

# **IVI Annual Meeting**

September 19, 2023

# Welcome and Overview



**Jason Spangler, MD, MPH, FACPM**

*IVI Chief Executive Officer*



**Michael Thompson**

*IVI Chair, Board of Directors*

# Welcome New Board Members

## *Class of 2024*



**Scott Brunner**  
*Kansas Department of  
Aging and Disability  
Services*



**Susan A. Cantrell, RPh,  
MHL, CAE**  
*Academy of Managed Care  
Pharmacy*



**Lisa Bo Feng, DrPH**  
*Alexion AstraZeneca Rare  
Disease*



**Kistein Monkhouse,  
M.P.A**  
*Patient Orator Inc.*

**2023 IVI Annual Meeting**

**Fireside Chat with Dr. Rhonda  
Robinson Beale**

# Fireside Chat with Rhonda Robinson Beale, MD



**Jason Spangler, MD, MPH, FACPM**

*Innovation and Value Initiative*



**Rhonda Robinson Beale, MD**

*UnitedHealth Group*



**2023 IVI Annual Meeting**

**MDD Value Model Symposium**

# MDD Value Model Symposium



**Richard Xie, PhD**

*Innovation and Value  
Initiative*

**MODERATOR**



**Bruny Kenou**

*George Washington School  
of Medicine and Health  
Sciences*



**Michael Mersky**

*OPEN Health*



**Warren Stevens, PhD**

*Medicus*

# A Path Forward: Improving Value Assessment for Major Depressive Disorder (MDD)



## IVI Open-Source Value Model

- > **IVI prototype model development is a laboratory:** opportunity to improve both the process and mechanics of considering value
- > **Focus on MDD based on:**
  - > Prevalence,
  - > Economic burden,
  - > Impact on overall health,
  - > Evolving treatment options,
  - > Opportunity to consider pharmacologic and non-pharmacologic sequences

## Model Development is a Team Effort



20+ member advisory group contributes to parameters and research components of the model



Insight on patient preference research (input) and decision contexts (outputs)



Allies for public comment periods and use cases (applied research questions)



# Model Design Snapshot (Health Economic Module)

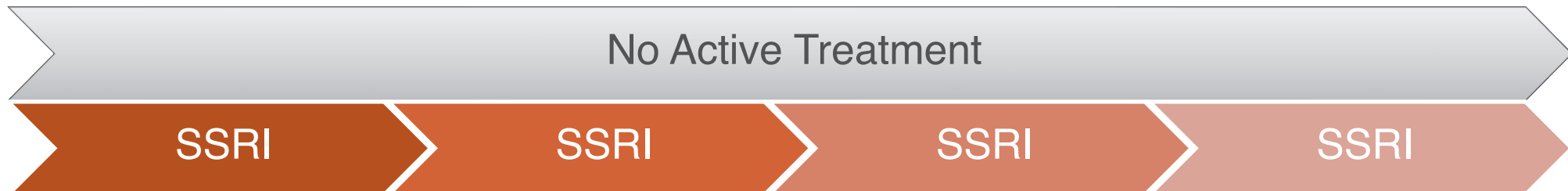
Dimension	Specification
Target Population	Treatment-naïve adults (18-64 years), diagnosed with MDD by a healthcare provider
Setting and Location	All settings of care (primary, specialty, and telehealth) in the United States
Study Perspective	Societal as base case, flexibility to customize based on specific stakeholder (e.g., employers)
Model Structure	Continuous-time, individual-level simulation
Comparators	Both treatment sequences and treatments, pharmaceutical and non-pharmaceutical options (up to 4 lines)
Time Horizon	Lifetime horizon, flexibility for users to study interim time points (e.g., 1 year)
Outputs	Flexibility to present a range of different economic and clinical outputs
Key Considerations	Including productivity, adherence, treatment gaps, delay in starting active treatments for MDD

