Real World Insights

Dr. John Doyle, Sr. Vice President and Managing Director
QuintilesIMS

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This transformation is leading to increased demand for real-world data, evidence, and insights

Expanding application of real-world data (RWD) in clinical development

Increasing use of innovative study designs to generate real-world evidence (RWE)

Scalable approaches to efficiently generate real world insights (RWI)

Real world insights are fueling the health care system transformation from volume, to value, to outcomes

Patient
- Need to maintain health
- Benefit/risk tradeoffs
- Affordability of care

Rx & Dx Manufacturer
- Incentives to develop evidence
- Reimbursement commensurate with value
- Reward for innovation

Policymaker
- Balance of quality and cost
- Societal considerations
- Health system statutes and guidelines

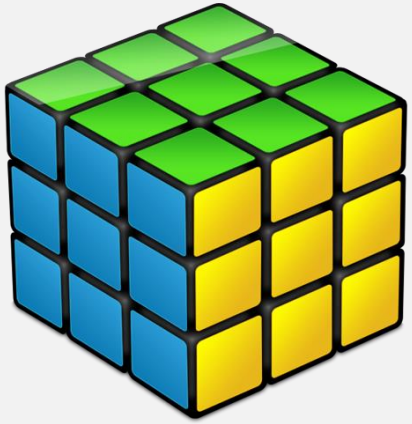
Payer & HTA
- Balance of quality and cost
- Evidence-based care
- Provision of appropriate care to appropriate populations
- Balancing care across the population

Laboratory
- Better, faster, cheaper
- Staff resource requirements and turn around
- Managing with a budget

Provider & Hospital
- Provision of appropriate care
- Provision of reimbursed services
- Financial efficiency & viability
- Managing with a budget

How do we solve for all healthcare stakeholder needs at once when generating evidence?

