WHITE PAPER

# Patient Outcomes Impact (POI™) metrics: A new way to assess patient-centered investments

Proof-of-concept study demonstrates the power of outcomes metrics

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In recent years, the life sciences industry has recognized the need to embrace patient centricity and deliver value beyond return on investment (ROI). Yet the industry has struggled to measure the true impact for patients. Instead, organizations more regularly measure activities as a proxy for impact, leaving a gap in understanding of where and how they have influenced change. We aim to change that.

ZS's long-term ambition is to develop an all-encompassing, universal metric that can be used across therapeutic areas and companies to index, assess and compare the impact of patient-focused investments on outcomes. As a first step to developing this measure, ZS developed an approach to Patient Outcomes Impact (POI™) measurement. This approach helps organizations identify metrics that are important to businesses and patients alike. It also outlines a robust analytical approach that helps organizations attribute impact to their patient-focused activities.

To demonstrate the feasibility of applying the POI metrics framework to life sciences investments, ZS performed a proof-of-concept study to understand how four unbranded disease awareness campaigns in the cardiovascular space influenced diagnosis, diagnostic delay, treatment and treatment delay. The analysis uncovers significant patient-focused impact created by each of the campaigns and identifies impact gaps where additional efforts are required to further drive improved outcomes for all. Ultimately, we demonstrate life sciences organizations can leverage POI metrics to compliantly measure the patient-focused impact of life sciences activities, including nonpromotional activities that should not be measured by ROI.

# As expectations evolve, so does the pressure to show impact

If you ask the CEO of just about any life sciences organization how investment into a product or workstream affects the bottom line, they will have an answer in an instant. If you ask that same CEO how those investments benefit patients, the answer is not nearly as clear. Yet just about every CEO of a life sciences company will tell you that they are patient-centric at the core and that they exist to help improve patient experiences and outcomes. But it's been hard to measure and demonstrate patient impact in a consistent, quantitative way.

The expectations of life sciences leaders from all involved stakeholders—regulators, payers and patients—are changing. No longer is it sufficient to develop even a superior drug or revolutionary device, as we saw during the height of the blockbuster boom. Regulatory bodies emphasize the need for patient experience data and expect patient-reported outcomes to be incorporated into submissions. Payers, too, are slowly shifting to value-based contracting, signaling a desire to move past using clinical outcomes as the sole criterion to evaluate success in healthcare. Perhaps most importantly, heightened consumerism in healthcare consistently drives life sciences to do more—to deliver more for patients. Today we are living in the age of experience, where value is derived not only from the functional benefits of the treatment, but also from how treatments are accessed, administered and received.

As market forces prompt the industry to shift toward patient centricity, it has become increasingly necessary to understand how patient-focused investments influence patient outcomes and drive value for patients. And, as we see continuing pressure on the industry around pricing, financial performance and the need to deliver more efficiently, every dollar spent receives greater scrutiny. What's more, there's a risk of turning back the tide on patient centricity if organizations cannot demonstrate the meaningful impact of their patient-centric investments.

# The challenge with existing approaches to impact measurement

Understanding the anticipated ROI of potential investments enhances an organization's ability to make critical decisions. Furthermore, generating a consistently positive ROI results in significant opportunity for organizations to innovate, for employees to grow and for consumers to access products and services.

But for businesses in life sciences, most of which have an organizational mission to improve the lives of patients, ROI alone does not capture the full value of their activities. To truly assess how well they are affecting the lives of consumers, life sciences companies need to complement financial metrics with indicators that reflect the health outcomes and well-being of the people they serve—the patients. Life sciences organizations need to continue to track their activities closely, but they also need to understand how such activities benefit patients. These kinds of quality metrics are not new. But none are built for life sciences.

ROI is a critical aspect of success measurement; however, nonpromotional functions such as medical affairs and patient support programs (PSPs) should not be evaluated using profitability metrics. If promotional metrics are used, it could compromise the ability of a nonpromotional function or activity to compliantly adhere to regulatory standards and guidance that applies to the function or activity. No ROI-like consensus exists for what constitutes accurate impact measures across these functions. In lieu of ROI, nonpromotional teams often rely on tracking inputs rather than measuring outcomes. But how do these or any life sciences efforts ultimately affect the patient?

The truth is that today, we don't definitively know. That's where our POI journey—our quest to find out and ultimately redefine how we measure success, by including the impact on the person, the patient we seek to serve—begins.

