

1. Introduction

Real-world data is being extensively used across different areas of clinical research. Furthermore, the FDA's commitment to considering real-world evidence in regulatory decision-making emphasizes the pivotal roles RWD will play in upcoming research. An important though niche use of RWD is to serve as a control arm (CA) in clinical trials, which can be a reliable alternative to randomized control trials. However, real-world data presents a unique set of challenges in its use as an external control arm due to the 3 V's – Volume, Velocity, and Veracity. In this poster, we will be exploring a scientific framework to conduct a fidelity assessment for the use of RWD in planning, execution, and reporting as a control arm.

2. Challenges in RWD

Real-world data is rich and vast but messy, incomplete, and inconsistent, like a jumble of puzzle pieces from different sets.

Top 3Vs that deal with RWD:

Velocity: The data is constantly flowing, like a rushing river, making it hard to keep up and analyse it all.

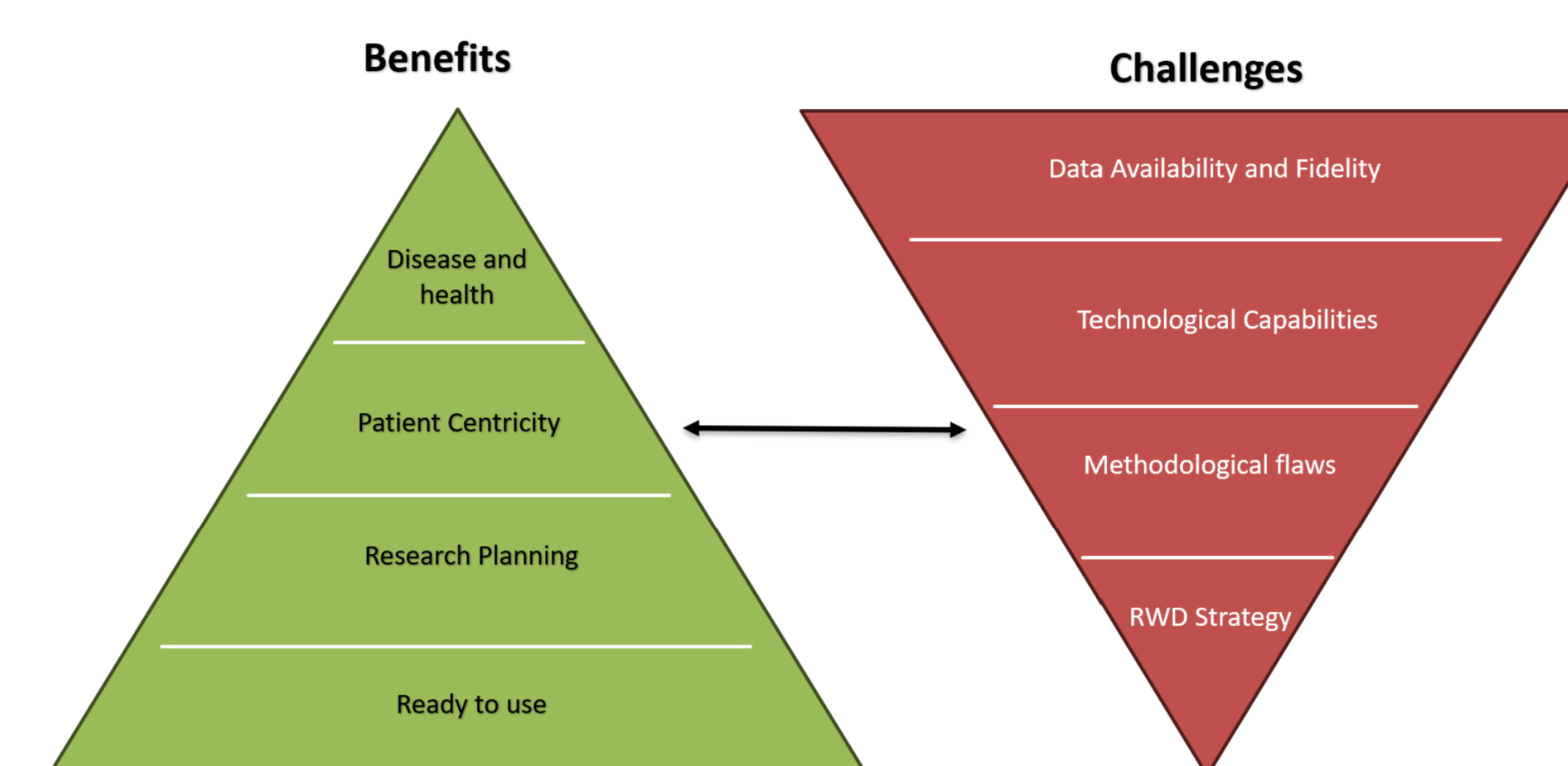
Volume: There's just so much of it! It's like trying to build a bridge out of every pebble on a beach. Medical records, sensor data, financial transactions – it's overwhelming.

