

BEST PRACTICES

Real World Data and Medical Affairs: Best Practices in Maximizing its Use and Producing Results

Best Practices

Strategic Benchmarking Research & Analysis



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Research Overview: Objectives & Methodology

The last decade has seen an explosion in the availability of Real World Data - from Electronic Medical Records and clinical trial data to medical claims and patient behavior data.

Research Overview

- With the growth in healthcare data sources, pharmaceutical companies have developed groups and programs to generate data and scientific insights.
- This benchmarking study is designed to understand what is Medical Affairs' role in the collection, generation, analysis and dissemination of Real World Data.

Research Methodology

- Best Practices, LLC engaged 28 leaders from 23 biopharmaceutical companies through a benchmarking survey.
- Created two data segments: Regional Segment: US-Only (N= 8), Global (N= 12) and Company-Size Segments: Large Companies (N= 18) and Small and Mid-sized Companies (N= 10)

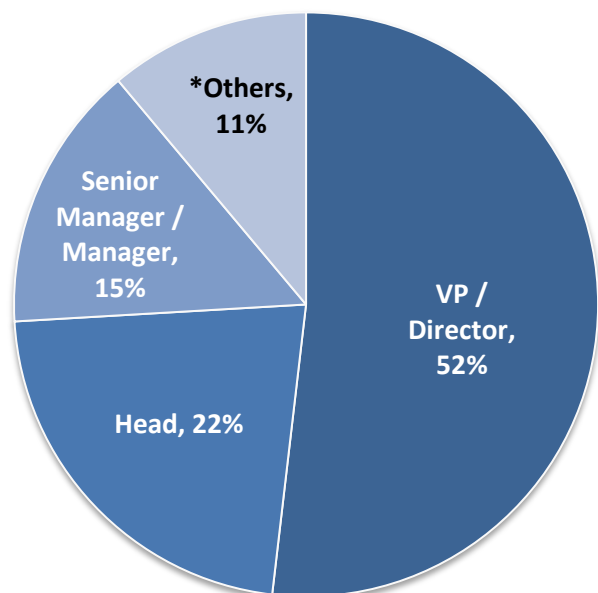
Topics Covered

- **Structure and Oversight:**
 - Real World Data Governance
 - Medical Affairs Role
- **Key Performance Indicators and Publications**
- **Collection of Real World Data:**
 - Sources of Data
- **Utilization of Real World Data:**
 - Current Use of Real World Data
 - Future Use of Real World Data
 - Barriers to Use of Real World Data
- **Valuation of Real World Data:**
 - Pros & Cons of Forms of Real World Data
 - Lessons Learned

Respondents Background

This study engaged 28 leaders working in Medical Affairs. Participants represent 23 leading biopharmaceutical companies. More than 75% of participants are at the director level or above.

