The Evolving Landscape of Real-World Evidence in Drug Pricing Decisions

RWE as a Strategic Lever in Access & Reimbursement

Presented by: Beni Turner

Evidence 360: RWE, Pricing & Reimbursement Summit USA

26th – 27th June 2025

Magnolia market access

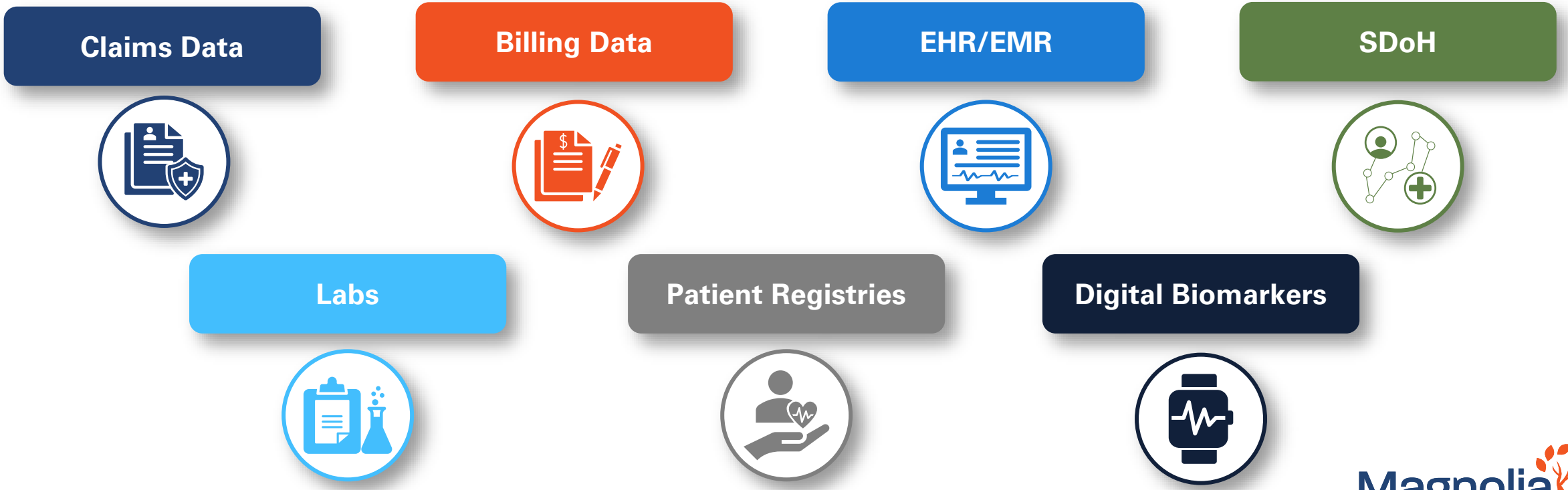
a medical knowledge group company

Agenda

1. Real-World Evidence
2. Traditional Drug Pricing Models
3. RWE's Emerging Role in Pricing & Reimbursement
4. Regulatory Momentum: Global and US Landscape
5. Strategic Insights
6. Emerging Trends in RWE
7. Actionable Strategies for RWE Integration

Real-World Evidence (RWE) Background

- ***Evidence*** or ***insights*** derived from the analysis of real-world data
- Frequently used to demonstrate clinical benefits and/or risks associated with medical therapy
- RWE versus RCT
- Sources of real-world data include:



Magnolia market access
a medical knowledge group company

Traditional Drug Pricing & Access Framework: RWE Integration Lags Behind as Post-Market Afterthought & Obligation

Development → Approval → Launch → Post-Market Data Collection

- Treatment Uniqueness
- Market Competition
- Clinical Trial Efficacy
- Research & Development Cost
- Market Size
- Insurance Benefit Design

Traditional Drug Pricing & Access Framework: RWE Integration Lags Behind as Post-Market Afterthought & Obligation

