

COLLEGE OF POPULATION HEALTH

PopTalk Webinar Series

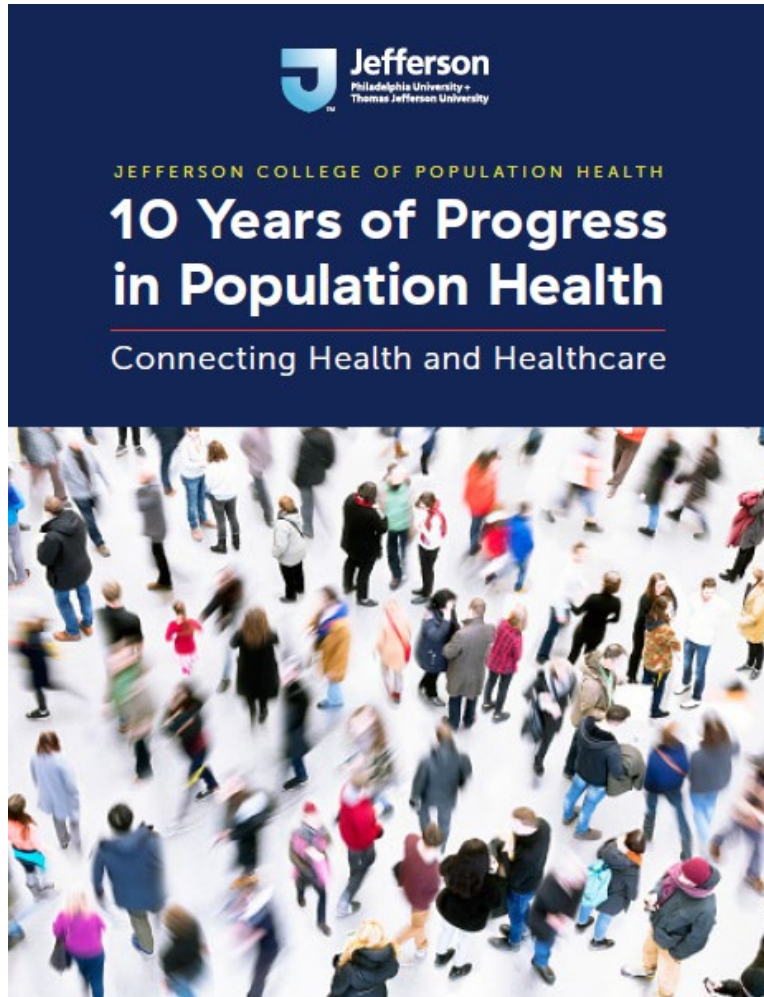
The Role of Medical Affairs in Health Outcomes Data Generation and Communication

May 13, 2021
12:00 pm ET



Jefferson
Thomas Jefferson University

Jefferson College of Population Health



To prepare leaders with global vision to *develop, implement* and *evaluate* health policies and systems that improve the health of populations and thereby enhance the quality of life

The Role of Medical Affairs in Health Outcomes Data Generation and Communication

Featuring:

