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2022
Year at a Glance

27 new members

86% of total revenue went towards programs

$1.6M total research spending

190 participants at the Annual Methods Summit
Reflecting on 2022

A Message from Our CEO

Jason Spangler, MD, MPH, FACPM
Chief Executive Officer

"I am incredibly excited for the future of IVI. We have an exceptionally talented team at IVI that is focused on decisive action to transform health technology assessment — in practice and policy — through our sustained action, innovation, and collaboration."

It is an honor to share my first Annual Report with you as IVI's Chief Executive Officer.

2022 was a very good year for the Innovation and Value Initiative (IVI). There was a return to normalcy as the COVID-19 pandemic abated: most of the world opened again, which made it possible for us to travel and meet each other after almost two years of isolation. Seeing our members, colleagues, and team in person has been one of the highlights of the year.

In this Annual Report, you will find a financial audit, key milestones, and significant accomplishments across all aspects of the organization. We have worked diligently with our members and partners to deliver for all patients and the field of health technology assessment (HTA). In 2022, IVI maintained a strong financial performance which enabled us to increase our investment in research, convenings, operations, and outreach. We brought on five new staff members and are proud to report the launch of three new programs in our research portfolio.

- **Economic Impact Project:** This project offers guidance on how to incorporate the full range of economic impacts on patients and caregivers into comparative effectiveness research and patient-centered HTA.

- **Health Equity Initiative:** This initiative seeks to embed health equity throughout our research projects, educational offerings, and patient and stakeholder engagement activities to catalyze action in the development of methods in HTA that promote equity in health access and outcomes.

- **Valuing Innovation Project:** A multi-phase initiative, this project will help advance the dialogue, identify gaps in current HTA approaches, and build consensus on practical methods to better measure and reward innovation.
We continue to expand the diversity of our Board of Directors and membership to include more perspectives. We have appointed three new patient advocates to join the 2023 board, and patient advocates, non-profits/associations, and researchers/academics now represent nearly 60 percent of our membership.

At IVI, collaboration and stakeholder engagement are integral to our work. We would like to express our sincere appreciation to all the patients, researchers, members, and partners who actively participated in our 3rd Annual Methods Summit, our Annual Meeting, key informant interviews, roundtable discussions, webinars, thought leadership programs, and other convenings throughout the year. Their dedication and support have been instrumental in achieving our collective goals.

Looking ahead, we are excited about the future. We have set ambitious goals to explore new approaches in HTA that advance our understanding of patient-centered outcomes in rare disease, release our Major Depressive Disorder Open-Source Value Model, develop a framework on how stakeholders can incorporate economic impacts into HTA, host our 4th Annual Methods Summit, and ensure that equity, patient-centricity, transparency, and value are at the forefront of all Inflation Reduction Act conversations, among other priorities.

We are grateful for our members’ commitment and enthusiasm, and their contribution to all that was accomplished in 2022. The unwavering dedication and expertise of our talented team has been instrumental in driving our success, and I believe IVI is well positioned to make an even greater impact on the lives of patients and the future of health technology assessment in 2023.

Sincerely,

Jason Spangler, MD, MPH, FACPM
The [economic] impact is personal first. The impact on your non-clinical expenses is immediate because you have to figure out how to care for your family, how to keep the lights on, how to keep the gas on, and keep your job. You still have to dress and feed your children. When we're talking about the financial impact of cancer, people don't take this into account.

— Economic Impacts Key Informant Interviewee
Health Equity Initiative

IVI launched the two-year Health Equity Initiative (HEI) to define gaps in health technology assessment (HTA) and develop best practices and methods that address health equity in HTA. We convened a steering committee, conducted nine key informant interviews, and the first of two roundtable discussions. This involved more than 30 stakeholders and resulted in 25+ hours of dialogue.

Key Informant Interviews

During September and October 2022, IVI conducted a series of nine interviews with key informants – individuals with lived experience, expertise, and skills in research clinical delivery, policy, or data analysis. An intentional focus on equity is essential in HTA. In all these engagements, we have heard broad consensus that there is no value without equity.

