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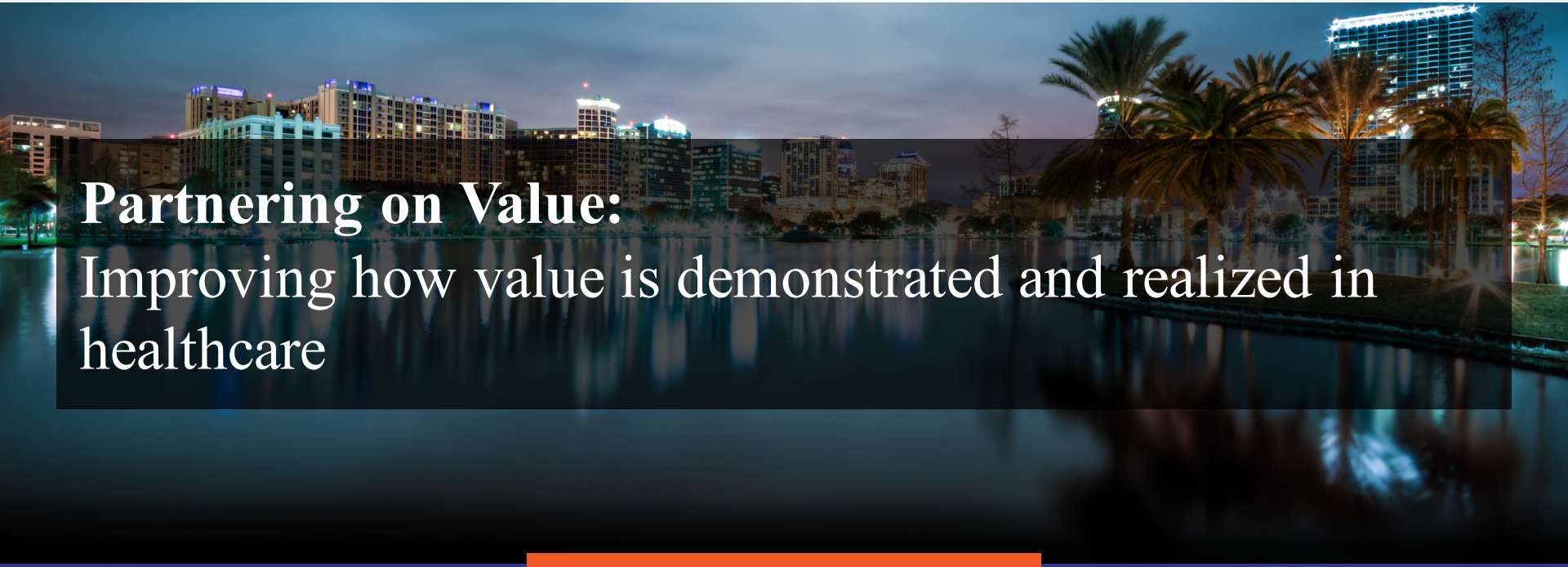
A HIMSS EVENT

FEBRUARY 12, 2019 | ORLANDO, FL



Partnering on Value:
Improving how value is demonstrated and realized in healthcare

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AGENDA

- RWD and its importance to life sciences companies
- Current barriers to designing and operationalizing value-based programs
- Partnership opportunities

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REAL WORLD DATA (RWD):

Usually refers to health-related data gathered outside the typical clinical research setting.[1]

Examples include:

- Insurance claims data
- Electronic medical records
- Prescription refill data
- Physician notes
- Patient surveys
- Wearable devices
- Social media data

1. RWD definitions vary by stakeholder; the above is consistent with FDA statements. Source: http://www.nejm.org/doi/full/10.1056/NEJMsb1609216.

