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WHITE PAPER

Dawn of a New Era: Evolving Needs, Solutions and Technology in U.S. HEOR

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I. Introduction

The U.S. health economics and outcomes research (HEOR) field has seen many changes over the last decade, including significant growth driven by payers, regulators and clinicians who are increasingly looking to Real-World Evidence (RWE) as a valuable source for patient-level data. To understand the implications of this growth, the Trinity Life Sciences Evidence Strategy team sought to gain a multi-disciplinary view on where and how HEOR experts see the field evolving and to better understand how HEOR capabilities can be best leveraged across the life sciences industry to improve patient outcomes.

Our goal was to gather HEOR thought leaders across the industry including representatives from pharmaceutical, medical devices/diagnostics and academia to weigh in on these topics. The objective was to gather perspectives on an extensive range of topics including the future of HEOR as a field, its ability to drive decision-making, its central role across the entire lifecycle and evidence generation overall—both in the U.S. and abroad. Our discussions centered around how HEOR and evidence generation will play a role in the evolution of the life sciences industry, from pharmaceuticals and biotechnology to devices and diagnostics. Most importantly, we discussed outcomes overall--including the individual and societal levels, as well as public health. Across the interviews, the discussion focused on the growing importance of Real-World Data (RWD) and specifically on data on social determinants of health (SDOH) and patient-reported outcomes (PROs).

In the paper that follows, we share with you our findings, the methods we used and most importantly, the great perspectives we heard. In addition, we offer (often in the words of the respondents themselves) insights into the current and future field of HEOR and evidence generation overall, articulating why this is an important function for any aspiring life sciences company. Through this initiative, we begin to illuminate how the healthcare industry can best utilize the HEOR specialty to unlock the potential value in a therapy or technology via rigorous analyses and well-articulated value stories.

II. Methodology

To gather a multi-dimensional perspective, Trinity recruited seven HEOR experts working in the life sciences industry (Pharma/Biotech and MedTech) and academia. These subject-matter experts volunteered their time for this project and were not compensated. Trinity thanks them for generously sharing their knowledge.

The respondents included: a Vice President of HEOR from a large pharmaceutical company, a Vice President of Data Generation & Observational Studies from a large pharmaceutical company, a Divisional Vice President of Health Economics and Reimbursement from a large medical device company, a Chief Ventures Investment Officer from a large university health ventures department who is formerly an elected voting member of a large HEOR institute, a Professor and Dean at a large university's School of Pharmacy, a Director and Professor of a School of Medicine and a Founding Dean Emeritus of a School of Medicine.

A panel of Trinity experts designed a Discussion Guide, working in partnership with a Pharmaceutical Executive with over 20 years of experience developing and implementing a wide variety of HEOR and Market Access initiatives. Questions focused on issues considered to be the most current and pressing across a spectrum of HEOR topics.

III. The Past, Present and Future of HEOR

i. **The Past Decade** > HEOR Today > The Next Decade

Capturing and quantifying value has always been the goal of HEOR. As one respondent put it, the pharmaceutical industry "*[has tried historically] to find a way to quantify the value that their products were bringing to the marketplace, [rather than only] speaking about them qualitatively… [and] individuals reached into the academic environment and created collaborations and relationships.*" These collaborations with economists and others enabled the development of the methods that have become the founding principles of HEOR.

These perspectives on the history of HEOR were further reflected in the ratings respondents provided on the importance of HEOR three to five years ago compared to today using a seven-point Likert scale, from one meaning "not at all important" to seven meaning "extremely important." All the participants indicated that the importance of HEOR has increased over time and will continue to increase in the future. However, their perceptions of the absolute importance of HEOR varied. Academic respondents were nuanced, agreeing on the field's growing importance, but were also mindful of other types of evidence and activities such as randomized controlled trials and Medical Education. Industry respondents provided similar assessments on HEOR's increasing importance. Looking forward, one respondent indicated that on the one-to-seven scale, if HEOR was a "three" in the past, it is currently at "five", and it would soon move to "nine."

ii. The Past Decade > **HEOR Today** > The Next Decade

The HEOR field has grown more specialized and, according to our panel of experts, today it has become a "*driver of commercial success.*" Methodologies have been refined, standards have been developed and guiding principles have been introduced. As one respondent noted: "*In the past, the HEOR function primarily augmented overall field dialogue. Today, HEOR capabilities play a more prominent role. The HEOR field is well positioned to drive the way businesses grow and be a strategic partner to the broader organization*." This shift to including HEOR earlier in the development process, helping to shape the value story and evidence to support a product has become more common practice today.