A set of criteria that established accountability and informed the framework was developed to address four key domains for equity in HTA:

• Power, People, and Processes
• Data, Inputs, and Infrastructure
• Methods
• Communications and Use

Domains for Equity in HTA

- **Power, People, Processes**
  - HTA is co-created with patient experts, whose contributions are documented and compensated

- **Data, Inputs, and Infrastructure**
  - HTA uses representative, quantitative and qualitative data that reflects outcomes and impacts relevant to patients and caregivers

- **Methods**
  - HTA uses mixed methods to identify relevant data; researchers employ existing equity-focused methods and test emerging methods

- **Communications and Use**
  - Transparent, plain language communication of HTA findings, including equity impact and subgroup analyses, and identification of data gaps
Patient-Driven Priorities for Major Depressive Disorder

With the goal of identifying ways to incorporate patient preference data into the Major Depressive Disorder (MDD) Value Model, IVI partnered with the PAVE Center of the University of Maryland and surveyed a representative sample of individuals living with MDD to understand their priorities in managing the disease. In Q1 2022, we completed this effort with a sample of 300 patients representing patient subgroups defined by race and ethnicity, income, and geographic area. After analyzing the data, we quantified how individuals with MDD made trade-offs in evaluating potential treatment options with different attributes and identified differences in patient preferences for treatments across patient subgroups. IVI is disseminating the findings and collaborating with the MDD advisory group to identify prioritized approaches to incorporate patient preference in the MDD model.

Patient-Engaged Healthcare Valuation

Following the successful pilot survey of using goal attainment scaling (GAS) to collect patient goals in rheumatoid arthritis, IVI, in partnership with the RAND Corporation, convened an expert panel of project steering committee members, patient representatives, and HTA methodologists to assess the feasibility of incorporating patient goals into multi-criteria decision analysis (MCDA). Based on the recommendations of the expert panel, we developed a practical guide to outline a systematic approach of incorporating qualitative and quantitative patient input in HTA. The next phase of the project includes dissemination of our findings and identifying practical applications for the approach. The findings were submitted to the Journal of Clinical Effectiveness Research for publication.

It has been an honor and a pleasure to serve on the IVI Health Equity Initiative Steering Committee. I’ve contributed to several health equity focused committees across the industry, but found the momentum and authenticity of IVI’s efforts to be genuine and encouraging.

— Lauren Powell, PhD, MPA, formerly Takeda Pharmaceuticals (IVI HEI Steering Committee)
Economic Impacts Initiative

In 2022, IVI partnered with AcademyHealth on a year-long initiative to develop a framework for researchers, value assessors, and other decision-makers to include a full range of economic impacts on patients and caregivers in patient-centered research. Together, we convened a 13-person multi-stakeholder steering committee to provide input and guide the project. In the fall, IVI conducted nine key informant interviews with individuals representing patient and caregiver advocates, payers, employers, researchers, and life sciences perspectives. The interviews served to refine and update the draft framework. Key takeaways from the interviews and the steering committee include:

- **Patient’s lived experience must guide the framework.** Ensuring that the compounding impact of patient or population characteristics (health disparities, race/ethnicity, gender, age, socio-economic status) and the experience of economic burden over time are reflected in how economic impacts are assessed.
- **Non-clinical healthcare costs and social impacts are significant** and often overlooked.
- **Caregiver and family impacts need fuller attention.** In many cases the economic and psychosocial impacts are similar to those experienced by the patient.
- **Time is an important factor when considering economic impacts.** These impacts compound over time and have a different level of severity based on the life stage of the patient.
- **Current benefit designs exacerbate economic impacts for patients, caregivers, and the healthcare system.** The impacts of medical and non-medical costs have significant influence on patient preference, decision-making, and ability to adhere to a treatment plan.

The final framework and report will be completed by spring 2023.

