

State of the Industry Report

Leveraging benefit-risk information to achieve better outcomes



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Executive summary

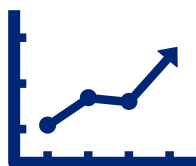
There is increasing awareness about the need for all health care stakeholders to focus on patient outcomes, with the goal of improving health, addressing disparities, and lowering the cost of health care. For many health care interventions, there is a substantial body of evidence about benefits and risks, and increasing evidence about comparative effectiveness. However, there is a significant variation in how different stakeholders, such as life science organizations, regulatory agencies, providers, health plans, and patients understand and measure benefit and risk. The different values and perspectives of stakeholders likely mean that we may not arrive at a single benefit-risk approach. That said, there is ample opportunity for better communication and understanding of benefit-risk information across stakeholder groups.

Promoting greater awareness and leading communication might be the role of an “integrator,” which could share leading practices, benefit-risk information, and clinical evidence as the foundation to guide stakeholder discussions. More communication and consistency would create greater alignment and focus, increasing potential for clinical trials that address questions relevant to different stakeholders and bringing therapies that improve outcomes to market more quickly.

This report discusses drivers that emphasize focus on outcomes, the variety of stakeholder perspectives on benefit-risk, and ideas to gain greater collaboration, communication, and innovation across the health care industry. Findings in this report are meant to encourage greater stakeholder dialogue between life science organizations, regulatory agencies, and health plans to identify methods for greater collaboration and better use of benefit-risk information to enhance health and patient outcomes.

Current state

Change drivers pushing health care for better outcomes



Rising health care costs: Health care costs are growing and health plans are putting pressure on providers and life sciences organizations to not only control their costs, but demonstrate value—that their patients have positive outcomes of care and a better experience. Medicare, Medicaid, employers, health plans, and providers are experimenting with new payment models that explicitly reward participants for controlling costs and improving outcomes.



Consumer demands: Consumers are dissatisfied with health care. Deloitte consumer surveys find that consumers are increasingly open to getting care from ambulatory clinics and clinics located in retail drug chains, which offer care that is convenient and potentially less expensive. Consumers are facing higher cost sharing as their employers shift to benefit designs that feature large deductibles and higher cost sharing for specialty drugs. This shift creates opportunities for new entrants into the health care industry and new products and services that generate positive outcomes and expectations of consumers⁶⁷.



Demonstrating outcomes through new innovations: Even as most stakeholders are concerned about current levels of spending, the industry is quickly delivering on the promise of new innovations resulting from new science. Many of these innovations are likely to be expensive, raising questions about whether and how health care stakeholders such as patients and health plans will be able to afford them. Life science organizations that can demonstrate their newly developed therapies improve outcomes will likely have their therapies covered. Some life science organizations are also offering therapies with disease management services that improve adherence to therapeutic regimens and have the potential for better outcomes as a result.

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Benefit-risk analysis: A critical part of getting to better outcomes

Benefit-risk analysis, when applied to health care, is the comparison of the risk of a treatment (including nontreatment) to its related benefits. A physician and patient considering treatment options for a given condition would likely sort through various alternatives to understand the *risks*—the potential negative outcomes, events, or adverse effects associated with the treatment—and the *benefits*—improvements in positive health outcomes, such as longer life, lower morbidity, and restoration of function.

Central to achieving better outcomes is improved benefit-risk decision making, which accounts for all outcomes to a patient from a particular treatment. Despite the importance of benefit-risk decision making, there is currently no universal approach or standardized method for making benefit-risk decisions. Establishing a consistent approach could drive better patient outcomes, improve point-of-care delivery and diagnoses, reduce clinical trials and provider costs, and shorten the time-to-market for life science products.

As the integration of benefit-risk decision making evolves across stakeholder groups, the understanding of how different stakeholders (life science organizations, regulatory agencies, providers, health plans, and patients) make benefit-risk decisions is becoming increasingly important, as one stakeholder's decision can significantly affect the goals of other stakeholders, which in turn could have positive or negative impacts on health and patient outcomes.

Stakeholders have different approaches to benefit-risk analysis

Stakeholders, including life sciences organizations, regulatory agencies, providers, health plans, and patients, have different priorities for benefit-risk decision making, so they value different criteria (Figure 1). Despite the differences, stakeholders interviewed for this report all said that safety and clinical effectiveness are important criteria to consider and four of the five groups believe cost is an important criterion.






