

**Realising the Potential
of Real World Data and
Evidence:** How Can
Pharmaceutical
Companies Optimise
through Capabilities,
Structure and
Governance?

Supported by the RWE Leadership Forum

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Meet the speakers



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The case for optimizing the use of RWD and RWE across the pharma value chain/lifecycle is increasingly evident

Why RWD/E?

Real-world data (RWD) and real-world evidence (RWE) are an integral part of the toolkit used by the pharmaceutical industry to meet business needs by defining, differentiating, and delivering value across the drug life cycle to regulators, payers, healthcare providers and, critically, patients.

Discovery phase

- ✓ Define target populations within the new paradigm of personalized or stratified medicine.

Development phase

- ✓ Establish and quantify the extent of unmet medical need
- ✓ To inform clinical trial design and feasibility
- ✓ Contribute to the evidence within regulatory submission packages.

Commercialization

- ✓ Fulfil regulatory and payer post-marketing commitments
- ✓ Generate evidence on the clinical, economic, humanistic and societal value of a drug.

Biopharmaceutical companies should consider establishing specific capabilities across six key areas

Capability Development

Integrated Evidence Optimization

Transparency and alignment across evidence generation teams and stakeholders

RWE Expertise and Innovation

Dedicated expertise in RWD and RWE and innovation in RWE applications and methodologies

RWE Dissemination and Communication

Consistent and relevant RWE communication to target stakeholders (e.g. payer, regulator)

Study Design and Operations

Design, operationalize and execute high-quality real world studies

Data Science and Analytics

Fast and robust translation of RWD into insight and scientific evidence, including through use of advanced analytic solutions and tools

Data Strategy and Information Management

Development and implementation of enterprise data strategies to efficiently address business needs

Guiding principles

- **scientific rigor** while designing and carrying out RW studies
- **consistency** of methodologies and processes for RWE generation
- **transparency** to uphold the ethical obligations industry is under when handling patient information
- **alignment** and **proximity** of evidence generation **to the business need**
- **efficiency** of teams in accessing and generating evidence

Optimizing an organization's structure, process and governance is a key consideration and will support the deployment of relevant competencies

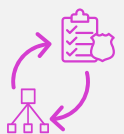
Organisational model overview



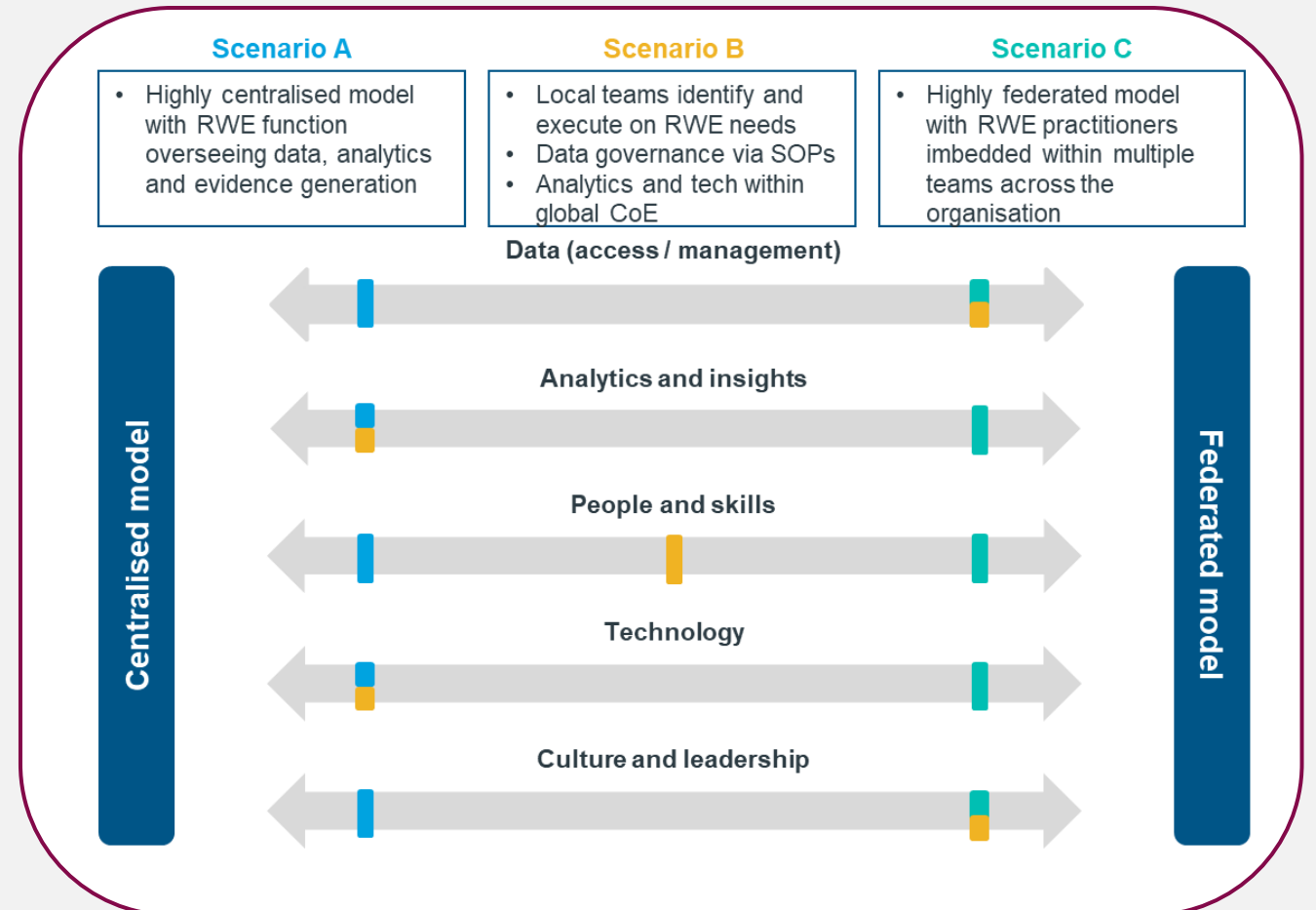
Centralised model – RWE practitioners are in one group/function or a CoE; governance driven by structure