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1 This initiative is funded in part by a Patient-Centered Outcomes Research Institute® (PCORI) Eugene Washington PCORI Engagement Award (EASCS-24272).

— Elizabeth Cope, Senior Director of Public and Population Health at AcademyHealth

While there has been a lot of progress in understanding the importance of including patient experiences into healthcare research and value assessment, we still need to develop specific measures to advance our goals. We hope that the insights from this series of roundtables and interviews will inform a sustainable framework for the future.
Advancing Methods and Practice of HTA

IVI is a research-driven organization dedicated to transparency, patient-centeredness, and equity of health technology assessment to real-world decisions and experiences of all stakeholders.

Valuing Innovation Project

The Valuing Innovation Project (VIP) was launched in Q2 of 2022 to advance the methods and practice to better define, measure, and reward innovations in HTA. This multi-phase project started with the 3rd Annual Methods Summit, where nearly 200 participants and thought leaders from across the healthcare ecosystem discussed the importance, status quo, challenges, and opportunities when considering innovations in HTA. The input from the Methods Summit, informed an expert roundtable with 11 multi-stakeholder experts resulting in the identification of prioritized attributes for subsequent research. Future phases of the VIP will include a call for papers to offer a global platform for individuals and organizations to identify actionable strategies to address identified gaps.

Open-Source Value Model for Major Depressive Disorder

IVI’s 20-member, multi-stakeholder advisory group provides ongoing feedback on model inputs, assumptions, and user interface, making sure the model includes outcomes important to patients and facilitates customizable decision-making for different stakeholders. This process was described in our 2022 article, “Early Reflections on Stakeholder Engagement in Economic Model Development to Inform Value Assessment.” Next steps will be to program the model and user interface. With the anticipated launch of the economic model in the fall of 2023, we look forward to building partnerships to test and implement the model.
We are asking, what are the gaps that are leading to why people are not accessing the treatment they need? When people do not access the treatment they need, then they often end up using the more expensive, more invasive, and possibly less effective treatment.

— Economic Impacts Key Informant Interviewee

Treatment Patterns and Outcomes for Commercially Insured Population in MDD

IVI completed a retrospective, commercial claims database study with researchers from HealthCore (now Carelon) to ensure the IVI-MDD model generates insights consistent with real-world clinical practice and patient experiences. The analysis examined treatment patterns, healthcare resource utilization, costs, and outcomes in the two years following initial diagnosis of MDD. While previous studies have examined real-world pharmacologic treatment patterns and costs among MDD patients, few examined the use of non-pharmacologic treatments and their association with utilization and costs. We observed an association between treatment modality and disease severity. Results of this study have been accepted for publication in the *Journal of Managed Care and Specialty Pharmacy* and provide useful insights on the key model assumptions and inputs for the MDD model.
Multi-Criteria Decision Analysis Module for the IVI-MDD Value Model

Reflecting IVI’s commitment to innovation in HTA, the IVI-MDD model will also feature a multi-criteria decision analysis (MCDA) module. MCDA provides an alternative to cost-effectiveness analysis allowing users to consider a wider range of criteria than most economic analyses, including qualitative inputs from patients. We partnered with an expert working group to incorporate specific details of the MCDA procedure into the model and to identify the set of attributes for use in the MCDA. Next steps in the development of the MCDA module include the procedures for weighting and scoring the defined attributes.

Disparities in Treatment Access and Outcomes in Youth in MDD

IVI initiated a project with researchers at the University of Southern California’s Leonard D. Schaeffer Center for Health Policy & Economics using medical claims from a large, national insurer to retrospectively analyze individuals with MDD aged 10-26 years old. We assessed the role of telemedicine in providing access to psychotherapy for children and young adults with incident MDD before and during the COVID-19 pandemic, and by race and ethnicity. We found that telemedicine increased access to psychotherapy during the pandemic across races and ethnicities, but racial and ethnic disparities in access persisted. Findings from these analyses will be used to inform inputs in the MDD model and future use cases for the model.
Bringing Stakeholders Together

IVI is committed to convening stakeholders across the healthcare industry to advance the methods and strategies for how value is defined.

