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A Message from Our Leadership

We are so pleased to share with you the Innovation and Value Initiative's first Annual Report. This report captures our progress and early impact as a growing voice in value assessment. Our Annual Report includes our collaboration with research partners to drive innovation in the methods used in the U.S. to measure value and in how we apply these assessments in real-world decision contexts. Since its creation, the Innovation and Value Initiative (IVI) has focused its mission on improving the science and practice of value assessment in healthcare. We transitioned to a 501(c)(3) in 2019. IVI is grateful to our members who have joined us in accelerating innovation through collaboration to achieve value assessment that is both scientifically credible and meaningful.

This report is timely for our organization, but also for the extraordinary situation brought before us by a global pandemic. While IVI has sought to be a disruptor in the conventional thinking about value assessment methods and models, COVID-19 has outstripped us in challenging every sector of our health system and highlighting the shortcomings and disparities that we've known existed for many years. As we look ahead to new approaches to value assessment, there are opportunities to improve the inputs in value assessment through new clinical research approaches and wider access to real-world data. There are growing calls for transparency and shared data to improve decision-making and there is wider recognition that traditional methods for cost-effectiveness analysis aren't sufficient. We are excited to see greater emphasis on the questions that IVI strives to answer: What is the most valuable sequence of treatment for patients? How do we assess which treatments work best and for whom? What affect does patient heterogeneity have on both treatment outcome and cost-effectiveness? Are there other cost considerations that should be represented in the measurement of value?

IVI's impact in the value assessment field will continue to grow as we develop new collaborations and launch innovative research projects to explore methods and measurements that are patient-driven and relevant to healthcare decision-makers. A few examples of our work in 2019 and 2020 that we are particularly proud of include:

- Hosting the Inaugural IVI Methods Summit in February 2020 convening of leaders across the healthcare system to identify gaps and prioritize action towards improvement in value assessment methods.
- Releasing an update to the Rheumatoid Arthritis (RA) model within the Open-Source Value Project that incorporates public feedback received from stakeholders and updates it to current practices.
- Publishing commentaries with thought leaders representing patients, employers, and methods experts to raise critical questions for stakeholders engaged in value assessment.

There are many challenges ahead to build a healthcare system that truly delivers value for patients and makes the most effective use of our healthcare resources.

Thank you to our members who are shaping the future and for those of you not yet members, we hope you will join us on this journey.





Sam Nussbaum Sam Nussbaum, MD Board Chair

IVI Board of Directors

The IVI Board of Directors is comprised of members representing various classes of stakeholders, including research and academia, providers, patients, payers, pharmaceutical and medical device companies, as well as other companies in the healthcare industry. The Board is responsible for overseeing the financial and strategic direction of the organization and provides advice and leadership support to IVI's Executive Director and internal leadership team to execute its work.



Alan Balch
Patient Advocate Foundation
Secretary



Donna Cryer
Global Liver Institute



Greg Daniel
Edwards Lifesciences



Dan Durham

Biotechnology Innovation
Organization
Treasurer



Patricia Fritz
UCB, Inc.



Andrea Maresca
ThornRun Partners



Sam Nussbaum
EBG Advisors



Michael Thompson

National Alliance of
Healthcare Purchaser
Coalitions



Neil Weissman

MedStar Health

MedStar Research Institute

IVI Leadership Team

IVI is managed by a multi-disciplinary team that includes professionals from patient advocacy, healthcare policy, administration and health economics outcomes and research.



Jennifer Bright
Executive Director



Mark Linthicum

Director of Scientific

Communications



Lisa Malecha
Chief Financial Officer



Erica de Fur Malik

Director of Membership and
Patient Engagement



Melanie Ridley
Director of Fundraising



Judy Thomas
Operations Manager



Richard Xie

HEOR Research Manager

NOVEL THINKING ABOUT VALUE

Improving Value Assessment

One significant and ongoing challenge in healthcare today is the measurement of value. Most healthcare providers, payers, and patients would agree the cost of medication, treatment or medical service should reflect the value it delivers. And yet, consensus does not yet exist about the component perspectives, methods and data that should be used to define value. This status quo demands better answers to the questions, "How do you measure value? And for whom?"