Demographics of Respondents



*Others: Medical Affairs Lead , Medical Affairs Associate, Genetic Counselor

N=27

Companies of Respondents

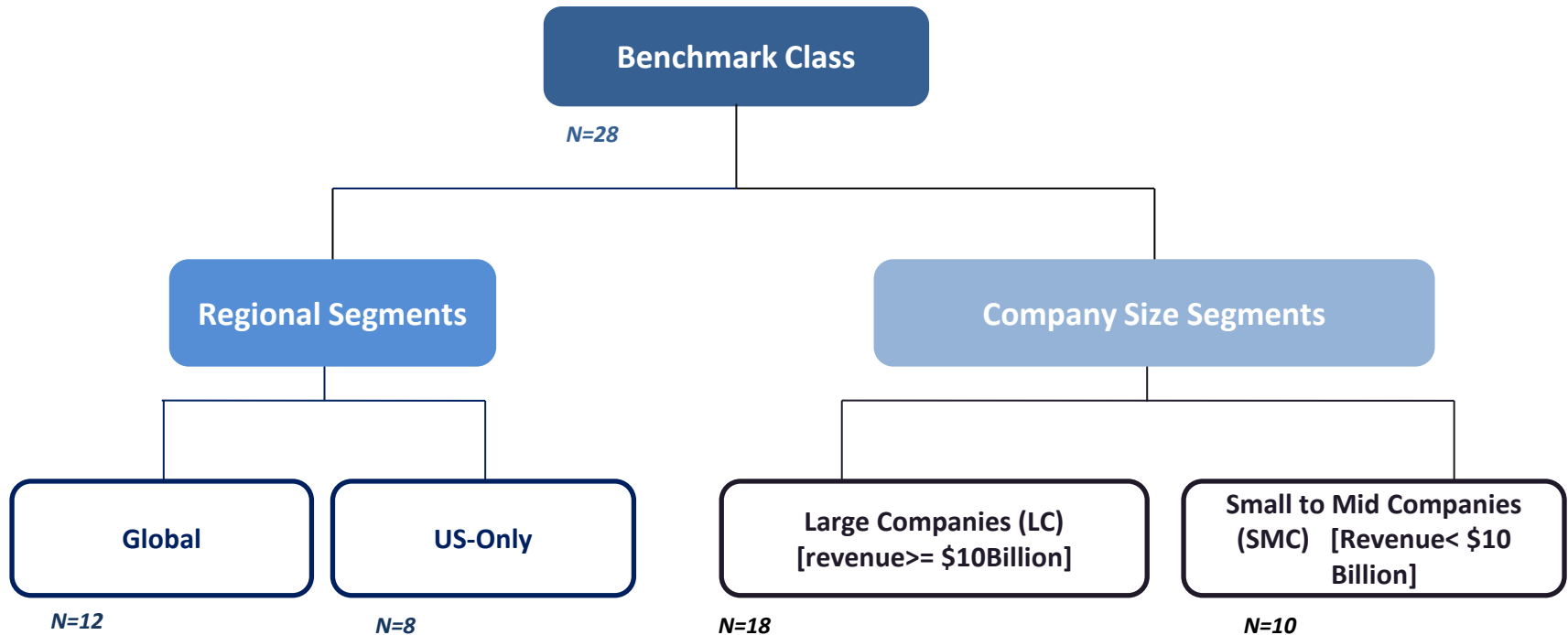


Key Insights

Few of the key findings and insights that emerged from this study:

- **Medical Affairs and Health Outcomes Teams Collaborate Most with Real World Data Group:** At more than 80% of the companies, the health outcomes team is included in the Real World Data leadership group, followed by medical strategy & operations (67%), clinical trials (59%), and data management (52%). Patient advocacy & thought leader services are least involved.
 - 75% of global teams collaborate with IT, while only 25% of US teams do so.
 - More than 60% of large companies collaborate with R&D and IT, while only a few small to mid-sized companies do so.
- **Most of the Collected Real World Data Falls Under Purchased External Data:** On average, 56% of Real World Data is purchased from external sources, while a small amount of data is available free on external sources. More than a third of Real World Data comes from internal sources.
- **Data Interpretation and Data Analysis are Among the Most Valuable Real World Data Activities that Contribute to the Success of the Medical Affairs Function:** Real World Data activities pertaining to data analysis and insight generation are most valuable to Medical Affairs, irrespective of company size. Additionally, data generation, identification and acquisition are also deemed highly valuable by benchmark respondents.

Study Analyzes Two Main Segments



Global respondents are those who said their responses represent Real World Data approaches used in and outside of US; US respondents are those who said their responses represent Real World Data approaches for US only.

***Please note: Additional regions were selected; however, there were not enough responses to form segments for those areas.**

Real Word Data Timeline in Healthcare Industry



- Pharmaceutical companies start using paper copies of clinical research data.
- Establishment of the Protein Data Bank.

1970s



- Computer-assisted drug development start 3D Modeling and Predictive and Data Analytics.
- Eli Lilly becomes the first pharma company to use a super computer.

