

# Putting Patients at the Center of Value Assessment

IVI ANNUAL REPORT

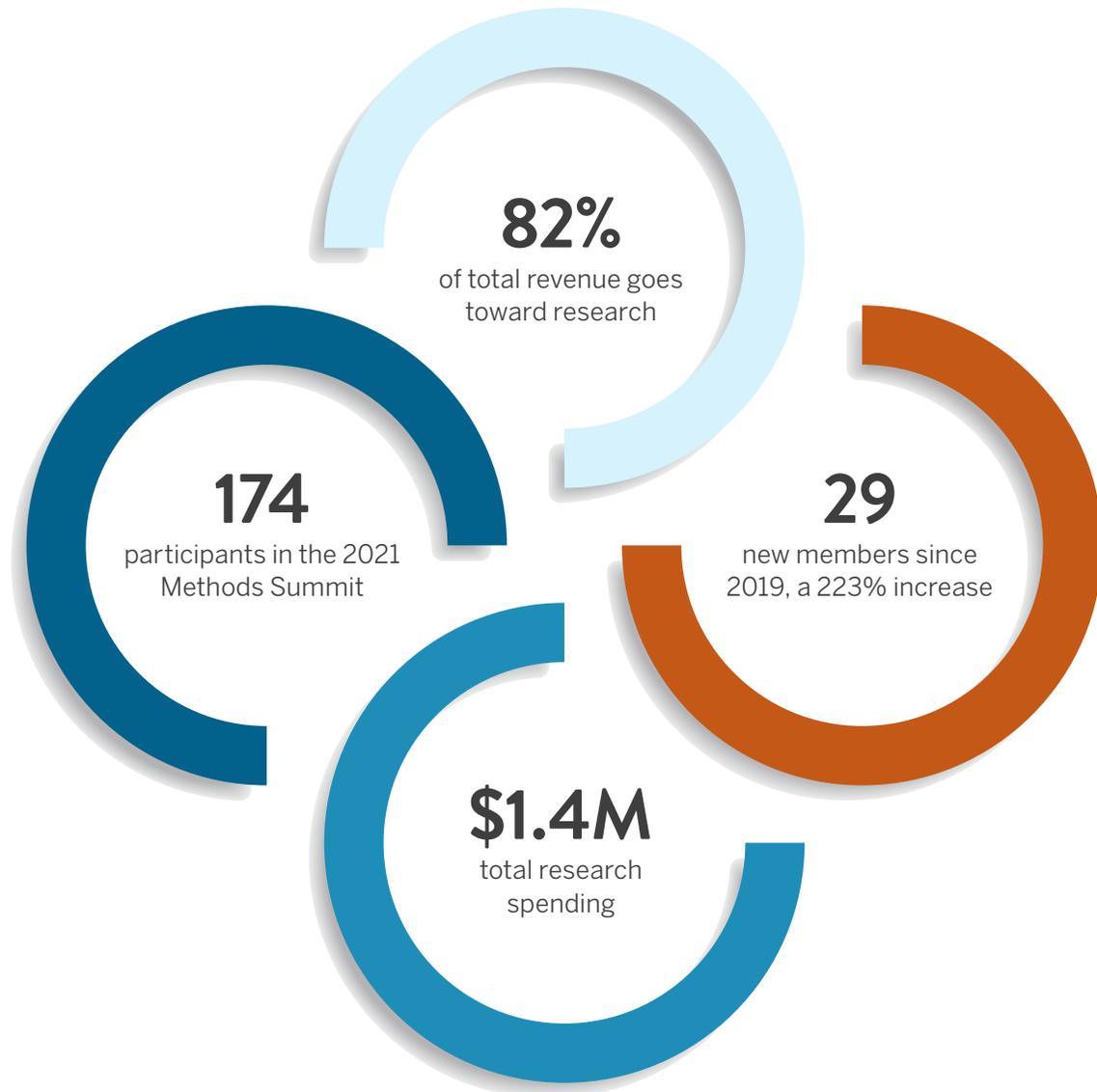
2021

Grounded in the principles of  
**patient-centricity, transparency,  
and open-source modeling**, IVI  
is a leader in the value assessment  
and health care community.