Methods Summit

The 3rd Annual IVI Methods Summit\(^1\) took place on October 6, 2022 and convened nearly 200 participants and thought leaders from across the healthcare ecosystem. The forum showcased multi-stakeholder perspectives on the “status quo” of how innovations in health technologies are being considered in decision-making, opportunities and challenges in the biopharmaceutical, digital, and diagnostic innovations, and delivery arenas for the science and practice of health technology assessment. Six key themes on valuing innovation emerged from the Summit:

- Definitions of innovation matter
- Expanding perspectives is important to balanced analyses of innovation
- Patients and caregivers should be co-creators
- Data is our hurdle, and our key
- Methods research needs attention
- Misaligned incentives in health systems lead to distortions

Annual Scientific Meeting

IVI’s Annual Scientific Meeting is the formal convening of IVI members to engage in productive and action-focused discussions that will ultimately inform and influence how value is defined in healthcare. The 2022 Annual Scientific Meeting was held October 17-18, 2022, at the Westin Hotel in Alexandria, Virginia. This year’s theme, Accelerating Impact, showcased the progress IVI has made the last year and opportunities for the future. The meeting offered an opportunity for members to hear from the IVI research team and partners about progress and provide input for the 2023 research agenda.

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\(^1\) The 3rd Annual IVI Methods Summit was funded by contributions from IVI’s diverse membership and a grant support from Pharmaceutical Research and Manufacturers of America (PhRMA).
Communications

IVI creates intentional communications to accentuate the importance of centering the patient in health technology assessment.

Our content and marketing strategy serves as a platform to raise visibility of the organization’s thought leadership, research acumen, and collaborative efforts through an integrated channel strategy that includes earned, owned, and social media content serving as vehicles for distribution. IVI will continue to create intentional communications and messaging to enhance IVI’s brand and stress the importance of centering the patient in health technology assessment. IVI’s research portfolio continues to grow and diversify with publications, posters, and reports with partners foundationally proving how patient-centered value assessment can be conducted transparently.

- **16** Blog Posts
- **6** Scientific Publications
- **15** Press Statements
- **5** Commentaries/White Papers
- **14** Speaking Engagements
- **2** Published Letters to the Editor

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When ISPOR released its 2022 Consolidated Health Economic Evaluation Reporting Standards (CHEERS 2022), IVI was pleased to see the updated standards regarding patient and stakeholder engagement reflected a growing recognition to incorporate them into economic evaluations and healthcare research from the conceptualization stage rather than after the project is completed. Following the release of the CHEERS report, IVI published a short blog series on how the reporting standards reflected IVI's work and core principles for health technology assessment.

For National Minority Health Awareness Month, IVI conversed with Sick Cells to highlight the Sickle Cell community experience in the U.S. healthcare system and lessons learned. It is imperative that the patient community has a seat at the table during healthcare decision-making and discussions.

In August 2022, IVI was featured in STAT News. The story detailed IVI's collaborative efforts to focus on health equity by emphasizing accountability and action from all stakeholders to enact change.

IVI contributed to the Health Affairs Forefront short series, "Enhancing Value by Evaluating Health Care Services." The series discussed ways to extend the use of tools for clinical and economic evaluation beyond medical technologies to the services and procedures that account for most of healthcare spending. The goal was to create a more robust evidence base for the impact and value of healthcare services.
Finding Equity in Value

IVI and Sick Cells released the Finding Equity in Value white paper, which was a collaborative effort to advance racial and health equity within the practice of health technology assessments (HTA). In the U.S., HTA has taken an increasingly influential role in pricing and coverage decisions, and it is essential to understand how racism and other biases arise in the HTA process, including the potential implications for health equity.

Equitable Access to Rare Diseases Therapies

Hosted by the Center for Healthcare Innovation, IVI joined other distinguished panelists representing diverse patient communities, healthcare providers, multifaceted manufacturers, and patient support providers to address opportunities and challenges in obtaining equitable access to rare disease therapies.

