

Introduction to Health Economics and Outcomes Research (HEOR) for Writers

Beth Lesher, PharmD, BCPS
Catherine O'Connor, BA

blesher@pharmerit.com

coconnor@pharmerit.com

Pharmerit International
4350 East West Highway, Suite 1110
Bethesda, MD 20814
United States of America

www.pharmerit.com

+1 240 821 1265

2017 AMWA Medical Writing & Communication Conference
Orlando, FL
November 2, 2017

Beth Leshner



Associate Director, Strategic Market Access
Pharmerit International
PharmD
BCPS
blesher@pharmerit.com

Catherine O'Connor



Senior Communications Analyst,
Strategic Market Access
Pharmerit International
BA
coconnor@pharmerit.com

About Pharmerit International



Our mission is to improve patient access to medical care through evidence, worldwide.



Modeling and
Meta-Analysis



Real World
Evidence



Strategic Market
Access



Patient Reported
Outcomes

- What is HEOR?
 - Definitions of health economics (HE) and outcomes research (OR)
 - Where does HEOR evidence come from?
 - When in the development process is it created?
 - Why do we need HEOR evidence?
- Who uses HEOR evidence?
 - How is it used?
- How can I break into HEOR writing/editing?
 - What roles can medical writers/editors play in HEOR?
 - Tips for freelance writer
 - Tips for writers with nontechnical backgrounds

Definitions of Health Economics & Outcomes Research (HEOR)

Health Economics

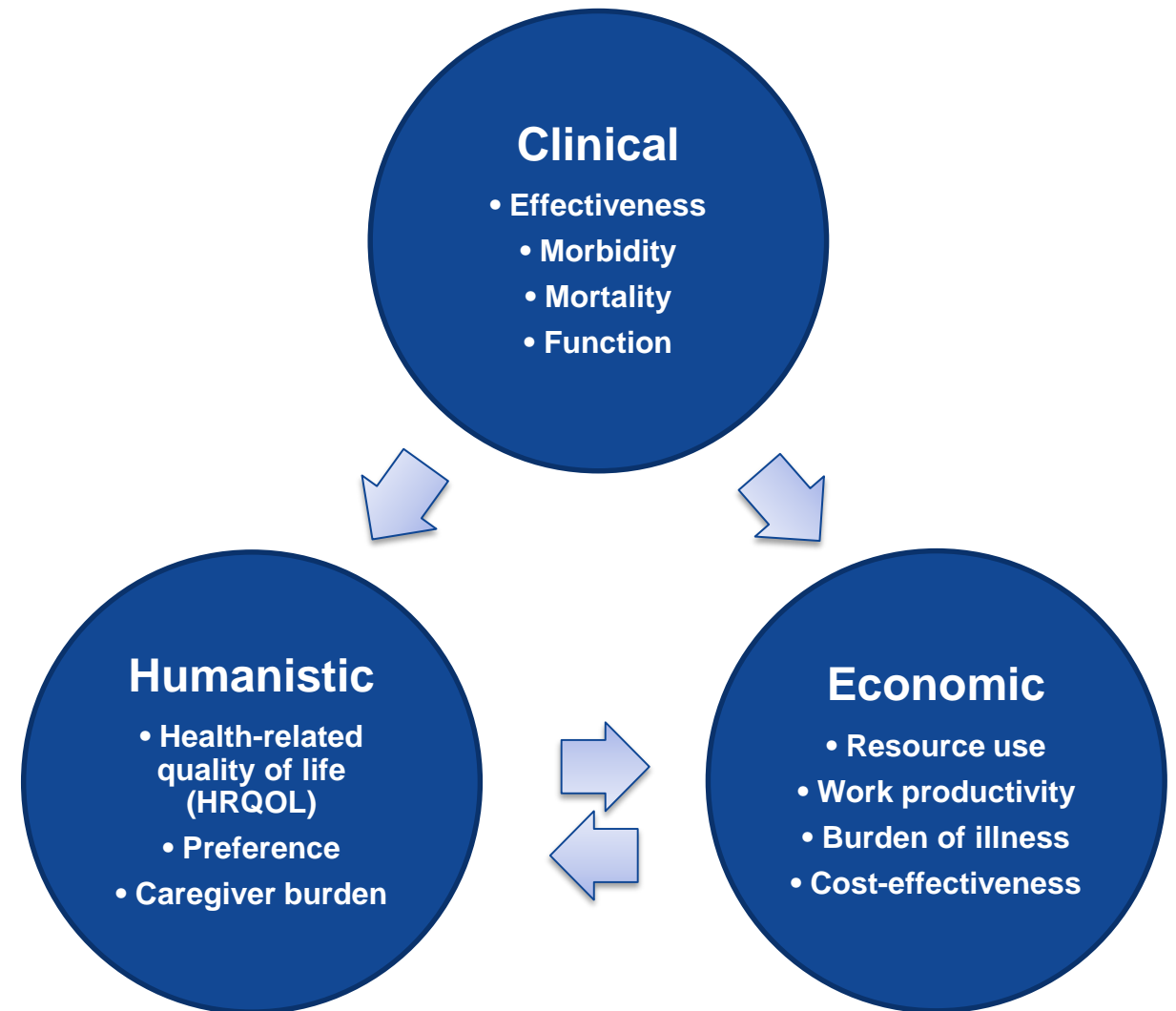
- Analyzes the economic aspects of health and healthcare, with a focus on the costs (inputs) and consequences (outcomes) of healthcare interventions.