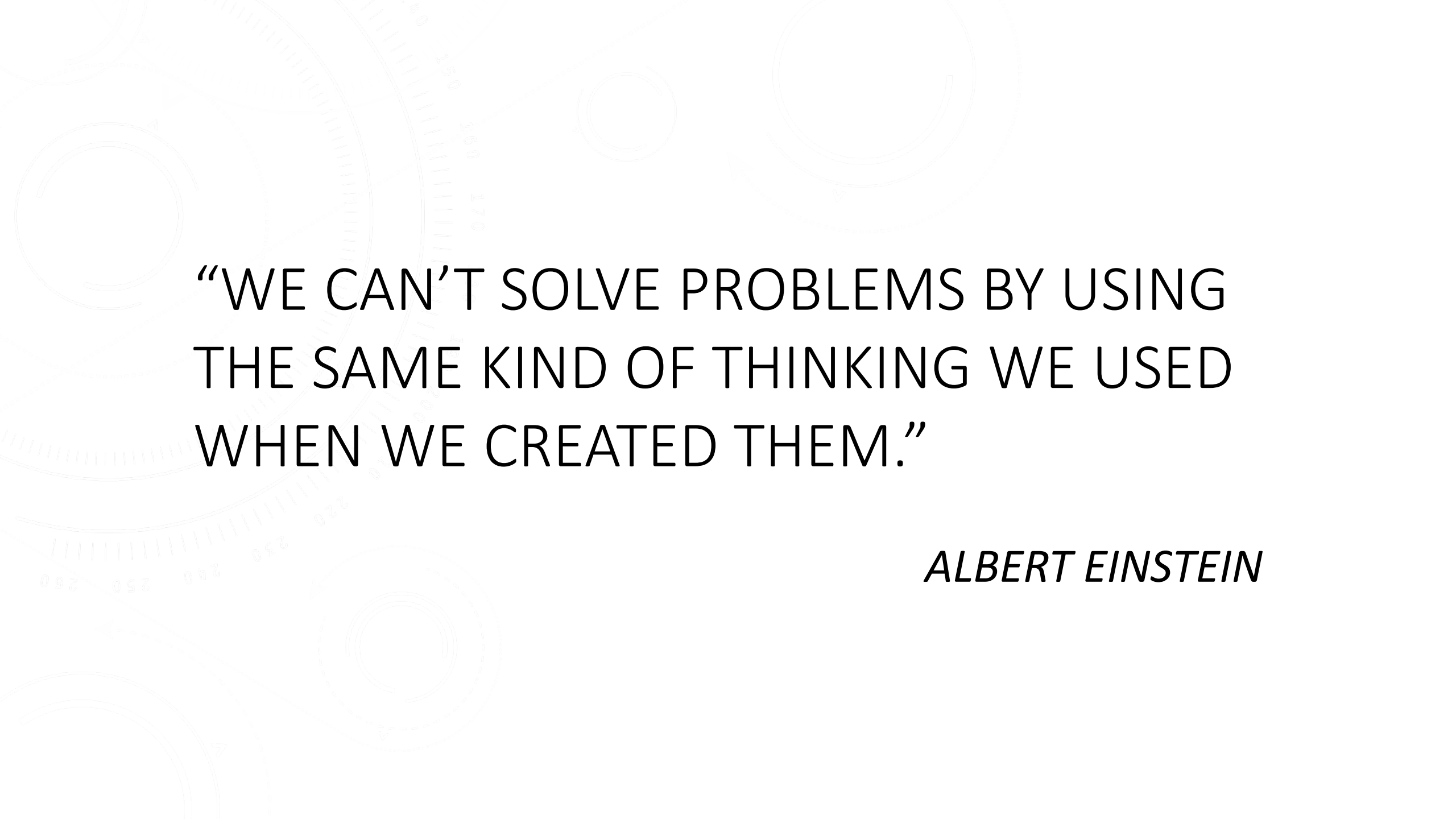


Ahmad B. Naim, MD
*Vice President, US Medical Affairs
Incyte Corp*

Moderated by:

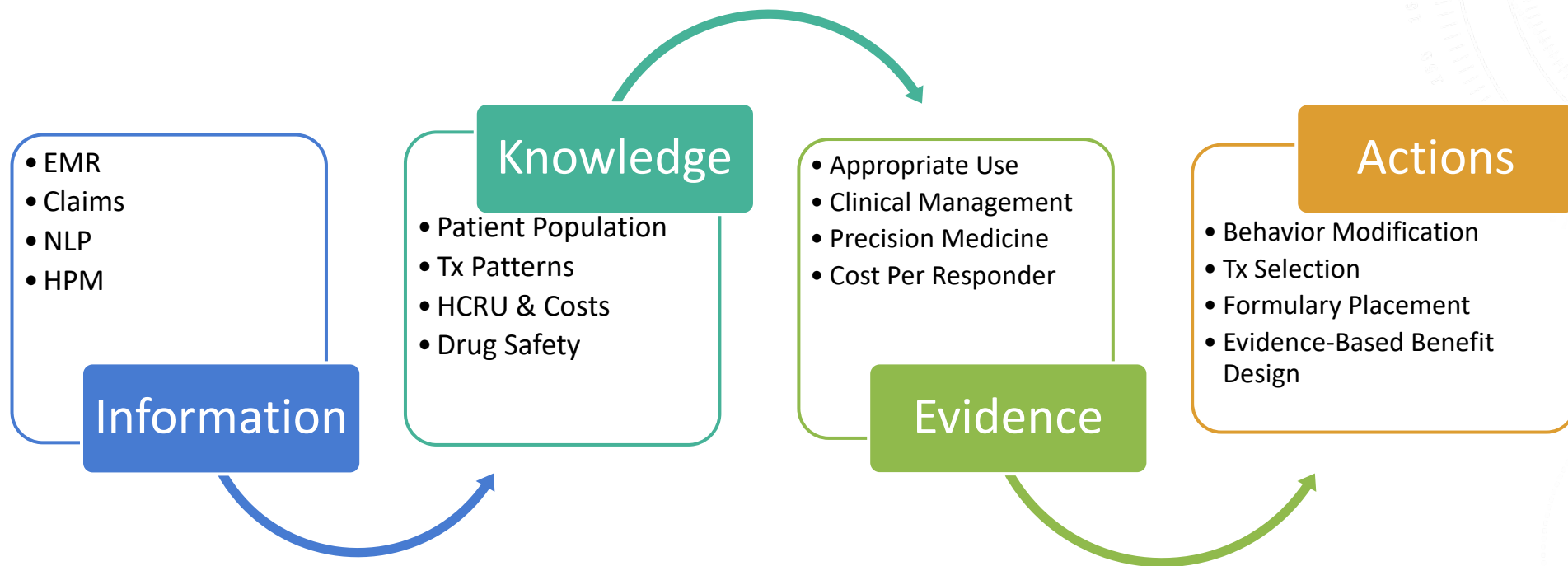


Vittorio Maio, PharmD, MS, MSPH
*Program Director, AHEOR
College of Population Health*

The background features faint, light-colored technical drawings and gear-like patterns. These include circular outlines, concentric circles, and radial lines, resembling mechanical or scientific diagrams. The drawings are scattered across the page, with some showing numerical scales and tick marks.

“WE CAN’T SOLVE PROBLEMS BY USING
THE SAME KIND OF THINKING WE USED
WHEN WE CREATED THEM.”

ALBERT EINSTEIN



The what, why, when, and for whom

What causes Disease? (MOD)

- Pathogenesis
- Role of various signaling cascades
- Genetic
- Autoimmune
- Environmental

What can work to modify/cure the Disease? (Discovery)