# Defining POI metrics

Our vision is to develop an all-encompassing, universal POI metric that can be used across disease areas and companies to index and assess the impact of patient-focused investments on patient outcomes, including and especially those most important to patients themselves.

In the future, this standardized POI metric will help organizations make decisions on which therapeutic areas to invest in, which functions to bolster and which approaches to patient centricity lead not only to business impact, but also to improved outcomes for people tackling an illness or injury. While a universal POI metric will never replace ROI, we believe that it will one day feature prominently in the decision-making of senior leaders in life sciences and grace the covers of annual reports.

To achieve such a bold vision, the universal POI metric must possess certain characteristics, resolve the issues of existing measurement approaches and address the dual purpose of life sciences companies. POI measurement, therefore, must start with the outcomes most important to patients and balance those important to the business in a compliant way. Measures should operate across the enterprise and be valid for both promotional and nonpromotional activities (for example, for both marketing impact and medical impact). While standardization is key to ultimately developing the universal POI metric, we must allow some flexibility for organizations to measure varying types of investments, from things like improving supply chain efficiency to disease awareness that accounts for nuances of a therapeutic area.

For example, the impact of a more reliable cold chain might be significant for cell and gene therapies, but it's irrelevant for treatment of chronic kidney disease or heart failure. Similarly, investments in training medical teams to support providers in recognizing the signs and symptoms of a rare disease will not translate to more prevalent conditions like Type 2 diabetes. Lastly, the POI metric should not be so complex or obtuse that organizations will not be able to identify the data to measure it. It's therefore critical that POI measures must begin with the data we have today and evolve over time.

We must recognize that getting to a universal POI metric is a journey. For today, it's critical that organizations begin to think about the set of POI metrics that can in the future be weighted and aggregated to inform the patient-focused correlation to ROI.

As a starting point, ZS developed a framework and a set of POI domains that help the industry take the first steps toward a holistic measure. Collaborating with our clients, patient advocates and leading thinkers in patient centricity, we defined seven dimensions through which organizations can assess the contribution of investments and activities on patient-focused outcomes:

- **Disease prevention:** Indicators of the extent of delay or avoidance of disease
  - **Example:** Number of people undergoing disease screening; number of people receiving immunizations
- **Clinical outcomes:** Measurable changes in symptoms, presence of disease and ability to function or overall health
  - **Example:** Morbidity, mortality rates; disease progression

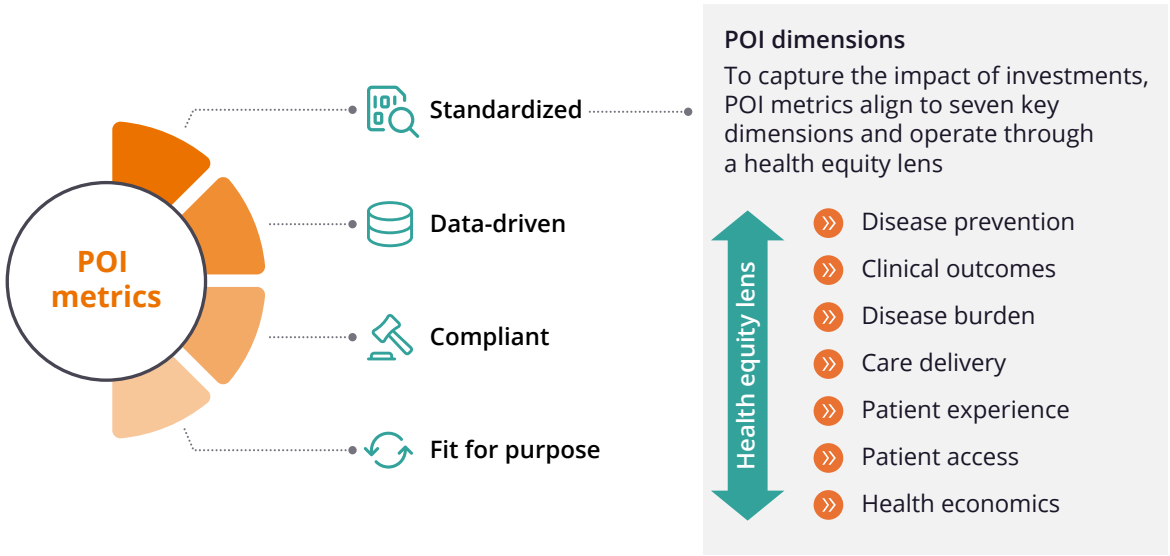
- **Burden of disease:** Impact of a health problem or disease on an individual or population
  - **Example:** Incidence and prevalence of disease and disease remission (for example, oncology)
- **Patient experience:** Subjective perception or understanding of an individual or population of the sum of interactions with care and or treatment
  - **Example:** Satisfaction with healthcare support mechanisms; level of effort
- **Patient access:** Ability to use or obtain healthcare services or treatments
  - **Example:** Time to specialist evaluation following diagnosis; fill rate or abandonment rate for a medication
- **Economics of health and care:** Cost and spending on health and care-related items
  - **Example:** Medication adherence; utilization of diagnostic resources
- **Care delivery:** Understanding of the effectiveness or efficiency of healthcare
  - **Example:** Number of primary care or specialist visits per year; time from diagnosis to treatment initiation