Outcomes Research

- Evaluates the effect of healthcare interventions on patient-related clinical, humanistic, and economic outcomes.

What Types of Outcomes?

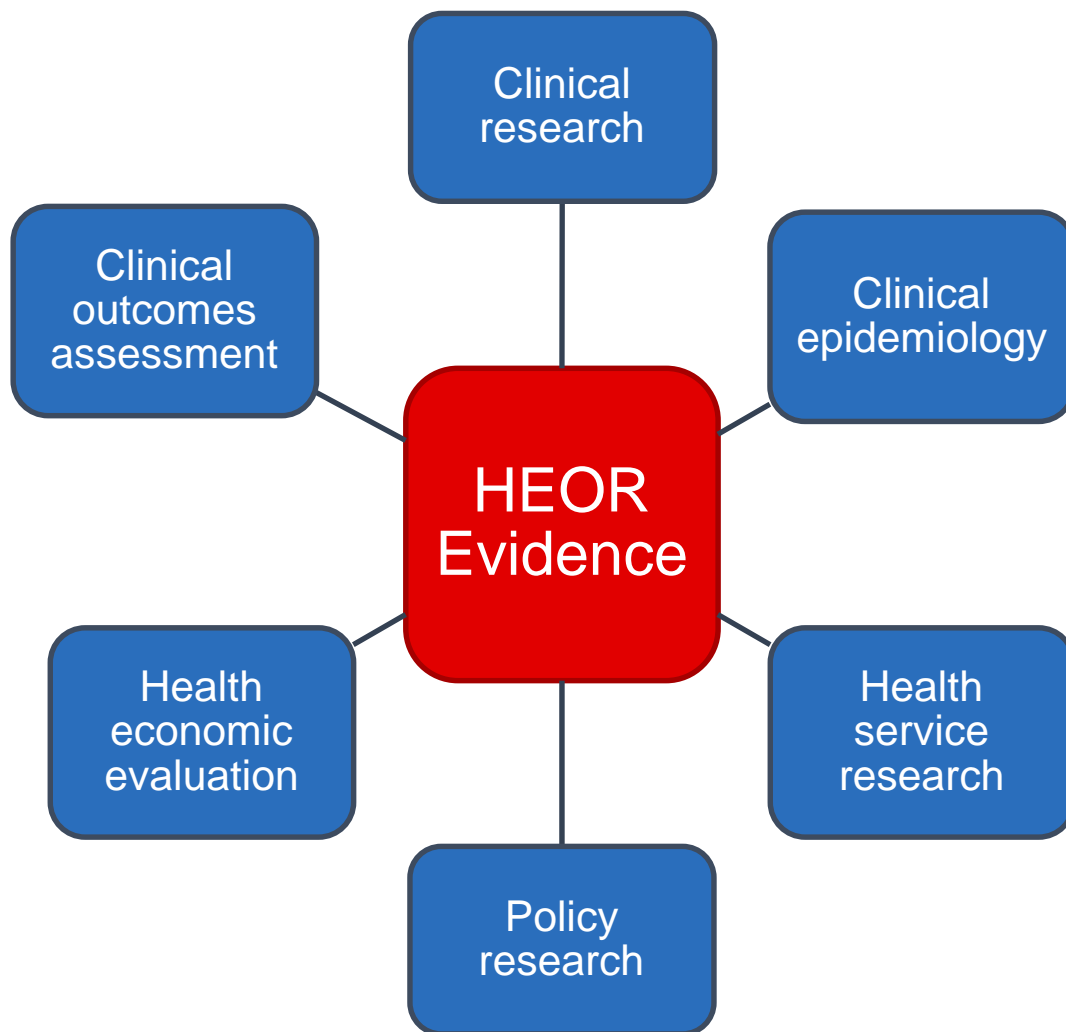
- **Clinical Outcomes:** Result from the disease or from treatment
- **Economic Outcomes:** Direct and indirect costs derived from the clinical outcomes
- **Humanistic Outcomes:** Also derived from clinical outcomes



