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## **Real-World Evidence – A Market at an Inflection Point and its impact on the CRO Industry**

June, 2019

# About the Author

Life Science Strategy Group, LLC (LSSG) report authors draw upon extensive business, consulting and life science experience and backgrounds.

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Mr. Meyer is a Founder and Principal Consultant with the Life Science Strategy Group, LLC (LSSG). With nearly 20 years of contract research services consulting experience, Mr. Meyer leads LSSG's contract research services consulting division which serves the leading global contract research organizations (CROs) across all phases of pharmaceutical discovery, development and commercialization.

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## **Executive Summary**

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## Executive Summary – Industry at an Inflection Point

- **Pharma understands the value proposition of RWE** and benefit as a product development and lifecycle management strategy tool.
  - Pharma **is investing** to build internal knowledge and expertise and is adopting RWE-based strategies to support commercial products and development needs.
  - **More than half (>50%) of respondents** state their company **is learning and gaining experience** about how to best utilize RWE for specific business.
- However, the **payback on its investment in RWE has been limited to date** and barriers to utilization are significant.
  - **RWD data and RWE services are costly** and there is a **lack of standardization and broad acceptance** among stakeholders despite the growing investment.

*“External stakeholders may not be willing to accept RWE as a substitute for traditional evidence...internal leadership is unsure if the cost will return value...and our internal RWE team may not have the necessary experience or capability.”*

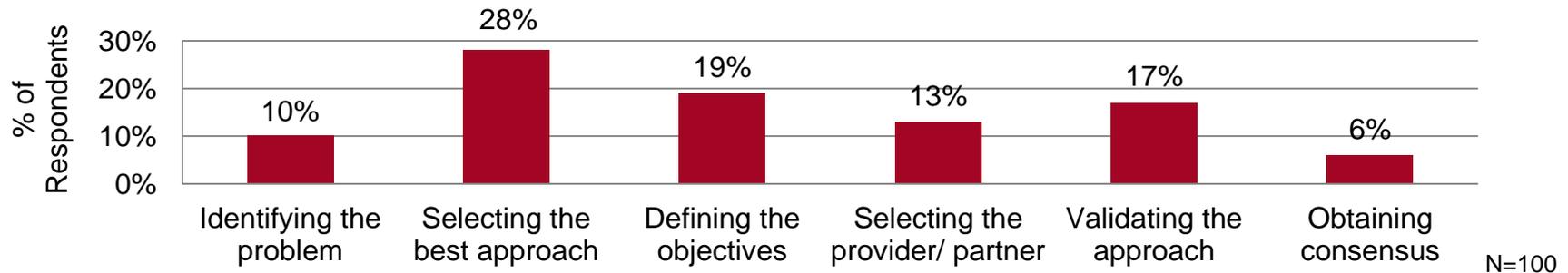
-Sr. Director/ Director, Large Biopharma (NA)

- Because of this, **Pharma is still hedging its bets** and is still not fully committed to RWE-based strategies.
  - Pharma executives are still holding back or placing extra scrutiny on RWD/RWE expenditures.
  - Pharma is split on whether to build necessary internal RWE expertise or to rely on external providers to fill the role.

# Executive Summary – Analytics Strong but Meaningful Insights Difficult to Find

- Real-world data and analytics are generally strong and available today across many vendors, but generation of **meaningful evidence** remains **complex and elusive**.
  - Vendors struggle to understand customers' unique products and markets which makes drawing insights from the RWD/analytics particularly challenging.
  - **Artificial intelligence**, long touted as the “silver bullet” which would enable RWE-based strategies **has had only point successes**, but has yet to deliver reproduceable, meaningful insights.
- When considering RWE use, Pharma respondents struggle the most with **selecting the best approach** that can solve their needs efficiently and effectively.