1980s

1990s



- Data mining becomes essential for analysis.
- Aggregated prescription claims data is used to identify therapeutic and regional preferences

2000s



- Digital record-keeping becomes the new standard.
- EMRs and EHRs used to understand how drugs are used worldwide.

2010s

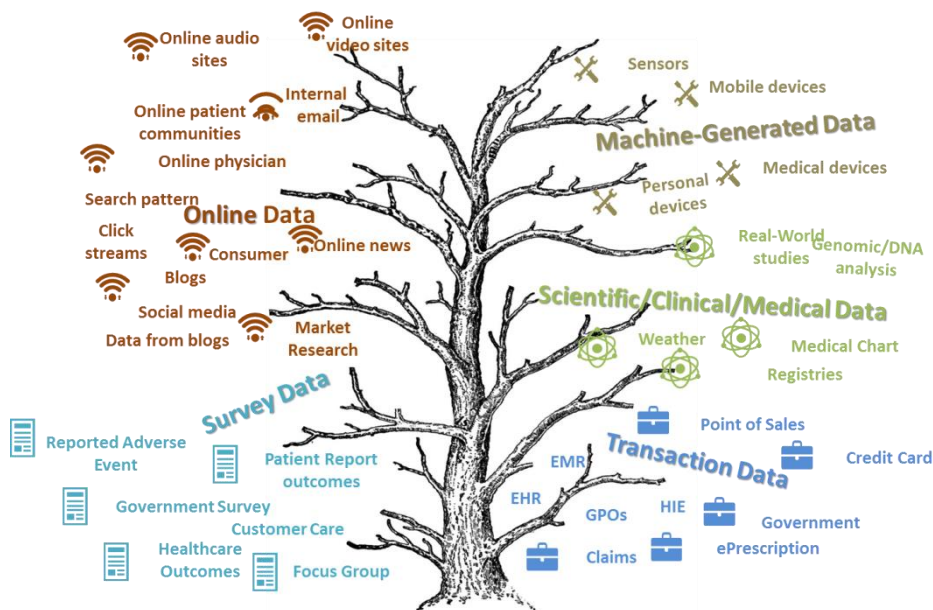


- Clinical trial transparency allowed in Europe.
- Digital audience identification access used to gather real-time data on online physician behavior.



- Prediction modeling and simulation for treatment effect, adverse drug reaction and regulatory approval
- Open data and collective knowledge

Understanding Real World Data (RWD) Use in Medical and HEOR Decision-Making



Why is real world data and research considered a separate department in some companies from HEOR?

How can Medical Affairs innovate its use of RWD to support/lead payer engagements to improve access?

RWD Decisions

- Go/No Clinical Decisions
- ID Market Opportunities
- Developing Economic Models/Assessments

