

# Real World Data – What is Fit For Purpose?



## Real World Evidence

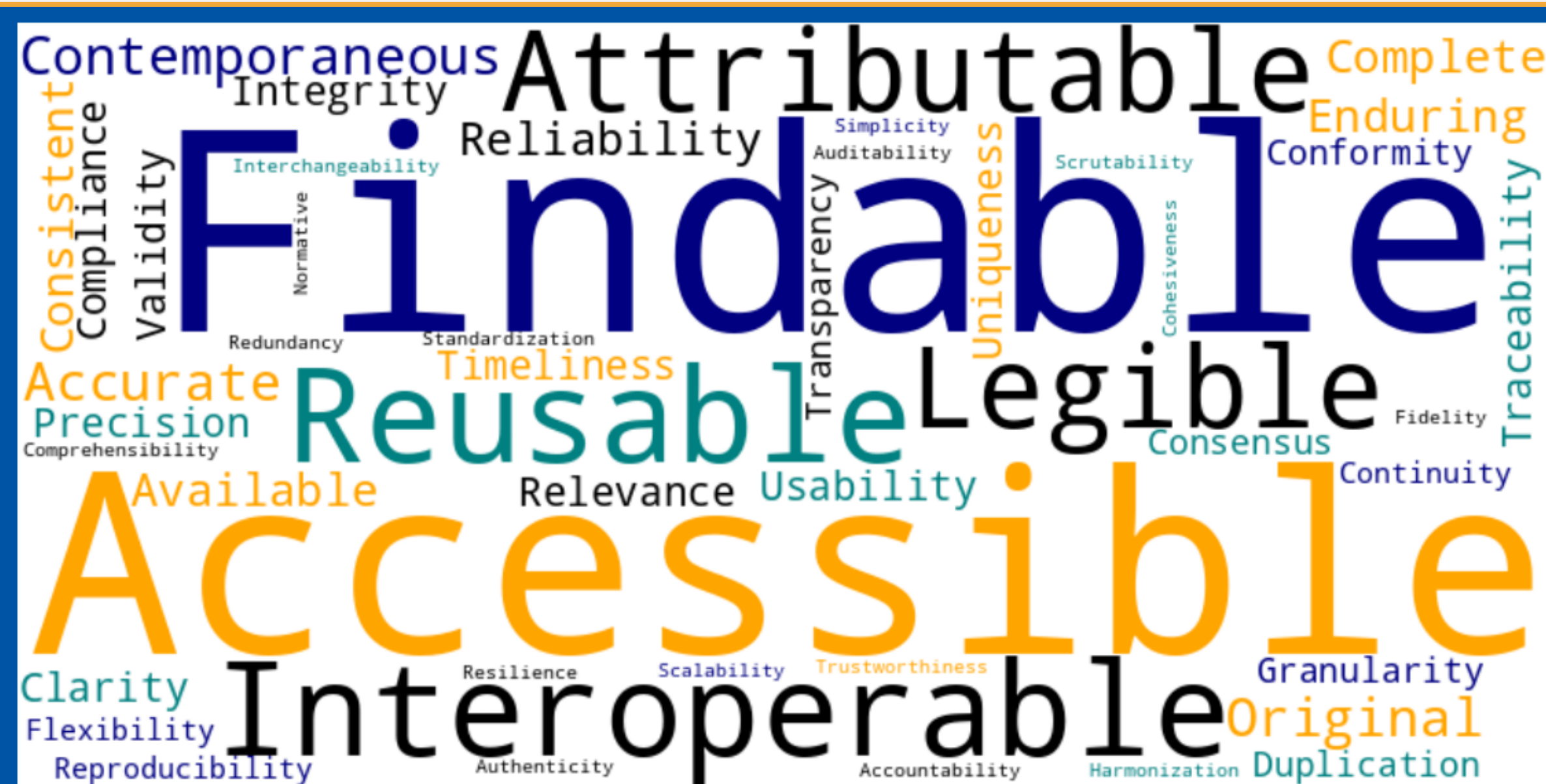
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Project:  
Quality and reusability  
of Real-World Data



This poster summarizes the RWE working group discussions from the recent 2023 PHUSE CSS. At the event, sponsors, vendors and regulators evaluated recent regulatory guidance, created definitions, and identified gaps for sponsors to utilize Real-world data (RWD) to generation Fit For Purpose Real-World-Evidence (RWE).

### How did we define data quality?



### Key dimensions of fit for purpose:

	FDA <sup>1</sup>	EMA <sup>2</sup>
Relevance	<ul style="list-style-type: none"> <li>Availability</li> </ul>	<ul style="list-style-type: none"> <li>Representativeness</li> <li>Timeliness</li> </ul>
Reliability	<ul style="list-style-type: none"> <li>Data accuracy</li> <li>Completeness</li> <li>Provenance</li> <li>Traceability</li> </ul>	<ul style="list-style-type: none"> <li>Precision</li> <li>Accuracy</li> <li>Plausibility</li> <li>Extensiveness</li> <li>Coherence</li> </ul>

1. US Food and Drug Administration. Framework for FDA's Real-World Evidence Program. US Department of Health & Human Services; December 2018.  
2. [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation_en.pdf)

### Identified Issues

#### Current Gaps

- Too many data transformations -> loss of meaning
- Traceability and transparency not accounted for
- No clear policy for vendors to establish provenance
- No quality control on EHR extraction practices

#### Shared Experiences

- Data not meeting the quality that was suggested
- Data difficult to validate
- Issues with geographical and patient info coverage
- Lack of standardization

### Follow-Up project plans

- Blogs on Use cases and Regulatory requirements
- Vendor alignment, characteristics and points of attention
- White paper: "Requirements for quality and reusability of Real-World data" based on input from regulatory agencies, industry and data vendors

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For more information or to join a project in the RWE working group:

