

Welcome!

Execution to Strategy:

Accelerating the Transformation of
Medical Affairs Vision 2030

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- The following faculty and planning members do disclose financial relationships- *(list las names here)*

Educational Objectives

This session will provide a learning opportunity for our audience by discussing:

Patient Centricity and Health Equity

Refocusing on bringing value to the patient. Through an approach focused on representation and inclusion, how do we ensure we are adequately finding and engaging diverse patient populations?

Precision Data Insights

Medical strategy should be as precise and evidence-based as the therapies you represent. Learn how patient-centric data and technology solutions are arming Medical Affairs teams to drive sound and effective strategy and engagement.

Measuring Impact

Accelerate impact by sensing and responding to your medical strategy using real-time analytics and solutions. Establishing a closed feedback loop to pivot and evolve strategies with the understanding of what is and is not working.

Road To The 2030 Vision

1950 - 2000

Predominantly operational support function

2000s

Separation of Medical Affairs from Commercial function

2010 - 2019

Initiation of becoming a strategic partner

2020

Medical Affairs strategy influenced by patient-centric real-world data and real-world evidence

2030

Medical Affairs to be the center of strategic vision for clinical development and commercial efforts and identifying and addressing unmet societal and healthcare issues.

Our discussion focuses on

- Patient-centricity
- RWD to Precision Insights
- Health Equity
- Medical Strategy Impact Measurement

...driving the 2030 Vision today

Patient Centricity Starts with the Patient

Through the lens of her lived experiences in health care...



A champion for patient voices

Patient Healthcare Data is Hard to Piece Together...



First Sign of
Health Issue

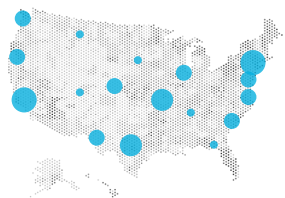


Second-Line
Therapy

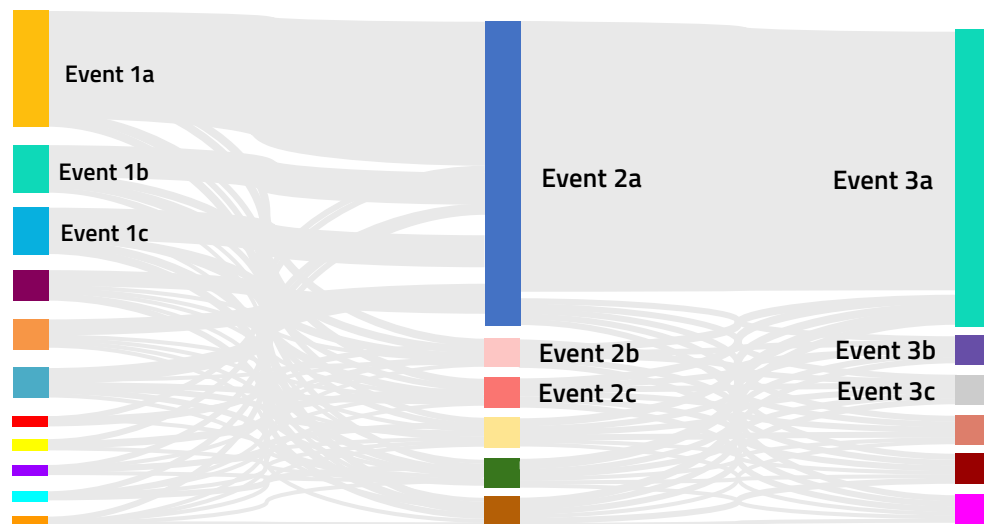
Data Connectivity: A Full View of the Patient Journey



Test/Support Hypothesis and Strategy Generation



Patient Event Pathways



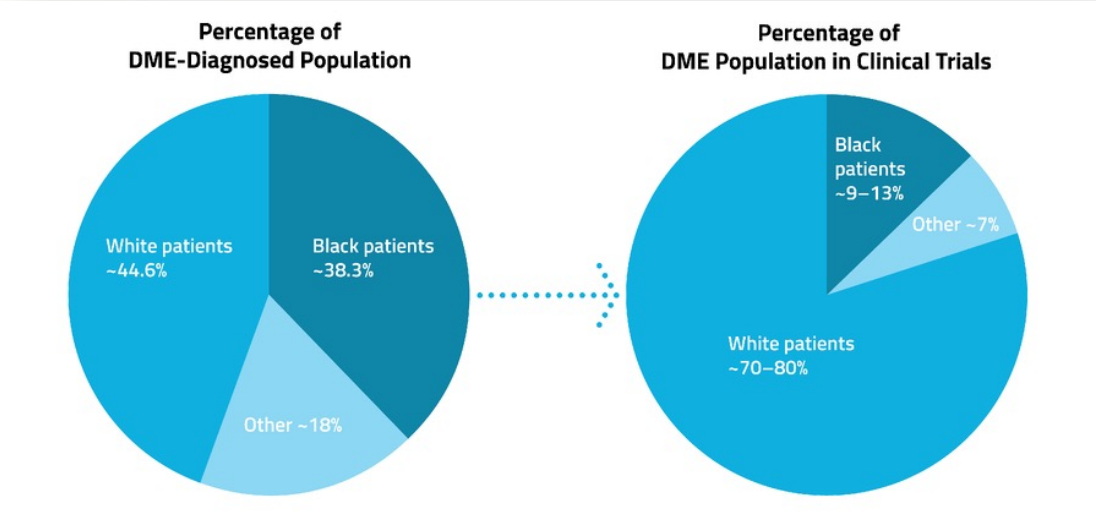
Granular patient-level data allows MA teams to ask questions to pressure test hypotheses and strategies