Federated model – RWE practitioners are within multiple teams spread throughout the organisation; governance mandated through SOPs



Mixed model – local teams identify and execute on RWE needs, data governance is outlined in SOPs but practitioners delivering on analytics and technology are aligned within centralized team (e.g., a global CoE)



Live Q&A

Thank you for listening!

Please visit

<https://secure.constellation.iqvia.com/RWELeadershipForum> for more information with regards to the opinion piece discussed in today's presentation and for more publications from the Real-World Evidence Leadership Forum.

What capabilities and organizational models are needed to realize the potential of real world data (RWD) and real world evidence (RWE) for biopharmaceutical companies?

This opinion piece is authored by four industry real world evidence (RWE) experts, with support from IQVIA, as part of the 'RWE Leadership Forum': a group of industry leaders who come together as non-competitive partners to understand and respond to internal and external RWD/E challenges and opportunities with a single expert voice.

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DEFINITIONS

Term	Definition
Real world data (RWD)...	... has been described as data that are routinely collected on a patient's health status, in a purely observational manner, for decision-making that are not collected in clinical trials [7]. These include EHR, disease registries, pharmacy data, product registries, device data...
Real world evidence (RWE)...	... refers to information on health care that is derived from analysis of RWD. [8]; it includes information on health care that is derived from analysis of RWD.

IQVIA

The Real World Evidence Leadership Forum A non-competitive collaborative between top pharma leaders

What is this leadership forum?

- The RWE Leadership Forum is a group of senior RWE executives across major pharma companies, supported and facilitated by IQVIA. This group works as a non-competitive collaborative to understand, discuss and respond to internal and external RWE challenges and opportunities with a single expert voice, with the aim of improving outcomes for patients globally.
- One of the top priorities of the RWE Leadership Forum is to clarify the way pharma and healthcare can work together to establish trust-based relationships, which will unlock unique value for society, the medical community and patients. The forum meets twice a year to discuss issues facing RWE in the industry and develop an aligned positioning.
- Several working groups are maintained throughout the year to dive deeper into priorities decided on by the forum. These working groups will produce whitepapers, publications, forecasts, and info graphics tackling RWE topics decided on by the forum.

Forum publications and resources

Strengthening Pharma's Contract With Society: The Value of Trusted Partnerships Between Pharma and Healthcare Facilitated by Real-World Data

How pharma can build trusted relationships around a common purpose and the role real world data plays in establishing these relationships.

Publication

Bringing the gap between RCTs and RWE through endpoint selection

The value in bridging the industry disconnect between RCTs and RWE, with a view to promoting the use of RWE in the RCT environment, has recently been published in *Theoretical Medicine & Regulatory Science*.

Publication

The skills of play in RWE

Key aggregated findings from a benchmarking survey of RWE capabilities across 9 global biopharma companies.

Infographic