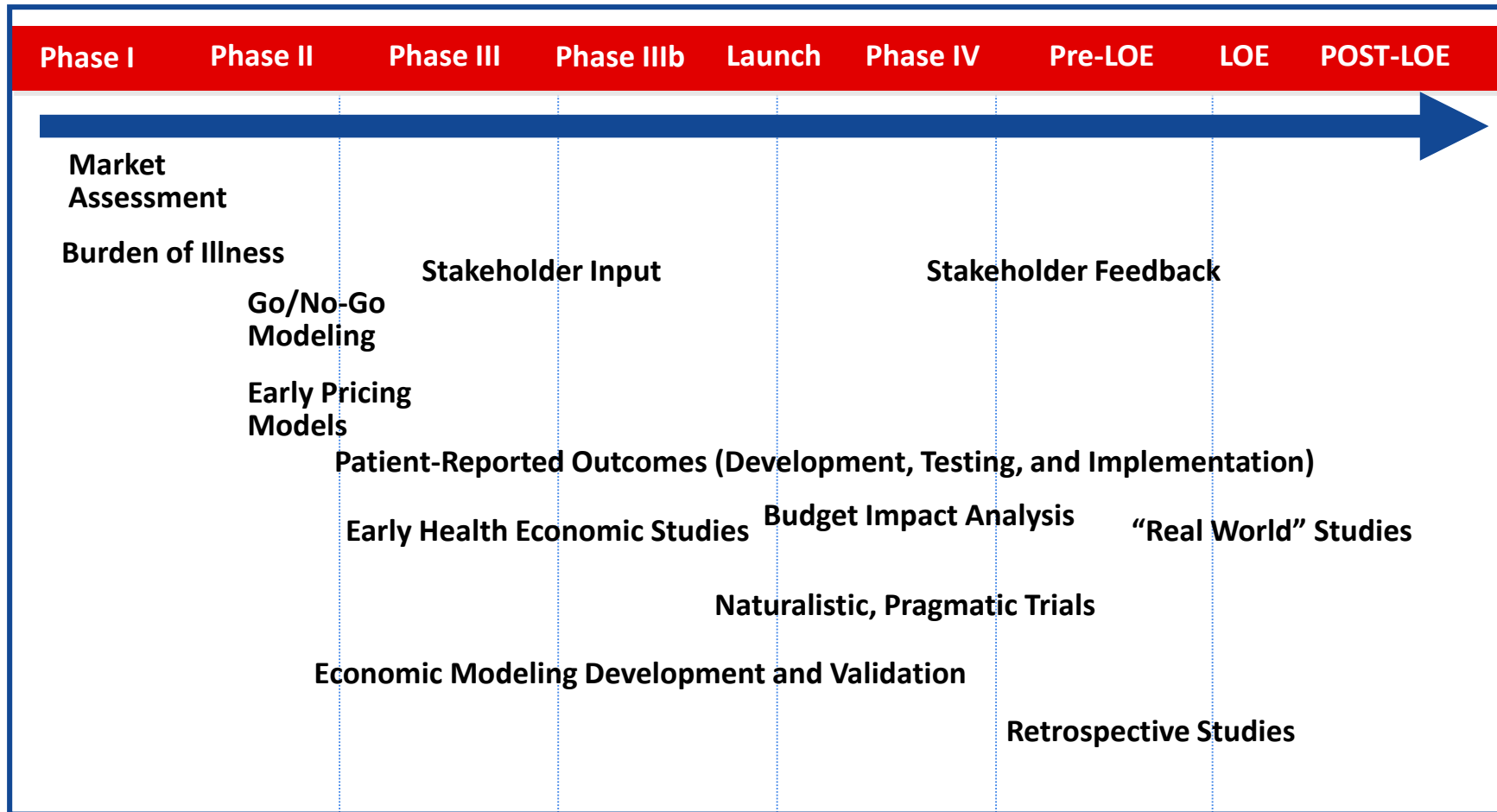
Where Does HEOR Evidence Come From?