- ? What adverse events are we seeing?
- ? What time frame are these drugs being initiated?
- ? What diagnoses come before drug initiation or treatment decisions?
- ? What diagnoses and tests are coming after drug initiation?

Demographic Insights to Drive Health Equity

Diabetic macular edema (DME) is the most common cause of vision loss in patients diagnosed with diabetic retinopathy (DR).

DR is the leading cause of blindness in American adults under the age of 65 and disproportionately impacts Black Americans.



25 DME/DR Clinical Trials were reviewed for Inclusion & Exclusion (I/E) Criteria

Patient Race & Ethnicity	White	Black
DME Patients (U.S. population)	44.6 ± 18.3%	38.3 ± 16.5%
DME Patients (NIH) - Trial Participants	69.5 ± 4.4%	12.6 ± 3.3%
DME Patients (Industry-Sponsored) - Trial Participants	80.0 ± 2.2%	8.6 ± 2.9%
% Change after modelling a sample DME Trial I/E criteria	+9%	- 23%

Sampled DME clinical trial I/E criteria boosted the pool of potential white participants by 9% while depressing the pool of potential black participants by 23%.

Modeling and adjusting I/E criteria can increase patient representation.

Improving Access to Novel Therapies: HER2+ Breast Cancer

Prevalence and Mortality Rate for HER2+ Breast Cancer

Patient Race and Ethnicity (per 100,000)	White	Black
Published Incidence	130.8	126.7
Published Mortality Rate	20.3	28.4

Komodo Analysis: Investigator Participation in HER2+ Therapy

HCP Participation in Clinical Trial	Total # Patients	Total # Black Patients
Did not participate: 2,993 HCPs	66,300	5,200
Did participate: 1,455 HCPs	40,500	3,400

Black women and White women have similar rates of developing HER2+ breast cancer.

Despite that, Black women face comparatively higher mortality rates.

67%

of physicians were not using the most novel therapy for HER2+ breast cancer patients

60%

of HER2+ Black breast cancer patients are seen by HCPs not participating in clinical trials

Network mapping may be used to identify opportunities for education, patient support, and trial recruitment strategies to help improve health equity.

Opportunity to Make a Difference: Chronic Conditions

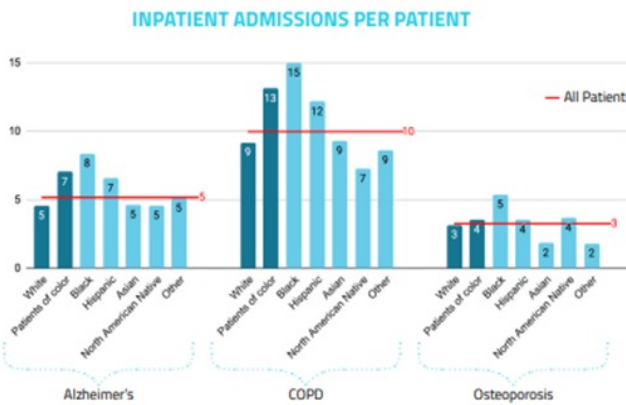
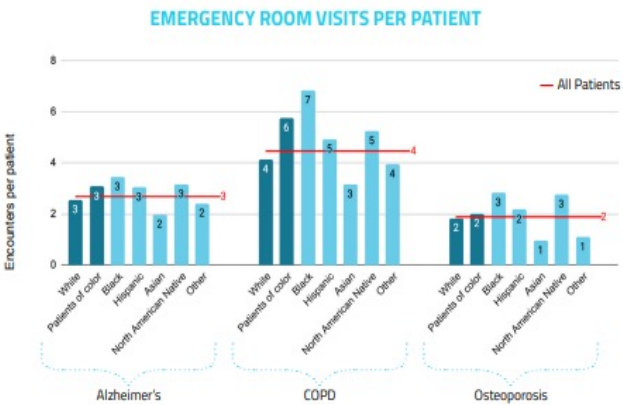
In an analysis of patients with Alzheimer’s Disease, COPD, or Osteoporosis, patients of color visited the emergency room (ER) and were admitted as inpatients more often than White patients, suggesting that there were more frequent and more serious complications of their chronic conditions.