Across each dimension, a vast array of data already exists, much of it in-house at life sciences companies. For example, information on things like HCP visits, diagnoses and prescription fills can be found in insurance claims, while EMR data is often a good source for diagnostics and immunizations. The Centers for Medicare and Medicaid Services and the National Institutes of Health maintain publicly available databases that cover a wide variety of topics including social drivers of health, disease incidence and prevalence and cost of care, among others. Primary market research, such as qualitative interviews and quantitative surveys, can be used to generate data for specific populations (for example, those with rare diseases where databases do not exist) or specific dimensions, like patient experience.

FIGURE 1:

## In 2022, ZS developed POI metrics to help assess how the industry's investments affect patients' lives

**By using a standard framework approach with POI metrics, the life sciences industry can apply advanced data methods to understand the true impact of its efforts.**




The combination of the dimensions to measure will differ by program and by therapeutic area, but at its core, defining POI metrics for a program or initiative requires three equally critical components:

**Clear alignment to organizational strategy:** Any outcome worth measuring must inform a function's ability to deliver on organization, therapeutic area or brand-level strategic objectives. It additionally must be directly linked to the change an individual intervention or program is looking to create.

**Compliant with respect to impact measurement for nonpromotional activities.** POI metrics must reflect the objectives of functions, such as medical affairs, PSPs and key account management. That is, selected measures cannot and should not suggest measuring the impact of an activity using promotional outcomes.

**Ability to be measured and tracked using available or obtainable data.** Unlocking the ability to use a given POI metric requires three types of data:

- **Intervention data:** Captures details of a program, including type of activity, content and channel used, frequency of engagement and recipient of intervention
- **Patient segment data:** Captures information on the ultimate beneficiary of an intervention (for example, patients) and associated demographic information that can be used to define specific patient cohorts and illuminate outcome differences between those groups

- **Healthcare outcomes data:** Captures changes in patient status, for example, via claims, EMR, remittance, hospital or primary market research data

ZS has often heard from our clients that defining strategy-aligned, nonpromotional metrics that are accurately and holistically measurable is a challenge. For example, proactive alignment of an intervention to a strategic objective may not have explicitly occurred, blurring the lines between activity and expected outcomes. Data standards across interventions and functions are not uniform, and there is variability in data capture across different disease states. Further, what may be compliant for one therapeutic area does not necessarily translate to another. While these are real challenges, none are insurmountable and none outweigh the value that having the impact of patient outcomes can provide to life sciences organizations and their stakeholders.

# Our proof-of-concept study to understand patient benefit

Taking the first step on our journey to a standardized, weighted POI metric, ZS pursued a proof-of-concept study to explore the feasibility of compliantly using real-world evidence to understand how patients benefitted from nonpromotional efforts launched by a handful of pharmaceutical organizations. The aim of this undertaking was not to be all-encompassing; that is, we did not aim to understand every outcome, every nonpromotional offering, every channel. Rather, we sought to:

- Develop a structured approach to impact measurement using multiple advanced data analytics techniques
- Pursue analysis with data available to all life sciences organizations—and define data needs for future iterations
- Demonstrate the feasibility and meaningfulness of establishing a causal link between life sciences efforts and shared outcomes of interest

For our proof-of-concept study, we opted to evaluate the impact of unbranded disease awareness campaigns. As part of our selection criteria, we sought to assess campaigns for which intervention data (such as launch, run time, target populations, geographies or channel mix) were available in the public domain. Further, we aimed to assess campaigns for which there were no major market events occurring during the campaign run period, to minimize the effects of proprietary actions such as branded promotion.