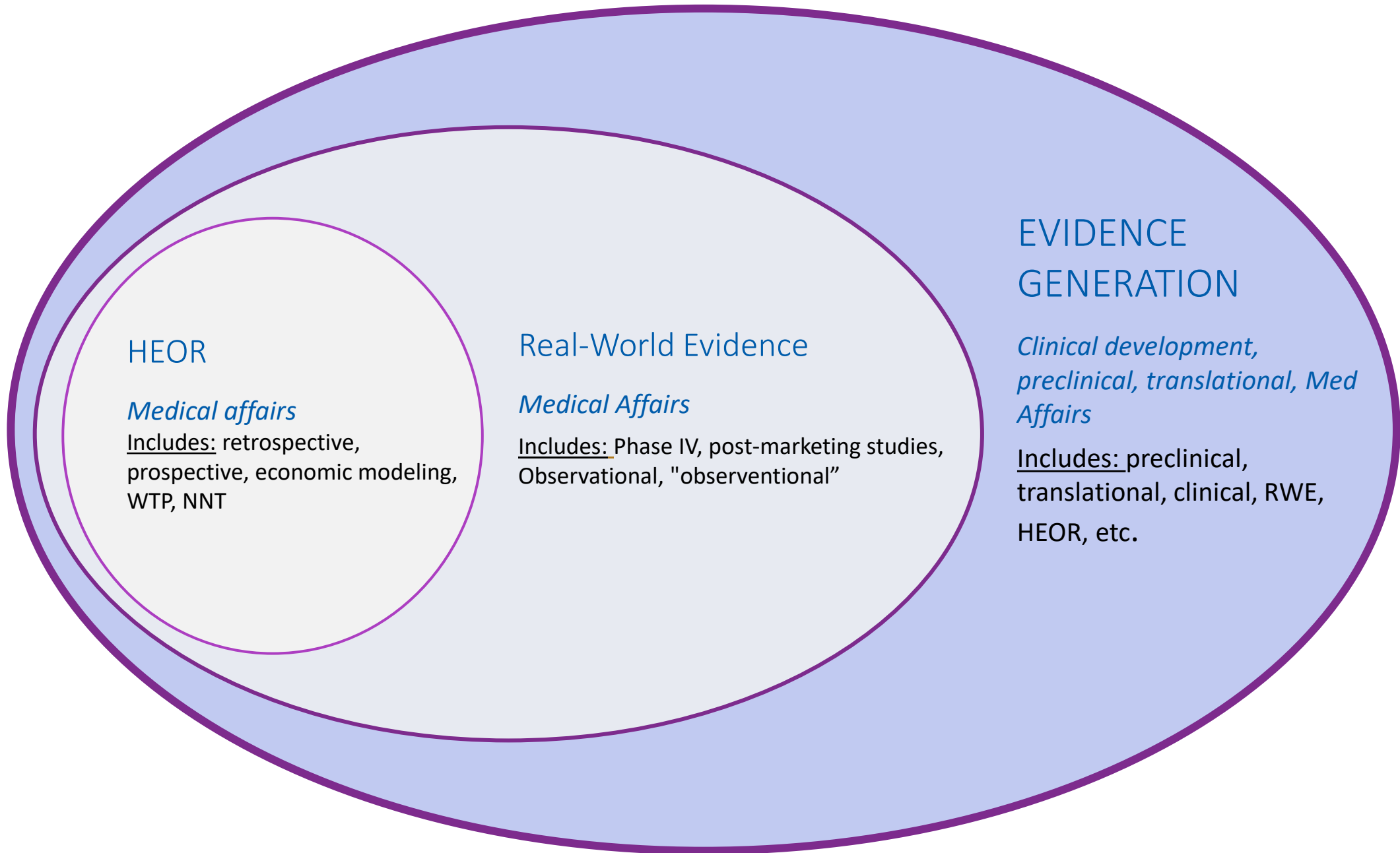
- In vitro/ In vivo experiments
- Agonists / Antagonists
- Small molecule vs. live medicines
- Receptor inhibitors
- DNA Repair (Gene therapy)
- MAB, bi-specifics

How does the drug work? (MOA)

- Regulating signaling
- Inhibitors of major regulatory pathways (MEK, cMyc, etc.)
- Mutation-driven (BRAF, VEGF)
- mRNA vaccines
- Combination regimens

How well does the drug work? (Clinical Exp)

- Discovery Clinical Trials
- Pivotal Clinical Trials (Regulatory)
- Longitudinal Design
- Observational / Pragmatic Studies
- Post-Marketing Studies (Phase IV)



HEOR

Medical affairs

Includes: retrospective, prospective, economic modeling, WTP, NNT

Real-World Evidence

Medical Affairs

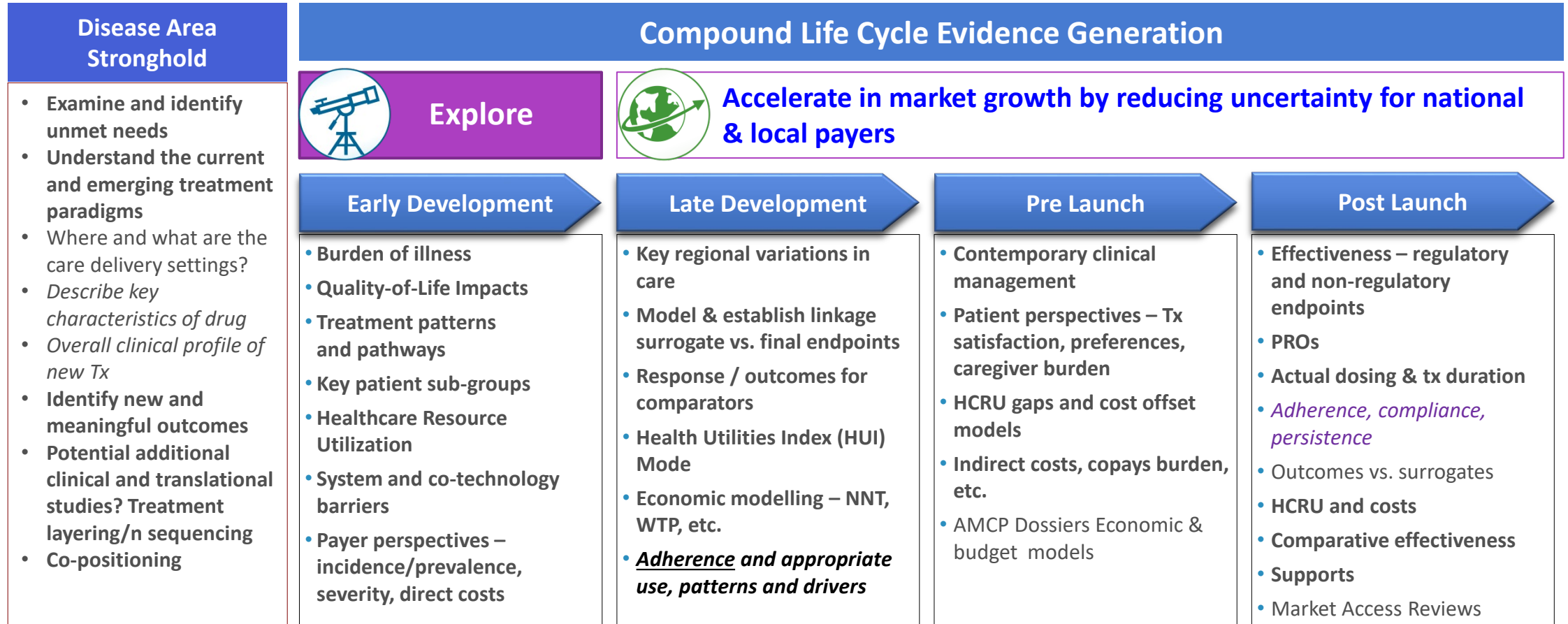
Includes: Phase IV, post-marketing studies, Observational, "observational"