# Potential Applications of the MDD Model

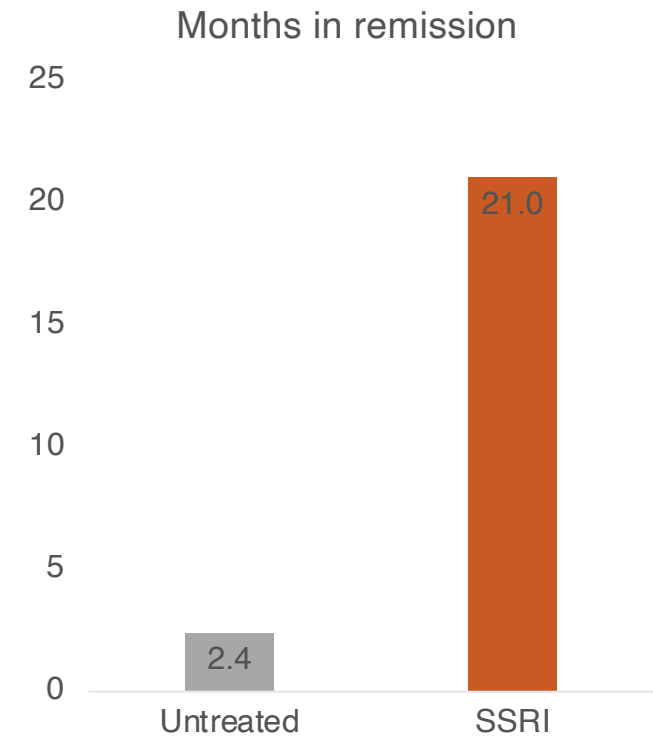
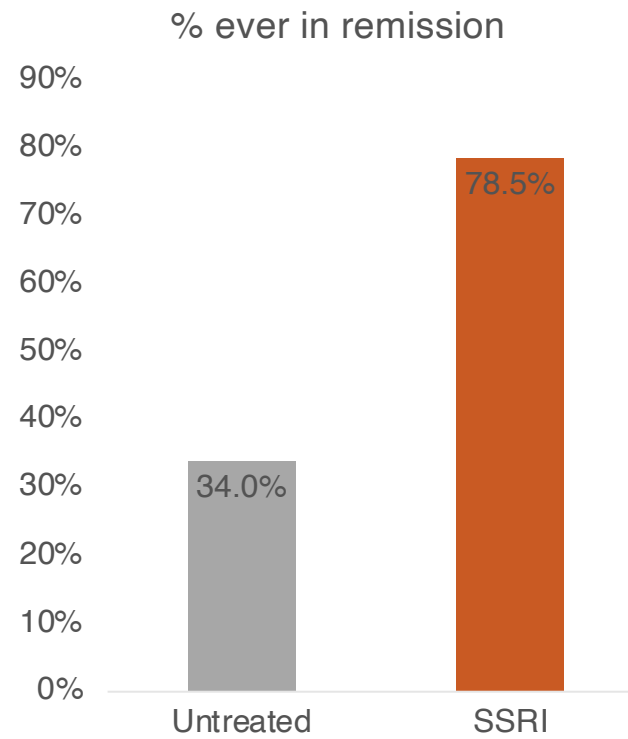
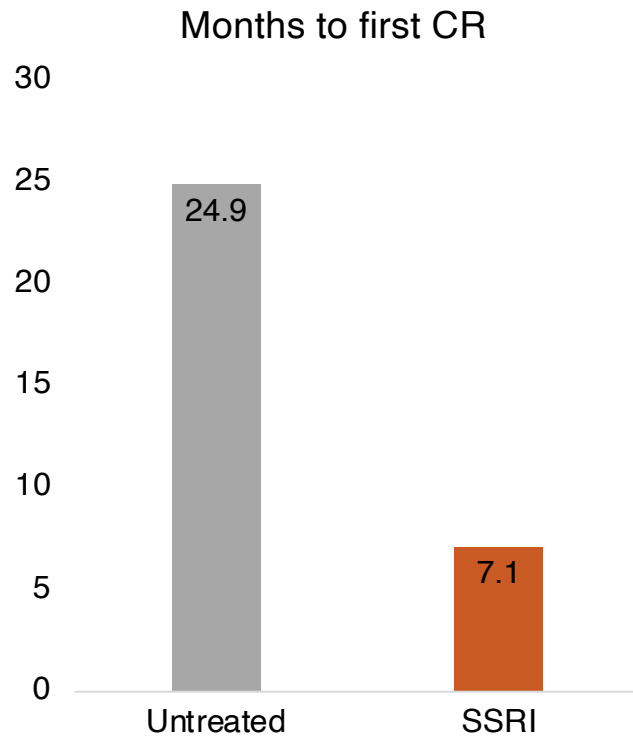
Themes	Sample Decision Questions
Optimizing Real-world Treatment Pathways	What are the long-term economic and clinical impacts if patients delay the start of active treatments following their diagnosis of MDD by a healthcare provider?
Productivity	How does the provision of digital health programs improve the well-being and productivity of employees?
Patient Preferences	What are the long-term impacts if patients are prescribed treatments that are more compatible with their preference profiles?
Medicaid Module	Could improvement in MDD care help Medicaid beneficiaries transition out of the Medicaid system?
Caregiver Burden	How would key model insights change if we also consider the quality-of-life impacts on caregivers and family?

# Demo Use Case – Value of Early Active Treatment

- > Approximately 39% of adults with MDD are not receiving active treatment following their diagnosis by a provider (*National Institute of Mental Health*)
- > What is the value of active treatment following diagnosis?
- > Approach using IVI-MDD Model:
  - > Specify two treatment pathways
  - > Run the simulation, and examine a set of clinical and economic outcomes