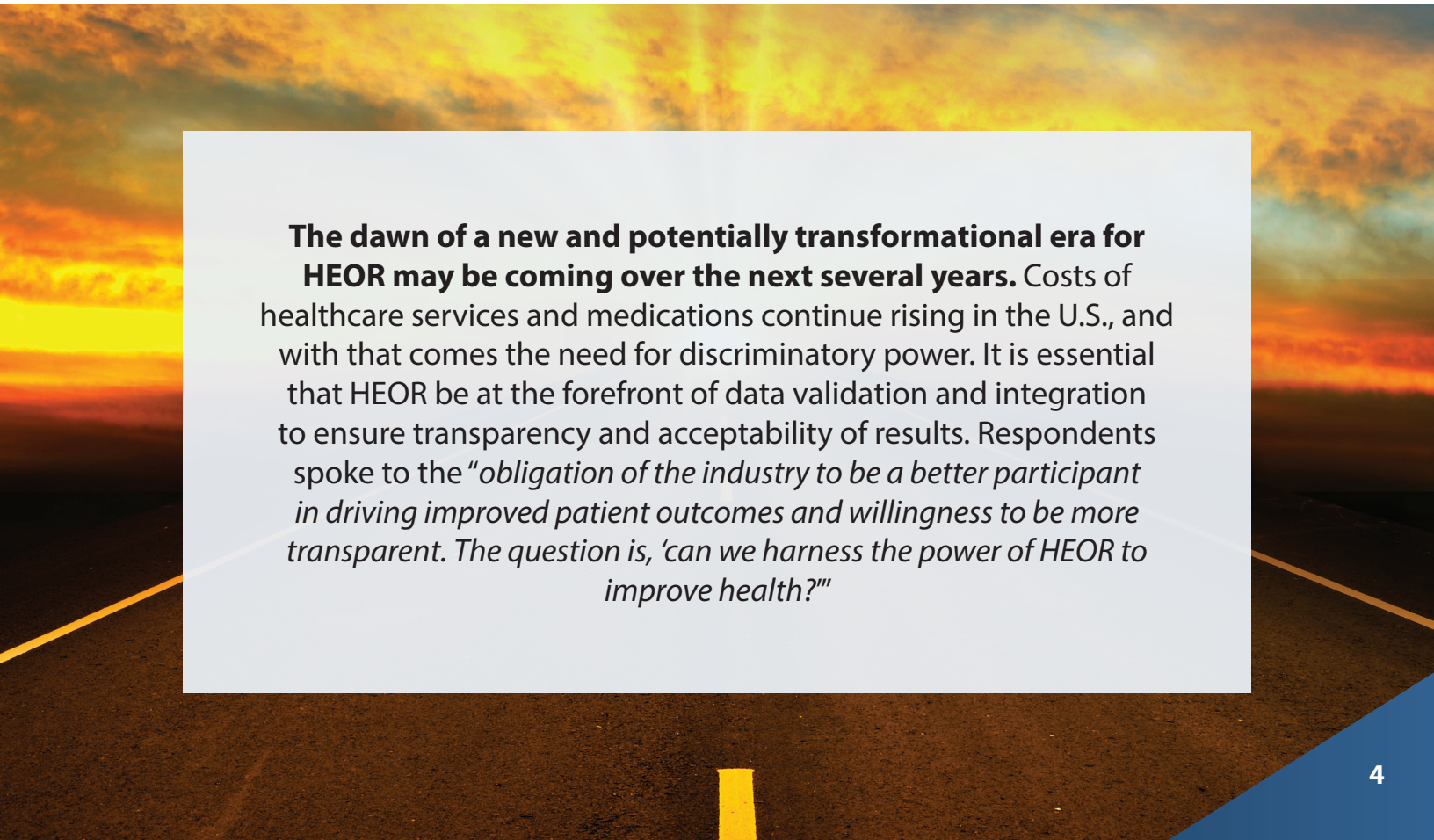
Organizations such as the Institute for Clinical and Economic Review (ICER) have matured. Databases and analytics have also improved. Leading organizations like The International Professional Society for Health Economics and Outcomes Research (ISPOR) are also charting a path for the industry, exploring and promoting new methodologies and bringing industry experts together to share ideas.