# CONTENTS

Message from the CEO & Board Chair	5
Authentic Patient-Centricity	7
Advancing Methods and Practice of Value Assessments	8
Bringing Stakeholders Together	10
Dissemination	14
Financials	17
2021 Board of Directors	18
2021 Members	20
2021 Leadership Team	21
In Memoriam: Samuel Nussbaum, MD	22

## 2021 AT A GLANCE





# MESSAGE FROM THE CEO & BOARD CHAIR

**As we entered year two of the COVID-19 pandemic,** a health care crisis unlike anything we have experienced in decades, IVI leaned into the challenge to provide insight and solutions of how value should and can be assessed in health care – helping patients, payers, employers, and decision-makers move forward.

IVI and our partners are implementing meaningful changes to the science and practice of value assessment. We are focused on: a shared commitment to patient needs, experiences, and perspectives; clarity on changes needed to reframe health care decisions around patient-centered value; and an environment that incentivizes, rather than discourages, investment in infrastructure that supports a rapid learning cycle.

We could not be more proud of the research community at IVI and the accomplishments they achieved. In fiscal year 2021, 82% of all revenue went toward research. We continue to expand the diversity of membership to include more perspectives, and were pleased that patient organizations now represent over 36% of membership.

In addition, IVI's efforts netted critical funding through a Patient-Centered Outcomes Research Institute (PCORI) Eugene Washington PCORI Engagement Award (# EAIN-21156) to convene our 2nd Annual Methods Summit.

To keep members, patient groups, researchers, and other stakeholders informed about the ever-changing landscape around value assessment, IVI published

numerous commentaries, blogs, and an 11-part Health Affairs Forefront series that communicated the challenges and innovative solutions facing value assessment in today's real-world environment.

In 2022, targeted efforts will include a comprehensive expansion of equitable representation throughout IVI initiatives, putting policy into real-world practice, and ensuring patients have a seat at the health care decision table.

For all that has changed in health care and in our world during this pandemic, IVI remains more committed than ever to elevating the patient voice, advancing equity, and embracing our mission to promote value assessment for the betterment of all people.



**Jennifer Bright, MPA**  
Chief Executive Officer



**Greg Daniel, PhD**  
Board of Directors, President

**IVI remains more committed than ever** to elevating the patient voice, advancing equity, and embracing our mission to promote value assessment for the betterment of all people.

“If we’re genuinely going to have a patient-centered health system, and if we’re genuinely going to get to value, **it’s my fervent belief that we have got to start listening to the patient communities that have expertise and experience in these disease categories** and ask them what the top five commonalities are. I know that that sounds very pat and simple, but it is an enormous amount of work.”

—JENNIFER BRIGHT, HEALTHHATS PODCAST,  
SEPTEMBER 5, 2021.

# Authentic Patient-Centricity

**IVI collaborates with patients, employers, payers, and providers** to assess what equitable value means to them and serve as a learning laboratory for testing new methods to improve value assessment.

## PATIENT-DRIVEN PRIORITIES FOR MANAGEMENT OF MDD

Based on direct input from people living with major depressive disorder (MDD), we developed a discrete choice experiment survey with researchers from the PAVE Center at University of Maryland-Baltimore. This survey will allow us to quantitatively assess how patients make trade-offs when evaluating pharmaceutical and non-pharmaceutical treatment options for MDD.

To ensure that we capture the heterogeneity in patient preference, we referenced the epidemiology studies in MDD and the US census and set specific recruitment targets for subgroups that were traditionally underrepresented in health-related research. While time-consuming, achieving a representative sample is crucial to addressing equity considerations in health-care research and value assessments.

Aligned with our mission to cultivate modernized methods, we are testing ways to incorporate patient preferences data into economic evaluations.

## PATIENT-ENGAGED HEALTHCARE VALUATION

In collaboration with researchers from the RAND Corporation, we are testing a different approach to “crowd-source” patient input for use in Health Technology Assessment (HTA) using goal-attainment scaling.

In 2021, we developed a survey instrument to collect patient goals based on literature reviews and feedback from a multi-stakeholder committee. The pilot test yielded response from 50 respondents and established the feasibility of using this instrument as an effective means to collecting individualized patient goals.



