



valeritas

Improving health and simplifying life for people with diabetes

Study Design & Quality Measures

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Real World Evidence Demonstrates Real Results

- Valeritas has focused on providing data that demonstrates clinical and economic benefits in a real-world setting
 - Based on standard clinical practice
 - Inclusive of a wide range of patients (good control to poor control)
 - No forced insulin titration algorithms
 - No mandated office visits or regular phone contact
 - Patients pay for product and office visits copays

Randomized Controlled Trials vs Real World Evidence

Randomized Controlled Trials

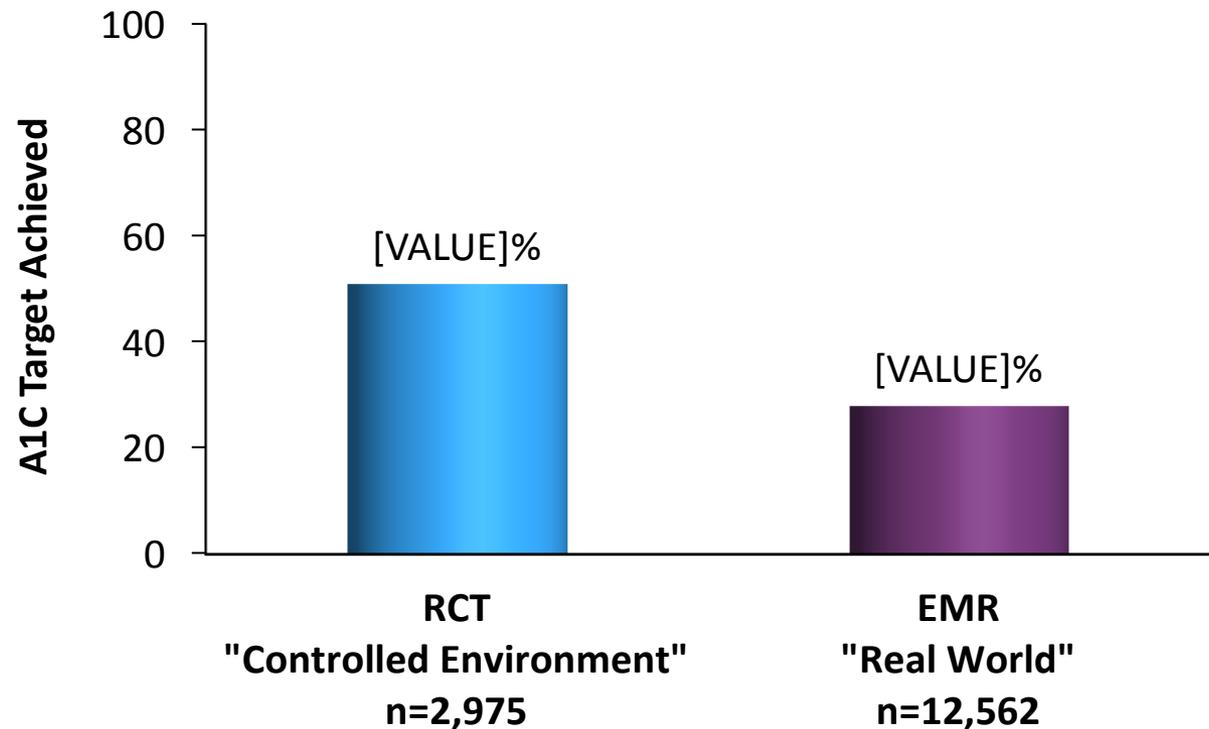
- Prospective in design
- Required for FDA submissions of pharmaceuticals, not devices
- Tests a pre-conceived hypothesis that may or may not be based on previous scientific observations
- Strict criteria for subjects studied; “sterile environment”
- Controls for concomitant diseases and medications; not “real-world”
- Tests for impact of a single treatment modality

Real World Evidence

- Prospective or retrospective in design
- Real-world; few controls other than standards for comparison for scientific credibility
- Rich database already exists via clinical observations and assessment notes and can be accessed
- Can compare several different treatment modalities in the same treatment environment
- Generates hypotheses for future prospective efficacy and safety studies

Disparity May Exist between Randomized Controlled Trials (RCTs) and Real World Clinical Practice

RCTs follow restrictive/controlled methodologies and patients are carefully screened based on precise clinical criteria. Findings may not be generalizable to everyday clinical practice.



Study in patients prescribed basal insulin to evaluate achievement of A1C target (<7.0%) after 6 months across 11 pooled RCTs and 1 electronic medical record (EMR) database representing "real world" clinical practice

A Changing Healthcare Landscape

Quality Measures and Performance Standards

- Health plans and physicians are being called on to close gaps in care and improve overall quality
 - “Quality of Diabetes Care” is measured across all performance standards
- The Centers for Medicare and Medicaid (CMS) use quality measures and performance to
 - Allocate shared savings for ACO’s
 - Assign *Star Ratings* highlighting the quality of medical/health care services provided by a plan which can influence rebates/bonuses to plans and allow for comparisons between plans by beneficiaries.
- Commercial plans also use quality measures for accreditation and have financial incentives for improving performance based on scores