RWD Users

- Medical
- Commercial
- HEOR

Analytics Team RWD Programs

RWD Info Types

- Electronic Health Records
- Government Cost Data
- Health Outcomes

RWD Projects

- Value Proposition Development
- Post-Launch Performance
- Real World Studies

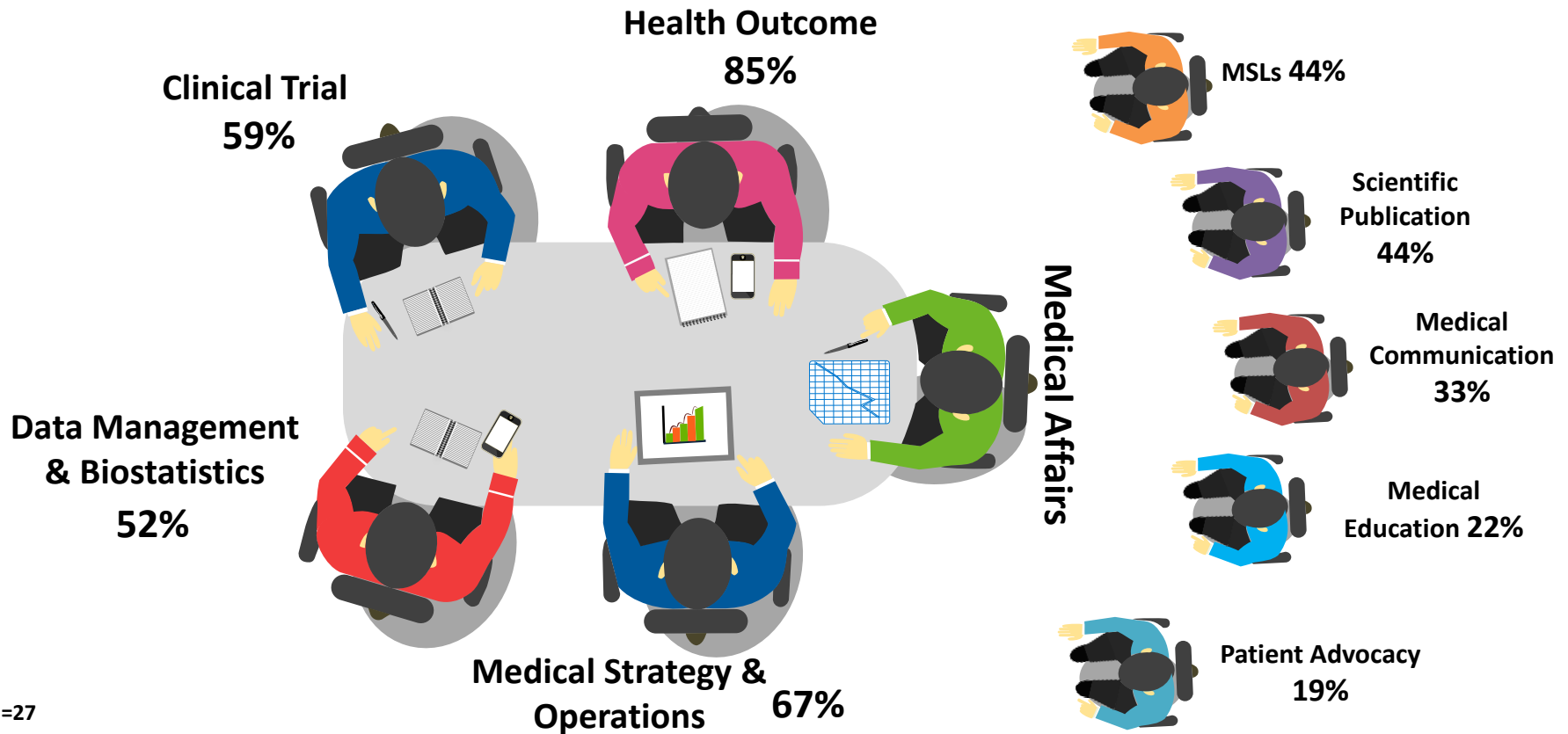
How do commercial and Medical Affairs partner on RWD (if at all)?

Why do we not include real world type endpoints in Phase III clinical trials?

Are Field Medical Affairs colleagues involved in studies? If yes, what parts (concepts, design, analyses, interpretation, and/or messaging for KOLs)?

Determine Your RWD Needs and Set Your RWD Leadership Accordingly

Medical Affairs and its RWD Leadership Team



N=27

% Respondents

More than Half of Real World Data is Purchased

Companies purchase 56% of Real World Data from external sources while 35% of the Real World Data is generated internally.

Categories of Collected Real World Data

Q20. What percentage of Real World Data collected falls under the following categories?