The Innovation and Value Initiative (IVI) was created to raise the level of discussion around value in healthcare by bringing together all participants in the system – academics, patients, patient advocates, payers, purchasers, life sciences companies, providers, delivery systems, and other stakeholders – to find common ground in the approach to measuring value.

As IVI works to find this common ground, our research reflects five key principles: scientific rigor, transparency, patient-centricity, innovation, and market-based solutions (see Figure 1).

Our History

Founded in late 2016 as a project by academics associated with Precision Health Economics. IVI sought to influence HEOR thinkers, academics and value assessors through policy papers, commentary and convening to make the case for novel approaches to value assessment methodologies that emphasized the ability to address key limitations in conventional cost-effectiveness analysis (CEA). IVI 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 value assessment models, and advocated for transparent, open-source model development to improve dialogue and build trust between users, decision-makers and patient communities. In 2018, IVI published its



VISION

IVI envisions a U.S.
healthcare system that
directs resources to the
most valuable treatment(s)
for every individual
patient, to the benefit of all
stakeholders.



MISSION

IVI seeks to advance the science, practice, and use of value assessment in healthcare to make it more meaningful to those who receive, provide, and pay for care.



GOAL

IVI has a goal of building a community to create rigorous, innovative, and relevant methods and translational research that facilitates patient-centered value assessment and emphasizes flexibility and usability for the unique decision contexts of individual decision-makers.

first Open-Source Value Project (OSVP) model addressing Rheumatoid Arthritis, updated in 2019 as the result of extensive public review and consensus of technical expert review.

In 2018, IVI also began the process of transition to a non-profit entity and the company was granted 501(c)(3) status in August 2019. Funding for IVI transitioned from sponsorships to an organized membership program for both organizations

and individuals. An initial Board of Directors (see Appendix A) was appointed and helped establish organizational bylaws and policies for conflict of interest and organizational management and decision-making. During 2019-2020, the organization has grown further in membership, has built standing professional staff and initiated collaborative research with additional external research partners to accelerate IVI work and testing of methods and models.

Figure 1. IVI Key Principles



SCIENTIFIC RIGOR.

IVI uses contemporary scientific methods to rigorously derive actionable insights directly from both clinical and real-world evidence.



TRANSPARENCY.

IVI develops open-source tools to promote value-based decision making in healthcare. To facilitate the evaluation and replication of our work, IVI will publicly release research methods, assumptions, results, and external reviews.



PATIENT-CENTRICITY.

IVI engages patients as active participants in value assessments. Our research attends to diversity across patients in their clinical characteristics, preferences, and other circumstances.



INNOVATION.

IVI examines how new treatment interventions and government policies affect the well-being of society and its stakeholders. We promote approaches that rapidly incorporate the latest scientific evidence in a changing healthcare landscape.



MARKET-BASED SOLUTIONS.

IVI aims to promote better value-based decision-making in a decentralized marketplace, not to use centralized authorities to mandate prices through bureaucratic processes.

OUR IMPACT

Transparency | Diversity of Voices | **Innovation in Methods**

IVI is pushing beyond the standard in value assessment today to engage a diversity of voices in discussion about improving methods. If we are to advance value-based care in our healthcare systems, together we must focus on the inputs that inform how we measure value, we must insist on transparency in our data and our models. Only then will we begin to improve dialogue and trust. This report offers insight into how IVI is leading efforts to convene thought leaders, patients, and researchers to make value assessment more flexible and transparent to make it more meaningful to those who receive, provide, and pay for care.

