

Complexity and costs of assessing real-world effectiveness of new drugs.

## Description

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Before a new drug can be sold, its manufacturer must obtain government regulatory approval following rigorous testing in expensive and lengthy clinical trials to demonstrate the drug's safety and effectiveness in patient test populations. Increasingly, regulators and health insurers are also requiring evidence of *real-world* benefits and risks of new drugs after they have been released to the market and are used by larger patient populations. While devising schemes and enacting legislation is relatively easy, putting processes like the measurement of real-world benefits into action is more complex. Some important issues about evaluating drugs in the real-world need consideration.