Veracity: Reliability and accuracy of the data, pondering whether it is trustworthy or fraught with noise and errors

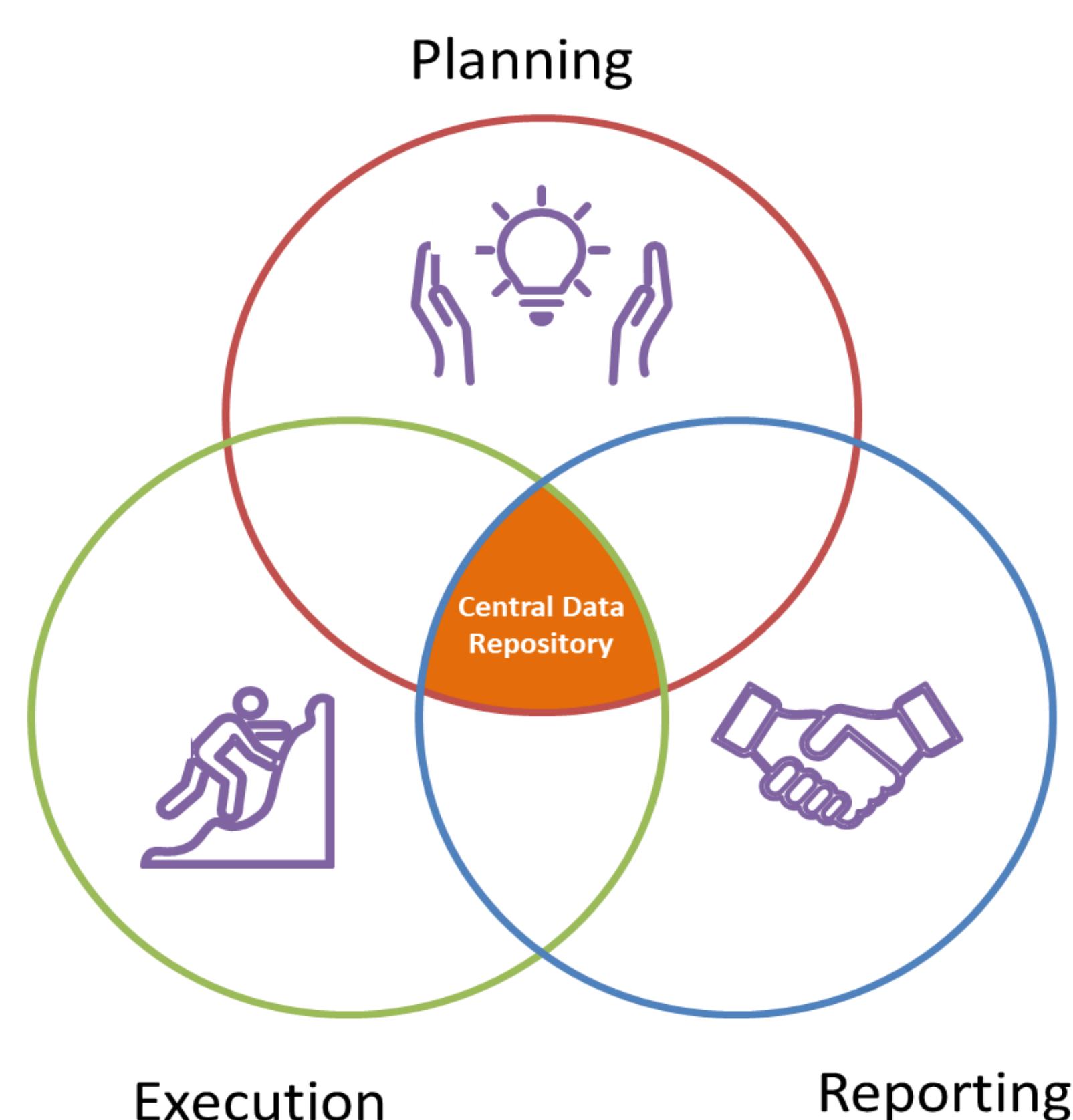
These challenges make it difficult to extract clean, reliable insights from real-world data that meet the strict standards for regulatory decisions.

3. Risk-Benefit- Balance

The emerging role of RWD as an alternative approach to traditional randomized clinical trials pose certain unique benefits as well as challenges.



4. Fidelity Assessment



By proficiently evaluating the elements within the three outlined stages and making knowledgeable choices, Real-World Evidence (RWE) data can be prepared for use as an external control arm.

Planning: Early Engagement, representative population, selection of data source, data collection elements, study design, compliance with regulations.

Execution: Data linkage, data transformation, advanced analytics, data quality standards like completeness, plausibility, traceability, interoperability, timeliness.

Reporting: Clinically relevant outcomes, regulatory-grade evidence generation, Informed decision making

5. Conclusions

Using real-world data as a control arm in clinical trials presents challenges regarding data quality standards. Engaging stakeholders early in the process, carefully assessing risks and benefits, and meticulously planning and executing its usage can create value for both patients and sponsors. Furthermore, as regulators continue to recognize the significance of real-world data (RWD) in uncovering previously unrecognized insights, RWD can be instrumental in understanding the patient journey and facilitating data-driven decision-making.