One respondent highlighted that "*the science is getting better, and the prices [of certain products] are getting higher, so the demand for HEOR will increase; the challenge is going to be ensuring that [patients and payers] have an understanding of the comprehensive value (of a product).*" With increasing standardization and the push toward value-based economic assessments, HEOR has an increasing influence on reimbursement and pricing. Additionally, one respondent commented: "*What does the success of HEOR look like? It means that the business understands their options and associated risks when it comes to evidence generation. That HEOR does their job of assessing the market from a policy and payer adoption perspective, puts the risks on the table and develop strategies to address those risks. HEOR needs to show up more proactively and play a critical role organizationally going forward.*"

The role of the HEOR professional has both expanded and become more defined over the past three to four years. Many manufacturers across the life sciences industry have formed their own data analytics groups to conduct analyses for publications in addition to existing HEOR and Market Access functions. With the formal integration of HEOR and specialized data analytics teams into the traditional structures of life sciences companies, HEOR has become a larger contributor to the development of forward-thinking strategies and responding to the needs of Payers and Regulators who are more routinely asking to see real-world evidence. With the addition of specialized data analytics teams, HEOR groups can focus more on front-line strategy. Pfizer, Merck and Johnson & Johnson have implemented data analytics groups and more are predicted in the future. According to respondents, the strategic importance of HEOR, particularly when it comes to deciding the appropriate use and utility of data, is only going to increase in the near future.

iii. The Past Decade > HEOR Today > **The Next Decade**

Over the next decade, respondents highlighted that there will be greater data availability and more high-quality data in other forms of Real-World Data (RWD), defined by one interviewee as "*any evidence that is not from pivotal or regulatory trials.*" The data sources becoming increasingly available are likely to move HEOR towards more patient-specific, personalized value narratives in the future. Additionally, practices that are presently more common in Europe, such as health technology assessments (HTA), cost-effectiveness analyses (CEA) and cost-utility analyses (CUA) will likely become more common in the U.S. There is an "*equal push from the U.S. and Europe for improving methods of these analyses and there is increased interest in implementing these types of evaluation in the U.S. with the payer audience in mind.*" Importantly, these practices evaluate not only the economic value of products but also increasingly the broader impact on quality of life (QoL), rather than cost alone.



The dawn of a new and potentially transformational era for HEOR may be coming over the next several years. Costs of healthcare services and medications continue rising in the U.S., and with that comes the need for discriminatory power. It is essential that HEOR be at the forefront of data validation and integration to ensure transparency and acceptability of results. Respondents spoke to the "*obligation of the industry to be a better participant in driving improved patient outcomes and willingness to be more transparent. The question is, 'can we harness the power of HEOR to improve health?'*"

IV. Evolving Data and Analytics

> "Payers and hospital administrators want to see their own data analyzed… they want to see their own population."

Data have always played a critical role in healthcare decision making. Historically, the primary source of healthcare data has been clinical trials, but the quantity and type of RWD available have expanded rapidly in the past 20 years. The abundance, specificity and continuously evolving nature of RWD means that even more data will be available in the future. However, with this volume of data – and new types of data - comes the need for refinement of analytical techniques and approaches to wade through the sheer amount of information available to researchers and enable the development of robust conclusions. A key contribution of HEOR experts will be understanding which data sources have the greatest utility for their specific asset, under what circumstances they should be leveraged, how they can be combined and which changes in data sources will influence healthcare in the future. More broadly, HEOR experts will need to be able to effectively communicate these concepts and their impact on analyses to non-HEOR stakeholders across their organizations.

i. Real-World Data

The data sources available for HEOR experts are varied and continue to evolve. One respondent noted that most HEOR research is performed using RWD, including disease-specific registries, patient-reported outcomes (PROs)—and, increasingly, biometric data from Internet of Things (IoT)-enabled devices and wearables used by patients. In the U.S., claims and electronic health records (EHR) data are currently major data sources. Primary data, such as studies conducted with patients or physicians, are common to help inform the treatment landscape in a disease area and burden of disease.

Respondents noted that some payers have expressed concerns that RWD can be "*cherry-picked*" and may not be representative of their member population or the broader population, and several noted the power of showing hospital administrators and payers their own populations represented in the data via partnerships with industry. As one respondent stated, "*Payers and hospital administrators want to see their own data analyzed…they want to see their own population*." As manufacturer-payer partnerships evolve, it will be the role of the HEOR function on both sides to access and analyze the right data to address these concerns. To have data be more widely accepted, respondents further advocated for the transparent validation of RWD methods, such as pre-registered statistical analysis plans (SPAs), studies and protocols. Payers are increasingly performing these analyses themselves, but one of HEOR's key contributions will be ensuring the validity, standardization, scientific rigor and transparency of the data.