## FIRST-HAND PERSPECTIVES IN RHEUMATOID ARTHRITIS (RA)

In a paper co-authored with the Arthritis Foundation and four people living with arthritis, we explored how we can ask questions that matter to people with lived experience in healthcare research.

In a commentary published by one of the co-authors, we noted three takeaways.

### Research should:

- Include patient perspectives throughout the entire process.
- Capture the impacts of RA on co-occurring health conditions, such as mental health.
- Focus on defining and measuring cost impacts related to chronic diseases, including transportation, work-related costs (lost wages, career impact, disability), caregiver financial impacts, and non-health related costs.

# Advancing Methods and Practice of Value Assessments

**Anchored by the Open-Source Value Project**, improving the science of transparent value assessment is key to IVI's mission.

## MAJOR DEPRESSIVE DISORDER (MDD) MODEL

In 2021, we hit the first major milestone of the MDD model development process. Together with our research partner, OPEN Health, we finalized the model scope document based on the insights from the continual stakeholder engagement with our 20-member multi-stakeholder advisory group, and the feedback from the public comment period.

Toward the end of 2021, we finished our draft model protocol and launched our public comment period for the protocol. This is an important step in our stakeholder-engagement approach to economic model development, where we are seeking feedback from all stakeholder groups affected by value assessments on key model assumptions, input sources, and potential applications of the

MDD model. This will help us ensure that the model can help facilitate customizable decision-making for different stakeholders. It is also an example of how we are advancing transparency in developing methods to inform HTA and fostering value discussions across different stakeholders.

## Multi-Criteria Decision Analysis

As a laboratory for testing novel methods, the IVI-MDD models also feature a multi-criteria decision analysis (MCDA) module. MCDA provides an alternative to other commonly used methods to inform HTA (e.g., economic models) and will allow us to consider a wider range of criteria (e.g., qualitative inputs from patients). In 2021, we officially launched an expert working group to guide us through the development of the module.



---

### HEALTHCORE TREATMENT PATTERNS STUDY

**To ensure that the MDD model can generate insights** consistent with real-world clinical practice, IVI launched a retrospective claims database study with researchers from HealthCore/Anthem. This study seeks to examine the treatment patterns, and treatment outcomes in the two years following the initial diagnosis of MDD. We recently finalized the study protocol and have started to create an analytic sample. Results of this study will provide useful insights on the key model assumptions and inputs for the MDD model.

---

### METHODS PAPER: SCIENTIFIC SPILLOVER

**IVI developed a methods paper** (in the International Journal of Technology Assessments in Health Care) with leading HTA experts Prof. Lou Garrison and Prof. Adrian Towse to explore the channels and magnitude of scientific spillover in the R&D process, and its implications for HTA.

The project finds that:

- (1) both successful and failed R&D efforts generated important learnings for concurrent and subsequent innovation efforts, but little is known about their magnitudes.
- (2) knowledge from failed R&D efforts is not being consistently shared with the community, and a set of policy instruments were proposed to incentivize more information sharing to improve the efficiency of the R&D system.

“For me, the side effects of not having enough treatment, or not having my experience taken seriously, are far worse than the side effects of the treatment. **People, even if they don’t look like they have a disability, want to be seen.**”

—RAQUEL MASCO, PATIENT,  
CO-AUTHOR, FIRST HAND  
PERSPECTIVES IN RHEUMATOID  
ARTHRITIS



# Bringing Stakeholders Together

As a leader in improving the methods for patient-centered value assessment, IVI convenes forums for broad input and collaboration.

## 2021 METHODS SUMMIT

Patient perspectives – including patient preferences, patient-reported outcomes, and impacts – are not adequately incorporated in patient-centered research or value assessment.

### What data on patient-centered outcomes and methods for analysis are needed to incorporate patient perspectives in a value-driven healthcare system?

This question was the focus of IVI's 2021 Methods Summit, held virtually over three days, convening more than 170 stakeholders to drive consensus on priority patient inputs, methods, and research. The event was partially supported by a PCORI Eugene Washington Engagement Award. Key priorities and principles that emerged from the summit include:

#### DOMAIN 1

Elevate Visibility and Policy Support for Patient-Centered Impacts as an Essential Element in Assessing Value and Facilitating Access

**Prioritize and define** patient-centered impacts and research questions as early as possible in comparative effectiveness research and value assessment.