	Internal (Self-generated Data)	External (Purchased Data)	External (Free Data)
Max	90%	100%	40%
75th Percentile	65%	90%	20%
Mean	35%	56%	9%
Median	30%	60%	5%
25th Percentile	0%	25%	0%
Min	0%	0%	0%
	50%	30%	20%

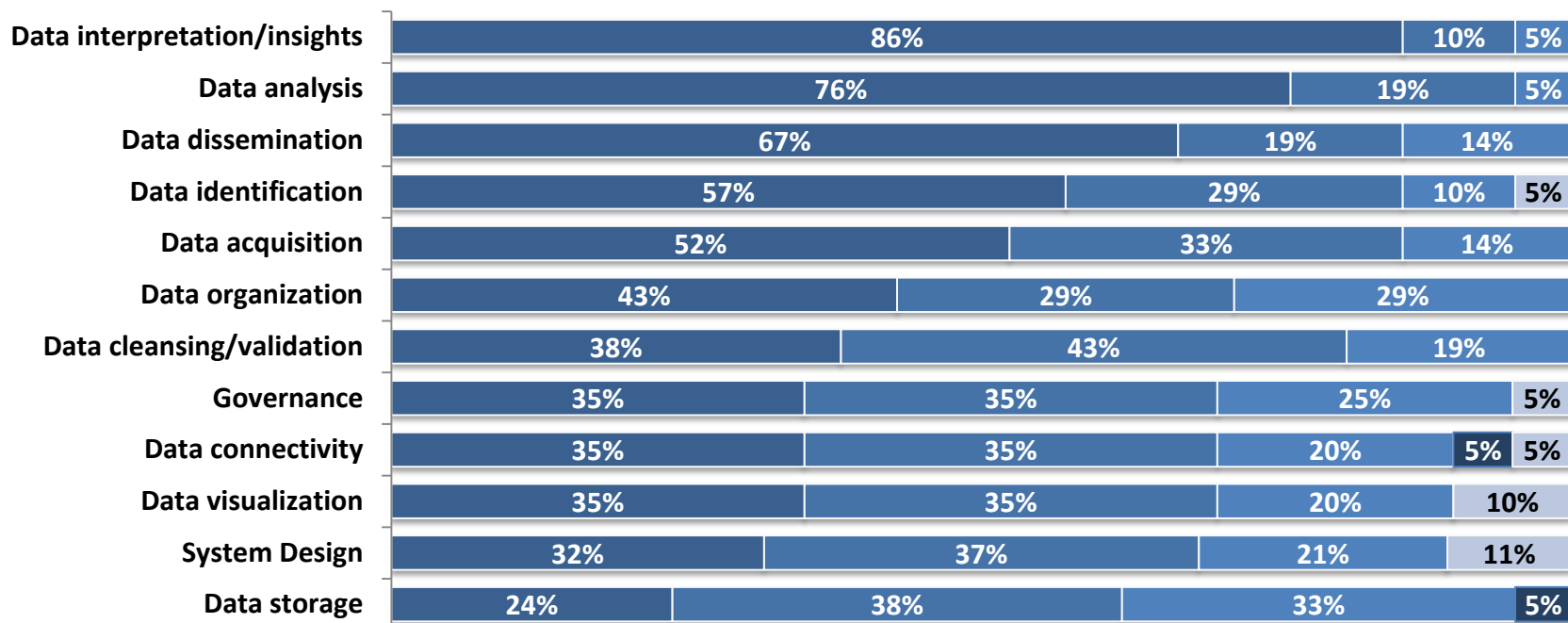
Real World Data Activities from Identification to Insight Generation Have High Value for Medical Affairs

Real World Data activities pertaining to data analysis and insight generation are most valuable to Medical Affairs.

Valuable Real World Data Activities

Q29. How valuable are the following Real World Data activities to Medical Affairs' success?