Several differences exist across stakeholder groups. When interviewed, life science organizations (i.e., pharma, biotech, drug manufacturers, diagnostics) prioritized factors such as revenue maximization and return on investment. Health plans prioritized factors such as treatment design, reasonability, and population outcomes. Patient advocacy groups identified factors such as ease of use, quality of care, and personal and cultural factors. Individual patients focused on the benefits and risks to themselves, their family, and caregivers, as opposed to a population. These differences make it challenging to build consensus towards a collaborative benefit-risk approach.

Stakeholder's differing opinions— John's situation



John, a 40-year-old male, goes to his provider's office suffering from extreme fatigue and numbness in his extremities. During his visit, John is diagnosed with Type 2 diabetes and his provider presents multiple treatment options that vary widely in cost, side effects, and ease of use. John has a very important decision to make. Which option should he choose? Why should he choose it? How effective would it be for him? Unfortunately for John, there is no straightforward way to answer these complex questions and arrive at a decision about his course of treatment. Chances are, if you ask each stakeholder within the health care ecosystem (life science organizations, regulatory agencies, providers, health plans, and patients), they would each have a different answer for the patient in this situation.

Figure 1: Representative examples of stakeholder benefit-risk criteria

<p>Life Science Organizations</p> 	<p>Adverse Effects, Benefits over Competitors, Cost*, Clinical Effectiveness*, Market Size, Population of Benefit, Safety*, Therapeutic Alternatives, Therapeutic Comparisons*</p>
<p>Regulatory Agencies</p> 	<p>Effectiveness*, Safety*</p>
<p>Providers</p> 	<p>Adherence, Clinical Effectiveness*, Compliance, Dosage and Administration, Outcomes*, Safety*</p>
<p>Health Plans</p> 	<p>Adherence, Clinical Effectiveness*, Compliance, Cost/Coverage*, Design, General Outcomes, Necessity/Reasonability, Population Outcomes, Return on Investment, Safety*</p>
<p>Patients</p> 	<p>Burden to Caregivers, Cost*, Cultural Factors, Potential for Reoccurrence, Quality of Life*, Ease of Use and Adherence*, Functionality, Life Expectancy/Longevity Outcomes*, Pain and Side Effects*, Personal Values, Provider Service, Safety*, Survival</p>

Note: * indicates commonalities of benefit-risk criteria across stakeholder groups. Definitions for each criterion varied depending on the stakeholder, preventing opportunities for direct comparisons/analysis.

While there are no standardized benefit-risk criteria across stakeholder groups, safety, outcomes, and cost were listed as common elements, which may form the basis for a collaborative benefit-risk approach

Variations in the application of benefit-risk methodologies

Life science organizations, regulatory agencies, and academic organizations use multiple methods to quantify benefits and risks. There are over 15 available frameworks, including the Multi-Criteria Decision Analysis (MCDA), Risk-Benefit Plane (RBP), Risk-Benefit Contour (RBC), Probabilistic Simulation Methods (PSM), and Incremental Net Health Benefit (INHB)¹⁻⁸.

While these frameworks show promise in supporting benefit-risk decisions, particularly with regard to drug and regulatory decisions, there is no standardized approach, guideline, or method for implementing such frameworks. Therefore, stakeholder benefit-risk analyses are often conducted in silos and include varying approaches.

Though the importance of patient input and engagement is growing, some organizations have not identified the best method to engage consumers, patients, and caregivers who are the expected beneficiaries of these therapies in the discussion or quantification of benefits and risks. Their input is important to improve the chances that products are brought to market that are of use and value to patients and providers.






Lack of stakeholder collaboration and engagement can result in failures to commercialize products

In a time of scrutiny about costs and patient outcomes, greater integration and communication among stakeholders and more explicit consideration of benefits and risks from all perspectives will likely prevent products being brought to market that lack positive health and patient outcomes.

For instance, a physician, expecting higher clinical effectiveness, might prescribe an expensive drug, which would be welcomed by the life science organization that manufactures it. However, the patient may or may not welcome this prescription depending on how long the course of medication is and how much he/she must pay out of pocket. The health plan paying for care might prefer that the physician prescribe a generic drug that is equally effective.

To reduce the potential for misaligned incentives, more stakeholders are needed at the table during the early phases of the product development process. If stakeholders were engaged during this time, factors such as cost, benefit-risk tolerance, and adverse effects might be sorted out earlier in the process. Better alignment and input from multiple stakeholders could also avoid downstream impacts that leave patients choosing suboptimal treatments, or in the case of the life science organization, development of an expensive drug that does not get used because it is not on a formulary or requires high cost sharing. Compounding these challenges are those specific to stakeholders who face several challenges when assessing benefits and risks (Figure 2). These unique challenges often prevent a collaborative approach across stakeholder groups.

