# Article information:

Interpretation and Impact of Real-World Clinical Data for the Practicing Clinician - PMC
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6223979/>

# Article summary:

1. Real-world studies provide evidence of treatment effectiveness in clinical practice, complementing the findings from randomized controlled trials (RCTs).

2. RCTs have strict inclusion and exclusion criteria, making their trial populations not representative of real-world patient populations.

3. Real-world studies use large datasets from diverse patient populations to provide information on long-term safety, effectiveness, utilization patterns, and health and economic outcomes of drugs in practice.

# Article rating:

Appears moderately imbalanced: The article provides some useful information, but is missing several important points or pieces of evidence that would be required to present the discussed topics in a balanced and reliable way. You are encouraged to seek a more balanced perspective on the presented issues by exploring the provided research topics and looking at different information sources.

# Article analysis:

The article titled "Interpretation and Impact of Real-World Clinical Data for the Practicing Clinician" provides an overview of the importance of real-world studies in complementing randomized controlled trials (RCTs) to gain a more complete understanding of treatment effectiveness in clinical practice. While the article provides valuable information on the benefits and limitations of real-world studies, there are several potential biases and missing points that need to be considered.

One potential bias in the article is its sponsorship by Sanofi US, Inc. The funding source may introduce a conflict of interest and influence the content and conclusions presented. It is important to critically evaluate the information provided in light of this potential bias.

The article highlights the limitations of RCTs, such as strict inclusion and exclusion criteria that may not represent real-world patient populations. While this is a valid point, it fails to acknowledge that RCTs are designed to minimize bias and confounding factors, which can provide more reliable evidence for treatment efficacy. Real-world studies, on the other hand, are observational in nature and subject to various confounders that may affect their validity.

The article also claims that real-world studies can provide information on long-term safety, particularly rare events, and effectiveness of drugs in large heterogeneous populations. While this is true to some extent, it fails to mention that real-world studies are often limited by incomplete or inaccurate data from electronic health records or claims databases. These sources may not capture all relevant information on adverse events or treatment outcomes.

Furthermore, the article suggests that real-world data can be used as external control arms for RCTs to provide comparative efficacy data. However, it does not address the challenges associated with using retrospective real-world data as controls, such as selection bias and confounding variables. Without addressing these issues, the validity of using real-world data as controls in RCTs may be questionable.

The article also mentions that regulatory bodies like the FDA and EMA recognize the importance of real-world data. While this is true, it fails to mention that these regulatory bodies still prioritize evidence from well-designed RCTs for drug approval and labeling decisions. Real-world data may be used to support post-marketing surveillance and monitoring, but they are not considered as strong evidence for initial drug approval.

Additionally, the article does not adequately address potential risks associated with real-world studies. For example, relying on retrospective data from electronic health records or claims databases may introduce biases and inaccuracies in the analysis. It is important to acknowledge these limitations and consider them when interpreting the results of real-world studies.

Overall, while the article provides some valuable insights into the role of real-world studies in complementing RCTs, it has several biases and missing points that need to be considered. Critical evaluation of the information presented is necessary to make informed decisions about treatment effectiveness in clinical practice.

# Topics for further research:

* Limitations of real-world studies in healthcare research
* Challenges of using retrospective real-world data as controls in clinical trials
* Biases and inaccuracies in electronic health records and claims databases
* Role of randomized controlled trials in drug approval and labeling decisions
* Risks and limitations of relying on real-world data for treatment effectiveness
* Conflict of interest in sponsored research and its impact on study conclusions

# Report location:

<https://www.fullpicture.app/item/093761aca92847c18ada8400d34f4d45>