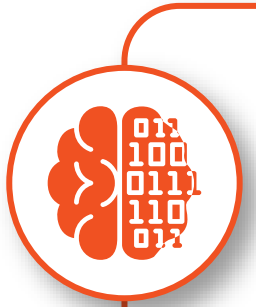
- Treatment Uniqueness
- Market Competition
- Clinical Trial Efficacy
- Research & Development Cost
- Market Size
- Insurance Benefit Design

Magnolia market access
a medical knowledge group company


RWD/RWE
Development
Approval
Launch
Post-Market
Data Collection

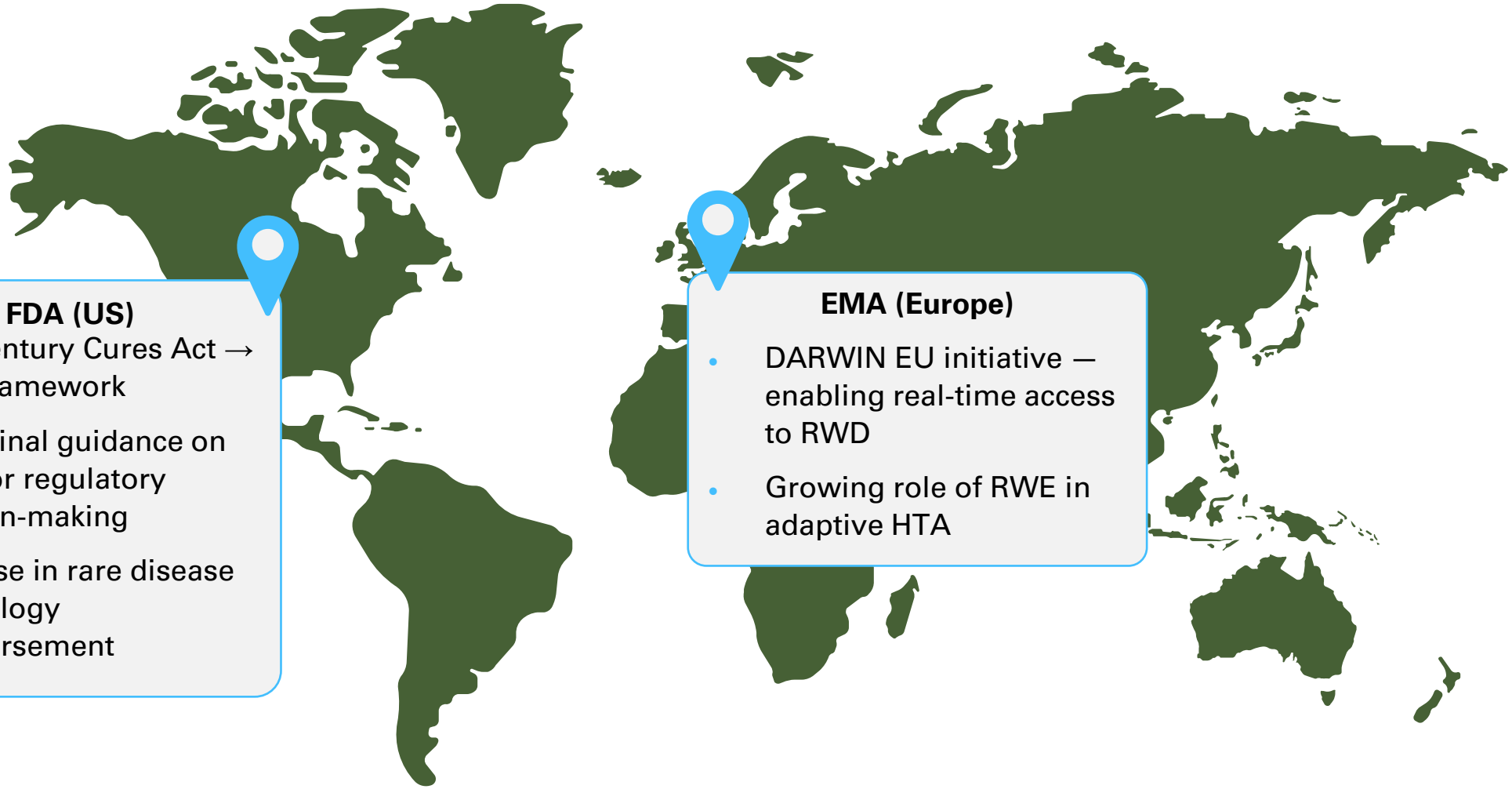
Early, Strategic Integration of RWE Adds Color to & Expands Context of Traditional RCT Insights