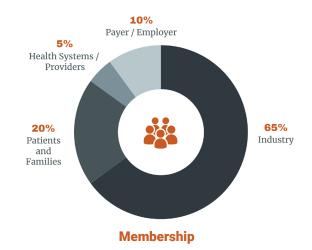
Engaging Diverse Voices in Value Assessment

IVI Members

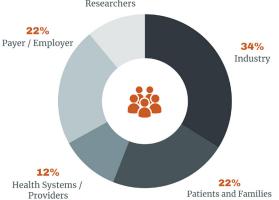
IVI members are the drivers of IVI's mission to improve the science and practice of value assessment in the healthcare system. IVI members help to set the strategy and vision to ensure that IVI fully addresses the many factors contributing to what value means in healthcare.

IVI formally launched its membership program in July 2019. This was part of a broader transformation of the organization from an incubated research project, to an independent, non-profit research organization. By transitioning to a membership organization, IVI is better positioned to engage with a diversity of voices and partners to support our mission to improve methods and approach of value assessment in healthcare. IVI's membership has grown from 11 founding

Figure 2. Sectors Represented in Membership and on the Board of Directors



10% Researchers



Board of Directors

member organizations in 2016 to 20 individual and organizational members today (see Page 10).

IVI has created a membership structure to include both organizations that are able to make significant financial and knowledge contributions as well as individuals and organizations that provide more intellectual contributions to the organization. Innovators Circle Members are organizations and individuals that have made significant investments and founding contributions to the mission and vision of IVI. Organizations and individuals representing both non-profit and for-profit stakeholders with an interest

IVI Members (2020)

IVI would like to thank the following members for their contributions to the work and mission of this organization. Without their resources and expertise, this work would not be possible.

Innovators Circle Members

- AbbVie
- Amgen
- Biotechnology Innovation Organization
- Bristol Myers Squibb
- Genentech
- Merck
- National Pharmaceutical Council
- Pfizer
- PhRMA
- UCB, Inc.

Organizational Members

- Boehringer Ingelheim
- Institute for Patient Access
- Janssen Scientific Affairs
- · MedStar Health Research Institute
- National Patient Advocacy Foundation
- Partnerships to Improve Patient Care

In addition, IVI would like to thank those who have elected to join our organization as individuals, demonstrating great commitment to this initiative.

Visit our website to learn more about IVI membership.

in value assessment are eligible to become IVI members. Interested in learning more about becoming an IVI member? Contact us at info@thevalueinitiative.org or visit our website for detailed information.

Changing the Conversation about Value

IVI has cemented its reputation as a solid thought leader on the science and practice of value assessment. But perhaps more importantly, IVI has used our communication channels in strategic ways to both educate and collaborate with patients, providers, and payers. This is critical because traditionally, those who receive, provide, and pay for healthcare have been largely left out of the value assessment process.

From co-authoring commentaries, to providing media interviews, to sharing insights at leading conferences and even on social

media, IVI uses communications to solicit the invaluable insight these stakeholders have about why value assessment must evolve. As part of this strategy, IVI has also used communications to identify common ground – areas where these stakeholders agree about *how* the value assessment process can be improved to ultimately be meaningful to those who receive care, provide care, and pay for care.

In 2019-2020 IVI worked closely with a variety of stakeholders to publish ten commentaries – across multiple publications – that reached diverse audiences. During the first half of 2020, IVI launched the first blog solely dedicated to the topic of value assessment, the **Value Source Blog**. This is yet another opportunity for strategic collaboration and for leading experts from the patient advocacy, payer, life sciences, and health economics community to share their insights.

Collaboration through Social Media

And of course in 2020, social media is a powerful avenue for impact. Much of IVI's work was shared and showcased by healthcare leaders.



The Innovation and Value Initiative (IVI) @IVI_health

Great interview!



Jennifer Bright and Dr Lou Garrison break down how #valueAssessment and #clinicalpathways should evolve together to meet the needs of value-based #cancercare. @IVI_health

Full interview > buff.ly/3g9aZT9 #oncology #valuebasedcare





IVI Video

In the ongoing spirit of collaboration, IVI leaders also joined top voices from the HEOR and patient advocacy space to share insights through short, informational videos about how to improve value assessment and address current gaps.