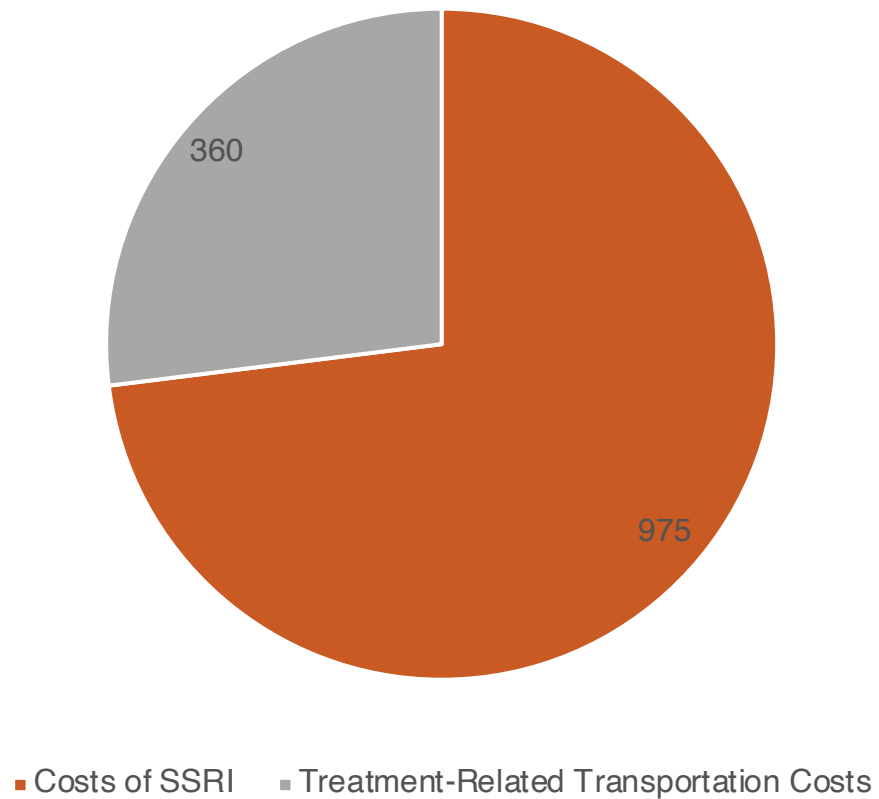


# Clinical Outcomes

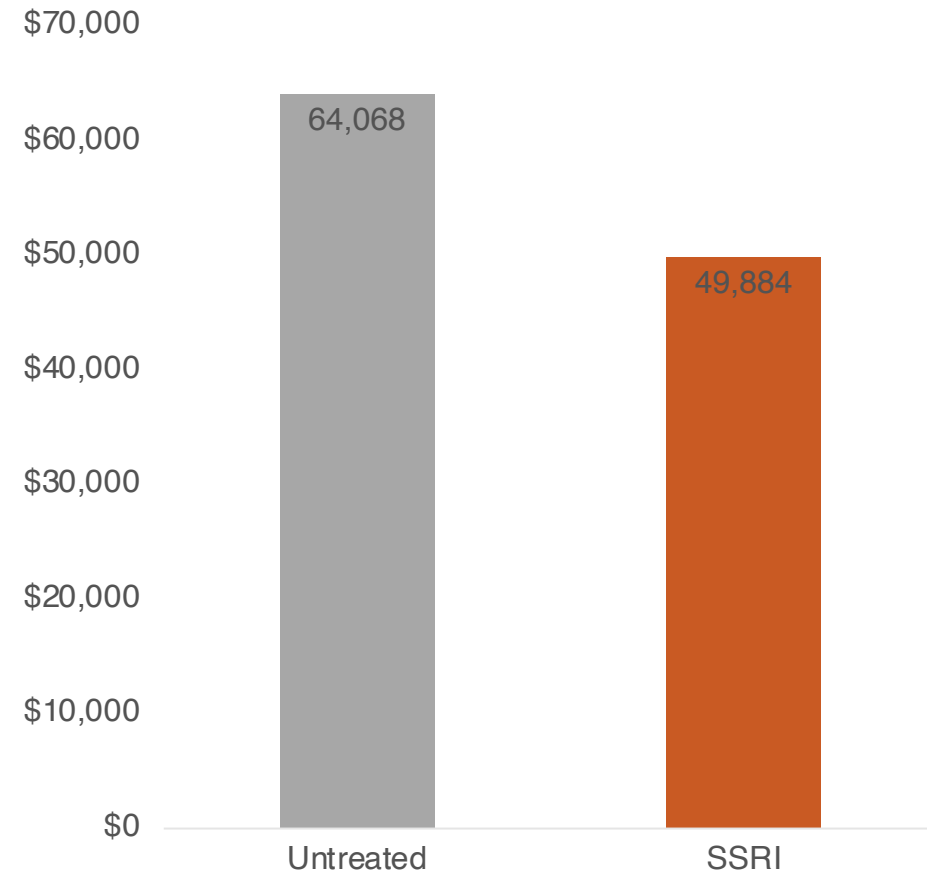


# Treatment & Total Healthcare Costs

Total Costs of Treatment

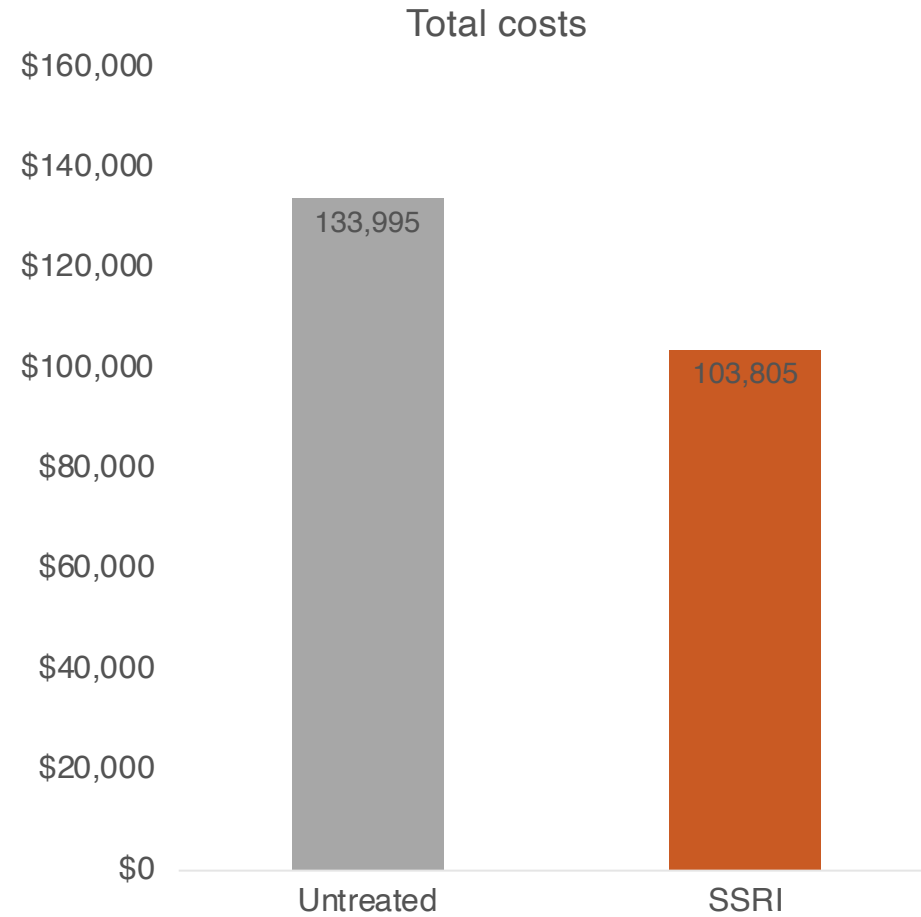
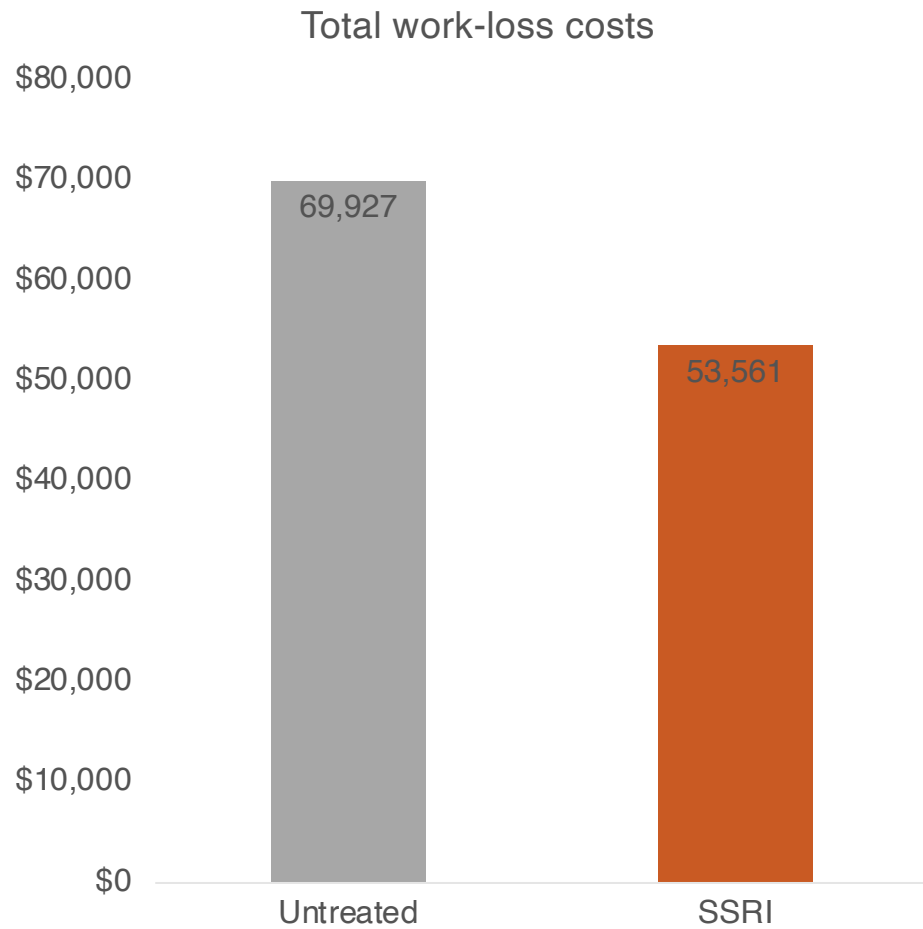


