

2020 Survey Report

BUILDING A FUTURE READY REAL WORLD EVIDENCE ORGANIZATION

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EXECUTIVE SUMMARY

In September 2020, at the IMPACCT: RWE conference, Mu Sigma Inc. surveyed multiple leaders from 24 pharmaceutical and medical device companies on their organizations' outlook for Real World Evidence. Survey questions were related to investment trends, focus areas and partnership models in RWE. RWE is becoming an integral part of every healthcare organization's transformation strategy to create a patient centric ecosystem.

Increased patient engagement by all stakeholders, empowered by digital health solutions, has resulted in an explosion of Real World Data. This coupled with competitive pricing and rising drug development costs, has further accelerated demand for RWE.

- Most survey respondents expect demand for RWE will grow rapidly in their organizations over the next 3 years. Medical Affairs will fuel most of this demand while newer applications in R&D and market access will compound this further
- 2. 50% respondents believe, in order to meet this demand, it's important for their organizations to prioritize building internal capabilities. However, given the wide RWE skill gap, developing these capabilities could take several years
- **3.** All respondents say entering long term strategic partnerships focused on internal capability development will be a relevant solution
- 4. Most companies, on an average, centralize close to 30% of their day to day RWE activities
- 5. Almost all respondents see cost effective RWE generation at scale and innovation as important value propositions from central RWE groups

Please note, as per survey design, respondents were not required to answer all questions.



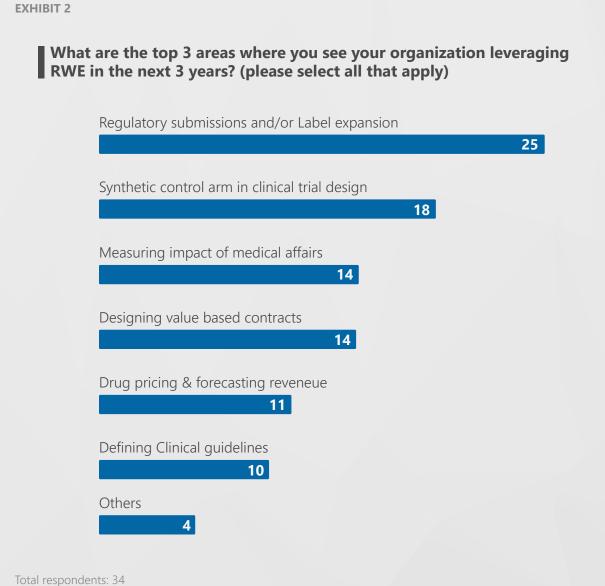
CROSS FUNCTIONAL DEMAND FOR RWE IS RAPIDLY INCREASING

Pharma organizations are focusing on transformative medicines that cater to unmet need. Also, outcomes based care is moving to center stage. In this environment, RWE plays an important role in providing deeper insights on drivers of patient outcomes, product performance and informing precision medicine efforts. Emerging technology and better data accessibility have further augmented cross functional demand.

Survey results show more than half of the respondents anticipate high year-on-year growth (40% and above) in demand for RWE, while a third expect moderate growth (20-40%). Most respondents who anticipate high growth represent Medical Affairs; indicating this function will continue to fuel most of the demand. Additionally, encouragement from FDA and EMA, coupled with the need for faster time to market is primarily expected to drive growth in R&D [exhibit 1].

EXHIBIT 1 How do you see the demand for RWE projects increasing in your group year on year (volume of projects)? **MODERATE** growth **HIGH growth** (40% & above) (20% to 40%) 33% 55% 33% 55% 12% 12% Respondents by functional areas 50% **Medical Affairs** 64% R&D 22% **HEOR** 18% Market Access R&D 11% **9%** Pharmacovigilance 11% Market Access Epidemiology 9% 6% Others

Total respondents: 31 'Others' includes Alliance management Traditionally Medical Affairs has used RWE to assess burden of disease and comparative effectiveness for external stakeholder engagement. As this function starts playing a more strategic role within the organization, using RWE to measure impact of medical team activities will become important. Over 50% respondents believe supporting regulatory submissions, designing synthetic control arms and value based contracts will be emerging applications for R&D and Market access in coming years. [exhibit 2].



'Others' includes execution of risk management plan, improving the patient journey and design a new clinical trial

LONG TERM CAPABILITY DEVELOPMENT WILL BE CRITICAL TO DELIVER AT SCALE

We asked our respondents how they see RWE investments being distributed over the next few years, particularly with respect to managing and analyzing RWD. Given the explosion of patient data, almost all respondents expect high investments to continue into data acquisition [exhibit 3]. As spending on data continues, it will be important for organizations to develop reusable frameworks for agile data assessment thereby optimizing spends. Investments are also expected to flow into advanced analytics which, powered by AI/ML, will further strengthen integration of data and insights.

Evidence on comparative effectiveness, safety and cost are frequently used for internal decision making as well as to engage external stakeholders through multi-channel interactions. Majority of the respondents anticipate strong investments into interactive visualization frameworks as well as self-service tools to enable effective consumption.

Additionally, more than 60% believe investments in learning management systems will be important to aid capability development and educate practitioners and business leaders alike on value generated [exhibit 3].

EXHIBIT 3

How do you believe investments will be distributed in the next 3 years to manage and analyze Real world data in your group? (please select all that apply)

| nteractive visualization framewo | orks for insights generation |
|----------------------------------|------------------------------|
| | 27 |
| Advanced analytics capabilities | |
| | 23 |
| earning management systems | |
| | 21 |

Total respondents: 31

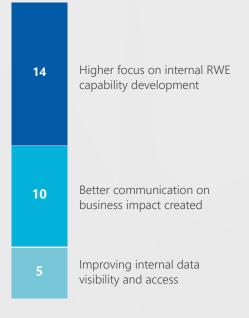
In order to deliver this demand at scale, half of the respondents believe their organizations will need to prioritize building internal capabilities across people, processes and platforms over the next 3 years [exhibit 4].