IVI Video Collection

- IVI Open-Source Development Process
- IVI in 2020
- IVI Inaugural Methods Summit (2020)
- · Patients at the Center of Value Assessment

Access IVI's full video collection here.



Follow us on Twitter: @IVI_health



Connect with us on LinkedIn:

The Innovation and Value Initiative

Traditional cost-effectiveness analysis is a strong foundation, but to identify optimal treatment for diverse patients - the essence of value - it must evolve. With all the innovation happening in healthcare, isn't it time to modernize our methods for understanding the value we're getting for every dollar?

Jennifer Bright, MPA Executive Director, IVI



Scientific Engagement

Collaborating with Healthcare, Health Economics and Outcomes Research (HEOR), and Research Leaders: Scientific Advisory Panel

IVI convenes an advisory committee to the Board of Directors – the Scientific Advisory Panel – which brings together expertise from employer, payer, industry, patient, and research communities. The panel offers insights to trends in methods and user needs, offers feedback on research protocols and stakeholder engagement and outreach initiatives, and participates in an annual scientific dialogue with IVI staff and Board members.

Vipan Sood, RPH, MBA, MRPHARMS

Vice President, HEOR, Specialty at AbbVie IVI Scientific Advisory Panel Member

Advancing the methods and tools that we use for rigorous, transparent value assessment delivers benefit to all stakeholders. As a community of health experts and scientific researchers, we must continue to share our learnings and ensure that we address evidence and methodology gaps in our current approach to value assessment.

The role of the Scientific Advisory Panel (SAP) is to provide advice and ensure the credibility in the research and policy products, and to ensure all parties have a voice in the work of IVI. Key activities of the SAP include:

- Serving in an advisory capacity to the IVI Board of Directors
- Advising IVI on development of its research agenda
- Ensuring the scientific rigor and relevance of IVI's research
- Supporting stakeholder engagement
- Supporting membership development efforts to engage with researchers, patient community, payer community, and other key stakeholders

Commentary: Leadership through the COVID-19 Pandemic

Writing with Sam Nussbaum, President of the IVI Board of Directors, and renowned health economist Lou Garrison, IVI shared insights in *STAT News* – a leading national public health publication – on how we should think about value assessment during a pandemic.

"How 'value' is determined will have long-term consequences on future investments in COVID-19 treatments... The win-win approach is to expand our national conversation about value to inform the long-term view of investment and the best use of our scarce health care resources."

In addition to these published commentaries, IVI reached an audience of several thousand health economics research experts, life science professionals, employers and payers by speaking at conferences hosted by the Biotechnology Innovation Organization (BIO), the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and the Integrated Benefits Institute (IBI).



IVI Executive Director, Jennifer Bright (IVI Methods Summit)

IVI Methods Summit: Defining Needs and Progress Toward Improving Methods in Value Assessment

The national discussion on value in healthcare is an important dialogue for all participants in the healthcare system: patients and families, clinicians, payers, employers, and researchers. The limitations of current value assessment methods hamper the ability of decision-makers within the U.S. healthcare system to make informed decisions on affordability, access, and value. There is a need to not only identify and prioritize the development

IVI Methods Summit February 27, 2020 Washington, D.C.

Read the full Proceedings Report for the inaugural IVI Methods Summit here.

Figure 3. Methods Summit Prioritized Key Areas for Action





Moderated Group Discussion (IVI Methods Summit)

of new methods, but also to include a wider group of stakeholders to invest resources and expertise in improving value assessment and its application to decision-making.

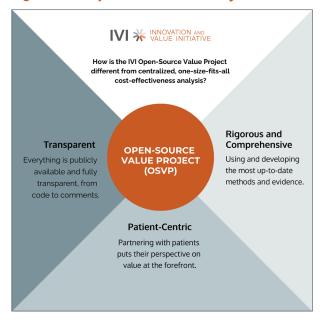
To that end, IVI received a Patient-Centered Outcomes Research Institute® (PCORI) Eugene Washington Engagement Award (EAIN#00101-IVIF) to convene a multistakeholder forum in Washington, D.C. in February 2020 to explore unmet needs and gaps in value assessment methods development and identify the ways in which these deficiencies can be addressed so that value assessment is more meaningful to all stakeholders, but most especially for patients.