ii. Data Sources

Evidence generated from PROs is of increasing importance. HCRU data from the literature has long been relevant as inputs in HEOR models, but PROs and social determinants of health (SDoH) data are receiving more attention as important inputs in their own right as the FDA is adopting a wider societal perspective when making decisions. As one respondent said, "*we need a broader perspective, a greater recognition that it's not just the pill and the price, and [we] have to be a part of the conversation of 'are we improving health and quality of life or not?*'" While useful in the eyes of some, payers may still fail to appreciate fully the value of RWD/RWE outside of clinical and EHR data sets, evidence derived from discrete choice experiments (DCEs), PROs scales

(particularly in cases when they are used outside of clinical trial settings) and disease registries. In addition, some payers view quality of life (QoL) or humanistic data with skepticism, seeing it as a way for manufacturers to differentiate products that do not meet clinical endpoints, unless the disease itself is defined by quality of life. Nonetheless, our respondents feel that the patient's perspective will become increasingly important to all stakeholders, including regulators, and the way we understand the holistic patient experience will become more nuanced as more data become available.

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One of our respondents noted that many regulatory agencies now require patient engagement in the design of clinical trials for registration because of the prevailing belief that patient input will result in better, more relevant evidence. For example, in the U.S., the FDA has a Patient Focused Drug Development Program (PFDD). The role of patients to inform observational/RWE studies conducted for informing payer decisions is less clear but some patient advocacy groups are pushing in this direction. Patient advocacy groups are also involved in generating evidence themselves to support payer decisions and are becoming more active in the value assessment and appraisal steps for payer adoption. Historically, payers have been reluctant to use patient-generated data (ostensibly for quality reasons), but most HTA agencies outside the U.S. engage patients who have the disease in question in their appraisals. P&T committees in the U.S. have not yet taken this step.

iii. Biometric Monitoring Data and Wearables

There is significant industry buzz around the data generated by wearables and IoT sensors that continuously track a wide range of patient physiological measures over time, which may help researchers understand the totality of illness for a patient and the impact of therapy. If appropriately tied to self-reported patient outcomes through surveys and co-registered information, these biometric monitoring data can be a valuable data source and an opportunity to learn about real-world effectiveness.

According to our respondents, some payers are currently skeptical of using data from wearables, but there is a significant uptake on the industry side. One respondent said that, for payers, "*it's always 'show me the clinical evidence first' … [Payers will always say] 'tell me how it's relevant. Tell me how it's changing the behavior of patients, or…supporting the patient in some way.*'" The onus will be on the HEOR expert to validate the utility of biometric monitoring data from wearables and other sensors, particularly for use in clinical trials and the regulatory environment, and the standards will likely be high. Notably, patients who are early adopters of self-monitoring may vary significantly from the general patient population, requiring correction for selection bias (although as more equipment includes biometric sensors by default, the skew in available data may decrease). One expert's summarized perspective on wearable technology is as follows: "So all of these technologies, even if they're amazing at measuring and delivering tangible improvements in health, are only as good as the behavioral actions that lead to patients using them."

on wearable technology is as follows: "*So all of these technologies, even if they're amazing at measuring and delivering tangible improvements in health, are only as good as the behavioral actions that lead to patients using them.*" HEOR experts will be critical to navigating the new world of wearables data, including establishing which metrics are important, how to quantify them and how to integrate them with other evidence from clinical trial or RWD.

Beyond direct measurement from wearables, remote patient monitoring will be increasingly utilized across a wide range of patients as treatments move to the home and other non-clinical settings. HEOR professionals will play an important and increasing role in integrating this massive flow of data to be used for clinical, regulatory and reimbursement purposes.

iv. Data Quality Challenges

A consistent talking point for all respondents was the payer requirement for HEOR evidence to be reliable, validated, transparent and relevant for their plan populations. According to our experts, there are currently no widely accepted standards in the industry on evidence quality. Requests for more comprehensive data on a larger scale are relatively recent in healthcare. EHRs, claims and other data sources were originally focused on reimbursement and regulation, not on the quality and granularity currently demanded, so efforts are underway to refine existing data, develop new data sets and the necessary complimentary analysis methods. This similarly applies to the quality and reliability of biometric data and wearables as well.

v. Generating Insights and Recommendations

RWD can generate RWE suitable for guiding regulatory and approval decisions, if analyzed effectively. Part of the challenge when using RWD, according to our experts, is creating appropriate and validated links between sometime disparate datasets. Data linkage describes when two or more sources—such as registries and claims data—are matched and common patients, treatments or encounters are identified. However, linkage errors occur often, particularly if one source is of poorer quality. Further, the entire process is complex and expensive, potentially leading to less than rapid adoption. The current thinking amongst respondents is that payers typically view linked data as less important or less valid if both claims and EHR data are available independently. This may be due to the nascent nature of linked datasets or overall reluctance by payers to fully trust these data sources over those with which they are more familiar.