EVIDENCE GENERATION

Clinical development, preclinical, translational, Med Affairs

Includes: preclinical, translational, clinical, RWE, HEOR, etc.

EVIDENCE-GENERATION STRATEGIES – THE SPECTRUM



Drive and inform Disease Area Stronghold strategies including portfolio planning and new business development and support key assets

EVIDENCE GENERATION PERSPECTIVES



Provider

- Epi / disease state
- Patient characteristics
- Clinical outcomes
- PROs
- QoL Impacts
- ADL, behavioral
- Shared-Decision Making (SDM)
- Variations in care
- Health utilities



Patient

- Effectiveness
- Safety
- PROs
- Pt. Preferences & Satisfaction
- QoL Impacts
- ADL, behavioral
- WTP
- copay/co-insurance
- Shared-Decision Making (SDM)



Payer

- AD BOI
- Comorbidities
- Clinical Outcomes
- HCRU
- ICER
- Health Utilities Index (HUI)
- Rx Adherence
- Quality metrics
- Network Meta-analysis (NMA)
- BIM / CEA/ CUA



Employer

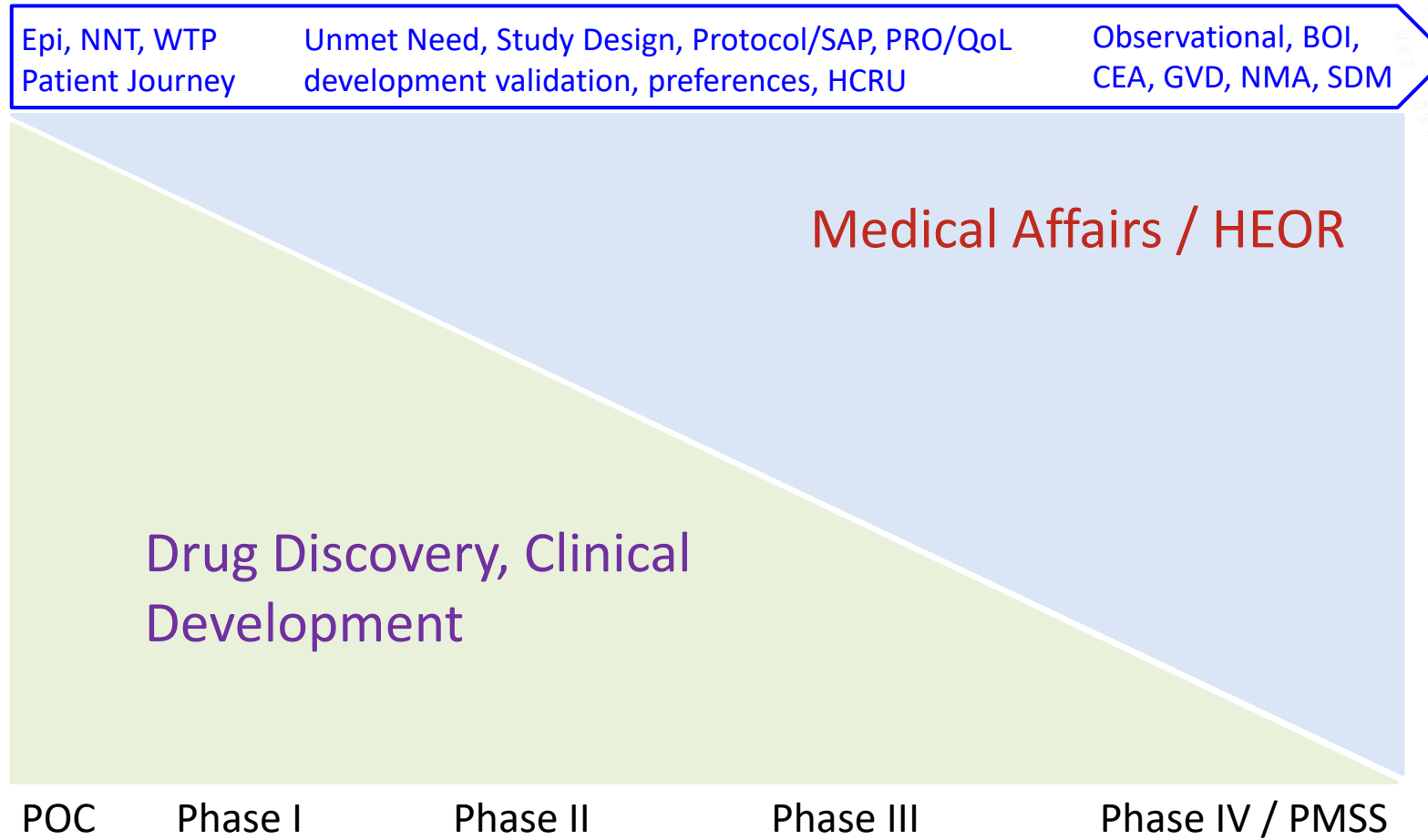
- Productivity
- Absenteeism, presenteeism
- Human capital management
- HUI
- Shared-Decision Making (SDM)
- Variations in care
- Quality metrics