Total Healthcare Costs Incurred





# Productivity Impacts & Total Costs



# Clinical Cost-Effectiveness



# Public Comment Period

- > Details to be announced in early October
- > R Code, UI, and supporting documentation (e.g., Technical Report)
- > Areas for feedback:
  - > Model design (structure, assumptions, key input)
  - > UI design
  - > Data gaps
  - > Potential applications

## *What were some of the key challenges?*

- > MDD has traditionally been modeled with HSTM – a highly structured form of model that tends to oversimplify complex processes.
  - > We have used a CT-IPS model for IVI, as it overcomes some of these simplifications
- > The biggest problem with any model is data.
  - > An over-reliance on RCT data
  - > Especially data from patients who are off-treatment

## *What makes MDD a difficult area to model?*

- > Heterogeneity and complexity – a disease that can have a multitude of causes, a wide array of severity levels, and is common as a co-morbidity to many adjacent conditions.
- > It's a good example of a disease where 'averages' are not a particularly useful source of information for decision-makers.
- > Some of the biggest problems are in getting data on patients who are not on/in treatment.
  - > Most MDD models don't have treatment gaps factored in



## ***Next Steps – Key Gaps to Address***

- > Enhancing our ability to reflect patient heterogeneity.
- > It would also be helpful to sub-classify MDD patients
  - > Treatments that rely less on daily-dosing, monthly prescriptions or weekly may in practice be much better effective choices over the long term.
- > Move away from an over-reliance on RCT data
  - > the relationship between delivery/provision and effectiveness are pretty much ignored in standard CEA but they are significant drivers of actual real-world effectiveness.