**Share data and synthesis of such data** collected as part of comparative effectiveness research or value assessment back with patients in a timely and actionable manner.

**Comprehensively include and fairly compensate** patient leadership, perspectives, and expertise (scientific, data collection, lived experience) in research and value assessment projects.

**Establish standards and accountability** that increase transparency for how patient inputs are considered and incorporated in decision-making.

“The COVID pandemic brought home the critical role health care plays in our daily lives. That role is determined by an endless stream of decisions affecting how finite health care resources get allocated: how much is spent, on what, and for whom. Every one of these decisions involves an assessment of value, whether explicitly or implicitly.”

—DONNA CRYER, “THE FUTURE OF VALUE ASSESSMENT IN A POST-PANDEMIC UNITED STATES,”  
*HEALTH AFFAIRS FOREFRONT*

2021 Methods Summit  
Attendees

174

Patient Organizations  
Represented

25

## DOMAIN 2

Incorporate Patient Impacts and Perspectives in Regulatory and Payer Decision-making by Improving Measures and Methods

**Create measures and methods to capture costs and other burdens** to patients/families as a result of their health or health care.

**Identify the purpose of measurement** within comparative effectiveness research or value assessments for specific decision contexts and address the tension between the utility of condition-specific and cross-cutting measures by investing in both areas of measurement development.

**Increase transparency in data collection** and consistency in data management with sharing of patient-centered data as a “public good.”

**Define and standardize meaningful measures** of health-related social needs that impact patient-centered outcomes and address health disparities.

**Invest in the science of decision analytic methods and workforce training** to support the research, patient, regulatory, and payer communities in collecting, interpreting, and incorporating patient-important impacts into decisionmaking.



### TOWARD EQUITY IN VALUE ASSESSMENT WEBINAR SERIES

In 2021, IVI hosted a three-part webinar series on health equity and value assessment. These webinars brought together thought partners to reframe how value assessment methods and practice can improve equity.

Three key themes emerged:

- The diversity of patients and their experience demands investment in representative research.
- Methods to incorporate equity perspective in value and health technology assessment must no longer be considered “novel.”
- Public policy at both organizational and governmental levels must uphold the importance of health equity as a fundamental component of value.

As a result of this work, IVI is launching a two-year Health Equity Initiative in 2022.

500+

Webinar Attendees  
in 2021

### 2021 ANNUAL SCIENTIFIC MEETING

The 2021 Annual Scientific Meeting offered an opportunity for members to hear from IVI research team and partners on what we are learning and to provide input on the 2022 research agenda.

What we heard from our members:

- IVI must prepare the broader value assessment community to share how the methods IVI is exploring can better inform equitable healthcare decision-making.
- IVI can make contributions to the field by:
  - Maintaining the focus on our principles for value assessment
  - Convening stakeholders and clearly defining best practices for incorporating health equity
  - Demonstrating how patient-centered value assessment can drive better solutions to today’s challenges.

Following the Annual Scientific Meeting, IVI hosted an all-member webinar to highlight achievements from the year and report back on how member input is informing IVI’s research agenda.

### ADVISORY BOARDS

The Patient Advisory Council is an advisory board to the IVI Board of Directors to ensure that our organization remains patient focused and transparent. Comprised of patient advocates and leaders, the Patient Advisory Council helps inform the IVI research strategy, methods and priorities, and supports patient engagement efforts.

Composed of experienced leaders from across the health care system, the Scientific Advisory Panel helps set IVI research priorities, steers the research agenda in collaboration with scientific leadership, and provides guidance on ongoing research efforts. Panel members represent diverse perspectives from across the health care community, including academia, patient advocates, payers, providers, and the life sciences industry. Their role is to provide advice and ensure the credibility and rigor in the research and policy products, and to ensure all parties have a voice in IVI activities.

“Patients wear multiple identities,  
and **we need to think through a  
lens of inclusivity** to understand  
patient heterogeneity.”

—UPAL BASU ROY, PHD, LUNGEVITY FOUNDATION,  
MEANINGFUL ACTION TOWARD HEALTH EQUITY WEBINAR, 2021

# Dissemination

Every day, IVI makes the case for patient-centered equitable value assessment.