## Greatest Challenge in the RWD/RWE Buying Process

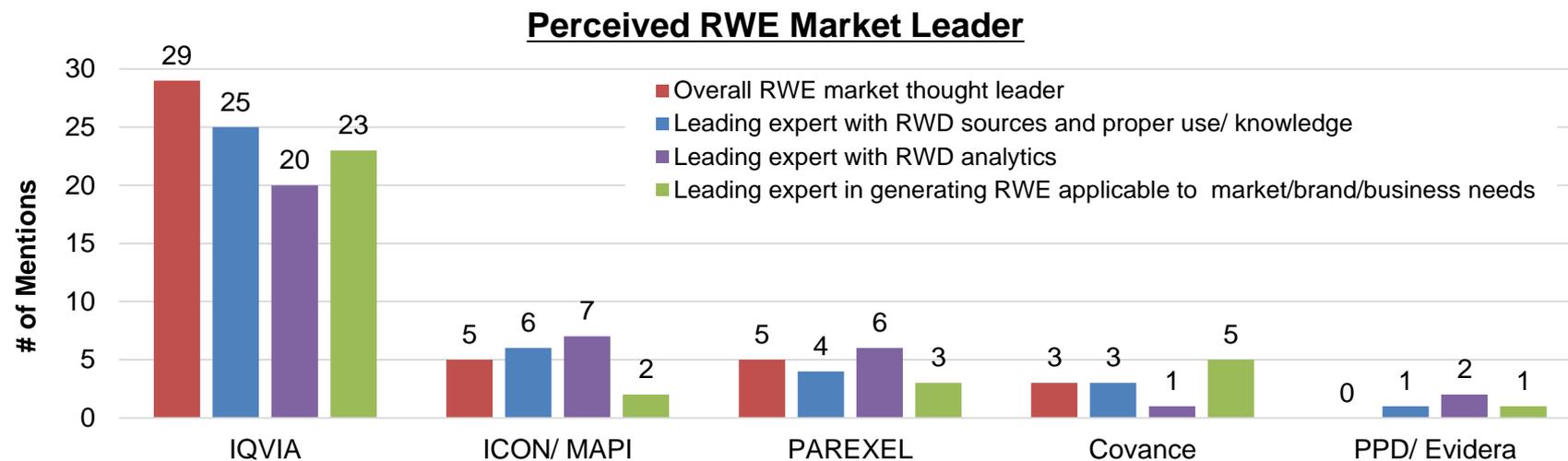


*“Evaluation of whether it is feasible and how to achieve objectives - are there data sources available, how reliable is the data, how long will it take and cost? That’s where we struggle.”*

*-Sr. Director/ Director, Small/ Emerging Biopharma (NA)*

## Executive Summary – There’s a Clear Market Leader

- Surveyed respondents expect to **increase their outsourcing of RWD analytics and RWE activities** from 57% to 62% next two to three years as Pharma continues its investment and vendors expand/improve RWD/RWE capabilities.
- Pharma decision makers select RWE vendors on the basis of their access to data, data validation processes, RWD analytical capabilities, and understanding of appropriate use of RWD.
- Among the vendors providing RWD and RWE services, **IQVIA is perceived as the dominant market leader** with no close challenger.



- Traditional, large CROs (Covance, PPD/Evidera, Parexel, etc.) do not appear to be high on Pharma’s radar as RWD/RWE thought leaders.

N=100

# Executive Summary – What Role will IQVIA Play? Who will Challenge them?

- As such, the **“ball is in IQVIA’s court”** to lead and shape the growing RWD/RWE field and market by:
  - Acting as an advisor to Pharma and key stakeholders (e.g., regulators)
  - Providing thought leadership around RWD/RWE best practices
  - Leveraging its rich clinical/therapeutic/disease area understanding to generate meaningful insights
  - Building expertise or partnering to deliver reproducible, valuable AI

*“IQVIA has been clear and vocal in delineating the aims, processes, outcomes and the future of RWE.”*  
-VP, Emerging/ Small Biopharma (Europe)

*“IQVIA has the ability to integrate multiple data sources and has experience within itself. They also can marry therapeutic area experts with data and bioinformatics experts.”*  
-Sr. Director/ Director, Mid-sized Biopharma (NA)

- Further, it appears that **RWE-based approaches will only grow in importance and utilization**, which draws several questions:
  - How will traditional, large CROs compete effectively in the market?
    - Will their strategic value as a partner to Pharma be diminished without RWE expertise?
    - Can a large CRO “catch up” to IQVIA in the RWE market?
    - Will need for RWE expertise drive further acquisition/consolidation between traditional clinical players and data/analytics providers?
  - Will lack of RWE expertise/thought leadership drive larger CROs to specialize in specific disease areas and build out only specialized capabilities?
- Lastly, what will be the **impact of non-traditional players** (e.g., Google, Amazon) possessing strong data/analytics/potential AI capabilities in the market going forward?

# Executive Summary – Ample Opportunity for Vendors to Step Up Their Game

## ***Solidify a strategy – How and where you will play***

- Devise and formalize a strategy for how to compete in the market. Should focus be on data, analytics, insights generation, comprehensive “RWE solutions”, or something else?
- Choose targets and markets carefully. The “one-off” nature of RWD/RWE generation makes it difficult for any one vendor to be a generalist. Focus will increase the probability of higher quality and success.
- Take cues from IQVIA, the perceived market leader. What have they done that’s been effective?

## ***Focus on the data (RWD) – It’s Pharma’s top focus when selecting vendors today***

- Pharma prioritizes access to data, data validation, RWD analytical capabilities, and understanding appropriate use of RWD when selecting vendors today.
- Form partnerships with institutions to expand access to RWD to generate a more accurate representation of the patient journey.
- Invest resources to gain expertise with and ensure data are robust and validated.

## ***Get smart(er) and build case RWD/RWE examples – Convince Pharma of your expertise***

- Add experts, attend and present at conferences and generate case studies to highlight success stories on proven RWE approaches adding value to products.
- Consider opportunities to add capabilities and expertise. Is there an acquisition that would be synergistic?

## ***Move up in the buying process – Be a strategic provider***

- Approach Pharma earlier in the buying process and help to evaluate different RWE strategies, methods and outcomes with the goal of moving from a transactional provider to a strategic advisor.

# Definitions of RWD and RWE

## Definitions:

Real world **data** (RWD) are the data relating to patient health status and/ or the delivery of health care routinely collected from a variety of sources. RWD can come from a number of sources, for example:

- Electronic health records (EHRs)
- Claims and billing activities
- Product and disease registries
- Patient-generated data including in home-use settings
- Data gathered from other sources that can inform on health status, such as mobile devices

Real world **evidence** (RWE) is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/ or retrospective).