IVI's ability to bring this diverse group together is key, and it is never easy...It was a pleasure and an honor to participate in this lively and important discussion [at the IVI Methods Summit] with implications for where we researchers need to focus our efforts in the months and years to come to meaningfully improve value assessment. No doubt, these participants and many others will want to carry forward this work.

Lou Garrison, PhD Professor Emeritus, University of Washington



Figure 4. IVI Open-Source Value Project



Building Innovative Methods and Transparent Models for Value Assessment

IVI's research contributes to the landscape of value assessment by addressing the lack of fit between current methods and tools for value assessment and the information needs of patients, clinicians, purchasers, and payers. IVI's work in value assessment is not intended to provide a single answer for an average patient profile, but rather to develop opensource, innovative, and transparent models. Our efforts to engage a diversity of voices power our research to better understand the needs of decision-makers and develop tools that are credible, flexible, and relevant.

Figure 5. Building and Advancing Models

research in novel methods and analytic frameworks for estimating value, most notably multicriteria decision analysis Developing open-source, transparent, and flexible models that account for the impact of patient heterogeneity on the value of treatment sequence choices

BUILDING AND ADVANCING MODELS

How does IVI contribute to the development of innovative models for value assessment?

Conducting applied research that explores decision-maker needs to understand and build tools relevant to a variety of decision contexts

Engaging patients and other stakeholders in the process of value assessment to find new ways to measure and incorporate patient preferences into modeling

IVI's Value Laboratory: The Open-Source Value Project

IVI's Open-Source Value Project (OSVP) serves as a laboratory for robust and rigorous research on methods for patient-centered value assessment. The models developed in this environment incorporate new methods for assessing value, including multi-criteria decision analysis (MCDA) and novel aspects of value (e.g., value of hope, insurance value) that are uniquely patient-focused, which are largely absent from conventional approaches to cost-effectiveness analysis.

During its initial period, IVI has built disease-specific platforms for rheumatoid arthritis and EFGR+ non-small cell lung cancer that demonstrate the proof-of-concept for novel approaches to value assessment model development and facilitate testing and improving on such methods for applied decision-making.

At the close of 2019, we released the latest update to the rheumatoid arthritis value assessment model (IVI-RA). The updated model now incorporates additional treatment options (triple therapy, Janus Kinase - or JAK - inhibitors, sarilumab, and biosimilars), updated treatment effect estimates based on additional randomized controlled trial (RCT) evidence, and updated cost estimates. Research Partners: Jeroen Jansen, PhD and Devin Incerti, PhD.

Visit our website to learn more about the Open-Source Value Project and the IVI value models.

IVI is building an avant-garde research laboratory through the Open-Source Value Project with the aspirations to test novel methods to directly incorporate patient perspectives of value in treatment, account for patient heterogeneity, and explore how decision-analytic frameworks, such as multi-criteria decision analysis, can help decision-makers understand value in ways other than the traditional Cost-Effectiveness Analysis approach.

Richard Xie, PhD Research Manager HEOR, IVI



Patient Engagement

Collaborating with Patients: IVI Patient Advisory Council

In the first part of 2020, IVI appointed seven members to its newly formed Patient Advisory Council. This board-level advisory body is designed to ensure the patient always remains at the forefront of IVI's value assessment work.

IVI's Patient Advisory Council was envisioned as key to its mission from the early beginnings of the organization. The Council was chartered in the IVI Foundation Inc. bylaws to ensure

Donna Cryer

President and CEO, Global Liver Institute IVI Board Member

Today's value assessment models neglect a myriad of elements and factors critical to the people who actually take a medication or experience therapy, such as data about side effects, preferred outcomes, or burden on caregivers. Thus we end up with models that assign a value to a treatment devoid of useful information to patients. It is time we change so that this math has meaning.

the organization remains patient-focused and transparent and informs IVI research, strategy, methods and priorities, and supports our patient engagement efforts. Advisory Council members serve 1-3 year terms. IVI will be accepting nominations for 2021 members at the Annual Scientific Meeting.