Figure 2: Compounding challenges specific to stakeholder groups

Life Science Organizations 	Life science organizations are still identifying the best method(s) to engage patients in the drug and product development process. This limitation precludes the development of solutions that are in alignment with stakeholder's specific needs.
Regulatory Agencies 	Despite the presence of available benefit-risk frameworks, regulators have not identified a single approach to evaluate benefits and risks. Challenges exist with the acceleration of product approvals and ambiguity of the best methods to engage product developers.
Providers 	Training, evidence-based research, and decision making tools that align with provider workflows are needed. Providers tend to understand the benefits of certain treatments but have limited knowledge about risks to patients.
Health Plans 	Health plans are challenged by health care reforms as they work to determine the relevant approach for reimbursement and meeting the specific needs of an increasing customer base, who are increasingly focused on personalized care and effective outcomes.
Patients 	While some patients are actively involved in their care, others choose not to or are unable to participate in their health care options. This lack of interaction may be due to the absence of a common decision making methodology, the lack of access to relevant information, health literacy challenges, or the dearth of patient engagement.

Forward progress

Moving towards a collaborative approach

While several challenges exist, some organizations are taking strides to achieve a collaborative approach as indicated in Figure 3. These collaborations are often undertaken to achieve better coordination, reduce cost, and improve health and patient outcomes.

Specific to advancements in benefit-risk collaborations, the FDA's 2012 Prescription Drug User Fee Act (PDUFA V) announced the development of a "five-year plan to further develop and implement a structured benefit-risk assessment in the new drug approval process as well as to include patients benefit-risk criteria in their review processes"^{1,25}.

Organizations are also developing decision-making tools to guide treatment recommendations across stakeholder groups:

- Health plans and disease-focused nonprofit organizations are developing algorithms to support patients with making decisions based on their specific situation;
- The Patient-Centered Outcomes Research Institute is funding numerous projects to develop patient-reported outcomes and related decision-making tools; and
- Organizations, such as the Caregiver Action Network, are providing decision-making tools to educate caregivers within specific therapeutic areas.

Figure 3: Collaboration examples



Case 1: A recent collaboration including 45 hospitals improved physician and patient satisfaction by creating a centralized scheduling system that reduced call abandonment rates by 39 percent and improved average hold time by 32 percent¹⁴.

Case 2: The partnership between Aetna, a health plan organization and NovaHealth, an independent physician association bridged the gap between profit incentives and mutually beneficial models. This partnership focused on shared data, financial incentives, and care management to improve health outcomes for approximately 750 Medicare Advantage members. The results of this pilot program were encouraging, showing 50 percent fewer hospital days per 1,000 patients, 45 percent fewer admissions, and 56 percent fewer readmissions than statewide unmanaged Medicare populations¹⁵.

From a global perspective, The Centre for Innovation in Regulatory Science (CIRS) is working with four regulatory agencies (Swissmedic (Switzerland), TGA (Australia), HAS (Singapore), and Health Canada) and drug companies to create a consistent framework to identify, assess, and communicate benefits and risks. Ultimately, this initiative seeks to achieve a global approval process for drug evaluation, greater collaboration, and consistency to support improvements in medical developments and regulation⁶⁵⁻⁶⁶.

These examples demonstrate the movement stakeholders are taking to achieve better collaboration and consistency across the health care industry.

As the health care industry continues to place greater emphasis on outcomes, stakeholder engagement, interagency partnerships, and a consistent benefit-risk approach may be required to achieving positive and sustainable results.

Bridging the gap

Potential role of an integrator

Several stakeholders we interviewed suggested a third-party organization might be best positioned to spur the integration of a common benefit-risk approach into health care. Third-party organizations are subject to less regulation, prone to less hierarchy, and are able to convene stakeholders in ways that are sometimes challenging for government agencies. Some organizations are already leading development of products and frameworks to support benefit-risk discussions and communications, but this activity is somewhat fragmented. An “integrator” might bring these pieces together into a more standardized approach, including resources and tools, communications, training, and increasing stakeholder engagement.

This activity could encompass better education for providers, bringing stakeholders together to create tools to support benefit-risk decisions, and working with federal agencies and policy makers to drive great ideas to practice. As this integration progresses and the repository of information grows, the integrator could analyze, track, and share this information with other stakeholder groups. In particular, developing a gold standard for surveillance tools to track benefit-risk information may serve as a platform for documenting and communicating those outcomes, feeding into new product development efforts in the future.