- Real-world evidence (RWE)
- Clinical outcomes assessments (COA)
- Patient-reported outcomes (PRO)
 - Symptoms, health status, health-related quality of life (HRQOL), patient preferences, utilities, satisfaction, productivity
- Systematic reviews
- Meta-analyses
- Clinical studies
 - Prospective randomized controlled trials (RCTs)
 - Pragmatic clinical trials
- Post-marketing/phase IV/open-label studies
- Observational studies
 - Retrospective (e.g., chart review studies, claims database analyses)
 - Prospective (e.g., registries, surveys)

Multiple Disciplines Contribute to HEOR



HEOR Evidence Generation Occurs Throughout the Product Life Cycle



Why Do You Need HEOR Evidence?

- Identify unmet needs
- Address evidence gaps
- Supplement RCTs with real-world data
 - Primary RCT endpoints (e.g., laboratory test results) may not be the most relevant clinical outcomes for physicians/healthcare decision makers (HCDMs)
 - RCTs may not include humanistic/economic outcomes
 - RCTs may not generate country-specific data, HRQOL data
- Promote patient-centered research and provide evidence about what actually happens to patients
- Helps develop and evaluate cost containment strategies
- Respond to changes in market environments (new products, cost pressures)
- Adapt to different regions/affiliates, HCDMs, populations, local treatment patterns (vs global RCTs with narrow populations and strict inclusion/exclusion criteria)
- Comply with additional requirements for economic information in HTA vs regulatory body submissions (not just efficacy, safety)

Who Uses HEOR Evidence?

Health Technology
Assessments
(HTAs)

Healthcare
Decision Makers
(HCDMs)

Physicians

Patients

How Is HEOR Evidence Used?

