



Overcoming Challenges – FDA Perspective

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Value of RWE



**World
Clinicians**



Patients

Value of RAPID

- Engages all stakeholders
- Provides proof-of-concept and demonstration
- Allows open, honest discussion of what works well and what can be improved

**GOAL → ↑ Quality & ↑ Reliability & ↑ Robustness
to support clinical and regulatory decision
making**



Challenges and Solutions

Sample Challenges

- Missing data
- Invalid data (eg, lesion length in mm rather than cm)
- Limited follow-up

Sample Solutions

- Standardized elements
- Prospective SAP to account for expected challenges and to reduce potential bias
- Adaptable, unbiased clinical and statistical committee
- Registry validation
- UDI utilization
- Linkages to other registries, EHRs, or CMS

Decision Making with RWE