Historic



One-dimensional, people-driven, supply-side organized

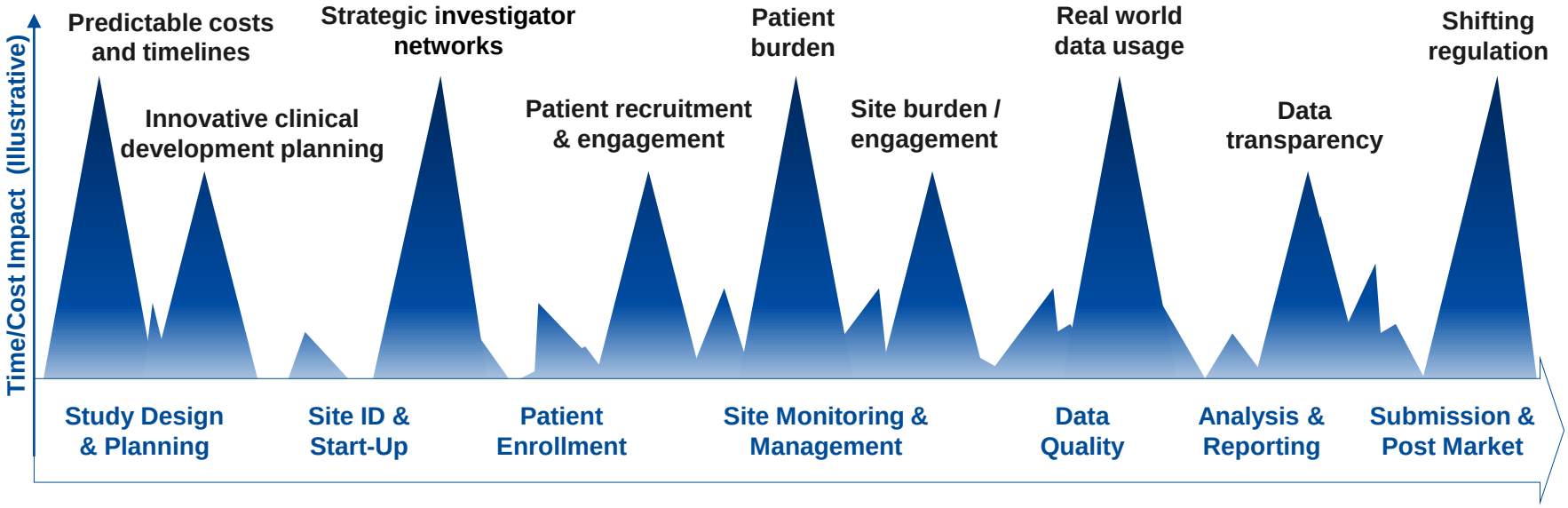
Emerging

Multi-dimensional, data-driven, demand-side organized

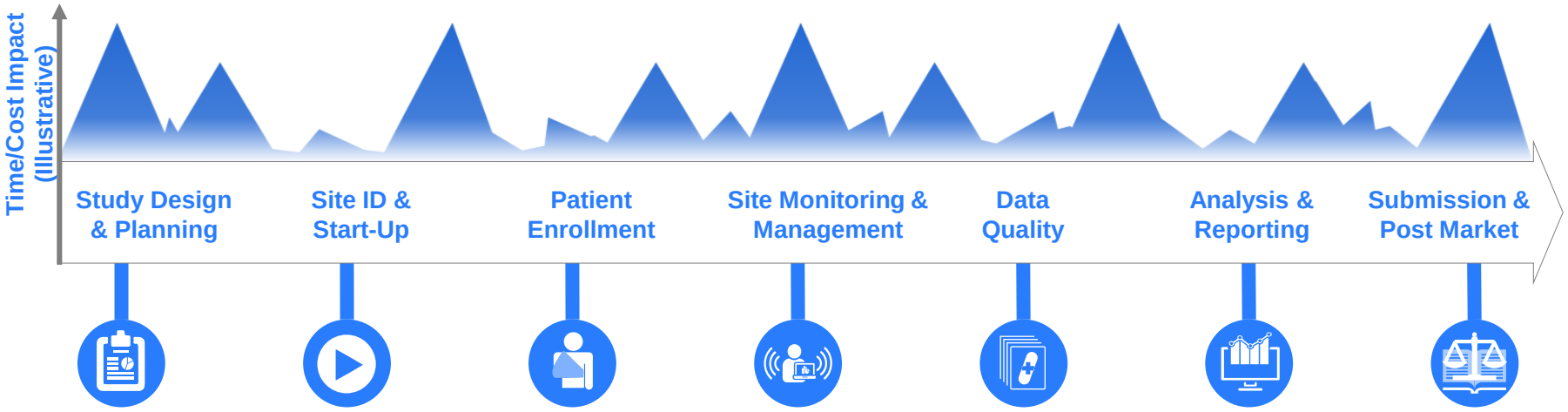
New approaches are needed to align stakeholders

Traditional approach	New approach
Assumptions	Evidence Based
Variable, Reactive	Predictable, Proactive
Siloed	Integrated
Risk Avoidance	Risk Sharing

However, barriers to optimizing evidence-generation exist across all stages in clinical development



A holistic approach to applying RWD in clinical development begins to address these barriers



- Validates protocol feasibility with RWD
- Finds alternative paths to shorter timelines
- Ensure comprehensive evidence generation

- Precision Recruitment
- Accelerates start up
- Expands investigator pool

- Empowers CRAs to boost recruitment
- Leverages technology to boost referral networks

- Improves efficiency and quality of data collection
- Supports Risk Based Monitoring

- Infrastructure, analytics and automation for near real time tracking, analysis and reporting

- Workflow automation and regulatory intelligence improves submission timelines

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RWD application has begun to realize improvements in evidence generation

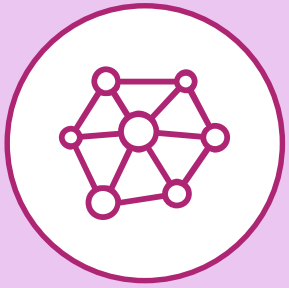
Integrated Process

Integrated clinical data and automated processes – **compressed start-up timelines**

Integrated Insights

Integrated clinical and real-world insights – **reduced recruitment time**

Connected to clinical community



Partner sites **increases recruitment rates**

Focus on efficiency

Risk Based Monitoring solutions results in **cost reduction**

Evidence needs are becoming more demanding, requiring data not always suited to RCTs