## HealthAffairs

### HEALTH AFFAIRS SERIES

IVI partnered with *Health Affairs* to produce a blog series exploring the future of value assessment in a post-pandemic U.S.

The series fostered inclusive conversations and actionable ideas for improving value assessment through IVI research initiatives. It featured a diversity of voices exploring a range of the most pressing issues in health economics and value assessment today.

## AJMC®

### AMERICAN JOURNAL OF MANAGED CARE

IVI was highlighted in a number of articles in *AJMC*, including a piece about patient-centricity co-authored with contributors from the National Health Council and the EveryLife Foundation for Rare Diseases.

## Value Source Blog

### IVI'S VALUE SOURCE BLOG

In addition to co-publishing the *Health Affairs* blog series, IVI's Value Source blog posted extensively this year, with spotlights on member organizations, an interview with IVI CEO Jennifer Bright MPA, and stories about the broad range of work IVI is involved in.



HEALTHECONOMICS.COM  
CONNECTED | COMMUNITY

### HEALTHECONOMICS.COM

IVI appeared numerous times on **HealthEconomics.com** this year, in articles spotlighting our new board members and our ongoing work in the field of value assessment.

## STAT

### STAT

In April, IVI CEO **Jennifer Bright** and Chief Science Officer **Richard H. Chapman** had a guest column in *STAT* titled "It's time to get health care value assessment right." They highlighted the release of principles for capturing patient-centered outcomes data by the Patient-Centered Outcomes Research Institute (PCORI)



PharmacoEconomics

### PHARMACOECONOMICS

In May, **Richard Z. Xie**, **Erica deFur Malik**, **Mark T. Linthicum** and **Jennifer L. Bright** published the article "Putting Stakeholder Engagement at the Center of Health Economic Modeling for Health Technology Assessment in the United States" in the journal *PharmacoEconomics*.

## PRINCIPLES FOR VALUE ASSESSMENT

Value assessment is an important process to inform national and local deliberations about allocating resources and achieving the best clinical health and quality-of-life outcomes. As exploration of a systematic, centralized process for review of drugs and other health interventions in the U.S. accelerates, IVI believes there is a need to define the principles that must guide future policy and practice.

An overarching theme in these principles is defining best practice in the applied use of value assessment; there must be consensus among stakeholder communities on the most effective methods and use cases that are relevant to the U.S. marketplace.



Sustains Authentic Patient-Centricity



Advances Transparency



Cultivates Modernized Methods



Focuses Value Discussion Across Treatment Interventions



Improves Clinical and Real-World Data



Facilitates Customizable Decision-Making



Adapts to and with Evolving Evidence



Supports Health Equity



Fosters Long-Run Innovation

### 2021 SOCIAL MEDIA

# 700

followers on Twitter, an increase of 13.4% over the previous year

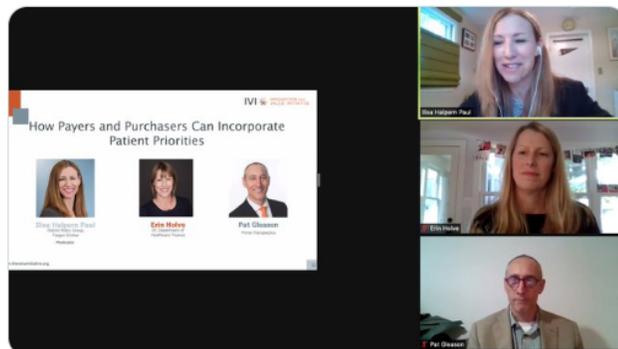
# 528

followers on LinkedIn, an increase of 52.6% over the previous year



The Innovation and Value Initiative (IVI) @IVI\_health · Oct 27, 2021

The Methods Summit next panel brings payers and purchasers into the discussion about measuring and incorporating patient priorities and lived experience into decision making.





“It was important to partner with IVI to show that there is a better way—  
**alternatives to current value assessment models exist and can be patient-centered!** As an IVI member, we look forward to carrying the vital message that additional investments are needed to advance patient-centered research.”