We identified three critical criteria for evaluation of specific unbranded disease awareness campaigns: high therapeutic area unmet need; diverse campaign characteristics (for example, rare to prevalent disease, broad channel mix, disparate U.S. geographies); and minimum one-year run time. Using these guidelines, we selected four campaigns for evaluation: Voices for the Heart (Pfizer); Matter of Moments (Pfizer and Bristol Myers Squibb [BMS]); Hear Your Heart (Eli Lilly and Boehringer Ingelheim); and Keep It Pumping (Novartis).

FIGURE 2:

## About the campaigns

| Campaign | Sponsor organizations | Condition | Demographic focus | Campaign start date |
|---|---|---|---|---|
| **Voices for the Heart** | Pfizer | Transthyretin amyloid cardiomyopathy (ATTR-CM) | Black, African American and Afro-Caribbean individuals | 2021 |
| **Matter of Moments** | Pfizer, BMS | Atrial fibrillation (Afib) | Age 65+ | 2018 |
| **Hear Your Heart** | Eli Lilly, Boehringer Ingelheim | Heart failure | Black and Latina women | 2022 |
| **Keep It Pumping** | Novartis | Heart failure | None | 2016 |

To ensure standardization of impact measurement across the campaigns, we first set out to identify appropriate POI metrics that could be commonly measured across the four disease awareness campaigns. Using information available in the public domain, we established five POI metrics that we believed to be commonly aligned to campaign objectives: number of diagnosed patients (disease level); number of treated patients (across all treatments, market basket level); treatment type (class level); diagnostic delay; and treatment delay. We were fortunate to have the opportunity to interview patients who confirmed our hypothesis that these outcomes are important and of interest to people actively diagnosed with cardiac disease.

Having established target POI metrics, we then set up our analysis. Our approach consisted of five steps: data validation, patient identification, test group development, control group identification, and matching and test-control analysis.

1. **Data validation:** Symphony claims data (Symphony Health, an ICON plc Company, IDV®, January 1, 2014, to December 31, 2022) was cleaned and evaluated for completeness. Capture rate was validated using ZS benchmarks.

2. **Patient identification:** To identify appropriate patients for analysis, business rules detailing inclusion and exclusion criteria were applied to the Symphony data set. Using these business rules, we were able to ensure inclusion only of patients with a confirmed

diagnosis (for example, validated by multiple diagnoses 90-plus days apart). Patients with presumed misdiagnosis or comorbid diagnosis believed to preclude eligibility for standard-of-care therapy were excluded. Patient identification occurred for three conditions: ATTR-CM, Afib and heart failure.

3. **Test group development:** Test groups for analysis were separately established for each campaign. These test populations accounted for multiple campaign-related factors, such as location (national versus local), demographic focus and campaign launch and run dates.

4. **Control group identification and matching:** Similar to test group development, appropriate control groups were established at a campaign level. Variables leveraged to define control groups differed on account of campaign design. For example, Voices for the Heart leveraged local, in-person events; as a result, test-control pairing could be established on the basis of geography. Contrastingly, publicly available information regarding Hear Your Heart did not reveal distinct geographical campaign nuances; in that case, test-control pairs were defined and matched using non-location-based demographic factors.

5. **Test-control analysis.** Multiple models were leveraged (causal inference, differential regression analysis) to assess for uplift between test-control pairs. Detection of impact was affirmed in the setting of agreement across analytical methodologies.

# Results: Seeing shifts in metrics

Our POI analysis revealed three key themes:

First, we saw that across the campaigns, there was more often a shift in treatment-related POI metrics than diagnosis-related outcomes (see Figure 3). Second, patient populations belonging to a campaign's demographic focus were not the only ones to see improvement in diagnosis or treatment; rather, the impact extended beyond demographic borders. And third, evaluating impact using POI metrics uncovered impact gaps that otherwise may have gone unrecognized and unaddressed by future industry efforts.

Let's take a closer look at the implications of these themes for pharma and for patients.

FIGURE 3:

### Improvement in POI metrics as a result of unbranded disease awareness campaigns

| Positive change in... | | Voices for the Heart | Matter of Moments | Hear Your Heart | Keep It Pumping |
|---|---|---|---|---|---|
| **Outcomes** | Diagnosis | ✓ | | | |
| | Diagnostic delay | ✓ | | | |
| | Treatment | ✓ | ✓ | ✓ | ✓ |
| | Treatment delay | ✓ | ✓ | | |

# Shifting treatment patterns is more likely than boosting diagnosis

Unbranded disease awareness campaigns aim to increase awareness of a disease, encourage early detection and inform people about symptoms, risk factors and available treatments. By focusing on the disease itself rather than a specific treatment, these campaigns can foster a broader understanding and prompt individuals to seek medical advice, ultimately (in theory) leading to both enhanced diagnosis and treatment of the disease.