Despite these challenges, data linking as a methodology can be highly advantageous for rare diseases. Linking is becoming more mainstream as processes and overall data quality improve and as more data aggregators enter this space and are providing better and more affordable data. Outside of data linking, payers are generally less familiar with—and as a result, less accepting of—machine learning and AI. Some of our respondents believe there will likely be a "*data adoption lag*", as has been the case historically with other new data sources in HEOR. Researchers driving study design do not have AI expertise, and available AI experts may not have familiarity with the complexities of healthcare data. There are significant growth opportunities, particularly in study design, once AI has a longer track record in healthcare and experts have the needed experience. As one respondent put it "*[When it comes to AI] I think we're in the early stages. [We're not] at some mature stage...Can I predict someone who has diabetes, the likelihood that they're going to have a micro macrovascular event? Not with any precision. Can I tell you, you're going to have an event of some kind within the next ten years? Yeah, sure. But that's not what our healthcare system needs for planning purposes.*" Various machine learning methods are showing promise in making the linkage process faster and more reliable. To gain trust, both the data and the machine learning process must be of verifiably high quality. As with wearables and other new data sources, our experts feel that it will be incumbent on the HEOR professional to understand the role and utility of AI-driven data and how to communicate the value of this emerging technology, both internally in their organizations and broadly to the life science community.

V. Emerging Trends

HEOR's influence has seen robust growth over the past decade and seems set to accelerate further. This is evident in the evolving role of HEOR, new analytics and insights driven by increased accessibility to data and the ways in which different industry players are starting to interact. Respondents highlighted several areas of future importance for HEOR, including:

- Growth of partnerships between manufacturers and payers in the U.S.
- Increasing use in MedTech
- Accounting for pandemic-related data disruptions
- Harmonization of U.S. and ex-U.S. approaches to HEOR
- Applications of HEOR

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i. Growth in Partnerships

Payers increasingly rely on HEOR evidence to assess new products across several attributes, including cost. Simultaneously, our experts are seeing payers forming more partnerships with pharmaceutical companies. While many of these partnerships are focused on value-based contracting, our respondents are increasingly seeing data-sharing partnerships and evidence generation that are providing more granular and specific quantification of the benefit drugs can deliver to specific patient populations. As these partnership models continue to evolve, both sides will face challenges. According to our respondents, pharmaceutical senior management generally understands the importance of these collaborations, but their expectations are often that the collaboration will happen more quickly than is possible. One respondent working in the pharmaceutical industry mentioned that "*somebody said to me, 'the most difficult part of your job must be convincing a payer of the value story for your product.' And I said 'actually, no, it's convincing our senior management that this is going to take significantly longer and be a little harder than they initially thought it was going to be.' There's still a surprisingly good deal of education that needs to be done internally*." It is likely to fall on the HEOR professionals within industry to lead the education on these collaborations and develop approaches and methods for effective, value-add partnership models.

ii. MedTech and Pharmaceutical Approaches to HEOR

When it comes to exploiting the full value of HEOR, our experts feel that as an industry MedTech (medical technology products, services and solutions) has been slower to adopt the full range of methods and evidence generation studies compared to the pharmaceutical industry. According to one expert: "*We've only had to demonstrate that we are as good as something on the market to get it out the door quickly... that's been the driving force in innovation and in research investments…In the past five to ten years you see medical technology showing up in health technology assessments… and payers ask the questions of how technologies are truly differentiated from each other and how we can justify premium pricing.*"

It is often the case that pharmaceutical companies have greater resources and incentive to use HEOR practices than MedTech companies. While there are many exceptions, MedTech often deals with a much more heterogeneous product set than drugmakers do, producing devices from CT scanners to point-of-care testing. In addition, whereas drug efficacy and safety data standards are well established, allowing clinical trial development around clearly defined endpoints, MedTech products are often approved as predicate devices or using other less-defined endpoints that preclude a quantitative assessment of effectiveness along similar parameters. A MedTech respondent said, "*we are reliant on clinical trials, and are challenged to deliver impactful real-world evidence…[and] make any meaningful conclusions about the correlation between our technology and the outcome that matters to our stakeholders.*"