Societal

- Direct and indirect costs
- Shared-Decision Making (SDM)
- Value over time
- Socio-economic impact

DRUG DEVELOPMENT / PRODUCT LIFE CYCLE



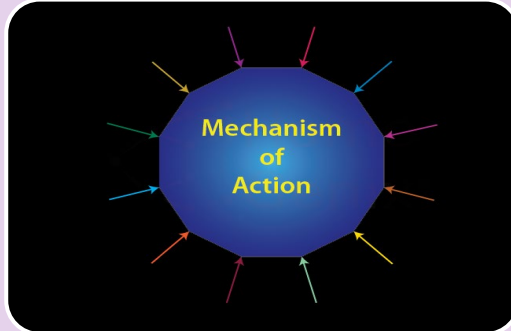
VISION

- To build an integrated cross-functional medical affairs organization that brings value to healthcare providers and decision makers, and patients and caregivers through objective and appropriate scientific evidence

MISSION

- Medical Affairs organization will serve as a key function in forming Business Unit(s) and ensuring its success both in short- and long-term, and;
- through its internal partnerships and external interactions will provide robust subject matter expertise and stakeholder insights

MEDICAL AFFAIRS-HEOR REMIT



SCIENCE COMMUNICATION

ENRICHMENT
EDUCATION
EMPOWERMENT

FOLLOW THE SCIENCE

Scientific Rationale
MOD-centric
Novel MOAs

DEVELOP THE SCIENCE

Observational /
interventional studies
Real-world evidence
IIRs

COMMUNICATE THE SCIENCE

Robust, objective,
appropriate scientific
exchange
Truthful, Non-misleading
Nuances and contexts of
data

Shared Vision,
Common Goals, and
Sense of Purpose



Shared Accountability for
Extraordinary Results



Well Coordinated &
highly collaborative



Medical
Affairs

Effective
Communications

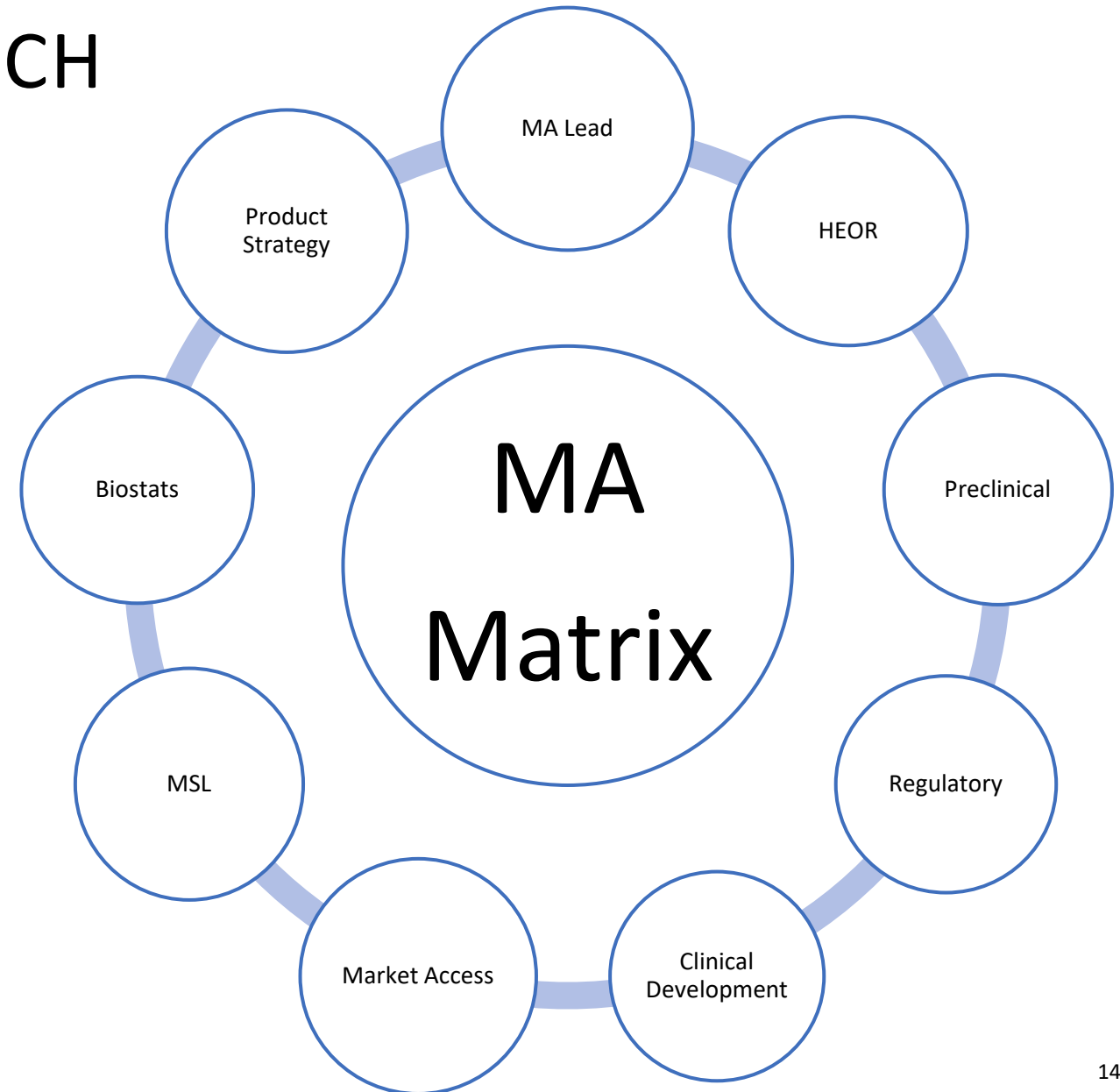


Purposeful
Dissemination



THE INTEGRATED APPROACH

- Strategy
- Tactics
- Integrated planning
- Therapeutic Area or Molecule level
- Integrate across projects/studies
- Oversee projects
- Design and enhance workflows
- Cross-functional
- Visibility and awareness



