Novartis Oncology

Real-World Evidence

What is real-world evidence?

- Real-world data (RWD) are collected outside traditional controlled clinical interventional trials under real-life practice circumstances. The scope of data can be product-specific but can also be on a disease area level. Real-world evidence (RWE) is RWD that have been organized to inform a conclusion or judgment.
- The US Food and Drug Administration (FDA) has created a framework for evaluating the potential use of RWE to help support the approval of a new indication for a drug already approved under section 505(c) of the FD&C Act or to help support or satisfy drug post-approval study requirements.
  - Section 505F(b) of the FD&C Act defines RWE as "data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials" (21 USC 355g[b]).

What are sources of real-world evidence?

- RWE is generated by analyzing data collected from a variety of sources:
  - Electronic health records
  - Medical claims
  - Billing activities databases
  - Patient-generated data
  - Mobile health technology devices
  - Non interventional observational studies and registries
  - Disease registries
  - Laboratory data
  - Survey data
  - Consumer data
  - Pharmacy data
  - Mortality data

How is real-world evidence used in a clinical trial?

- RWE can significantly impact clinical study design and the speed of analysis.
- Traditional randomized clinical trial design normally begins with creating a hypothesis, defining the patient cohort, and following the patients prospectively over time.
- By contrast, RWE can be used to test a hypothesis retrospectively across existing information, rather than collecting new data.

How can real-world evidence help researchers and clinicians?

- While randomized clinical trials offer insights into the safety and efficacy of medications in a controlled setting, with significant supervision over participants, RWE can offer insights into how broader patient populations may use medications day-to-day and uncover treatment patterns or demographic trends. These insights can be used to support both regulatory and policy decisions and help clinicians develop care plans.

As part of our commitment to reimagine medicine, Novartis is exploring ways to bring treatments to patients in need more quickly, including through the use of real-world evidence in clinical trials.

NOVARTIS

Novartis Pharma AG
CH-4002 Basel Switzerland

1/22 170033

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080