

21 U.S. Code § 355g

Utilizing real world evidence

(a) In general

The Secretary shall establish a program to evaluate the potential use of real world evidence—

- (1) to help to support the approval of a new indication for a drug approved under section 355(c) of this title; and
- (2) to help to support or satisfy postapproval study requirements.

(b) Real world evidence defined

In this section, the term “real world evidence” means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials.

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