Real-World Evidence Landscape

Stakeholders often require evidence generated from real-world settings to make decisions regarding treatment, coverage, and reimbursement. This is most evident in the recent passage of the 21st Century Cures Act, which requires the Food and Drug Administration (FDA) to develop guidance for the use of real-world evidence (RWE) in regulatory decisions on new indications and post-approval requirements for existing medical products.

RWE is derived from the aggregation and analysis of real-world data (RWD). According to FDA authors of a recent *New England Journal of Medicine* article, RWD is collected from sources outside traditional clinical trials, such as:

- Observational studies
  - Databases (eg, electronic medical records, administrative claims)
  - Chart reviews
  - Product and disease registries
  - Prospective studies +/- interventions (eg, visits, procedures, tests)
- Pragmatic trials with post-randomization standard of care

Fit-for-Purpose Virtual RWE (vRWE) Studies

Improved technologies and the availability of platforms for patient identification, access, and data capture open the door to innovative and efficient study designs to collect RWD virtually. Through consultation and collaboration, Covance experts determine the best study design to meet your RWE needs. We are challenging the traditional site-based paradigm by integrating virtual components into otherwise traditional study designs.

![Customized Study Design Spectrum](image)

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The LabCorp Advantage in vRWE

As part of LabCorp, we can reduce the burden on investigators by collecting samples at LabCorp Patient Service Centers when routine or esoteric laboratory tests are required.

Figure 2. Sample vRWE Study With Laboratory Testing

Let’s start the conversation and begin customizing an optimal study design for your RWE needs.

#vRWE

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