Social Media

991
Followers on LinkedIn, an increase of 87% from the previous year

779
Followers on Twitter, an increase of 11% from the previous year

IVI at ISPOR 2022

At ISPOR’s Annual Conference, IVI explored a series of case studies presenting unique solutions to the health technology assessment challenges health authorities have dealt with and were fueled during the COVID-19 pandemic. IVI’s participation included two issue panels, one workshop, one podium presentation, and one poster.
Membership

IVI values diverse member perspectives and strives for representation across the healthcare space – from researchers and healthcare systems to patients and providers.

IVI expanded its engagement of stakeholders in 2022 to inform the large number of projects described in this report. This growth included an increase in organizational members, as well as a considerable increase in the number of individuals joining as members.

58% of IVI’s membership is composed of patient advocates, non-profits/associations, and researchers/academics.

<table>
<thead>
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<th>Category</th>
<th>Count</th>
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<tbody>
<tr>
<td>Individual Members</td>
<td>24</td>
</tr>
<tr>
<td>Organizational Members</td>
<td>32</td>
</tr>
</tbody>
</table>

- 28% Industry
- 16% Researcher/University
- 9% Payer/Employer
- 5% Other
- 42% Patient/Non-Profit/Association

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## Financials

### Statement of Activities for the Year Ending December 31, 2022

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<thead>
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<th></th>
<th>Without Donor Restrictions</th>
<th>With Donor Restrictions</th>
<th>Total</th>
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<tbody>
<tr>
<td><strong>Support and Revenue</strong></td>
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<td>Membership Dues</td>
<td>$1,840,125</td>
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<td>Grants</td>
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<td>Program Revenue</td>
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<td>Interest Income</td>
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<td>Net Assets Released from Restrictions</td>
<td>235,550</td>
<td>(235,550)</td>
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<td></td>
<td></td>
<td></td>
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</tr>
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<td><strong>Total</strong></td>
<td>2,384,658</td>
<td>100,375</td>
<td>2,485,033</td>
</tr>
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| **Expenses**          |                            |                         |         |
| Program               |                            |                         |         |
| Research Projects     | 1,576,677                  |                         | 1,576,677 |
| Stakeholder and Patient Engagement | 255,569 | - | 255,569 |
| Media Communications  | 515,565                    |                         | 515,565 |
| Membership            | 118,128                    |                         | 118,128 |
|                      |                            |                         |         |
| **Total**             | 2,465,939                  |                         | 2,465,939 |

| Supporting Services   |                            |                         |         |
| General and Administrative | 293,121       | -                      | 293,121 |
| Fundraising           | 50,979                     |                         | 50,979  |
|                      |                            |                         |         |
| **Total**             | 2,810,039                  |                         | 2,810,039 |

| **Change in Net Assets** | (425,381) | 100,375 | (325,006) |

| **Net Assets, Beginning of the Year** | 1,723,701 | 235,550 | 1,959,251 |
| **Net Assets, End of the Year**      | 1,298,320 | 335,925 | 1,634,245 |
Advisory Boards

High-profile leaders with deep experience in patient engagement, health technology assessment, health equity, and policy issues.

Patient Advisory Council

The Patient Advisory Council (PAC) 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 PAC helps inform the IVI research strategy, methods and priorities, and supports patient engagement efforts.

Scientific Advisory Panel

Composed of experienced leaders from across the healthcare system, the Scientific Advisory Panel (SAP) helps set the IVI research agenda in collaboration with scientific leadership, and provides guidance on ongoing research efforts. Panel members represent diverse perspectives from across the healthcare 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.

As the pace of healthcare innovation rapidly accelerates, it's important that we match it from both the scientific and policy perspective to best determine the value of innovation. This [Methods Summit Proceedings] report and the key principles support these efforts while continuing to keep the focus on patients, families and caregivers.