**2023 IVI Annual Meeting**

**Change Leadership for Equity in  
HTA and Economic Impacts**

# Change Leadership for Equity in HTA and Economic Impacts



**Elridge Proctor, MPA**  
*GO2 for Lung Cancer*  
**MODERATOR**



**Nicole Boschi, PhD**  
*National Multiple  
Sclerosis Society*



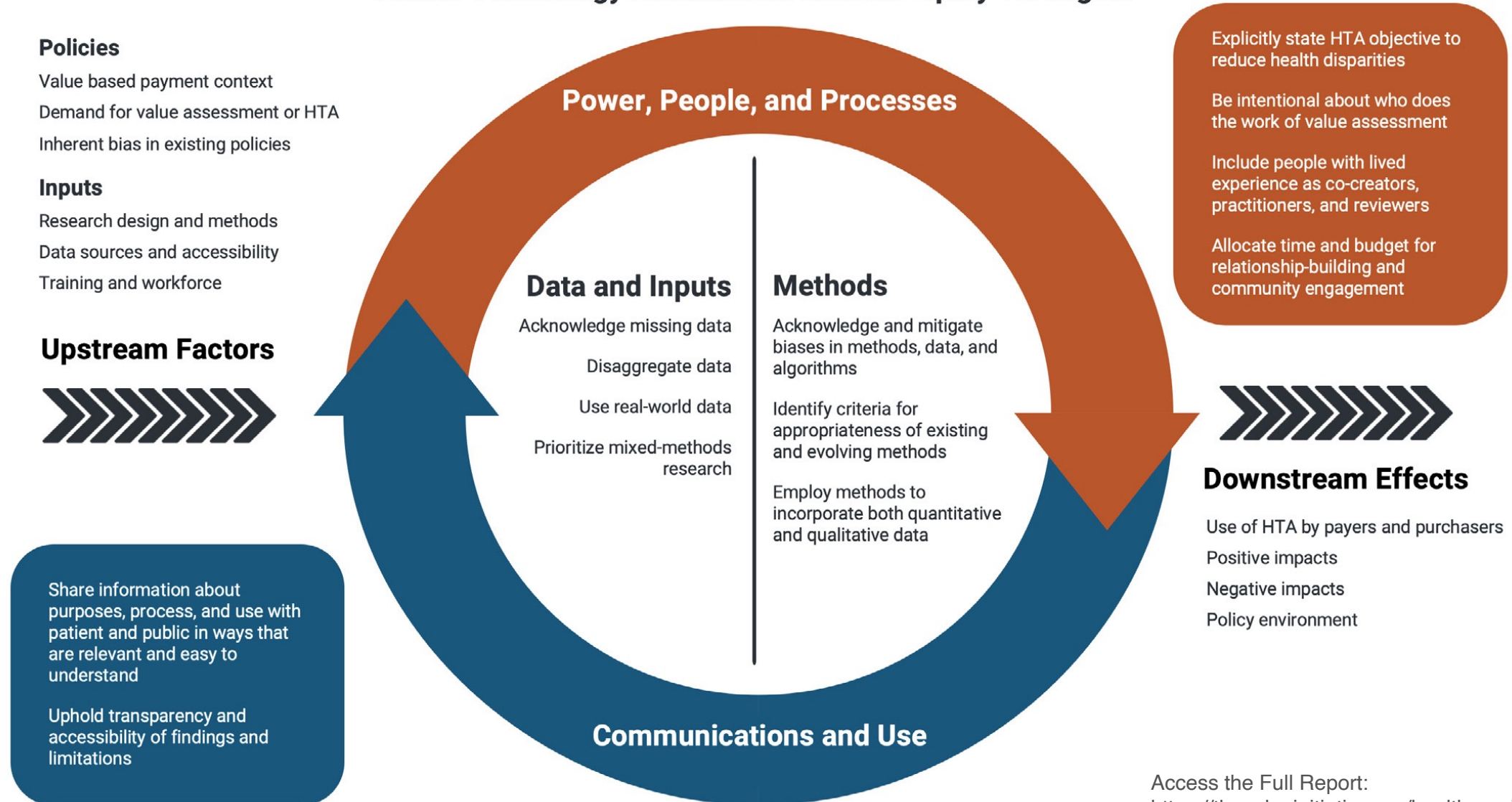
**Kate Davidson, LCSW**  
*CMS/CMMI*



**Olivia G. Dieni, MPH**  
*Cystic Fibrosis Foundation*

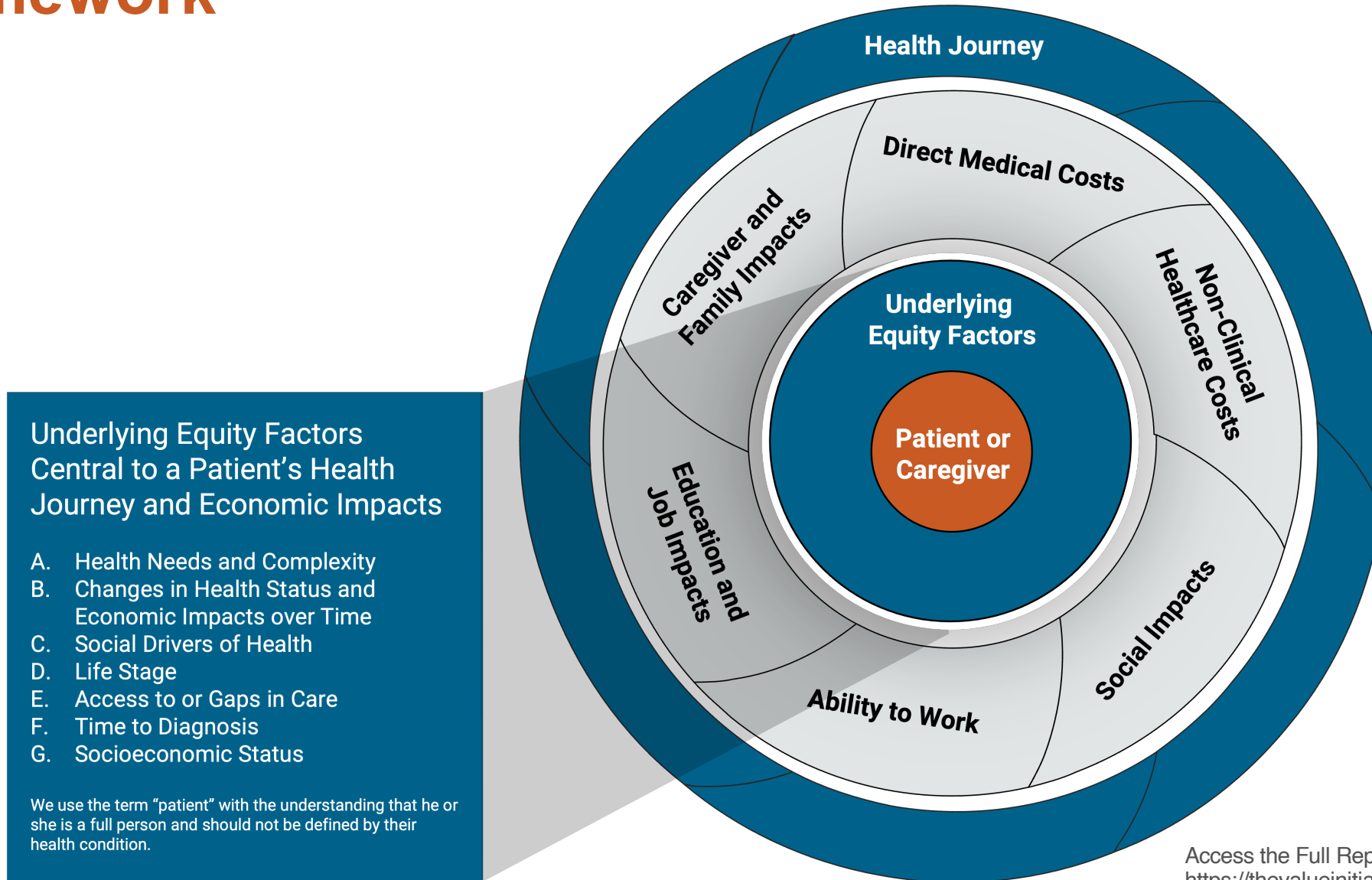
# Health Equity in HTA Framework

## Health Technology Assessment Centers Equity Through...



Access the Full Report:  
<https://thevalueinitiative.org/health-equity-initiative/>

