AMCP | Regulatory NewsBREAK

FDA Issued Guidance on Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products

- On August 30, 2023, the Food and Drug Administration (FDA) announced the availability of guidance on Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products (Guidance).
- This guidance discusses the applicability of FDA's investigational new drug application (IND) regulations to various clinical study designs that utilize real-world data (RWD) and clarifies the Agency's expectations regarding clinical studies using RWD submitted to FDA in support of a regulatory decision regarding the effectiveness or safety of a drug that are not subject to the IND regulations.
- This Guidance finalizes the draft guidance of the same title issued on December 9, 2021.

See the Guidance for additional details.

More on This Topic:

- Guidance

For questions, please reach out to Vicky Jucelin.