Interestingly, our analysis demonstrated that only Voices for the Heart generated an increase in diagnosis. Specifically, we found that the campaign was responsible for a 12% increase in ATTR-CM diagnoses per month in the year following its initial launch. We can't be sure why Voices for the Heart achieved this impact whereas other campaigns didn't. But it's notable that the campaign sought to raise awareness of ATTR-CM, a rare disease, whereas the

remaining campaigns addressed prevalent disease states (Afib, heart failure). In addition, Voices for the Heart's unique approach to form community partnerships with local leaders, medical schools, churches and health systems in 16 U.S. cities may have led to differential impact on diagnosis.

We were also able to demonstrate that all four of the campaigns evaluated directly led to increases in treatment across the populations already diagnosed with ATTR-CM, Afib or heart failure. We hypothesize that impacting treatment decisions for patients already diagnosed with a condition can be more straightforward and rapid than helping a patient reach a new diagnosis. Whatever the explanation, helping patients receive the treatment they need—as evidenced, for example, by an increase in anti-coagulant use of 4.6% seen as a result of Matter of Moments—is demonstrative of a significant positive impact on patients' lives.

# Broad patient groups can benefit from targeted unbranded disease awareness campaigns

As we've previously noted, three of the four campaigns evaluated sought to preferentially focus on demographic cohorts disproportionately affected by the condition for which they sought to raise awareness. We demonstrated that each of these campaigns did, in fact, deliver impact within these demographic cohorts. Take, for example, the impact on diagnostic delay seen as a result of the Voices for the Heart campaign. Black patients in cities where an in-person event was held reached ATTR-CM diagnosis four weeks faster than those in cities where the campaign did not run. But impact was not limited to the Black, African American and Afro-Caribbean population. Non-Black patients, too, saw a decrease in diagnostic delay by two weeks, deriving benefit from a campaign not expressly designed for them.

Similar cross-demographic effects were seen in treatment changes resulting from Hear Your Heart. Our analysis showed that as a direct result of the campaign, 2.2% of individuals in our sample had at least one drug pertaining to guideline-directed medical therapy.[1]

While there was a slight predilection for additional medications to be added to the regimens of Black and Latina women, this effect was distributed across patients of all genders, races or ethnicities and ages. We believe this has significant implications for planning and execution not only of unbranded disease awareness campaigns, but also for any investment the life sciences industry makes. Tailoring communications, outreach and efforts doesn't exclude population segments from seeing positive impact. Rather, it enables organizations to invest where there may be the greatest need, while still seeing a broader positive impact.

[1] Guideline-directed medical therapy was assessed per the 2022 AHA/ACC/HFSA Guidelines for the Management of Heart Failure. This included use of 1) renin-angiotensin inhibition (angiotensin-converting enzyme inhibitor, angiotensin receptor blocker (ARB), or angiotensin receptor/neprilysin inhibitor [ARNi]); 2) beta blocker; 3) sodium-glucose cotransporter 2 inhibitors (SGLT2i); and mineralocorticoid antagonists (MRA) for heart failure with reduced ejection fraction (HFrEF) or 1) ARB or ARNI; 2) SGLT2i, and MRA for heart failure with preserved ejection fraction added to their heart failure regimen.

# POI metrics can highlight impact gaps where life sciences still has work to do

In addition to the clear positive impact our analysis was able to attribute to the unbranded disease awareness campaigns by using our POI metrics, the analysis too uncovered care gaps—areas of opportunity where some impact was felt, but there was room for more.

Consider, for example, the change in guideline-directed medical therapy drugs that occurred as a result of Keep It Pumping. While this particular campaign did not selectively focus on a particular demographic experiencing an unmet need in heart failure diagnosis or care, we were able to detect a significant increase in the number of GDMT therapies initiated in white, Black and Latina women (0.4%, 0.5% and 1.1%, respectively) as a result of the campaign. There was insufficient evidence, however, to demonstrate an increase in GDMT for Asian women.