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Eichler et al, Clinical Pharmacology & Therapeutics, 2015: 97

Regulatory guidance opens the door to RWE

Hypothesis generation for prospective clinical study

Control groups (historical or concurrent) or mechanisms for collecting data

Evidence to support approval, requests, or reclassification

Evidence for label expansion to include additional indications or safety and effectiveness information

Ongoing public health surveillance efforts

Post-approval and post-market studies

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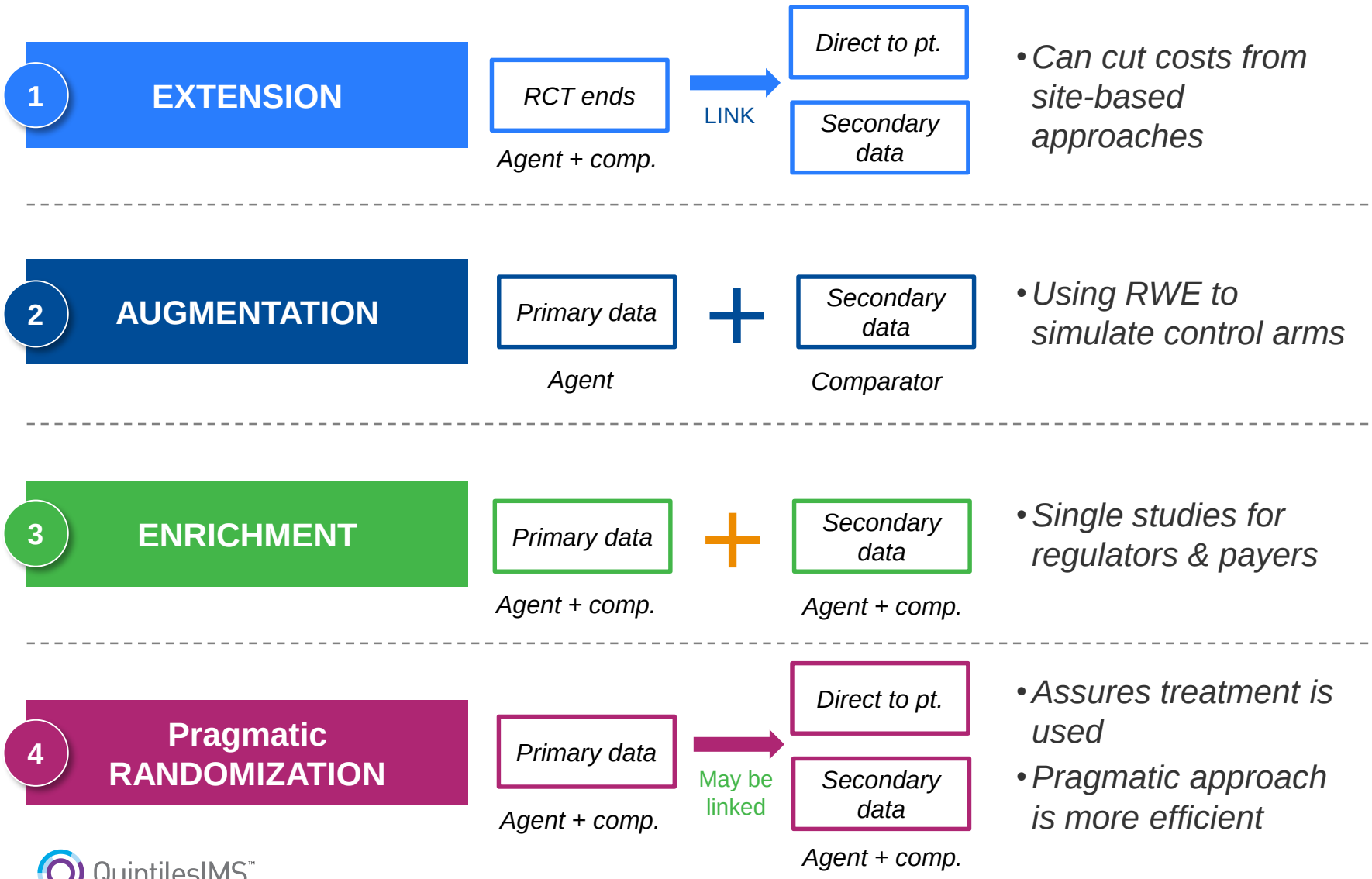
Adapted from: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices – Guidance for Industry and Food and Drug Administration Staff, August 31 2017