The Patient Advisory Council is comprised of high-profile leaders with deep experience in patient engagement and value assessment processes and policy issues.

Patient Advisory Council Members

- · Alan Balch, PhD
- · Donna Cryer, JD
- Anna Hyde, MA
- Annie Kennedy
- · Eleanor Perfetto, PhD, MS
- · Jeanne Regnante
- · Leslie Ritter. MA

Commentary: Calling for Innovation with Patients Leading the Way

IVI Executive Director, Jennifer Bright, partnered with Amy Miller, former Executive Director of the Society for Women's Health Research, to educate healthcare leaders about why it is critical to include patient's perspectives and real world data in value assessment. This thought leadership piece, published online in the *American Journal of Managed Care*, reached an audience of over 35,000 healthcare leaders monthly.

"We need to accelerate initiatives to incorporate real-world data into value assessment through partnership between researchers and decision-makers — including providers, payer, and patients. We must also firmly position patients in lead roles to define meaningful factors that should be inherent components of assessing value..."

What's Ahead for IVI

IVI is advancing and prioritizing a select set of research projects that will help address our research goals. Below are highlights from a few exciting new projects that are in development.

COVID-19 Methods Webinar Series

IVI and ISPOR are collaborating, with the help from an expert advisory committee, to define and host a series of dialogues that will highlight key challenges confronting HEOR methodologists, patients, clinicians, and policy-makers during the COVID-19 pandemic. The **webinar series** will explore multiple viewpoints and focus on potential pathways for solutions in international and U.S.-focused value assessment and health technology assessment (VA/HTA). Tentatively, the series will feature five one-hour moderated sessions from July to November 2020. Research partners include Dick Willke, PhD and Lou Garrison, PhD.

Defining Patient-Important Outcomes

IVI is working with research partners at RAND to pilot test the use of Goal Attainment

Scaling to capture rheumatoid arthritis patient preference inputs and explore its applications in multi-criteria decision analysis (MCDA). This exploratory research is searching for new methods to directly incorporate the patient perspectives into optimal treatment choice, which could help inform value assessment. The project is in its early stages, but the team is aiming to move towards applied MCDA research in 2021. Research partners include: Lori Frank, PhD and Thomas W. Concannon, PhD.

Engaging Patients and Employers in Value Assessment

The National Health Council and National Alliance for Healthcare Purchaser Coalitions are joining with IVI to host a series of roundtables for patient and employer groups to explore the alignment between patient and employer needs related to value in healthcare. This formative dialogue and research will identify opportunities to better reflect patient and employer preferences, inputs and needs in future value assessment frameworks. Research partners include: Eleanor Perfetto, PhD, MS, Elisabeth Oehrlein, PhD, MS, Michael Thompson, and Margaret Rehayem.

Since the organization's inception, IVI has put patients first in asking questions about what and how we calculate or assess the value of treatment options. I'm thrilled the Patient Advisory Council has come together and look forward to this collective input as IVI continues to explore and invest in research that puts patient perspectives at the forefront of value assessment models, while also improving healthcare decision-makers' understanding of health outcomes that matter most to patient lives.

Alan Balch, PhD CEO, Patient Advocate Foundation IVI Board Member



Collaboration with Employers

Employers as Payers for Healthcare are Important Partners

Dialogue with a broad spectrum of stakeholders in healthcare has furthered IVI's understanding of the cascade of decision contexts within which value assessment takes place. Depending on the entity charged with making decisions about one or more interventions or populations, the need for information value will change. Each circumstance may require different value assessment methods, inputs and outputs. Employers represent a poignant case in that they are commonly in a position to make decisions along with their advisors on health benefit design but often find themselves without the information needed to make an informed selection.