This finding is particularly important given that in the two decades preceding the launch of the Keep It Pumping Campaign, Asian American women saw significant increases in age-standardized mortality rates (2.5% per year in Filipina American women, 4.5% in Asian Indian American women, 3.2% in Japanese American women and 7.5% in Vietnamese American women). Recognizing this impact gap can help organizations refine their strategy to better address the treatment journey of an underserved population cohort.

Similar examples of impact gaps were seen across each of the campaigns. While Hear Your Heart resulted in a 12% increase in ATTR-CM diagnosis among Black individuals, there was no detectable change in the number of Black patients initiated on treatment for the disease. Delay between Afib diagnosis and anti-coagulant initiation decreased by nearly 10% for patients aged 50-64 as a result of Matter of Moments, but patients 65 and above did not experience any reduction in treatment delay.

Hear Your Heart saw an increase in guideline-directed medical therapy drugs initiated on patients who were already taking one or more treatments for heart failure but did not see a lift in initiation of new regimens for treatment-naïve patients. It's important to recognize that one unbranded disease awareness campaign—or any one life sciences intervention—cannot address every gap in care. Rather, detection of impact gaps reveals opportunity for future tailoring of strategy to ensure no patient is left behind.

# Limitations of this study

The aim of this proof-of-concept study was to demonstrate the feasibility of using real-world data and POI metrics to capture the impact of unbranded disease awareness campaigns in a compliant manner. However, we identified several limitations during our investigation.

First, the study was constrained by data limitations. Only publicly available intervention data was used and therefore the exact objectives of each campaign were inferred, but they were not explicitly known. This lack of precise data may have affected the accuracy of our analysis and the conclusions drawn. Furthermore, we did not have access to direct intervention data.

We inferred exposure to a campaign based on geography, time period and channel mix, for example, but we could not directly verify campaign exposure.

Second, we did not have access to the financial investments made into each campaign. This limitation hindered our ability to perform a comparative assessment of the impact across different campaigns accurately. Without knowing the scale of investment, it's challenging to correlate the extent of campaign reach and effectiveness with the resources allocated.

Lastly, the scope of this study was limited to the United States and did not encompass a global perspective. As a result, the findings may not be generalizable to other regions with different regulations, patient populations and data environments.

# Implications and the road ahead for POI metrics

Our proof-of-concept study demonstrated the power of using POI metrics to uncover significant insights about where programs are successful. It also revealed specific opportunities to engage the healthcare system to have truly meaningful outcomes across patient groups. Imagine the profound impact possible when we connect investments and activities to the ways in which they change the dynamic for patients. When used for decision-making, POI metrics have the power to hold all of us accountable for delivering on the promise we make when working in life sciences: to improve the lives of people dealing with conditions and managing their illness and care.

Establishing a universal POI metric will require a great deal of experimentation and evaluation; the important thing is that we start on the journey and don't wait for the perfect moment. Today, most use cases for POI metrics are at the therapeutic area and activity level in nonpromotional activities. They range from scientific exchange led by field medical teams to clinical nurse educators to key account management with integrated delivery networks or engagement with patient advocacy groups and patient support programs. As we continue to build understanding of impact by therapeutic area, activity and function, we will be able to further standardize the POI metric and assign weighting to various elements. This will allow for comparison of a standardized POI metric first across functions, then across therapeutic areas and in the future, across organizations around the world.

We sometimes hear an inclination from our clients to wait to relegate such measurement to another team with more budget or dismiss the power of POI metrics as an emerging process. But, to truly change the experience and outcomes for patients, organizations must start reframing their thinking and approaches now or risk falling behind. Many of our clients have already found success by layering POI metrics into measurement activities they are already pursuing, such as marketing mix modeling, patient support measurement or the impact of medical affairs activities. We believe that in the future, POI metrics can help fuel a patient-focused mindset shift that creates changes within the organization and the industry in profound ways.

# About the authors

**Sharon Suchotliff** leads ZS's patient centricity work in the U.S. She brings over 15 years of marketing communications experience across a broad range of categories, from fashion and lifestyle to pharma and healthcare. Sharon has developed and implemented strategic solutions that combine marketing efforts with patient support programs and a focus on patient experience for pharmaceutical, biotech, OTC and wellness clients.

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# About ZS

ZS is a management consulting and technology firm that partners with companies to improve life and how we live it. We transform ideas into impact by bringing together data, science, technology and human ingenuity to deliver better outcomes for all. Founded in 1983, ZS has more than 13,000 employees in over 35 offices worldwide.

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