■ Very Valuable ■ Valuable ■ Somewhat Valueable ■ Not Valuable ■ Not Applicable



N=19-21

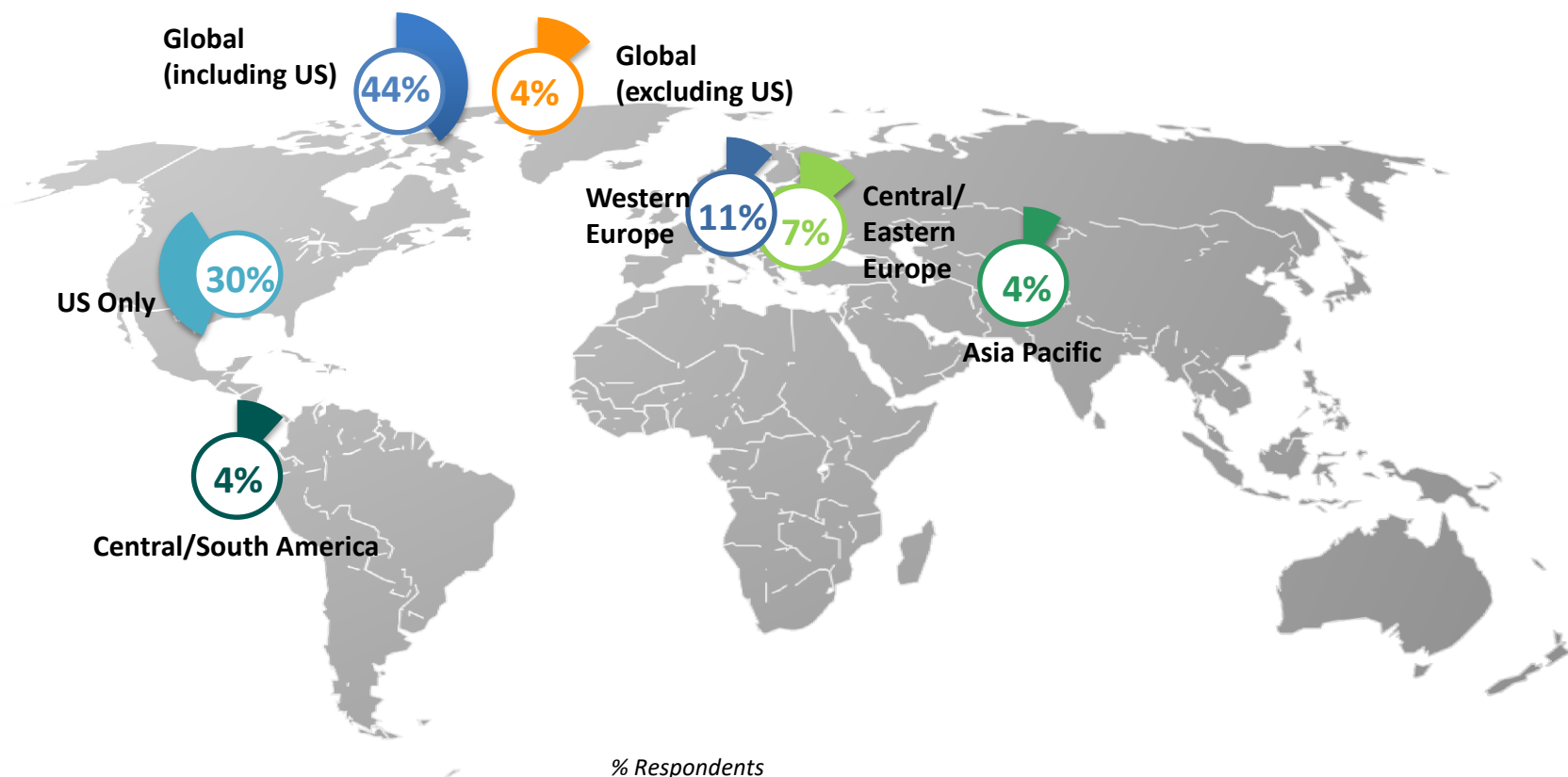
% Respondents

Participants Primarily Use Real World Data in the US Region

74% of the benchmark companies are using Real World Data in the US, and 48% of them are using Real World Data across the globe.

Geographic Span

Q2. In which part or parts of the world is your Medical Affairs group involved with utilizing Real World Data? Please select all that apply.