- Similarly, patients of color experienced more healthcare encounters overall compared with the White patient population.
- Race-based disparities in care persisted in disease-specific care.

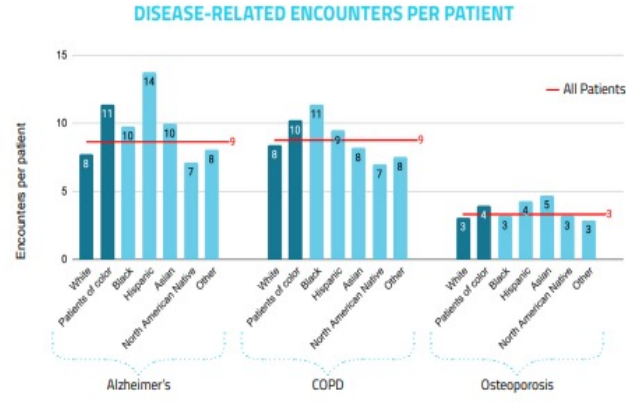
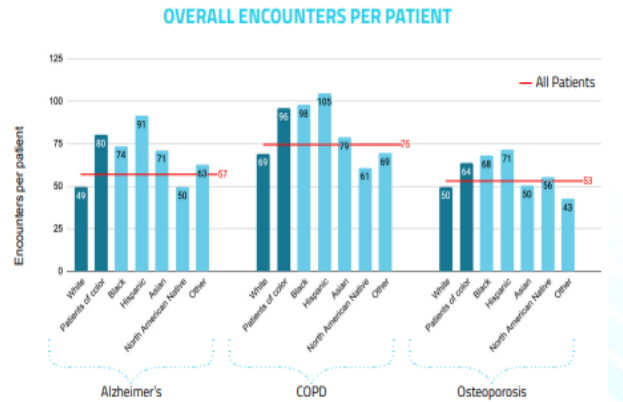
BREAKDOWN OF PATIENTS BY RACE ACROSS DISEASES

Race	Alzheimer’s	COPD	Osteoporosis
White	76%	80%	76%
Patients of Color	24%	20%	24%
Black	10%	11%	7%
Hispanic	10%	6%	10%
Asian	3%	2%	5%
North American Native	<1%	<1%	<1%
Other	<1%	1%	2%
Total Number of Patients	1.8M	2.9M	5.9M

Hypothesis test & explore the patient journey to identify opportunities to better manage conditions.



Patients of color with Alzheimer’s disease experienced 20% more ER visits and 54% more inpatient admissions compared with White patients. Patients of color with chronic obstructive pulmonary disease (COPD) visited the ER 39% more than White patients and were admitted to the hospital 43% more often. Patients of color with osteoporosis had 10% more ER visits and 12% more inpatient admissions compared with white patients.