Addresses outcomes and provides evidence on what happens to a patient

Evaluates product's cost, budget impact, and cost-effectiveness

Produces meaningful evidence to inform selection of appropriate cost-effective therapy

Helps illustrate product's value

Informs clinical guidelines development

Guides formulary coverage and reimbursement

HEOR in Decision Making

	Can It Work? (Efficacy)	Does It Work? (Effectiveness)	Is It Worth It? (Value)
Evidence Generation	RCT	Pragmatic clinical trial Observational studies	Economic evaluation Budget impact
Evidence Synthesis	Systematic review of trials (SRT) Clinical guidelines	Systematic review of evidence (SRE) Clinical guidelines	Budget impact Coverage reimbursement decision
Decision Making	Product approval	Product approval Physician/patient decision	Coverage reimbursement decision Price

The Choice of HEOR Tool Depends on Customer Evidence Needs and Feasibility

Increasing Complexity



Epidemiology Study

- Provides accurate, up-to-date, and region-specific estimates of the incidence, prevalence, morbidity, mortality, and natural history of target conditions

Cost-of-illness Analysis

- Determines the economic impact of an illness or condition

Cost-benefit Analysis (CBA)

- Compares costs and benefits, both of which are quantified in common monetary units

Budget Impact Model (BIM)

- Quantifies additional costs and cost offsets associated with adopting new products

Cost-effectiveness Analysis (CEA)

- Compares costs in monetary units with outcomes in quantitative non-monetary units, e.g., reduced mortality or morbidity
 - **Cost-minimization analysis** – Determination of the least costly among alternative interventions that are assumed to produce equivalent outcomes
 - **Cost-utility analysis (CUA)** – Comparison of costs in monetary units with outcomes in terms of their utility, usually to the patient, measured in QALYs
 - **Cost-consequence analysis** – Presentation of costs and outcomes in discrete categories, without aggregating or weighing them

Summary: Value of HEOR

Addresses business needs

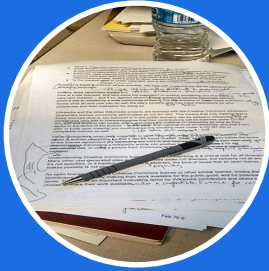
- Demonstrate the product's added value

Addresses physicians and HCDMs' needs

- Evidence on “real world” patients
- Outcomes that address evidence gaps (economic and humanistic)
- Broader patient populations with fewer inclusion and exclusion criteria
 - Comorbidities
 - Disease severity
 - Older patients

Addresses patients' needs

- Evidence on patients who look like them
- More “meaningful” outcomes
 - Clinical events not laboratory results
 - Quality-of-life information
- Patient-centered outcomes research



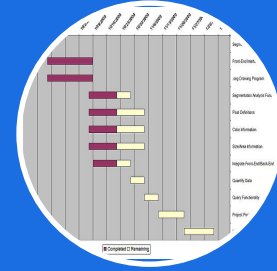
WRITING

- Dossiers
 - GVD, AMCP, CVD, EUnetHTA
- Publications
 - Economic models, DBA, SLR, NMA
- Value messaging
- Objection handlers



EDITING

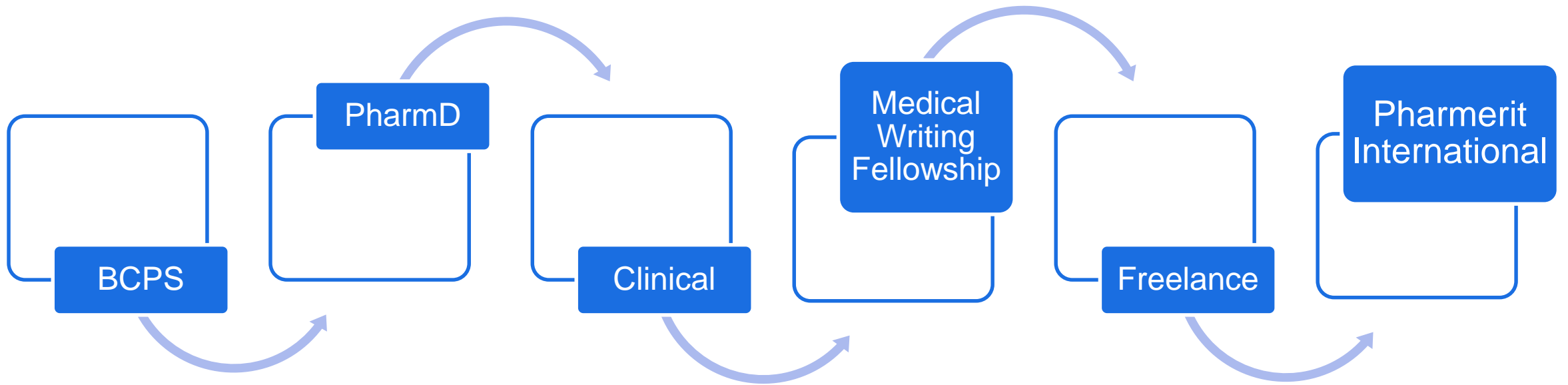
- Dossiers
- Publications
- Slide decks
- Reports