FROM MARKET ACCESS TO MEDICAL AFFAIRS

TRADITIONAL APPROACH

- Support market access tactics
- Value proposition driven models
- And more models...
- Narrow stakeholder perspective (P&T, PBM, etc.)
- Limited Applicability & Potential (self-serving)
- And even more models...
- Unmet Needs [oxymoron]

CONTEMPORARY & BOLD

- ✓ Medical Affairs-HEOR Bridge
- ✓ Highly trained scientists
- ✓ Multi-stakeholder perspective (ECHO model)
- ✓ Invaluable in shaping the environment
- ✓ Well-informed drug discovery programs
- ✓ Clinical experience + RWE = Outcomes-driven solutions
- ✓ Systems development



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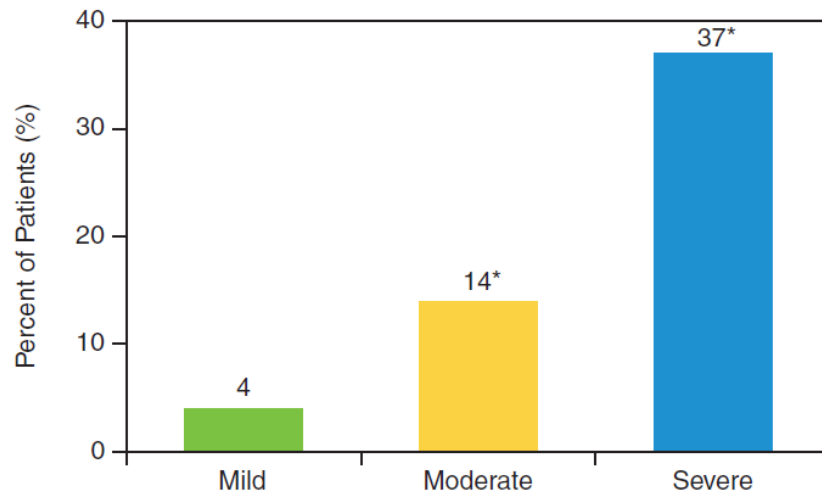
tion

Impact of Disease on Career Choices, Absenteeism, and Work Loss Among Individuals with Psoriasis in the United States

A. B. Naim,¹ J. H. Lofland,¹ D. Freedman,² K. Annunziata²

¹Centocor Ortho Biotech Services, LLC., Horsham, Pa.; ²KantarHealth, Princeton, NJ

Figure 2. Psoriasis Has Ever Affected Career Choice by Disease Severity



*p<0.05

Conclusions

- PsO is a debilitating disease which impacts multiple aspects of an individual's lifestyle, including career choices and physical functioning
- Among the actively employed, moderate-to-severe PsO has a greater impact on their previous and current career choices as compared with patients with mild PsO
- In addition, patients with severe PsO are associated with greater work loss and activity impairment

***Developing a
Health & Productivity-driven,
Evidenced-based Approach
to Benefit Design
for Biologic Treatments***

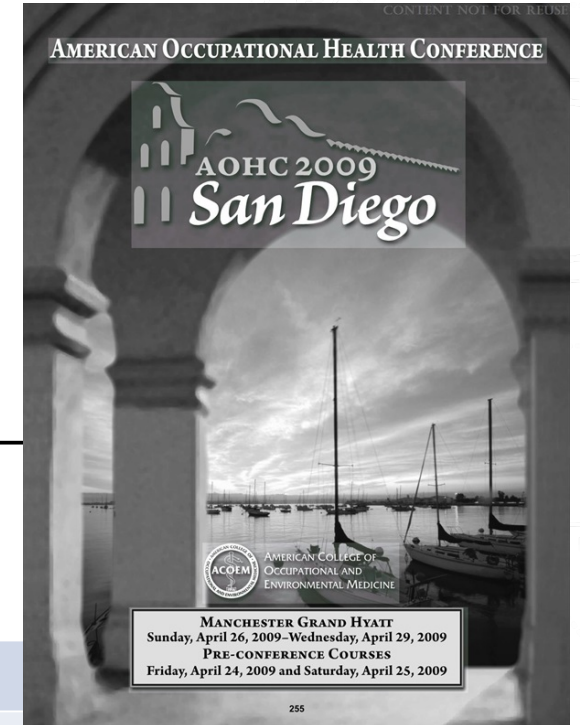
Faculty: Gregg M. Stave, MD, JD, MPH
William B. Bunn, MD, JD, MPH
Ahmad B. Naim, MD, MPH