Innovative approaches provide further incentives to increase use of RWD in clinical trials



Robust and relevant evidence from Randomized Pragmatic Trials (RPTs)

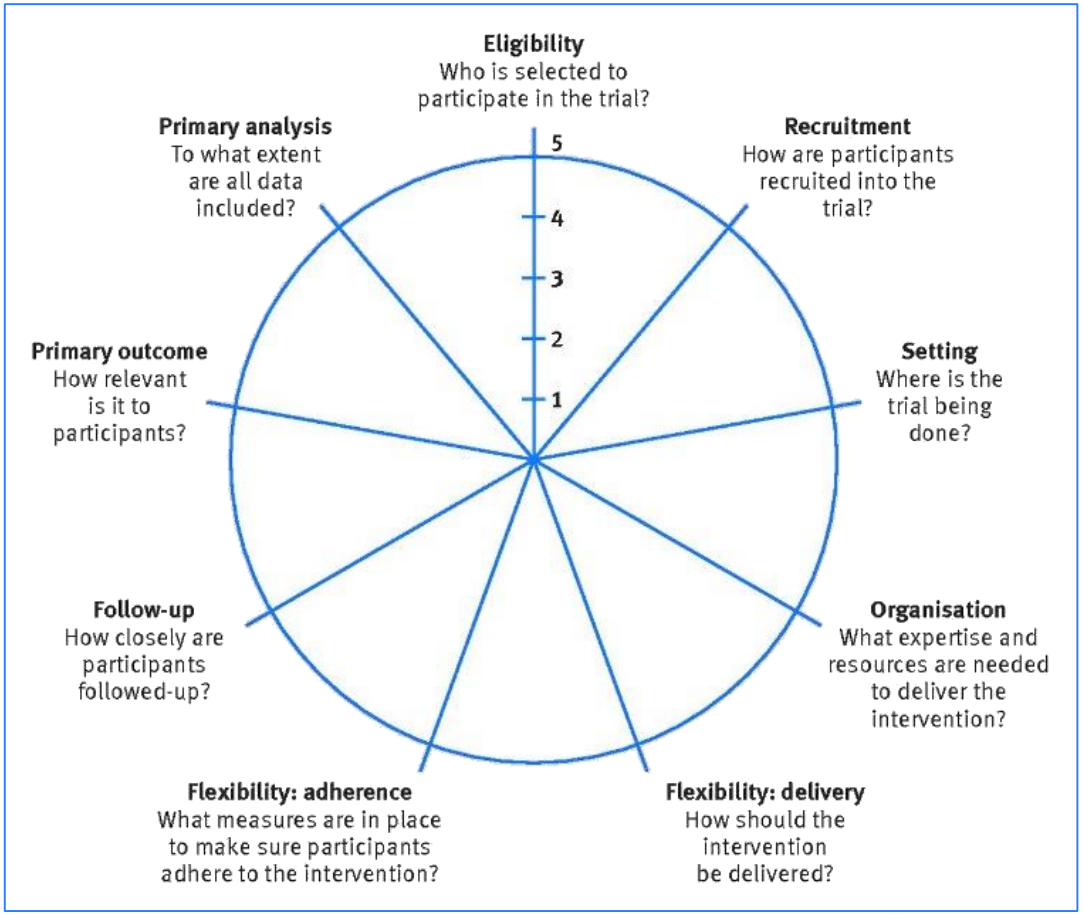
Key Benefit

Randomization coupled with the RW implications (“best of both worlds”)

Regulatory Standpoint

Emerging interest from FDA in using pragmatic trials for label expansions & other regulatory requirements

Design considerations for RPT



Source: BMJ 2015;350:h2147

Digital health innovation is breaking silos and unlocking new scale and depth of non-identified patient data