Development → Approval → Launch → Post-Market Data Collection



- **Value-Based Pricing & Contracting**
- **Health Technology Assessments**
- **Conditional Approval**
- **Adaptive Pathways**
- **Market Access Optimization**
- **Personalized Medicine**

Global Regulatory Shifts



FDA (US)

- 21st Century Cures Act → RWE framework
- 2024: Final guidance on RWE for regulatory decision-making
- RWE use in rare disease & oncology reimbursement

EMA (Europe)

- DARWIN EU initiative — enabling real-time access to RWD
- Growing role of RWE in adaptive HTA

Global Regulatory Shifts

HTA Bodies

- NICE (UK), CADTH (Canada), HAS (France) using RWE in conditional pricing
- ICER (US) incorporating RWE in cost-effectiveness re-evaluations

Magnolia market access
a medical knowledge group company

FDA Guidance Highlights: RWE Use to Support Regulatory Submissions

Methodological Considerations

- **Relevance:** Availability, timeliness, and generalizability
- **Reliability:** Accrual, quality, and integrity of data, with sufficient sample size for representative patient populations
- **Data Quality:** Accurate, complete, and representative data
- **Statistical Approaches:** Appropriate statistical methods to address biases and confounders
- **Validation:** Confirmation of findings through validation studies and/or RCT data comparisons

Regulatory Uses of RWE

- **Pre-Market Submissions:** Supporting evidence for effectiveness and safety during the approval process
- **Post-Market Studies:** Monitoring ongoing safety and effectiveness in the general population
- **Labeling Changes:** Providing data that may justify modifications to product labeling based on real-world usage