Wayne Burton, MD

Former CMO at American Express IVI Scientific Advisory Panel Member

Employers have an important role to play as healthcare purchasers in redesigning value assessment to make it more meaningful for employers and employees. Today's methods for assessing value don't fully incorporate real-world outcomes. As employers we can ask the right questions to bring value-based benefits that improve employee health and wellness.

Commentary: Engaging Employers in Value Assessment

IVI's Jennifer Bright co-authored a piece, writing with Mike Thompson, President and CEO of the National Alliance for Healthcare Purchasers, sharing how depression can be used as a "case study" for why employers must engage in value assessment to make the process meaningful for those who pay for care. The piece was published in *Employee Benefits News*, which reaches an audience of over 47,000 employers monthly.

Current value assessment approaches often miss the more important components of value to patients and employers, such as impact on ability to work, mode of administration and how that may impact

taking time off work, and burden on caregivers and family members. The article identifies three action steps for employers: 1) get more engaged in value assessment, 2) set firm expectations for pharmacy benefit managers and other third party vendors for benefit plans, and 3) demand "real world data" to get a truer understanding of costs, outcomes and value.

"So how do we get to a better method to asses patient-purchaser value? While depression is a good case study, this is not a battle we can fight one health condition at a time, nor one drug at a time. We need to change the entire process so that a patient-purchaser 'value lens' is applied up front. First, employers have to be more engaged..."

IVI-Major Depressive Disorder (MDD) Model

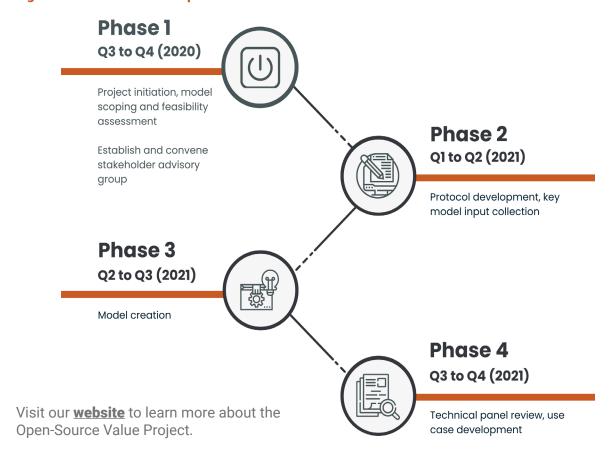
IVI has identified major depressive disorder as the focus of the next OSVP model. Strong employer and patient community awareness of the value discussion and interest in mental health is one of the key factors in IVI's choice. Given the importance of mental health in the current COVID-19 environment. IVI is accelerating the model development. Compared with prior OSVP efforts, IVI will form and engage a multi-stakeholder advisory body, which comprise the patients, employers, providers, payers and pharmaceutical companies, continuously throughout the model conceptualization and development process. This will help address one of the key challenges identified in the previous OSVP efforts, where a lack of dialogue and mutual understanding among different stakeholders during the model development process has

limited the wider application of the value assessment tools. IVI is currently identifying one or multiple research partners to build towards the IVI-MDD value tool.

Patient Preferences in Treatment for Depression

IVI is partnering with the PAVE (Patient-Driven Values in Healthcare Evaluation) Center at the University of Maryland to develop attributes and criteria for a patient-informed value assessment for treatment and outcomes among individuals with difficult-to-treat depression. Study findings will be used to influence the key modeling considerations for the IVI-MDD tool. This study will serve as a proof of concept (POC) for how patient preferences influence our understanding of cost-effectiveness measures such as the Quality-Adjusted Life Year (QALY).

Figure 6. OSVP-MDD Development Timeline



Sharing Our Learning: Value Blueprints

In 2019, IVI published a series of research briefs – *Value Blueprints* – that address relevant questions for value assessment and explore what we are learning through IVI-funded research.

What drives value for patients making treatment decisions?

Focus groups with patients diagnosed with EGFR+ non-small cell lung cancer identified key factors of value, which included affordability, side effect profile/severity, and convenience of treatment administration. The IVI-NSCLC model uses MCDA to incorporate mode of administration and side effects into assessment of value.