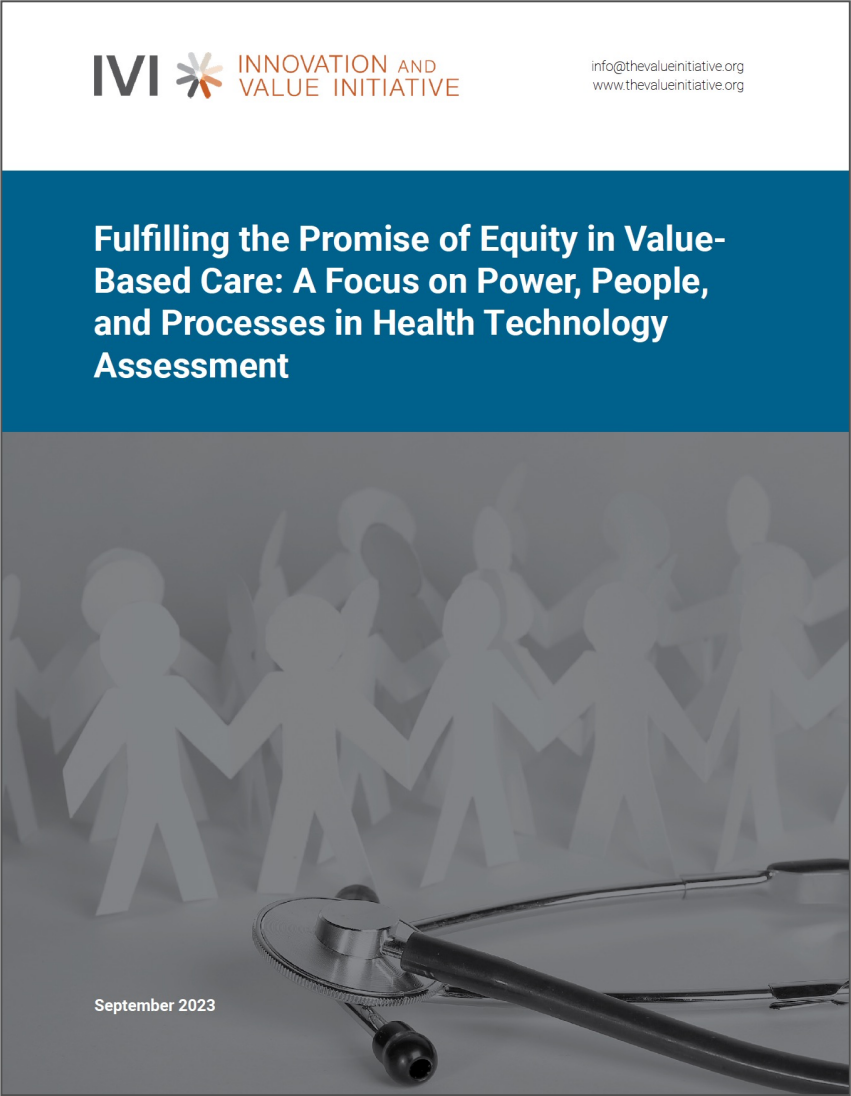
# Economic Impacts on Patients and Caregivers Framework



Access the Full Report:  
<https://thevalueinitiative.org/economic-impacts-project/>









# New Health Equity Report Available!



## Action Guides

Readers can find all of the action steps from this report, organized by stakeholder role, within the brief, 2-page action guides linked below. These guides are meant to provide ideas on where to begin taking action to foster change in the practice of HTA. Each stakeholder guide includes links to best-in-class resources and tools to help readers create impact. These action guides will continue to grow and evolve over time as new actions and resources are identified by partners. Click below to download the guide that aligns with your role or explore the [full set of action guides](#).

**To fulfill the promise of value-based care, integrate equity throughout HTA by taking the actions highlighted in these guides.**

 Researchers	 Patients and Caregivers	 Professional Association Leaders
 Journal Editors	 Research Sponsors	 Payers and Purchasers

Access the Full Report:  
<https://thevalueinitiative.org/health-equity-initiative/>