MedTech is continuing to learn from the HEOR experience in the pharmaceutical industry to potentially learn both what to do and what to avoid. For example, the pharmaceutical industry lags in providing solid data with head-to-head drug comparisons and economic data that enable reliable decision making for payers, providers and other market participants. Similar standards are likely to be applied to the evaluation of MedTech evidence generation, so establishing comparative studies that provide relevant clinical data and quantitative measures of the impact on cost are key. Respondents noted that the pharmaceutical industry must focus more on value and remember that "*if patients cannot afford your drug, they are not going to take it.*" MedTech will need to continue to invest in HEOR and Market Access teams to evaluate value for each product type and establish a pathway to payment for that product type.

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iii. Long-term Effects of COVID-19 on HEOR Research

The pandemic's disruption to healthcare systems, both in the U.S. and globally, has created data gaps and disruptions as patients have interacted less with the healthcare system. Additionally, certain patients are potentially sicker vs. pre-COVID-19 because of missed preventative and other care appointments, leading to downstream outcomes that may not be identifiable for years to come. Overall, our respondents feel that secondary data (i.e., EMR or claims data) from 2020 to 2022 may be considerably less generalizable than in the past. This challenge needs to be addressed particularly for longitudinal studies across longer periods, such as 2020 to 2025. The pandemic and resulting impact on data may resonate for years to come. Our respondents feel it will partially be the responsibility of the HEOR professional to navigate this challenge and communicate mitigation approaches to their organizations. A positive result of COVID-19 is a greater recognition of SDOH, as well as understanding across manufacturers that communities influence drug selection and prescribing behavior. As touched on earlier, our respondents feel that SDOH and associated data will only become more important in the years to come.

In addition, COVID-19 has driven the expanded use of telehealth, which has become a significant source of healthcare data. Many respondents believe this trend will continue, but it is unclear how telehealth data will be used in the future or how HEOR will assess the effectiveness of telehealth initiatives. As HEOR professionals, perspective and active incorporation of new methods for analyzing and utilizing telehealth data will likely be needed today and in the future.

iv. HEOR on the Global Stage: Key Differences Between the U.S. and EU

Given the considerable differences between the U.S. and European healthcare systems, payers in these regions have different HEOR needs and expectations. The U.S. has long been a source of innovations in technologies, data sources, data linking, AI and precision medicine. However, health technology assessment (HTA) and HEOR are more formalized processes in Europe. For example, in the United Kingdom, the National Institute for Health and Care Excellence (NICE) is part of the government and makes reimbursement decisions based on cost-effectiveness analyses, but no analogous government group exists in the U.S. As HEOR becomes more important in a variety of healthcare decisions, cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) are becoming more common and accepted; however, one respondent noted that the U.S. is not leading but is instead "*being dragged*" toward these types of analyses. While not a government entity, the Institute for Clinical and Economic Review (ICER) has grown to fill the void as a neutral third-party information provider in the U.S. ICER's recommendations are widely respected—but it is a private organization, with no authority over reimbursement or regulatory decisions. Although respondents indicated that ICER's influence is growing over time, due to the budget impact perspective of the U.S., it is anticipated to have only advisory influence in the U.S. One respondent summed up the distinction as "*which perspective are we going to be using? In Europe, it's all about the societal perspective. In the U.S., it's all about the business bottom line.*"

VI. The Future of HEOR Leadership

Participants agreed that HEOR will have a more prominent seat at the table in the future--from setting the strategy to negotiating the tactics and being responsible for the pull-through of evidence generation. One respondent said that HEOR leadership will be expected to play the "*data expert*" roles and be able to understand and explain a variety of data and analytics approaches to others. As one expert put it "*HEOR folks are going to be very busy analyzing the gene therapies, the cell therapies, the rare disease drugs and the new vaccines and therapeutics, and it's an exciting time, I mean, compared to 20 - 30 years ago when we were still looking at 'me too' drugs for hypertension and statins.*"

It is an exciting time to be a HEOR professional, but not one without its challenges and needs for continued refinement in techniques and methodologies in the face of increasingly complexity.