Moderator: Ron Loepke, MD, MPH, FACOEM, FACPM

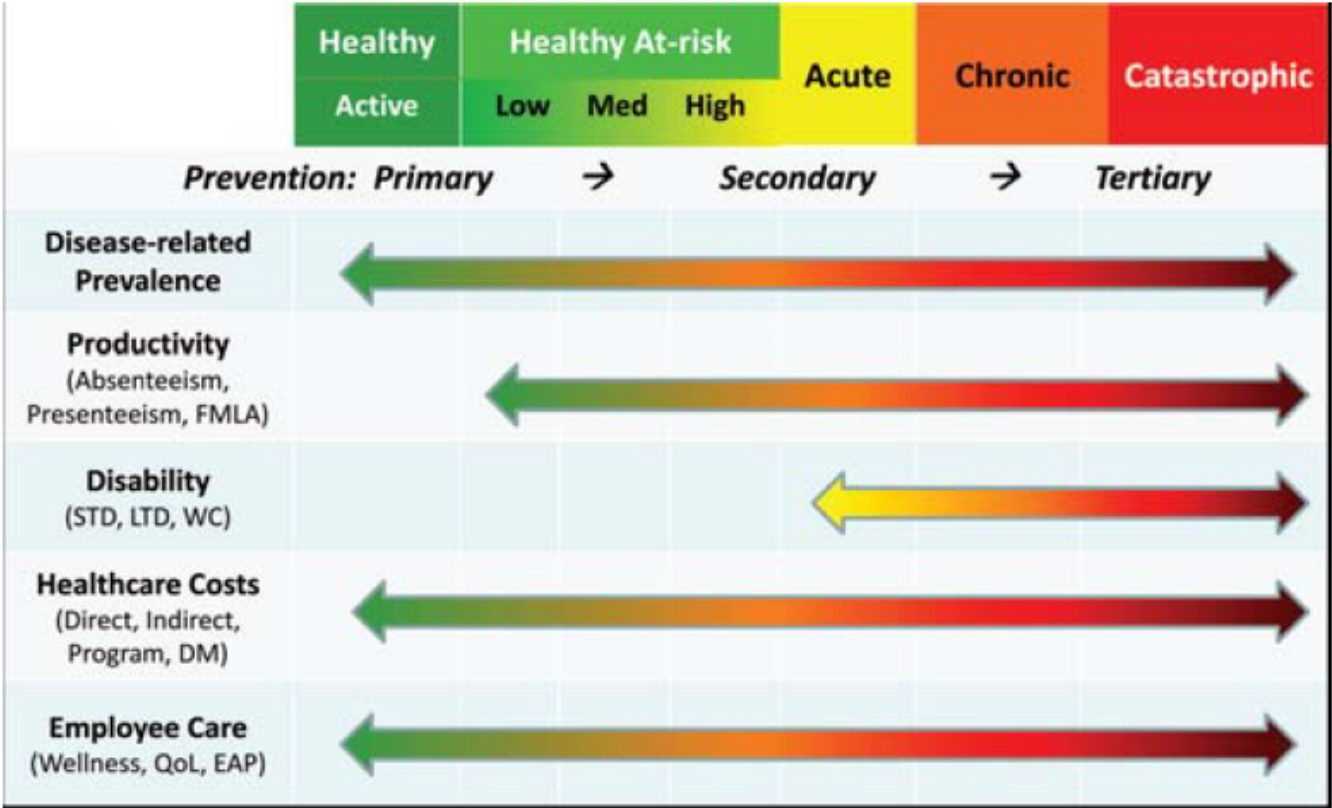


Session Overview

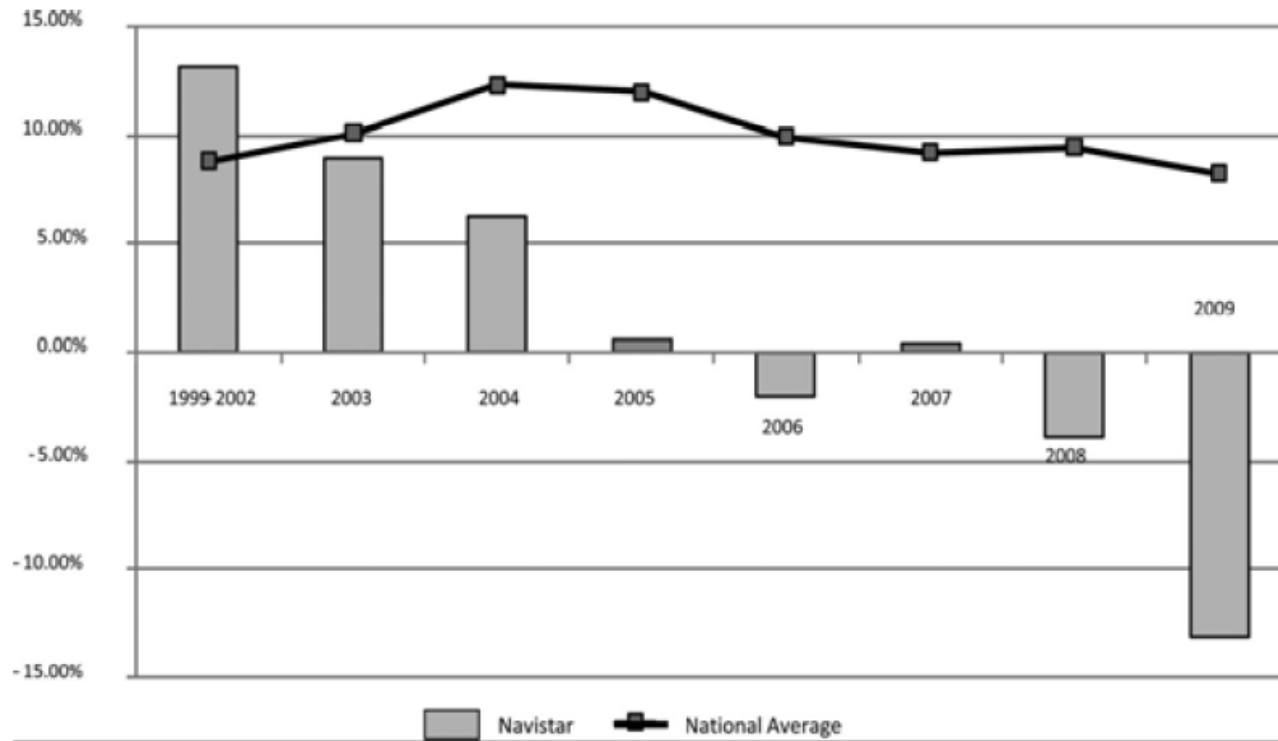
Overview of Evidence-Based Benefit Design	Dr. Stave
How to Align Evidence Based Benefit Design with Employer Bottom Line and A Case Study	Dr. Bunn
Applying Evidence-Based Benefits Design to Management of Biologic Medicines	Dr. Naim
Q &A	