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REAL WORLD EVIDENCE (RWE):

Clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD. [2]

2. Source: https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RealWorldEvidence/UCM627769.pdf

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MACRO TRENDS DRIVE CHANGE IN THE US HEALTH CARE FUNDING MODEL

Unsustainable health care spend

2016 US spend:[1] $3.3 trillion 17.9% of GDP → Projected 2026 spend:[1] $5.7 trillion 19.7% of GDP

High cost of innovation

$2.7 billion to bring a new drug to market [2]

~$500K–800K per patient per year for the highest cost specialty drugs[3]

Public policy pressure

In 2017, more than 80 pharmaceutical pricing bills were proposed in over 30 states around the country [4]

Challenges with access to therapies

Increasing out of pocket burden on patients, often leading to difficult choices on treatments

At times, clinical pathway programs are suboptimal in getting patients to the most effective treatment early

Sources: (1) CMS (2) Tufts Center for the Study of Drug Development (3) AHIP (4) Global Health Justice Partnership of the Yale Law School

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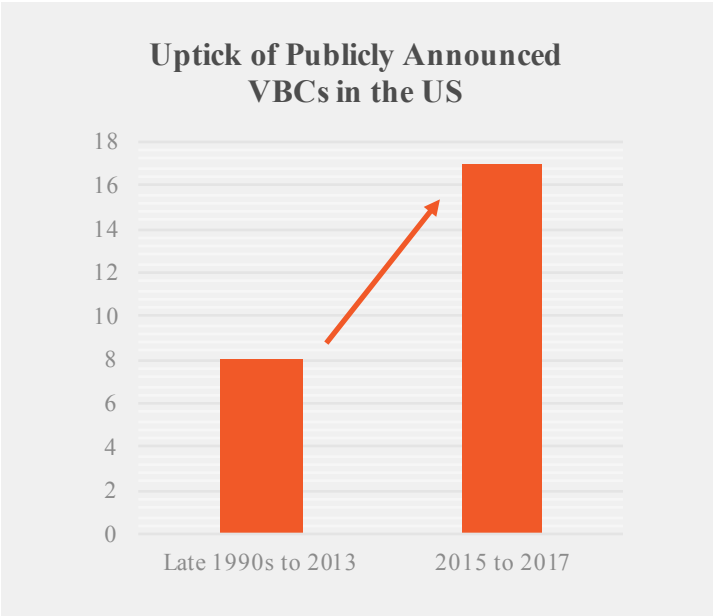
GROWING INTEREST IN VALUE-BASED PROGRAMS

What are value-based programs?

An arrangement between a manufacturer and a payer that tie the reimbursement of a drug or device to the value (i.e., outcomes) it delivers in a real world setting

These programs can take many forms:

- Outcomes-based risk sharing
- Indication-based pricing



Source: Journal of Managed Care & Specialty Pharmacy JMCP October 2017 Vol. 23, No. 10

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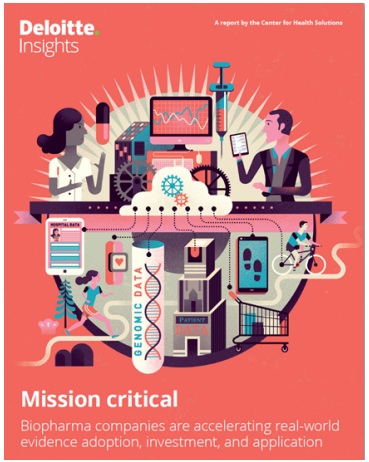
BUT BARRIERS EXIST TO WIDESPREAD ADOPTION