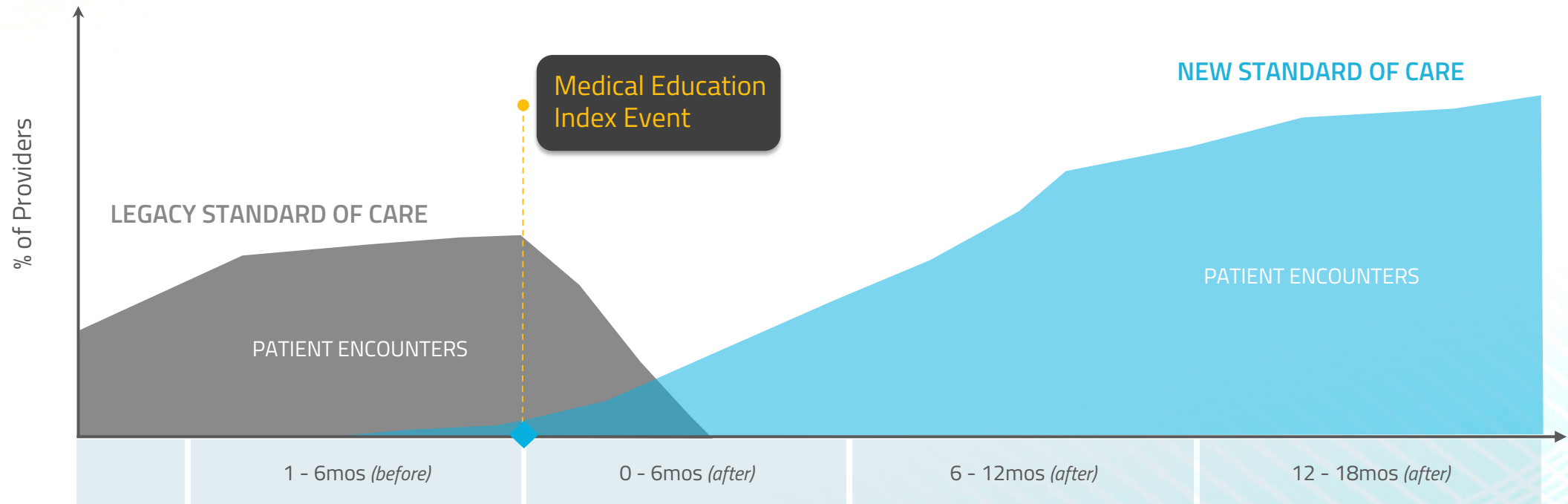


Patients of color with Alzheimer’s disease had 1.62 times more healthcare encounters overall and 1.47 times the number of disease-related encounters compared with White patients. Patients of color with COPD had 1.39 times more healthcare encounters overall and 1.21 times the number of disease-related encounters compared with White patients. Patients of color with osteoporosis had 1.28 times the number of encounters overall and 1.28 times the number of disease-related encounters compared with White patients

Visualize Patient-Level Impact In Real Time

LANDSCAPE OF CLINICAL BEHAVIOR PATTERNS

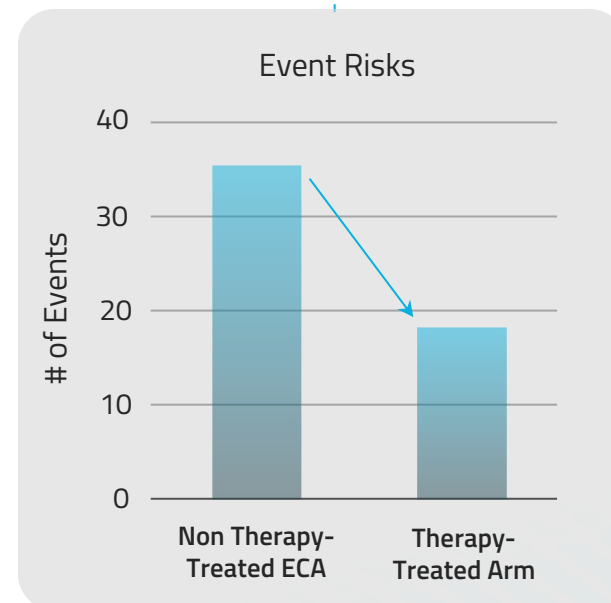
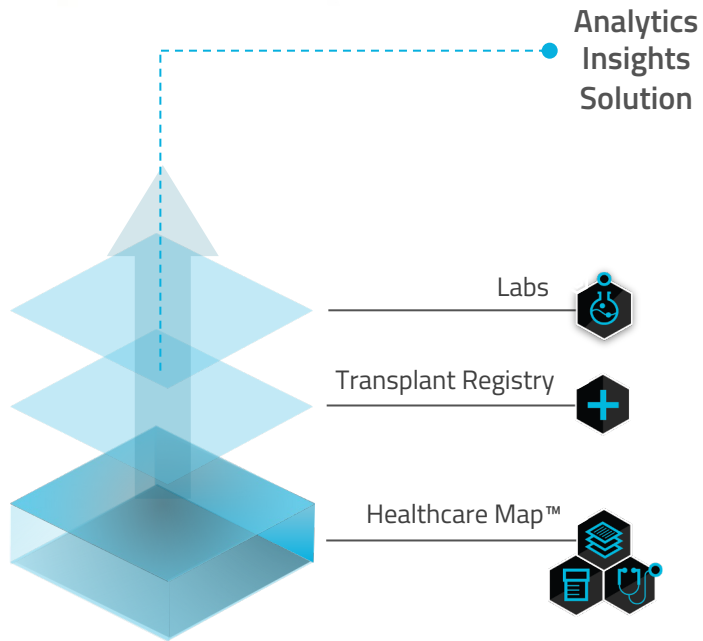
Aggregate View of HCP Behavior



Leveraging RWD for Evidence Generation

RWD Drives External Control Arm (ECA)

Phase 3b/Phase 4 trial was terminated early due challenges with enrolling and maintaining patients in a placebo-controlled study of a rare disease (primary biliary cholangitis). By partnering with Komodo, Intercept was able to use RWD to accelerate evidence generation and assess the real-world impact of its therapy.



Impact



Overcome trial enrollment and adherence challenges with RWD capabilities



Uncover new clinical insights and evidence generation to support rare disease therapies



Lower cost with trial design focused on external control arms leveraging RWD

Our Journey



Where are we now?



How do we do our part to get going or to continue on this journey?





Q&A Session