PROJECT MANAGEMENT

- Dossiers
- Publications
- Reports

Beth's Path



Tips for Freelance Writers

Leverage Skill Set

- Manuscript writing
- Editing
- Scientific background
- Slide decks
- Reports

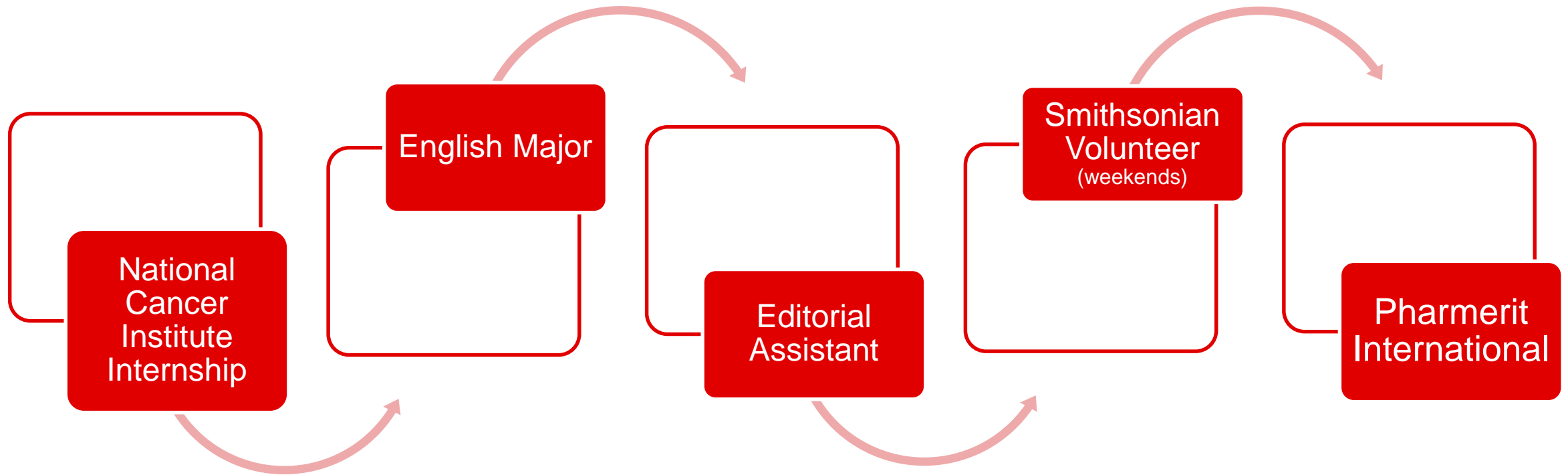
Know Your Audience

- Journal selection,
- HCDMs
- Global
- National

Know Your Resources

- ISPOR website
- AMCP Format for Formulary Submissions
- HealthEconomics.com

Catherine's Path



Tips for Writers with Nontechnical Backgrounds

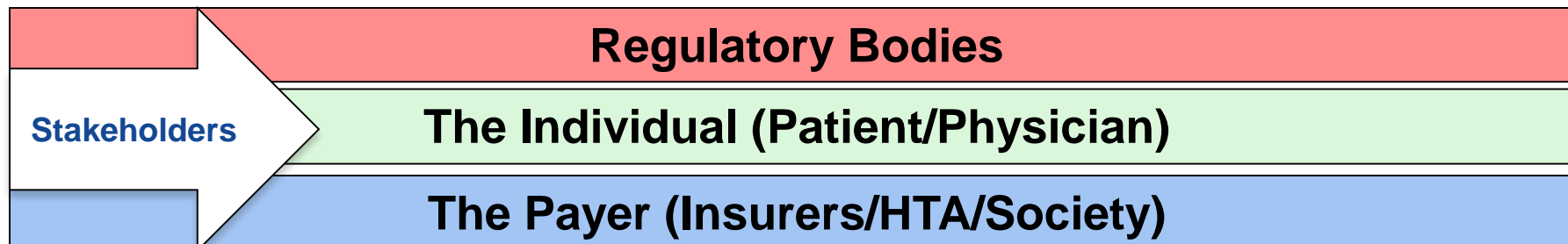
- Statistics!
- Promote your Microsoft Word knowledge
- Don't take your liberal arts skills for granted
 - Audience analysis
 - Big-picture thinking
 - Writing mechanics
 - Idea organization
- Use insight into non-expert audiences
- Attend AMWA workshops
- Focus on your “highest and best use” (i.e., maximally productive skills/tasks)

Where Can I Get More Information?

- Associations (e.g., [ISPOR](#), [ISOQOL](#), [AMCP](#))
- Dossiers: [AMCP Format for Formulary Submissions, version 4](#)
- National Information Center on Health Services Research and Health Care Technology ([NICHSR](#))
 - Self-study courses with glossaries
 - [HTA 101](#)
 - [Health Economics Information Resources](#)
 - [Finding and Using Health Statistics](#)
 - Core library recommendations (e.g., [Health outcomes](#), [Methodology](#))
- AMWA events
 - Intermediate HEOR session at 2:00 PM today
- [CHEERS guidelines](#)
- Websites
 - [HealthEconomics.com](#)
 - [Health Affairs blog](#)

Integrated Overview of HEOR

