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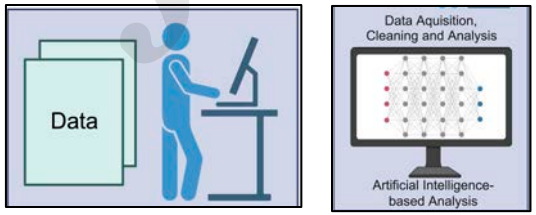
Real-world data and evidence: pioneering frontiers in precision oncology

Key words: Real-world study (RWS); Precision oncology; Real-world data (RWD); Study design; Data characterization

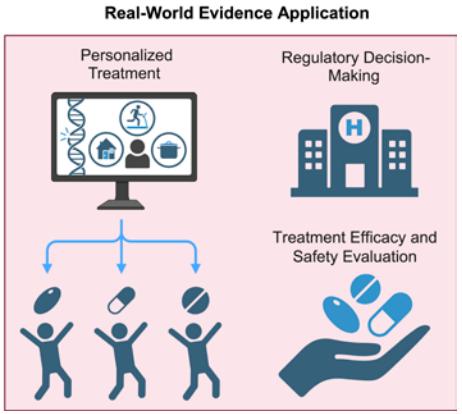
Research Summary

This review mainly focused on the evolving landscape of RWSs in oncology and their impact on precision medicine. We provided a comprehensive analysis in the following aspects:

- **Process of RWSs leveraging diverse data sources to generate evidence**
- **Key contributions of RWSs in precision oncology research**
- **Design essentials for real-world studies**
- **Application of AI in RWD analysis**
- **Significant challenges and advancements**



Data process and analysis



Innovation points

- **The CHARACTERISTICS of RWSs compared with RCTs**

Table 1 Characteristics of Real-World Studies (RWSs) and Randomized Controlled Trials (RCTs)

Characteristic	RWSs	RCTs
Study Design	Observational studies using routine clinical data; multiple design options	Controlled experiments with randomization; standardized protocols
Population	Broad, diverse patient populations; includingcomplex cases	Selected participants meeting strict criteria; excludingcomorbidities
Data Quality	Variable quality; potential bias and confounding	High quality; minimized bias through randomization
Outcomes	Long-term effectiveness; patient-reported outcomes; real-world safety	Specific endpoints; efficacy under ideal conditions; short-term focus
Implementation	Cost-effective; faster recruitment; applyingexisting data	Resource-intensive; lengthy recruitment; complex logistics
Strengths	Real-world applicability; population representativeness; long-term insights	Strong causal inference; internal validity; standardized evidence
Limitations	Data quality concerns; bias control challenges; privacy issues	Limited generalizability; high cost; artificial setting
Regulatory Role	Complementary evidence; growing acceptance	Primary evidence; established standard

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Innovation points

- **The essentials to design RWSs.**

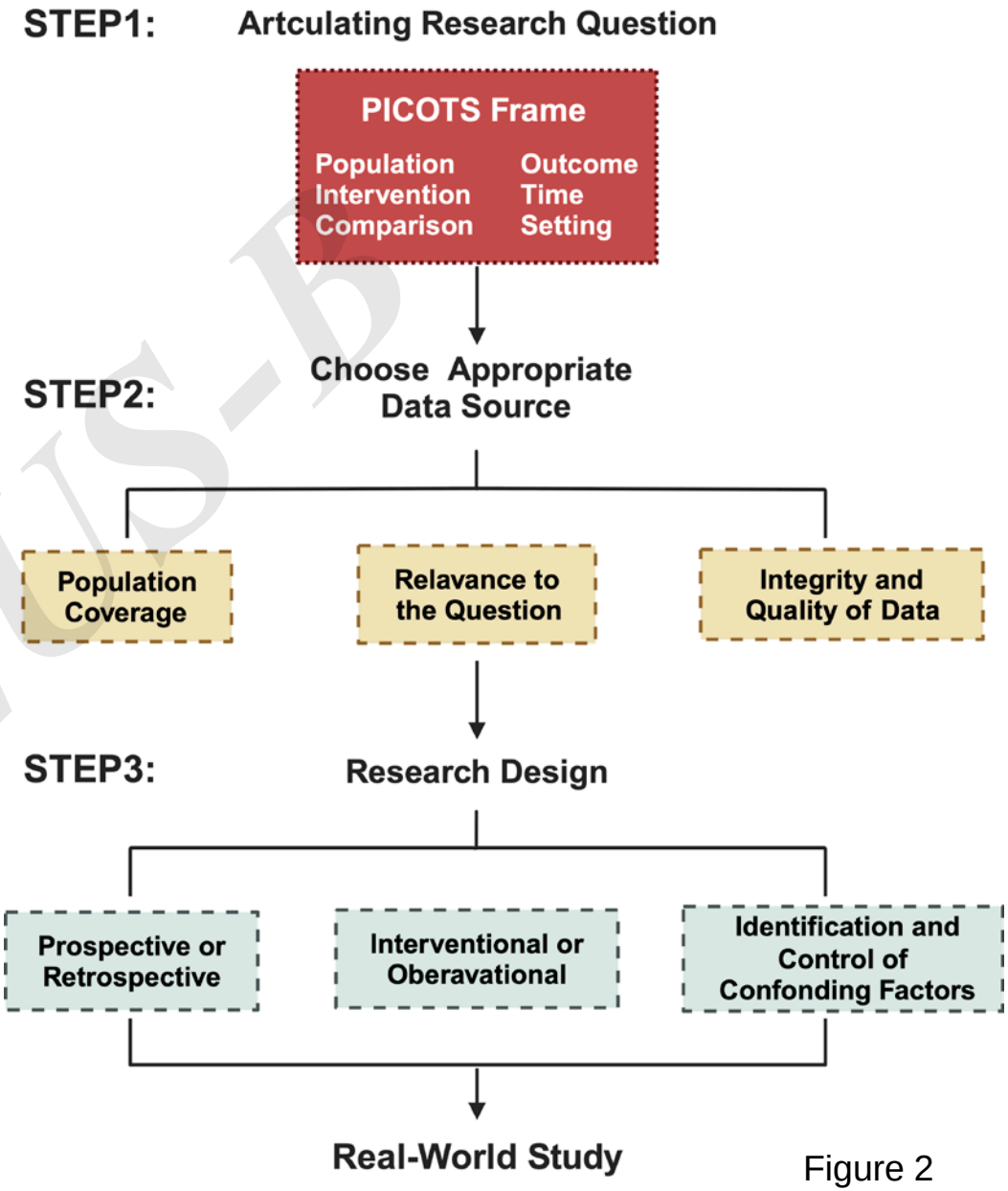

Figure 2

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