— Jason Spangler, MD, MPH, FACPM (Chief Executive Officer, IVI)
IVI remains more committed than ever to elevating the patient voice, advancing equity, and embracing our mission to promote health technology assessment for the betterment of all people.

— Greg Daniel, PhD (President, 2022 IVI Board of Directors)
Members

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

Innovators Circle Members
- AbbVie
- Alexion
- Biotechnology Innovation Organization
- Bristol Myers Squibb
- Janssen Scientific Affairs
- National Pharmaceutical Council
- Pfizer, Inc.
- PhRMA
- Takeda Pharmaceuticals
- UCB, Inc.

Organizational Members
- Alliance for Aging Research
- Amgen
- AiArthritis
- Arthritis Foundation
- BlueCross BlueShield Venture Partners
- Boehringer Ingelheim
- Coalition of Skin Diseases
- Edwards Lifesciences
- Eli Lilly
- EveryLife Foundation for Rare Diseases
- Genentech, Inc.
- Institute for Patient Access
- MedStar Health Research Institute
- National Alliance of Healthcare Purchaser Coalitions
- National Patient Advocate Foundation
- Network for Excellence in Health Innovation
- Neurocrine Biosciences
- Partnership to Improve Patient Care
- Sage Therapeutics
- Sick Cells
- SynGap Research Fund
- The Assistance Fund
- The Haystack Project
Individual Members
Kirsten Beronio, JD
Harold Carter, PharmD
Elizabeth Cope, PhD, MPH
Chuck Cutler, MD, MS
Mark Cziraky (Innovators Circle Member)
Margo Edmunds, PhD, FAMIA
Omar Escontrías, DrPH, MPH
Nelly Ganesan, MPH
Louis Garrison, PhD
Juan Marcos González Sepúlveda, PhD
Maureen Hensley-Quinn
Bruny Kenou
Olivia Lubarsky
Joff Masukawa
Tan Nguyen, BOralHlth, MPH, MSc (ClinEd)
Laura Pizzi, PharmD, MPH
Elridge Proctor, MPA
Claire Sachs
Abby Sears, MBA
Richard Seiden, JD
Vipan Sood, RPh, MBA, MRPharmS
Cristie Travis
Josh Trent
Danny Van Leeuwen, OPA, RN, MPH
Gretchen Wartman, BA
Kimberly Westrich, MA

Value assessments can discriminate against communities experiencing health inequities. That's why IVI's work to make value assessment more equitable is so important.

— IVI Member
2022 IVI Team

Jason Spangler
Chief Executive Officer

Jennifer Bright
Chief Engagement and Strategy Officer

Jessica Brown
Membership and Marketing Manager

Rick Chapman
Chief Science Officer

Michelle Cheng
Research Associate

Tiffany Huth
Chief Communications Officer

Mark Linthicum
Director of Scientific Communications

Lisa Malecha
Chief Financial and Operating Officer

Erica deFur Malik
Director of Patient Engagement
The unwavering dedication and expertise of our talented team has been instrumental in driving our success, and I believe IVI is well positioned to make an even greater impact on the lives of patients and the future of health technology assessment in 2023.

— Jason Spangler, MD, MPH, FACP (IVI Chief Executive Officer)
About Us

What We Do

Since inception, IVI has championed a focus on patient-centered outcomes and preferences as drivers of change, emphasized modern thinking about methods and value elements that should be included in health technology assessment models, and advocated for transparent, open-source model development to improve dialogue and build trust between users, decision-makers, and patient communities.

MISSION

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

VISION

A U.S. learning healthcare system focused on value that is informed by patient-centered health technology assessment and that delivers high quality, efficient, innovative and equitable care for all people and communities.
IVI is a 501(c)(3) tax-exempt, non-profit research organization dedicated to advancing the science and improving the practice of health technology assessment through the development of novel methods and the creation and application of enhanced health technology assessment models to support local decision-making needs in healthcare.

www.thevalueinitiative.org

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tiffany.huth@thevalueinitiative.org