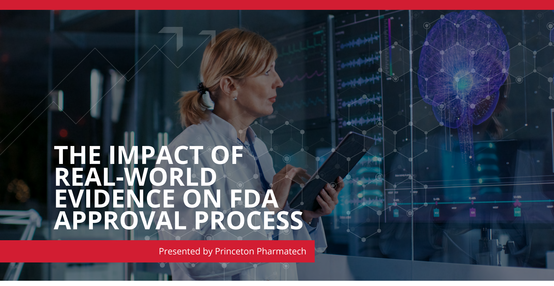

THE IMPACT OF REAL-WORLD EVIDENCE ON FDA APPROVAL PROCESS

Presented by Princeton Pharmatech

INTRO

Since the passage of the 21st Century Cures Act (aka Cures Act) in 2016, the FDA has been releasing new protocols and programs to expedite the approval process for new medical drugs and devices.

The Real-world Evidence (RWE) program allows for the use of data collected outside of clinical trials to be incorporated into research submitted for FDA approval.

The use of RWE can be beneficial throughout the entire research and development process of new drugs and devices, provided it appear as though it was generated through a randomized clinical trial.

ABOUT

Princeton Pharmatech provides clinical trial biostatistics and programming solutions to the pharmaceutical, biotechnology, life science and research industry.

REAL-WORLD EVIDENCE

Clinical evidence that is extrapolated from real-world data

REAL-WORLD DATA

Data routinely collected regarding patients' health status and delivery of healthcare

IMPACT OF RWE ACROSS FDA APPROVAL PROCESS PHASES

Pre-clinical Phase

- Drug development
- Animal toxicity trials
- Pharmacokinetic research
- Can take 3-7 years

RWE BENEFITS

- Provide information on burden of diseases
- Indicate need for medical interventions
- Influence drug development efforts

Phase 1

- First trials in human subjects
- Small study population (20-80) of healthy participants
- Emphasis on safety of drug or device
- Can take 1-2 years

RWE BENEFITS

- Identify characteristics of patient population
- Provide evidence of patient pathway from disease diagnosis through treatment
- Aid clinical study design

GET OUR NEW E-BOOK ON THE RWE PROGRAM

The distinction between RWD and RWE is technical but important to understand nonetheless, you can also read our new E-Book on RWE, and check out our blog.

LEARN MORE

Phase 2

- Medium-sized studies with hundreds of participants
- Evaluates effectiveness of treatment in persons with disease or condition
- Safety and short-term side effects measured
- Can take 1-2 years

RWE BENEFITS

- Provide evidence of feasibility of clinical treatment
- Generate hypotheses for future clinical studies
- Aid clinical study design for larger-scale studies in phase 3

Phase 3

- Large-scale controlled trials with thousands of participants
- Evaluate effects in different populations and with different dosages
- Evaluates safety, especially when used with other drugs
- Can take 1-2 years

RWE BENEFITS

- Provide necessary information for real-world implementation of treatment or intervention
- Provide evidence on pharmacology, toxicology, and safety
- Inform about unmet need and standard of care

Post-market

- Post-market research
- Safety and efficacy
- Can take 1-2 years or more

RWE BENEFITS

- Provide up-to-date information on clinical uses and patient status
- Maintain access and demonstrate continued value of intervention method
- Demonstrate real-world uses of intervention

SOURCES

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United States, Food & Drug Administration. (2018, December). FRAMEWORK FOR FDA'S REAL-WORLD EVIDENCE PROGRAM. Retrieved from https://www.fda.gov/media/120060/download

What is the Big Deal with the FDA's new RWE Program?

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