**2023 IVI Annual Meeting**

**Value and HTA in an Evolving Policy  
Landscape**

# Value and HTA in an Evolving Policy Landscape



**Mark Linthicum, MPP**  
*Innovation and Value  
Initiative*

**MODERATOR**



**Daniel Heider**  
*Centers for Medicare and  
Medicaid Services*



**Barry Liden, JD**  
*University of Southern  
California*



**Karen Mancera-Cuevas,**  
**DrPH, MPH, MS**  
*National Health Council*

**2023 IVI Annual Meeting**

**Keynote Conversation with  
Dr. Carolyn Clancy**



# Keynote Conversation with Dr. Carolyn M. Clancy



**Jason Spangler, MD, MPH, FACPM**  
*Innovation and Value Initiative*



**Carolyn M. Clancy, M.D., MACP**  
*U.S. Department of Veterans Affairs*



**2023 IVI Annual Meeting**

**Rare Disease in HTA: Update  
and Looking Forward**

# Rare Disease in HTA: Update and Looking Forward



**Rick Chapman, PhD**  
*Innovation and Value Initiative*  
**MODERATOR**



**Karin Hoelzer, DVM, PhD**  
*NORD*



**Annie Kennedy**  
*EveryLife Foundation for  
Rare Diseases*



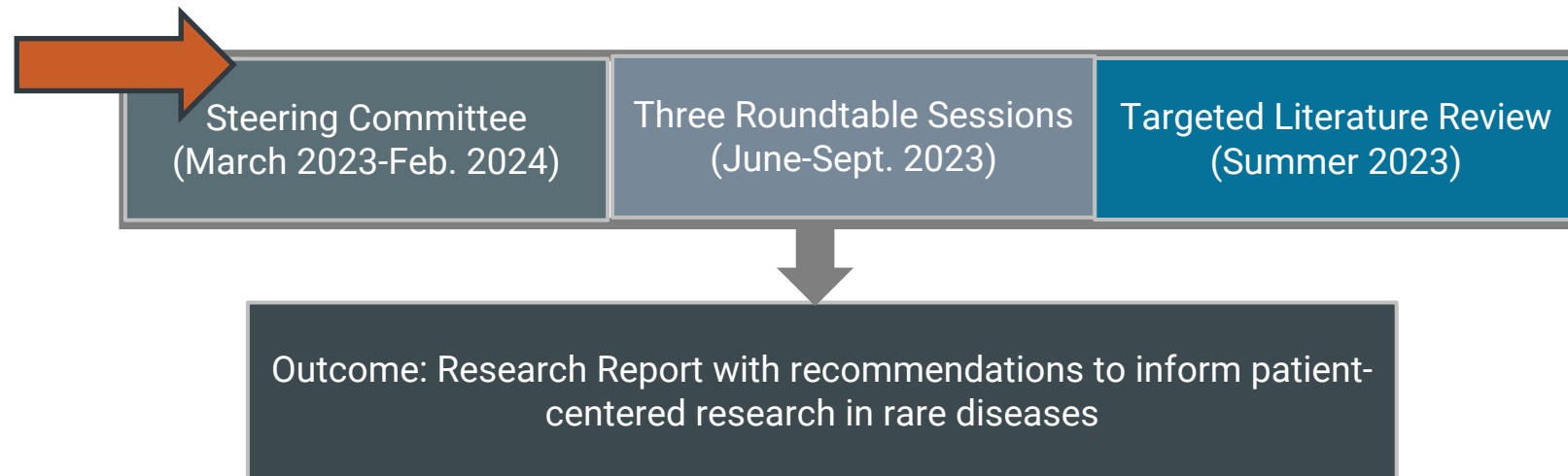
**Tamar Thompson**  
*Alexion*

# Engaging Patients with Rare Disease in Identifying Meaningful Approaches to Comparative Effectiveness Research and Value Assessment

**Project Co-Lead:** EveryLife Foundation for Rare Diseases

**Project Aim:** Advance understanding of patient-centered outcomes in rare disease, by convening experts from across patient and family, research, and healthcare communities to identify new approaches in outcomes and comparative effectiveness research for rare disease. Project seeks to:

- > Explore gaps and challenges in rare disease outcomes data and research
- > Explore range of cross-cutting outcomes important to patients and caregivers
- > Identify priority steps to address evidence challenges and approaches to patient engagement



Funded in part by PCORI Eugene Washington Engagement Award (EASCS-26726) and Alexion

# Key Activities and Timeline



**March 2023**

Convened multi-stakeholder Steering Committee



**Summer 2023**

Conducted targeted literature review



**Jun-Sep 2023**

Hold 3 roundtable meetings to explore key challenges and approaches to methods



**Oct 2023 - Feb 2024**

Produce final report with recommendations to inform patient-centered research in rare diseases

# Targeted Literature Review Results

Row Labels - IN Category	Broad rare disease	Specific RD(s)	Total	% of IN Count
HTA - framework (e.g., conceptual resources, frameworks, key definitions, principles, guidance and recommendation)	37	5	42	18.4%
HTA - method for economic evaluation (e.g., MCDA, CEA, cost of illness)	23	18	41	18.0%
HTA - reimbursement and pricing	31	6	37	16.2%
HTA - method for CER/ PCOR (e.g., PRO, patient-centered outcome)	15	18	33	14.5%
HTA - tools (e.g., evaluation criteria, checklist)	16	2	18	7.9%
Policy	13	4	17	7.5%
HTA - data	6	5	11	4.8%
HTA - patient engagement process specifically	6	4	10	4.4%
Budget impact	4	2	6	2.6%
Diagnosis issue	2	3	5	2.2%
HTA - engagement process	2	2	4	1.8%
Other	3	1	4	1.8%
OUT	0	0	51	22.4%
Total	158	70	279	

- > More articles on health technology assessment (HTA) frameworks and methods
- > Patient engagement process is not often the focus

# Common Outcomes Across >5/10 Rare Diseases

- > Physical Functioning
  - > Motor
  - > Respiratory
  - > Speech
- > Fatigue
- > Social Relationships
- > Pain
- > Cognitive Issues (Memory/Thinking/Concentration)
- > Mental Health (Depression/Anxiety)
- > Employment/Work
- > Sleep

# Recommendations Categorized into Domains Below

- > Patient Journey/Time
- > Patient Engagement
- > Data
- > Methods
- > Economic Impacts
- > Scientific Spillovers
- > Identifying Common Patient-Centered Outcomes

# Key Recommendations Example

Domain	Recommendations
Patient Journey/Time	<ul style="list-style-type: none"><li>• Researchers should include time to diagnosis, age at diagnosis, disease severity, delays in treatment, time spent on treatment, and time spent as a caregiver as items which need to be explored and addressed as part of the patient journey.</li><li>• Researchers developing clinical trials and other studies should collaborate with patients, patient advocacy groups and rare disease organizations to include outcomes that are meaningful across the patient journey for individuals with rare diseases and high unmet need, including economic impacts, severity of disease, value of hope, and real option value throughout the patient journey.</li></ul>