HEOR DATA SOURCE	DATA TYPE	DATA USE
<p>Clinical Studies</p> <ul style="list-style-type: none"> • Prospective RCT, PCT • Observational • Registry <p>Retrospective</p> <ul style="list-style-type: none"> • Observational • Database <p>Cross-sectional surveys</p> <ul style="list-style-type: none"> • Patients, caregivers • Physician experts 	<p>Humanistic (PRO)</p> <ul style="list-style-type: none"> • Symptoms • Health Status • HRQOL • Preference/Utilities • Satisfaction • Productivity <p>Adherence/persistence</p> <p>Treatment patterns</p> <p>Resource use / economic</p> <p>Epidemiology</p>	<p>Internal Decisions</p> <p>Label Claims</p> <ul style="list-style-type: none"> • Indication • Clinical study section <p>Value Messages</p> <ul style="list-style-type: none"> • Dossier • Promotion <p>Publications</p> <p>Economic Models and Analyses</p>



- Berger ML, Binglefors K, Hedblom EC, et al. *Health Care Cost, Quality, and Outcomes: ISPOR Book of Terms*. Lawrenceville, NJ: ISPOR, 2003.
- Kozma CM, Reeder CE, Schulz RM. Economic, clinical, and humanistic outcomes: a planning model for pharmacoeconomic research. *Clin Ther*. 1993;15(6):1121-1132.
- Luce BR, Drummond M, Jönsson B, et al. EBM, HTA, and CER: clearing the confusion. *Milbank Q*. 2010;88(2):256-276.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2980346/>.
- Goodman CS. *HTA 101: Introduction to Health Technology Assessment*. Bethesda, MD: National Library of Medicine. 2014.
<https://www.nlm.nih.gov/nichsr/hta101/ta10101.html>



Thank you!