The Payer Perspective: 5 Key Payer Considerations for RWE

Population Relevance

Predictive Indicators for Budget Impact

Consistency of RWE vs RCTs

Transparent Methodologies

Support for Value-Based Contracts

The Payer Perspective: 5 Key Payer Considerations for RWE

Population Relevance

Predictive Indicators for Budget Impact

Transparent Methodologies

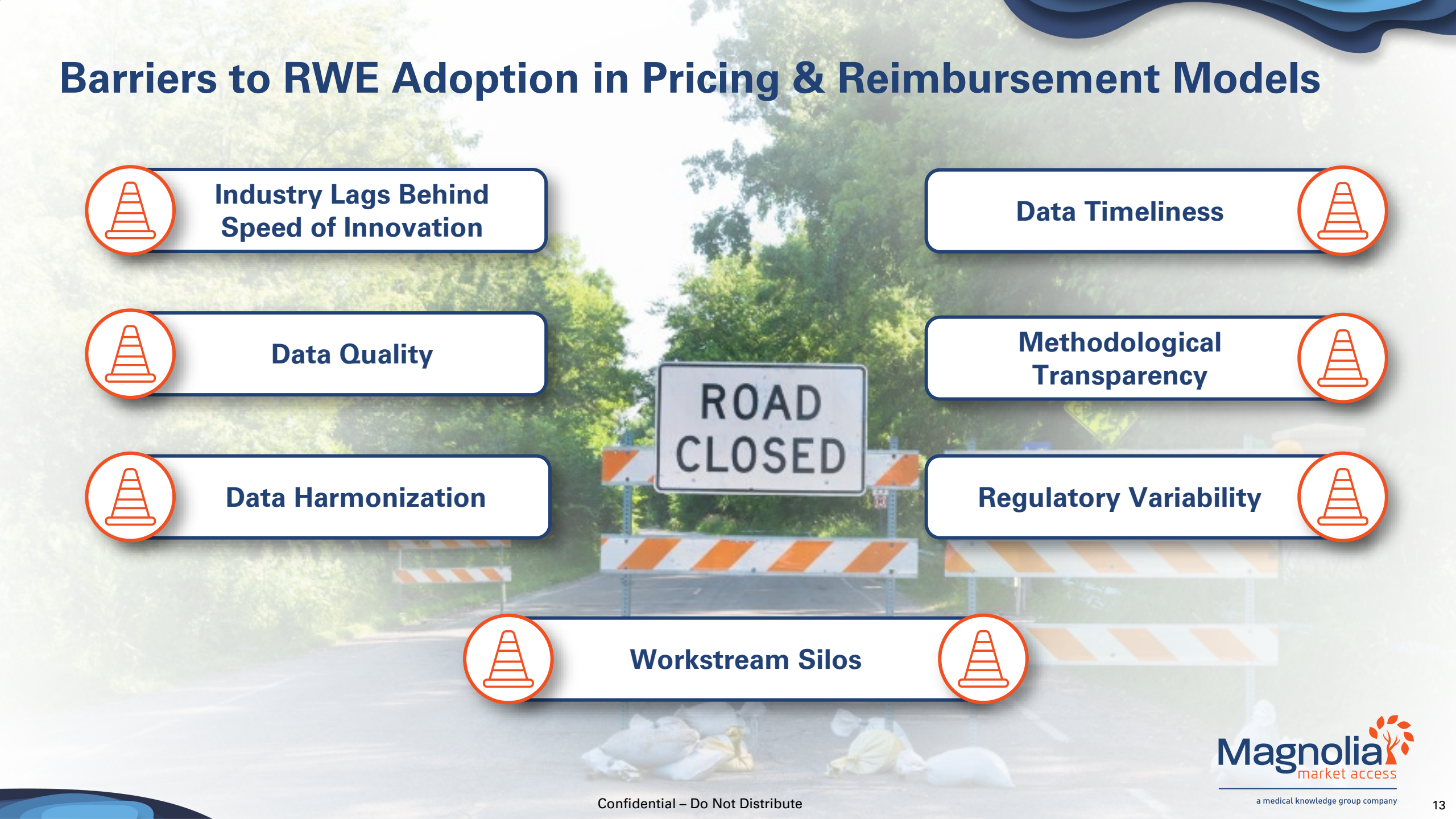
Consistency of RWE vs RCTs

Support for Value-Based Contracts

Strategic Insight

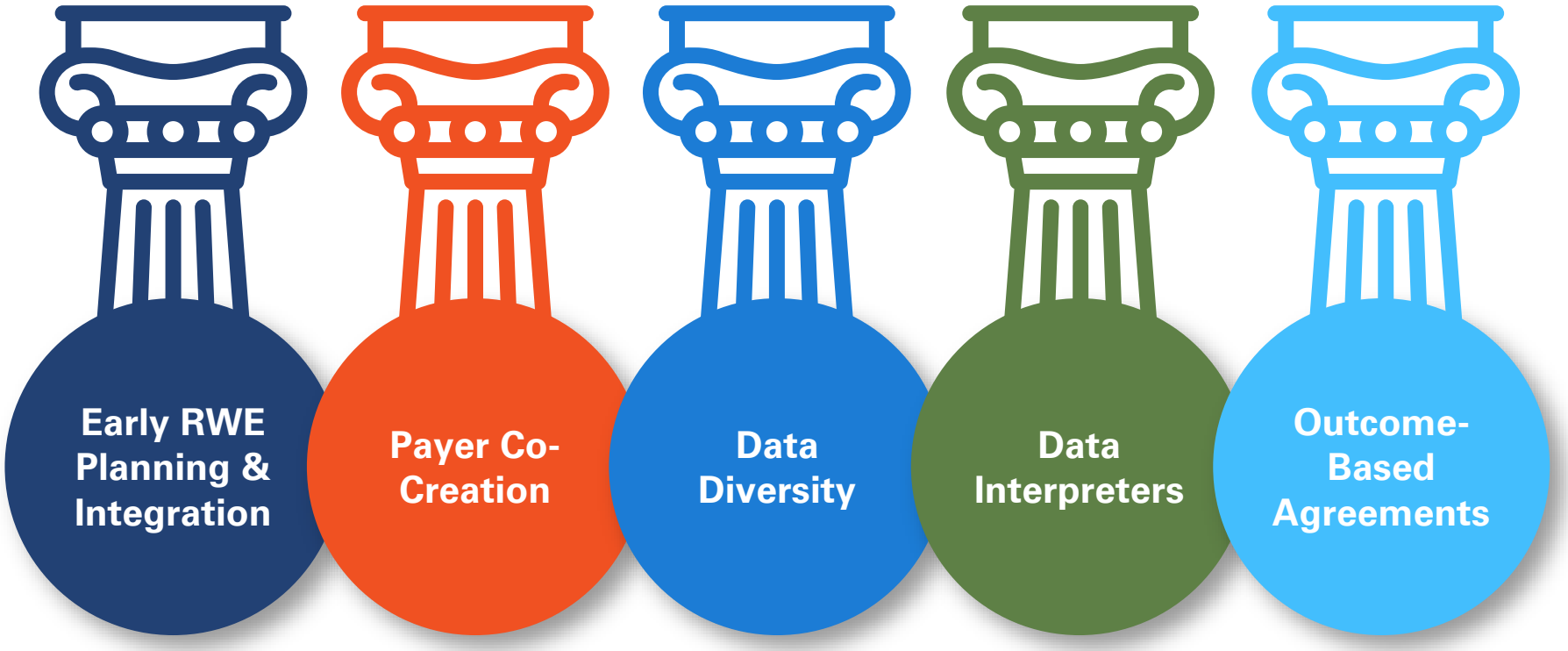
Presenting payer-relevant RWE (cost offsets, QoL, adherence) is more influential than purely clinical results.

Barriers to RWE Adoption in Pricing & Reimbursement Models



- Industry Lags Behind Speed of Innovation
- Data Quality
- Data Harmonization
- Data Timeliness
- Methodological Transparency
- Regulatory Variability
- Workstream Silos

Strategic Framework for RWE-Driven Pricing Models: The Necessary Foundation For Success



The Product Lifecycle: Building Strategies Rooted in RWE & Market Access

Discovery

- Market access landscape assessment
- Epidemiology
- Burden of disease
- Patient journey
- Healthcare disparities

Clinical Trials

- Health policy and advocacy strategy
- HEOR planning
- Packaging, distribution, and reimbursement strategy
- Dossier development

Phase IV and Beyond

- Evolve value prop and contracting strategies to encourage uptake
- Health policy monitoring
- Outcomes-based contract tracking
- Adherence trends
- Safety surveillance
- Comparative effectiveness, adherence, and persistence studies
- Refine predictive models, dossier, HTA
- Support label changes/ extensions
- Scientific conference/publication execution

Prelaunch

- Finalize value prop, pricing, and distribution model
- Establish patient assistance programs
- Create resources for patients, payers, and providers
- Field training
- Health policy monitoring
- Develop scientific dissemination strategy
- Update data studies
- Finalize dossier/HTA work
- Disease/risk prediction and economic models
- Comparator benchmarking

Launch

- Secure billing codes
- Distribute field resources
- Execute HEOR/scientific dissemination strategy
- Budget impact
- Cost-effectiveness

Emerging Trends: Innovations in Real-World Data & Real-World Evidence for Expanded & Timely Insights

Real-World Data Blending

- Expansion of RWD sources with curated (semi-structured, unstructured) data, especially SDoH and PROs
- AI integration into data blending
- Adds granularity to value narratives
- Address equity in pricing/access decisions