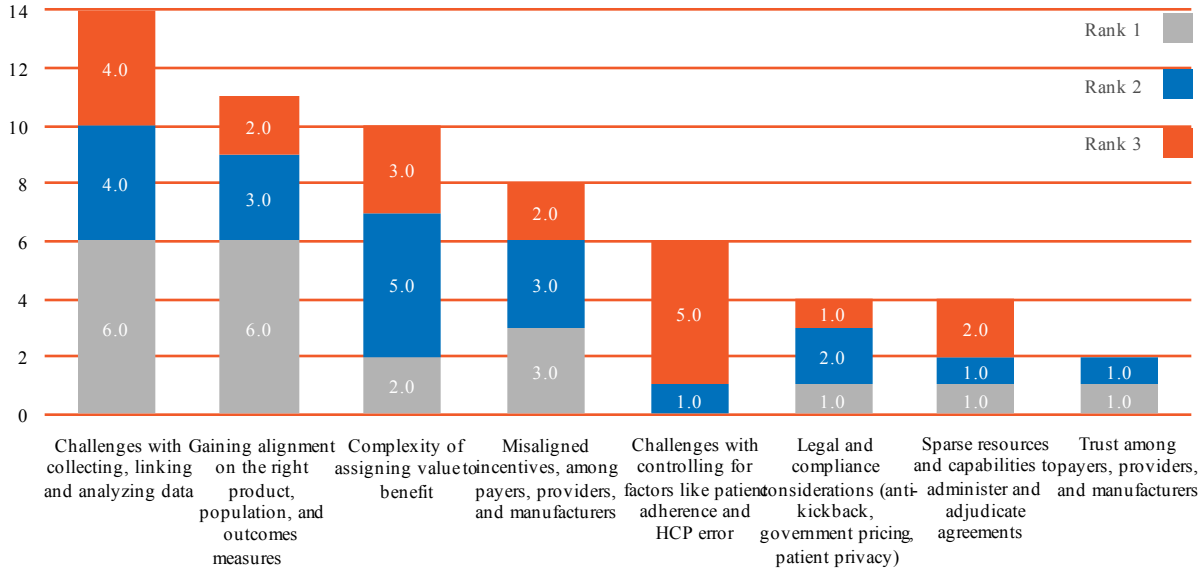


2nd Annual Survey of 20 biopharmaceutical organizations on the current state, trends, investments and use of RWD and RWE.

This year's survey had a dedicated spotlight on value-based contracting.

Deloitte's 2018 RWE benchmarking survey assessed today's perceived challenges with establishing and operationalizing VBCs

Survey question 27: What do you believe is the biggest barrier to value-based contracting (rank top 3)?



Source: https://www2.deloitte.com/insights/us/en/industry/life-sciences/2018-real-world-evidence-benchmarking.html

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EMERGING TRENDS
OPEN OPPORTUNITIES
FOR BROADER ADOPTION

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WHY IS RWE IMPORTANT TO LIFE SCIENCES COMPANIES:

Evidence requirements are increasing across the drug lifecycle, specifically for commercial products due to pricing pressures and value-based reimbursement landscape shifts

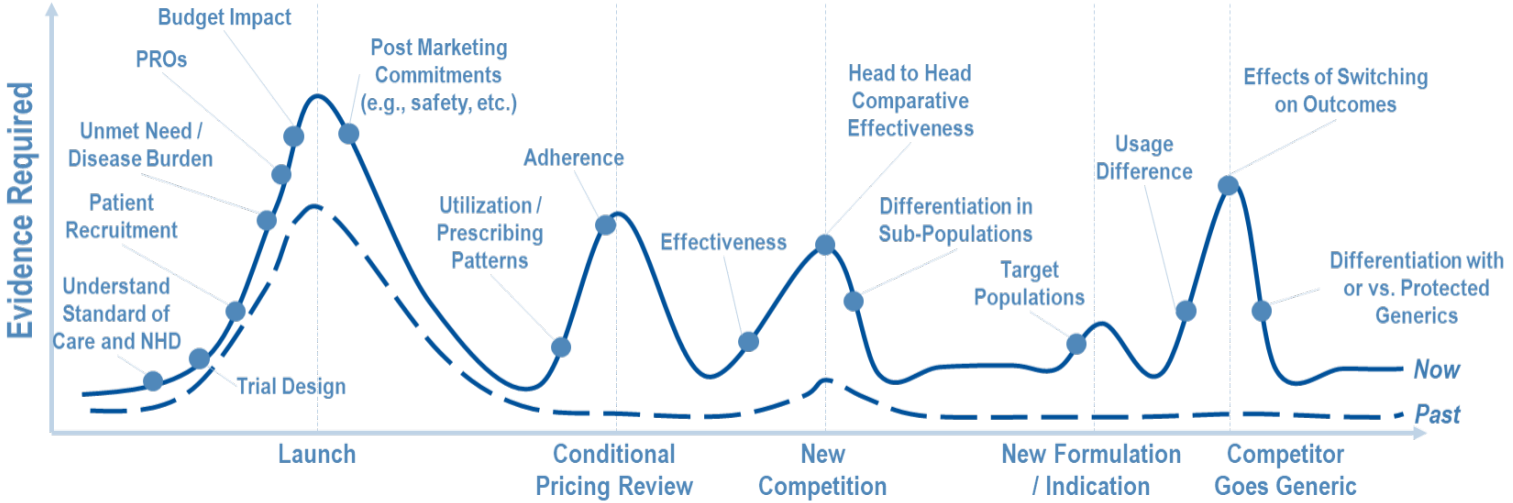

Image source: https://www.slideshare.net/3GDR/the-importance-of-postmarketing-registries-for-payers-and-regulators-to-manage-drug-pricing-and-conditional-reimbursement