- New technology will enrich the data stream and transform what evidence is available and the utility of that evidence from an HEOR perspective. The vast volume of biometric monitoring data from wearables and other IoT sensors has the potential to be integrated with other data sources to provide a more comprehensive picture of how patients respond to treatment, including how it affects their behavior in the context of their social surroundings. For example, these data could provide a deeper knowledge of the underlying causes of non-adherence to therapies and, with proper communication, enable patients to participate more in their treatment.
- HEOR leaders will also be essential in assessing the risks of data integration, particularly when enabled by sophisticated AI algorithms whose functioning, in the view of some respondents, is opaque. Health outcomes researchers and analytics experts will have to take a leadership role in developing best practices in combining data sources, implementing analytics, and exploring the full potential of these increasingly rich data.

When asked to rate the field of HEOR's relevance in the past, present and future, one respondent noted that "*if HEOR was a 'five' before COVID-19, today, with more limited or dispersed funding and the need for making a data-driven return on an investment decision, it is a 'nine' now. As data science becomes more sophisticated, it can be an 'eleven' tomorrow.*"

VII. Conclusion

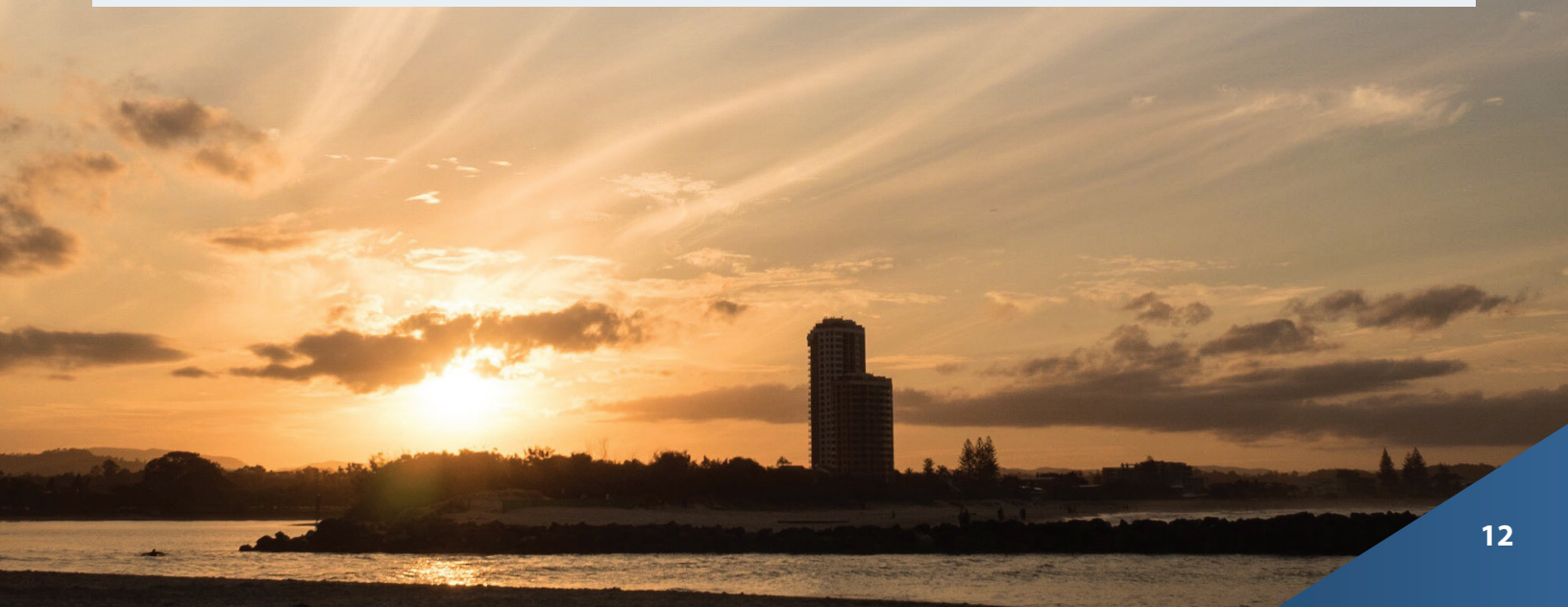
This series of interviews illuminates the current trends and viewpoints of HEOR from a diverse set of healthcare industry leaders:

- Life Sciences is a complex industry, and success is contingent on cross-functional teams with domain knowledge and expertise.
- The role of HEOR has never been more important for healthcare decision making, and there is consensus that earlier utilization of HEOR in the product life cycle is associated with better results for industry, payers and patients.
- As the field of HEOR continues to evolve, our experts believe that the role of the HEOR professional will also need to evolve—and is likely a role that is only going to grow in terms of relevance and importance.

It is safe to say that "HEOR has arrived!"