Typically, this involves

- Developing transparent and reliable data platforms for insight generation
- Building reusable analytical modules adaptable to emergent data sources
- Designing frameworks to integrate brand insights across functions and regions
- Developing inter-disciplinary talent with relevant scientific, math and business acumen

Evidence on comparative effectiveness, safety and cost are frequently used for internal decision making and to engage external stakeholders through multi-channel interactions. However, building these enterprise wide capabilities need sustained executive sponsorship and buy in. There remains an opportunity for organizations to adopt RWE as a strategic lever for growth and move beyond its current perception as a supplementary resource. As a result, many respondents identify socializing impact of RWE within the organization as an important transition [exhibit 4].

What do you feel is the most important shift your Organization needs to make in order to meet the increasing demand for RWE in the next 3 years?



Total respondents: 29

STRATEGIC PARTNERSHIPS EMERGE AS A MODEL FOR SUCCESS

Given the wide RWE skill gap, developing these capabilities internally could take several years. Organizations have tried many outsourcing models for RWE like working with external vendors on a project basis, functional partnerships and platform based models. Shaping new partnership models for data and analytics will be key to deliver RWE at scale in a sustainable manner. All survey respondents believe entering a few long term strategic partnerships focused on internal capability development offer the opportunity to scale while also delivering immediate results [exhibit 5].

EXHIBIT 5



Trends like personalized medicine, focus on rare diseases and innovative modalities have augmented demand for deeper data by disease area; thereby spearheading strategic data partnerships. Many organizations deployed the strategy of centralized data acquisition early on and those groups are now able to champion cross functional data visibility and access. However, translation of data into insights continues to be done in a mixed model across companies with one or a combination of the following:

- Functions or regions directly outsource to external partners
- Functions or regions have their own centralized teams. Often, such teams compete for demand
- Centralized insights and analytics cutting across functions and regions

Respondents say they typically centralize ~30% of their day to day work, the proportion varying among functions [exhibit 6]. For a brand to truly succeed in the current market dynamics, functions and regions need to strengthen collaboration and facilitate greater interactions of real world data and insights. This underlines the growing relevance of centralized insights and analytics model.

| : What is the volume of work your group exec WE team (in %)? | |
|---|-----|
| Medical Affairs | |
| | 44% |
| HEOR | |
| 30% | |
| Pharmacovigilance | |
| 30% | |
| | |
| R&D | |
| 26% | |

Total respondents: 32

The % represent average of all values selected by respondents within a functional area

CENTRALIZATION WILL HELP DELIVER COST EFFECTIVE RWE GENERATION AT SCALE

We asked our respondents how much they currently spend, on an average, per RWE study. The overall average spend was around \$150,000 with a wide range across business functions indicating opportunities for cost optimization [exhibit 7].

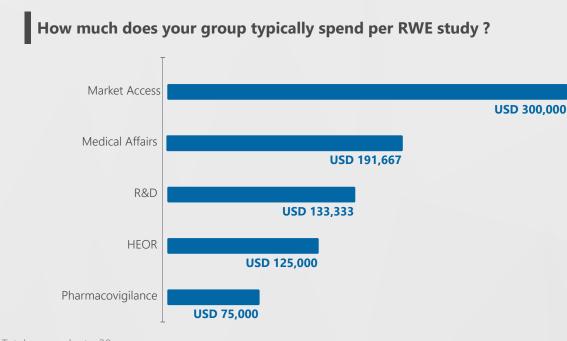


EXHIBIT 7

Total respondents: 30

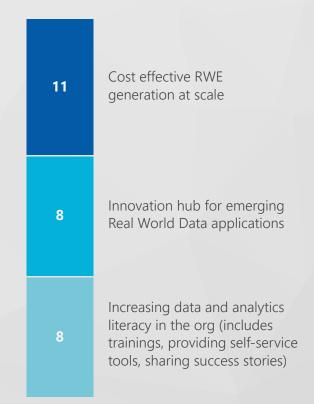
The spends represent average of all values selected by respondents within a functional area

Central insights and analytics groups have been instrumental in standardizing RWE methodologies and quality to a large extent. Given the culture of capability development deeply embedded within such groups, as demand rises further, most respondents see delivering cost effective RWE generation at scale as their critical value proposition. This will be realized by central groups directly building few long term а strategic partnerships with data analytics and companies.

They are also well positioned to drive innovation through low cost experimentation in collaboration with business functions. Several organizations are already benefitting from advanced analytics during product development and commercialization. With growing belief in value of RWE and openness to new applications, some respondents feel central groups should champion data and analytics literacy to unleash the full potential of RWE within an organization [exhibit 8].

EXHIBIT 8

What do you percieve will be a critical value proposition of the RWE central group in the medium to long term?



Sponsorship from executive leadership will be necessary to define operating models and governance that empower central groups to build RWE capabilities for the long run while creating impact in the short run. Visibility into the integrated evidence generation plans and better linkage of RWE activities to brand priorities will enable central groups to drive higher consciousness in decision making. A few mature organizations have already started on this journey and the growing importance of RWE will propel a larger change across the industry.

For more imformation, get in touch with: Pravleen.Grewal@mu-sigma.com | Nitesh.Ray@mu-sigma.com



Mu Sigma is the world's largest pure-play big data analytics and decision sciences company, helping organizations institutionalize data-driven decision making. Our unique engagement model consists of an interactive ecosystem of people, processes & training, and platforms, which has enabled more than 140 Fortune 500 companies to build capabilities in the long term while creating an impact in the short term.