—MICHAEL WARD, ALLIANCE FOR  
AGING RESEARCH, MEMBER SPOTLIGHT



# FINANCIALS

## Statement of Activities for the year ended December 31, 2021

	Without donor restrictions	With donor restrictions	Total
<b>Support and revenue</b>			
Membership dues	\$ 1,181,750	\$ 235,550	\$ 1,417,300
Contributions	115,000	-	115,000
Program revenue	75,000	-	75,000
SBA Paycheck Protection Program forgiveness	56,405	-	56,405
Interest income	586	-	586
Net assets released from restrictions	853,400	(853,400)	-
	<u>2,282,141</u>	<u>(617,850)</u>	<u>1,664,291</u>
<b>Expenses</b>			
Program			
Research projects	1,408,358	-	1,408,358
Stakeholder and patient engagement	167,252	-	167,252
Media communications	441,457	-	441,457
Membership	21,666	-	21,666
	<u>2,038,773</u>	<u>-</u>	<u>2,038,773</u>
Supporting services			
General and administrative	178,070	-	178,070
Fundraising	41,711	-	41,711
	<u>2,258,514</u>	<u>-</u>	<u>2,258,514</u>
<b>Change in net assets</b>	23,627	(617,850)	(594,223)
<b>Net assets, beginning of year</b>	1,700,074	853,400	2,553,474
<b>Net assets, end of year</b>	<u>\$ 1,723,701</u>	<u>\$ 235,550</u>	<u>\$ 1,959,251</u>



# 2021 BOARD OF DIRECTORS



**Sam Nussbaum**  
**(President, in Memoriam)**  
Strategic Consultant,  
EBG Advisors



**Alan Balch**  
**(Secretary, Interim President)**  
CEO, Patient Advocate  
Foundation



**Greg Daniel**  
**(Interim Treasurer)**  
Head, U.S. Healthcare  
Policy, Eli Lilly



**Donna Cryer**  
Founder, President, and  
CEO, Global Liver Institute



**Patty Fritz**  
**(Interim Secretary)**  
Vice President, U.S.  
Corporate Affairs, UCB



**Andrea Maresca**  
Federal Policy Director,  
Health Management  
Associates



**Michael Thompson**  
President and Chief  
Executive Officer,  
National Alliance of  
Healthcare Purchaser  
Coalitions



**Neil Weissman**  
President, MedStar  
Health Research Institute

---

#### IVI VISION

A U.S. learning healthcare system supported by patient-centered value assessment to deliver high-quality, efficient, innovative, and equitable care for all people and communities.

---

#### IVI MISSION

To advance the science, practice, and use of patient-centered value assessment to support decisions that make healthcare more meaningful and equitable.

“The success of the patient often depends on the family caregivers, but often they’re not even identified. Plus **the family caregivers’ health and employment is often at risk** ... Is this being considered for inclusion in these measures?”

—PATIENT LEADER, AT THE 2021 METHODS SUMMIT



# 2021 MEMBERS

**IVI thanks our members for their contributions.** Without their resources and expertise, this work would not be possible.

---

## INNOVATORS CIRCLE MEMBERS

AbbVie  
Amgen  
Biotechnology Innovation Organization  
Bristol Myers Squibb  
Janssen Scientific Affairs  
National Pharmaceutical Council  
Pfizer  
PhRMA  
UCB, Inc.

---

## ORGANIZATIONAL MEMBERS

Alliance for Aging Research  
Arthritis Foundation  
Boehringer Ingelheim  
Edwards Lifesciences  
The Everylife Foundation  
for Rare Diseases  
Genentech  
Global Liver Institute  
Institute for Patient Access  
MedStar Health Research Institute  
National Patient Advocate Foundation  
Neurocrine  
Partnership to Improve Patient Care  
Sage Therapeutics  
Sick Cells  
The Assistance Fund

---

## INDIVIDUAL MEMBERS

Louis Garrison, PhD  
Andrea Maresca, JD  
Joff Masukawa  
Tan Nguyen, PhD  
Danny van Leeuwen, OPA RN MPH