How does a patient factor alter assessment of value?

Analysis showed that when Value of Hope was included as a factor, the resulting assessment of value differed based on patient risk profile. Consideration of patients' risk preferences is an important component of moving toward more patient-centered value assessments.

How does insurance value impact value assessment?

Accounting for the insurance value to a covered healthy population provides a more complete assessment of value for the overall population. Insurance value offers insights into the broader value of new treatments for both treated patients and healthy individuals, who may be at risk of needing such treatments in the future.

What impact can model design assumptions have on cost-effectiveness estimates?

Models are used to integrate relevant evidence and predict outcomes and costs for healthcare interventions over time. Choices and assumptions are made when determining the structure of a model. These choices can have an impact, introducing a new level of uncertainty in the model's results. However, this structural uncertainty is frequently overlooked when cost-effectiveness analyses are preformed. Using our IVI-RA value model we were able to show that there are **28 different estimates** for the incremental cost-effectiveness ratio (ICER) based on different model assumptions. IVI is calling for cost-effectiveness analysis reports to document and acknowledge structural uncertainty in models to ensure that decision-makers relying on estimates have complete information to quide their decisions.

Do conventional value assessments address the questions most relevant to real-world decisions about treatment pathways for chronic disease?

A long-held premise of the OSVP models is that they offer the ability to move beyond a head-to-head comparison on interventions and offer more relevant analysis on sequential treatment pathways that many patients with chronic disease experience. IVI is leading advancements in modeling methods to assess the value of sequential treatments through the IVI-RA value model. While our ability to model the value of treatment sequences is currently constrained by the lack of real-world data for analysis, IVI continues to forge new partnerships that will help us improve data inputs that can inform clinical pathway design.

Visit our website to read more of the Value Blueprints research briefs.

IVI FINANCIALS

Fiscal Year January - December 2019

This inaugural IVI Annual Report documents a period of significant transition and growth for the organization. IVI received notice of nonprofit status in 2019. The financial report included below illustrates the organizational changes through the numbers. IVI maintains its public profile on Guidestar.org, including IRS Form 990 and other financial details.

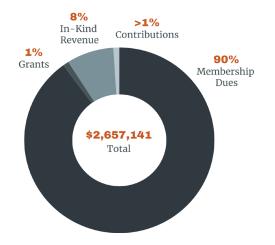
Revenue 2019

IVI recorded revenues in 2019 of \$2,657,141. This was comprised of sponsorships (or contributions from members prior to nonprofit status award), grants, membership dues, and in-kind or other donations.

Table 1, 2019 Total Revenue

Category	Amount
Membership Dues	\$2,404,291
Grants	\$30,000
In-Kind Revenue	\$227,750
Contributions	\$100
Total Revenue 2019	\$2,657,141

Figure 4. 2019 Recorded Revenue



Expenses 2019

IVI appreciates the support received from members through member dues. These resources are used to underwrite operations, research projects, and stakeholder engagement. In addition, IVI is actively raising important questions around value assessment through conference presentations, scientific meetings, and media engagement. IVI maintains an efficient and lean administrative infrastructure in order to direct resources to research and stakeholder engagement activity. Currently the proportion of resources dedicated to G&A is 16%. Revenues not expended annually are reinvested in future year research projects.

Table 2. 2019 Total Expenses

Category	Amount
G & A	\$276,057
Research Projects	\$839,021
Patient/Stakeholder Engagement	\$157,998
Media & Communications	\$272,235
Fundraising	\$167,680
Total Expenses 2019	\$1,712,991

Figure 5. 2019 Recorded Expenses



About the Innovation and Value Initiative

IVI is a 501(c)(3) nonprofit research organization committed to advancing the science, practice, and use of value assessment in healthcare to make it more meaningful to those who receive, provide, and pay for care.



IVI Foundation, Inc. 917 Prince Street Alexandria, VA 22314

www.thevalueinitiative.org info@thevalueinitiative.org