The integrator must work closely with regulatory agencies to provide these results to other stakeholders in a timely manner. Support from a government champion would help the integrator develop policy and other guidance to nudge stakeholders into alignment. Patients need this information to select relevant treatments and measure the outcomes of the care they are receiving; life science organizations for surveillance, effectiveness, and product improvement efforts; researchers to support ongoing and comparative effectiveness studies; and health plans to cover patient services and treatments. Patient advocacy groups also have a large role to play in assisting the integrator by convening patients and caregivers.



Conclusions and stakeholder considerations

While the role of the integrator evolves, three considerations are proposed to help stakeholders including life science organizations, regulatory agencies, and health plans identify methods to achieve better outcomes through the use of benefit-risk information. While the considerations below are highlighted to achieve progress, broader dialogue among stakeholders is required to co-create plans and discuss an integrated path forward.

Consideration 1: Demonstrating outcomes and sharing data across stakeholder groups:

Organizations may be increasingly responsible and accountable for testing business cases, demonstrating value, and showing evidence of improved health and patient outcomes. To do this, organizations need to invest in better assessment, communication, measurement, and tracking of benefit-risk information.

Ideally, the data these organizations use to develop products' business cases could also be used to support patients with a better and more comprehensive understanding of their treatment options. It also might be used by life science organizations conducting surveillance and effectiveness analysis; researchers who require this information for comparison, analytics, and tracking purposes; and health plans to make decisions when accepting services and treatments.

Call to action:

- Determine how your organization can better **leverage benefit-risk information to demonstrate health and patient outcomes.**
- **Identify stakeholder groups and relevant interagency partnerships** that your organization could establish to enable greater collaboration, sharing, and evaluation of benefits, risks, and outcomes data.
- **Identify innovative methods and solutions** that will enable better collection, assessment, communication, measurement, and tracking of benefit-risk information.

Consideration 2: Improving patient outcomes through education, communication, and decision support tools: Being patient-centered and improving the patient experience is a new business imperative, which includes a focus on patient engagement, precision medicine, compliance, and adherence. A leader in Deloitte's provider practice pointed out that achieving improved patient outcomes requires more meaningful conversations between patients and clinicians/pharmacists and more transparency regarding the benefit-risk profile. In order to successfully engage patients, more investment is needed to:

1. Properly educate providers to engage in benefit-risk discussions
2. Develop communication and decision support tools that align across stakeholder groups
3. Foster greater understanding of medication nonadherence, including the reasons why patients fail to adhere. For example, someone taking medicine for high blood pressure might stop taking it because he/she is tired of taking pills or because of the negative side effects. It is here that patient engagement enters the equation and the point at which benefits and risks need to be properly weighed to support decision making.

Call to action:

- **Invest in research and programs to enhance education, training, communication, and tools to support benefit-risk decisions.**
- **Develop incentives to change behaviors** needed to create a collaborative approach including greater emphasis on stakeholder engagement and alignment.

Consideration 3: Assessing benefits and risks through effective stakeholder engagement:

Companies should develop strategies to engage patients, caregivers, and other relevant stakeholders throughout the development process to tailor products to their specific needs. For example, one interviewee shared that a device manufacturer developed a tool to measure a patient's blood glucose level, but it failed because it was too big for a patient to carry around. Effective engagement with patients and caregivers could unleash untapped sources and generate novel ideas that could enhance innovation and increase adoption of products in the market. These elements may be considered by investors and funders when choosing whether to invest in certain product development efforts. Therefore, life science organizations need to understand stakeholders' benefit-risk equations and effectively align their solutions in order to demonstrate successful outcomes.

Call to action:

- **Establish a patient-centric office or a capability within your organization** to focus on patient-centeredness and solid methods for engaging patients and caregivers throughout the product development process.
- **Invest in performance metrics, surveillance, and tracking tools** to create a repository of evidence and data to support your organization with business cases for future investments as well as the evaluation of product developments.
- As the integrator evolves, work closely with this entity to **share leading practices and lessons learned.**

As stakeholders in the health care industry are incentivized to be accountable to each other and patients, innovation can be revitalized, research synergies can emerge and collaboration can be centralized. The adoption of an integrator paradigm can transform the patient experience and associated health care outcomes. Decisions around benefits and risks will no longer play an ancillary role in health care; instead, it will be a driver for pivotal decisions that are made with patient outcomes at the epicenter.

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