Furthermore, it is here to stay—engaging with multiple cross-functional stakeholders, actively debating and prioritizing strategies from early developmental stages to post launch activities, executing high-impact studies and communicating the value story, thereby driving company success.

And then there is the best outcome of all – high-value therapies in the hands of patients who need them. A true win that resonates with industry and patients.



Authors

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Matt has over 20 years of life sciences consulting experience. During his career, Matt has worked with both pharmaceutical and medical device clients across business/commercial, HEOR and medical communications. Matt focuses on driving strategic insights for clients and delivering innovative HEOR solutions within the broader strategic context of product development, market access and market shaping/medical communications. Most recently, Matt has been instrumental in the novel application of Real World Evidence to inform product development, quantifying unmet clinical needs and raising overall market awareness. Matt earned a dual degree from Bowdoin College in Government and Environmental Science and an MBA from the Tuck School of Business at Dartmouth College.

Jeff Skaar, PhD | Managing Director, Evidence Strategy

Jeff supports pharmaceutical, device, and diagnostic companies in demonstrating and communicating the value of their products. His work is informed by broader experiences in market access and business and clinical strategy, allowing him to craft health economics and outcomes research solutions that dovetail with overall strategic plans for products across their life cycle stages. In addition to overall strategic and/or evidence generation plans, Jeff drives the tactical execution of these plans, bringing a deep understanding of multiple disease states and markets, including psychiatric disorders, rare neurological diseases, osteoarthritis, orthopedic surgery, movement disorders, and infectious diseases. Jeff received an A.B. in Molecular Biology from Princeton University and a Ph.D. in Virology from Harvard University.

Abby Silber, MPH | Associate Principal, Evidence Strategy

Abby has 5+ years of experience in life sciences consulting and focuses on Health Economics, Outcomes Research, and Evidence Strategy. She leads strategy and health economics and outcomes research (HEOR) projects, including systematic and targeted literature reviews, economic models, value dossiers, primary research studies, value proposition development/evidence planning, and studies utilizing large real-world datasets. From a therapeutic area perspective, Abby has experience in rare diseases, pulmonology, gastroenterology, cardiology, oncology, gene and cell therapy, and medical devices/diagnostics. Abby has a BA and a Master of Public Health degree from Boston University.

Ellie Goldman, MPH | Consultant, Evidence Strategy

Ellie focuses on a range of Health Economics and Outcomes Research projects. She has therapeutic area experience in rare disease, as well as experience with quantitative and qualitative research, systematic literature reviews, epidemiology, and strategic work. Ellie has a BS from Boston University as well as a Master of Public Health degree from Columbia University.

Vipan C. Sood, MBA, RPh, MRPharmS | Health Economics and Outcomes Research (HEOR) Executive

Vipan C. Sood is known globally as a strategic, results-driven pharmaceutical business leader offering deep experience and broad expertise in Healthcare Economics and Outcomes Research (HEOR), Medical Affairs (MA), Market Access & Reimbursement (MA & R), and Real-World Evidence / Real-World Data (RWE/RWD) platforms. Throughout his accomplished career, Vipan has combined his business acumen with a diverse clinical background to achieve strong revenue growth and profitability, drive operational excellence and ensure brand awareness. He led several global teams that achieved sustained market success and long-term growth. Vipan currently serves on the board of directors of the Innovation and Value Initiative (IVI), an independent, nonprofit research organization that puts patients at the center of value assessment to advance the science, practice, and use of all health technology assessments. Vipan has a degree in pharmacy from Robert Gordon University (Aberdeen, Scotland) and an MBA from the University of Illinois.

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Trinity's Evidence Strategy Focus

In today's competitive markets, the challenge is not only to articulate and quantify the value of a product—but also to differentiate it from competitors and the existing standard of care, to support a strategic price point and to ensure a successful medical communication, market access and reimbursement strategy.

Trinity's Evidence Strategy team helps clients build and **develop** a compelling value story, **demonstrate** must-have evidence and drive scientific **dissemination**:

- Critical Evidence Review & Gap Assessment
- Evidence Generation Plan & RWE Roadmap
- Medical Chart Audits, BoI & Patient Journey, HCP & Patient Choice / Preference
- Systematic Literature Reviews
- Predictive Analytics & HECON Modeling
- KOL Mapping and Engagement
- Publications Planning & Scientific Dissemination (Posters/Manuscripts)
- PIE Deck / AMCP Dossier / GVDs / Objection Handler
- And much more…

For more information, please contact us at info@trinitylifesciences.com.