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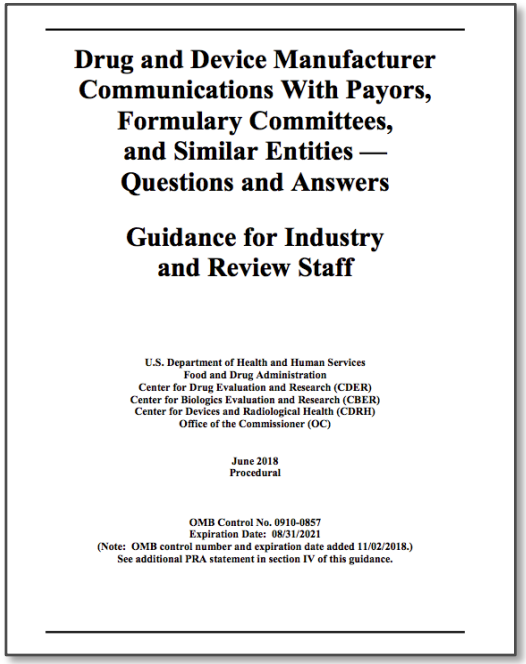
FDA GUIDANCE - COMMUNICATIONS WITH PAYORS, FORMULARY COMMITTEES

This guidance provides answers to common questions:

- Regarding firms' communication of health care economic information (HCEI) regarding prescription drugs to payors with expertise in health care economic analysis
- Relating to dissemination to payors of information about medical products that are not yet cleared for use and unapproved uses of cleared medical products



Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities — Questions and Answers

Guidance for Industry and Review Staff

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of the Commissioner (OC)

June 2018
Procedural

OMB Control No. 0910-0857
Expiration Date: 08/31/2021
(Note: OMB control number and expiration date added 11/02/2018.)
See additional PRA statement in section IV of this guidance.

Source: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf

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COMMUNICATION BY FIRMS TO PAYORS REGARDING UNAPPROVED PRODUCTS:

- Indication(s) sought
- Clinical study protocol(s) about endpoint(s) being studied
- Patient population under investigation (e.g., Number of subjects enrolled, subject enrollment criteria, subject demographics)
- Anticipated timeline for possible FDA approval
- Patient utilization
- Product-related programs or services
- Factual presentations of results from studies

Earlier information can provide more time to design and plan value-based programs

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FRAMEWORK FOR FDA'S RWE PROGRAM

FDA created a framework for evaluating the potential use of RWE to help support:

- The approval of a new indication for a drug already approved
- Drug post-approval study requirements

"RWE also has the potential to make America's health care system more competitive and efficient as validated outcomes measures based on real world data are incorporated into value-based payment contracts."

– Scott Gottlieb, M.D. | Jan 28, 2019 | Bipartisan Policy Center Conference

Source: https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RealWorldEvidence/UCM627769.pdf

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APPLYING FRAMEWORK FOR DESIGNING VALUE-BASED PROGRAMS

ASSESSING FIT

Assessing fitness of RWD for use in value based programs:

- Reliability and Relevance: validated measures
- Gaps – complete picture, linkages
- Common data model

GENERATING RWE

Generating RWE that provides adequate scientific evidence to answer value-based program questions:

- Randomized pragmatic trials
- Non-randomized-single arm studies
- Observational studies

CONSIDERATIONS

Other considerations and requirements for collecting and using data:

- HIPAA

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VALUE LABS

Joint ventures between industry, payers and other stakeholders to research, evaluate and deliver value to the health care system.

Safe and transparent forum to develop solutions to common issues related to defining and measuring outcomes and data sharing

Economies of scale can enable greater use of "hard to capture" outcomes measures and expand the number of therapeutic areas amenable to performance-based agreements.

Sources: (1) https://invivo.pharmaintelligence.informa.com/IV005130/The-Value-Lab-Moving-ValueBased-Health-Care-From-Theory-To-Practice
(2) https://theactuarymagazine.org/partnering-to-share-the-risk/

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VALUE LAB:
Stakeholder joint-venture

EARLIER INFORMATION:
FDA guidance: communications with payors, formulary committees

DESIGN AND DATA:
Framework for FDA's RWE program

Source: DaVinci Project | http://www.hl7.org/about/davinci/