**2023 IVI Annual Meeting**

**Quality and Value In Healthcare**

# Quality and Value In Healthcare



**Jason Spangler, MD,  
MPH, FACPM**

*Innovation and Value Initiative*

**MODERATOR**



**Richard Schmitz, MA**  
*Pharmacy Quality Alliance*



**Norris Turner, PharmD, PhD**  
*Turner Healthcare Quality  
Consulting*



**Gretchen Wartman**  
*National Minority Quality  
Forum*

**2023 IVI Annual Meeting**

**Valuing Innovation Project  
'Call for Papers'**

# VIP 'Call for Papers' with Award Winners



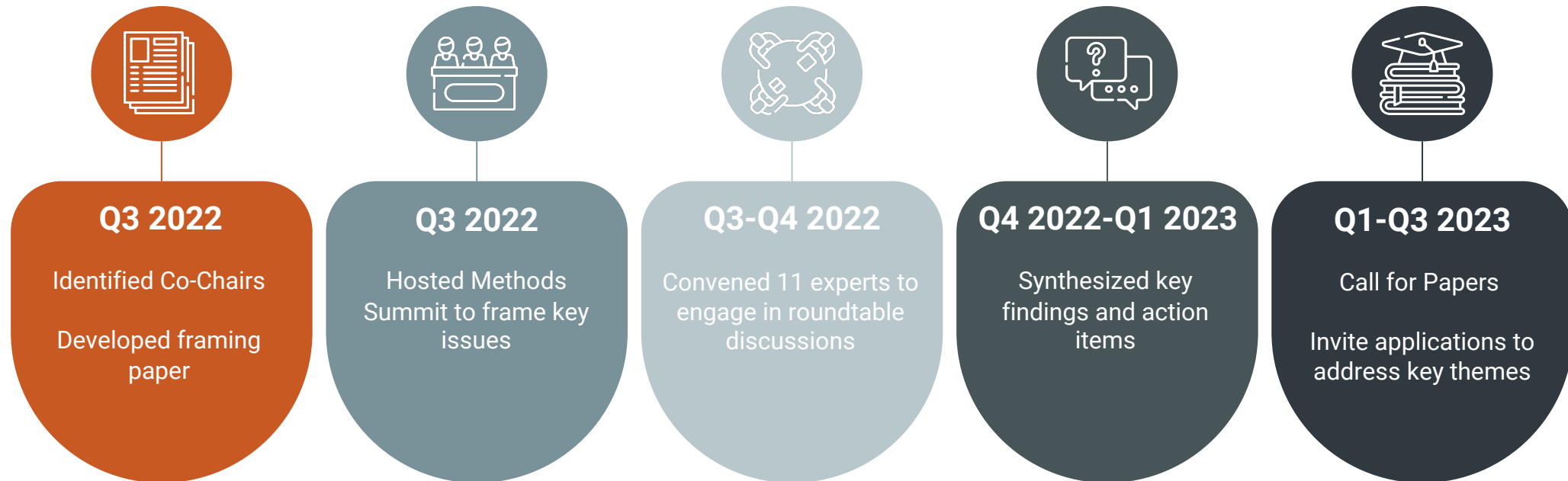
**Rick Chapman, PhD**  
*Innovation and Value Initiative*  
**MODERATOR**



**Anna Hyde, MA**  
*Arthritis Foundation*

# Valuing Innovation Project – Overview

**AIM:** Convene stakeholders to advance HTA methods and practices to better define, measure, and reward innovation

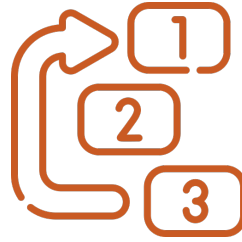


The 2022 IVI Methods Summit was funded by contributions from IVI's diverse membership and grant support from PhRMA.

# Objectives



Define innovation in the context of health technology assessment (HTA) and the need for exploration of process and methods improvements



Identify and prioritize areas for methods exploration and applied research needed to improve how HTA accounts for innovation



Identify additional research for IVI investment to accelerate change and shared learning on these improvements

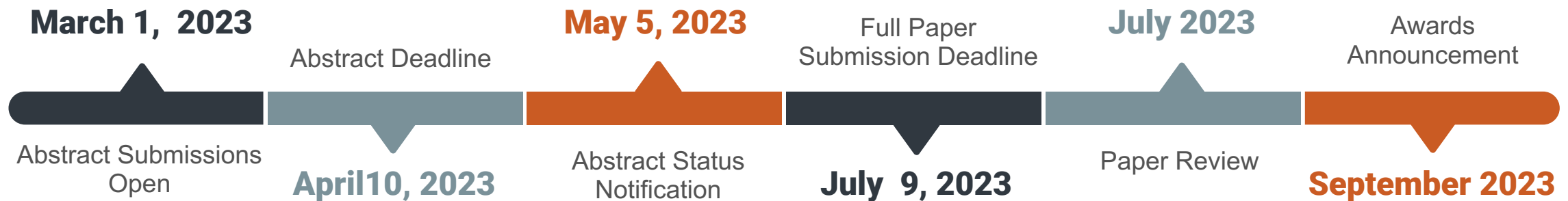
# Roundtable Identified Key Areas to Prioritize

- > Multi-stakeholder roundtable discussion aimed to identify prioritized gap areas to address to better measure and reward innovation in health technology assessment
- > Roundtable identified:
  - > Prioritized areas with data and method gaps
  - > Concrete steps that different stakeholders can take to address such gaps
- > Key themes summarized by the project team were disseminated via white paper, conference submissions
- > Prioritized areas informed IVI's Call for Papers in 2023



# Valuing Innovation Project – Call for Papers

- > 9 abstracts received and invited to full-paper submissions from academic and for-profit organizations on the following topics:
  - > How do we better define, measure, and reward **scientific spillovers** in HTA?
  - > How do we better define, measure, and reward **real options value** in HTA?
  - > How can HTA better account for **impacts of innovation on broader society** beyond the healthcare sector?





# Valuing Innovation Project Call for Papers Judging Panel



**Rick Chapman, PhD**  
*Innovation and Value Initiative*



**Mike Graglia, MBA, MA**  
*SynGAP Research Fund*



**Anna Hyde, MA**  
*Arthritis Foundation*



**Walter Kowtoniuk, PhD**  
*Third Rock Ventures*



**Josh Krieger, PhD**  
*Harvard Business School*



**Erica de Fur Malik, MA**  
*Innovation and Value Initiative*



**Richard Xie, PhD**  
*Innovation and Value Initiative*

# Valuing Innovation Project Call for Papers Awardees



## **“Incorporating real option value in valuing innovation: A way forward”**

- Meng Li, PhD, ScM (University of Texas MD Anderson Cancer Center) and Louis P. Garrison, PhD (CHOICE Institute, University of Washington School of Pharmacy)



## **“The value of flexible vaccine manufacturing capacity: Value drivers, estimation methods, and approaches to value recognition in health technology assessment”**

- Fred McElwee (Office of Health Economics, United Kingdom) and Anthony T. Newall (UNSW School of Population Health, Australia)



## **“Estimating and rewarding the value of healthcare interventions beyond the healthcare sector: A conceptual framework”**

- Askal Ayalew Ali (Florida A&M University), Amit Kulkarni, Sandipan Bhattacharjee, and Vakaramoko Diaby (Otsuka Pharmaceutical Development Corporation)

# Thank You



Post Event Survey