---

## PATIENT ADVISORY COUNCIL, 2021

**Alan Balch**  
National Patient Advocacy Foundation

**Donna Cryer**  
Global Liver Institute

**Anna Hyde**  
Arthritis Foundation

**Annie Kennedy**  
The Everylife Foundation for Rare Diseases

**Stephanie Marshall**  
The Assistance Fund

**Eleanor Perfetto**  
National Health Council

**Jeanne Regnante**  
LungEvity

**Leslie Ritter**  
National MS Society

**Michael Ward**  
Alliance for Aging Research



# 2021 LEADERSHIP TEAM



**Jennifer Bright, MPA**  
Chief Executive Officer



**Rick Chapman, PhD**  
Chief Science Officer



**Todd Bentsen**  
Director of  
Communications



**Mark Linthicum, MPP**  
Director of Scientific  
Communications



**Lisa Malecha, MBA**  
Chief Financial &  
Operating Officer



**Erica de Fur Malik**  
Director of Membership  
and Patient Engagement



**Melanie Ridley**  
Chief Development Officer



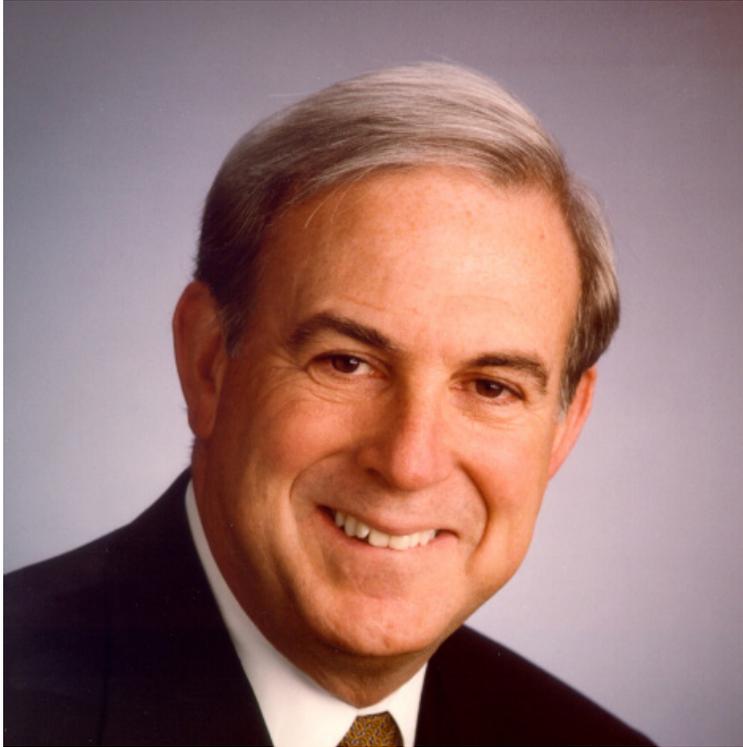
**Judy Thomas**  
Operations Manager



**Richard Xie, PhD**  
Director of Research



## IN MEMORIAM



---

### **SAMUEL NUSSBAUM, MD**

The staff and volunteer leaders of the Innovation and Value Initiative (IVI) mourn the passing of Samuel Nussbaum, MD, on September 23, 2021. Dr. Nussbaum chaired the IVI Board of Directors since 2019 and was involved in IVI's founding in 2016.

A brilliant and caring endocrinologist and teacher, Dr. Nussbaum was a longtime leader of efforts to improve health care quality and access, both locally and nationally. Transforming health systems and research enterprises to be truly patient-centered was one of his passions. A consummate leader and convener, his warmth, inclusiveness, and thoughtful positivity were instrumental in bringing diverse stakeholders to the table to advance often challenging conversations.

Dr. Nussbaum gave his time and expertise generously, and his visionary leadership was instrumental in launching IVI and creating the thriving organization it is today.

Moving beyond academic concepts requires not only identifying emerging and promising practices in achieving improved care, but also establishing **clear expectations for transparency, data sharing, and investment in research defined with equity and patient-defined priorities in mind.**

—JENNIFER BRIGHT, “PATIENT VALUE IS THE ROOT OF A LEARNING HEALTH SYSTEM” (DEC 2021), *AJMC*



917 Prince Street · Alexandria, VA 22314 · [www.thevalueinitiative.org](http://www.thevalueinitiative.org)