiveness and safety of a medicine for an approved indication in patients. These data may be collected in one country or collected from all over the world.<sup>1</sup>

### HOW ARE RWD COLLECTED?

RWD can be collected through a number of different sources:<sup>2</sup>



Electronic medical records



Claims databases



Health surveys



Registries



Health-related apps, mobile devices, and social media



RWD may include larger and more diverse patient groups that can complement clinical trial data, which come from randomized, controlled studies evaluating pharmaceutical products in specific patient populations.



### HOW ARE RWD USED?

RWD analyses generate insights about the effectiveness and safety profile of a medicine. RWD studies can help explore additional research questions, complement clinical trial findings, and fill gaps related to how a medicine is used in real-world medical settings. RWD may also be used to inform future investigational plans to increase efficiency and reduce cost.<sup>1</sup>



### WHAT ARE SOME OF THE LIMITATIONS OF RWD?

Real-world data analyses have several limitations. For example, the source and type of data used may limit the generalizability of the results and of the endpoints. Observational real-world studies can only evaluate association and not causality. Due to these limitations, real-world data analyses are not used as stand-alone evidence to validate the efficacy and/or safety of a treatment.

### WHO MAY BE INTERESTED IN RWD?



#### PROVIDER & PAYER ORGANIZATIONS

to increase their knowledge about the effectiveness, safety and costs associated with a treatment option.



#### HEALTHCARE PRACTITIONERS

to help inform the real-world implications of their treatment decisions.



#### PATIENTS

to help discussions with their healthcare professional about treatment options.