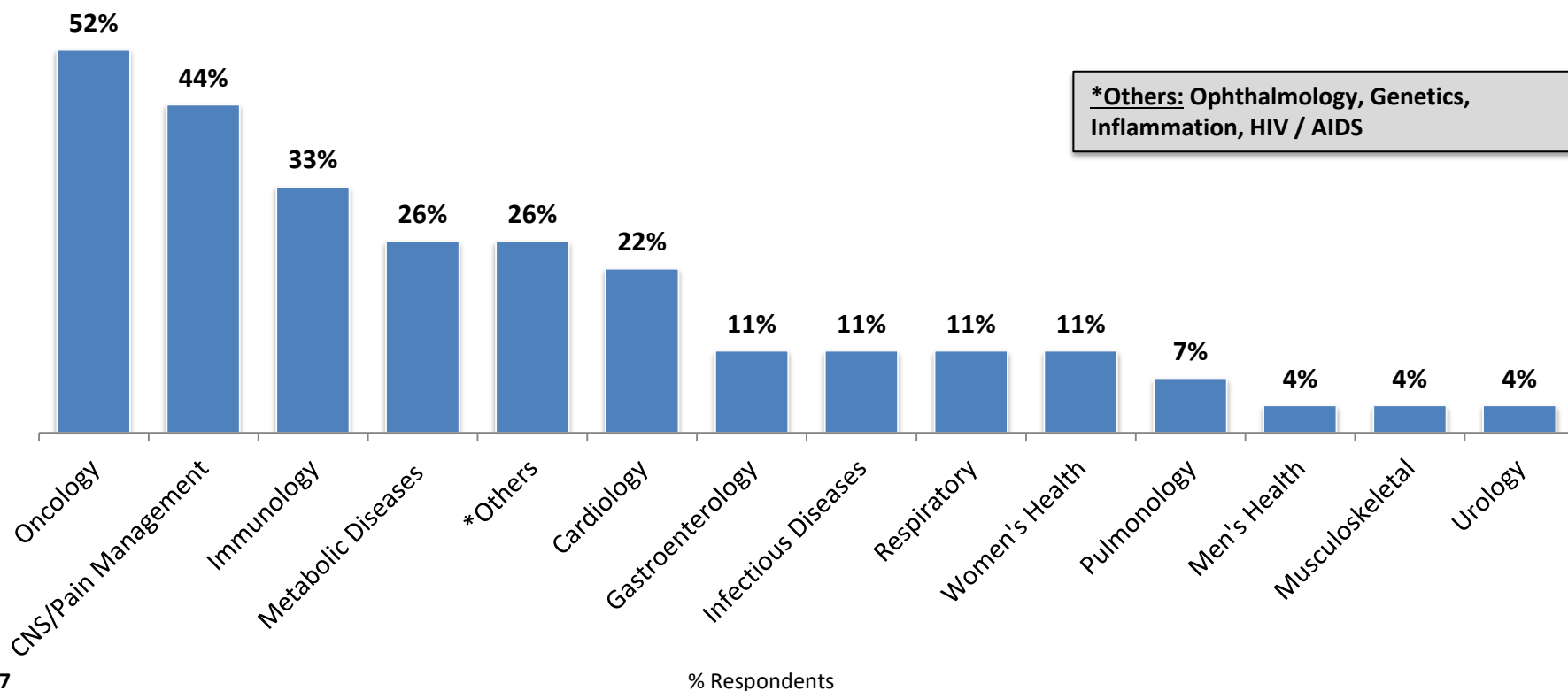


Benchmark Class Represented Various Therapeutic Areas, Primarily Oncology

A majority of participants utilize Real World Data to support oncology products, with many benchmark Medical Affairs teams also supporting CNS, immunology, metabolic and other therapy areas.

Therapeutic Areas

Q3. Please indicate the top three therapeutic areas that you will fill out the survey for. (The top choice should represent the most important therapeutic area for your Medical Affairs group in Real World Data.)





Best Practices is an internationally recognized thought leader in the field of best practice benchmarking. We are a research, consulting, benchmark database, publishing and advisory firm that conducts work based on the simple yet profound principle that organizations can chart a course to superior economic performance by leveraging the best business practices, operating tactics and winning strategies of world-class companies.

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