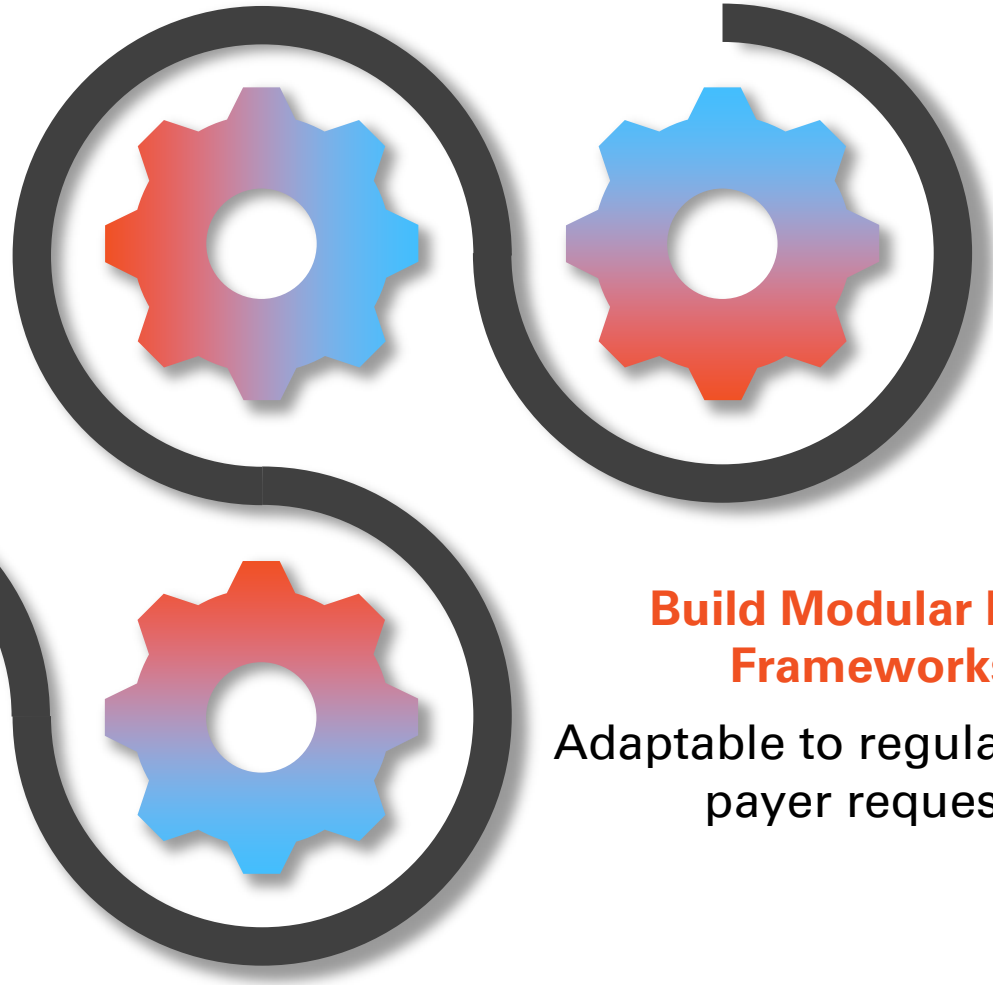
Real-Time RWE Dashboards

- Cloud-based dashboards to track treatment effectiveness in near real-time
- Used in ongoing reimbursement negotiations and safety monitoring
- Enables dynamic pricing adjustments

Actionable Strategies for RWE Integration: Pharma & Biotech Companies

Develop Global Playbooks

Align RWE submission with regulatory, HTA, and payer timelines



Create & Maintain Cross-Functional Workstreams

Medical Affairs + HEOR + Market Access

Invest in Blended Data & Linkages

Claims + EHR + PRO

Structured + Unstructured

Build Modular RWE Frameworks

Adaptable to regulatory and payer requests

Actionable Strategies for RWE Integration: Pharma & Biotech Companies

Develop Global Playbooks

Align RWE submission with regulatory, HTA, and payer timelines

Create & Maintain Cross-Functional Workstreams

Medical Affairs + HEOR + Market Access

Strategic Insight

Companies that embed RWE in product development and access planning will shape—not react to—pricing trends.

Invest in Blended Data & Linkages

Claims + EHR + PRO

Structured + Unstructured

Build Modular RWE Frameworks

Adaptable to regulatory and payer requests

Magnolia
market access