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

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Meet the speakers

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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.

**Why RWD/E?**

Real-world data (RWD) and real-world evidence (RWE) are increasingly evident across the pharma value chain/lifecycle.

**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**
- Fulfill 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

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<tr>
<th>Capability Development</th>
<th>Guiding principles</th>
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<td><strong>Integrated Evidence Optimization</strong></td>
<td>• <strong>scientific rigor</strong> while designing and carrying out RW studies</td>
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<td>Transparency and alignment across evidence generation teams and stakeholders</td>
<td>• <strong>consistency</strong> of methodologies and processes for RWE generation</td>
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<td><strong>RWE Expertise and Innovation</strong></td>
<td>• <strong>transparency</strong> to uphold the ethical obligations industry is under when handling patient information</td>
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<td>Dedicated expertise in RWD and RWE and innovation in RWE applications and methodologies</td>
<td>• <strong>alignment</strong> and <strong>proximity</strong> of evidence generation to the business need</td>
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<td><strong>RWE Dissemination and Communication</strong></td>
<td>• <strong>efficiency</strong> of teams in accessing and generating evidence</td>
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<td>Consistent and relevant RWE communication to target stakeholders (e.g. payer, regulator)</td>
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<td><strong>Study Design and Operations</strong></td>
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<td>Design, operationalize and execute high-quality real world studies</td>
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<td><strong>Data Science and Analytics</strong></td>
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<td>Fast and robust translation of RWD into insight and scientific evidence, including through use of advanced analytic solutions and tools</td>
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<td><strong>Data Strategy and Information Management</strong></td>
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<td>Development and implementation of enterprise data strategies to efficiently address business needs</td>
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Optimizing an organization’s structure, process and governance is a key consideration and will support the deployment of relevant competencies.

**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).

**Organisational model overview**

- **Scenario A**
  - Highly centralised model with RWE function overseeing data, analytics and evidence generation

- **Scenario B**
  - Local teams identify and execute on RWE needs
  - Data governance via SOPs
  - Analytics and tech within global CoE

- **Scenario C**
  - Highly federated model with RWE practitioners imbedded within multiple teams across the organisation
Live Q&A
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.