Stratification Criteria for Monitoring Health and Productivity Components in Covered Populations



Hospital Cost Trend per Employee/Retiree





FAST TRACK ARTICLES

Evidence-Based Benefit Design: Toward a Sustainable Health Care Future for Employers

Bunn, William B. III MD, JD, MPH; Stave, Gregg M. MD, JD, MPH; Allen, Harris PhD; Naim, Ahmad B. MD

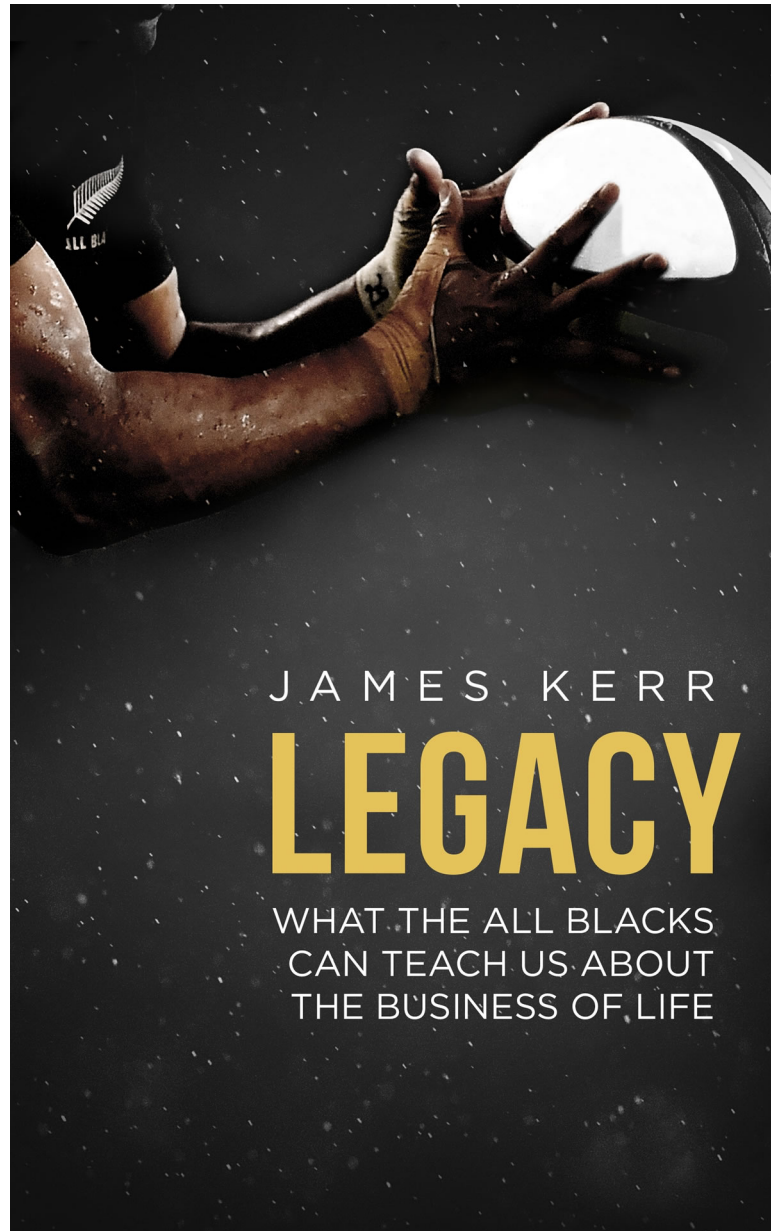
Author Information 

Journal of Occupational and Environmental Medicine: October 2010 - Volume 52 - Issue 10 - p 951-955

doi: 10.1097/JOM.0b013e3181f72acb

Abstract

Health care costs for employers are rising much faster than inflation. The common approach to health benefit design of increasing cost sharing has failed to contain costs. Some employers, however, have been successful at mitigating the cost trend or actually reducing health care costs. These **employers have in common a dedication to data analysis, a search for cost drivers, and a willingness to adjust their approach to health benefit design to address these cost drivers.** This approach has much in common with the movement in clinical practice toward evidence-based medicine. **We propose that employers adopt a similar approach toward health benefits termed evidence-based benefit design, which is based on a health and productivity framework** focused on direct and indirect costs. Evidence-based benefit design incorporates the relevant literature and employer-specific data that are integrated and regularly analyzed.



heart of how great leaders are - **and we are all leaders** - 'reboot' and reframe their future

**Champions do extra.
They sweep the sheds.
They follow the spearhead.
They keep a blue head.**

My Approach to My Profession, Career, and Life in General

- "optimal experience"
- genuinely satisfying
- state of consciousness
- achieve deep enjoyment, creativity, and a total involvement with life



<https://www.nytimes.com/2017/01/13/jobs/in-choosing-a-job-focus-on-the-fun.html?contentCollection=smarter-living& r=0>

Wabeeja Medawagse Mersi unalchéesh Tingki Komapsumnida Shukuria Paldies Hatir hui Sanco Maake Denkauja gozaimashita Fakaau Spasibo Ekhmet Mehribani Nemachalhya Maiteka ekoju Tevtapuch Maiteka Siksomo Baika Yuspagaratam Minmonchar Atto Gaejtho Yaqhanyelay Efcharisto Gui Dankscheen

YOU Merci Tashakkur Maketai bolzin Spassibo Baika Yuspagaratam Minmonchar Atto Gaejtho Merastawhy Juspaxar

Thank Shukria lah Dhanyabaad Chaltu

Gracias nuluh Biyan Grazie Snachallhuya



Thank you for attending

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JCPH Virtual Open House

May 24
5:30-7:30 pm EDT

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May 19, 2021 | 12:00 -1:00 pm ET

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Women in Health Data Science

June 2, 2021 | 12:00 -1:00 pm ET

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